Appendix B Included studies

Abu Dayyeh, 2022

Guideline record ID: 10004

Study characteristics		
Citation	Abu Dayyeh, B. K., Bazerbachi, F., Vargas, E. J., Sharaiha, R. Z., Thompson, C. C., Thaemert, B. C., Teixeira, A. F., Chapman, C. G., Kumbhari, V., Ujiki, M. B., Ahrens, J., Day, C., Group, M. S., Galvao Neto, M., Zundel, N., & Wilson, E. B. (2022). Endoscopic sleeve gastroplasty for treatment of class 1 and 2 obesity (MERIT): a prospective, multicentre, randomised trial. The Lancet, 400(10350), 441-451. https://doi.org/https://dx.doi.org/10.1016/S0140-6736(22)01280-6	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Endoscopic sleeve gastroplasty for treatment of class 1 and 2 obesity (MERIT): a prospective, multicentre, randomised trial	
Location	USA	
Trial name	Multicentre ESG Randomised Interventional Trial (MERIT)	
Methods		
Inclusion criteria	"Included individuals were aged 21-65 years, with BMI between 30 kg/m² and less than 40 kg/m², with a history of failure with non-surgical weight loss methods, and who agreed to comply with the lifelong dietary restrictions required by the procedure."	
Exclusion criteria	"Exclusion criteria included a history of gastrointestinal surgery and any inflammatory disease in the gastrointestinal tract."	
Setting	Hospital	
Intervention	"ESG plus moderate-intensity lifestyle modifications (ESG group)-ESG is an incisionless, organ-sparing, transoral endoscopic procedure done in an outpatient setting under general anaesthesia (appendix pp 3-4). Lifestyle modifications included a low-calorie diet plan and physical activity counselling, which was customised for each participant's goals and lifestyle and provided during each study visit. Conditions to facilitate lifestyle modification compliance were identical in both groups. Patients in the ESG group were followed up for a total of 104 weeks. After the 52-week visit, some patients received an oesophagogastroduodenoscopy for retightening either on the basis of a suboptimal response to the primary intervention or at the discretion of the treating investigator. During the first year, 12 total visits were completed at week 1, week 4, and then every 4 weeks until the 52-week visit."	
Control/Comparator	"Moderate-intensity lifestyle modifications alone (control group)- Lifestyle modifications included a low-calorie diet plan and physical activity counselling, which was customised for each participant's goals and lifestyle and provided during each study visit. Conditions to facilitate lifestyle modification compliance were identical in both groups. At 52 weeks, participants in the control group who did not reach the target primary weight loss goal (≥25% EWL) and completed the 52-week visit were offered crossover to receive ESG and were followed up for an additional 52 weeks after crossover."	
Treatment duration	52 weeks	
Follow-up from baseline	52 weeks	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 209
Intervention group/s: ESG (n=85)

Comparator group: Control (n=124)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 47.3y (9.3); Control: 45.7y (10.0)</td></tr>
<tr><td>Sex</td><td>76.56% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline BMI, kg/m2
Mean (SD)

Weight, kg
Mean (SD)

Waist circumference, cm
Mean (SD)</td><td>ESG: 35.5
(2.6)

ESG: 98.4
(12.3)

ESG: 110.3
(10.4)</td><td>Control: 35.7
(2.6)

Control: 99.1
(12.8)

Control: 109.7
(12.5)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight, kg
Mean (SD)</td><td>ESG: 85.1
(13.6)</td><td>Control: 98.4
(13.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Percentage of EWL
Mean (SD)

Percentage of total body Weight loss
Mean (SD)

Weight loss (kg)
Mean (SD)</td><td>ESG: 49.2
(32)

ESG: 13.6
(8)

ESG: -13.4
(8.2)</td><td>Control: 3.2
(18.6)

Control: 0.8
(5)

Control: -0.8
(5)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Adab, 2018

Guideline record ID: 10163--1

Study characteristics		
Citation	Adab, P., Pallan, M. J., Lancashire, E. R., Hemming, K., Frew, E., Barrett, T., Bhopal, R., Cade, J. E., Canaway, A., Clarke, J. L., Daley, A., Deeks, J. J., Duda, J. L., Ekelund, U., Gill, P., Griffin, T., McGee, E., Hurley, K., Martin, J., . . . Cheng, K. K. (2018). Effectiveness of a childhood obesity prevention programme delivered through schools, targeting 6 and 7 year olds: cluster randomised controlled trial (WAVES study). BMJ, 360, k211. https://doi.org/https://dx.doi.org/10.1136/bmj.k211	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effectiveness of a childhood obesity prevention programme delivered through schools, targeting 6 and 7 year olds: cluster randomised controlled trial (WAVES study)	
Location	UK	
Trial name	West Midlands ActiVe lifestyle and healthy Eating in School children (WAVES)	
Methods		
Inclusion criteria	"Primary schools in the West Midlands, UK, within 35 miles of the study centre were eligible for inclusion."	
Exclusion criteria	"We excluded schools with fewer than 17 year 1 (aged 5 and 6 years) pupils (minimum cluster size) or schools in "special measures" (unlikely to have capacity to contribute to study)."	
Setting	School	
Intervention	"The intervention programme comprised four overlapping components: (1) Thirty minutes of additional moderate to vigorous physical activity on each school day-at least 15 minutes to be outside of break times, although class teachers customised timing of delivery and exact activities undertaken according to their class circumstances, supported by resources supplied as part of the study. Class teachers selected two preferred resources out of four offered and were taken through each selected resource and its detailed delivery materials by a researcher (2) Termly cooking workshops during school time, which parents were invited to attend to participate in with their child and that were preceded by short classroom sessions for the children. School staff responsible for implementation (with the exception of two schools where equivalent training was delivered in school by the same researcher) attended a one day training session. To minimise teacher preparation time and ensure delivery of consistent nutritional messages, the presentation and interactive activity materials, together with take home information sheets and suggested lesson and workshop plans were provided, but timing of sessions and how parents were involved was left to the discretion of teachers (3) A six week programme (Villa Vitality) developed to encourage healthy eating and increase physical activity and delivered by staff from an iconic sporting institution. School classes spent two days undertaking activities (indoor based movement routines, using dance mats, ball skills session, interactive nutritional sessions, and an opportunity to practise cooking skills) at an English premier league football club, separated by a six week period during which teachers were asked to spend curriculum time working on a class project and involving children and their parents with weekly health challenges. The teacher customised the elements undertaken in school supported by a school visit from a member of staff from Villa Vitality (4) Information sheets signposting children and their families on ways to be active over the summer (identical for all schools) and physical activity opportunities in their local area (school specific sheets produced by the study team and checked before distribution by the school)."	

<table>
<tr><td>Control/Comparator</td><td>“Schools allocated to the comparator arm continued with ongoing year 2 health related activities. In addition, we provided citizenship education resources, excluding topics related to healthy eating and physical activity.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>30 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 1397
Intervention group/s: Intervention (n=662)

Comparator group: Control (n=735)</td></tr>
<tr><td>Mean age ± SD</td><td>6.3 (0.3)</td></tr>
<tr><td>Sex</td><td>51.40% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion (%) overweight (≥85th and <95th centiles)
Proportion (%)</td><td>Intervention: 61</td><td>Control: 9.2</td></tr>
<tr><td>Proportion (%) obese (≥95th centile)
Proportion (%)</td><td>Intervention: 12.73</td><td>Control: 11.89</td></tr>
<tr><td>Proportion (%) obese or overweight
Proportion (%)</td><td>Intervention: 21.97</td><td>Control: 20.49</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion (%) obese (≥95th centile)
Proportion (%)</td><td>Intervention: 16.2</td><td>Control: 14.81</td></tr>
<tr><td>Proportion (%) obese or overweight
Proportion (%)</td><td>Intervention: 28.75</td><td>Control: 24.74</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion (%) obese (≥95th centile)
Proportion (%)</td><td>Intervention: 20.61</td><td>Control: 18.04</td></tr>
<tr><td>Proportion (%) obese or overweight
Proportion (%)</td><td>Intervention: 33.59</td><td>Control: Not reported</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Ahern, 2017

Guideline record ID: 10005--1

Study characteristics		
Citation	Ahern, A. L., Wheeler, G. M., Aveyard, P., Boyland, E. J., Halford, J. C. G., Mander, A. P., Woolston, J., Thomson, A. M., Tsiountsioura, M., Cole, D., Mead, B. R., Irvine, L., Turner, D., Suhrcke, M., Pimpin, L., Retat, L., Jaccard, A., Webber, L., Cohn, S. R., & Jebb, S. A. (2017). Extended and standard duration weight-loss programme referrals for adults in primary care (WRAP): a randomised controlled trial. The Lancet, 389(10085), 2214-2225. https://doi.org/10.1016/S0140-6736(17)30647-5	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Extended and standard duration weight-loss programme referrals for adults in primary care (WRAP): a randomised controlled trial	
Location	England	
Trial name	Weight loss Referrals for Adults in Primary care (WRAP)	
Methods		
Inclusion criteria	"Eligible participants (those aged 18 years or older and had a body-mass index [BMI] of 28 kg/m² or higher) were identified through practice records."	
Exclusion criteria	"Exclusion criteria were planned (within 2 years) or current pregnancy; previous or planned bariatric surgery; current participation in a structured, monitored weightloss programme; participation in other research that could confound outcome measures; eating disorders; and non-English speaking or special communication needs. Practices could exclude additional patients who they felt were inappropriate to invite, but were asked to report reasons for exclusion. Additional reasons for exclusion included terminal illness or palliative care, dementia, a severe mental health problem or learning difficulty, carer for a terminally ill relative, or recently bereaved."	
Setting	GP clinic, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Participants assigned to the behavioural programme were asked to attend a local Weight Watchers meeting once a week for the duration of their intervention (12 weeks or 52 weeks). At the baseline visit, participants were given a list of local meeting times and locations, a voucher booklet for 12 visits (the expiry date was set for 14 weeks from baseline), and a unique code to access digital tools for the duration of their intervention. Meeting vouchers were identical to those used in the National Health Service (NHS) referral schemes operating throughout the country and allowed participants to attend meetings without charge. At the meeting, participants were asked to give the voucher to the group leader, but were asked not to mention their participation in the trial to the group leader or other members. Participants assigned to the 52-week programme were given three additional books of vouchers when they returned for their 3-month visit (expiry date set for 54 weeks from baseline)."	
Control/Comparator	"Participants allocated to the brief intervention were given a 32-page printed booklet by the British Heart Foundation of self-help weight-management strategies10 and research staff read a scripted introduction that drew attention to each section of the booklet."	
Treatment duration	12-week programme: 12 weeks; 52-week programme: 52 weeks; brief intervention: minutes	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 1267
Intervention group/s: 12-week programme (n=528); 52-week programme (n=528)

Comparator group: Brief intervention (n=211)</td></tr>
<tr><td>Mean age ± SD</td><td>12-week programme: 53.6y (13.3); 52-week programme: 53.3y (14.0); brief intervention: M=51.9y (14.1)</td></tr>
<tr><td>Sex</td><td>67.80% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Crude weight kg
Mean (SD)</td><td>12-week programme: 96.6 (17.9)
52-week programme: 95.7 (16.4)</td><td>Brief intervention: 96.1 (16.4)</td></tr>
<tr><td>Crude waist circumference cm
Mean (SD)</td><td>12-week programme: 111 (12.4)
52-week programme: 110 (12.7)</td><td>Brief intervention: 110 (11.9)</td></tr>
<tr><td>Baseline BMI (kg/m2)
Mean (SD)</td><td>12-week programme: 34.7 (5.4)
52-week programme: 34.5 (5.1)</td><td>Brief intervention: 34.4 (4.6)</td></tr>
</table>
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<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change from baseline
Mean (SE)</td><td>12-week programme: -4.75 (0.35)
52-week programme: -6.76 (0.42)</td><td>Brief intervention: -3.26 (0.68)</td></tr>
<tr><td>Change in waist circumference - cm
Mean (SE)</td><td>12-week programme: -5.15 (0.43)
52-week programme: -7.28 (0.45)</td><td>Brief intervention: -3.18 (0.64)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change from baseline
Mean (SE)</td><td>12-week programme: -3 (0.37)
52-week programme: -4.29 (0.44)</td><td>Brief intervention: -2.3 (0.73)</td></tr>
<tr><td>Change in waist circumference - cm
Mean (SE)</td><td>12-week programme: -4.36 (0.47)
52-week programme: -5.57 (0.45)</td><td>Brief intervention: -3.64 (0.72)</td></tr>
</table>
</td></tr>
</table>

Compliance with treatment	At 3 months, 950 participants reported intervention use at 3 months. Seven (5%) of 132 participants in the brief intervention group had attended a commercial weight-management programme, compared with 259 (68%) of 382 participants in the 12-week programme and 300 (69%) of 436 participants in the 52-week programme (table 5). Only ten (1%) of 950 participants in all groups attended an NHS-led programme and three (<1%) used weight-loss medication. For participants referred to the behavioural programmes, the mean number of sessions attended was 8·4 (SD 4·2) in the 12-week programme and 28·2 (SD 14·8) in the 52-week programme.
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Akers, 2012

Guideline record ID: 10006

Study characteristics		
Citation	Akers, J. D., Cornett, R. A., Savla, J. S., Davy, K. P., & Davy, B. M. (2012). Daily self-monitoring of body weight, step count, fruit/vegetable intake, and water consumption: a feasible and effective long-term weight loss maintenance approach. Journal of the Academy of Nutrition and Dietetics, 112(5), 685-692.e682. https://doi.org/10.1016/j.jand.2012.01.022	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Daily Self-Monitoring of Body Weight, Step Count, Fruit/Vegetable Intake, and Water Consumption: A Feasible and Effective Long-Term Weight Loss Maintenance Approach	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"WL participants were overweight and obese (BMI 25-40 kg/m2) adults aged 55-75 years who were recruited through local newspaper advertisements (29). To be included in the WL study, individuals were required to be weight stable (± 2kg, > one year), and non-smokers."	
Exclusion criteria	"History of depression, eating disorders, diabetes, uncontrolled hypertension, heart/lung/kidney disease, cancer, or use of medications known to alter food intake or body weight (i.e. antidepressants, thyroid medications)."	
Setting	Home	
Intervention	"Participants in the WL intervention trial were randomly assigned to one of two groups: 1) intervention group (1200-1500 kcal hypocaloric diet + 16 floz water prior to each daily main meal)"	
Control/Comparator	"Control group (1200-1500 kcal hypocaloric diet alone)."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 40 Intervention group/s: WEV+ (water group) (n=19) Comparator group: WEV (non water group) (n=21)	
Mean age ± SD	62.7y (0.9)	
Sex	55.00% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	Body weight (kg) Mean (SE)	WEV+ (water group): 83.7 (2.7)	WEV (non water group): 82.7 (3.7)

	BMI (kg/m2) Mean (SE) Waist circumference (cm) Mean (SE) Body fat (%) Mean (SE) Fat mass (kg) Mean (SE)	WEV+ (water group): 29.1 (0.8) WEV+ (water group): 99 (2.1) WEV+ (water group): 36.2 (2.2) WEV+ (water group): 28.2 (2.3)	WEV (non water group): 29.4 (1.3) WEV (non water group): 99.2 (2.8) WEV (non water group): 38.5 (1.9) WEV (non water group): 30 (2)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Body weight (kg) Mean (SE) BMI (kg/m2) Mean (SE) Waist circumference (cm) Mean (SE) Body fat (%) Mean (SE) Fat mass (kg) Mean (SE)	WEV+ (water group): 81.8 (2.6) WEV+ (water group): 28.6 (0.7) WEV+ (water group): 98.4 (2.2) WEV+ (water group): 36 (2.1) WEV+ (water group): 28.4 (2.1)	WEV (non water group): 81.6 (4.3) WEV (non water group): 29.6 (1.5) WEV (non water group): 98.7 (3.5) WEV (non water group): 38.5 (2.3) WEV (non water group): 30.2 (2.5)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Aller, 2014

Guideline record ID: 10009--1

Study characteristics		
Citation	Aller, E. E. J. G., Larsen, T. M., Claus, H., Lindroos, A. K., Kafatos, A., Pfeiffer, A., Martinez, J. A., Handjieva-Darlenska, T., Kunesova, M., Stender, S., Saris, W. H. M., Astrup, A., & van Baak, M. A. (2014). Weight loss maintenance in overweight subjects on ad libitum diets with high or low protein content and glycemic index: the DIOGENES trial 12-month results. International Journal of Obesity, 38(12), 1511-1517. https://doi.org/https://doi.org/10.1038/ijo.2014.52	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight loss maintenance in overweight subjects on ad libitum diets with high or low protein content and glycemic index: the DIOGENES trial 12-month results	
Location	Netherlands; Denmark	
Trial name	DIOGENES	
Methods		
Inclusion criteria	"Families (two parent or single parent) were eligible for participation if family members were generally healthy and if (1) at least one parent was overweight (body mass index >27 kg m2) and aged 65 years; (2) at least one overweight child was between 8 and 15 years of age."	
Exclusion criteria	Not reported	
Setting	University/research centre	
Intervention	"After these baseline measurements, subjects initiated an 8-week weight loss phase on a LCD providing 3.4-3.7 MJ per day (800-880 kcal per day). If at least one of the parents of a two-parent family or the parent in a single parent family had attained a weight loss of ⩾8% of initial body weight after 8 weeks, the family was randomized into one of five diet groups, varying in protein content and GI, for the 12-month dietary intervention period. After the post-LCD test day, families started the ad libitum diets. Laboratory shops were established to provide families with the majority of foods at no cost for 6 months. The shop system allowed us to more tightly control dietary intake of subjects, in this case on a family level. During the second 6 months of the intervention, families had to purchase foods again in their own shops. Subjects came to the research center at regular intervals to meet a dietitian. At all visits, body weight was monitored and dietary counseling was provided. At 4 weeks into the randomized phase, subjects completed a 3-day weighed dietary record and collected 24-h urine to check compliance to the diets. After 6 and 12 months, subjects returned to the research center for the third and fourth test day (post intervention, week 26 and 52), which were the same as the previous test days including the 3-day weighed food diary and 24-h urine collection. Subjects were randomized into five diet groups: (1) low protein, LGI (LP/LGI); (2) LP, high GI (LP/HGI); (3) high protein, LGI (HP/LGI); (4) HP, HGI; and (5) a diet according to national healthy eating recommendations (healthy). All diets were low in fat (25-30% of energy from fat) and ad libitum, that is, no energy restriction was imposed. We aimed at a protein consumption of 10-15% of total energy intake in the LP groups and of 23-28% in the HP groups. With respect to GI, a distinction was made between HGI and LGI foods within each food group. The assignment of GI values to foods was performed as described by Aston et al. Subjects in the LGI groups were advised to mainly consume the LGI foods within a food group, those in the HGI groups the HGI foods. The aim was to attain a 15-unit difference in GI between the HGI and LGI groups. During the first 6 months, adherence to dietary compositions was optimized by providing >80% of all relevant foods for each of the different diet groups at no cost through a lab-based shop system as previously described to increase compliance."	

<table>
<tr><td>Control/Comparator</td><td>“Subjects were randomized to a diet according to national healthy eating recommendations (healthy).”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 256
Intervention group/s: LP/LGI (n=47); LP/HGI (n=53); HP/LGI (n=50); HP/HGI (n=54)

Comparator group: Healthy (n=52)</td></tr>
<tr><td>Mean age ± SD</td><td>42y (6)</td></tr>
<tr><td>Sex</td><td>59.77% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>LP/LGI: 30.2
(4.3)
LP/HGI: 29.7
(3.7)
HP/LGI: 29.9
(4.2)
HP/HGI: 29.5
(3.9)</td><td>Healthy: 30.2
(4.2)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>LP/LGI: 96.6
(10.8)
LP/HGI: 96.4
(10.1)
HP/LGI: 97.3
(12.2)
HP/HGI: 96
(11.1)</td><td>Healthy: 98.9
(12.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Changes in Waist circumference (cm)
Mean (95% CIs)</td><td>LP/LGI: 6.8
(3.4-10.2)
LP/HGI: 5.4
(1.7-9.1)
HP/LGI: 4.4
(1-7.7)
HP/HGI: 3.4
(0.1-6.7)</td><td>Healthy: 4.7
(1.2-8.3)</td></tr>
</table>
</td></tr>
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<table>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Almeida, 2023

Guideline record ID: 10941--1

Study characteristics		
Citation	Almeida, F. A., You, W., Brito, F. A., Alves, T. F., Goessl, C., Wall, S. S., Seidel, R. W., Davy, B. M., Greenawald, M. H., Hill, J. L., & Estabrooks, P. A. (2023). A randomized controlled trial to test the effectiveness of two technology-enhanced diabetes prevention programs in primary care: the DiaBEAT-it study. Frontiers in Public Health, 11, 1000162. https://doi.org/ https://doi.org/10.3389/fpubh.2023.1000162	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A randomized controlled trial to test the effectiveness of two technology-enhanced diabetes prevention programs in primary care: The DiaBEAT-it study	
Location	USA	
Trial name	DiaBEAT-it	
Methods		
Inclusion criteria	"Individuals were eligible if they were 18 years of age or older with a BMI of at least 25 kg/m2 (BMI > 22 for Asian), spoke English, were not pregnant or planning to become pregnant in the following 18 months, were not diagnosed with T2D, congestive heart failure, or coronary artery disease, had no contraindication for physical activity (PA) or weight loss, had access to a phone, and had a DRC test score indicative of high risk for developing T2D (Score of 5 or higher)."	
Exclusion criteria	Not reported	
Setting	GP clinic, Home	
Intervention	"Class/IVR group: 2- h small group session class. During the class participants were encouraged to develop their own personal action plan to preventing T2D by setting a goal of losing 10% of their current weight over 12 months and to be physically active for 60 min, 5 days per week. They also, received a workbook, completed a "Live" counselling call and received 22 tailored IVR calls over a period of 12 months to assist with healthful diet and regular physical activity with the final 6 months focusing on maintenance and relapse prevention based on DPP's after Core program; DVD/IVR group: identical to the Class/IVR group but was initiated with a DVD that replicated the class content. The DVD included the following segments: (1) What is pre-diabetes? (2) What are the risk factors for diabetes? (3) Developing your DiaBEAT-it action plan, (4) Goal setting for physical activity and healthy eating, (5) putting together a toolbox of resources, and (6) making a commitment to change"	
Control/Comparator	"2- h small group session class. During the class participants were encouraged to develop their own personal action plan to preventing T2D by setting a goal of losing 10% of their current weight over 12 months and to be physically active for 60 min, 5 days per week."	
Treatment duration	12 months	
Follow-up from baseline	18 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 334 Intervention group/s: Class/IVR group (n=110); DVD/IVR group (n=107) Comparator group: Standard care (n=117)	

Mean age ± SD	Control (SC): 54.2y (12.1); Class/IVR: 51.4y (11.8); DVD/IVR: 51.2y (12.1)		
Sex	67.96% female		
Pre-existing medical condition	No pre-existing medical condition		
Results			
Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	BMI (kg/m2) Mean (SE)	Class/IVR group: 37.07 (0.04) DVD/IVR group: 37.13 (0.04)	Standard care: 37.09 (0.04)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	BMI (kg/m2) Mean (SE)	Class/IVR group: 36.25 (0.25) DVD/IVR group: 36.25 (0.2)	Standard care: 36.73 (0.18)
	At least 5% Weight Loss, % Proportion (%)	Class/IVR group: 21.62 (4.2) DVD/IVR group: 26.87 (4.39)	Standard care: 16.85 (3.61)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	BMI (kg/m2) Mean (SE)	Class/IVR group: 36.48 (0.23) DVD/IVR group: 36.35 (0.22)	Standard care: 36.9 (0.17)
	At least 5% Weight Loss, % Proportion (%)	Class/IVR group: 18.59 (3.97) DVD/IVR group: 20.69 (4.13)	Standard care: 16.85 (3.62)
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in BMI Mean (SE)	Class/IVR group: -0.82 (0.25) DVD/IVR group: -0.88 (0.2)	Standard care: -0.36 (0.19)
	Weight change (kg) Mean (SE)	Class/IVR group: -2.04 (0.6) DVD/IVR group: -2.79 (0.6)	Standard care: -1.56 (0.46)
	Weight change % Mean (SE)	Class/IVR group: -1.8 (0.5) DVD/IVR group: -2.56 (0.5)	Standard care: -1.47 (0.44)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in BMI Mean (SE)	Class/IVR group: -0.58 (0.23) DVD/IVR group: -0.78 (0.22)	Standard care: -0.18 (0.17)
	Weight change (kg) Mean (SE)	Class/IVR group: -1.46 (0.55)	Standard care: -1.15 (0.44)

	Weight change % Mean (SE)	DVD/IVR group: -2.55 (0.63) Class/IVR group: -1.27 (0.48) DVD/IVR group: -2.18 (0.54)	Standard care: -1.11 (0.44)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Alustiza, 2021

Guideline record ID: 10010--1

Study characteristics		
Citation	Alustiza, E., Perales, A., Mateo-Abad, M., Ozcoidi, I., Aizpuru, G., Albaina, O., Vergara, I., & en representación del Grupo PRE-STARt Euskadi. (2021). Tackling risk factors for type 2 diabetes in adolescents: PRE-STARt study in Euskadi. Anales de Pediatría (English Edition), 95(3), 186-196. https://doi.org/https://dx.doi.org/10.1016/j.anpede.2020.11.005	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Tackling risk factors for type 2 diabetes in adolescents: PRE-STARt study in Euskadi	
Location	Basque Country (Spain)	
Trial name	PRE-STARt	
Methods		
Inclusion criteria	"The study included adolescents aged 12---14 years with excess weight (overweight in case of a BMI between 1 and 2 standard deviations [SDs] above the mean for age and sex, obesity in case of a BMI more than 2 SDs above the mean for age and sex using the WHO child growth standards35) recruited through the primary care paediatric clinics of the Public Health System of the Basque Country (Osakidetza)."	
Exclusion criteria	"We excluded individuals with a previous diagnosis of any type of diabetes or with secondary obesity."	
Setting	University/research centre	
Intervention	"The IG underwent an intensive multidisciplinary group-based intervention to promote healthy lifestyle habits along with their parents or legal guardians. The intervention was implemented by 2 dietitians/nutritionists with training and experience in the delivery of programmes for management of excess weight in the paediatric population. The protocol applied cognitive-behavioural and psychodynamic methods to address the basic principles of healthy nutrition, develop self-control, improve body image, increase communication, facilitate conflict resolution and assertiveness, improve self-esteem, increase physical activity, reduce sedentary behaviour and facilitate affective changes in the household environment. Participants were also given the space to explore and express their feelings regarding excess weight and its repercussions. The intervention targeted adolescents and their home environment, that is, the proposed changes were aimed at the entire household with the aim of facilitating adherence to the programme. The goal was to achieve long-term changes in lifestyle. The programme consisted of 11 sessions with a cumulative duration of 16.5 h, and was divided in 2 phases: an intensive phase with 1 weekly session lasting 1.5 h for 8 consecutive weeks, and a booster phase consisting of 3 sessions at 9, 12 and 21 months (Fig. 1). In each session, 2 groups were set up that worked simultaneously, one of adolescents (12 per group) and one of parents or guardians (approximately 20 per group). All sessions were held after school hours outside the school setting."	
Control/Comparator	"The CG received the routine care established by the Osakidetza, with recommendation of healthy dietary and physical activity habits and interventions aimed at changing household habits, but with the time constraints applicable to routine primary care visits."	
Treatment duration	24 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 92
Intervention group/s: IG (n=47)

Comparator group: CG (n=45)</td></tr>
<tr><td>Mean age ± SD</td><td>13y (0.7)</td></tr>
<tr><td>Sex</td><td>56.52% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body mass index (BMI), kg/m
Mean (SD)

BMI z-score
Mean (SD)

Percent Excess weight - Overweight (BMI z > 1)
Proportion (%)

Percent Excess weight - Obesity (BMI z > 2)
Proportion (%)

Waist circumference, cm
Mean (SD)</td><td>IG: 26.4
(3.7)

IG: 1.6
(1.3)

IG: 51.1%

IG: 48.9%

IG: 86.2
(10.1)</td><td>CG: 26.6
(3)

CG: 1.7
(1.2)

CG: 37.8%

CG: 62.2%

CG: 87.7
(10.1)</td></tr>
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<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body mass index (BMI), kg/m
Mean (SD)

BMI z-score
Mean (SD)

Waist circumference, cm
Mean (SD)</td><td>IG: 26.1
(3.4)

IG: 1.4
(1.2)

IG: 84.3
(9.4)</td><td>CG: 27.1
(3.8)

CG: 1.8
(1.4)

CG: 86.7
(8.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body mass index (BMI), kg/m
Mean (SD)

BMI z-score
Mean (SD)

Waist circumference, cm
Mean (SD)</td><td>IG: 26.9
(3.6)

IG: 1.9
(1.2)

IG: 85.9
(9.5)</td><td>CG: 27.5
(3.6)

CG: 2.4
(1)

CG: 91.4
(9.2)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
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<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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Compliance with treatment	Percentage of participants that adhered to dietary recommendations at different timepoints in the intervention group. Fruit ≥ 3/day at 12 months 40%, at 24 months 52%; Vegetables ≥ 2/day at 12 months 60%, at 24 months 67%; Snacks < 1/week at 12 months 33%, at 24 months 33%; Sugary drinks < 1/week at 12 months 28%, at 24 months 39%. Percentage of participants that adhered to dietary recommendations at different timepoints in the control group. Fruit ≥ 3/day at 12 months 25%, at 24 months 21%; Vegetables ≥ 2/day at 12 months 33%, at 24 months 42%; Snacks < 1/week at 12 months 12%, at 24 months 11%; Sugary drinks < 1/week at 12 months 25%, at 24 months 16%.
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Amer, 2020

Guideline record ID: 10012--1

Study characteristics		
Citation	Amer, O. E., Sabico, S., Alfawaz, H. A., Aljohani, N., Hussain, S. D., Alnaami, A. M., Wani, K., & Al-Daghri, N. M. (2020). Reversal of prediabetes in Saudi adults: results from an 18 month lifestyle intervention. Nutrients, 12(3), 804. https://doi.org/https://dx.doi.org/10.3390/nu12030804	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Reversal of Prediabetes in Saudi Adults: Results from an 18 Month Lifestyle Intervention	
Location	Saudi Arabia	
Trial name	N/A	
Methods		
Inclusion criteria	"Overweight or obese individuals (body-mass index (BMI) ≥ 25 kg/m2) with impaired fasting serum glucose levels were eligible for the study. Impaired fasting glucose was defined based on the American Diabetes Association (ADA) criteria (serum glucose = 5.6-6.9 mmol/L (100-125 mg/dL) [21]. The use of ADA criteria in the present study, instead of the cut-off proposed by World Health Organization (WHO) (fasting glucose 6.1-69 mmol/L), was to include a bigger number of individuals, given the wider range of glucose level proposed by ADA."	
Exclusion criteria	"Exclusion criteria were: (1) those with T2DM or on T2DM medications; (2) history of malignancy; (3) diagnosed or suspected disease of the liver, pancreas, endocrine organs, or kidney; (4) ischemic heart disease or cerebrovascular disease (or a history of such disease). All study participants had prediabetes at baseline."	
Setting	GP clinic, Hospital	
Intervention	"Participants were informed individually about T2DM risk factors, its pathogenesis, and the role of dietary restriction and increased physical activity in delaying the onset of T2DM. Participants were advised to modify their lifestyle through shifting to a healthy diet and implementing good exercise behaviors, to increase physical activity and to reduce their body weight. All participants received information about the recommended lifestyle changes in the form of pamphlets and booklets also employed in previous studies [16,22]. In addition, participants were educated every three months through educational sessions about the lifestyle modifications necessary to prevent T2DM. These educational activities took place at the auditoriums of the respective hospitals across both study centres. The Intee control group (CG) received the normal advice for lifestyle modifications as detailed above. The intensive lifestyle intervention group (ILIG), in addition to the above lifestyle modifications, followed a strict lifestyle modification with individually tailored counseling for improving their diet and exercise behaviors. These strict lifestyle changes suggested were as follows: reducing body intake, receiving at least a fiber intake of 15 g/1000 kcal, and lastly, exercising over 150 min/week or 30 min/day at moderate intensity. At each visit with an intervening 6 month interval, the ILIG group had their lifestyle modifications tailored to each participant according to their lifestyle, using a diary, by a registered nutritionist. In addition, ILIG participants were educated about the effect of exercise on the regulation of blood glucose in individuals with prediabetes, and were prescribed aerobic exercise of 30 min five times per week (e.g., bicycling, swimming, badminton, walking, etc.). Based on their health conditions or lifestyle, the frequency, duration, and exercise type were personalized."	
Control/Comparator	"Participants were informed individually about T2DM risk factors, its pathogenesis, and the role of dietary restriction and increased physical activity in delaying the onset of T2DM. Participants were advised to modify their lifestyle through shifting to a healthy diet and	

<table>
<tr><td></td><td>implementing good exercise behaviors, to increase physical activity and to reduce their body weight. All participants received information about the recommended lifestyle changes in the form of pamphlets and booklets also employed in previous studies [16,22]. In addition, participants were educated every three months through educational sessions about the lifestyle modifications necessary to prevent T2DM. These educational activities took place at the auditoriums of the respective hospitals across both study centres. The e control group (CG) received the normal advice for lifestyle modifications The CG did not receive lifestyle education sessions, dietary counselling and an on-demand support system.”</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 158
Intervention group/s: ILIG (n=73)

Comparator group: CG (n=85)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 43.4y (7.8); Control: 42.3y (11.3)</td></tr>
<tr><td>Sex</td><td>72.78% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>ILIG: 31.3
(6.4)</td><td>CG: 32.6
(5.8)</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>ILIG: 79.6
(16)</td><td>CG: 81.7
(13.9)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>ILIG: 97.9
(13)</td><td>CG: 95.6
(6.8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>ILIG: 30.6
(6.6)</td><td>CG: 32.8
(5.7)</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>ILIG: 77.7
(16.2)</td><td>CG: 82.2
(13.4)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>ILIG: 96.3
(13)</td><td>CG: 95.5
(6.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
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<table>
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<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Andersen, 2021

Guideline record ID: 10014--1

Study characteristics		
Citation	Andersen, E., van der Ploeg, H. P., van Mechelen, W., Gray, C. M., Mutrie, N., van Nassau, F., Jelsma, J. G. M., Anderson, A. S., Silva, M. N., Pereira, H. V., McConnachie, A., Sattar, N., Sorensen, M., Roynesdal, O. B., Hunt, K., Roberts, G. C., Wyke, S., & Gill, J. M. R. (2021). Contributions of changes in physical activity, sedentary time, diet and body weight to changes in cardiometabolic risk. International Journal of Behavioral Nutrition and Physical Activity, 18, 166. https://doi.org/https://dx.doi.org/10.1186/s12966-021-01237-1	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Contributions of changes in physical activity, sedentary time, diet and body weight to changes in cardiometabolic risk	
Location	England; Netherlands; Norway; Portugal	
Trial name	European Fans in Training (EuroFIT)	
Methods		
Inclusion criteria	"Men were eligible if they were aged 30-65, had a body mass index (BMI) of ≥27 kg/m2 based on self-reported height and body weight and consented to study procedures."	
Exclusion criteria	"Men were excluded if they reported a contraindication to moderate- to vigorous PA in the PARQ+, participated in an existing health promotion program at the club, or were unable to provide at least four days of usable activity monitor data at baseline. In this secondary analysis, only men with valid accelerometer recordings and blood samples at baseline and 12-month follow-up were included."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Briefly, the EuroFIT intervention aimed to support men to become gradually more physically active, reduce their sedentary time, improve their diet, and to maintain these changes to at least 12 months after baseline. We trained coaches at the football clubs to deliver the intervention to male fans of the clubs in an accessible style, including encouraging positive banter, making sessions enjoyable, promoting a 'team' environment, and using interactional approaches congruent with other male contexts. The program was delivered at club stadia, to groups of 15-20 men over 12 weekly, 90-minute sessions that combined the interactive development of self-regulation skills via a toolkit of behaviour change techniques (including goal setting and review, action planning, self-monitoring, and provision of information about health and emotional benefits of change), with graded group-based moderate intensity PA. In addition, men were provided with a novel validated, pocket-worn device (SitFIT) to enable self-monitoring of sedentary time and physical activity [26]. Peer support was also encouraged via social media platforms, and an interactive social team-based step-challenge app (MatchFIT) [23]. An additional reunion meeting was scheduled 6-9 months after the start of the program."	
Control/Comparator	"Men allocated to the comparison group were offered the opportunity to take part in the EuroFIT intervention after the 12-month measures."	
Treatment duration	12 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 707
Intervention group/s: Intervention (n=349)

Comparator group: Comparison (n=358)</td></tr>
<tr><td>Mean age ± SD</td><td>46.0y (9.0)</td></tr>
<tr><td>Sex</td><td>100.00% male</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 104.1
(16.1)

Intervention: 32.8
(4.2)

Intervention: 110.3
(11.3)</td><td>Comparison: 106.1
(17.3)

Comparison: 33.2
(4.4)

Comparison: 111.1
(12.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Body weight (kg)
Mean (SD)

Change in Waist circumference (cm)
Mean (SD)</td><td>Intervention: -3
(6.5)

Intervention: -3.3
(6.7)</td><td>Comparison: -0.6
(5)

Comparison: -0.5
(5.6)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Anderson, 2014

Guideline record ID: 10016--1

Study characteristics		
Citation	Anderson, A. S., Craigie, A. M., Caswell, S., Treweek, S., Stead, M., Macleod, M., Daly, F., Belch, J., Rodger, J., Kirk, A., Ludbrook, A., Rauchhaus, P., Norwood, P., Thompson, J., Wardle, J., & Steele, R. J. C. (2014). The impact of a bodyweight and physical activity intervention (BeWEL) initiated through a national colorectal cancer screening programme: randomised controlled trial. BMJ, 348(7950), g1823. https://doi.org/10.1136/bmj.g1823	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The impact of a bodyweight and physical activity intervention (BeWEL) initiated through a national colorectal cancer screening programme: randomised controlled trial	
Location	Scotland	
Trial name	N/A	
Methods		
Inclusion criteria	"Diagnosis of adenoma confirmed by histopathology following a positive faecal occult blood test result, as part of the national bowel screening programme aged 50 to 74 years (in line with the Scottish age criteria for routine colorectal cancer screening) who had undergone polypectomy for adenoma, had a body mass index >25, and were able to undertake physical activity and provide informed consent."	
Exclusion criteria	"Exclusion criteria were pregnancy, insulin dependent diabetes mellitus, and any cancer diagnosis."	
Setting	Home, University/research centre	
Intervention	"Within two weeks of obtaining the baseline measures, participants randomised to the intervention group participated in the 12 month BeWEL programme. This was delivered by trained lifestyle counsellors in three, one hour, one to one visits during the first three months (including spouse or friend when possible), followed by nine, monthly, 15 minute telephone consultations. Thus each participant had a total of 5.25 hours contact over a 12 month period. Motivational interviewing techniques were utilised to explore self assessed confidence, ambivalence, and personal values concerning weight change.31 All intervention participants were set a target goal of a 7% reduction in body weight and provided with a personalised energy prescription of 2508 kJ (600 kcal) below that required for weight maintenance, and bodyweight scales for self monitoring. No drugs were provided or promoted. In the first face to face visit, a 24 hour recall of dietary intake was undertaken to promote discussion around current food and drink intake and to allow counsellors to introduce the concept of personalised dietary change. The components of the British Heart Foundation booklet received at baseline were discussed in detail in relation to the participant's eating habits.23 Topics covered caloric reduction through decreasing portion sizes and reducing intakes of sugary drinks, alcohol, fast foods, snack foods, and processed and red meat. Higher consumption of fruits, vegetables, and whole grains were encouraged. Counselling about personalised physical activity (according to individual ability and disability) was guided by baseline data and largely focused on brisk walking, with pedometers provided for self monitoring. Counsellors were encouraged to concentrate on one topic (diet or physical activity) for the remainder of the first visit, on the outstanding topic in the second visit, and to review progress and revisit goals based on achievements to date at the final visit. Participants were encouraged to identify specific behavioural goals and make short term specific "implementation-intentions."32 Telephone consultations focused on support for making lifestyle changes drawing on recent experience, checking progress, and discussing areas of success and difficulty. Advice was given on relapse (as appropriate) and support for restarting behavioural changes. Weight was self monitored through the duration of the study, reported to the counsellors, and	

<table>
<tr><td></td><td>feedback provided at each consultation. The detailed intervention protocol for all intervention procedures has been published elsewhere.33”</td></tr>
<tr><td>Control/Comparator</td><td>“Participants allocated to the control group after baseline measures had been obtained received no further contact until recall for three and 12 month follow-up measures.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 329
Intervention group/s: Intervention (n=163)

Comparator group: Control (n=166)</td></tr>
<tr><td>Mean age ± SD</td><td>63.6y (6.8)</td></tr>
<tr><td>Sex</td><td>26.14% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Diagnosis of adenoma</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 90.2
(14.9)

Intervention: 31
(4.5)

Intervention: 104.7
(10.9)</td><td>Control: 88.4
(14.3)

Control: 30.4
(3.9)

Control: 103.9
(10.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 87.2
(15.7)

Intervention: 29.9
(4.8)

Intervention: 100.2
(12)</td><td>Control: 88.1
(14.2)

Control: 30.1
(3.8)

Control: 102.1
(11.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in body weight (kg)
Mean (95% CIs)

Change in BMI (kg/m2)
Mean (95% CIs)

Change in waist circumference (cm)
Mean (95% CIs)</td><td>Intervention: -3.5
(-4.3--2.71)

Intervention: -1.22
(-1.5--0.94)

Intervention: -4.91
(-5.79--4.03)</td><td>Control: -0.78
(-1.38--0.19)

Control: -0.27
(-0.47--0.07)

Control: -2.16
(-2.85--1.47)</td></tr>
</table>
</td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	93%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Anderson, 2018

Guideline record ID: 10017

Study characteristics		
Citation	Anderson, Y. C., Leung, W., Grant, C. C., Cave, T. L., Derraik, J. G. B., Cutfield, W. S., Pereira, N. M., Hofman, P. L., & Sullivan, T. A. (2018). Economic evaluation of a multi-disciplinary community-based intervention programme for New Zealand children and adolescents with obesity. Obesity Research & Clinical Practice, 12(3), 293-298. https://doi.org/https://dx.doi.org/10.1016/j.orcp.2018.04.001	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Economic evaluation of a multi-disciplinary community-based intervention programme for New Zealand children and adolescents with obesity	
Location	New Zealand	
Trial name	Whānau Pakari	
Methods		
Inclusion criteria	“Children and adolescents from the Taranaki region aged 5-16 years with a body mass index (BMI) ≥98th centile (obese) or those >91st centile (overweight) with weight-related comorbidities [20] were referred to Whanau ¯ Pakari by health professionals within the community.”	
Exclusion criteria	“Children with significant medical or psychological conditions thatlimited their ability to participate in physical activity, or who were identified as not ready to make lifestyle changes, were not eligible for the programme.”	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	“Participants entered either the intensive intervention (n = 100) or minimal intensity control (n = 99) arm, herein referred to as the high-intensity group and low-intensity group respectively. Two participants were excluded prior to the 6-month assessment in the low-intensity group, resulting in an n = 97. Both groups were offered 6-monthly home visits and assessments with advice from a healthy lifestyle coordinator (replacing the paediatrician hospital visit) at baseline, six, and 12 months. A multi-disciplinary team meeting review with paediatrician oversight to address any identified weight-related comorbidities was held to discuss all assessments. Those in the high-intensity group were also invited to participate in a 12-month multi-disciplinary programme with weekly group sessions during the school year delivered by a physical activity coordinator, dietitian, and psychologist. Sessions occurred at community sporting venues, and incorporated family physical activity sessions (including introduction to various sports to find a participant's interests), psychology sessions (discussing topics such as how to make and maintain healthy lifestyle change, and self-esteem), and dietary sessions (including virtual supermarket tours, cooking sessions, portion size, and the concept of healthy food). A home visit by the dietitian and physical activity coordinator was also offered to the high-intensity group within the first month.”	
Control/Comparator	“Included in intervention section.”	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 197
Intervention group/s: High-intensity (n=100)

Comparator group: Low-intensity (n=97)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 10.8y (3.1); Control: 10.5y (3.3)</td></tr>
<tr><td>Sex</td><td>54.82% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI SDS
Mean (SD)</td><td>High-intensity: 3.12
(0.59)</td><td>Low-intensity: 3.11
(0.58)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Incremental BMI SDS reduction
Mean (95% CIs)</td><td>High-intensity: -0.03
(-0.07-0.13)</td><td>Low-intensity: -0.03
(-0.08-0.13)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Anderson, 2021

Guideline record ID: 10015--1

Study characteristics		
Citation	Anderson, A. S., Chong, H. Y., Craigie, A. M., Donnan, P. T., Gallant, S., Hickman, A., McAdam, C., McKell, J., McNamee, P., Macaskill, E. J., Mutrie, N., O'Carroll, R. E., Rauchhaus, P., Sattar, N., Stead, M., & Treweek, S. (2021). A novel approach to increasing community capacity for weight management a volunteer-delivered programme (ActWELL) initiated within breast screening clinics: a randomised controlled trial. International Journal of Behavioral Nutrition and Physical Activity, 18, 34. https://doi.org/10.1186/s12966-021-01099-7	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A novel approach to increasing community capacity for weight management a volunteer-delivered programme (ActWELL) initiated within breast screening clinics: a randomised controlled trial	
Location	Scotland	
Trial name	N/A	
Methods		
Inclusion criteria	“Attending, or invited to attend, routine breast screening clinics (not recall clinics) Measured BMI > 25 kg/m2 Age 50 to 70 years.”	
Exclusion criteria	“Currently undergoing treatment for any malignant condition (excluding basal or squamous cell skin cancers) Reported contra-indication to physical activity (e.g. recent surgery) Reported contra-indication to weight loss (e.g. currently following a recovery programme for weight gain) On a specialised medical diet e.g. gluten free Diagnosis of Type 1 diabetes Current use of insulin No telephone contact Unable to consent.”	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	“The intervention was based on the COM-B model of behaviour change [27]. This incorporated increased capability for lifestyle change (via a volunteer coach delivered personalised programme), enhanced opportunities for greater physical activity (via pedometer based programmes and introduction to local leisure centres) and increased motivation for weight management e.g. by raising awareness of breast cancer risk reduction within screening. The programme was delivered in two individual, one to one sessions (60 min and 45 min) in the first 12 weeks of the intervention period and 9 (15-min) support calls over the following 9 months, totalling 4 h contact over a 12-month period. The programme was delivered by volunteer coaches who were recruited and managed by the charity Breast Cancer Now. The charity recruited volunteers who had relevant experience with assisting people undertake life changes (e.g. nurses, teachers, church work) and they underwent a 2 day bespoke training programme from the experts in the research team (including physical activity and dietetics). Coaches were then asked to undertake 2 full coaching sessions (with feedback) from participant volunteers. On going support (e.g. frequently asked questions, local WhatsApp group for coaches and questions and queries were handled by the Breast Cancer Now project officer on an on-going basis. Face-to-face visits between volunteer coach and participants took place in non-gym space (e.g. an office) in local leisure centres. The main physical activity component of the intervention was a pedometer-based walking programme, introduced at the first face-to-face visit with a 10-min "walk and talk" session. Participants were supported to increase physical activity towards accumulating at least 150 min of moderate intensity physical activity per week through the provision of graduated walking goals and then, where appropriate, towards 300 min per week (Based on Scottish Intercollegiate Guidelines Network (SIGN) guidance on weight management). All intervention participants were set a target goal of a 7% reduction in body weight and provided with a personalised energy	

<table>
<tr><td></td><td>prescription of 2508 kJ (600 kcal) below that required for weight maintenance. Bodyweight scales were offered in order to undertake self-monitoring. If the weight loss target was attained then guidance was given on weight loss maintenance. Behavioural change techniques (BCTs) included education, motivational interviewing, goal setting, action and coping planning implementation intentions, self monitoring of body weight and steps and feedback. The content and design of the programme was based on the feasibility study findings, views of the target group and those involved in facilitating the programme. At the end of the study we also offered referrals to NHS weight loss services to women who still had a BMI > 25 kg/m2 as well as information on other weight management programmes (including internet based programmes). All participants (including all the comparison group participants) underwent all data collection procedures at baseline, 12 weeks and 12 months including weighing”</td></tr>
<tr><td>Control/Comparator</td><td>“Comparison group All participants (including all the comparison group participants) underwent all data collection procedures at baseline, 12 weeks and 12 months including weighing. On completion of baseline measures all participants received a breast cancer prevention leaflet (which noted the relevance of lifestyle factors). On completion of their 12 months follow up visit women in the comparison group were offered a single personalised coaching session from volunteers and the ActWELL intervention written pack.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 560
Intervention group/s: Intervention (n=279)

Comparator group: Control (n=281)</td></tr>
<tr><td>Mean age ± SD</td><td>59.1y (5.4)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Measured body weight (kg)
Mean (SD)</td><td>Intervention: 80.9
(13.3)</td><td>Control: 81.9
(12.8)</td></tr>
<tr><td>Self-reported body weight (kg)
Mean (SD)</td><td>Intervention: 79.4
(12.9)</td><td>Control: 80.4
(12.7)</td></tr>
<tr><td>Mean waist circumference (cm)
Mean (SD)</td><td>Intervention: 98.1
(12.5)</td><td>Control: 98.7
(11.7)</td></tr>
<tr><td>BMI (measured)
Mean (SD)</td><td>Intervention: 31
(4.7)</td><td>Control: 31.3
(4.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Measured body weight (kg)
Mean (SD)</td><td>Intervention: 77.8
(12.6)</td><td>Control: 80.2
(12.7)</td></tr>
</table>
</td></tr>
</table>

	Self-reported body weight (kg) Mean (SD) Mean waist circumference (cm) Mean (SD) BMI (measured) Mean (SD) Percent weight loss at 12 months ≥ 5% Proportion (%) Percent weight loss at 12 months ≥ 5% Odds Ratio (OR) and 95% CIs	Intervention: 76.9 (12.7) Intervention: 95.5 (11.7) Intervention: 29.9 (4.6) Intervention: 27.2% Intervention: 2.15 (1.41-3.29)	Control: 78.9 (12.7) Control: 97.4 (12) Control: 30.6 (4.3) Control: 16.4%
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Difference to baseline Measured body weight (kg) Mean (SD) Difference to baseline Measured body weight (kg) Mean (95% CIs) Difference in Self-reported body weight (kg) to baseline Mean (SD) Difference in Self-reported body weight (kg) to baseline Mean (95% CIs) Difference in Mean waist circumference (cm) to baseline Mean (SD) Difference in Mean waist circumference (cm) to baseline Mean (95% CIs) Difference in BMI (measured) to baseline Mean (SD) Difference in BMI (measured) to baseline Mean (95% CIs)	Intervention: -2.5 (4.4) Intervention: -2.5 (-3.1--1.9) Intervention: -2.1 (4.8) Intervention: -2.1 (-2.8) Intervention: -2.3 (6) Intervention: -2.3 (-3.1--1.5) Intervention: -1 (1.6) Intervention: -1 (-1.2--0.7)	Control: -1.2 (5) Control: -1.2 (-1.8--0.6) Control: -0.9 (5.5) Control: -0.9 (-1.6--0.1) Control: -1 (6.6) Control: -1 (-1.8--0.2) Control: -0.5 (1.9) Control: -0.5 (-0.7--0.2)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Most (90%) participants attended both face-to-face consultations (mean visits 1.9 SD 0.28) and 59% completed the 9 planned telephone calls (mean 7.1 SD 2.81). Self-reported fidelity data was provided by 32 coaches who described "always" delivering key intervention components (n = 7) (range 67 to 96%). Independent fidelity analysis of recordings of 35 coaching sessions and 22 support calls found 69-88% adherence to protocol.		

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Annesi, 2016

Guideline record ID: 10023--1

Study characteristics		
Citation	Annesi, J. J., Johnson, P. H., Tennant, G. A., Porter, K. J., & McEwen, K. L. (2016). Weight loss and the prevention of weight regain: evaluation of a treatment model of exercise self-regulation generalizing to controlled eating. The Permanente Journal, 20(3), 15-146. https://doi.org/https://dx.doi.org/10.7812/TPP/15-146	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight Loss and the Prevention of Weight Regain: Evaluation of a Treatment Model of Exercise Self-Regulation Generalizing to Controlled Eating	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"1) women of at least 21 years of age, 2) BMI ≥ 30 and < 40 kg/ m2, and 3) a self-reported goal of weight loss."	
Exclusion criteria	"Self-reported 1) present or soon-planned pregnancy; 2) present use of medications for weight loss or a psychological/psychiatric condition; 3) current participation in a medical, commercial, or self-help weight-loss program; and 4) participation in a program of regular physical activity/exercise that averaged at least 20 minutes per week during the year before the start of the study."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Both the EXP and COM treatments were based on the social cognitive11 and self-efficacy12 theories of behavior where individuals are viewed as 1) directing their own actions through self-organization, 2) being able to manage their environments, and 3) possessing capabilities to be self-reflective of their internal abilities. Both the EXP and COM curricula incorporated cognitive-behavioral methods designed to empower participants with self-regulatory skills and abilities to deal with barriers to managing their weight effectively, while increasing their feelings of mastery and competence (ie, self-efficacy). Both treatment protocols informed participants of the recommended volume of weekly exercise to gain health benefits,30 but also suggested that any amount was also likely to be beneficial. However, the administration formats and the proposed role of physical activity/exercise in facilitating changes in eating behaviors differed substantially between the EXP and COM treatments. The EXP treatment incorporated The Coach Approach exercise-support protocol32 paired with a nutrition behaviorchange component developed for this research. It was based on 1) results from previous behavioral weight-management treatments,14,17,33,62-64 2) exploratory studies of psychosocial predictors of weight-loss behaviors,33,39,57 3) findings suggesting that behavioral mechanisms required to foster weight loss differ from those required to maintain lost weight,16,65 and 4) the suggested benefits of targeting specific and measurable behaviors for change (eg, increasing FV rather than addressing numerous and detailed elements of the diet).66 Beginning at baseline, The Coach Approach protocol32 supported adherence to newly initiated exercise through six 45-minute meetings with a trained wellness counselor possessing at least 1 national certification (eg, American College of Sports Medicine). These were conducted in a private office over 6.5 months. Each participant's exercise plan, both initially and in revisions during subsequent meetings, was based on the participant's preferred type of physical activity and tolerance. Most of the meeting time was, however, spent on the development of specific self-regulatory skills such as long- and short-term goal setting paired with progress monitoring, dissociation from discomfort, cognitive restructuring, stimulus control, behavioral contracting, controlling behavioral prompts and triggers, and relapse prevention. Exercise-induced changes in mood (eg, anxiety, energy level) were assessed	

	both in response to a single bout of physical activity and for 1 to 2 months, and displayed through responses to items embedded in the supporting computer application. After 8 weeks of concentration exclusively on maintaining regular exercise, the components for eating behavior change were sequentially added. First, guidance and practice on methods for kcal tracking was individually provided in two 30-minute meetings over 2 weeks. Energy-intake goals were based on each participant's weight (eg, 1500 kcal/day for a weight range of 79-99 kg), and various methods for recording food and corresponding kcal intake were made available (eg, through an approved Web site, an approved application for hand-held devices, or a provided paper form and use of an approved "calorie counter" book). Next, 10 nutrition sessions of 60 minutes each focused on weight reduction were administered by trained wellness counselors (supported by a manual) at 2-week intervals in groups of 8-15 participants. Their primary aim was to generalize, adapt, and extend self-regulatory skills developed during The Coach Approach exercise-support protocol, 32 to self-regulating eating behaviors (eg, dissociating from exercise-induced discomfort was generalized to dissociating from feelings of hunger; recovering from and rescheduling a missed exercise session was generalized to recovering from a day of excess kcal intake and immediately recommitting to the appropriate limit for the next day). There was a combination of brief lectures, individual tasks, and group activities within each session. The next component, now 28 weeks after baseline, was 4 group sessions in which self-regulatory skills were addressed in the context of maintaining lost weight. The final 10 sessions of the EXP treatment covered skills of self-regulation in both weightloss and weight-loss maintenance contexts (Figure 1). Treatment content related to the diet was primarily concentrated on increasing FV intake, although there was a limited focus on minimizing the consumption of fat and sugar. Because meeting time was primarily centered on the development of self-regulatory skills and the ability to increase self-efficacy for controlling overeating, participants were referred to the ChooseMy- Plate.gov Web site67 for access to detailed, evidence-based information on nutrition.”
Control/Comparator	“The COM treatment replicated methods used previously in studies,21,42 and consisted of participants reviewing 1 of the 12 "lessons" of a 265-page print manual entitled The LEARN (lifestyle, exercise, attitudes, relationships, nutrition) Program for Weight Management (10th edition)68 every 2 weeks. Sections related to behavior change included "Dealing with Pressures to Eat," "Preventing Lapse, Relapse, and Collapse," "Interpreting Your Progress," and "Making Physical Activity Count." Sections related to diet included "Fast Foods," "Rating Your Diet," "Vegetables in Your Diet," and "Breads, Cereals, Rice, and Pasta in Your Diet." Each lesson was followed by a 15-minute phone conversation initiated by a wellness counselor to clarify chapter contents, review each participant's plans for carrying out behavioral changes, and answer the participant's questions. The process of participants reading chapters and obtaining telephone follow-ups started at baseline and lasted 24 weeks (Figure 1). The LEARN manual68 suggested that women limit their energy intake to 1200 kcal per day. A paper monitoring form was provided for participants to record foods and drinks consumed, the amount consumed and their associated kcal, their corresponding food group categorization, and optional comments.”
Treatment duration	Experimental: 14 months; comparison: 6 months
Follow-up from baseline	24 months
Eligible outcome(s) reported	Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 110 Intervention group/s: Experimental (n=55) Comparator group: Comparison (n=55)
Mean age ± SD	48.2y (7.8)

<table>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Crude weight
Mean (SD)</td><td>Experimental: 94.95
(11.44)</td><td>Comparison: 95.36
(10.56)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Crude weight
Mean (SD)</td><td>Experimental: 89.4
(11.86)</td><td>Comparison: 93.51
(11.07)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Crude weight
Mean (SD)</td><td>Experimental: 89.84
(13.58)</td><td>Comparison: 94.11
(11.23)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight, kg</td><td>Experimental: -4.59</td><td>Comparison: -1.86</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Annesi, 2017

Guideline record ID: 10020--1

Study characteristics		
Citation	Annesi, J. J. (2017). Mediation of the relationship of behavioural treatment type and changes in psychological predictors of healthy eating by body satisfaction changes in women with obesity. Obesity Research & Clinical Practice, 11(1), 97-107. https://doi.org/https://dx.doi.org/10.1016/j.orcp.2016.03.011	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Mediation of the relationship of behavioural treatment type and changes in psychological predictors of healthy eating by body satisfaction changes in women with obesity	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Women with class 1 or 2 obesity (body mass index[BMI] ≥ 30 < 40 kg/m2) and were physically inactive inactive(<20 min/week average over the previous year)were recruited through local print and electronic advertisements. Because research indicates that body satisfaction might be influenced more acutely in young women (defined as <30 years of age [29]),and older women have less concern with body image than younger ages [30,31], the age requirement was set at 30-65 years."	
Exclusion criteria	"Exclusion criteria basedon self-report were: present/soon-planned preg-nancy; present use of medications for weight loss ora diagnosed psychiatric condition; and participationin a commercial, self-help, or medical weight-lossprogram."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Both the experimental and comparison treatments were based on social cognitive [18] and self-efficacy [19]theory, which view individuals as capable of self-organizing their actions, managing environments,and reflecting on their capabilities. Both treatments similarly employed cognitive-behaviouralmethods intended to bring to bear self-regulatoryskills to overcome barriers to behaviour changeand increase perceptions of competence (i.e., self-efficacy) and the overall self. Both treatment protocols informed participants of the recom-mended 150 min of moderate exercise per week togain health benefits [43], but also indicated thatlesser amounts are also likely to hold benefits. Experimental group: The experimental treatment first initiated The Coach Approach exercise-support protocol [27]which incorporated 6, 45-minute personal meet-ings with the same wellness leader over 6 months.Most of that meeting time was spent on the development of self-regulatory skills such as long- and short-term goal setting linked with progress monitoring, cognitive restructuring, stimulus control,behavioural contracting, dissociation from discom-fort, controlling behavioural cues and triggers,and relapse prevention. These were intended toovercome barriers to maintaining regular exercise[27]. After introducing participants to tracking theirfoods, beverages, and associated energy intakes via either an electronic devise or by paper, group sessions of 8-15 participants applied a newly developed curriculum focused on nutritional weightloss beginning at week 10. These sessions wereheld every 2 weeks over 20 weeks, and adaptedself-regulatory skills previously intended for main-taining exercise, for controlling eating. Increasedfruit and vegetable intake, a suggested proxyfor an overall healthy diet and predictive of ahealthy body weight [44-48], was emphasised.Assigned energy intake was based on each par-ticipant's weight (e.g., 79-99 kg = 1500 kilocalories[kcal]/day). Participants were encouraged toreview the U.S. Department of Agriculture's web-site, www.ChooseMyPlate.gov, for evidence-basednutrition information not covered within sessions.Over the next 8 weeks, the group sessions trans-ferred the learned and practiced self-regulatoryskills to maintaining lost weight. The final 20 weeksof the treatment (ending	

<table>
<tr><td></td><td>at week 56) focused onapplying self-regulatory methods to both losing andmaintaining lost weight, based on each participant's weight-loss goals.”</td></tr>
<tr><td>Control/Comparator</td><td>“The comparison treatment consisted of partic-ipants reviewing 1 of the 12 lessons (chapters)of a print manual entitled The LEARN (lifestyle,exercise, attitudes, relationships, nutrition) Pro-gram for Weight Management [25] every 2 weeks (24 weeks total). Sections of the manual wererelated to eating behaviour change (e.g.,''Conquering the Cravings), physical activitybehaviour change (e.g., ''Maximizing the Pleasureof Walking''), diet (e.g., ''Watch out for Fat),and psychological factors (e.g., ''Developing aPositive Body Image''). It was suggested thatwomen limit their energy intake to 1200 kcal/day,while recording foods and drinks consumed andtheir associated kcal and food group. Each lessonwas followed by a 15-minute phone conversationinitiated by a wellness leader that reviewedchapter contents and the participant's plans for behavioural changes.”</td></tr>
<tr><td>Treatment duration</td><td>Experimental group: 56 weeks; comparison group: 24 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 107
Intervention group/s: Experimental group (n=53)

Comparator group: Comparison group (n=54)</td></tr>
<tr><td>Mean age ± SD</td><td>48.6y (7.1)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Crude weight at baseline, kg Mean (SD)</td><td>Experimental group: 94.63 (11.53)</td><td>Comparison group: 95.6 (10.52)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight, kg Mean (SD)</td><td>Experimental group: -5.57 (4.64)</td><td>Comparison group: -1.7 (4.8)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight, kg Mean (SD)</td><td>Experimental group: -4.95 (8.18)</td><td>Comparison group: -1.11 (4.93)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Annesi, 2019

Guideline record ID: 10021--1

Study characteristics		
Citation	Annesi, J. J. (2019). Relationship of emotional eating and mood changes through self-regulation within three behavioral treatments for obesity. Psychological Reports, 122(5), 1689-1706. https://doi.org/https://dx.doi.org/10.1177/0033294118795883	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Relationship of Emotional Eating and Mood Changes Through Self-Regulation Within Three Behavioral Treatments for Obesity	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	“Women with obesity (i.e., body mass index (BMI) 30 kg/m2) were recruited . Inclusion criteria included: self-reporting less than the recommended 150 minutes/week of moderate physical activity per week (U.S. Department of Health and Human Services, 2008), a goal of weight loss, not presently participating in another weight-management treatment, free from psychotropic medication use, and no present/soon-planned pregnancy.”	
Exclusion criteria	“None stated.”	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	“In Group 2, participants were administered six sessions (45 minutes/session) of one-on-one exercise support over 28 weeks that emphasized behavioral goal setting and contracting, setting graded tasks, self-monitoring of behaviors, performance feedback, barrier identification, identification of prompts/cues, selftalk/ cognitive restructuring, relapse prevention, stress management, and time management-as described by Abraham and Michie (2008) as falling within the "social-cognitive theory," "operant conditioning," and "control" treatment models. After the initial eight weeks of structured, cognitive-behaviorally based exercise support (Annesi, 2012), food/calorie tracking was added. Beginning at Week 10, 24 structured nutrition change sessions (60 minutes/session) were administered in groups of 8-15 participants every two weeks. Consistent with research suggesting an ability to generalize self-regulatory skills developed in a physical activity context, to other health behavior contexts (Oaten & Cheng, 2006), the content of the nutrition-change sessions focused on adapting the physical activity-centered self-regulatory skills for eating behavior changes. Research-based suggestions on the use of moderate physical activity to improve mood (Landers & Arent, 2007) and controlling emotion-based eating (Mata et al., 2009) were addressed in approximately half of the sessions. The primary focus of the full 58-week protocol of Group 2 was addressing barriers to physical activity and nutrition change. In Group 3, participants were administered the same treatment methods as Group 2, with the addition of five conference phone calls (with the instructor and three to four participants on the call), each spaced by eight weeks. These 15- to 20-minute calls that reinforced learned self-regulation skills were held after the group nutrition change sessions concluded at Week 58. This lengthened Group 3 treatment protocol to 98 weeks.”	
Control/Comparator	“In Group 1, participants reviewed 12 topics over 28 weeks derived from weight management manuals used in previous research and applications (Brownell, 2004; Kaiser Permanente Health Education Services, 2008). Every two weeks, a wellness leader lead a conference phone call of 15-20 minutes (with three to four participants on the call) that encouraged questions, comments, and practical aspects of the assigned content. Examples of topics included: United States government's dietary guidelines, controlling food and	

<table>
<tr><td></td><td>calorie intake, benefits and types of physical activities, and benefits and disadvantages of food types within a challenging food environment. The primary focus of the treatment for Group 1 was education related to the weight loss process-as described by Abraham and Michie (2008) as falling within the "informationalmotivation- behavioral skills" treatment model.”</td></tr>
<tr><td>Treatment duration</td><td>Group 1: 28 weeks; Group 2: 58 weeks; Group 3: 99 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 171
Intervention group/s: Group 2: CBT (n=57); Group 3: CBT followed with phone-based reviews of materials (n=57)

Comparator group: Group 1: phone-supported education (n=57)</td></tr>
<tr><td>Mean age ± SD</td><td>48.6y (7.0)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Group 2: CBT: 34.65
(3.28)
Group 3: CBT followed with phone-based reviews of materials: 35.01
(3.18)</td><td>Group 1: phone-supported education: 36.11
(3.13)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Group 2: CBT: 32.58
(3.75)
Group 3: CBT followed with phone-based reviews of materials: 33.07
(3.59)</td><td>Group 1: phone-supported education: 35.51
(3.71)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Group 2: CBT: 32.77
(4.26)
Group 3: CBT followed with phone-based reviews of materials: 33.09
(3.26)</td><td>Group 1: phone-supported education: 35.76
(3.77)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in BMI
Mean (SD)</td><td>Group 2: CBT: -2.08
(1.63)
Group 3: CBT followed with phone-based reviews of materials: -1.94
(2.4)</td><td>Group 1: phone-supported education: -0.6
(1.84)</td></tr>
</table></td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in BMI
Mean (SD)</td><td>Group 2: CBT: -1.88
(3.16)
Group 3: CBT followed with phone-based reviews of materials: -1.92
(2.41)</td><td>Group 1: phone-supported education: -0.36
(1.9)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Annesi, 2020

Guideline record ID: 10022--1

Study characteristics		
Citation	Annesi, J. J. (2020). Psychosocial correlates of emotional eating and their interrelations: implications for obesity treatment research and development. Journal of Primary Prevention, 41(2), 105-125. https://doi.org/10.1007/s10935-020-00580-6	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Psychosocial Correlates of Emotional Eating and Their Interrelations: Implications for Obesity Treatment Research and Development	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Women; aged 30 or older; BMI of 30 or more; on average, no more than 1 day per week exercise during the previous year; no present use of psychotropic medications or substances; not pregnant or currently planning a pregnancy; and seeking weight loss, but not presently on a program (commercial, medical, self-help, or otherwise)."	
Exclusion criteria	"Scores less than 5 on our emotional eating scales."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"In the behavioral treatment group, we administered a previously validated protocol (Annesi, Unruh, Marti, Gorjala, & Tennant, 2011) of six, one-on-one sessions of exercise support of 45 min each from weeks 1 to 26. It emphasized self-regulatory skills described by Abraham and Michie's (2008) taxonomy such as goal setting and contracting, setting graded tasks, identification of prompts/cues, self-monitoring of behaviors, self-talk/cognitive restructuring, relapse prevention, and stress management. Exercise modalities and volumes were largely based on each participant's preference. At week 8, instruction in food and calorie logging was added. At week 10, group nutrition classes began. One instructor led 10-15 participants every 2 weeks, ending at week 56. The group nutrition classes predominantly adapted the exerciserelated self-regulatory skills to enable more controlled eating behaviors. Nutrition suggestions focused on increasing fruit/vegetable intake and reducing sweets. Written materials and websites were distributed to guide brief homework assignments and enable further inquiry into dietary suggestions, if desired. All in-person meetings were held at a community health-promotion center, with only minor schedule deviations required for holidays and inclement weather."	
Control/Comparator	"In the education treatment group, we provided participants written materials adapted from the LEARN (Brownell, 2004) and Cultivating Health (Kaiser Permanente Health Education Services, 2008) books. From weeks 1 to 28, each participant interacted with an instructor during 15-min sessions every 2 weeks to review one."	
Treatment duration	Behavioural group: 56 weeks; education group: 28 weeks	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 75 Intervention group/s: Behavioral group (n=39) Comparator group: Education group (n=36)	

<table>
<tr><td>Mean age ± SD</td><td>Behavioural group: 48.5 (8.6); education group: 50.2 (5.4)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Crude weight
Mean (SD)</td><td>Behavioral group: 94.26 (11.37)</td><td>Education group: 95.98 (10.6)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Crude weight
Mean (SD)</td><td>Behavioral group: 88.12 (11.62)</td><td>Education group: 93.23 (10.26)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Crude weight
Mean (SD)</td><td>Behavioral group: 87.81 (13.58)</td><td>Education group: 94.28 (11.02)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (%)
Mean (SD)</td><td>Behavioral group: -6.5</td><td>Education group: -2.9</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (%)
Mean (SD)</td><td>Behavioral group: -6.8</td><td>Education group: -1.8</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Apolzan, 2019

Guideline record ID: 11004

Study characteristics		
Citation	Apolzan, J. W., Venditti, E. M., Edelstein, S. L., Knowler, W. C., Dabelea, D., Boyko, E. J., Pi-Sunyer, X., Kalyani, R. R., Franks, P. W., Srikanthan, P., Gadde, K. M., & for the Diabetes Prevention Program Research Group. (2019). Long-term weight loss with metformin or lifestyle intervention in the Diabetes Prevention Program Outcomes Study. Annals of Internal Medicine, 170(10), 682-690. https://doi.org/https://doi.org/10.7326/M18-1605	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-Term Weight Loss With Metformin or Lifestyle Intervention in the Diabetes Prevention Program Outcomes Study	
Location	USA	
Trial name	Diabetes Prevention Program Outcomes Study (DPPOS)	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	University/research centre	
Intervention	"Metformin: Treatment with metformin was initiated at a dose of 850 mg taken orally once a day, with placebo tablets also given once a day initially. At one month, the dose of metformin was increased to 850 mg twice daily, unless gastrointestinal symptoms warranted a longer titration period. The initiation of treatment with half a tablet was optional. The standard lifestyle recommendations for the medication groups were provided in the form of written information and in an annual 20-to-30-minute individual session that emphasized the importance of a healthy lifestyle. Participants were encouraged to follow the Food Guide Pyramid14 and the equivalent of a National Cholesterol Education Program Step 1 diet,15 to reduce their weight, and to increase their physical activity.; ILS: The goals for the participants assigned to the intensive lifestyle intervention were to achieve and maintain a weight reduction of at least 7 percent of initial body weight through a healthy low-calorie, low-fat diet and to engage in physical activity of moderate intensity, such as brisk walking, for at least 150 minutes per week. A 16-lesson curriculum covering diet, exercise, and behavior modification was designed to help the participants achieve these goals. The curriculum, taught by case managers on a one-to-one basis during the first 24 weeks after enrollment, was flexible, culturally sensitive, and individualized. Subsequent individual sessions (usually monthly) and group sessions with the case managers were designed to reinforce the behavioral changes."	
Control/Comparator	"Standard lifestyle recommendations plus placebo twice daily. The standard lifestyle recommendations for the medication groups were provided in the form of written information and in an annual 20-to-30-minute individual session that emphasized the importance of a healthy lifestyle. Participants were encouraged to follow the Food Guide Pyramid14 and the equivalent of a National Cholesterol Education Program Step 1 diet,15 to reduce their weight, and to increase their physical activity."	
Treatment duration	6 years	
Follow-up from baseline	15 years	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= Not reported
Intervention group/s: Metformin (n=Not reported); Intervention Lifestyle Intervention (ILS) (n=Not reported)

Comparator group: Placebo (n=Not reported)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Data could not be extracted</td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Data could not be extracted</td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Ard, 2018

Guideline record ID: 10025--1

Study characteristics		
Citation	Ard, J. D., Gower, B., Hunter, G., Ritchie, C. S., Roth, D. L., Goss, A., Wingo, B. C., Bodner, E. V., Brown, C. J., Bryan, D., Buys, D. R., Haas, M. C., Keita, A. D., Flagg, L. A., Williams, C. P., & Locher, J. L. (2018). Effects of calorie restriction in obese older adults: the CROSSROADS randomized controlled trial. The Journals of Gerontology: Series A, 73(1), 73-80. https://doi.org/10.1093/gerona/glw237	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of Calorie Restriction in Obese Older Adults: The CROSSROADS Randomized Controlled Trial	
Location	US	
Trial name	Calorie Restriction in Overweight SeniorS: Response of Older Adults to a Dieting Study (CROSSROADS)	
Methods		
Inclusion criteria	"Potential participants had to be at least 65 years old; be weight stable and obese (body mass index of 30-40 kg/m2); and prescribed at least one oral medication for control of lipids, blood pressure, and/or blood glucose, resulting in adequate control of the risk factor (e.g., blood pressure < 160/100 mm Hg)."	
Exclusion criteria	"Volunteers were excluded from participation during a series of one telephone and three in-person screening visits if they had significant medical, psychiatric, or physical limitations that would prevent adoption of the lifestyle recommendations or ongoing treatments that would independently affect body weight and composition."	
Setting	University/research centre	
Intervention	"The basis for the intervention was a behavioral lifestyle modification program that provided group-based counseling and healthy recommendations to improve physical activity in all groups, diet quality in the Maintenance group, and diet quality and body weight in the Weight Loss group. Because standard lifestyle interventions would generally include exercise prescriptions, the recommendations for exercise were consistent across all groups and included 90-150 min/ wk of moderate to vigorous cardio-aerobic exercise such as walking based on monitoring their heart rate. Participants also received a written program to guide participation in two sessions/ week of resistance training using resistance bands focused on major muscle groups of the extremities. Both the Maintenance group and the Weight Loss group received recommendations for improving diet composition by increasing consumption of low-energy dense fruits, vegetables, lean protein, and whole grains with a targeted macronutrient intake pattern of 25% of calories from protein, 47% from carbohydrates, and 28% from fat. In addition to recommended changes in diet composition, the Weight Loss group had a primary goal to reduce caloric intake by 500 kcal/d below estimated total energy needs based on measured resting energy expenditure, with a minimum intake of 1,000 kcal/d. Dietary intake was monitored with three 24-hour dietary recalls, including one weekend day, via the multiple pass approach at each time point. All groups received behavioral group counseling weekly for the first 24 weeks of the intervention, then every 2 weeks for the remainder of the 12-month intervention, to provide a high-frequency contact intervention consistent with obesity treatment guidelines. Each session that took place in our research facility lasted 60 minutes and included 30 minutes of group discussion related to a dietary, exercise, or behavioral topic, followed by 30 minutes of supervised exercise using resistance band exercises. All remaining exercise was unsupervised, and participants self-reported exercise using written diaries."	

<table>
<tr><td>Control/Comparator</td><td>“The Exercise group served as a control, allowing for isolation of the effects of dietary changes and calorie restriction on body composition and physical function. The basis for the intervention was a behavioral lifestyle modification program that provided group-based counseling and healthy recommendations to improve physical activity in all groups, The Exercise group served as a control, allowing for isolation of the effects of dietary changes and calorie restriction on body composition and physical function. All groups received behavioral group counseling weekly for the first 24 weeks of the intervention, then every 2 weeks for the remainder of the 12-month intervention, to provide a high-frequency contact intervention consistent with obesity treatment guidelines. Each session that took place in our research facility lasted 60 minutes and included 30 minutes of group discussion related to a dietary, exercise, or behavioral topic, followed by 30 minutes of supervised exercise using resistance band exercises. All remaining exercise was unsupervised, and participants self-reported exercise using written diaries.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 164
Intervention group/s: Weight Maintenance (n=55); Weight Loss (n=55)

Comparator group: Exercise Only (n=54)</td></tr>
<tr><td>Mean age ± SD</td><td>70.3y (4.7)</td></tr>
<tr><td>Sex</td><td>62.20% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Weight Maintenance: 95.1
(1.9)
Weight Loss: 94.1
(2.1)</td><td>Exercise Only: 95.2
(1.7)</td></tr>
<tr><td>Total percent body fat
Mean (SD)</td><td>Weight Maintenance: 46.4
(0.8)
Weight Loss: 45
(0.8)</td><td>Exercise Only: 46.4
(0.8)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Weight Maintenance: 33.8
(0.4)
Weight Loss: 33.3
(0.4)</td><td>Exercise Only: 33.9
(0.4)</td></tr>
<tr><td>Total fat mass (kg)
Mean (SD)</td><td>Weight Maintenance: 42
(0.9)
Weight Loss: 40.4
(1.1)</td><td>Exercise Only: 42.1
(0.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td>Body weight (kg) Change at 1 year
Mean (SD)</td><td>Weight Maintenance: -0.9
(0.7)
Weight Loss: -3.9
(0.7)</td><td>Exercise Only: -1.3
(0.7)</td></tr><tr><td>Total percent body fat Change at 1 year
Mean (SD)</td><td>Weight Maintenance: -0.3
(0.3)
Weight Loss: -1.6
(0.3)</td><td>Exercise Only: -0.7
(0.3)</td></tr><tr><td>BMI (kg/m2) Change at 1 Year
Mean (SD)</td><td>Weight Maintenance: -0.5
(0.2)
Weight Loss: -1.6
(0.2)</td><td>Exercise Only: -0.7
(0.2)</td></tr><tr><td>Total fat mass (kg) Change at 1 Year
Mean (SD)</td><td>Weight Maintenance: -0.9
(0.5)
Weight Loss: -3
(0.5)</td><td>Exercise Only: -1.2
(0.5)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Arguin, 2012

Guideline record ID: 10026--1

Study characteristics		
Citation	Arguin, H., Dionne, I. J., Sénéchal, M., Bouchard, D. R., Carpentier, A. C., Ardilouze, J.-L., Tremblay, A., Leblanc, C., & Brochu, M. (2012). Short- and long-term effects of continuous versus intermittent restrictive diet approaches on body composition and the metabolic profile in overweight and obese postmenopausal women: a pilot study. Menopause: The Journal of The North American Menopause Society, 19(8), 870-876. https://doi.org/10.1097/gme.0b013e318250a287	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Short- and long-term effects of continuous versus intermittent restrictive diet approaches on body composition and the metabolic profile in overweight and obese postmenopausal women: a pilot study	
Location	Canada	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were as follows: no menstruation for more than 1 year, waist circumference greater than 90 cm, sedentary (G30 min/wk of structured exercise), nonsmokers, and low to moderate alcohol consumption (fewer than two drinks per day)."	
Exclusion criteria	Not reported	
Setting	Home, University/research centre	
Intervention	"Both groups followed the same weight loss protocol for the first 5 weeks, before undergoing their specific programs. Weight stabilization periods Before (4-wk ambulatory run-in period) and after (5-wk final weight stabilization period) the study, participants were asked to maintain their body weight stable (T2 kg) to reduce the acute effects of body weight fluctuations on outcome variables.23,24 The intermittent diet group was also asked to do two 5-week weight stabilization periods during the weight loss program. Dietary intervention This intervention was designed to reduce body weight by 1% of initial body weight per week during weight loss phases. Food was self-selected with dietitian supervision on macronutrient composition (55%, 30%, and 15% of energy intake from carbohydrates, fats, and proteins, respectively25,26), without the use of modified food supplements. articipants were asked to contact the dietitian for a quick adjustment of their caloric intake when body weight was not adequately following the prescribed slope of weight loss. During the interventions, women from the intermittent group (Wednesdays) were invited to 17 weekly group lessons on nutrition, health, and lifestyle habits. At the term of the weight loss program, they were also invited to a final group lesson, during which information was given on how to maintain their reduced body weight in the long term. They were allowed to keep the dietary guide used during the intervention. They were told that they would be called in 1 year for a follow-up visit."	
Control/Comparator	"Both groups followed the same weight loss protocol for the first 5 weeks, before undergoing their specific programs. Weight stabilization periods Before (4-wk ambulatory run-in period) and after (5-wk final weight stabilization period) the study, participants were asked to maintain their body weight stable (T2 kg) to reduce the acute effects of body weight fluctuations on outcome variables.Dietary intervention This intervention was designed to reduce body weight by 1% of initial body weight per week during weight loss phases. Food was self-selected with dietitian supervision on macronutrient composition (55%, 30%, and 15% of energy intake from carbohydrates, fats, and proteins, respectively25,26), without the use of modified food supplements. Participants were asked to contact the dietitian for a quick adjustment of their caloric intake when body weight was	

<table>
<tr><td></td><td>not adequately following the prescribed slope of weight loss. During the interventions, women from the continuous group (Mondays) were invited to 17 weekly group lessons on nutrition, health, and lifestyle habits. At the term of the weight loss program, they were also invited to a final group lesson, during which information was given on how to maintain their reduced body weight in the long term. They were allowed to keep the dietary guide used during the intervention. They were told that they would be called in 1 year for a follow-up visit.”</td></tr>
<tr><td>Treatment duration</td><td>Intermittent: 30 weeks; Continuous: 20 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>Intermittent: 82 weeks; Continuous: 72 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 22
Intervention group/s: Intermittent diet (n=12)

Comparator group: Continuous diet (n=10)</td></tr>
<tr><td>Mean age ± SD</td><td>Intermittent diet: 60.8y (5.5); Continuous diet: 61.0y (7.3)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline Body weight (kg)
Mean (SD)

Baseline waist circumference (cm)

Percentage Fat Mass (%)
Mean (SD)

Fat Mass (kg)
Mean (SD)</td><td>Intermittent diet: 81.3 (11.4)

Intermittent diet: 101.5 (9.6)

Intermittent diet: 46.8 (4.8)

Intermittent diet: 37.2 (7.8)</td><td>Continuous diet: 77.5 (9.8)

Continuous diet: 96.3 (5.7)

Continuous diet: 48 (6.1)

Continuous diet: 36.5 (9.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight change (kg)
Mean (SD)

Waist circumference change (cm)
Mean (SD)

Percentage Fat Mass change (%)
Mean (SD)</td><td>Intermittent diet: -8.5 (4.2)

Intermittent diet: -6.9 (9.3)

Intermittent diet: -4.5 (3.2)</td><td>Continuous diet: -7.1 (4.7)

Continuous diet: -2.7 (9.1)

Continuous diet: -3.2 (2.5)</td></tr>
</table></td></tr>
</table>

	Fat mass change (kg) Mean (SD)	Intermittent diet: -6.8 (3.7)	Continuous diet: -5.1 (3.8)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Arlinghaus, 2019

Guideline record ID: 10028--1

Study characteristics		
Citation	Arlinghaus, K. R., O'Connor, D. P., & Johnston, C. A. (2019). Frequency of school-based intervention needed to improve weight outcomes of Mexican-American adolescents with overweight or obesity: a randomized controlled trial. Pediatric Obesity, 14(12), e12568. https://doi.org/https://dx.doi.org/10.1111/ijpo.12568	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Frequency of school-based intervention needed to improve weight outcomes of Mexican-American adolescents with overweight or obesity: a randomized controlled trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	“Self-identified as Mexican-American, were between the ages of 10 and 17, and had overweight status or obesity according to the Centers for Disease Control and Prevention's classification (i.e., BMI percentile ≥85th percentile).”	
Exclusion criteria	“Participants were excluded from the study if they were pregnant, the school identified them as having a cognitive impairment significantly below average age or grade level, they used weight loss medication, or they had a medical diagnosis of type 1 or 2 diabetes.”	
Setting	School	
Intervention	“The intervention lasted 24 weeks and occurred during student's 40-minute physical education (PE) class. All intervention activities were led by research staff trained in behaviour modification by a clinical child psy chologist. The intervention was designed to be consistent with tradi tional Mexican values such as familismo and respeto. Foods included as examples during lessons were commonly eaten by students. The intervention consisted of nutrition lessons based on the traffic light diet, circuit-based physical activity, behaviour modification techniques (token economy system, goal setting, and self-monitoring), and paren tal involvement (materials sent home and monthly parent meetings). No matter the frequency at which the intervention was received (1, 3, or 5 d a week), 80% of time was spent on physical activity, and 20% was spent on nutrition, as this 4:1 ratio has established efficacy among this population.20-23 Behaviour modification was incorporated into both physical activity and nutrition time. Parental contact was held constant across all treatment conditions. The parents of all stu dents who received intervention were invited to attend monthly meetings, and materials were sent home once a week. Specifically, instruction and activity time during PE class lasted approximately 40 minutes. Table 1 outlines the specific breakdown of time allocated to intervention activities for each condition”	
Control/Comparator	“Students participated in a traditional PE class with sports-based skill development and practice. These classes were led by the students' assigned PE teacher. Parents and students were told to contact the research team with any questions or to report adverse side effects.”	
Treatment duration	24 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		

Number of participants	n= 243 Intervention group/s: 1 d/wk (n=59); 3 d/wk (n=58); 5 d/wk (n=63) Comparator group: 0 d/wk (n=63)
Mean age ± SD	Not reported
Sex	Not reported
Pre-existing medical condition	No pre-existing medical condition
Results	

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Weight, kg - Baseline (Completers only) Mean (SD)	1 d/wk: 63.93 (15.29) 3 d/wk: 61.63 (13.82) 5 d/wk: 64.19 (13.48)	0 d/wk: 65.12 (17.85)
BMI (kg/m2) - Baseline (Completers only) Mean (SD)	1 d/wk: 26.85 (4.79) 3 d/wk: 26.52 (4.29) 5 d/wk: 27.34 (4.41)	0 d/wk: 27.43 (6.21)
Baseline zBMI (Completers only) Mean (SD)	1 d/wk: 1.78 (0.49) 3 d/wk: 1.79 (0.41) 5 d/wk: 1.86 (0.41)	0 d/wk: 1.78 (0.55)
Baseline BMI percentile - (Completers only) Mean (SD)	1 d/wk: 94.53 (4.56) 3 d/wk: 95.19 (3.72) 5 d/wk: 95.79 (3.44)	0 d/wk: 94.22 (4.8)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point

Variable	Intervention arm/s	Comparator
Change in weight (kg) (ITT) Mean (SD)	1 d/wk: 5.76 (3.78) 3 d/wk: 3.17 (4.35) 5 d/wk: 3.86 (5.05)	0 d/wk: 6.08 (4.91)
Change in BMI (kg/m2) (ITT) Mean (SD)	1 d/wk: 0.5 (1.37) 3 d/wk: -0.33 (1.4) 5 d/wk: -0.25 (1.75)	0 d/wk: 0.9 (1.35)

<table>
<tr><td></td><td>
<table>
<tr><td>Change in zBMI (ITT)
Mean (SD)</td><td>1 d/wk: -0.08
(0.18)
3 d/wk: -0.19
(0.22)
5 d/wk: -0.2
(0.25)</td><td>0 d/wk: -0.01
(0.15)</td></tr>
<tr><td>Change in BMI percentiles (ITT)
Mean (SD)</td><td>1 d/wk: -1.17
(3.3)
3 d/wk: -2.8
(4.5)
5 d/wk: -3.03
(4.66)</td><td>0 d/wk: -0.46
(2.43)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Aronne, 2024

Guideline record ID: 12002--1

Study characteristics		
Citation	Aronne, L. J., Sattar, N., Horn, D. B., Bays, H. E., Wharton, S., Lin, W.-Y., Ahmad, N. N., Zhang, S., Liao, R., Bunck, M. C., Jouravskaya, I., Murphy, M. A., & for the SURMOUNT-4 Investigators. (2024). Continued treatment with tirzepatide for maintenance of weight reduction in adults with obesity: the SURMOUNT-4 randomized clinical trial. JAMA, 331(1), 38-48. https://doi.org/10.1001/jama.2023.24945	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Continued Treatment With Tirzepatide for Maintenance of Weight Reduction in Adults With Obesity: The SURMOUNT-4 Randomized Clinical Trial	
Location	Argentina; Brazil; Taiwan; USA	
Trial name	SURMOUNT-4	
Methods		
Inclusion criteria	"Eligible participants (18 years or older) had a body mass index (BMI) greater than or equal to 30 or greater than or equal to 27 and at least 1 weight-related complication (i.e., hypertension, dyslipidemia, obstructive sleep apnea, or cardiovascular disease)."	
Exclusion criteria	"Key exclusion criteria included diabetes, prior or planned surgical treatment for obesity, and treatment with a medication that promotes weight loss within 3 months prior to enrollment."	
Setting	University/research centre	
Intervention	"Tirzepatide (10 or 15 mg). All participants received lifestyle counseling by a qualified health care professional throughout the study to encourage adherence to a healthy 500 kcal/d deficit diet and at least 150 minutes of physical activity per week."	
Control/Comparator	"Placebo. All participants received lifestyle counseling by a qualified health care professional throughout the study to encourage adherence to a healthy 500 kcal/d deficit diet and at least 150 minutes of physical activity per week."	
Treatment duration	52 weeks	
Follow-up from baseline	52 weeks	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 670 Intervention group/s: Tirzepatide (n=335) Comparator group: Placebo (n=335)	
Mean age ± SD	Intervention: 49y (13); Control: 48y (12)	
Sex	70.60% female	
Pre-existing medical condition	At least 1 weight-related complication (ie, hypertension, dyslipidemia, obstructive sleep apnea, or cardiovascular disease).	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight, kg
Mean (SD)

BMI
Mean (SD)

Waist circumference, cm
Mean (SD)</td><td>Tirzepatide: 84.6
(19.8)

Tirzepatide: 30.3
(6)

Tirzepatide: 96.8
(14.1)</td><td>Placebo: 85.8
(22.3)

Placebo: 30.7
(6.8)

Placebo: 98.2
(16)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Participants maintaining >=80% body weight lost (%)
Proportion (%)</td><td>Tirzepatide: 89.5</td><td>Placebo: 16.6</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in body weight (%)
Least squares mean (95% CI)

Change in body weight, kg
Least squares mean (95% CI)

Change in waist circumference, cm
Least square means (95% CI)</td><td>Tirzepatide: 5.5
(-6.8--4.2)

Tirzepatide: 4.7
(-5.7--3.6)

Tirzepatide: 4.3
(-5.3--3.2)</td><td>Placebo: 14
(12.8-15.2)

Placebo: 11.1
(10.1-12.2)

Placebo: 7.8
(6.9-8.8)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Arredondo, 2022

Guideline record ID: 10031--1

Study characteristics		
Citation	Arredondo, E. M., Haughton, J., Ayala, G. X., Slymen, D., Sallis, J. F., Perez, L. G., Serrano, N., Ryan, S., Valdivia, R., Lopez, N. V., & Elder, J. P. (2022). Two-year outcomes of Faith in Action/Fe en Acción: a randomized controlled trial of physical activity promotion in Latinas. International Journal of Behavioral Nutrition and Physical Activity, 19, 97. https://doi.org/10.1186/s12966-022-01329-6	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Two-year outcomes of Faith in Action/Fe en Acción: a randomized controlled trial of physical activity promotion in Latinas	
Location	US	
Trial name	Faith in Action	
Methods		
Inclusion criteria	"Inclusion Criteria: 18-65 years of age, Latino, Must be a member of a participating church for at least six months, Live within 10-15 minutes driving distance from the church, Able to travel to the church during the week, Able to attend activities at the church during the week, Attend church activities (worship or otherwise) at least 4 times a month, Plan on living in same residence for the next 24 months, Engage in less than 150 minutes of moderate-to-vigorous physical activity per week."	
Exclusion criteria	"Exclusion Criteria: Attendance at other churches participating in the study, Must not have any conditions limiting ability to be physically active, Pregnant."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Each week over 24months, promotoras led six weekly classes in each church (cardio dance, strength training, and walking groups) scheduled at times to accommodate participants' schedules and occurring both indoors and outdoors, at the church site (e.g., halls, meeting rooms, and parking lots), and in the community (e.g., parks, recreation centers, and trails). PA classes were programmed as follows: a welcoming prayer, 5-min warm-up, 30-40 min of MVPA, 10-minute cool-down, and a brief discussion of the month's health topic (e.g., proper hydration, injury prevention, myths about PA). To assess the intensity and quality of promotora-led PA classes, we used System for Observing Fitness Instruction Time in Group Exercise Classes (SOFIT-X), an observational tool to evaluate group exercise classes. Promotoras recorded attendance at classes and called absent participants to encourage them to attend classes. Promotoras conducted up to four motivational interviewing (MI) calls each year over the course of the 2-year intervention. Calls included discussions of the participant's engagement in MVPA, barriers to PA, personal values, and goal setting. Participants received monthly health handouts on various topics related to PA, and promotoras reinforced these topics at the end of each PA class. Promotoras worked with churchgoers to identify projects to improve the built environment for PA at their church site and in the surrounding neighborhood. For example, participants identifed sidewalk improvements, park clean-up projects, trail restoration, community gardens, and planting natural buffers between the church site and a trolley stop to increase safety."	
Control/Comparator	"Participants in the control condition received general cancer prevention information including colon, skin, breast, and cervical cancer conducted in the same manner as the PA intervention condition. Promotoras held 1h group workshops each week promoting cancer prevention using the similar protocols outlined in the PA intervention condition. The promotoras were responsible for conducting MI calls on the same set of participants each	

<table>
<tr><td></td><td>month. The PA intervention and cancer screening conditions were designed to be equivalent in all respects except for content.”</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 436
Intervention group/s: Physical Activity Intervention (n=217)

Comparator group: Cancer Screening Intervention (n=219)</td></tr>
<tr><td>Mean age ± SD</td><td>44.4y (9.6)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Physical Activity Intervention:
30.8
(6.6)

Physical Activity Intervention:
95.7
(15)</td><td>Cancer Screening Intervention:
29.9
(5.8)

Cancer Screening Intervention:
94.1
(14.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Physical Activity Intervention:
30.7
(6.4)

Physical Activity Intervention:
96.2
(14.3)</td><td>Cancer Screening Intervention:
30.1
(6.1)

Cancer Screening Intervention:
95.7
(15.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Physical Activity Intervention:
31.2
(6.8)

Physical Activity Intervention:
97.1
(15.3)</td><td>Cancer Screening Intervention:
29.7
(5.9)

Cancer Screening Intervention:
94.9
(14.3)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Artene, 2017

Guideline record ID: 10032--1

Study characteristics		
Citation	Artene, D. V., Bordea, C. I., & Blidaru, A. (2017). Results of 1-year diet and exercise interventions for ER+/PR+/-/HER2- breast cancer patients correlated with treatment type. Chirurgia, 112(4), 457-468. https://doi.org/https://dx.doi.org/10.21614/chirurgia.112.4.457	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Results of 1-year Diet and Exercise Interventions for ER+/PR+/-/HER2- Breast Cancer Patients Correlated with Treatment Type	
Location	Romania	
Trial name	N/A	
Methods		
Inclusion criteria	"(1) ER+/PR±/HER2-luminal A and B breast cancer patients after surgery and chemoterapy, on antiestrogenic medication; (2) Overweight."	
Exclusion criteria	"Diabetes, thyroid or renal disease, eating disorders, depression, osteoporosis."	
Setting	Home	
Intervention	"A high protein diet based on foods naturally high in proteins, omega-3 fatty acids, calcium, pro- and prebiotics can improve body composition by increasing insulin and leptin sensitivity, ameliorating dysbiosis and counteracting skeletal muscle protein catabolism. Additionally, it can assist in recurrence prevention through a moderate intake of glucose. Patients were given a table on which foods were classified as proteins, carbohydrates or fibres supplying sources and were taught to consume them at each meal. Toprevent sarcopenia and to counteract the Warburg effect (especially in patients during neoadjuvant chemotherapy) we decreased the recommended percentage of carbohydrate intake from the common 55-60% to only 40%. Protein intake was calculated to reach 1.5g/ kg body, which practically meant a 25-30 g protein intake per meal for most patients. Also, current scientific literature does not support a low-fat approach for ER+ breast cancer patients, thus we recommended a 25-30% fat intake from foods sources of omega-3 fatty acids (fish, olive oil, raw nuts and seeds) and medium chain triglycerides mainly from fermented dairy foods (yoghurt, sour milk and kephir). To prevent anaemia, we instructed them to eat foods high in proteins and calcium such as yoghurt, sour milk and kephir, raw seeds and nutsat different meals than foods high in iron just like fish, chicken, eggs, beans, chickpeas and other lentils. To prevent dysbiosis we instructed them to vary the food they eat as much as possible from day to day, to avoid eating foods containing unpasteurized raw animal ingredients (like unpasteurized ice cream or mayonnaise, sauces, deli meats or cheese, smoked raw fish, canned fish or roe), and to eat at least two fermented dairies portions per day. To improve eating behaviour, we explained the metabolic differences between eating when not hungry and eating when physically hungry and we asked patients to learn to recognize gastric hunger and to respect it by not eating when not feeling hungry and by eating within a maximum of 1 hour after feeling this way (25). To sustain an effective lipolysis, beta-oxidation and complete fatty acids catabolism for energy, when not hungry patients could only drink plain water when not feeling hungry and they were asked not to consume snacks, and other drinks. One coffee was allowed at the first meal of the day, and tea with other meals. However, they were not allowed in between meals due to caffeine and theine impact on insulin secretion. In addition, no soft drinks were allowed due to their impact on presynaptic dopamine re-transporters and on hypothalamic leptin sensitivity. Also, to ensure a proper gastric emptying time, an interval of 2 hours' minimum was recommended between taking any meal and sleeping. And, to avoid phytoestrogen interaction with antiestrogenic treatments, we recommended the complete avoidance of plant supplements and we asked patients to only take vitamins and minerals at their	

	oncologists' recommendation. As for the isometric exercises, patients were taught how to perform 7 of them, one for each day of the week. All 7 exercises involved maintaining whole body balance for 1 minute, four times per day."
Control/Comparator	"A high protein diet based on foods naturally high in proteins, omega-3 fatty acids, calcium, pro- and prebiotics can improve body composition by increasing insulin and leptin sensitivity, ameliorating dysbiosis and counteracting skeletal muscle protein catabolism. Additionally, it can assist in recurrence prevention through a moderate intake of glucose. Patients were given a table on which foods were classified as proteins, carbohydrates or fibres supplying sources and were taught to consume them at each meal. Toprevent sarcopenia and to counteract the Warburg effect (especially in patients during neoadjuvant chemotherapy) we decreased the recommended percentage of carbohydrate intake from the common 55-60% to only 40%. Protein intake was calculated to reach 1.5g/ kg body, which practically meant a 25-30 g protein intake per meal for most patients. Also, current scientific literature does not support a low-fat approach for ER+ breast cancer patients, thus we recommended a 25-30% fat intake from foods sources of omega-3 fatty acids (fish, olive oil, raw nuts and seeds) and medium chain triglycerides mainly from fermented dairy foods (yoghurt, sour milk and kephir). To prevent anaemia, we instructed them to eat foods high in proteins and calcium such as yoghurt, sour milk and kephir, raw seeds and nutsat different meals than foods high in iron just like fish, chicken, eggs, beans, chickpeas and other lentils. To prevent dysbiosis we instructed them to vary the food they eat as much as possible from day to day, to avoid eating foods containing unpasteurized raw animal ingredients (like unpasteurized ice cream or mayonnaise, sauces, deli meats or cheese, smoked raw fish, canned fish or roe), and to eat at least two fermented dairies portions per day. To improve eating behaviour, we explained the metabolic differences between eating when not hungry and eating when physically hungry and we asked patients to learn to recognize gastric hunger and to respect it by not eating when not feeling hungry and by eating within a maximum of 1 hour after feeling this way (25). To sustain an effective lipolysis, beta-oxidation and complete fatty acids catabolism for energy, when not hungry patients could only drink plain water when not feeling hungry and they were asked not to consume snacks, and other drinks. One coffee was allowed at the first meal of the day, and tea with other meals. However, they were not allowed in between meals due to caffeine and theine impact on insulin secretion. In addition, no soft drinks were allowed due to their impact on presynaptic dopamine re-transporters and on hypothalamic leptin sensitivity. Also, to ensure a proper gastric emptying time, an interval of 2 hours' minimum was recommended between taking any meal and sleeping. And, to avoid phytoestrogen interaction with antiestrogenic treatments, we recommended the complete avoidance of plant supplements and we asked patients to only take vitamins and minerals at their oncologists' recommendation."
Treatment duration	12 months
Follow-up from baseline	12 months
Eligible outcome(s) reported	Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 165 Intervention group/s: Diet + exercises (n=82) Comparator group: Diet (n=83)
Mean age ± SD	Not reported.
Sex	100.00% female
Pre-existing medical condition	ER+/PR±/HER2- breast cancer

<table>
<tr><td colspan="4">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td colspan="3"><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Crude weight, kg
Mean (SD)</td><td>Diet + exercises: 79
(14.83)</td><td>Diet: 74.55
(14.15)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td colspan="3"><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Crude weight, kg
Mean (SD)</td><td>Diet + exercises: 72.66
(12.69)</td><td>Diet: 70.88
(13.93)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td colspan="3"><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td colspan="3"><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td colspan="3"><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td colspan="3">51% dropout; compliance not reported for those remaining in study</td></tr>
<tr><td colspan="4">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td colspan="3"></td></tr>
</table>

N/A – Not applicable

Astbury, 2021

Guideline record ID: 10033--1

Study characteristics		
Citation	Astbury, N. M., Edwards, R. M., Ghebretinsea, F., Shanyinde, M., Mollison, J., Aveyard, P., & Jebb, S. A. (2021). Extended follow-up of a short total diet replacement programme: results of the Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET) randomised controlled trial at 3 years. International Journal of Obesity, 45(11), 2432-2438. https://doi.org/https://dx.doi.org/10.1038/s41366-021-00915-1	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Extended follow-up of a short total diet replacement programme: results of the Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET) randomised controlled trial at 3 years	
Location	UK	
Trial name	Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET)	
Methods		
Inclusion criteria	"Eligible participants included all those who had taken part in the DROPLET trial, except the few participants who withdrew prior to the 1-year followup."	
Exclusion criteria	"BMI <30kg/m2."	
Setting	GP clinic, Home	
Intervention	"The TDR programme was provided by Cambridge Weight Plan UK, which manages a network of counsellors providing behavioural support and food products. Participants were asked to contact a local counsellor who delivered a 24-week TDR weight loss programme consisting of 8 weeks TDR, 4 weeks gradual food-reintroduction, and a further 12 weeks weight maintenance. Behavioural support was provided weekly for 8 weeks, biweekly for 4 weeks, and monthly for 3 months. Consistent with the pragmatic design, participants in both groups were free to use other weight loss programmes or products during and after their assigned interventions, but GPs were asked not to refer participants to other weight loss programmes for the first 12 months."	
Control/Comparator	"For participants randomised to the UC comparator, practice nurses offered a weight loss programme for 12 weeks, at a frequency typically used in the practice (e.g. weekly or bi-weekly). Consistent with the pragmatic design, participants in both groups were free to use other weight loss programmes or products during and after their assigned interventions, but GPs were asked not to refer participants to other weight loss programmes for the first 12 months."	
Treatment duration	6 months	
Follow-up from baseline	3 years	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 179 Intervention group/s: Total diet replacement (n=96) Comparator group: Usual care (n=83)	

<table>
<tr><td>Mean age ± SD</td><td>Intervention: 50.7y (11.2); Control: 50.9y (11.7)</td></tr>
<tr><td>Sex</td><td>55.31% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Total diet replacement: 107.4 (18.8)

Total diet replacement: 37.5 (6)

Total diet replacement: 116.5 (13.5)</td><td>Usual care: 105.6 (18.8)

Usual care: 36.1 (4.3)

Usual care: 114 (10.5)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion (%) with ≥5% weight loss from baseline
Proportion (%)

Proportion (%) with at least ≥10% weight loss from baseline
Proportion (%)</td><td>Total diet replacement: 45.8%

Total diet replacement: 24.0%</td><td>Usual care: 34.90%

Usual care: 13.30%</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) Change from baseline
Mean (SD)

Waist circumference (cm)
Change from baseline
Mean (SD)</td><td>Total diet replacement: -6.3 (9.1)

Total diet replacement: -10.5 (9.1)</td><td>Usual care: -2.7 (7.7)

Usual care: -5.5 (7.3)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Baillot, 2018

Guideline record ID: 10036--1

Study characteristics		
Citation	Baillot, A., Vallée, C.-A., Mampuya, W. M., Dionne, I. J., Comeau, E., Méziat-Burdin, A., & Langlois, M.-F. (2018). Effects of a pre-surgery supervised exercise training 1 year after bariatric surgery: a randomized controlled study. Obesity Surgery, 28(4), 955-962. https://doi.org/https://dx.doi.org/10.1007/s11695-017-2943-8	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of a Pre-surgery Supervised Exercise Training 1 Year After Bariatric Surgery: a Randomized Controlled Study	
Location	Canada	
Trial name	Pre-Surgical Exercise Training program (PreSET)	
Methods		
Inclusion criteria	“Only patients with BMI ≥ 35 kg/m2 and comorbidities or ≥ 40 kg/m2, aged between 18 and 65 years and without uncontrolled neuropsychiatric illnesses receive a laparoscopic Roux-en-Y gastric bypass or sleeve gastrectomy at the CHUS.”	
Exclusion criteria	“We excluded persons with (i) inabilities to regularly attend supervised exercise sessions, (ii) medical contraindications for PA, (iii) functional limitations not allowing them to complete the 6-min walking test (6MWT), (iv) inability to speak fluently the language in which the intervention was provided (French), or (v) uncontrolled neuropsychiatric illnesses.”	
Setting	Hospital	
Intervention	“All participants benefited from individual counseling sessions every 6-8 weeks before BS during at least 6 months and at 3, 6, 9, and 12 months after BS with a dietitian and a PA specialist, and 52% of participants (without significant difference between groups) participated to voluntary group educational sessions, called the BMotivated's Club^ on PA and nutrition and psychological issues related to weight management. In addition, the PreSET group underwent three weekly 80-min sessions consisting of 10 min of warm-up, 30 min of endurance activity at 55 to 85% of the heart rate reserve (treadmill, walking circuit, arm-ergocycle, elliptical, dance/aerobic exercise), 20 to 30 min of strength exercises with small equipment (dumbbells, elastic bands, medicine balls and sticks), and 10 min of a cool-down period, with monthly aquagym session, which lasted until 2 weeks before BS.”	
Control/Comparator	“All participants benefited from individual counseling sessions every 6-8 weeks before BS during at least 6 months and at 3, 6, 9, and 12 months after BS with a dietitian and a PA specialist, and 52% of participants (without significant difference between groups) participated to voluntary group educational sessions, called the BMotivated's Club^ on PA and nutrition and psychological issues related to weight management.”	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 25 Intervention group/s: PreSET group (n=13) Comparator group: Usual care group (n=12)	

<table>
<tr><td>Mean age ± SD</td><td>Intervention: 44.5y (8.8); Control: 41.1y (10.3)</td></tr>
<tr><td>Sex</td><td>80.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in BMI
Mean (SD)</td><td>PreSET group: -16.8
(4.4)</td><td>Usual care group: -13.5
(5.3)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>The PreSET group attended a median of 70 (45-90) % of the total recommended exercise sessions (3×/week) from the baseline of the PreSET until 2 weeks before BS. Seven participants (47%) attended more than 70% of the sessions.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Balducci, 2012

Guideline record ID: 10037--1

Study characteristics		
Citation	Balducci, S., Zanuso, S., Cardelli, P., Salerno, G., Fallucca, S., Nicolucci, A., Pugliese, G., & for the Italian Diabetes Exercise Study (IDES) Investigators. (2012). Supervised exercise training counterbalances the adverse effects of insulin therapy in overweight/obese subjects with type 2 diabetes. Diabetes Care, 35(1), 39-41. https://doi.org/https://dx.doi.org/10.2337/dc11-1450	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Supervised exercise training counterbalances the adverse effects of insulin therapy in overweight/obese subjects with type 2 diabetes	
Location	Italy	
Trial name	Italian Diabetes Exercise Study (IDES)	
Methods		
Inclusion criteria	"Sedentary patients with type 2 diabetes and the metabolic syndrome."	
Exclusion criteria	Not reported	
Setting	Not reported	
Intervention	"Twice-a week supervised mixed (aerobic and resistance) training plus exercise counseling (exercise [EXE] group) for 12 months. Each supervised session lasted 75 min and included aerobic exercise plus four resistance exercises. All participants received structured exercise counseling, encouraging any type of leisure-time PA."	
Control/Comparator	"Counseling alone as part of standard care (control [CON] group) for 12 months. All participants received structured exercise counseling, encouraging any type of leisure-time PA."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference	
Participant characteristics		
Number of participants	n= 73 Intervention group/s: EXE (n=37) Comparator group: CON (n=36)	
Mean age ± SD	Intervention: 59.6y (8.7); Control: 61.6y (7.8)	
Sex	45.21% female	
Pre-existing medical condition	Insulin-treated subjects with type 2 diabetes	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	BMI (kg/m2) Mean (SD)	EXE: 30.7 (4.1)	CON: 31.8 (5.3)

	Waist circumference (cm) Mean (SD)	EXE: 107.4 (13.6)	CON: 100.5 (10.1)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	BMI (kg/m2) Mean (SD) Waist circumference (cm) Mean (SD)	EXE: 31 (4) EXE: 103.6 (11.9)	CON: 30.7 (4.9) CON: 101.9 (10)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Bartels, 2013

Guideline record ID: 10042--1

Study characteristics		
Citation	Bartels, S. J., Pratt, S. I., Aschbrenner, K. A., Barre, L. K., Jue, K., Wolfe, R. S., Xie, H., McHugo, G., Santos, M., Williams, G. E., Naslund, J. A., & Mueser, K. T. (2013). Clinically significant improved fitness and weight loss among overweight persons with serious mental illness. Psychiatric Services, 64(8), 729-736. https://doi.org/https://doi.org/10.1176/appi.ps.003622012	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Clinically significant improved fitness and weight loss among overweight persons with serious mental illness	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were age 21 or older; diagnosis of major depression, bipolar disorder, schizoaffective disorder, or schizophrenia, (based on the Structured Clinical Interview for DSM-IV); serious mental illness, defined by an axis I disorder and persistent impairment in multiple areas of functioning (such as work, school, and self-care) (13); body mass index (BMI) .25; and ability and willingness to provide informed consent for participation. Participants must also have been on stable pharmacological treatment, defined as receiving the same psychiatric medications over the prior two months."	
Exclusion criteria	"Exclusion criteria were residing in a nursing home or other institution, primary diagnosis of dementia or significant cognitive impairment as determined by a Mini-Mental Status Exam (14) score,24, terminal illness expected to cause death within one year, or current diagnosis of substance dependence (based on the substance abuse module of the Structured Clinical Interview for DSM-IV)."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"In SHAPE is a health promotion intervention consisting of a free fitness club membership and a health mentor. The mentor has basic certification as a fitness trainer and has received training for providing instruction on principles of healthy eating and nutrition and for tailoring individual wellness plans to the needs of persons with serious mental illness. Before enrollment, participants were required to obtain medical clearance by their primary care provider. After conducting comprehensive lifestyle and fitness evaluations, the health mentors developed personalized fitness plans using shared goal setting. Thereafter, they met with participants once a week for 45-60 minutes at a local fitness club (YMCA) and provided fitness coaching, support, and reinforcement of physical activity. The nutrition component focused on healthy eating as opposed to caloric restriction and involved discussions at each session, individual meetings with a registered dietitian, and group cooking classes or grocery store tours (or both), depending on participant goals and preferences."	
Control/Comparator	"The fitness club membership and education comparison condition also consisted of a free membership to the same local fitness club and included introduction to the exercise equipment and educationalmaterials on the health benefits of exercise and healthy diet."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 133
Intervention group/s: In SHAPE (n=67)
Comparator group: Fitness club membership and education (n=66)</td></tr>
<tr><td>Mean age ± SD</td><td>43.8 (11.5)</td></tr>
<tr><td>Sex</td><td>61.65% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Diagnosis of major depression, bipolar disorder, schizoaffective disorder, or schizophrenia, (based on the Structured Clinical Interview for DSM-IV); serious mental illness, defined by an axis I disorder and persistent impairment in multiple areas of functioning (such as work, school, and self-care)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (lbs)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>In SHAPE: 227.3
(55.3)

In SHAPE: 36.8
(7.8)</td><td>Fitness club membership and education: 236.3
(54.4)

Fitness club membership and education: 38.3
(8.5)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (lbs)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>In SHAPE: 228.7
(63.9)

In SHAPE: 36.8
(8.4)</td><td>Fitness club membership and education: 227.9
(60)

Fitness club membership and education: 37.1
(8.8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Over the 12-month duration of the program, 40% (N=27) of In SHAPE participants attended a minimum of half of their weekly visits to the YMCA, compared with only 11% (N=7) of participants in the fitness club membership and education group (x2=15.41, df=1, p.001). At the 12-month follow-up, In SHAPE contributed to more than three times greater attendance at the YMCA and more than twice as much moderate to vigorous exercise (192 versus 95 minutes per week).</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Bathrellou, 2010

Guideline record ID: 10044--1

Study characteristics		
Citation	Bathrellou, E., Yannakoulia, M., Papanikolaou, K., Pehlivanidis, A., Pervanidou, P., Kanaka-Gantenbein, C., Tokou, I., Tsiantis, J., Chrousos, G. P., & Sidossis, L. S. (2010). Parental involvement does not augment the effectiveness of an intense behavioral program for the treatment of childhood obesity. Hormones, 9(2), 171-175. http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med8&NEWS=N&AN=20687401	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Parental involvement does not augment the effectiveness of an intense behavioral program for the treatment of childhood obesity	
Location	Greece	
Trial name	N/A	
Methods		
Inclusion criteria	"Overweight or obese children, aged between 7 and 12 years, without any chronic physical or mental illness."	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"The intervention has been described in detail elsewhere.14 Briefly, it was a multidisciplinary program involving many CBT principles and some novelties as regards the dietetic practice, such as supervision of the dieticians by the psychiatrists and implementation with booster sessions after the intensive program (6 monthly sessions from 3 to 9 months and one final session at 5 months). The intensive program consisted of 12 weekly sessions, each lasting 1 hour and conducted individually. In the Child-and-parent group, parents were asked to act as helpers: apart from attending two individual sessions with the dietician, they also participated in the last 10 minutes of each session, while their cooperation was actively requested in supporting their child to implement the goals set."	
Control/Comparator	"In the Child-alone group, sessions were conducted without any parental involvement and parental help was not required unless the child requested it."	
Treatment duration	9 months	
Follow-up from baseline	18 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 42 Intervention group/s: Child-and-parent group (n=23) Comparator group: Child-alone group (n=19)	
Mean age ± SD	Child-and-parent: 9.4(0.3); child-alone: 9.1(0.3)	
Sex	76.19% female	
Pre-existing medical condition	No pre-existing medical condition	

<table>
<tr><td colspan="4">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td colspan="3"><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (percent overweight)
Mean (SE)

BMI (kg/m2) - Baseline
Mean (SE)</td><td>Child-and-parent group: 37.5
(3.8)

Child-and-parent group: 26.7
(0.8)</td><td>Child-alone group: 42.5
(3.9)

Child-alone group: 27.4
(0.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td colspan="3"><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td colspan="3"><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td colspan="3"><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td colspan="3"><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td colspan="3">Although most children attended the intensive phase of the intervention (88%), only three quarters of the children completed all stages of the 18-month follow-up assessment.</td></tr>
<tr><td colspan="4">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td colspan="3"></td></tr>
</table>

N/A – Not applicable

Bea, 2010

Guideline record ID: 10046--1

Study characteristics		
Citation	Bea, J. W., Cussler, E. C., Going, S. B., Blew, R. M., Metcalfe, L. L., & Lohman, T. G. (2010). Resistance training predicts 6-yr body composition change in postmenopausal women. Medicine & Science in Sports & Exercise, 42(7), 1286-1295. https://doi.org/https://dx.doi.org/10.1249/MSS.0b013e3181ca8115	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Resistance training predicts 6-yr body composition change in postmenopausal women	
Location	US	
Trial name	Bone Estrogen Strength Training (BEST)	
Methods		
Inclusion criteria	"Inclusion criteria were as follows: 40-65 years of age; surgical or natural menopause (3.0-10.9 years); body mass index (BMI) greater than 19.0 kg/ m2 and less than 33.0 kg/m2 ; non-smoking; no history of osteoporotic fracture and an initial BMD greater than Z-score of -3.0; undergoing hormone therapy (HT) (1.0-5.9 years) or not undergoing HT (>one year); no weight gain or loss greater than 13.6 kg (30 lbs) in the previous year; free of cancer and cancer treatment for last five years (excluding skin cancer); not using BMD-altering medications, beta-blockers, or steroids; dietary calcium intake >300 mg/day; performing less than 120 minutes of low intensity, low impact exercise per week and no weightlifting or similar physical activity."	
Exclusion criteria	Not reported	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Participants randomized to the exercise intervention were asked to attend training sessions three days per week, on non-consecutive days, in one of four community facilities under the supervision of study on-site trainers. Sessions lasted 60-75 minutes and included warm-up (5- 10 min), progressive weight bearing (25 min, walking and stair stepping with weighted vests and circuit of skipping, hopping, jumping, jogging without added weight), resistance exercises (30 min), abdominal strengthening (5 min), and stretching and balance (5 min).(34) ExFreq, weightlifting loads, sets and repetitions, steps with weighted vests, and minutes of progressive weight bearing activity were recorded in exercise logs which were monitored regularly by onsite study trainers for the intervention year. Following the initial intervention year, participants were asked to continue resistance training and record the resistance activities in their study logs; other components of the program were not specifically monitored following the first year of intervention or crossover. Trainers had a degree (B.S. or M.S.) in exercise science or a related field and certification by a nationally recognized fitness and strength training organization. In addition, a study physical therapist further educated the trainers on the BEST program specifically. The participant-totrainer ratio was five-to-one in the first year. Supervision was reduced during the second year, and in the third through sixth years, trainers were available at each facility one morning or afternoon per week. Resistance exercises were done using free weights and machines. Eight core exercises focused on major muscles. These exercises included the seated leg press, lat (latissimus dorsi) pull down, weighted march, seated row, back extension, one-arm military press (right and left), squats (wall squats initially, progressing to Smith or hack squats), and the rotary torso machine. Women completed two sets of six to eight repetitions (four to six repetitions for the military press to decrease injury to the shoulder) at 70% (two days per week) or 80% (one day per week) of the one-repetition maximum (1-RM), determined by monthly testing during year 1. An essential part of the intervention program was a comprehensive social support program designed to foster continued resistance training beyond the 1 year study design and to avoid poor adherence which may	

<table>
<tr><td></td><td>bias results. The program was based on social cognitive/social ecological theory constructs and encompassed a variety of interpersonal, intrapersonal and environmental reinforcement strategies to motivate participants and promote the high levels of retention (83%) the study experienced for the Year 1 intervention. Primary components of the social cognitive constructs underlying the program included: education and skill development, self-efficacy, incentive programs, social support, and modeling. Within this context, participation was based on individual improvement rather than competition among participants and a fun, social environment that challenged the women to improve their daily exercise performance. Some examples of the intervention support programs included: orientation workshops, monthly newsletters, Personal Best testing every two months to monitor progress, yearly evaluation results, goal-setting logs, personal contracts, motivational meals scheduled every two months, and two major promotional events held at the exercise facilities each year.”</td></tr>
<tr><td>Control/Comparator</td><td>“Continue their usual dietary practices, maintain their HT status, and take daily calcium citrate supplements for the duration of the intervention period.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>6 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 90
Intervention group/s: Exercisers (n=65)

Comparator group: Control (n=25)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 56.4y (4.2); Control: 55.9y (3.9)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/M2)
Mean (SD)

% Body Fat
Mean (SD)

Total Body Fat (kg)
Mean (SD)</td><td>Exercisers: 67.9
(12.1)

Exercisers: 25.4
(3.6)

Exercisers: 38.3
(6.3)

Exercisers: 26.2
(8.4)</td><td>Control: 65.4
(10.7)

Control: 25.2
(3.9)

Control: 37.4
(6.7)

Control: 24.6
(7.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Weight (kg)</td><td>Exercisers: 0.43</td><td>Control: 2.08</td></tr>
</table></td></tr>
</table>

12 months or closest time point	Mean (SD) Change in Total Body Fat (kg) Mean (SD)	(6.16) Exercisers: 0.28 (5.74)	(4.25) Control: 1.84 (4.3)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Beavers, 2014

Guideline record ID: 10049--1

Study characteristics		
Citation	Beavers, K. M., Beavers, D. P., Nesbit, B. A., Ambrosius, W. T., Marsh, A. P., Nicklas, B. J., & Rejeski, W. J. (2014). Effect of an 18-month physical activity and weight loss intervention on body composition in overweight and obese older adults. Obesity, 22(2), 325-331. https://doi.org/10.1002/oby.20607	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of an 18-month physical activity and weight loss intervention on body composition in overweight and obese older adults	
Location	US	
Trial name	Cooperative Lifestyle Intervention Program (CLIP)	
Methods		
Inclusion criteria	"Individuals were eligible to participate if they were identified as ambulatory, overweight or obese (BMI > 28 but <40 kg/m2), community-dwelling older (60-79 years) adults who either had CVD or cardiometabolic dysfunction and self-reported limitations in mobility."	
Exclusion criteria	Not reported	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The PA + WL arm involved a PA intervention in conjunction with a dietary WL intervention. The PA program consisted of a combination of daily walking and interactive, group-mediated, behavioral focused sessions (48 total sessions over 18 months), with the primary goal of gradually increasing home-based, moderate intense activity to >150 min/week. The PA intervention was divided into two phases: an intensive phase (first 6 months) and maintenance phase (6-18 months). During the intensive phase, participants attended weekly, supervised behavioral sessions, focused on increasing PA, and reducing caloric intake. Three group sessions (90 min, consisting of 30-45 min period of walking followed by a behavioral focused session) and one individual session (30 min) were conducted each month. Individual sessions included one-on-one interactions with staff based on the unique needs of the participant (including review of behavioral tools, execution of techniques or strategies for lifestyle change, brainstorming or problem solving barriers to change, motivation, or simply to touch base with study staff on overall program progress). In addition to the behavioral sessions, participants were asked to walk for 30 min on most days of the week at a moderate level of intensity (defined as a self-reported rating of perceived exertion of 13 on the Borg Scale).During the next 12 months (maintenance phase), frequency of contact was reduced (1 group session of 90 min and 1 telephone contact per month), and group discussion focused on PA goals, specific plans of action to be implemented, and the reinforcement of self regulatory skills. The WL goal was a reduction in body mass of 0.3 kg per week for the first 6 months, for a total loss in mass of 7-10% of initial body mass. During the weight maintenance phase, participants were encouraged to continue WL as long as their BMI was >20 kg/m2; however, the primary focus was on maintenance of WL. The PA-only arm consisted of the PA intervention described above."	
Control/Comparator	"The SA health education intervention was an active control arm. Participants randomized to the SA group met in groups, weekly for the first 8 weeks, monthly through the sixth month, and bimonthly until the end of the study (18 sessions total). Sessions included health topics relevant to older adults such as how the body changes with aging, prevention or delaying disease, eating for good health, positive attitudes toward aging, family relationships and care giving, and talking to health care providers."	
Treatment duration	18 months	

<table>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 288
Intervention group/s: PA + WL (n=98); PA (n=97)

Comparator group: SA (n=93)</td></tr>
<tr><td>Mean age ± SD</td><td>67.0y (4.8)</td></tr>
<tr><td>Sex</td><td>67.01% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body mass (kg)
Mean (SD)</td><td>PA + WL: 92.8
(16.1)
PA: 91.7
(13.1)</td><td>SA: 91.2
(15.1)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>PA + WL: 33.1
(4.1)
PA: 32.8
(3.9)</td><td>SA: 32.6
(3.5)</td></tr>
<tr><td>Fat mass (kg)
Mean (SD)</td><td>PA + WL: 36.5
(8.9)
PA: 36.3
(8.9)</td><td>SA: 35.3
(7.5)</td></tr>
<tr><td>% Fat (%)
Mean (SD)</td><td>PA + WL: 39
(6.8)
PA: 39
(7.6)</td><td>SA: 38.6
(6.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body mass (kg)
Mean (SD)</td><td>PA + WL: 85.7
(15.5)
PA: 90.9
(14.4)</td><td>SA: 90.3
(16)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>PA + WL: 30.7
(4.2)
PA: 32.6
(4.5)</td><td>SA: 32.5
(3.9)</td></tr>
<tr><td>Fat mass (kg)
Mean (SD)</td><td>PA + WL: 31.7
(9)
PA: 35.7
(9.6)</td><td>SA: 35.4
(7.7)</td></tr>
<tr><td>% Fat (%)
Mean (SD)</td><td>PA + WL: 36.4
(7.5)
PA: 38.8
(7.6)</td><td>SA: 39
(6.6)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>On average, participants in the PA + WL arm attended 88.2 +- 25.2% of sessions, participants in the PA group attended 79.8 +- 24.6% of sessions, and participants in the SA group attended 70.9 +- 26.5% of sessions.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Beavers, 2015

Guideline record ID: 10050--1

Study characteristics		
Citation	Beavers, K. M., Beavers, D. P., Newman, J. J., Anderson, A. M., Loeser, R. F., Jr., Nicklas, B. J., Lyles, M. F., Miller, G. D., Mihalko, S. L., & Messier, S. P. (2015). Effects of total and regional fat loss on plasma CRP and IL-6 in overweight and obese, older adults with knee osteoarthritis. Osteoarthritis and Cartilage, 23(2), 249-256. https://doi.org/10.1016/j.joca.2014.11.005	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of total and regional fat loss on plasma CRP and IL-6 in overweight and obese, older adults with knee osteoarthritis	
Location	US	
Trial name	Intensive Diet and Exercise for Arthritis (IDEA)	
Methods		
Inclusion criteria	"Community-dwelling persons age > 55 years with: (1) grade II-III (mild to moderate) radiographic tibiofemoral OA or tibiofemoral plus patellofemoral OA of one or both knees; (2) 27.0 < Body mass index (BMI) < 40.5 kg/m2 ; and (3) a sedentary lifestyle, defined as not participating in a program that incorporates more than 30 min per week of formal exercise within the past 6 months."	
Exclusion criteria	Not reported	
Setting	Home, University/research centre	
Intervention	"Both the D and D + E groups received the same dietary intervention, consisting of group and individual nutrition education and behavioral sessions, as well as an individualized dietary prescription plan providing an energy-intake deficit of 800e1000 kcals/day to reach a study goal of 10% of baseline weight lost.; The D+E group additionally received the exercise intervention consisting of aerobic walking (15 min), strength training (20 min), a second aerobic phase (15 min), and cool-down (10 min), 3 days per week. During the first 6 months, participation was center-based; afterward, participants could remain in the facility program, opt for a home-based program, or combine the two."	
Control/Comparator	"The E-only group was not counseled to restrict caloric intake during the study intervention period. E group received the exercise intervention, consisting of aerobic walking (15 min), strength training (20 min), a second aerobic phase (15 min), and cool-down (10 min), 3 days per week. During the first 6 months, participation was center-based; afterward, participants could remain in the facility program, opt for a home-based program, or combine the two."	
Treatment duration	18 months	
Follow-up from baseline	18 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 454 Intervention group/s: Diet (n=152); Diet+Exercise (n=152) Comparator group: Exercise (n=150)	
Mean age ± SD	65.6y (6.2)	

<table>
<tr><td>Sex</td><td>70.70% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Osteoarthritis</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in body mass (kg)
Mean (SE)</td><td>Diet: -8.4
(0.6)
Diet+Exercise: -9.3
(0.6)</td><td>Exercise: -1.3
(0.6)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Miller, G. D., Beavers, D. P., Hamm, D., Mihalko, S. L., & Messier, S. P. (2017). Nutrient intake during diet-induced weight loss and exercise interventions in a randomized trial in older overweight and obese adults. The Journal of Nutrition, Health & Aging, 21(10), 1216-1224. https://doi.org/https://dx.doi.org/10.1007/s12603-017-0892-5</td></tr>
</table>

N/A – Not applicable

Beavers, 2017

Guideline record ID: 10048--1

Study characteristics		
Citation	Beavers, K. M., Ambrosius, W. T., Rejeski, W. J., Burdette, J. H., Walkup, M. P., Sheedy, J. L., Nesbit, B. A., Gaukstern, J. E., Nicklas, B. J., & Marsh, A. P. (2017). Effect of exercise type during intentional weight loss on body composition in older adults with obesity. Obesity, 25(11), 1823-1829. https://doi.org/10.1002/oby.21977	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Exercise Type During Intentional Weight Loss on Body Composition in Older Adults with Obesity	
Location	US	
Trial name	Cooperative Lifestyle Intervention Program II (CLIP II)	
Methods		
Inclusion criteria	"Eligibility criteria consisted of men and women aged 60 to 79 years who engaged in <60 min/wk of moderately intense physical activity, had BMI 28 kg/m2 and < 42 kg/m2, had self-reported limitations with mobility, and had documented evidence of cardiovascular disease (CVD) or a National Cholesterol Education Program Adult Treatment Panel III (ATP III) diagnosis of metabolic syndrome (MetS)."	
Exclusion criteria	"Individuals were excluded if they had a myocardial infarction or cardiovascular procedure in the past 3 months, fasting blood glucose 140 mg/dL, or a diagnosis of type 1 diabetes or insulin dependent type 2 diabetes or if their primary care physician had concerns regarding their ability to safely participate."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Weight loss. The three study arms received the same behavior based WL intervention in three 6-month phases: intensive (months 1-6), transition (months 7-12), and maintenance (months 13-18), with the goal of eliciting a 0.3 kg/wk weight loss in the intensive phase (330 kcal/d reduction) and a total weight loss of 7% to 10%. During the intensive phase, participants met at the YMCA for three group sessions and one individual sessions per month (all 60 minutes in duration). Group sessions tapered off to three and then one per month for the subsequent phases, with individual sessions scheduled as needed. In accordance with the 2010 dietary guidelines (25), the macronutrient breakdown of the diet was 20% to 25% protein, 25% to 30% fat, and 45% to 55% carbohydrate. Aerobic training. The primary mode of AT was an individually tailored, supervised, over-ground walking program. The program frequency was 4 d/wk, progressing to a duration goal of 45 min/d and walking intensity of 12 to 14 on the Borg Rating of Perceived Exertion (RPE) Scale (26). Resistance training. The RT intervention was also individually tailored and involved a training frequency of 4 d/wk, progressing to 45 min/d, with an RPE of 15 to 18 as a target intensity for each RT exercise. Participants completed three sets of 10 to 12 repetitions on eight machines, with initial resistance determined from one repetition maximum (1RM) testing (goal of 75% of 1RM). When a participant completed 12 repetitions in the third set for two consecutive days, the resistance was increased to ensure progressive overload. To assist with recovery time, participants rotated exercises on a 2- day schedule: day one included leg press, hip adduction, hip abduction, calf extension, seated row, pectoral fly, shoulder press, and rotary torso; day two included leg extension, leg curl, lateral pull down, seated chest press, lateral raise, arm curl, triceps extension, and abdominal crunch."	
Control/Comparator	"Weight loss. The three study arms received the same behavior based WL intervention in three 6-month phases: intensive (months 1-6), transition (months 7-12), and maintenance (months 13-18), with the goal of eliciting a 0.3 kg/wk weight loss in the intensive phase (330 kcal/d reduction) and a total weight loss of 7% to 10%. During the intensive phase,	

<table>
<tr><td></td><td>participants met at the YMCA for three group sessions and one individual sessions per month (all 60 minutes in duration). Group sessions tapered off to three and then one per month for the subsequent phases, with individual sessions scheduled as needed. In accordance with the 2010 dietary guidelines (25), the macronutrient breakdown of the diet was 20% to 25% protein, 25% to 30% fat, and 45% to 55% carbohydrate. For the WL-only group, participants were instructed not to begin a formal exercise program while actively enrolled in the study.”</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 249
Intervention group/s: WL + AT (n=86); WL + RT (n=81)

Comparator group: WL (n=82)</td></tr>
<tr><td>Mean age ± SD</td><td>66.9y (4.7)</td></tr>
<tr><td>Sex</td><td>71.08% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)</td><td>WL + AT: 33.9
(3.5)
WL + RT: 34.8
(3.6)</td><td>WL: 34.7
(4)</td></tr>
<tr><td>Body mass (kg) - Baseline
Mean (SD)</td><td>WL + AT: 92.4
(13.5)
WL + RT: 95.6
(14.2)</td><td>WL: 95.1
(16.7)</td></tr>
<tr><td>Fat mass (kg) - Baseline
Mean (SD)</td><td>WL + AT: 41.4
(7.6)
WL + RT: 43.2
(8.2)</td><td>WL: 42.6
(8.8)</td></tr>
<tr><td>Fat mass (%) - Baseline
Mean (SD)</td><td>WL + AT: 45
(5.7)
WL + RT: 45.3
(6)</td><td>WL: 44.9
(5.6)</td></tr>
<tr><td>Trunk fat mass (kg) - Baseline
Mean (SD)</td><td>WL + AT: 23.5
(4.9)
WL + RT: 24.4
(5.1)</td><td>WL: 24.3
(5.6)</td></tr>
<tr><td>Body mass (kg)
Mean (95% CIs)</td><td>WL + AT: 85.9
(84.4-87.3)
WL + RT: 85.6
(84.3-87)</td><td>WL: 88.6
(87.2-90)</td></tr>
<tr><td>Fat mass (kg)
Mean (95% CIs)</td><td>WL + AT: 35.5
(34.4-36.6)</td><td>WL: 37.6
(36.5-38.7)</td></tr>
</table>
</td></tr>
</table>

		WL + RT: 34.5 (33.4-35.6)	
	Fat mass (%) Mean (95% CIs)	WL + AT: 41.1 (40.4-41.8) WL + RT: 40 (39.4-40.7)	WL: 42.6 (41.9-43.3)
	Trunk fat mass (kg) - Baseline Mean (95% CIs)	WL + AT: 19.6 (18.9-20.3) WL + RT: 19.2 (18.5-19.9)	WL: 21.1 (20.3-21.8)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in Body Mass at 18 months Mean (95% CIs)	WL + AT: -9.1 (-10.9--7.3) WL + RT: -8.9 (-10.7--7.2)	WL: -5.3 (-7.1--3.5)
	Change in Fat mass (kg) at 18 months Mean (95% CIs)	WL + AT: -7.3 (-8.7--5.9) WL + RT: -7.9 (-9.2--6.5)	WL: -4.4 (-5.8--3)
	Change in Fat mass (%) at 18 months Mean (95% CIs)	WL + AT: -9.9 (-12.2--7.6) WL + RT: -11.3 (-13.5--9.1)	WL: -4.4 (-7.1--2.5)
	Change in Trunk fat mass (kg) Mean (95% CIs)	WL + AT: -4.8 (-5.7--3.8) WL + RT: -4.9 (-5.8--4)	WL: -2.7 (-3.7--1.8)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Median (25th, 75th percentiles) attendance to scheduled WL intervention sessions was 71.1% (40.5, 83.3) for WL only, 83.1% (47.6, 92.9) for WL 1 AT, and 85.7% (70.7, 92.7) for WL 1 RT.		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Bellicha, 2022

Guideline record ID: 10054--1

Study characteristics		
Citation	Bellicha, A., Ciangura, C., Roda, C., Torcivia, A., Aron-Wisnewsky, J., Poitou, C., & Oppert, J.-M. (2022). Effect of exercise training after bariatric surgery: A 5-year follow-up study of a randomized controlled trial. PLOS ONE, 17(7), e0271561. https://doi.org/https://dx.doi.org/10.1371/journal.pone.0271561	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of exercise training after bariatric surgery: A 5-year follow-up study of a randomized controlled trial	
Location	France	
Trial name	N/A	
Methods		
Inclusion criteria	“Female gender, age between 18 and 65 years, living in Paris (France) or its region, and displaying the usual inclusion criteria for bariatric surgery (i.e. body mass index (BMI) ≥40 kg/m2, or BMI ≥35 kg/m2 with at least one obesity comorbidity).”	
Exclusion criteria	Not reported	
Setting	Hospital, Home	
Intervention	“UC + From the first week post-surgery, protein supplementation was provided to patients included in the PRO and PRO+EX groups in the form of whey-protein-enriched powder (48 g/day of whey protein). From week 6 post-RYGB, patients in the PRO+EX group participated in an exercise training program including 3 sessions per week of resistance training. Patients were initially followed up for six months after RYGB during the RCT [27] and onwards for routine care at 12 months and 5 years in accordance with international recommendations for management of patients after surgery”	
Control/Comparator	“All patients received usual care in a standardized manner by our multidisciplinary team during planned pre- and post-surgery visits at 1, 3, and 6 months.”	
Treatment duration	5 years	
Follow-up from baseline	5 years	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 76 Intervention group/s: PRO (n=31); PRO + EX (n=23) Comparator group: CON (n=22)	
Mean age ± SD	Not reported	
Sex	100.00% female	
Pre-existing medical condition	Unclear ("at least 1 obesity-related comorbidity" in inclusion criteria)	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in weight (kg) Mean (95% CIs)	PRO: -32.4 (-35.3--29.4) PRO + EX: -34 (-37.6--30.5)	CON: -32.1 (-35.5--28.8)
	Change in BMI (kg/m2) Mean (95% CIs)	PRO: -12 (-13.1--11) PRO + EX: -13 (-14.3--11.7)	CON: -12.1 (-13.3--10.9)
	Change in fat mass (kg) Mean (95% CIs)	PRO: -21 (-23.5--18.5) PRO + EX: -23.8 (-26.8--20.8)	CON: -22.1 (-24.8--19.3)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	71%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Belski, 2011

Guideline record ID: 10055--1

Study characteristics		
Citation	Belski, R., Mori, T. A., Puddey, I. B., Sipsas, S., Woodman, R. J., Ackland, T. R., Beilin, L. J., Dove, E. R., Carlyon, N. B., Jayaseena, V., & Hodgson, J. M. (2011). Effects of lupin-enriched foods on body composition and cardiovascular disease risk factors: a 12-month randomized controlled weight loss trial. International Journal of Obesity, 35(6), 810-819. https://doi.org/10.1038/ijo.2010.213	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of lupin-enriched foods on body composition and cardiovascular disease risk factors: a 12-month randomized controlled weight loss trial	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	"Overweight and obese (body mass index 27-35 kgm-2), otherwise healthy volunteers aged 20-71 years."	
Exclusion criteria	"Exclusion criteria included history of cardiovascular or peripheral vascular disease, diabetes, history of asthma, renal disease, liver disease or gout, a psychiatric illness, history of major gastrointestinal problems, other major illnesses such as cancer, hypertension (systolic blood pressure 4150mmHg or diastolic blood pressure 495mmHg), use of antihypertensive agents, total cholesterol 46.2mmoll-1 or triglycerides 42.0mmoll-1, use of lipid-lowering medications, women who were pregnant or intended to become pregnant, history of food allergies, current/recent weight loss/gain (change of 46% body weight over last 6 months) and alcohol intake 4140 g alcohol per week for women and 4280 g alcohol per week for men. In addition, individuals with no history of diabetes, but with fasting plasma glucose concentrations X6.0mmoll-1 were excluded."	
Setting	Home, University/research centre	
Intervention	"Eligible participants were randomized into either a control group (consuming control foods) or a lupin group (consuming foods enriched with lupin flour). . After randomization, participants commenced on a 3-month weight loss program (B35% energy restriction) designed by a dietitian to achieve an average weight loss in all participants of between 7 and 8% of body weight. This incorporated the consumption of the assigned foods, monthly dietetic visits and fortnightly dietary phone consultations. This was followed by a 1-month weight stabilization period where participants ceased weight loss and maintained body weight within 1.5 kg. During the following 8-month weight maintenance stage, participants followed an ad libitum diet incorporating the assigned foods. The aim during this period was to maintain the weight loss achieved."	
Control/Comparator	"Eligible participants were randomized into either a control group (consuming control foods) or a lupin group (consuming foods enriched with lupin flour). . After randomization, participants commenced on a 3-month weight loss program (B35% energy restriction) designed by a dietitian to achieve an average weight loss in all participants of between 7 and 8% of body weight. This incorporated the consumption of the assigned foods, monthly dietetic visits and fortnightly dietary phone consultations. This was followed by a 1-month weight stabilization period where participants ceased weight loss and maintained body weight within 1.5 kg. During the following 8-month weight maintenance stage, participants followed an ad libitum diet incorporating the assigned foods. The aim during this period was to maintain the weight loss achieved."	
Treatment duration	12 months	

<table>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 131
Intervention group/s: Lupin group (n=68)

Comparator group: Control group (n=63)</td></tr>
<tr><td>Mean age ± SD</td><td>Lupin: 46.5y (10.1); Control: 46.7y (9.4)</td></tr>
<tr><td>Sex</td><td>48.09% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Lupin group: 91.8
(13.5)</td><td>Control group: 93.7
(15.2)</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Lupin group: 31.3
(2.7)</td><td>Control group: 31.4
(2.8)</td></tr>
<tr><td>Body fat mass (kg)
Mean (SD)</td><td>Lupin group: 34.1
(7.2)</td><td>Control group: 34.7
(7.3)</td></tr>
<tr><td>Body fat (%)
Mean (SD)</td><td>Lupin group: 39.1
(7.3)</td><td>Control group: 39.3
(7.7)</td></tr>
<tr><td>Android fat (%)
Mean (SD)</td><td>Lupin group: 47.7
(6.7)</td><td>Control group: 48.3
(6.3)</td></tr>
<tr><td>Gynoid fat (%)
Mean (SD)</td><td>Lupin group: 40.8
(9)</td><td>Control group: 40.7
(9.7)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (95% CIs)</td><td>Lupin group: 85.2
(84.2-86.2)</td><td>Control group: 85.8
(84.8-86.8)</td></tr>
<tr><td>Body fat mass (kg)
Mean (95% CIs)</td><td>Lupin group: 28.9
(28-29.9)</td><td>Control group: 29.9
(28.9-30.8)</td></tr>
<tr><td>Android fat (%)
Mean (95% CIs)</td><td>Lupin group: 44
(43-45.1)</td><td>Control group: 44.3
(43.3-45.4)</td></tr>
<tr><td>Gynoid fat (%)
Mean (95% CIs)</td><td>Lupin group: 38.2
(37.5-39)</td><td>Control group: 38.7
(37.9-39.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</table>

<table>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Belzile, 2023

Guideline record ID: 10942--1

Study characteristics		
Citation	Belzile, D., Auclair, A., Roberge, J., Piché, M. E., Lebel, A., Pettigrew, M., Marceau, S., Biertho, L., & Poirier, P. (2023). Heart rate variability after bariatric surgery: the add-on value of exercise. European Journal of Sport Science, 23(3), 415-422. https://doi.org/ https://doi.org/10.1080/17461391.2021.2017488	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Heart rate variability after bariatric surgery: The add-on value of exercise	
Location	Canada	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were adults (≥ 18 years), severe obesity based on the National Institute of Health criteria [body mass index (BMI) ≥ 40 kg/m2 or BMI ≥ 35 kg/m2 with ≥ 1 comorbidities], and interest in participating in a supervised exercise training programme."	
Exclusion criteria	"Exclusion criteria were: 1) previous bariatric surgery, 2) vagotomy pro cedure, 3) use of weight-loss drugs in the last 3 months and, 4) implanted pacemaker."	
Setting	University/research centre	
Intervention	"The patients randomised to the exercise training pro gramme group underwent a supervised training pro gramme at the the Pavillon de Prévention des Maladies Cardiaques (PPMC) at the Institut Universitaire de Cardiologie et de Pneumologie de Québec-Université Laval 3 times weekly for 12 weeks, beginning 3 months after the bariatric surgery. A period of 3 months before the start of the training programme was planned to allow complete recovery after surgery and to maximise the training programme's potential benefits. The train ing was divided into 1) 35 min of moderate to vigorous aerobic exercise (60-75% of heart rate reserve), and 2) 25 min of resistance exercises."	
Control/Comparator	"Patients randomized to the control group had an hour meeting with a certified Clinical Exercise Specialist at 3 and 6 months after the bariatric surgery. Patients were taught general advice regarding physical activity and healthy behaviour."	
Treatment duration	12 weeks/surgical	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 59 Intervention group/s: Surgery + Exercise Program (n=40) Comparator group: Surgery + usual care (n=19)	
Mean age ± SD	Intervention: 41.6y (11.6); Control: 42.3y (10.8)	
Sex	76.27% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Surgery + Exercise Program: 133.9
(12.1)</td><td>Surgery + usual care: 132.6
(12.8)</td></tr>
<tr><td>Body mass index (kg/m2)
Mean (SD)</td><td>Surgery + Exercise Program: 47
(6.5)</td><td>Surgery + usual care: 44.3
(5)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Surgery + Exercise Program: 91.6
(11.6)</td><td>Surgery + usual care: 94.2
(14.4)</td></tr>
<tr><td>Body mass index (kg/m2)
Mean (SD)</td><td>Surgery + Exercise Program: 28.2
(4.8)</td><td>Surgery + usual care: 27.5
(3.7)</td></tr>
<tr><td>Weight at 12 months
Mean (SD)</td><td>Surgery + Exercise Program: 77
(16.8)</td><td>Surgery + usual care: 77.1
(15.1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change (%) at 12 months
Mean (SD)</td><td>Surgery + Exercise Program: 37.8%
(9.0%)</td><td>Surgery + usual care: 38.4
(10.1)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Benasi, 2022

Guideline record ID: 10056--1

Study characteristics		
Citation	Benasi, G., Gostoli, S., Zhu, B., Offidani, E., Artin, M. G., Gagliardi, L., Rignanese, G., Sassi, G., Fava, G. A., & Rafanelli, C. (2022). Well-being therapy and lifestyle intervention in type 2 diabetes: a pilot randomized controlled trial. Psychosomatic Medicine, 84(9), 1041-1049. https://doi.org/10.1097/PSY.0000000000001115	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Well-Being Therapy and Lifestyle Intervention in Type 2 Diabetes: A Pilot Randomized Controlled Trial	
Location	Italy	
Trial name	N/A	
Methods		
Inclusion criteria	"Participants were eligible if they a) were overweight or obese (body mass index ≥25 kg/m2), b) were adult (18-65 years old), and c) had a diagnosis of type 2 diabetes."	
Exclusion criteria	"Reasons for exclusion included a) inability to speak Italian fluently; b) inability to provide informed consent; c) medical conditions that could interfere with study participation or associated with unintentional weight change (i.e., any cancer, congestive heart failure, untreated or unstable hyperthyroidism, kidney failure on dialysis, and severe orthopedic disorders); d) untreated, severe, or recently diagnosed (≤6 months) mental illness or personality disorder; e) history of eating disorders or substance abuse; f) use of appetite suppressants, lipase inhibitors, and dietetic products; g) involvement in another behavioral intervention; h) history of weight loss surgery or weight loss surgery scheduled within the next year; i) pregnancy or intention to become pregnant within the next year; and l) inability to control meal contents (e.g., institutionalized patients)."	
Setting	Hospital, by phone	
Intervention	"The well-being intervention was adapted from the WBT protocol (8) and delivered in four individual, weekly sessions. Each session lasted for about an hour and was conducted in-person in a private room at each clinic. The intervention was characterized by the following features: a) participants were encouraged to identify episodes of well-being that recently occurred and to set them in a situational context with the use of a structured diary; b) once the instances of well-being were recognized, the participant learned to identify thoughts and/or behaviors leading to premature interruption of well-being, as is performed in cognitive behavioral therapy; c) homework assignments that elicit psychological well-being and, particularly, optimal experiences were prescribed; d)monitoring of the diary allowed to discover specific impairments or, conversely, excessive levels of well-being dimensions according to Jahoda's conceptual framework (9); and e) participants were not encouraged to pursue the highest possible levels of psychological well-being but to obtain an optimal balanced functioning, that is, euthymia (17). The participant thus became able to readily identify moments of well-being, to be aware of interruptions to well-being feelings (interfering thoughts and/or behaviors), and to apply cognitive behavioral techniques to address these interruptions and pursue optimal experiences (see Data, Supplemental Digital Content Table S1, http://links.lww.com/PSYMED/A857, for a session-by-session description of the intervention)."	
Control/Comparator	"The lifestyle intervention was delivered in 12 individual weekly sessions. Four sessions (i.e., session numbers 1, 4, 8, and 12) were conducted in-person in a private room at each clinic and lasted for about an hour, whereas the remaining sessions were conducted over the telephone and lasted for about 30 minutes. The intervention has been modeled after the Small Changes and Lasting Effects (SCALE) trial protocol (18) and developed in the	

<table>
<tr><td></td><td>context of the Small Changes Approach (19) and the Social Cognitive Theory (20). Specifically, it assumes that small changes in diet and physical activity, being more feasible to achieve and maintain, may increase feelings of self-efficacy, stimulate additional changes, and result in gradual weight loss over time. The objective of the lifestyle intervention was therefore to help participants gradually lose weight by making small changes in their lifestyle. The intervention included three key components: monitoring of lifestyle changes and weight, goal setting, and problem solving."</td></tr>
<tr><td>Treatment duration</td><td>4 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 58
Intervention group/s: Well-being therapy - Lifestyle (n=30)

Comparator group: Lifestyle Alone (n=28)</td></tr>
<tr><td>Mean age ± SD</td><td>55.5y (6.6)</td></tr>
<tr><td>Sex</td><td>39.66% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Crude weight
Mean (SD)</td><td>Well-being therapy - Lifestyle:
94.8
(23.4)</td><td>Lifestyle Alone: 95.6
(19.1)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Crude weight
Mean (SD)</td><td>Well-being therapy - Lifestyle:
93
(19.9)</td><td>Lifestyle Alone: 90.6
(17.6)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Bennett, 2012

Guideline record ID: 10058

Study characteristics		
Citation	Bennett, G. G., Warner, E. T., Glasgow, R. E., Askew, S., Goldman, J., Ritzwoller, D. P., Emmons, K. M., Rosner, B. A., Colditz, G. A., & the Be Fit, Be Well Study Investigators. (2012). Obesity treatment for socioeconomically disadvantaged patients in primary care practice. Archives of Internal Medicine, 172(7), 565-574. https://doi.org/https://dx.doi.org/10.1001/archinternmed.2012.1	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Obesity treatment for socioeconomically disadvantaged patients in primary care practice	
Location	US	
Trial name	Be Fit, Be Well	
Methods		
Inclusion criteria	"Body mass index (calculated as weight in kilograms divided by height in meters squared) from 30 to 50, weight less than 180 kg, use of 1 or more antihypertensive medication, age at least 21 years, and 1 or more medical visits in the 12 months before study entry. In addition, we required English or Spanish fluency, written informed consent, and willingness to change diet, physical activity, and weight."	
Exclusion criteria	"Exclusion criteria included history of a vascular event 6 months or less before study entry or of a medical condition that might affect measurement or trajectory of weight loss, previous or planned bariatric surgery, use of weight loss medications or medications known to increase weight, recent pregnancy or breastfeeding or plans to become pregnant within 2 years, and/or plans to relocate within the 2-year study period."	
Setting	GP clinic, Home	
Intervention	"The intervention used theory-based32 and evidence-based33,34 principles to promote weight loss and hypertension selfmanagement for 24 months. The intervention is described in greater detail elsewhere.29 Briefly, we used a behavioral weight loss approach designed for use in resource-constrained settings.29 The intervention approach was designed for delivery in populations with limited literacy and numeracy and impaired access to health-promoting resources. Patients are prescribed 3 tailored goals to modify routine obesogenic lifestyle behaviors.29,33 Behavior change goals were modeled on evidencebased recommendations31,34 that were tailored to the patient population and phrased so that they could be easily selfmonitored. New goals were selected at subsequent 13-week intervals. For the duration of the study, participants maintained a hypertension medication adherence goal (to take their medication as prescribed daily). Participants chose to self-monitor their progress using either the study website or an interactive voice response system, available in English and Spanish. Both tracking systems provided real-time tailored feedback. Participants could switch their intervention platform at any time. Trained community health educators delivered counseling calls monthly during the first 12 months of intervention and bimonthly during the second year (18 total scheduled calls). The community health educators were trained by study investigators in principles of motivational interviewing35,36 and conducted 15- to 20-minute calls (in English or Spanish) that covered self-monitoring data, problem solving, and behavioral skills training. The community health educators also led 12 optional monthly group sessions that were held at a community location. The community health educators were trained and certified at baseline, were recertified annually, and received weekly supervision throughout the study. Primary care providers delivered at least 1 brief, standardized message about the importance of intervention participation. We also provided a personalized behavior change "prescription" that included the primary care provider's electronic signature.37 Finally, we	

<table>
<tr><td></td><td>provided tailored behavioral skills training materials, adapted from previous studies.34 We also provided tailored information on community resources (eg, public parks, walking groups, and farmers' markets) and distributed a walking kit that included a pedometer and maps (with step counts) of destinations in the local community”</td></tr>
<tr><td>Control/Comparator</td><td>“We provided the National Heart, Lung, and Blood Institute's "Aim for a Healthy Weight" self-help booklet31 to the usual care participants at baseline. The research team made no other at.”</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 365
Intervention group/s: Intervention (n=180)

Comparator group: Control (n=185)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 54.58y (10.77); Control: 54.67y (11.03)</td></tr>
<tr><td>Sex</td><td>68.49% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 99.7
(16.29)

Intervention: 37.03
(4.96)</td><td>Control: 100.6
(18.67)

Control: 36.99
(5.24)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SE)

Change in weight (%)
Mean (SE)

Change in BMI (kg/m2)
Mean (SE)</td><td>Intervention: -1.37
(0.38)

Intervention: -1.54
(0.39)

Intervention: -0.54
(0.14)</td><td>Control: -0.32
(0.36)

Control: -0.42
(0.37)

Control: -0.12
(0.13)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SE)

Change in weight (%)
Mean (SE)</td><td>Intervention: -1.53
(0.37)

Intervention: -1.68
(0.38)</td><td>Control: -0.5
(0.35)

Control: -0.67
(0.36)</td></tr>
</table></td></tr>
</table>

	Change in BMI (kg/m2) Mean (SE)	Intervention: -0.58 (0.14)	Control: -0.2 (0.13)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Bennett, 2013

Guideline record ID: 10057--1

Study characteristics		
Citation	Bennett, G. G., Foley, P., Levine, E., Whiteley, J., Askew, S., Steinberg, D. M., Batch, B., Greaney, M. L., Miranda, H., Wroth, T. H., Holder, M. G., Emmons, K. M., & Puleo, E. (2013). Behavioral treatment for weight gain prevention among black women in primary care practice: a randomized clinical trial. JAMA Internal Medicine, 173(19), 1770-1777. https://doi.org/10.1001/jamainternmed.2013.9263	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Behavioral treatment for weight gain prevention among black women in primary care practice: a randomized clinical trial	
Location	US	
Trial name	Shape Program (Shape)	
Methods		
Inclusion criteria	"Age of 25 to 44 years, BMI of 25 to 34.9, at least 1 visit to a Piedmont Health center in the prior 24 months, North Carolina residency, and self-reported English fluency."	
Exclusion criteria	"Exclusion criteria included pregnancy or postpartum status (≤12 months post partum), a history of myocardial infarction or stroke in the prior 2 years, and any history of cognitive, developmental, or psychiatric disorders."	
Setting	GP clinic, Home	
Intervention	"Briefly, it was a theory-based and evidence-based treatment designed to create a slight (<200 kcal) daily energy deficit to offset 12-month weight gains. Although a small amount of weight loss is advantageous to prevent future gains, we explicitly informed participants that Shape was not a weight loss trial. We did not expect participants to be motivated to lose weight. Instead, we informed participants that Shape was an approach designed to improve their overall well-being and to maintain their current body shape. The 12-month intervention used the interactive obesity treatment approach (iOTA)31,32 and comprised 5 mutually reinforcing components: (1) tailored behavior change goals; (2) weekly self-monitoring via interactive voice response (IVR) telephone calls; (3) 12 counseling calls delivered monthly by a trained registered dietitian; (4) tailored skills training materials; and (5) a 12-month YMCA membership. Our intervention assigned participants a series of behavior change goals selected from a library of more than 20 goals. If achieved, these goals (eg, no sugar-sweetened beverages, no fast food, replacing energy-dense foods with ≥5 fruits or vegetables per day) will create the intended energy deficit. At baseline and at the 6-month assessment, a computer algorithm assigned each participant 3 behavior change goals based on her need for change, self-efficacy, and readiness. Participants self-monitored their daily adherence to the behavior change goals during IVR calls (2-4 min) that were issued weekly by our computer systems. Brief tailored feedback and short skills training tips were provided after entry of selfmonitoring data. Every 2 months, we provided participants with personalized progress reports and replaced 2 of their assigned goals based on their baseline and 6-month survey responses. Piedmont Health registered dietitians ("Shape coaches"), who were trained inmotivational interviewing principles,34 led monthly 20-minute counseling calls. Coaches reviewed patient self-monitoring data, provided skills training and social support, and used goal setting and problem-solving strategies to enhance behavior change self-efficacy. Study staff provided Shape coaches with a 2-day baseline training session, weekly supervision, and refresher trainings every 6months. Study staff reviewed 5% of coaching calls for protocol adherence. At baseline and every 2 months thereafter, participants were provided with a set of printed tailored skills training materials (designed for low-literacy audiences)."	

<table>
<tr><td>Control/Comparator</td><td>“Study staff made no attempts to influence the medical treatment provided to those in the usual-care arm. Every 6months, we sent usual-care participants newsletters that covered general wellness topics but did not discuss weight, nutrition, or physical activity.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 185
Intervention group/s: Intervention (n=91)

Comparator group: Usual care (n=94)</td></tr>
<tr><td>Mean age ± SD</td><td>35.4y (5.5)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 81.3
(8.8)

Intervention: 30.1
(2.7)

Intervention: 98.2
(8.5)</td><td>Usual care: 81
(8.8)

Usual care: 30.2
(2.4)

Usual care: 97.3
(8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SE)

Change in BMI (kg/m2)
Mean (SE)

Change in waist circumference (cm)
Mean (SE)</td><td>Intervention: -1
(0.5)

Intervention: -0.3
(0.2)

Intervention: -1
(0.7)</td><td>Usual care: 0.5
(0.5)

Usual care: 0.3
(0.2)

Usual care: 0.3
(0.7)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Bergman, 2018

Guideline record ID: 10059--1

Study characteristics		
Citation	Bergman, F., Wahlström, V., Stomby, A., Otten, J., Lanthén, E., Renklint, R., Waling, M., Sörlin, A., Boraxbekk, C.-J., Wennberg, P., Öhberg, F., Levine, J. A., & Olsson, T. (2018). Treadmill workstations in office workers who are overweight or obese: a randomised controlled trial. The Lancet Public Health, 3(11), e523-e535. https://doi.org/https://dx.doi.org/10.1016/S2468-2667(18)30163-4	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Treadmill workstations in office workers who are overweight or obese: a randomised controlled trial	
Location	Sweden	
Trial name	N/A	
Methods		
Inclusion criteria	"Office workers with mainly sedentary work tasks, were aged 40-67 years, and had a body-mass index (BMI) between 25 kg/m² and 40 kg/m². All participants had a sit-stand desk as their ordinary workstation. To be included, participants needed to be in their office at least 4 days per week, including not working from home more than 1 day per week. For part-time workers, we asked for their working hours and analysed the activity data according to that."	
Exclusion criteria	"We excluded those with type 1 and type 2 diabetes, stress-related exhaustion disorder, moderate or severe depression or anxiety (as assessed with the Hospital Anxiety and Depression Scale questionnaire), severe kidney disease, severe cardiovascular disease, severe gastrointestinal or lung disease, untreated thyroid disease (determined by bloosd test by study investigators), a previous cardiovascular event such as transient ischaemic attack or stroke, more than 6% weight loss during the past 6 months, engagement in extensive aerobic exercise training, or musculoskeletal pain making treadmill walking difficult. Pregnant women and people with more than 1 day of travel per workweek or with plans to leave the organisation during the study period were also excluded."	
Setting	Workplace	
Intervention	"Those randomly assigned to the intervention group received a portable treadmill workstation (Walkplace AB, Spånga, Sweden), which was installed in their usual space at their everyday sit-stand desk. The unit's maximum speed was 8 km/h. The participants were instructed to use the treadmill at a self-chosen walking speed (not running) for at least 1 h per day, but preferably more if possible. The 1 h per day recommendation was based on what was assumed to work for most participants, according to their work tasks. The participants could allocate their daily time on the treadmill as they wished, and individually choose which work tasks to do on the treadmill. At four timepoints during the study (after 5-6 weeks, 19-20 weeks, 31 weeks, and 50 weeks), the participants in the intervention group received emails from the research team, including information about the health risks of sedentary behaviour and reminders to use the treadmill as much as possible."	
Control/Comparator	"The participants randomly assigned to the control group continued to work as usual at their office desk."	
Treatment duration	13 months	
Follow-up from baseline	13 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 80
Intervention group/s: Intervention group (n=40)

Comparator group: Control group (n=40)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 52·4 (6·8); Control: 50·3 (6·7)</td></tr>
<tr><td>Sex</td><td>55.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (95% CIs)</td><td>Intervention group: 88.7
(84.9-92.5)</td><td>Control group: 87.2
(83.5-90.9)</td></tr>
<tr><td>BMI (kg/m2)
Mean (95% CIs)</td><td>Intervention group: 29.6
(28.5-30.6)</td><td>Control group: 28.9
(27.8-29.9)</td></tr>
<tr><td>Waist circumference (cm)
Mean (95% CIs)</td><td>Intervention group: 99.2
(96.4-101.9)</td><td>Control group: 96.5
(93.7-99.2)</td></tr>
<tr><td>Fat mass (g)
Mean (95% CIs)</td><td>Intervention group: 33162
(30692-35633)</td><td>Control group: 30456
(28026-32887)</td></tr>
<tr><td>Android fat mass (%)
Mean (95% CIs)</td><td>Intervention group: 48
(46-50)</td><td>Control group: 45.9
(43.9-47.9)</td></tr>
<tr><td>Gynoid fat mass (%)
Mean (95% CIs)</td><td>Intervention group: 41.5
(39.8-43.2)</td><td>Control group: 39.4
(37.7-41.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Weight (kg)
Mean (95% CIs)</td><td>Intervention group: 0.6
(-0.4-1.5)</td><td>Control group: 0.2
(-0.7-1.1)</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (95% CIs)</td><td>Intervention group: 0.2
(-0.1-0.5)</td><td>Control group: 0.1
(-0.2-0.4)</td></tr>
<tr><td>Change in Waist circumference (cm)
Mean (95% CIs)</td><td>Intervention group: -0.2
(-1.3-0.9)</td><td>Control group: 0.03
(-1-1.1)</td></tr>
<tr><td>Change in Fat mass (g)
Mean (95% CIs)</td><td>Intervention group: 374
(-426-1173)</td><td>Control group: 302
(-461-1065)</td></tr>
<tr><td>Change in Android fat mass (%)
Mean (95% CIs)</td><td>Intervention group: -0.2
(-1-0.6)</td><td>Control group: 0.1
(-0.7-0.9)</td></tr>
<tr><td>Change in Gynoid fat mass (%)</td><td>Intervention group: 0.2</td><td>Control group: -0.003</td></tr>
</table>
</td></tr>
</table>

	Mean (95% CIs)	(-0.4-0.8)	(-0.6-0.6)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Bergström, 2013

Guideline record ID: 10060--1

Study characteristics		
Citation	Bergström, H., Hagströmer, M., Hagberg, J., & Elinder, L. S. (2013). A multi-component universal intervention to improve diet and physical activity among adults with intellectual disabilities in community residences: a cluster randomised controlled trial. Research in Developmental Disabilities, 34(11), 3847-3857. https://doi.org/10.1016/j.ridd.2013.07.019	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A multi-component universal intervention to improve diet and physical activity among adults with intellectual disabilities in community residences: a cluster randomised controlled trial	
Location	Sweden	
Trial name	N/A	
Methods		
Inclusion criteria	"Community residences were eligible for inclusion if they were intended for residents with mild or moderate ID and if at least three of the residents chose to participate in the study. The level of ID was not individually examined, but all participants had the ability to understand basic information about the intervention and to decide upon participation. Participants gave informed written consent and their trustees received written information."	
Exclusion criteria	"Not explicitly reported."	
Setting	Community residences for adults with ID	
Intervention	"A three component intervention based on Social Cognitive Theory was developed, including: (1) appointment of a health ambassador in each community residence attending network meetings, (2) a study circle for caregivers, and (3) a health course for the residents."	
Control/Comparator	"Community residences in the control group continued to work as usual, but were promised the possibility of taking part in the intervention after completion of the study (wait-list control."	
Treatment duration	12-16 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference	
Participant characteristics		
Number of participants	n= 130 Intervention group/s: Intervention (n=64) Comparator group: Control (n=66)	
Mean age ± SD	Intervention: 36.2y (10.1); Control: 39.4y (11.3)	
Sex	56.92% female	
Pre-existing medical condition	Intellectual disabilities	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline BMI (kg/m2)
Mean (SD)

Baseline waist circumference (cm)
Mean (SD)</td><td>Intervention: 30
(7.6)

Intervention: 94.5
(16.5)</td><td>Control: 28.5
(6.6)

Control: 92.8
(13.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Linear regression of change in BMI (kg/m2)
Linear regression of Beta coefficient and 95% CIs

Linear regression of change in waist circumference (cm)
Beta coefficient and 95% CIs</td><td>Intervention: -0.3
(-1.1-0.5)

Intervention: -1.7
(-4-0.6)</td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Bhopal, 2014

Guideline record ID: 10063--1

Study characteristics		
Citation	Bhopal, R. S., Douglas, A., Wallia, S., Forbes, J. F., Lean, M. E. J., Gill, J. M. R., McKnight, J. A., Sattar, N., Sheikh, A., Wild, S. H., Tuomilehto, J., Sharma, A., Bhopal, R., Smith, J. B. E., Butcher, I., & Murray, G. D. (2014). Effect of a lifestyle intervention on weight change in south Asian individuals in the UK at high risk of type 2 diabetes: a family-cluster randomised controlled trial. The Lancet Diabetes & Endocrinology, 2(3), 218-227. https://doi.org/https://dx.doi.org/10.1016/S2213-8587(13)70204-3	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a lifestyle intervention on weight change in south Asian individuals in the UK at high risk of type 2 diabetes: a family-cluster randomised controlled trial	
Location	Scotland	
Trial name	Prevention of Diabetes and Obesity in South Asians (PODOSA)	
Methods		
Inclusion criteria	"Self-identified men and women of Indian or Pakistani origin aged 35 years or older were eligible for screening if: their waists measured 90 cm or greater in men and 80 cm or greater in women; there was no diagnosis of diabetes (other than gestational diabetes); and the family cook was cooperative."	
Exclusion criteria	"Participants receiving long-term oral corticosteroids, or weight loss medication, or with health disorders making adherence contraindicated or improbable, or pregnant, or who were unlikely to remain in the UK for 3 years, were excluded."	
Setting	GP clinic, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The intervention was consultation with a dietitian; both participants and family volunteers were part of this intervention (appendix pp 5-10 summarise the contents of the intervention). Dietitians were trained in venepuncture, anthropometric and blood pressure measurement, delivery of information, behaviour change using the stages of change model,17 and promotion of physical activity. Each family was mostly seen by the same dietitian throughout the study. Families in the intervention group had 15 visits from a dietitian over 3 years (baseline, monthly for the first 3 months, then every 3 months. The dietitians advised participants and family volunteers on achieving weight loss through a calorie-deficit diet and physical activity of at least 30 min daily brisk walking, using culturally adapted and translated resources, including the Counterweight Programme. Other advice included information on shopping and cooking (with demonstrations). 3-day food diaries and a dietary patterns questionnaire were used to collect data to inform dietitians' advice. Participants were invited to attend annual group sessions, including a food shopping tour and brisk walking. Pedometers were given to the participants to provide step counts for motivation through self-monitoring and for the dietitians to assess progress. Bodyweight and waist circumference data, and the Chester step test,20 were used as motivational devices by dietitians. In both the intervention and control groups family volunteers were asked to follow the advice given and to help the participants to follow it."	
Control/Comparator	"The control group was given standardised written and verbal advice on healthy eating, diabetes prevention, promotion of physical activity, and on accessing other weight control and physical activity services over four visits (baseline, then annually) with a dietitian. This advice aimed to halt increasing weight. In both the intervention and control groups family volunteers were asked to follow the advice given and to help the participants to follow it."	
Treatment duration	3 years	

<table>
<tr><td>Follow-up from baseline</td><td>36 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 171
Intervention group/s: Intervention group (n=85)

Comparator group: Control group (n=86)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 52.8y (10.2); Control: 52.2y (10.3)</td></tr>
<tr><td>Sex</td><td>54.39% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m²)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention group: 79.77 (16.23)

Intervention group: 30.59 (5.02)

Intervention group: 102.69 (11.16)</td><td>Control group: 80.68 (14.98)

Control group: 30.49 (4.6)

Control group: 103.26 (11.01)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m²)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention group: 78.82 (16.11)

Intervention group: 30.18 (5.04)

Intervention group: 101.55 (11.34)</td><td>Control group: 80.36 (14.8)

Control group: 30.39 (4.56)

Control group: 103.45 (11.66)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m²)
Mean (SD)

Waist circumference (cm)
Mean (SD)

Proportion of participants Losing ≥2.5 kg
Proportion (%)

Proportion of participants Losing ≥5% of body weight
Proportion (%)

Proportion of participants gaining ≥2.5 kg
Proportion (%)</td><td>Intervention group: 78.76 (16.57)

Intervention group: 30.18 (5.5)

Intervention group: 100.51 (11.51)

Intervention group: 39

Intervention group: 25

Intervention group: 23</td><td>Control group: 80.99 (15.34)

Control group: 30.65 (4.83)

Control group: 102.85 (11.14)

Control group: 14

Control group: 5

Control group: 19</td></tr>
</table>
</td></tr>
</table>

	Proportion of participants gaining ≥5% of bodyweight Proportion (%)	Intervention group: 10	Control group: 9
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Weight change (kg) Mean (SD)	Intervention group: 1.13 (4.12)	Control group: 0.51 (3.65)
Compliance with treatment	Mean number of visits for the intervention group was 13.7 (SD 2.1) and for the control group was 3.9 (SD 0.3).		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Black, 2010

Guideline record ID: 10067--1

Study characteristics		
Citation	Black, M. M., Hager, E., Le, K., Anliker, J., Arteaga, S. S., DiClemente, C., Gittelsohn, J., Magder, L., Papas, M., Snitker, S., Treuth, M. S., & Wang, Y. (2010). Challenge! Health promotion/obesity prevention mentorship model among urban, black adolescents. Pediatrics, 126(2), 280-288. https://doi.org/https://doi.org/10.1542/peds.2009-1832	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Challenge! Health promotion/obesity prevention mentorship model among urban, black adolescents	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligibility criteria for both samples included age (11 to 16y) and residence in the low income communities surrounding the medical center. Eligibility was not based on body weight, nor was body weight mentioned in recruitment materials."	
Exclusion criteria	Not reported	
Setting	Hospital, School, University/research centre	
Intervention	"A home- and community-based health promotion/obesity prevention controlled trial, anchored in social cognitive theory and involving motivational interviewing techniques, and delivered by college-enrolled, African-American mentors"	
Control/Comparator	"Control adolescents did not receive the intervention or a mentor."	
Treatment duration	10 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 235 Intervention group/s: Intervention (n=121) Comparator group: Control (n=114)	
Mean age ± SD	Intervention: 13.3y (1.0); Control: 13.3y (1.0)	
Sex	49.36% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	Overweight/Obese Proportion (%)	Intervention: 44.63	Control: 31.58
	Total percentage of body fat (overweight/obese participants)	Intervention: 35.18 (5.8)	Control: 36.88 (6.38)

	Mean (SD) Fat mass (overweight/obese participants) Mean (SD)	 Intervention: 26.22 (7.22)	 Control: 29.14 (10.06)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Overweight/Obese Proportion (%) Total percentage of body fat (overweight/obese participants) Mean (SD) Fat mass (overweight/obese participants) Mean (SD)	Intervention: 39.33 Intervention: 33.98 (8.97) Intervention: 29.01 (10.42)	Control: 42.7 Control: 38.2 (7.97) Control: 31.85 (10.67)
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Black, 2021

Guideline record ID: 10068A--1

Study characteristics		
Citation	Black, M. M., Hager, E. R., Wang, Y., Hurley, K. M., Latta, L. W., Candelaria, M., & Caulfield, L. E. (2021). Toddler obesity prevention: a two-generation randomized attention-controlled trial. Maternal & Child Nutrition, 17(1), e13075. https://doi.org/https://dx.doi.org/10.1111/mcn.13075	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Toddler obesity prevention: A two-generation randomized attention-controlled trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligible mothers were age 18 years or older, not pregnant, WIC eligible, English speaking and without medical/physical conditions that limited physical activity (Physical Activity Readiness Questionnaire [PAR-Q]) (Thomas, Reading, & Shephard, 1992). Eligible toddlers were age 12-32 months, term birth (>37 weeks), birthweight >2,500 g, without health restrictions, congenital problems or developmental delays, and ambulatory."	
Exclusion criteria	Not reported	
Setting	WIC clinics; Paediatric clinics	
Intervention	"Tot-TOPS: The responsive parenting intervention (Tot-TOPS) emphasized parents' role in recognizing and responding to toddlers' signals, behaviour management, soothing without relying on food, promoting toddler emerging autonomy and providing opportunities for healthy toddler meals and physical activity. ; Mom-TOPS: The maternal lifestyle intervention (Mom-TOPS) focused on maternal diet and physical activity, with no mention of responding to toddler diet, physical activity or behaviour. Both interventions incorporated fruits and Key messages • Despite no impact on weight gain, intervention effects on physical activity, fruit intake, and mealtime interactions warrant additional research to examine two-generation interventions among toddler-mother dyads. • A maternal lifestyles intervention resulted in increased physical activity among toddlers and mothers, compared to controlled • A responsive parenting intervention led to improvements in mealtime interactions, compared to a maternal lifestyles intervention, suggesting caution in mother-toddler dietary interventions that exclude responsive parenting. • Intervention-related improvements in physical activity, mealtime interactions, and fruit consumption were significant for older (21-32 months), but not younger toddlers (12-20 months), suggesting that intervention impact may vary by toddlers' developmental readiness. 1 Special Supplemental Nutrition Program for Women, Infants, and Children. 2 of 16 BLACK ET AL. bs_bs_banner 17408709, 2021, 1, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/mcn.13075 by NHMRC National Cochrane Australia, Wiley Online Library on [12/02/2023]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License vegetables into group activities, snacks and goal setting"	
Control/Comparator	"Control/Safe-TOPS: The attention control intervention (Safe-TOPS) provided a home safety intervention that significantly improved home safety scores (Wang, Gielen, Magder, Hager, & Black, 2018) with no mention of responsivity, diet or physical activity."	
Treatment duration	4 months	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 277
Intervention group/s: Mom-TOPS (n=94); Tot-TOPS (n=92)

Comparator group: Control (n=91)</td></tr>
<tr><td>Mean age ± SD</td><td>Mothers: 27.28 y (6.17); Toddlers: 20.11 mon (5.50)</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Maternal BMI (kg/m2)
Mean

Proportion of Maternal overweight/obese (%)
Proportion (%)

Proportion of Maternal Obese (%)
Proportion (%)</td><td>Mom-TOPS: 31.98
Tot-TOPS: 31.9

Mom-TOPS: 72
Tot-TOPS: 75

Mom-TOPS: 54
Tot-TOPS: 50</td><td>Control: 31.51

Control: 71

Control: 48</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Maternal BMI (kg/m2)
Mean

Proportion of Maternal overweight/obese (%)
Proportion (%)

Proportion of Maternal Obese (%)
Proportion (%)</td><td>Mom-TOPS: 32.22
Tot-TOPS: 32.21

Mom-TOPS: 69
Tot-TOPS: 78

Mom-TOPS: 56
Tot-TOPS: 54</td><td>Control: 31.85

Control: 73

Control: 49</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
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<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Black, 2021

Guideline record ID: 10068B--1

Study characteristics		
Citation	Black, M. M., Hager, E. R., Wang, Y., Hurley, K. M., Latta, L. W., Candelaria, M., & Caulfield, L. E. (2021). Toddler obesity prevention: a two-generation randomized attention-controlled trial. Maternal & Child Nutrition, 17(1), e13075. https://doi.org/https://dx.doi.org/10.1111/mcn.13075	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Toddler obesity prevention: A two-generation randomized attention-controlled trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligible mothers were age 18 years or older, not pregnant, WIC eligible, English speaking and without medical/physical conditions that limited physical activity (Physical Activity Readiness Questionnaire [PAR-Q]) (Thomas, Reading, & Shephard, 1992). Eligible toddlers were age 12-32 months, term birth (>37 weeks), birthweight >2,500 g, without health restrictions, congenital problems or developmental delays, and ambulatory."	
Exclusion criteria	Not reported	
Setting	WIC clinics; Paediatric clinics	
Intervention	"Tot-TOPS: The responsive parenting intervention (Tot-TOPS) emphasized parents' role in recognizing and responding to toddlers' signals, behaviour management, soothing without relying on food, promoting toddler emerging autonomy and providing opportunities for healthy toddler meals and physical activity. ; Mom-TOPS: The maternal lifestyle intervention (Mom-TOPS) focused on maternal diet and physical activity, with no mention of responding to toddler diet, physical activity or behaviour. Both interventions incorporated fruits and Key messages • Despite no impact on weight gain, intervention effects on physical activity, fruit intake, and mealtime interactions warrant additional research to examine two-generation interventions among toddler-mother dyads. • A maternal lifestyles intervention resulted in increased physical activity among toddlers and mothers, compared to controlled • A responsive parenting intervention led to improvements in mealtime interactions, compared to a maternal lifestyles intervention, suggesting caution in mother-toddler dietary interventions that exclude responsive parenting. • Intervention-related improvements in physical activity, mealtime interactions, and fruit consumption were significant for older (21-32 months), but not younger toddlers (12-20 months), suggesting that intervention impact may vary by toddlers' developmental readiness. 1 Special Supplemental Nutrition Program for Women, Infants, and Children. 2 of 16 BLACK ET AL. bs_bs_banner 17408709, 2021, 1, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/mcn.13075 by NHMRC National Cochrane Australia, Wiley Online Library on [12/02/2023]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License vegetables into group activities, snacks and goal setting"	
Control/Comparator	"Control/Safe-TOPS: The attention control intervention (Safe-TOPS) provided a home safety intervention that significantly improved home safety scores (Wang, Gielen, Magder, Hager, & Black, 2018) with no mention of responsivity, diet or physical activity."	
Treatment duration	4 months	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 277
Intervention group/s: Mom-TOPS (n=94); Tot-TOPS (n=92)

Comparator group: Control (n=91)</td></tr>
<tr><td>Mean age ± SD</td><td>Mothers: 27.28 y (6.17); Toddlers: 20.11 mon (5.50)</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Toddler proportion of BMI ≥ 85th percentile (%)
Proportion (%)

Toddler proportion of BMI ≥ 95th percentile (%)
Proportion (%)</td><td>Mom-TOPS: 30
Tot-TOPS: 26

Mom-TOPS: 18
Tot-TOPS: 16</td><td>Control: 36

Control: 17</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Toddler proportion of BMI ≥ 85th percentile (%)
Proportion (%)

Toddler proportion of BMI ≥ 95th percentile (%)
Proportion (%)</td><td>Mom-TOPS: 31
Tot-TOPS: 27

Mom-TOPS: 13
Tot-TOPS: 15</td><td>Control: 29

Control: 12</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Blomster, 2014

Guideline record ID: 10069

Study characteristics		
Citation	Blomster, H., Laitinen, T., Lyyra-Laitinen, T., Vanninen, E., Gylling, H., Peltonen, M., Martikainen, T., Sahlman, J., Kokkarinen, J., Randell, J., Smirnov, G., Seppä, J., & Tuomilehto, H. (2014). Endothelial function is well preserved in obese patients with mild obstructive sleep apnea. Sleep and Breathing, 18(1), 177-186. https://doi.org/https://dx.doi.org/10.1007/s11325-013-0867-7	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Endothelial function is well preserved in obese patients with mild obstructive sleep apnea	
Location	Finland	
Trial name	N/A	
Methods		
Inclusion criteria	"The inclusion criteria in the follow-up groups were (1) working age (18-65 years), (2) body mass index (BMI) of 28-40 kg/m2, and (3) AHI of 5-15 events/hour. Baseline cross-sectional control group consisted of subjects who presented habitual snoring, fulfilled inclusion criteria 1-2, and had AHI < 5."	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"The intervention group received a 1-year lifestyle intervention including an initial weight reduction program with 12 weeks on a very low calorie diet"	
Control/Comparator	"For the control group, a single general dietary and exercise counselling session was implemented."	
Treatment duration	1 year	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 81 Intervention group/s: Intervention group (n=40) Comparator group: Control group (n=41)	
Mean age ± SD	Intervention: 51.8y (9.0); Control: 50.9y (8.6)	
Sex	25.93% female	
Pre-existing medical condition	Mild obstructive sleep apnea	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	Baseline BMI (kg/m2) Mean (SD)	Intervention group: 33.4 (2.8)	Control group: 31.4 (2.7)

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI change (kg/m2)
Mean (95% CIs)

Weight change (kg)
Mean (95% CIs)</td><td>Intervention group: -3.47
(-4.1--2.8)

Intervention group: -10.38
(-12.5--8.3)</td><td>Control group: -0.63
(-1.3-0.2)

Control group: -1.85
(-3.7-<0.0)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Bocca, 2012

Guideline record ID: 10070

Study characteristics		
Citation	Bocca, G., Corpeleijn, E., Stolk, R. P., & Sauer, P. J. J. (2012). Results of a multidisciplinary treatment program in 3-year-old to 5-year-old overweight or obese children: a randomized controlled clinical trial. Archives of Pediatrics & Adolescent Medicine, 166(12), 1109-1115. https://doi.org/https://dx.doi.org/10.1001/archpediatrics.2012.1638	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Results of a multidisciplinary treatment program in 3-year-old to 5-year-old overweight or obese children: a randomized controlled clinical trial	
Location	Netherlands	
Trial name	Groningen Expert Center for Kids with Obesity (GECKO)	
Methods		
Inclusion criteria	"Overweight or obese children, as defined by the International Obesity Task Force,10 were referred to the Outpatient Clinic by youth health care physicians, general practitioners, or pediatricians."	
Exclusion criteria	"Children with mental retardation, severe behavioral problems, or other criteria interfering with participation were excluded. Also, children who were overweight or obese owing to known medical conditions or eating disorders, according to the Dutch Eating Behavior Questionnaire, were excluded from the study."	
Setting	Hospital, Home	
Intervention	"Children and parents in the multidisciplinary intervention program received dietary advice, physical activity sessions and, for parents only, psychologic counseling. Dietary advice consisted of 6 sessions of 30 minutes each, guided by a dietician. During these sessions, a normocaloric diet was advised based on the required daily intake for this age group. In addition, education and advice to improve eating behavior was given. Parents and children were advised to have breakfast every morning, abstain from soft drinks, and have at most 3 snacks per day. Personal goals regarding the diet were set for parents and children. On consecutive sessions, feedback was given on these goals. The physical activity sessions consisted of 12 group sessions of 60 minutes each and were supervised by a physiotherapist. The exercise program focused on an active lifestyle and mimicked the type and intensity of habitual elementary school exercise (eg, ball playing and dancing to music). Motor skills were taught, and sessions were aimed at having fun during exercise, thereby improving the child's well being. Participants were advised to reduce sedentary activities. Every week, parents were asked to stimulate their child's physical activity to achieve daily physical activity of at least 60 minutes, according to the Dutch Standard of Healthy Activities. Behavioral therapy for parents comprised 6 group sessions of 120 minutes each that were guided by a psychologist. In these sessions, parents learned to be a healthy role model and work with feasible goals and healthy rewards. They also learned how to use sticker charts to motivate the children and keep track of their progress. Parents were taught to change family attitudes toward healthy eating and physical activity, learn practical ways to remove unhealthy food triggers, and know the difference between hunger and cravings. In total, the multidisciplinary intervention program consisted of 25 sessions, together approximately 30 hours in 16 weeks"	
Control/Comparator	"Children and parents in the usual-care group were followed up by a pediatrician, also during a period of 16 weeks. In this period, they were seen 3 times for 30 to 60 minutes each time. Information on healthy eating behavior was provided, and they were advised to perform physical activity for 1 hour per day, according to the Dutch Standard of Healthy	

<table>
<tr><td></td><td>Activities. Furthermore, children were advised to play outside every day, walk or bike to school, and watch television or play with the computer at most 2 hours per day.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 75
Intervention group/s: Multidisciplinary Intervention Group (n=40)

Comparator group: Usual-Care Group (n=35)</td></tr>
<tr><td>Mean age ± SD</td><td>4.7y</td></tr>
<tr><td>Sex</td><td>72.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of population Overweight (%) Proportion (%)</td><td>Multidisciplinary Intervention Group: 35.0%</td><td>Usual-Care Group: 42.9%</td></tr>
<tr><td>Proportion of population Obese (%) Proportion (%)</td><td>Multidisciplinary Intervention Group: 65.0%</td><td>Usual-Care Group: 57.1%</td></tr>
<tr><td>Weight, kg Mean (SD)</td><td>Multidisciplinary Intervention Group: 28.4 (6.3)</td><td>Usual-Care Group: 28.1 (6.8)</td></tr>
<tr><td>Body mass index, kg/m2 Mean (SD)</td><td>Multidisciplinary Intervention Group: 21.2 (2.9)</td><td>Usual-Care Group: 21 (2.7)</td></tr>
<tr><td>Body mass index z score Mean (SD)</td><td>Multidisciplinary Intervention Group: 2.7 (1)</td><td>Usual-Care Group: 2.7 (1)</td></tr>
<tr><td>Waist circumference, cm Mean (SD)</td><td>Multidisciplinary Intervention Group: 64.6 (7.1)</td><td>Usual-Care Group: 65.2 (8)</td></tr>
<tr><td>Waist circumference z score Mean (SD)</td><td>Multidisciplinary Intervention Group: 2.7 (1)</td><td>Usual-Care Group: 2.7 (1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
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<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight, kg Mean (SD)</td><td>Multidisciplinary Intervention Group: 1.9</td><td>Usual-Care Group: 3.1 (2.2)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>12 months or closest time point</td><td><table>
<tr><td></td><td>(2.6)</td><td></td></tr>
<tr><td>Change in weight, kg
Mean (95% CIs)</td><td>Multidisciplinary Intervention Group: 1.9
(1-2.85)</td><td>Usual-Care Group: 3.1
(2.2-4.01)</td></tr>
<tr><td>Change in Body mass index, kg/m
Mean (SD)</td><td>Multidisciplinary Intervention Group: -1
(1.4)</td><td>Usual-Care Group: 0
(1.6)</td></tr>
<tr><td>Change in Body mass index, kg/m
Mean (95% CIs)</td><td>Multidisciplinary Intervention Group: -1
(-1.52--0.47)</td><td>Usual-Care Group: 0
(-0.67-0.62)</td></tr>
<tr><td>Change in Body mass index z score
Mean (SD)</td><td>Multidisciplinary Intervention Group: -0.6
(0.5)</td><td>Usual-Care Group: -0.3
(0.5)</td></tr>
<tr><td>Change in Body mass index z score
Mean (95% CIs)</td><td>Multidisciplinary Intervention Group: -0.6
(-0.82--0.44)</td><td>Usual-Care Group: -0.3
(-0.49--0.05)</td></tr>
<tr><td>Change in Waist circumference, cm
Mean (SD)</td><td>Multidisciplinary Intervention Group: 0.9
(4.6)</td><td>Usual-Care Group: 0.3
(5)</td></tr>
<tr><td>Change in Waist circumference, cm
Mean (95% CIs)</td><td>Multidisciplinary Intervention Group: 0.9
(-0.73-2.59)</td><td>Usual-Care Group: 0.3
(-1.73-2.37)</td></tr>
<tr><td>Change in Waist circumference z score
Mean (SD)</td><td>Multidisciplinary Intervention Group: -0.4
(0.6)</td><td>Usual-Care Group: -0.3
(0.7)</td></tr>
<tr><td>Change in Waist circumference z score
Mean (95% CIs)</td><td>Multidisciplinary Intervention Group: -0.4
(-0.57--0.14)</td><td>Usual-Care Group: -0.3
(-0.61--0.01)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Bogart, 2016

Guideline record ID: 10072--1

Study characteristics		
Citation	Bogart, L. M., Elliott, M. N., Cowgill, B. O., Klein, D. J., Hawes-Dawson, J., Uyeda, K., & Schuster, M. A. (2016). Two-year BMI outcomes from a school-based intervention for nutrition and exercise: a randomized trial. Pediatrics, 137(5), e20152493. https://doi.org/10.1542/peds.2015-2493	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Two-Year BMI Outcomes From a School-Based Intervention for Nutrition and Exercise: A Randomized Trial	
Location	USA	
Trial name	Students for Nutrition and Exercise (SNaX)	
Methods		
Inclusion criteria	"The present study was an RCT that included schools in the Los Angeles Unified School District (LAUSD), a primarily Latino school district in Los Angeles County y in which 15% of seventh-graders (~12-13 years old) and 19% of ninth-graders (~14-15 years old) were estimated to be obese in the 2012-2013 school year, and 22% of seventh-graders and 25% of ninth-graders were estimated to be overweight."	
Exclusion criteria	Not reported	
Setting	School	
Intervention	"SNaX combined school-wide food environmental changes with a seventh-grade peer leader club that incorporated social marketing. The environmental changes included offering a greater variety of sliced/bite-sized food and freely available chilled filtered water at lunch; posters promoting physical activity, cafeteria food, and healthy eating; and nutritional postings about cafeteria food. using role-plays, seventh-grade student peer leaders were taught skills for approaching other students during lunchtime activities, as well as family members at home, to promote SNaX messages (regarding cafeteria food, water, sugar-sweetened beverages, fruits/ vegetables, and physical activity/inactivity) with a motivational interviewing (nonconfrontational and encouraging) style. The social marketing aspect also included taste tests of cafeteria foods, delivered by peer leaders, and a short film shown to the entire seventh-grade class that encouraged physical activity (eg, through a dance video) and healthy eating. Students were encouraged to eat in the cafeteria because the district had reformulated its offerings to be healthier. All seventh-graders were given take-home activities to do with their parents during each week of the program (eg, a worksheet to indicate parents' and adolescents' likes and dislikes for fruits and vegetables, and the types of fruits and vegetables kept at home)."	
Control/Comparator	"Control schools were not offered the SNaX program until ~2 years after the last baseline BMI assessment and 1 year after seventhgraders exposed to SNaX would have graduated from middle school)."	
Treatment duration	Intervention: 5 weeks; Control: 2 years	
Follow-up from baseline	2 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 1368
Intervention group/s: SNaX (n=829)

Comparator group: Control (n=539)</td></tr>
<tr><td>Mean age ± SD</td><td>12.2y (0.68)</td></tr>
<tr><td>Sex</td><td>50.88% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI percentile obese students
Mean (SD)

BMI percentile overweight students
Mean (SD)</td><td>SNaX: 97.92
(1.24)

SNaX: 90.6
(2.94)</td><td>Control: 97.67
(1.3)

Control: 91.22
(2.74)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI percentile obese students
Mean (SD)

BMI percentile overweight students
Mean (SD)</td><td>SNaX: 93.22
(10.85)

SNaX: 84.76
(11.38)</td><td>Control: 95.16
(5.52)

Control: 84.26
(13.94)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Bolinder, 2014

Guideline record ID: 11011--1

Study characteristics		
Citation	Bolinder, J., Ljunggren, Ö., Johansson, L., Wilding, J., Langkilde, A. M., Sjöström, C. D., Sugg, J., & Parikh, S. (2014). Dapagliflozin maintains glycaemic control while reducing weight and body fat mass over 2 years in patients with type 2 diabetes mellitus inadequately controlled on metformin. Diabetes, Obesity & Metabolism, 16(2), 159-169. https://doi.org/https://doi.org/10.1111/dom.12189	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Dapagliflozin maintains glycaemic control while reducing weight and body fat mass over 2 years in patients with type 2 diabetes mellitus inadequately controlled on metformin	
Location	Bulgaria; Czech Republic; Hungary; Poland; Sweden	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were: patients with T2DM; women aged 55-75 years who were postmenopausal for a period of at least 5 years or men aged 30-75 years; haemoglobin A1c (HbA1c) 6.5-8.5%; fasting plasma glucose (FPG) ≤13.2 mmol/l; body mass index (BMI) ≥25 kg/m2; body weight ≤120 kg [due to limitations imposed by dual-energy X-ray absorptiometry (DXA) equipment]; and treatment with metformin at a stable dose of ≥1500 mg/day for ≥12 weeks before enrolment."	
Exclusion criteria	"In order to reliably ascertain the effect of dapagliflozin on changes in BMD it was necessary to recruit patients with a stable rate of BMD change. Thus, in order to avoid the possibility of including women who were perimenopausal, and who would be expected to show an unstable rate of BMD change, women <55 years of age were not recruited for participation. In addition, women had to have been postmenopausal (or to have had an oophorectomy) for at least 5 years prior to consenting to participate."	
Setting	University/research centre	
Intervention	"Dapagliflozin 10 mg/day as add-on therapy to continuing open-label metformin All patients received diet and lifestyle counselling for T2DM, including advice on exercise, according to usual clinical routine, commencing during the lead-in period and continuing throughout the study."	
Control/Comparator	"Placebo as add-on therapy to continuing open-label metformin All patients received diet and lifestyle counselling for T2DM, including advice on exercise, according to usual clinical routine, commencing during the lead-in period and continuing throughout the study."	
Treatment duration	102 weeks	
Follow-up from baseline	102 weeks	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 180 Intervention group/s: Dapagliflozin 10 mg + Metformin (n=89) Comparator group: Placebo + Metformin (n=91)	
Mean age ± SD	Dapagliflozon 10mg + metformin: 60.6y (8.2); Placebo + metformin: 60.8y (6.9)	

<table>
<tr><td>Sex</td><td>44.44% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Body weight (kg) - Baseline
Mean (SD)</td><td>Dapagliflozin 10 mg + Metformin: 92.1
(14.1)</td><td>Placebo + Metformin: 90.9
(13.7)</td></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)</td><td>Dapagliflozin 10 mg + Metformin: 32.1
(3.9)</td><td>Placebo + Metformin: 31.7
(3.9)</td></tr>
<tr><td>Waist circumference (cm) - Baseline
Mean (SD)</td><td>Dapagliflozin 10 mg + Metformin: 105.6
(10.1)</td><td>Placebo + Metformin: 104.5
(12.3)</td></tr>
<tr><td>Body fat mass (kg) - Baseline
Mean</td><td>Dapagliflozin 10 mg + Metformin: 33.7</td><td>Placebo + Metformin: 33.4</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
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</table>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
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<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
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</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in Body weight (kg)
Mean (95% CIs)</td><td>Dapagliflozin 10 mg + Metformin: -4.54
(-5.43- -3.66)</td><td>Placebo + Metformin: -2.12
(-2.97- -1.27)</td></tr>
<tr><td>Change in waist circumference (cm)
Mean (95% CIs)</td><td>Dapagliflozin 10 mg + Metformin: -5.0
(-6.3- -3.6)</td><td>Placebo + Metformin: -2.9
(-6.3- -3.6)</td></tr>
<tr><td>Change in fat mass (kg)
Mean (95% CIs)</td><td>Dapagliflozin 10 mg + Metformin: -2.8
(-3.67- -1.93)</td><td>Placebo + Metformin: -1.46
(-2.25- -0.68)</td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>76.9%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Bonn, 2023

Guideline record ID: 12003--1

Study characteristics		
Citation	Bonn, S. E., Hult, M., Spetz, K., Eke, H., Andersson, E., Wirén, M., Löf, M., & Trolle Lagerros, Y. (2023). Effect of a smartphone application on physical activity and weight loss after bariatric surgery-results from a randomized controlled trial. Obesity Surgery, 33(9), 2841-2850. https://doi.org/https://doi.org/10.1007/s11695-023-06753-6	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a Smartphone Application on Physical Activity and Weight Loss After Bariatric Surgery-Results from a Randomized Controlled Trial	
Location	Sweden	
Trial name	N/A	
Methods		
Inclusion criteria	"All patients fulfilled the indication for surgery (i.e., body mass index (BMI) ≥ 35 kg/m2). Inclusion criteria for the trial were being accepted for gastric bypass or sleeve gastrectomy, age 18-60 years, ability to read and understand Swedish, and access and ability to handle a smartphone."	
Exclusion criteria	"Exclusion criteria were disability preventing daily walking."	
Setting	Home	
Intervention	"Both groups received routine information, including general information on diet and post-operative physical activity, as a part of standard care. They all had pre-operative visits and post-operative visits at 6 weeks and 12 months after surgery. Participants in the intervention group were given access to the smartphone application at their post-operative appointment 6 weeks after surgery. They received a personal login and were asked to use the application during the following 12 weeks. Every Monday, participants were asked to set a weekly physical activity goal of 100, 150, 210, or 250 min of moderate-to-vigorous physical activity (MVPA) per week. The user was encouraged to set a goal corresponding to 30 min of daily MVPA, i.e., 210 min per week. Users were asked to record all physical activities of at least moderate intensity eve ry day. If the performed activity was perceived as vigorous, the user was instructed to double the number of minutes recorded. It was possible to record several bouts of activity during the same day and to add activity to previous days. A daily reminder to record activity was sent to everyone at 8 pm regardless if they already had recorded activity or not. The individual weekly goal and the total minutes recorded each week of the intervention were illustrated by a graph in the smartphone application. On Sundays, users who reached their personal goal and/or had recorded at least 150 min of activity received an encouraging message telling them to keep up the good work during the upcoming week. Those who did not reach their goal received a message with encouragement to try again next week. In addition to the physical activity component of the smartphone application, information regarding the health benefits of physical activity, medications, vitamin supplementation, and diet recommendations after surgery was also included. This information was based on the information given within standard care, but was here also made available within the app. Users received push messages with information and encouraging texts of different lengths connected to this information on a pre-determined schedule. The frequency of information messages was higher in the beginning of the intervention period with multiple messages per week and less frequent towards the end with a message every other week."	
Control/Comparator	"Both groups received routine information, including general information on diet and post-operative physical activity, as a part of standard care. They all had pre-operative visits and post-operative visits at 6 weeks and 12 months after surgery. The control group did not	

<table>
<tr><td></td><td>receive any intervention or additional information on for example benefits of physical activity, medications, or vitamins, other than that routinely included in standard care.”</td></tr>
<tr><td>Treatment duration</td><td>12 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 146
Intervention group/s: Intervention (n=74)

Comparator group: Control (n=72)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 41.2y (10.1); Control: 40.6y (9.5)</td></tr>
<tr><td>Sex</td><td>79.45% female</td></tr>
<tr><td>Pre-existing medical condition</td><td></td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI, kg/m2
Mean (SD)

Mean total weight loss (%)
Mean (SD)</td><td>Intervention: 40.4
(5.6)

Intervention: 15.5
(3.4)</td><td>Control: 40.7
(5.7)

Control: 16.2
(3.5)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI, kg/m2
Mean (SD)

Mean total weight loss (%)
Mean (SD)</td><td>Intervention: 27.6
(4.6)

Intervention: 31.6
(6.2)</td><td>Control: 27
(4.9)

Control: 33.7
(6.4)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Boutelle, 2017

Guideline record ID: 10077A--1

Study characteristics		
Citation	Boutelle, K. N., Rhee, K. E., Liang, J., Braden, A., Douglas, J., Strong, D., Rock, C. L., Wilfley, D. E., Epstein, L. H., & Crow, S. J. (2017). Effect of attendance of the child on body weight, energy intake, and physical activity in childhood obesity treatment: a randomized clinical trial. JAMA Pediatrics, 171(7), 622-628. https://doi.org/https://dx.doi.org/10.1001/jamapediatrics.2017.0651	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Attendance of the Child on Body Weight, Energy Intake, and Physical Activity in Childhood Obesity Treatment: A Randomized Clinical Trial	
Location	USA	
Trial name	Family, Responsibility, Education, Support and Health (FRESH)	
Methods		
Inclusion criteria	"Eligibility included a child between 8.0 and 12.9 years of age with a BMI between the 85th and 99.9th percentiles, a parent in the household with a BMI of at least 25 who could read English at a minimum of a fifth-grade level, and availability to participate in the study on designated evenings."	
Exclusion criteria	"Exclusionary criteria included a major child or parent psychiatric disorder, child diagnosis of a serious current physical dis ease, child with physical limitations, or a family with food restrictions."	
Setting	Hospital, University/research centre	
Intervention	"Parents attended a 1-hour parent group. Children in FBT attended a 1-hour simultaneous child group. Parents and children in FBT also attended 30-minute meetings with a behavioral coach on the same evening"	
Control/Comparator	"Parents attended a 1-hour parent group. Children did not attend sessions. Parents in PBT attended 30-minute meetings with a behavioral coach on the same evening."	
Treatment duration	6 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 300 Intervention group/s: Family based treatment (n=150) Comparator group: Parent based treatment (n=150)	
Mean age ± SD	Children: Intervention: 10.39y (1.27); Control: 10.43y (1.28); Parents: Intervention: 42.59y (6.18); Control: 43.21y (6.65)	
Sex	Not reported	
Pre-existing medical condition	No pre-existing medical condition	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2) - Parents Mean (SD)</td><td>Family based treatment: 31.7 (6.53)</td><td>Parent based treatment: 32.11 (6.11)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2) - Parents Mean (SD)</td><td>Family based treatment: 30.48 (5.94)</td><td>Parent based treatment: 31.77 (6.54)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2) - Parents Mean (SD)</td><td>Family based treatment: 30.9 (6.17)</td><td>Parent based treatment: 32.95 (7.07)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Boutelle, 2017

Guideline record ID: 10077B--1

Study characteristics		
Citation	Boutelle, K. N., Rhee, K. E., Liang, J., Braden, A., Douglas, J., Strong, D., Rock, C. L., Wilfley, D. E., Epstein, L. H., & Crow, S. J. (2017). Effect of attendance of the child on body weight, energy intake, and physical activity in childhood obesity treatment: a randomized clinical trial. JAMA Pediatrics, 171(7), 622-628. https://doi.org/https://dx.doi.org/10.1001/jamapediatrics.2017.0651	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Attendance of the Child on Body Weight, Energy Intake, and Physical Activity in Childhood Obesity Treatment: A Randomized Clinical Trial	
Location	USA	
Trial name	Family, Responsibility, Education, Support and Health (FRESH)	
Methods		
Inclusion criteria	"Eligibility included a child between 8.0 and 12.9 years of age with a BMI between the 85th and 99.9th percentiles, a parent in the household with a BMI of at least 25 who could read English at a minimum of a fifth-grade level, and availability to participate in the study on designated evenings."	
Exclusion criteria	"Exclusionary criteria included a major child or parent psychiatric disorder, child diagnosis of a serious current physical dis ease, child with physical limitations, or a family with food restrictions."	
Setting	Hospital, University/research centre	
Intervention	"Parents attended a 1-hour parent group. Children in FBT attended a 1-hour simultaneous child group. Parents and children in FBT also attended 30-minute meetings with a behavioral coach on the same evening"	
Control/Comparator	"Parents attended a 1-hour parent group. Children did not attend sessions. Parents in PBT attended 30-minute meetings with a behavioral coach on the same evening."	
Treatment duration	6 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 150 Intervention group/s: Family based treatment (n=75) Comparator group: Parent based treatment (n=175)	
Mean age ± SD	Children: Intervention: 10.39y (1.27); Control: 10.43y (1.28); Parents: Intervention: 42.59y (6.18); Control: 43.21y (6.65)	
Sex	Not reported	
Pre-existing medical condition	No pre-existing medical condition	

<table>
<tr><td>Results</td><td colspan="3"></td></tr>
<tr><td>Outcome measure at baseline</td><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td>BMIz (kg/m2) -Children Mean (SD)

BMI (kg/m2) - Children Mean (SD)

BMI % at baseline - Children Mean (SD)</td><td>Family based treatment: 1.98 (0.32)

Family based treatment: 26.13 (3.74)

Family based treatment: 97.02 (2.4)</td><td>Parent based treatment: 2.02 (0.36)

Parent based treatment: 26.56 (3.52)

Parent based treatment: 97.11 (2.6)</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td>BMIz (kg/m2) -Children Mean (SD)</td><td>Family based treatment: 1.77 (0.44)</td><td>Parent based treatment: 1.82 (0.49)</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td>BMIz (kg/m2) -Children Mean (SD)</td><td>Family based treatment: 1.82 (0.4)</td><td>Parent based treatment: 1.81 (0.52)</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>Compliance with treatment</td><td colspan="3">Not reported</td></tr>
<tr><td>Notes</td><td colspan="3"></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td colspan="3"></td></tr>
</table>

N/A – Not applicable

Boutelle, 2022

Guideline record ID: 10076--1

Study characteristics		
Citation	Boutelle, K. N., Eichen, D. M., Peterson, C. B., Strong, D. R., Kang-Sim, D.-J. E., Rock, C. L., & Marcus, B. H. (2022). Effect of a novel intervention targeting appetitive traits on body mass index among adults with overweight or obesity: a randomized clinical trial. JAMA Network Open, 5(5), e2212354. https://doi.org/10.1001/jamanetworkopen.2022.12354	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a Novel Intervention Targeting Appetitive Traits on Body Mass Index Among Adults With Overweight or Obesity: A Randomized Clinical Trial	
Location	US	
Trial name	Providing Adult Collaborative Interventions for Ideal Changes (PACIFIC)	
Methods		
Inclusion criteria	"Adults of any sex and race or ethnicity were eligible if they (1) had a body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) of 25 to 45, (2) were aged 18 to 65 years, and (3) did not meet any other exclusion criteria (eg, type 2 diabetes, recent stroke or angina, pregnancy, inability to speak or read English, or plan to relocate)."	
Exclusion criteria	Not reported	
Setting	University/research centre	
Intervention	"26x 90-minute group treatments over 12 months. Regulation of Cues (ROC): 4 components: psychoeducation to increase awareness of situations, thoughts, moods, and environments that lead to overeating; experiential learning; coping skills; and self-monitoring. P Behavioral Weight Loss (BWL): recommended a balanced deficit diet based on the US Department of Agriculture's MyPlate guidelines. Individualized energy intake goals were based on body weight by multiplying the participant's weight in pounds by 12 to determine an estimate of maintenance energy intake and subtracting 500 and 1000 kcal per day to promote a weight loss of 1 to 2 pounds per week. Behavior change recommendations included stimulus control, self-monitoring, goal setting, managing high-risk situations, meal planning, slowing eating, problem solving, social support, cognitive restructuring relapse prevention skills, and skills for maintaining weight loss. Participants were instructed to self-monitor their food intake, calories, physical activity, and step counts either on paper or using an app. Combined Program (ROC+): integrated the focus on diet and energy intake from BWL with the ROC program. Participants learned all of the ROC model components, including psychoeducation, the management of SR and FR, and participated in experiential learning, as well as a focus on decreasing energy intake and behavioral skills from BWL. Participants in this group were taught to self-monitor hunger,cravings, food intake, caloric intake, physical activity, and step counts either on paper or in an app."	
Control/Comparator	"The AC program included psychoeducation on diet, stress management, and social support. Participants were provided information about dietary intake and reading food labels. Participants learned about how stress leads to weight gain, as well as mindfulness-based stress reduction, sleep hygiene, and time management. Participants were provided with assertiveness training along with conflict management skills and were encouraged to build positive support networks. At each session, a mindfulness exercise was conducted, and participants were encouraged to practice mindfulness at home. Participants were not instructed to self-monitor."	
Treatment duration	12 months	

<table>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 271
Intervention group/s: Regulation of cues (n=69); Behavioral weight loss (n=69); Regulation of cues+ (n=67)

Comparator group: Active comparator (n=66)</td></tr>
<tr><td>Mean age ± SD</td><td>46.97y (11.80)</td></tr>
<tr><td>Sex</td><td>81.55% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body mass index (kg/m2) at Baseline
Mean (SD)</td><td>Regulation of cues: 35.2 (5.6)
Behavioral weight loss: 35.4 (5.2)
Regulation of cues+: 34.2 (5.6)</td><td>Active comparator: 34.4 (4.8)</td></tr>
<tr><td>Weight (kg) at baseline
Mean (SD)</td><td>Regulation of cues: 97.1 (18.3)
Behavioral weight loss: 97.9 (19.9)
Regulation of cues+: 93.8 (17.7)</td><td>Active comparator: 95.1 (16.1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in BMI
Mean (SD)</td><td>Regulation of cues: -1.29 (2.11)
Behavioral weight loss: -2.55 (2.53)
Regulation of cues+: -2.03 (2.42)</td><td>Active comparator: -0.32 (2.06)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in body fat (%)
Mean (95% CIs)</td><td>Regulation of cues: -45.48 (43.2-47.5)
Behavioral weight loss: -43.79 (41.9-45.8)
Regulation of cues+: -43.36 (41.6-45.3)</td><td>Active comparator: -45.37 (43.1-47.6)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Bowen, 2018

Guideline record ID: 10078--1

Study characteristics		
Citation	Bowen, D. J., Quintiliani, L. M., Bhosrekar, S. G., Goodman, R., & Smith, E. (2018). Changing the housing environment to reduce obesity in public housing residents: a cluster randomized trial. BMC Public Health, 18, 883. https://doi.org/10.1186/s12889-018-5777-y	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Changing the housing environment to reduce obesity in public housing residents: a cluster randomized trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"24 family developments that had 200 or more residents, that were not planning to undergo renovations that would require residents to move, were eligible to participate. Inclusion criteria were: be female; be aged 18-72; live in one of the recruited PHDs and not planning to move for at least 2 years; have responsibility for a girl age 8-15 (also living in the public housing residence), be English or Spanish speaking, and report being willing to make changes to their diet and physical activity habits if desired."	
Exclusion criteria	"Exclusion criteria were: the adult female resident was not able to complete the survey tools or was not interested in participating."	
Setting	Home, public housing developments	
Intervention	"The year-long intervention included components to change the dietary and physical activity-related environments of the developments"	
Control/Comparator	"did not receive intervention."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 211 Intervention group/s: Intervention (n=116) Comparator group: Control (n=95)	
Mean age ± SD	38.1y (7.6)	
Sex	100.00% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	BMI (kg/m2) Mean (SD)	Intervention: 30.6 (7.7)	Control: 31.8 (7.7)

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intervention: 29.1
(10.2)</td><td>Control: 32
(7.8)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Boyraz, 2015

Guideline record ID: 10079--1

Study characteristics		
Citation	Boyraz, M., Pirgon, Ö., Dündar, B., Çekmez, F., & Hatipoğlu, N. (2015). Long-term treatment with n-3 polyunsaturated fatty acids as a monotherapy in children with nonalcoholic fatty liver disease. Journal of Clinical Research in Pediatric Endocrinology, 7(2), 121-127. https://doi.org/https://dx.doi.org/10.4274/jcrpe.1749	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-Term Treatment with n-3 Polyunsaturated Fatty Acids as a Monotherapy in Children with Nonalcoholic Fatty Liver Disease	
Location	Turkey	
Trial name	N/A	
Methods		
Inclusion criteria	"Obese when the calculated body mass index (BMI) was above the 95th percentile for age and sex (according to the charts developed by the National Center for Health Statistics and the National Center for Chronic Disease Prevention and Health Promotion, US, 2000). persistently elevated serum aminotransferase levels, diffusely echogenic liver in imaging studies suggestive of fatty liver, exclusion of hepatic virus infections, no alcohol consumption, no history of parenteral nutrition and no use of drugs known to induce steatosis (e.g. valproate, amiodarone or prednisone)."	
Exclusion criteria	"Other liver conditions (hepatitis B surface antigen, hepatitis C antibody, prothrombin time, iron, total iron-binding capacity, ferritin and antinuclear antibodies)."	
Setting	Hospital, Home	
Intervention	"Group 1 (PUFA group) included 56 obese children who received an adequate diet plus a 1000 mg dose of PUFA (MarincapR Special 1000 mg; Kocak-Farma Company) once daily for 12 months and also lifestyle intervention. The recommended diet was composed of 50% carbohydrates, 20% protein and 30% fat, in accordance with the American Heart Association diet. All obese patients were advised to lose weight with a restriction of daily caloric intake to 25-30 kcal/kg per day (23). The lifestyle intervention programme consisted of scheduled exercise (three times per week for 1 hour) and the promotion of self-initiated physical activities."	
Control/Comparator	"Group 2 (placebo) included 52 obese children, who received a diet plus placebo and lifestyle intervention. The recommended diet was composed of 50% carbohydrates, 20% protein and 30% fat, in accordance with the American Heart Association diet. All obese patients were advised to lose weight with a restriction of daily caloric intake to 25-30 kcal/kg per day (23). The lifestyle intervention programme consisted of scheduled exercise (three times per week for 1 hour) and the promotion of self-initiated physical activities."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 108 Intervention group/s: PUFA (n=56) Comparator group: Placebo (n=52)	

<table>
<tr><td>Mean age ± SD</td><td>13.7y (3.6)</td></tr>
<tr><td>Sex</td><td>49.07% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Nonalcoholic fatty liver disease (NAFLD)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

BMIz
Mean (SD)</td><td>PUFA: 90.6
(16.4)

PUFA: 29.7
(4.8)

PUFA: 2.7
(0.5)</td><td>Placebo: 96.6
(11.3)

Placebo: 27.2
(3.3)

Placebo: 2.8
(0.4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

BMIz
Mean (SD)</td><td>PUFA: 75.6
(22.5)

PUFA: 23.7
(3.5)

PUFA: 2.3
(0.2)</td><td>Placebo: 80.2
(9.3)

Placebo: 23.6
(2.56)

Placebo: 2.2
(0.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Bräutigam-Ewe, 2020

Guideline record ID: 10080--1

Study characteristics		
Citation	Bräutigam-Ewe, M., Lydell, M., Bergh, H., Hildingh, C., Baigi, A., & Månsson, J. (2020). Two-year weight, risk and health factor outcomes of a weight-reduction intervention programme: primary prevention for overweight in a multicentre primary healthcare setting. Scandinavian Journal of Primary Health Care, 38(2), 192-200. https://doi.org/10.1080/02813432.2020.1753379	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Two-year weight, risk and health factor outcomes of a weight-reduction intervention programme: Primary prevention for overweight in a multicentre primary healthcare setting	
Location	Sweden	
Trial name	N/A	
Methods		
Inclusion criteria	“40 and 65 years of age with a body mass index (BMI) of 28-35.”	
Exclusion criteria	“Undergoing treatment that could be affected by participating in the study, if they had known drug addictions or if they could not under stand or produce Swedish in speech or writing.”	
Setting	GP clinic, Home	
Intervention	“The high-intensity programme included motivational interviewing (MI), a grocery store lecture, website communication and weekly e-mails.The participants participated in MI conversations three times about lifestyle habits (diet, physical activity, sleep, stress, alcohol, support, tobacco and mental health), and advice was provided in a dialogue with the patient and included verbal and written indi vidualised lifestyle recommendations from the nurse. The plate model for weight loss was recommended,w ith a diet composed of approximately 50% vegeta bles, 25% protein, mostly chicken and fish, and 25% carbohydrates. The focus was not only on the diet but also on how to eat. The participants received DAP Advice (three postcards with the messages 1. 'Eat only at the dinner table'; 2. 'Place your knife and fork on the plate after every mouthful of food'; and 3. 'Try to regularly eat breakfast, lunch and dinner')”	
Control/Comparator	“dietary advice from the nurse reflecting care as usual.”	
Treatment duration	2 years	
Follow-up from baseline	2 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 286 Intervention group/s: High-intensity group (n=113) Comparator group: Low-intensity group (n=173)	
Mean age ± SD	55.7y (7.1)	
Sex	80.77% female	

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist Circumference (cm)
Mean (SD)</td><td>High-intensity group: 89.5 (11.3)

High-intensity group: 31.6 (2.1)

High-intensity group: 105.5 (7.8)</td><td>Low-intensity group: 88.9 (12.3)

Low-intensity group: 31.2 (1.9)

Low-intensity group: 104 (9.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist Circumference (cm)
Mean (SD)</td><td>High-intensity group: 88.4 (11.5)

High-intensity group: 31.2 (2.4)

High-intensity group: 103.3 (12.2)</td><td>Low-intensity group: 88 (12.3)

Low-intensity group: 31 (2.7)

Low-intensity group: 104 (9.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Brown, 2020

Guideline record ID: 10082--1

Study characteristics		
Citation	Brown, A., Dornhorst, A., McGowan, B., Omar, O., Leeds, A. R., Taheri, S., & Frost, G. S. (2020). Low-energy total diet replacement intervention in patients with type 2 diabetes mellitus and obesity treated with insulin: a randomized trial. BMJ Open Diabetes Research & Care, 8(1), e001012. https://doi.org/https://dx.doi.org/10.1136/bmjdrc-2019-001012	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Low-energy total diet replacement intervention in patients with type 2 diabetes mellitus and obesity treated with insulin: a randomized trial	
Location	England (UK)	
Trial name	N/A	
Methods		
Inclusion criteria	"Type 2 diabetes and obesity treated with IT were identified and recruited from UK primary and secondary care. Participants had type 2 diabetes, were treated with insulin, had a body mass index (BMI) of ≥30kg/m2, were aged 18-70 years and provided written informed consent."	
Exclusion criteria	"Type 1 diabetes mellitus (based on clinical classification), insulin therapy for more than 10 years with a fasting circulating C-peptide of less than 600pmol, significant diabetes microvascular complications, a cardiovascular event within 6 months, left bundle branch block confirmed by electrocardiographic (ECG), estimated glomerular filtration rate (eGFR) of less than 30 mL/min/1.73m2, a condition precipitating fluid overload (e.g. New York Heart Association class III-IV congestive heart failure), mental incapacity, unwillingness and/or inability to understand and be able to complete the mental health questionnaires. Other exclusions included uncontrolled psychiatric disorder, uncontrolled depression, clinically diagnosed binge eating disorder, known or suspected substance use, concomitant medication use clinically deemed to affect metabolic rate and weight, participation in a weight management drug trial in the previous 3 months, pregnancy, lactating or planning pregnancy within study period, uncontrolled International Normalising Ratio (INR), uncontrolled epilepsy, lactose intolerance, severe musculoskeletal condition preventing walking, gout, active gallstones or known asymptomatic gallstones and clinically assessed hypoglycaemia unawareness. Glucagon-like peptide-1 (GLP-1) receptor agonists and sodium-dependent glucose co-transporters 2 (SGLT-2) inhibitors were ceased at the start of the study."	
Setting	Hospital	
Intervention	"At randomization, participants commenced a 12-week TDR formula LED (Cambridge Weight Plan, Northants, UK) followed by 12 weeks of structured food reintroduction and then ongoing follow-up in combination with an energy deficit diet at 3-month intervals until 12 months. For the first 12weeks, all meals were replaced with four formula LED products per day (800-820 kcal/day, 57% carbohydrate, 14% fat, 26% protein and 3% fiber) in addition to at least 2.25 liters of energy-free beverages. A fiber supplement was recommended, if required, to avoid constipation, a common side effect of using a TDR. Both groups were seen by the same specialist dietician after 1week and then monthly for the first 6 months (eight face-to-face sessions of 30-60min), in addition to seven telephone consultations of 15-20min in between. The maintenance phase matched standard type 2 diabetes healthcare provision with two face-to-face sessions from 6 to 12 months. Participants received behavioral support to aid lifestyle adherence and maintenance19 20 and were encouraged to undertake moderate exercise, as per guidelines, of at least 30minutes, 5days per week including both aerobic and resistance exercise.17 QoL was measured using EuroQol-5 Dimension. Participants in both groups received concomitant	

	standard diabetes care based on UK national guidelines.21 Insulin was titrated by algorithm to ensure glycemic control and safety. At randomization, insulin dose was reduced by 50% in the intervention group"
Control/Comparator	"Participants followed a standardized weight management program using a 600 kcal deficit diet for 12 months, aiming for weight loss of 0.5-1.0kg/week, based on current national guidelines.17 This was based on total energy expenditure estimated from their basal metabolic rate using the Mifflin St-Jeor equation18 and physical activity levels (online supplementary figure S1). Both groups were seen by the same specialist dietician after 1week and then monthly for the first 6 months (eight face-to-face sessions of 30-60min), in addition to seven telephone consultations of 15-20min in between. The maintenance phase matched standard type 2 diabetes healthcare provision with two face-to-face sessions from 6 to 12 months. Participants received behavioral support to aid lifestyle adherence and maintenance19 20 and were encouraged to undertake moderate exercise, as per guidelines, of at least 30minutes, 5days per week including both aerobic and resistance exercise.17 QoL was measured using EuroQol-5 Dimension. Participants in both groups received concomitant standard diabetes care based on UK national guidelines.21Insulin was titrated by algorithm to ensure glycemic control and safety. At randomization, insulin dose was reduced by 30% in the control group."
Treatment duration	12 months
Follow-up from baseline	12 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 90 Intervention group/s: Intervention (low-energy total diet replacement) (n=45) Comparator group: Control (standardized dietetic care) (n=45)
Mean age ± SD	Not reported
Sex	56.67% female
Pre-existing medical condition	Type 2 diabetes
Results	

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Weight (kg) Mean (SD)	Intervention (low-energy total diet replacement): 104 (20.2)	Control (standardized dietetic care): 103.1 (18.9)
BMI (kg/m2) Mean (SD)	Intervention (low-energy total diet replacement): 36.6 (5.1)	Control (standardized dietetic care): 36.8 (5.3)
Waist circumference (cm) Mean (SD)	Intervention (low-energy total diet replacement): 120.3 (12.7)	Control (standardized dietetic care): 121.5 (12.4)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator
Weight (kg) Mean (SD)	Intervention (low-energy total diet replacement): 89.3 (12.9)	Control (standardized dietetic care): 99.4 (22.8)
BMI (kg/m2)		

	Mean (SD) Waist circumference (cm) Mean (SD)	Intervention (low-energy total diet replacement): 32 (3.8) Intervention (low-energy total diet replacement): 107.5 (8.8)	Control (standardized dietetic care): 35.5 (6.8) Control (standardized dietetic care): 119.1 (15.2)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in weight (kg) Mean (SD) Change in weight (%) Mean (SD) Change in waist circumference (cm) Mean (SD)	Intervention (low-energy total diet replacement): -9.8 (4.1) Intervention (low-energy total diet replacement): -9.7 (4.8) Intervention (low-energy total diet replacement): -9.9 (1.1)	Control (standardized dietetic care): -5.6 (6.1) Control (standardized dietetic care): -5.8 (6.5) Control (standardized dietetic care): -4.6 (1.2)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Brown, 2021

Guideline record ID: 10083--1

Study characteristics		
Citation	Brown, J. C., Sarwer, D. B., Troxel, A. B., Sturgeon, K., DeMichele, A. M., Denlinger, C. S., & Schmitz, K. H. (2021). A randomized trial of exercise and diet on body composition in survivors of breast cancer with overweight or obesity. Breast Cancer Research and Treatment, 189(1), 145-154. https://doi.org/https://dx.doi.org/10.1007/s10549-021-06284-7	
Design & type	Randomised controlled trial (RCT)	Factorial design
Title	A randomized trial of exercise and diet on body composition in survivors of breast cancer with overweight or obesity	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligible participants had stage I-III breast cancer; completed surgery, chemotherapy, radiotherapy, and targeted ther apy≥6 months before study enrollment (concurrent endo crine therapy was allowed); had a body mass index (BMI) of 25-50 kg/m2; had breast cancer related lymphedema, defned using the Common Terminology Criteria for Adverse Events (CTCAE; version 4), or a prior clinical diagnosis of lymphedema; and were aged 18-80 years. In addition, eli gible participants had no evidence of residual or recurrent cancer; no medical conditions that would preclude participa tion in an exercise or diet program; were not engaging in any resistance exercise or≥3 bouts of aerobic exercise of mod erate intensity (e.g., brisk walking) weekly over the prior 52 weeks; were not using any medications for the purpose of weight loss; had no weight loss≥4.5 kg in the previous 12 weeks; and had no history of bariatric or metabolic surgery."	
Exclusion criteria	Not reported	
Setting	Hospital, Home	
Intervention	"Participants assigned to the exercise group performed a combination of in-person and home-based exercise. Exercise included resistance and aerobic activity. In-person exercise, supervised by an exercise oncology professional, occurred weekly in the frst six weeks of the study, and once per month thereafter in groups of 2-6 participants. Participants performed resistance exercise using adjustable dumbbell weights. The resistance program included nine exercises that were performed twice weekly for 2-3 sets using a weight that permitted 10 repetitions with proper form and didn't exacerbate lymphedema symptoms. Moderate-intensity aerobic exercise was prescribed to a goal of 180 min weekly distributed over 3-6 days per week (e.g., 30 min on most days of the week). Participants assigned to the diet group attended 24 weekly sessions of lifestyle modifcation instruction led by a registered dietitian in groups of 2-12 participants. The goal of the diet was a 10% loss of body weight. Weekly counseling sessions included a weigh-in, review of the week, and behavioral modifcation lesson (e.g., self-monitoring, goal setting, stimulus control). During the frst 20 weeks, participants followed a meal replacement program that also included seven daily servings of fruits and vegetables. During weeks 21-24, the focus shifted to applying the behavioral modifcation techniques to food shopping and preparation. During weeks 24-52, the groups met in-person monthly for additional behavioral modifcation lessons (e.g., problem-solving, relapse prevention). Participants assigned to the exercise plus diet group started with six weeks of exercise instruction. At week seven, they began receiving the diet intervention in addition to the exercise intervention. Thereafter, participants received the exercise and diet interventions simultaneously."	

<table>
<tr><td>Control/Comparator</td><td>“Participants assigned to the control group were instructed to refer to their physician regarding what types of exercise or diet would be safe and efective. No other guidance regarding exercise or diet was provided.”</td></tr>
<tr><td>Treatment duration</td><td>52 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 351
Intervention group/s: Exercise (n=87); Diet (n=87); Exercise & Diet (n=87)

Comparator group: Control (n=90)</td></tr>
<tr><td>Mean age ± SD</td><td>59.4y (8.7)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Breast cancer</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg) - baseline
Mean (SD)</td><td>Exercise: 89.7
(16.2)
Diet: 89.9
(16.5)
Exercise & Diet: 91.2
(16.3)</td><td>Control: 89.3
(16.9)</td></tr>
<tr><td>Fat Mass (kg) at baseline
Mean (SD)</td><td>Exercise: 40.3
(10.9)
Diet: 40.6
(10.3)
Exercise & Diet: 41.7
(10.2)</td><td>Control: 40.9
(10.7)</td></tr>
<tr><td>Visceral adipose tissue (cm2) at baseline
Mean (SD)</td><td>Exercise: 164.8
(75.5)
Diet: 158.2
(62.2)
Exercise & Diet: 155
(69.6)</td><td>Control: 158.6
(57.2)</td></tr>
<tr><td>Subcutaneous adipose tissue (cm2) at baseline
Mean (SD)</td><td>Exercise: 491.9
(133.2)
Diet: 507.2
(125.9)
Exercise & Diet: 502.7
(136.1)</td><td>Control: 515.2
(128)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in Body weight at 12 months
Mean (SE)</td><td>Exercise: -0.33
(0.66)
Diet: -5.66
(0.69)
Exercise & Diet: -6.95
(0.67)</td><td>Control: -0.27
(0.63)</td></tr>
<tr><td>Change in Fat mass (kg)
Mean (SE)</td><td>Exercise: -0.79
(0.52)
Diet: -4.52
(0.52)
Exercise & Diet: -5.22
(0.53)</td><td>Control: -0.94
(0.51)</td></tr>
<tr><td>Change in Visceral adipose tissue, cm2
Mean (SE)</td><td>Exercise: -12.09
(3.9)
Diet: -27.87
(3.68)
Exercise & Diet: -26.46
(3.67)</td><td>Control: -6.59
(3.63)</td></tr>
<tr><td>Change in Subcutaneous adipose tissue (cm2)
Mean (SE)</td><td>Exercise: 2.64
(7.16)
Diet: -44.59
(7.4)
Exercise & Diet: -50.24
(7.46)</td><td>Control: -5.05
(7.17)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Burke, 2015

Guideline record ID: 10085--1

Study characteristics		
Citation	Burke, L. E., Ewing, L. J., Ye, L., Styn, M., Zheng, Y., Music, E., Loar, I., Mancino, J., Imes, C. C., Hu, L., Goode, R., & Sereika, S. M. (2015). The SELF trial: a self-efficacy-based behavioral intervention trial for weight loss maintenance. Obesity, 23(11), 2175-2182. https://doi.org/10.1002/oby.21238	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The SELF trial: A self-efficacy-based behavioral intervention trial for weight loss maintenance	
Location	USA	
Trial name	Self-Efficacy Lifestyle Focus (SELF)	
Methods		
Inclusion criteria	"BMI >27 to <43, Presence of an additional risk factor for coronary heart disease, e.g., dyslipidemia, positive family history (first-degree relative, Age 18 years or older, Successful completion of screening requiring 5-day recording of food intake in the paper diary, Willing to be randomized to one of the two treatment conditions."	
Exclusion criteria	"Physical limitations precluding ability to exercise, Participation in a weight loss program within the past 5 years or cur rent use of weight loss medication, presence of an eating disorder, Current serious illness or unstable condition requiring physician supervised diet and exercise including a glucose level above 125 at baseline, Planning an extended vacation, absence, or relocation within the next 18 months, Pregnant or planning to become pregnant in the next 18 months, Current treatment for a psychological disorder, Reported alcohol intake >4 drinks/day."	
Setting	University/research centre	
Intervention	"The calorie goal was based on weight and gender (women: 1,200 kcal for <200 lbs. or 1,500 kcal for >200 lbs.; men: 1,500 kcal for <200 lbs. or 1,800 kcal for >200 lbs.) Participants were asked to limit their fat intake to 25% of their total calories and to self monitor their calorie and fat intake. The home-based physical activ ity goal advanced from 150 min/week at 12 weeks to 180 min/week at 6 months, then 210 min/week at 12 months. Participants also were asked to record minutes of physical activity and number of daily steps using the pedometer provided. All participants attended group sessions weekly the first month, biweekly the second month, monthly for next 10 months, and every6 weeks for months 13-18. Group sessions covered nutrition and reinforced principles of behavior change (goal setting, self-monitoring, feedback). Participants in the SBT-SE received 30 self-efficacy (SE) enhancing, one-on-one sessions. Participants in the SBT-SE group met with their interventionist prior to the first group session to collaboratively develop their calorie and activity goals with a target date for goal achievement. During the first 12 months, one-on-one meetings were held every 2 weeks to review progress and establish new diet and activity goals; thereafter, sessions were held at least monthly. Sources of self-efficacy were incorporated through collaborative goal-setting of specific, proximal and attainable goals; cognitive behavioral and problem solving strategies were offered to increase the participant's confidence in attaining the newly established goal; vicarious experience occurred by using credible models to demonstrate behavior change (e.g., Leslie SansoneTM exercise tapes) and physiological cues (e.g., less fatigue with physical exertion) were highlighted as evidence that supported behavior changes were occurring."	
Control/Comparator	"The calorie goal was based on weight and gender (women: 1,200 kcal for <200 lbs. or 1,500 kcal for >200 lbs.; men: 1,500 kcal for <200 lbs. or 1,800 kcal for >200 lbs.)	

<table>
<tr><td></td><td>Participants were asked to limit their fat intake to 25% of their total calories and to self monitor their calorie and fat intake. The home-based physical activ ity goal advanced from 150 min/week at 12 weeks to 180 min/week at 6 months, then 210 min/week at 12 months. Participants also were asked to record minutes of physical activity and number of daily steps using the pedometer provided. All participants attended group sessions weekly the first month, biweekly the second month, monthly for next 10 months, and every6 weeks for months 13-18. Group sessions covered nutrition and reinforced principles of behavior change (goal setting, self-monitoring, feedback).”</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td>Participant characteristics</td><td></td></tr>
<tr><td>Number of participants</td><td>n= 130
Intervention group/s: SBT+SE (n=58)

Comparator group: SBT (n=72)</td></tr>
<tr><td>Mean age ± SD</td><td>53.02y (9.57)</td></tr>
<tr><td>Sex</td><td>83.08% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td>Results</td><td></td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>SBT+SE: 90.82
(13.27)</td><td>SBT: 91.32
(13.65)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>SBT+SE: 83.63
(15.89)</td><td>SBT: 82.79
(13.26)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>SBT+SE: 83.71
(16.24)</td><td>SBT: 84.05
(13.9)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% Weight change over time
Mean (SD)</td><td>SBT+SE: -8.4%
(7.48)</td><td>SBT: -6.95%
(-6.67)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% weight change over time
Mean (SD)</td><td>SBT+SE: -8.0%
(7.9%)</td><td>SBT: -5.96
(7.35)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>SBT group attended 68.75% of the 20 group sessions while the SBT1SE group attended 60.00% of the group sessions and 65.11% of the 30 one-on-one sessions.</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Burke, 2022

Guideline record ID: 10086--1

Study characteristics		
Citation	Burke, L. E., Sereika, S. M., Bizhanova, Z., Parmanto, B., Kariuki, J., Cheng, J., Beatrice, B., Cedillo, M., Pulantara, I. W., Wang, Y., Loar, I., & Conroy, M. B. (2022). The effect of tailored, daily, smartphone feedback to lifestyle self-monitoring on weight loss at 12 months: the SMARTER randomized clinical trial. Journal of Medical Internet Research, 24(7), e38243. https://doi.org/10.2196/38243	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Effect of Tailored, Daily, Smartphone Feedback to Lifestyle Self-Monitoring on Weight Loss at 12 Months: the SMARTER Randomized Clinical Trial	
Location	US	
Trial name	SMARTER	
Methods		
Inclusion criteria	"Inclusion criteria were BMI between 27 and 43 kg/m2, completion of a 5-day electronic food diary, and ability to engage in moderate PA."	
Exclusion criteria	"Exclusion criteria were needing supervision of diet or PA, pregnancy, serious mental illness (eg, schizophrenia), alcohol abuse or eating disorder, and current weight loss treatment."	
Setting	Home, University/research centre	
Intervention	"At baseline, all participants had a 90-minute, one-on-one, in-person intervention session with a dietitian on the core concepts of SBT followed by a demonstration of the Fitbit app to enter foods eaten for SM of diet, a Fitbit activity tracker to monitor PA, and a smart scale for daily self-weighing. Use of the investigator-developed SMARTER app, which was used only for random retrieval of FB messages from the message library and delivery of messages to the participant's smartphone, was demonstrated to the SM+FB participants, so they could view the prompt icon for the FB messages and open the app to read the message. Participants used the Fitbit app to view food nutrient values, app-generated subtotals, and the daily intake summaries. The calorie goal was determined from baseline body weight (women: 1200 kcal for <200 lb or 1500 kcal ≥200 lb; men: 1500 kcal for <200 lb or 1800 kcal for ≥200 lb) and individualized as needed [23]. Fat gram goals approximated 25% of the calorie goal (eg, 33 or 42 grams per day for females). All participants monitored PA using a wrist-worn activity tracker, the Fitbit Charge 2, synced with their smartphone. Staff instructed participants to increase their PA gradually, primarily by walking, and to aim for 150 minutes per week by 12 weeks [38]. Once at goal, they were encouraged to add 10 minutes per week until they reached 300 minutes per week [23]. All aerobic activities counted toward PA goals. The Fitbit database stored total steps, sedentary minutes, and active minutes. The FB algorithm was programmed on the study's server and used real-time synced SM data to send the FB message up to 3 times per day. Individuals in the SM+FB group received up to 3 FB messages per day on their smartphone during waking hours tailored to the most recent SM data and addressing caloric as well as fat and added-sugar intake daily and PA every other day. Weekly weight FB was based on whether self-weighing occurred and the amount or rate of weight change. FB messages addressed 1 behavior at a time. The participant received a prompt that there was a new FB message on the smartphone. If the FB message was not opened within 1 hour of being sent, the SMARTER icon prompt and message disappeared; if the message was opened, the participant could save it for future review. More details on the FB messages and study infrastructure for message delivery are available elsewhere [23,37]. Engagement with SM tools was a crucial component of the intervention, as the algorithm used the SM data to determine an appropriate FB message. If the participant did not SM, FB messages were sent encouraging SM. After 2 weeks of missing SM data, staff sent an email query about	

<table>
<tr><td></td><td>technical issues and encouraged SM. Additional details on the algorithm and FB messages are published elsewhere [23]. The message library was changed at least monthly to avoid participant desensitization to FB [29].”</td></tr>
<tr><td>Control/Comparator</td><td>“At baseline, all participants had a 90-minute, one-on-one, in-person intervention session with a dietitian on the core concepts of SBT followed by a demonstration of the Fitbit app to enter foods eaten for SM of diet, a Fitbit activity tracker to monitor PA, and a smart scale for daily self-weighing. Participants used the Fitbit app to view food nutrient values, app-generated subtotals, and the daily intake summaries. The calorie goal was determined from baseline body weight (women: 1200 kcal for <200 lb or 1500 kcal ≥200 lb; men: 1500 kcal for <200 lb or 1800 kcal for ≥200 lb) and individualized as needed [23]. Fat gram goals approximated 25% of the calorie goal (eg, 33 or 42 grams per day for females). All participants monitored PA using a wrist-worn activity tracker, the Fitbit Charge 2, synced with their smartphone. Staff instructed participants to increase their PA gradually, primarily by walking, and to aim for 150 minutes per week by 12 weeks [38]. Once at goal, they were encouraged to add 10 minutes per week until they reached 300 minutes per week [23]. All aerobic activities counted toward PA goals. The Fitbit database stored total steps, sedentary minutes, and active minutes. Individuals in the SM group did not receive FB messages or staff emails.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 502
Intervention group/s: SM-FB (n=251)

Comparator group: SM (n=251)</td></tr>
<tr><td>Mean age ± SD</td><td>45.0y (14.4)</td></tr>
<tr><td>Sex</td><td>79.48% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Mean (SD)

Change in weight (%)
Mean (95% CIs)</td><td>SM-FB: -1.98
(0.38)

SM-FB: -2.12
(-3.04--1.21)</td><td>SM: -2.39
(0.38)

SM: -2.39
(-3.34--1.47)</td></tr></table></td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	<table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table>
Compliance with treatment	SM+FB: 80.5%; SM: 76.5%
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Butryn, 2017

Guideline record ID: 10088--1

Study characteristics		
Citation	Butryn, M. L., Forman, E. M., Lowe, M. R., Gorin, A. A., Zhang, F., & Schaumberg, K. (2017). Efficacy of environmental and acceptance-based enhancements to behavioral weight loss treatment: the ENACT trial. Obesity, 25(5), 866-872. https://doi.org/10.1002/oby.21813	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Efficacy of environmental and acceptance-based enhancements to behavioral weight loss treatment: The ENACT trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were as follows: BMI of 27 to 45 kg/m2, age 18 to 70 years, ability to engage in physical activity, completion of a 7-day food diary, and two prerandomization screening/assessment visits."	
Exclusion criteria	"Exclusion criteria included medical or psychiatric conditions that may have limited ability to comply with the behavioral recommendations of the program or posed a risk to the participant during weight loss, pregnancy, recently began a course of or changed the dosage of medication that could cause significant change in weight, or current or planned participation in another weight loss program."	
Setting	University/research centre	
Intervention	"In all conditions, participants were given calorie goals based on weight, in accordance with standard balanced deficit diet guidelines, and were instructed to gradually increase their physical activity until they reached an ultimate goal of at least 250 minutes per week of moderate activity. In the BT + E condition, participants learned all of the core BT skills. However, the session content associated with these standard activities and discussions in session was reduced to allow sufficient time for other treatment components. The primary focus of BT + E was learning how to modify the home environment (or other settings in which the participant could make changes, such as the workplace) in a way that would facilitate healthy eating. Treatment strategies emphasized reducing the availability of foods that promote overconsumption (e.g., through "cabinet cleanouts") and increasing the availability of foods that were likely to facilitate weight control (e.g., preportioned foods, fruits and vegetables) (8). Second, participants learned how to modify the home environment in a way that would promote physical activity (e.g., increasing cues for exercise in the home). They also learned to navigate the macroenvironment in a way that reduced the need for self-control (e.g., rather than buying coffee each morning from a store in which donuts were prominently displayed, make coffee at home or order from a drive-thru window). In the BT + EA condition, participants were taught core BT skills and learned to make key modifications to the home environment, but the time devoted to these activities was abbreviated so that there was ample opportunity to teach acceptance-based skills. Acceptance-based skills were designed to facilitate greater adherence to behavioral and environmental targets. Participants were encouraged to adopt a stance of acceptance towards uncomfortable internal experiences encountered as part of weight loss efforts (e.g., feeling an urge to buy a bag of potato chips in the grocery store or having the thought that watching television after dinner would be more enjoyable than going for a walk). Willingness was framed as a skill that positions individuals to choose behaviors that are consistent with their values and long-term goals (e.g., refrain from buying chips, go for the walk after dinner), regardless of how pleasurable or uncomfortable these behaviors may feel in the short term. Discussions and exercises were used to develop greater clarity about what is most important in one's life. Ultimately, treatment was designed to enhance	

<table>
<tr><td></td><td>psychological flexibility so that individuals could choose values-driven behavior rather than allow transient internal experiences to dictate eating and activity choices."</td></tr>
<tr><td>Control/Comparator</td><td>"In all conditions, participants were given calorie goals based on weight, in accordance with standard balanced deficit diet guidelines, and were instructed to gradually increase their physical activity until they reached an ultimate goal of at least 250 minutes per week of moderate activity. The BT intervention was adapted from the Look AHEAD and the Diabetes Prevention Program protocols. Self-monitoring of calorie intake, physical activity, and weight was a core skill. Participants also learned to identify triggers for overeating; set specific goals for calorie intake, physical activity, and associated behaviors; use problem-solving skills as a way of overcoming obstacles to behavior change; develop social support for behavior changes; and use relapse prevention techniques to prepare for lapses, anticipate challenges, and develop strategies for addressing them. Of note, reflecting standard practice, stimulus control techniques were taught in BT but were not a primary focus of session activities or participant assignments outside of the session."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 283
Intervention group/s: BT + E (n=93); BT + EA (n=102)

Comparator group: BT (n=88)</td></tr>
<tr><td>Mean age ± SD</td><td>BT + E: 53.41 (10.28); BT + EA: 53.23 (9.43); BT: 53.02 (9.32)</td></tr>
<tr><td>Sex</td><td>78.80% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI
Mean (SD)</td><td>BT + E: 35.38
(5.17)
BT + EA: 35.23
(4.64)</td><td>BT: 34.96
(5.19)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight loss (%) at 12 months
Mean (SD)</td><td>BT + E: -10.62
(7.82)
BT + EA: -10.84
(7.04)</td><td>BT: -10.21
(7.98)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
</table>

Compliance with treatment	On average, participants attended 74.6% of group treatment sessions.
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Butryn, 2021

Guideline record ID: 10089--1

Study characteristics		
Citation	Butryn, M. L., Godfrey, K. M., Call, C. C., Forman, E. M., Zhang, F., & Volpe, S. L. (2021). Promotion of physical activity during weight loss maintenance: a randomized controlled trial. Health Psychology, 40(3), 178-187. https://doi.org/https://dx.doi.org/10.1037/hea0001043	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Promotion of physical activity during weight loss maintenance: A randomized controlled trial	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were BMI 27- 45 kg/m2 (measured in clinic), age 18 -70 years, and completion of all steps in the enrollment process."	
Exclusion criteria	"Exclusion criteria were medical or psychiatric conditions that could pose a risk during lifestyle modification or significantly limit the ability to begin a program of PA; history of bariatric surgery; current use of weight-affecting medication; weight loss of 5% or more in the past 6 months; current pregnancy, lactation, or plans to become pregnant during the study period; participation in or plan to participate in another weight loss program during the study period; or having an immediate family member or household member participating in the study."	
Setting	Home	
Intervention	"Phase I (Months 1 to 6) consisted of 16 closed-group sessions, held on a weekly (8 sessions) and then biweekly (8 sessions) basis, with approximately 12 participants in each group. During Phase I, all participants received BWL treatment designed to induce 10% weight loss, with materials adapted from the Look AHEAD Research Group (2006) and the Diabetes Prevention Program Research Group (2002). Participants were instructed to keep daily records of dietary intake. Calorie intake was emphasized as the key determinant of weight loss. Stimulus control, problem solving, goal setting, and social support skills were taught. Participants were instructed to gradually self monitor and increase free-living moderate-to-vigorous physical activity (MVPA), with a goal of maintaining 250 min per week of MVPA by 6 months and beyond. Participants were instructed to conduct MVPA in bouts of 10 min or more. Participants self-reported weekly MVPA minutes and average calorie intake during each session's group check-in, and counselors also provided brief written feedback on self-monitoring records on which exercise and dietary intake were reported. Phase II Interventions (Months 7-18) Group sessions (14 total) continued in Phase II, beginning with 7 weekly sessions followed by 4 biweekly sessions. Each participant also had a 15-min phone call with a counselor between the quarterly sessions (three calls total) to promote continued engagement. Behavioral Therapy With Physical Activity Emphasis (BT PA) - The intervention was created by adapting material from the Look AHEAD (Look AHEAD Research Group, 2006) and Diabetes Prevention Program (Diabetes Prevention Program Research Group, 2002) protocols to be PAfocused, and by incorporating techniques from Michie's behavior change taxonomy (Michie et al., 2011). For example, when a session on "maintaining motivation" was conducted, exercises and discussion in session were focused primarily on enhancing motivation for PA. As another example, the application of goal setting skills was primarily focused on PA goals. Progress toward PA goals, particularly the barriers or facilitators of such progress, was reviewed in each session in greater detail than occurred in the BT condition. PA, rather than eating behavior, was the primary target for problem solving skills. Group leaders frequently encouraged development of	

	implementation intentions for PA. Acceptance-Based Behavioral Therapy With Physical Activity Emphasis (ABT PA) The amount of emphasis on promoting PA was designed to be similar in BT PA and ABT PA. However, in ABT PA, acceptance-based behavioral skills were taught, rather than traditional behavioral skills. This approach was adapted primarily from an acceptance-based weight loss protocol (Forman & Butryn, 2016). A key goal was to increase awareness of internal experiences that shape PA behaviors. The approach validated the sense that many aspects of PA are "uncomfortable," meaning that it can be difficult to tolerate the thoughts (e.g., "I would rather be doing something else"), emotions (e.g., boredom), urges (e.g., to avoid or end exercise), or physical sensations (e.g., sweating) that occur while one attempts to engage in PA or while making PA-related decisions. Participants learned how to respond to internal experiences with a stance of nonjudgmental acceptance, which enables flexibility (i.e., the ability to engage in a wide range of behaviors, regardless of the accompanying internal experiences). Ultimately, acceptance was intended to promote long-term persistence in PA. Values clarity, which is integral to the use of acceptance skills, included the ability to consider the ways in which being physically active enables pursuit of what is most important in one's life (e.g., being physical fit can make travel or community service more feasible). Participants were encouraged to use their "long-term mind" to have a heightened awareness of their values at moments of PA-related decision making, rather than being driven by transient internal experiences."
Control/Comparator	"Phase I (Months 1 to 6) consisted of 16 closed-group sessions, held on a weekly (8 sessions) and then biweekly (8 sessions) basis, with approximately 12 participants in each group. During Phase I, all participants received BWL treatment designed to induce 10% weight loss, with materials adapted from the Look AHEAD Research Group (2006) and the Diabetes Prevention Program Research Group (2002). Participants were instructed to keep daily records of dietary intake. Calorie intake was emphasized as the key determinant of weight loss. Stimulus control, problem solving, goal setting, and social support skills were taught. Participants were instructed to gradually self monitor and increase free-living moderate-to-vigorous physical activity (MVPA), with a goal of maintaining 250 min per week of MVPA by 6 months and beyond. Participants were instructed to conduct MVPA in bouts of 10 min or more. Participants self-reported weekly MVPA minutes and average calorie intake during each session's group check-in, and counselors also provided brief written feedback on self-monitoring records on which exercise and dietary intake were reported. Behavioral Therapy (BT) The BT condition in Phase II continued to be based on Look AHEAD (Look AHEAD Research Group, 2006) and Diabetes Prevention Program (Diabetes Prevention Program Research Group, 2002) materials. Sessions were designed to apply traditional behavioral skills such as problem solving and goal setting to the challenges of long-term lifestyle modification. Approximately two thirds of intervention content and session time was designed to be applied to eating behavior, with a secondary emphasis on PA."
Treatment duration	18 months
Follow-up from baseline	18 months
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 320 Intervention group/s: BT + PA (n=105); ABT + PA (n=105) Comparator group: BT (n=110)
Mean age ± SD	BT: 51.3 (11.4); BT + PA: 54.3 (9.01); ABT +PA: 52.7 (10.4)
Sex	78.13% female

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI - Baseline
Mean (SD)</td><td>BT + PA: 34.5
(4.6)
ABT + PA: 35.8
(5.3)</td><td>BT: 35.1
(4.3)</td></tr>
<tr><td>Waist circumference (inches)
Mean (SD)</td><td>BT + PA: 42.6
(4.7)
ABT + PA: 41.8
(4.5)</td><td>BT: 42.6
(5.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference (inches)
Mean (SD)</td><td>BT + PA: 38.8
(4.9)
ABT + PA: 38.2
(4.6)</td><td>BT: 38.6
(5.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference (inches)
Mean (SD)</td><td>BT + PA: 38.9
(5.3)
ABT + PA: 38.5
(4.7)</td><td>BT: 39.2
(5.8)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>% Weight loss
Mean (SD)</td><td>BT + PA: -12.8
ABT + PA: -11.6</td><td>BT: -12.3</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>% Weight loss
Mean (SD)</td><td>BT + PA: -12.4
ABT + PA: -9.1</td><td>BT: -10.2</td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>At 12 months, 21.8% of BT participants, 20.0% of BT PA participants, and 16.0% of ABT PA participants were meeting the MVPA prescription (250 min/week of MVPA). At 18 months, 250 min/week of MVPA was observed in 13.2% of BT participants, 13.0% of BT PA participants, and 7.6% of ABT PA participants.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Butryn, M. L., Crane, N. T., Lufburrow, E., Hagerman, C. J., Forman, E. M., & Zhang, F. (2023). The role of physical activity in long-term weight loss: 36-month results from a randomized controlled trial. Annals of Behavioral Medicine, 57(2), 146-154. https://doi.org/https://doi.org/10.1093/abm/kaac028</td></tr>
</table>

N/A – Not applicable

Butryn, 2023

Guideline record ID: 10943--1

Study characteristics		
Citation	Butryn, M. L., Crane, N. T., Lufburrow, E., Hagerman, C. J., Forman, E. M., & Zhang, F. (2023). The role of physical activity in long-term weight loss: 36-month results from a randomized controlled trial. Annals of Behavioral Medicine, 57(2), 146-154. https://doi.org/https://doi.org/10.1093/abm/kaac028	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Role of Physical Activity in Long-term Weight Loss: 36-month Results From a Randomized Controlled Trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligible participants had a body mass index (BMI) between 27 and 45 kg/m2 (measured in clinic), were 18-70 years old, and had completed all steps in the enrollment process."	
Exclusion criteria	"Exclusion criteria included: medical or psychiatric conditions that could pose a risk during lifestyle modification or significantly limit the ability to begin a program of PA; history of bariatric surgery; current use of weight-affecting medication (e.g., anti-psychotic, tricyclic antidepressants, insulin, oral corticosteroids, anti-seizure medication, stimulant or appetitive suppressant medications; additional questionable medications were reviewed by a physician); weight loss of 5% or more in the past 6 months; current pregnancy, lactation, or plans to become pregnant during the study period; participation in or plan to participate in another weight loss program during the study period; having an immediate family member or household member participating in the study."	
Setting	University/research centre	
Intervention	"Phase I Intervention (Months 1-6): 16 closed-group sessions: eight weekly sessions, followed by eight bi-weekly sessions. Across participants, Phase I consisted of standard behavioral weight loss treatment adapted from Look AHEAD and the Diabetes Prevention Program designed to induce 10% weight loss. Session content included instructions for daily self-monitoring of dietary intake, stimulus control, problem-solving, goal setting, and social support skills. An emphasis was placed on caloric intake as a driver of weight loss. Additionally, participants were instructed to self-monitor and gradually increase free-living moderate-to-vigorous phys ical activity (MVPA), in bouts of 10 min or more, with a goal of maintaining 250 min per week of MVPA by 6 months. Phase II Interventions (Months 7-18): consisted of three intervention arms, each with 14 group sessions: seven weekly sessions followed by four bi-weekly sessions, and the final three sessions occurring in months 12, 15, and 18. To sustain engagement, counselors conducted 15-min phone calls with participants between the quarterly sessions (three calls total). Approximately two-thirds of the session time and content focused on PA, with a secondary emphasis on eating behavior. The ABT-PA condition was unique in that participants were taught acceptance-based behavioral skills (rather than tra ditional behavioral skills), adapted primarily from an acceptance-based weight loss protocol."	
Control/Comparator	"The BT condition continued the traditional behavioral weight loss approach from Phase I (adapted from Look AHEAD (2006) [24] and Diabetes Prevention Program (2002) [25] materials). Participants learned to apply traditional behav ioral skills (e.g., problem-solving and goal setting) to the unique challenges associated with long-term maintenance of lifestyle changes. The majority of session time and content was focused on eating behavior (about two-thirds), with a secondary emphasis on PA."	

<table>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>36 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 320
Intervention group/s: BT-PA (n=105); ABT-PA (n=105)

Comparator group: BT (n=110)</td></tr>
<tr><td>Mean age ± SD</td><td>52.72y (10.35)</td></tr>
<tr><td>Sex</td><td>78.13% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Waist circumference (inches)
Mean (SD)</td><td>BT-PA: 38.12
(4.91)
ABT-PA: 39.03
(5.5)</td><td>BT: 39.44
(5.04)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Waist circumference (inches)
Mean (SD)</td><td>BT-PA: 39.47
(5)
ABT-PA: 40.95
(5.49)</td><td>BT: 40.47
(4.83)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% Weight loss
Mean (SD)</td><td>BT-PA: -12.2
(9.8)
ABT-PA: -9.8
(10.8)</td><td>BT: -9.3
(12.3)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% Weight loss
Mean (SD)</td><td>BT-PA: -6
(7.8)
ABT-PA: 4.7
(8.2)</td><td>BT: -4.3
(9.5)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Butryn, M. L., Godfrey, K. M., Call, C. C., Forman, E. M., Zhang, F., & Volpe, S. L. (2021). Promotion of physical activity during weight loss maintenance: a randomized controlled trial. Health Psychology, 40(3), 178-187. https://doi.org/https://dx.doi.org/10.1037/hea0001043</td></tr>
</table>

N/A – Not applicable

Cabrera-Rode, 2013

Guideline record ID: 10090--1

Study characteristics		
Citation	Cabrera-Rode, E., Orlandi, N., Padrón, Y., Arranz, C., Olano, R., Machado, M., Hernández-Yero, A., Calderín, R., & Dominguez, E. (2013). Effect of Diamel in patients with metabolic syndrome: a randomized double-blind placebo-controlled study. Journal of Diabetes, 5(2), 180-191. https://doi.org/https://dx.doi.org/10.1111/1753-0407.12007	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Diamel in patients with metabolic syndrome: a randomized double-blind placebo-controlled study	
Location	Cuba	
Trial name	N/A	
Methods		
Inclusion criteria	"The inclusion criteria accepted individuals of either gender aged between 19 and 70 years who fulfilled the WHO diagnostic criteria for MS and had no history of previous or current use of oral anti diabetic agents."	
Exclusion criteria	"Patients who declined to take part in the study were excluded, as were those who exhibited one or more of the following contraindications: type 1 diabetes, type 2 diabetes treated with anti diabetic agents at any time before the trial, any clinical disability, the use of special diets, a history of chronic medication use, the use of mineral and/or vitamin supplements, pregnancy, breast feeding, chronic disease, a history of any acute infection, and the use of immunosuppressant drugs."	
Setting	Hospital, Home	
Intervention	"Subjects received Dialmel at a dose of two capsules before each of the three main meals each day for 1 year while maintaining a diet appropriate to their weight and level of physical activity, as well as appropriate hypertensive drugs (angiotensin-converting enzyme inhibitors) in the case of subjects with hypertension. A maximum maintenance dose of diamel 3960 mg (six capsules) was used. All subjects received advice and counselling regarding diet and nutrition at the Dietetic Department of the Diabetes Care Centre of the National Institute of Endocrinology, where their personal diets were drawn up based on their daily calorie intake requirements per kg body weight and their level of physical activity. Subjects were provided with diets with the following proportion of nutrients:55-60% carbohydrates, 15-20% protein and 20% fat. Diets ranged from 1200 to 1500 calories. Patients in both groups were also encouraged to increase their physical activity(e.g. walking for 30-45 min/day 3-4 days/week)."	
Control/Comparator	"Subjects received a placebo at a dose of two capsules before each of the three main meals each day for 1 year while maintaining a diet appropriate to their weight and level of physical activity, as well as appropriate hypertensive drugs (angiotensin-converting enzyme inhibitors) in the case of subjects with hypertension. All subjects received advice and counselling regarding diet and nutrition at the Dietetic Department of the Diabetes Care Centre of the National Institute of Endocrinology, where their personal diets were drawn up based on their daily calorie intake requirements per kg body weight and their level of physical activity. Subjects were provided with diets with the following proportion of nutrients:55-60% carbohydrates, 15-20% protein and 20% fat. Diets ranged from 1200 to 1500 calories. Patients in both groups were also encouraged to increase their physical activity(e.g. walking for 30-45 min/day 3-4 days/week)."	
Treatment duration	12 months	

<table>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 100
Intervention group/s: Diamel (n=50)

Comparator group: Placebo (n=50)</td></tr>
<tr><td>Mean age ± SD</td><td>Diamel: 42.1 (10.3); Placebo: 45.5 (13.9)</td></tr>
<tr><td>Sex</td><td>55.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Diamel: 98.6
(19.5)</td><td>Placebo: 97.5
(20.1)</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Diamel: 36.3
(5.1)</td><td>Placebo: 37.6
(7.3)</td></tr>
<tr><td>Waist circumference
Mean (SD)</td><td>Diamel: 108
(15)</td><td>Placebo: 108
(10)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Diamel: 91.3
(17.9)</td><td>Placebo: 92
(19.2)</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Diamel: 33.6
(5)</td><td>Placebo: 35.5
(7.1)</td></tr>
<tr><td>Waist circumference
Mean (SD)</td><td>Diamel: 104
(14)</td><td>Placebo: 105
(12)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight
Mean (SE)</td><td>Diamel: -7.37
(1.25)</td><td>Placebo: -5.47
(1.13)</td></tr>
<tr><td>Change in BMI
Mean (SE)</td><td>Diamel: -2.68
(0.44)</td><td>Placebo: -2.1
(0.43)</td></tr>
<tr><td>Change in waist circumference
Mean (SE)</td><td>Diamel: -4.39
(1.22)</td><td>Placebo: -2.23
(1.09)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>There was no significant difference between the Diamel and placebo groups in terms of dietary compliance at the end of the study (70.8% [17/24] and 70.0% [21/30], respectively)</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Cadmus-Bertram, 2016

Guideline record ID: 10091--1

Study characteristics		
Citation	Cadmus-Bertram, L., Nelson, S. H., Hartman, S., Patterson, R. E., Parker, B. A., & Pierce, J. P. (2016). Randomized trial of a phone- and web-based weight loss program for women at elevated breast cancer risk: the HELP study. Journal of Behavioral Medicine, 39(4), 551-559. https://doi.org/https://dx.doi.org/10.1007/s10865-016-9735-9	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Randomized trial of a phone- and web-based weight loss program for women at elevated breast cancer risk: the HELP study	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Women aged 40-75 years with BMI C27.5 kg/m2 . Women were eligible if they had a previous history of ductal or lobular carcinoma in situ (DCIS/LCIS) or a Gail model score of C1.7. The Gail model is a standard risk assessment tool that incorporates age, family history, age at menarche, age at first live birth, and previous biopsy to estimate the 5-year risk of incident breast cancer. A score of 1.7 refers to a 1.7 % risk of developing breast cancer within the next 5 years and is used as a standard cutoff for elevated risk."	
Exclusion criteria	"Women were excluded if they were performing[150 min/ week of moderate-to-vigorous intensity physical activity (MVPA), were currently enrolled in another dietary or physical activity trial, did not have access to high speed internet, or were not fluent in English. Participants were excluded if they reported that they had any medical or psychological condition or other problem that would interfere with participation (e.g., advanced osteoarthritis, cardiac problems, severe depression)."	
Setting	Hospital, Home	
Intervention	"Participants received a 12-month weight loss intervention that focused on the development and practice of self-monitoring and self-regulatory skills. Participants were asked to perform 150 min/ week of moderate-to-vigorous intensity physical activity and to restrict calories at a level sufficient to induce initial weight loss of 1-2 lbs/week (approximate deficit of 500 kcal/day), although it was understood that not all participants would attain this rate of weight loss. Dietary goals emphasized increased intake of fruits, vegetables, and fiber, and decreased intake of unhealthy fats and refined grains. The first 3-6 months of the intervention were focused on weight loss (goal: 10 % loss from baseline weight), with the remaining 6-9 months focused on maintenance. The intervention was delivered via 18, 30-min phonebased health coaching sessions delivered by trained lay coaches following a protocol previously shown to be effective in achieving major dietary change, physical activity promotion, and short-term weight loss. Each participant was matched with a single coach to provide continuity throughout the intervention. The schedule of these sessions was designed to provide maximum support and training during the early phase of behavior change, followed by a gradual transition to greater self reliance. The initial call was scheduled in Week 1; participants then received twice weekly calls in Weeks 2-3, weekly calls in Weeks 5-8, biweekly call in Weeks 10-12, monthly calls in Weeks 16-24, and quarterly calls in weeks 28-52. The intervention was based on Social Cognitive Theory and followed a phased, step-wise approach focused on (a) helping the person to establish a series of short-term goals and (b) assisting the participant to evaluate performance in a manner that would maintain or improve self-efficacy. Each call included a specific behavioral focus. Example topics include meal planning, increasing vegetable intake, reducing refined carbohydrates, dining out, increasing daily steps, increasing moderate-intensity physical activity, managing stress, and proper sleep. Each participant	

<table>
<tr><td></td><td>received a manual that included detailed information on these topics. Participants were taught to self-monitor their diet and physical activity using the free website Sparkpeople.com, which offers online food and physical activity logs. To speed the process of logging dietary intake, Sparkpeople's dietary tracker offers a large database of nutritional data for various food items and the ability to save frequently consumed meals or combinations of foods. As foods are entered, the user is provided with daily totals for calories and macronutrients. The website also has forums where users can obtain social support and motivation as well as share recipes and tips. Participants were taught how to set up an account, use basic features (e.g., entering daily steps), log food intake, and interpret caloric and macronutrient feedback. This feedback could be viewed simultaneously by the counselor and participant to facilitate discussion during coaching calls. The coaching sessions allowed for sufficient flexibility to provide website training at a pace appropriate to the individual participant. A basic step-counting pedometer was provided as an intervention tool to assist with physical activity monitoring."</td></tr>
<tr><td>Control/Comparator</td><td>"the usual care group received a copy of the US Dietary Guidelines for Americans. To maintain engagement with the study and reduce loss to follow-up, they also received a brief 15-min telephone call every 3 months. These calls did not include in-depth coaching or recommendations for diet or physical activity change. The coach would simply re-establish rapport with the participant, ask whether the participant had reviewed the materials and which sections had been most helpful. If a participant mentioned a personal weight loss goal, this was acknowledged but not followed with specific recommendations or coaching."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 105
Intervention group/s: Intervention group (n=71)

Comparator group: Usual care group (n=34)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention group: 60.0 (6.3); Usual care grouop: 60.8 (6.2)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention group: 84.9
(12.1)

Intervention group: 32
(3.6)</td><td>Usual care group: 85.3
(13.4)

Usual care group: 32.2
(4.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intervention group: 81.6
(14.2)</td><td>Usual care group: 84.9
(13.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight at 12 months (kg)
Mean (SD)

Change in weight at 12 months (%)
Mean (SD)</td><td>Intervention group: -2.9 (4.3)

Intervention group: -3.7 (5.4)</td><td>Usual care group: -1.2 (3.8)

Usual care group: -1.3 (4.2)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>64% completed at least 15 of the 18 calls across the entire 12-month intervention.</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Cai, 2019

Guideline record ID: 10092--1

Study characteristics		
Citation	Cai, R., Chao, J., Li, D., Zhang, M., Kong, L., & Wang, Y. (2019). Effect of community-based lifestyle interventions on weight loss and cardiometabolic risk factors in obese elderly in China: a randomized controlled trial. Experimental Gerontology, 128, 110749. https://doi.org/https://dx.doi.org/10.1016/j.exger.2019.110749	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of community-based lifestyle interventions on weight loss and cardiometabolic risk factors in obese elderly in China: A randomized controlled trial	
Location	China	
Trial name	N/A	
Methods		
Inclusion criteria	"The inclusion criteria for the subjects were as follows: aged 60 years and over; obese, defined as body mass index greater than or equal to 28 kg/m2, using the Chinese BMI classification standard developed by the WGOC (Chen and Lu, 2004); and local permanent resident."	
Exclusion criteria	"The exclusion criteria were: cognitive defects, severe psychological disorders or mental illnesses that could affected adherence to the study; cancer, recent cardiovascular disease and other severe chronic diseases that could seriously reduce the ability to participate in the study; participating in or had participated in other trials within the past 30 days (Nakanishi et al., 1995)."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The intervention group participated in a community-based behavioral lifestyle intervention program, which targeted weight loss through dietary changes and increased physical activity, with a combination mode of intervention delivery. The mixed delivery mode including group-based and individual based interventions, was used to support weight loss. The group-based intervention provided classroom-style sessions for 2 h every two weeks in the first 12 months and every month from month 13 through month 24 to impart health knowledge by the clinicians in communities. These sessions included not only basic health knowledge, but also specific guidance regarding physical activity and diet. The individual-based intervention offered health evaluation, individualized counseling sessions with ongoing telephone support, and health promoting materials. The intervention components focused on diet and exercise as well as encouragement of self-monitoring. In terms of diet, participants met with dieticians who instructed the participants on how to modify their diet to achieve their weight loss goals. Individual advice was given, which included intake of appropriate energy; reduction of pickled food, high-fat food and high-sugar food; and inclusion of more cereal, vegetables and fruits. In addition, participants were provided Dietary Guidelines for Chinese Residents and food scales. The physical activity intervention included two aspects: more moderate exercise and less sedentary behavior. A tailored exercise program based on an earlier evaluation was implemented to increase physical activity. Participants were instructed to perform moderate intensity exercise for at least 150 min per week (e.g., walking, cycling), as recommended by the WHO (2010). Moreover, community clinicians gave sessions to help participants recognize the hazards of prolonged sedentary behavior (Vella et al., 2018; Rosique-Esteban et al., 2018) and encouraged participants to reduce their sitting time. Some materials and tools were provided to participants in the intervention group to enhance their health self-management ability, including health behavior handouts for elderly individuals developed by our research group, and a self-monitoring card that records information about weight, waist circumference, daily diet and physical activity"	

<table>
<tr><td>Control/Comparator</td><td>“Participants in the control group received usual care, including a two-hour education session every two months to impart basic health knowledge, such as the dangers of obesity and the benefits of lifestyle changes.”</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 480
Intervention group/s: Intervention group (n=242)

Comparator group: Control group (n=238)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention group: 66.84 (5.32); Control group: 66.86 (4.73)</td></tr>
<tr><td>Sex</td><td>53.54% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)

BMI (Kg/m2)
Mean (SD)</td><td>Intervention group: 78.65
(5.47)

Intervention group: 88.23
(5.31)

Intervention group: 30.01
(1.77)</td><td>Control group: 78.35
(5.17)

Control group: 88.42
(6.18)

Control group: 30.12
(1.81)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight ≤ baseline, n (%)
Mean (SD)

Weight loss ≥5%, n(%)
Mean (SD)</td><td>Intervention group: 161
(75.2)

Intervention group: 72
(33.6)</td><td>Control group: 84
(40.4)

Control group: 11
(5.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight ≤ baseline, n (%)
Mean (SD)

Weight loss ≥5%, n(%)
Mean (SD)</td><td>Intervention group: 164
(76.6)

Intervention group: 88
(41.1)</td><td>Control group: 77
(37)

Control group: 29
(13.9)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)

Change in weight (%)
Mean (SD)

Change in Waist circumference (cm)
Mean (SD)</td><td>Intervention group: -2.48
(2.94)

Intervention group: -0.03
(0.04)

Intervention group: -2.64
(4.47)</td><td>Control group: -0.02
(2.29)

Control group: 0
(0.03)

Control group: -0.13
(3.29)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in weight (kg)
Mean (SD)

Change in weight (%)
Mean (SD)

Change in waist circumference (cm)
Mean (SD)</td><td>Intervention group: -3.22 (3.43)

Intervention group: -0.04 (0.04)

Intervention group: -3.81 (5.72)</td><td>Control group: -0.03 (2.51)

Control group: 0 (0.03)

Control group: -0.07 (3.53)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Approximately 88.43% and 87.39% of the participants in the intervention and control groups, respectively, completed the assessment at 24 months</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Caiazzo, 2020

Guideline record ID: 10093--1

Study characteristics		
Citation	Caiazzo, R., Branche, J., Raverdy, V., Czernichow, S., Carette, C., Robert, M., Disse, E., Barthet, M., Cariou, B., Msika, S., Behal, H., Denies, F., Dervaux, B., Duhamel, A., Verkindt, H., & Pattou, F. (2020). Efficacy and safety of the duodeno-jejunal bypass liner in patients with metabolic syndrome: a multicenter randomized controlled trial (ENDOMETAB). Annals of Surgery, 272(5), 696-702. https://doi.org/https://dx.doi.org/10.1097/SLA.0000000000004339	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Efficacy and Safety of the Duodeno-Jejunal Bypass Liner in Patients With Metabolic Syndrome: A Multicenter Randomized Controlled Trial (ENDOMETAB)	
Location	France	
Trial name	ENDOMETAB	
Methods		
Inclusion criteria	"Participants were patients with obesity [body mass index (BMI) >30 kg/m2] and a clinical diagnosis of MS, defined by the presence of at least 3 of the 5 following criteria derived from the US National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III): waist circumference >102 cm in men and >88 cm in women; triglycerides >50 mg/dL; HDL-c <40 mg/dL in men and <50 mg/dL in women; systolic blood pres sure >130 mm Hg or diastolic blood pressure >85 mm Hg; and fasting glucose >100 mg/dL, and/or the prescription of correspond ing medications to manage hypertriglyceridemia, low HDL-c, hypertension, and hyperglycemia."	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"Endobarrier endoscopic liner, dietary, psychological, and physical activity counseling. All patients were seen by a multidisciplinary team at 1, 3, 6, 9, 12, 15, and 24 months. Recommended daily calorie intake was between 1200 and 1500 kcal for women and between 1500 and 1800 kcal for men. Physical activity goals were to include 150 minutes a week of moderate-intensity and 75 minutes a week of vigorous-intensity aerobic activity and muscle-strengthening activities, on >2 days a week"	
Control/Comparator	"Dietary, psychological, and physical activity counseling. All patients were seen by a multidisciplinary team at 1, 3, 6, 9, 12, 15, and 24 months. Recommended daily calorie intake was between 1200 and 1500 kcal for women and between 1500 and 1800 kcal for men. Physical activity goals were to include 150 minutes a week of moderate-intensity and 75 minutes a week of vigorous-intensity aerobic activity and muscle-strengthening activities, on >2 days a week."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 80 Intervention group/s: DJBL (n=49) Comparator group: Control (n=31)	

<table>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>67.50% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Metabolic syndrome</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference (cm)
Mean (95% CIs)

BMI (kg/m2)
Mean (95% CIs)</td><td>DJBL: 119
(115.4-122.7)

DJBL: 38.4
(36.8-39.9)</td><td>Control: 117.3
(113.4-121.17)

Control: 37.9
(36.3-39.5)</td></tr>
</table>
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<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference (cm)
Mean (95% CIs)

BMI (kg/m2)
Mean (95% CIs)</td><td>DJBL: 113.8
(108.6-119.1)

DJBL: 34.6
(32.8-36.3)</td><td>Control: 114.9
(109.4-120.3)

Control: 37.2
(34.6-39.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Percent weight loss
Mean (95% CIs)</td><td>DJBL: -9.7%
(-11.8-7.7)</td><td>Control: -2.1
(-4.6-0.48)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Calleja Fernández, 2012

Guideline record ID: 10094A--1

Study characteristics		
Citation	Calleja Fernández, A., Vidal Casariego, A., Cano Rodríguez, I., & Ballesteros Pomar, M. D. (2012). One-year effectiveness of two hypocaloric diets with different protein/carbohydrate ratios in weight loss and insulin resistance. Nutrición Hospitalaria, 27(6), 2093-2101. https://doi.org/10.3305/nh.2012.27.6.6133	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	One-year effectiveness of two hypocaloric diets with different protein/carbohydrate ratios in weight loss and insulin resistance	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	"Body mass index (BMI) between 28 to 35 kg/m2 ; aged between 18 to 70 years old."	
Exclusion criteria	"The exclusion criteria were participation in a weight loss treatment in the 6 months prior to the trial, any severe psychiatric illness, pregnancy, diabetes (fasting plasma glucose > 126 mg/dL or > 200 mg/dL at 120 min after an oral 75 g glucose tolerance test (OGTT), previous bariatric surgery, and eating disorders."	
Setting	University/research centre	
Intervention	"Patients with and without insulin resistance received diets with different carbohydrate/ protein/fat ratios (40/30/30 or 55/15/30) for 16 weeks,"	
Control/Comparator	"participants without insulin resistance were prescribed a hypocaloric diet (Diet B) with carbohydrate/protein/fat ratios (55/15/30)."	
Treatment duration	16 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 40 Intervention group/s: IR+Diet A (n=13); IR+Diet B (n=12); IS+Diet A (n=8) Comparator group: IS+Diet B (n=7)	
Mean age ± SD	Diet A (Insulin resistant (IR)): 35.85y (12.42); Diet B (IR): 42.17y (15.08); Diet A (Insulin sensitive (IS)): 47.25y (11.76); Diet B (IS): 40.57y (14.55)	
Sex	67.50% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	Baseline Weight (kg) - Insulin resistant participants Mean (SD)	Diet A: 90.78 (15.72)	Diet B: 88.09 (11.46)

	BMI (kg/m2) - Insulin resistant participants Mean (SD)	Diet A: 31.18 (2.71)	Diet B: 32.02 (2.01)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	BMI (kg/m2) - Insulin resistant participants Mean (SD)	Diet A: 29.26 (2.63)	Diet B: 29.84 (2.18)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight loss % at 12 months - Insulin resistant participants Mean (SD)	Diet A: -6.87 (3.29)	Diet B: -7.38 (1.96)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Calleja Fernández, 2012

Guideline record ID: 10094B--1

Study characteristics		
Citation	Calleja Fernández, A., Vidal Casariego, A., Cano Rodríguez, I., & Ballesteros Pomar, M. D. (2012). One-year effectiveness of two hypocaloric diets with different protein/carbohydrate ratios in weight loss and insulin resistance. Nutrición Hospitalaria, 27(6), 2093-2101. https://doi.org/10.3305/nh.2012.27.6.6133	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	One-year effectiveness of two hypocaloric diets with different protein/carbohydrate ratios in weight loss and insulin resistance	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	"Body mass index (BMI) between 28 to 35 kg/m2 ; aged between 18 to 70 years old."	
Exclusion criteria	"The exclusion criteria were participation in a weight loss treatment in the 6 months prior to the trial, any severe psychiatric illness, pregnancy, diabetes (fasting plasma glucose > 126 mg/dL or > 200 mg/dL at 120 min after an oral 75 g glucose tolerance test (OGTT), previous bariatric surgery, and eating disorders."	
Setting	University/research centre	
Intervention	"Patients with and without insulin resistance received diets with different carbohydrate/ protein/fat ratios (40/30/30 or 55/15/30) for 16 weeks,"	
Control/Comparator	"participants without insulin resistance were prescribed a hypocaloric diet (Diet B) with carbohydrate/protein/fat ratios (55/15/30)."	
Treatment duration	16 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 15 Intervention group/s: Diet A (n=8) Comparator group: Diet B (n=7)	
Mean age ± SD	Diet A: 47.25y (11.76); Diet B: 40.57y (14.55)	
Sex	11.00% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	Baseline Weight (kg) - Insulin sensitive participants Mean (SD)	Diet A: 85.38 (8.44)	Diet B: 85.56 (8.8)

	BMI (kg/m2) - Insulin sensitive participants Mean (SD)	Diet A: 32.99 (2.45)	Diet B: 31.44 (2.21)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	BMI (kg/m2) - Insulin sensitive participants Mean (SD)	Diet A: 30.52 (2.9)	Diet B: 29.98 (2.63)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight loss % at 12 months - Insulin sensitive participants Mean (SD)	Diet A: 10.57 (5.51)	Diet B: -8.55 (0.83)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment			
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Campbell, 2010

Guideline record ID: 10098--1

Study characteristics		
Citation	Campbell, P. T., Gross, M. D., Potter, J. D., Schmitz, K. H., Duggan, C., McTiernan, A., & Ulrich, C. M. (2010). Effect of exercise on oxidative stress: a 12-month randomized, controlled trial. Medicine & Science in Sports & Exercise, 42(8), 1448-1453. https://doi.org/10.1249/MSS.0b013e3181cfc908	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of exercise on oxidative stress: a 12-month randomized, controlled trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Age = 50-75 yr; body mass index (BMI) between 25 and 40 kgImj2 (or between 24.0 and 24.9 kgImj2 if body fat percentage 9 33%); postmenopausal, not taking hormones in the previous 6 months; nonsmoker; sedentary at baseline (moderate- or vigorousintensity activity G 60 minIwkj1 and maximal O2 uptake G 25 mLIkgj1 Iminj1); alcohol consumption of fewer than two drinks per day; fasting glucose G 140 mgIdLj1 ; and no history of cancer, diabetes, or cardiovascular disease."	
Exclusion criteria	Not reported.	
Setting	Home, Study facility at university or commercial gym	
Intervention	"The exercise intervention progressed to ≥45 min.d-1 of moderate-intensity aerobic exercise (60%-75% of observed maximal HR), 5 d.wk-1, by the eighth week of the trial, where it was maintained to the end of study. For months 1-3, the intervention participants attended three mandatory exercise sessions at a study facility (University of Washington or a commercial gym) and exercised twice per week at home. For months 4-12, the intervention group attended at least one session per week at a study facility and conducted the remaining sessions at home or at a study facility. Exercisers wore Polar HR monitors during all exercise sessions and maintained exercise logs that included information on the duration, mode, relative perceived exertion, and peak HR of all sport and recreational activities estimated at ≥METs (1). Exercise logs were reviewed weekly by study staff to monitor adherence with the study protocol and to intervene when needed"	
Control/Comparator	"Women in the control group attended once-weekly 45-min stretching and relaxation sessions and were asked to not otherwise change exercise habits for the duration of the trial."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 173 Intervention group/s: Exercisers (n=87) Comparator group: Controls (n=86)	
Mean age ± SD	Intervention: 60.7y (6.7); Control: 60.6y (6.8)	

<table>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Body fat (%)
Mean (SD)</td><td>Exercisers: 30.4
(4.1)

Exercisers: 47.5
(4.8)</td><td>Controls: 30.5
(3.8)

Controls: 47.4
(4.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean

Change in Body fat (%)
Mean</td><td>Exercisers: -1.3

Exercisers: -1.4</td><td>Controls: 0.1

Controls: -0.1</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Carter, 2019

Guideline record ID: 10102--1

Study characteristics		
Citation	Carter, S., Clifton, P. M., & Keogh, J. B. (2019). The effect of intermittent compared with continuous energy restriction on glycaemic control in patients with type 2 diabetes: 24-month follow-up of a randomised noninferiority trial. Diabetes Research and Clinical Practice, 151, 11-19. https://doi.org/10.1016/j.diabres.2019.03.022	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The effect of intermittent compared with continuous energy restriction on glycaemic control in patients with type 2 diabetes: 24-month follow-up of a randomised noninferiority trial	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	">18 years of age with diagnosed type 2 diabetes of any duration managed with diet, oral hypoglycaemic agents (OHA) and/or insulin and who were overweight or obese (body mass index 27)."	
Exclusion criteria	"Not pregnant or breastfeeding with no previous weight loss surgery."	
Setting	Home, University/research centre	
Intervention	"The intermittent energy restriction group followed a diet of 2100 to 2500 kJ/day (500-600 kcal/day) for 2 days of the week and followed their usual diet for the other 5 days. Both groups received written dietary information booklets with portion advice and sample menus; no food or meal replacements were provided. Dietary counselling was provided by a dietitian (S.C.) and occurred every 2 weeks for the first 3 months and every 2 to 3 months for the final 9 months. After the end of this 12-month trial, participants were followed-up again 12 months later (24 months after baseline) for measurement of HbA1c, body composition and a fasting blood sample."	
Control/Comparator	"The continuous energy restriction group followed a diet of 5000 to 6300 kJ/day (1200-1500 kcal/day) (45% carbohydrate, 30% protein and 25% fat). Both groups received written dietary information booklets with portion advice and sample menus; no food or meal replacements were provided. Dietary counselling was provided by a dietitian (S.C.) and occurred every 2 weeks for the first 3 months and every 2 to 3 months for the final 9 months. After the end of this 12-month trial, participants were followed-up again 12 months later (24 months after baseline) for measurement of HbA1c, body composition and a fasting blood sample."	
Treatment duration	12 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 137 Intervention group/s: Intermittent energy restriction group (n=70) Comparator group: Continuous energy restriction group (n=67)	
Mean age ± SD	61 (9.1)	

<table>
<tr><td>Sex</td><td>56.20% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intermittent energy restriction group: 100
(19)</td><td>Continuous energy restriction group: 102
(17)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intermittent energy restriction group: 35
(5.8)</td><td>Continuous energy restriction group: 37
(5.7)</td></tr>
<tr><td>Total Body Fat (%)
Mean (SD)</td><td>Intermittent energy restriction group: 42
(7.3)</td><td>Continuous energy restriction group: 44
(6.6)</td></tr>
<tr><td>Total Fat Mass (kg)
Mean (SD)</td><td>Intermittent energy restriction group: 40
(9.4)</td><td>Continuous energy restriction group: 42
(9.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
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</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in Weight (kg)
Mean (SE)</td><td>Intermittent energy restriction group: -3.9
(1.1)</td><td>Continuous energy restriction group: -3.9
(1.1)</td></tr>
<tr><td>Change in Weight (kg)
Mean (95% CIs)</td><td>Intermittent energy restriction group: -3.9
(-6.1--1.7)</td><td>Continuous energy restriction group: -3.9
(-6--1.7)</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (SE)</td><td>Intermittent energy restriction group: -1.3
(0.4)</td><td>Continuous energy restriction group: -1.4
(0.4)</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (95% CIs)</td><td>Intermittent energy restriction group: -1.3
(-2.1--0.6)</td><td>Continuous energy restriction group: -1.4
(-2.2--0.7)</td></tr>
<tr><td>Change in Total Body fat (%)
Mean (SE)</td><td>Intermittent energy restriction group: -2.3
(1.8)</td><td>Continuous energy restriction group: -2.6
(1.4)</td></tr>
<tr><td>Change in Total Body fat (%)
Mean (95% CIs)</td><td>Intermittent energy restriction group: -2.3
(-6-1.3)</td><td>Continuous energy restriction group: -2.6
(-5.4-0.3)</td></tr>
<tr><td>Change in Total Fat Mass (kg)
Mean (SE)</td><td>Intermittent energy restriction group: -5.1</td><td>Continuous energy restriction group: -3.7</td></tr>
</table>
</td></tr>
</table>

	Change in Total Fat Mass (kg) Mean (95% CIs)	(2.1) Intermittent energy restriction group: -5.1 (-9.3--1)	(1.9) Continuous energy restriction group: -3.7 (-7.4-0.1)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Cassidy, 2023

Guideline record ID: 10944--1

Study characteristics		
Citation	Cassidy, S., Trenell, M., Stefanetti, R. J., Charman, S. J., Barnes, A. C., Brosnahan, N., McCombie, L., Thom, G., Peters, C., Zhyzhneuskaya, S., Leslie, W. S., Catt, C., Catt, M., McConnachie, A., Sattar, N., Sniehotta, F. F., Lean, M. E. J., & Taylor, R. (2023). Physical activity, inactivity and sleep during the Diabetes Remission Clinical Trial (DiRECT). Diabetic Medicine, 40(3), e15010. https://doi.org/https://doi.org/10.1111/dme.15010	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Physical activity, inactivity and sleep during the Diabetes Remission Clinical Trial (DiRECT)	
Location	Scotland; England	
Trial name	Diabetes Remission Clinical Trial (DiRECT)	
Methods		
Inclusion criteria	“Eligible participants were aged 20-65 years, had been diagnosed with type 2 diabetes within the previ ous 6 years, and had a BMI of 27-45kg/m2.”	
Exclusion criteria	Not reported	
Setting	GP clinic	
Intervention	“The intervention programme consisted of three phases: 1 - Total Diet Replacement (TDR, 825-853kcal per day for mula diet) for 3 months(with option to extend to 5 months depending on individual goals and circumstances), 2 - Stepped Food Reintroduction (FR, 6-8weeks), and 3 - Structured support for Weight-Loss Maintenance (WLM, up to 24months).7 All these were delivered in a primary care setting by trained practitioners, which included NHS practice nurses and dietitians. After an initial 1-h appoint ment in TDR and FR, participants attended 30-min ap pointments fortnightly during these phases, and monthly in WLM. One to one training on promotion of physical activity was provided for practitioners. This training included information on physical activity in the general population, and discussion of common barriers to and enablers of physical activity. Checklist-based fidelity assessments of the information and support provided at participant visits were carried out by the senior research dietitians, with immediate feedback to practitioners. During TDR appointments, participants were advised not to change their usual physical activity patterns. During the FR and WLM appointments with a practitioner, participants were encouraged to increase their daily physical activity. During the first FR appointment, practitioners provided participants with a step counter and instructions on measuring current activity (steps) and gradually increasing it to reach and maintain their individual sustainable maximum, up to 15,000 steps/day.7 During subsequent FR and WLM appointments, an individually tailored goalsetting approach was used to increase activity. Recognised behavioural strategies8 were used to support individuals to increase activity, including self monitoring, barrier identification, problem solving, and goal setting (Appendix A). Emphasis was given to goal setting and action planning as well as practical methods to achieve the goals. To measure changes in physical activity and sleep, participants were asked to wear a GENEActiv accelerometerfor 7 continuous days at baseline, 12 and 24months. The GENEActiv accelerometer is a fully waterproof wrist-worn tri-axial, raw data accelerometer for activity and sleep tracking in free living studies.”	
Control/Comparator	“Usual care: best-practice care in accordance with guidelines (control).”	
Treatment duration	24 months	
Follow-up from baseline	24 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 170
Intervention group/s: Intervention (n=66)

Comparator group: Control (n=104)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 55.8y (6.6); Control: 57.0y (6.3)</td></tr>
<tr><td>Sex</td><td>40.59% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 97.1
(15.6)

Intervention: 34.5
(4.3)</td><td>Control: 98.7
(16.7)

Control: 34.1
(4.4)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 86.3
(15.2)

Intervention: 30.7
(4.7)</td><td>Control: 97.8
(17.2)

Control: 33.8
(4.6)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 88.5
(15.2)

Intervention: 31.5
(4.7)</td><td>Control: 96.5
(16.7)

Control: 33.4
(4.6)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Catalan-Lamban, 2023

Guideline record ID: 12005--1

Study characteristics		
Citation	Catalán-Lambán, A., Ojeda-Rodríguez, A., Marti Del Moral, A., & Azcona-Sanjulian, C. (2023). Changes in objectively measured sleep after a multidisciplinary lifestyle intervention in children with abdominal obesity: a randomized trial. Sleep Medicine, 109, 252-260. https://doi.org/https://doi.org/10.1016/j.sleep.2023.07.004	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Changes in objectively measured sleep after a multidisciplinary lifestyle intervention in children with abdominal obesity: A randomized trial	
Location	Spain	
Trial name	Intervention of Grupo Estudio Navarro de Obesidad Infantil (IGENOI)	
Methods		
Inclusion criteria	"Children and adolescents (7-16 years old) with abdominal obesity, defined as a waist circumference above the 90th percentile according to the national reference chart. Participants were recruited from the Paediatric Endocrinology Units at both Clínica Universidad de Navarra and Complejo Hospitalario de Navarra and Health Primary Care Centres in Pamplona, Spain."	
Exclusion criteria	"The exclusion criteria included prevalent prediabetes or any other endocrine disorders, food intolerance, eating disorders or psychiatric disease, pharmacological treatment, regular alcohol consumption, or special diet treatment."	
Setting	GP clinic, Home	
Intervention	"The multidisciplinary intervention consisted of a two-year program that comprised a 2-month intensive phase with individual and group sessions and a follow-up period at 12 and 24 months. A multidisciplinary team, including registered dieticians, pediatricians, physical activity experts, and nurses, conducted the intervention in a clinical setting. Parents or legal guardians accompanied them to the visits. IG was advised to follow a fully-day meal plan during the intensive phase, consisting of a moderately hypocaloric Mediterranean diet [15]. The dietary pattern was based on high consumption of fruits (3 portions per day) and vegetables (2 portions per day), legumes, whole grains, and olive oil; moderate consumption of dairy products, poultry, and fish; and the reduction of processed and red meats, limiting them to 1 portion per week. The energy expenditure was calculated using the Schofield equation (adapted to age and sex) [16]. The calorie restriction applied varied from 10 to 40% depending on the standard deviation score of Body Mass Index (SDS-BMI) and trying not to interfere with the participant's body growth [17,18]. Caloric diets below 1300 Kcal and above 2200 Kcal were not prescribed. Energy intake (percentage) was distributed into five meals according to the Spanish Society of Community Nutrition [19]: breakfast 20%, morning snack 5-10%, lunch 30-35%, afternoon snack 10-15% and dinner 20-25% of total energy. The distribution of main macronutrients was as follows: carbohydrates 55%, lipids 30%, and proteins 15% of total energy intake. During the 2-month intensive phase, patients were prescribed to follow up on a diet, and they received six 30-min sessions every two weeks, conducted by dieticians, to evaluate the accomplishment of diet and anthropometric measurements. In addition, they received one parallel group session where children and adolescents learned about healthy lifestyles, including eating behavior (portion control) and the importance of being physically active (sedentary activities and physical activity) [15]. The parents or legal guardians were taught about their role in the study and obesity-related problems. During the follow-up period, intervention participants had monitoring visits at 3, 4, 5, 6, 9, and 12 months, where nutrition educational topics about healthy breakfast and food choices were given at months 3 and 5 from baseline and at month 4 a group session about groups of foods and	

	frequency of food consumption was taught to children and parents or legal tutors. No advice was given to participants regarding to the timing of meals that could potentially affect the timing of sleep. Regarding physical activity, both groups were advised to accumulate 200 min of physical activity per week at 60-75% of their maximum heart rate as recommended by The American College of Sports Medicine [20]. The subjects were advised to enroll in biweekly physical activities organized by their schools or public or private sports centers. No advice was given to participants regarding sleep habits."
Control/Comparator	"UCG received one 30-min individual session with the dietitian and standard pediatric recommendations for a healthy diet (SENPE 2016) (Aranceta Bartrina et al., 2016) and ten monitoring visits to assess nthropometric measurements during the first year of intervention. During the two months, usual care subjects and their parents received a 30 min individual session with the dietician and five monitoring visits to assess anthropometric parameters. Regarding physical activity, both groups were advised to accumulate 200 min of physical activity per week at 60-75% of their maximum heart rate as recommended by The American College of Sports Medicine [20]. The subjects were advised to enroll in biweekly physical activities organized by their schools or public or private sports centers. No advice was given to participants regarding sleep habits."
Treatment duration	2 years
Follow-up from baseline	2 years
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference
Participant characteristics	
Number of participants	n= 122 Intervention group/s: Intervention group (n=90) Comparator group: Usual Care group (n=32)
Mean age ± SD	Intervention: 11.5y (2.5); Control: 10.7y (2.3)
Sex	37.70% female
Pre-existing medical condition	
Results	

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
BMI-SDS Mean (SD)	Intervention group: 2.3 (1.1)	Usual Care group: 2.6 (0.9)
Waist circumference (cm) Mean (SD)	Intervention group: 86.2 (11.2)	Usual Care group: 86.6 (11)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator
BMI-SDS Mean (SD)	Intervention group: 2.5 (1.3)	Usual Care group: 1.9 (1.3)
Waist circumference (cm) Mean (SD)	Intervention group: 82.6 (12.1)	Usual Care group: 84.2 (10.8)

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator
BMI-SDS Mean (SD)	Intervention group: 2 (0.7)	Usual Care group: 1.5 (1.5)
Waist circumference (cm)	Intervention group: 81.5	Usual Care group: 86.3

	Mean (SD)	(9.2)	(9.5)
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Cesa, 2013

Guideline record ID: 10107--1

Study characteristics		
Citation	Cesa, G. L., Manzoni, G. M., Bacchetta, M., Castelnuovo, G., Conti, S., Gaggioli, A., Mantovani, F., Molinari, E., Cárdenas-López, G., & Riva, G. (2013). Virtual reality for enhancing the cognitive behavioral treatment of obesity with binge eating disorder: randomized controlled study with one-year follow-up. Journal of Medical Internet Research, 15(6), e113. https://doi.org/10.2196/jmir.2441	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Virtual reality for enhancing the cognitive behavioral treatment of obesity with binge eating disorder: randomized controlled study with one-year follow-up	
Location	Italy	
Trial name	Virtual reality in eating disorders (VEPSY)	
Methods		
Inclusion criteria	"(1) Women aged 18-50 years, (2) who met DSM-IV-TR criteria for BED for at least 6 months prior to the beginning of the study, (3) no other concurrent severe psychiatric disturbance (psychosis, depression with suicidal risk, alcohol or drug abuse), (4) no concurrent involvement in other treatment for binge eating disorder (BED), including pharmacotherapy, (5) no concurrent medical condition not related to the disorder, and (6) written and informed consent to participate."	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"CBT: During the inpatient program, participants received 15 additional cognitive behavior therapy (CBT) sessions over 5 weeks. Therapists followed a detailed manual that outlined the contents of each session. In particular, after the first inpatient week, participants entered 5 weekly group sessions and 10 biweekly individual sessions. The first 8 individual sessions were structured according to Stage 1 of the CBT manual for binge eating. They focused on an overview of the goals of the treatment program, the use of self-monitoring records to identify high-risk situations that might trigger binge eating, support in normalizing eating patterns, and the identification of behavioral strategies for coping with high-risk situations for binge eating. The final 2 individual sessions focused on the maintenance of improvement and on relapse prevention. The group sessions were structured according to Stage 2 of the CBT manual for binge eating. They focused on problem-solving strategies and cognitive interventions targeting concerns about body weight and shape and problematic eating.; ECT: Like the CBT condition, participants allocated to VR-enhanced cognitive behavior therapy (ECT) received 15 additional sessions over 5 weeks. After the inpatients' first week, participants entered 5 weekly group sessions similar to the CBT ones (focused on concerns about body weight and shape and problematic eating) and 10 biweekly VR sessions. ECT treatment was based on a detailed protocol describing the contents of each of the 15 sessions. For the virtual reality sessions, NeuroVR open-source software was used. NeuroVR includes 14 virtual environments used by the therapist during a 60-minute session with the patient. The environments present critical situations related to the maintaining/relapse mechanisms (Home, Supermarket, Pub, Restaurant, Swimming Pool, Beach, Gymnasium) and two body image comparison areas. Through the VR experience, patients practiced both eating/emotional/relational management and general decision-making and problem-solving skills. By directly practicing these skills within the VR environment, patients were helped in developing specific strategies for avoiding and/or coping with triggering situations. The first session was used to assess any stimuli that could elicit abnormal eating behavior. Specifically, the attention was focused on a patient's concerns about food, eating, shape, and weight. The next 14	

<table>
<tr><td></td><td>sessions were used to assess and modify the following. Expectations and Emotions Related to Food and Weight (Functional Analysis), Strategies Used to Cope With Difficult Interpersonal and Potential Maintenance Situations, Body Experience of the Subject”</td></tr>
<tr><td>Control/Comparator</td><td>“The integrated multimodal medically managed inpatient program (IP) was the common treatment condition for all the participants. It consisted of hospital-based living for a duration of 6 weeks. Inpatients received medical, nutritional, physical, and psychological care. In particular, they maintained a low-calorie diet (tailored to patients' needs), entered weekly nutritional groups held by dieticians, received psychological support both in individual and group settings, and undertook physical training.”</td></tr>
<tr><td>Treatment duration</td><td>6 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 66
Intervention group/s: ECT (n=27); CBT (n=20)

Comparator group: IP (n=19)</td></tr>
<tr><td>Mean age ± SD</td><td>31.79y (7.9)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI
Mean (SD)</td><td>ECT: 103
(18.2)
CBT: 106.6
(8.9)

ECT: 39.2
(5.3)
CBT: 41.1
(3.3)</td><td>IP: 111.7
(22.9)

IP: 41.8
(6.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI
Mean (SD)</td><td>ECT: 96
(16.3)
CBT: 101
(9.4)

ECT: 36.6
(5)
CBT: 39
(3.6)</td><td>IP: 109.3
(22.6)

IP: 40.9
(6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
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<table>
<tr><td>12 months or closest time point</td><td></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Chair, 2024

Guideline record ID: 12006--1

Study characteristics		
Citation	Chair, S.-Y., Lo, S. W. S., Cheng, H. Y., Choi, K. C., Liu, T., Wang, Q., & Sit, J. W. H. (2024). Effects of a theory-based educational program on health behaviors and cardiovascular health outcomes among overweight postmenopausal women: a randomized controlled trial. Journal of Cardiovascular Nursing, 39(1), 79-87. https://doi.org/10.1097/JCN.0000000000001032	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of a Theory-Based Educational Program on Health Behaviors and Cardiovascular Health Outcomes Among Overweight Postmenopausal Women: A Randomized Controlled Trial	
Location	China (Hong Kong)	
Trial name	Not reported	
Methods		
Inclusion criteria	"The inclusion criteria were (a) postmenopausal Chinese women (ie, experienced amenorrhea not attributed to other causes for at least 12months),26 (b) 65years or younger, (c) being overweight/obese (body mass index [BMI] > 22.9 kg/m2) or with central obesity (waist circumference > 80 cm),27 and (d) attained >6 years of formal education."	
Exclusion criteria	"Exclusion criteria included (a) given a diagnosis of any cardiovascular disease; (b) concurrent participation in another clinical trial, lifestyle/dietary intervention, or weight control program; (c) concurrent use of hormone replacement therapy; or (d) known history of psychiatric disorders."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The intervention group received the 3-month theory-based educational program. Its content is shown in Supplemental Digital Content 1, Figure 1, http://links.lww.com/JCN/A236. The delivery of the program was designed to increase the levels of interaction to enhance the learning experience of participants. This program was composed of 1 individual introduction session of the webpage/booklet (30 minutes), three 2-hour group meetings, and 5 individual telephone contacts (20 min/time). The delivery plan is illustrated in Supplemental Digital Content 2, Figure 2, http://links.lww.com/JCN/A236. The individual session was delivered by a trained research nurse to introduce the website/booklet (the same as that for the control group). It involved both learner-content and learner-instructor interactions and emphasized practical and specific information for healthy lifestyles. Then, 2 biweekly group discussion sessions (10-15 participants/ group) and 1 individual telephone follow-up (call 1) were conducted to enhance participants' skills in maintaining a healthy lifestyle. The group sessions focused on preparation of an individualized action plan and skills in incorporating dietary modification and PA into daily life and were conducted by a trained dietitian and a trained physiotherapist, respectively. Another telephone follow-up (call 2) was made between the group meetings to provide support and enhance participants' problem-solving abilities. Three biweekly telephone calls (calls 3, 4, and 5) were made to provide support for adherence to their plan and to discuss strategies for solving the encountered problems. The last group meeting was held by the end of the third month to acknowledge the achievement of the participants and provide further advice on plan modification if necessary."	
Control/Comparator	"Participants in the control group received a link to an established cardiovascular health information website (http://cvhealth.nur.cuhk.edu.hk/) or a self-developed information booklet with contents like the website, depending on the participants' preference. The website/ booklet provided basic knowledge on menopause and its association with	

<table>
<tr><td></td><td>cardiovascular health and recommendations on PA and diet. One co-investigator provided a didactic lecture (20-30 participants/session, 30 min/session) to introduce the website/booklet.”</td></tr>
<tr><td>Treatment duration</td><td>3 months</td></tr>
<tr><td>Follow-up from baseline</td><td>14 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 288
Intervention group/s: Intervention (n=144)

Comparator group: Control (n=144)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 59.0y (3.9); Control: 59.2y (3.9).</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td></td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 60.2
(7.5)

Intervention: 24.9
(2.9)

Intervention: 87
(7.2)</td><td>Control: 61.2
(10.1)

Control: 25.1
(4)

Control: 87.7
(8.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 58.9
(8)

Intervention: 24.4
(3.1)

Intervention: 85.8
(8.1)</td><td>Control: 60.1
(9.8)

Control: 24.7
(3.6)

Control: 86.6
(10.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported.</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Chan, 2021

Guideline record ID: 10109--1

Study characteristics		
Citation	Chan, D. L., Cruz, J. R., Mui, W. L., Wong, S. K. H., & Ng, E. K. W. (2021). Outcomes with intra-gastric balloon therapy in BMI < 35 non-morbid obesity: 10-year follow-up study of an RCT. Obesity Surgery, 31(2), 781-786. https://doi.org/https://dx.doi.org/10.1007/s11695-020-04986-3	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Outcomes with Intra-gastric Balloon Therapy in BMI < 35 Non-morbid Obesity: 10-Year Follow-Up Study of an RCT	
Location	China	
Trial name	N/A	
Methods		
Inclusion criteria	"Aged 18-60 years, BMI 27- 35, agreeing to undergo invasive weight reduction therapy and intensive follow-up, and without a history of weight reduction > 5% body weight for 6 months before recruitment."	
Exclusion criteria	"Patients with coronary heart disease, controlled hypertension (> 160/90 mmHg), unstable cerebrovascular or cardiovascular disease, renal disease, liver disease, diabetes mellitus, eating disorder, psychiatric illness, pregnant, or breastfeeding."	
Setting	University/research centre	
Intervention	"Initial phase: Patients in the IGB arm underwent placement of Orbera® (Apollo Endosurgery, TX, USA) IGB, filling with 500 ml and placebo pill for a single 6-month period. Multi-disciplinary lifestyle modification advice is provided to both groups. All patients received education on a balanced (50% carbohydrates, 30% fats, and 20% proteins) hypocaloric diet. All patients were encouraged to achieve target physical activity of at least moderate activity, such as walking, jogging, or cycling, for at least 30 min daily for 5 days/week. At a 10-year follow-up, participants attended a once-off clinic follow-up to undertake repeat anthropometric and blood pressure measurements, fasting glucose and lipid profile investigations, and a structured questionnaire (patient's willingness to undertake further intervention and development of new comorbidities)."	
Control/Comparator	"Initial phase: Sibutramine arm received diagnostic (sham) endoscopy and commenced at 10 mg sibutramine daily for 4 weeks and then 15 mg daily for a total duration of 6 months only. Multi-disciplinary lifestyle modification advice is provided to both groups. All patients received education on a balanced (50% carbohydrates, 30% fats, and 20% proteins) hypocaloric diet. All patients were encouraged to achieve target physical activity of at least moderate activity, such as walking, jogging, or cycling, for at least 30 min daily for 5 days/week. At a 10-year follow-up, participants attended a once-off clinic follow-up to undertake repeat anthropometric and blood pressure measurements, fasting glucose and lipid profile investigations, and a structured questionnaire (patient's willingness to undertake further intervention and development of new comorbidities)."	
Treatment duration	24 months	
Follow-up from baseline	10 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 99
Intervention group/s: IGB (n=50)

Comparator group: control (n=49)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 38.1y (7.9); Control: 35.3y (7.2)</td></tr>
<tr><td>Sex</td><td>72.73% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>IGB: 30.2
(2.3)</td><td>control: 30.7
(2.1)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>IGB: 30.97
(1.6)</td><td>control: 30.38
(1.8)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg); total weight loss
Mean (SD)</td><td>IGB: -6.52</td><td>control: -4.42</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg); total weight loss
Mean (SD)

Total weight loss (%)
Mean (SD)

Change in BMI from baseline
Mean (SD)</td><td>IGB: -0.03

IGB: -0.16
(12.8)

IGB: -0.8</td><td>control: 2.32

control: -2.84
(5.6)

control: 0.3</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Chang, 2019

Guideline record ID: 10110--1

Study characteristics		
Citation	Chang, S.-H., Chien, N.-H., & Yu, C.-Y. (2019). Long-term lifestyle intervention in elderly with metabolic syndrome. Clinical Nursing Research, 28(6), 658-675. https://doi.org/10.1177/1054773817749923	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-Term Lifestyle Intervention in Elderly With Metabolic Syndrome	
Location	Taiwan	
Trial name	N/A	
Methods		
Inclusion criteria	"Elderly people with metabolic syndrome (MetS), with good cognitive function and no hearing or vision problems."	
Exclusion criteria	"Respondents with myocardial infarctions were excluded."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The experimental group was provided simple suggestions for diet plans based on the age and education level of the participants. For the diet intervention strategy, two nutrition seminars lasting 1.5 hr each were held once a month. These seminars presented healthy sample meals that participants could taste, which included less salt, less oil, appropriate and sufficient amounts of whole grains, proteins, fruits, vegetables, and dairy products. The diet intervention instructed the proper amount of carbohydrates, protein, vegetables, and fruits to be included in each meal. They ate healthy sample meals once a month until 18 months. In addition, illustrated healthy meal plans were created for participants to put in their kitchen or attach to their refrigerators. All participants undertook an exercise intervention for MetS: creating a supportive environment, improving exercise skills, and strengthening the power of community between residents from the same communities, where they could help, encourage, and remind each other to exercise. Two village heads, under the guidance of researchers, found suitable locations for creating supportive environments. To develop skills needed for exercise, elderly adults joined aerobic exercise programs, which included endurance training. The programs were designed by physiatrists for the elderly adults, who then exercised for 40 min each session 3 times a week. Moreover, participants also joined a 40-min per day, 5-days per week walking plan, which required participants to follow experts and complete three exercises: warm up, endurance, and stretch. All elderly adults were encouraged to exercise at least 150 min every week. This supportive environment and exercise sessions continued to 18 months. Moreover, the interventions included regular reminders for exercise from well-trained volunteers in each group. Volunteers regularly reminded participants to exercise through phone calls once per week for the first month. Volunteers' phone calls to participants were changed to a monthly phone call from 2 to 18 months."	
Control/Comparator	"No diet intervention was supplied to the control group. All participants undertook an exercise intervention for MetS: creating a supportive environment, improving exercise skills, and strengthening the power of community between residents from the same communities, where they could help, encourage, and remind each other to exercise. Two village heads, under the guidance of researchers, found suitable locations for creating supportive environments. To develop skills needed for exercise, elderly adults joined aerobic exercise programs, which included endurance training. The programs were designed by physiatrists for the elderly adults, who then exercised for 40 min each session 3 times a week. Moreover, participants also joined a 40-min per day, 5-days per week walking plan, which required participants to follow experts and complete three exercises:	

<table>
<tr><td></td><td>warm up, endurance, and stretch. All elderly adults were encouraged to exercise at least 150 min every week. This supportive environment and exercise sessions continued to 18 months. Moreover, the interventions included regular reminders for exercise from well-trained volunteers in each group. Volunteers regularly reminded participants to exercise through phone calls once per week for the first month. Volunteers' phone calls to participants were changed to a monthly phone call from 2 to 18 months.”</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 69
Intervention group/s: Experimental group (n=36)

Comparator group: Control group (n=33)</td></tr>
<tr><td>Mean age ± SD</td><td>71.80y (6.15)</td></tr>
<tr><td>Sex</td><td>46.38% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Experimental group: 62.76 (7.86)

Experimental group: 25.51 (2.47)

Experimental group: 90.22 (6.32)</td><td>Control group: 66.67 (9.35)

Control group: 27.06 (3.89)

Control group: 93.22 (8.84)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Experimental group: 61.23 (8.13)

Experimental group: 24.92 (2.22)

Experimental group: 85.82 (8.14)</td><td>Control group: 65.91 (9.43)

Control group: 26.62 (4.16)

Control group: 91.54 (7.34)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
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<tr><td></td><td></td><td></td></tr>
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</td></tr>
</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Chang, 2023

Guideline record ID: 12007

Study characteristics		
Citation	Chang, S.-H., Chang, Y.-Y., Jeng, W.-J., & Wai, J. P. M. (2023). Efficacy of a multidimensional self-management intervention on low-education women with metabolic syndrome: a cluster randomized controlled trial. Scientific Reports, 13(1), 10358. https://doi.org/https://doi.org/10.1038/s41598-023-36971-y	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Efficacy of a multidimensional self-management intervention on low-education women with metabolic syndrome: a cluster randomized controlled trial	
Location	China (Taiwan)	
Trial name	N/A	
Methods		
Inclusion criteria	"Having abdominal adiposity (waist circumference ≥ 80 cm in Chinese females or body mass index (BMI)> 30 kg/m2, plus two or more of the following define the presence of metabolic syndrome according to the International Diabetes Federation: (1) triglycerides ≥ 150 mg/dL or specific treatment for this lipid abnormality; (2) high-density lipoprotein cholesterol < 50 mg/dL in females or specific treatment for this lipid abnormality; (3) systolic blood pressure ≥ 130 mm Hg or diastolic blood pressure ≥ 85 mm Hg, or treatment of previously diagnosed hypertension; and (4) fasting plasma glucose ≥ 100 mg/ dL, or previously diagnosed type 2 diabetes. Inclusion criteria were (1) adult women with age ≥ 50 years, (2) low education, defined as having less than 6 years of education or being primary school graduates, (3) presence of metabolic syndrome, (4) community dwelling."	
Exclusion criteria	"Participants with hearing and visual acuity difficulties, unconscious, or individuals with cognitive impairment or dementia were excluded."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The self-management program. The intervention consisted of five dimensions-lifestyle modification, goal setting, coaching and peer support, problem-solving, and self-monitoring. Lifestyle modification. We applied three of the five World Health Organization's Key Actions for Health Promotion37- create supportive environments, strengthen community action, and develop personal skills38,39. Providing supportive environments and accessible resources. We worked with the intervention community managers to identify vicinity sites, such as community-based activity centers, for administering exercise classes, nutrition courses, and related physical and clinical assessments. Providing simple exercise skills and group course. We offered daytime community health volunteer-supervised aerobic exercise classes for 40 min a day, 5 days a week, throughout the 18-month intervention. Exercise specialists designed the exercises, which composed of three parts-warm-up, main activity (aerobics), and cool down (stretching). Additional supervised 40-min and 5 days a week nighttime walking session were offered. Providing nutrition courses and simple healthy meal plans. To implement the dietary guidelines10,40, we held two monthly 1.5-h nutrition courses during the first month of intervention. Each course consisted of lectures and presentations of simple diet plans and samples of healthy meals-briefly, reduced salt and oil intake; proper portions of whole grains, vegetables, fruits, proteins, dairy products, and nuts. Participants learned about the association of subtypes of consumed oil consisting of polyunsaturated fatty acids, monounsaturated fatty acids,saturated fatty acids, and trans-fatty acids; with cardiometabolic risks. They experienced the sample meals and studied their proper proportion of vegetables, fruits, protein, and carbohydrates. Laminated pictures of healthy meal plans were distributed to post on kitchen walls or refrigerator doors to cue healthy dieting38,39. Goal setting. The goal was to engage in moderate to vigorous exercise 30 min or more per day, five days or	

<table>
<tr><td></td><td>more per week, and to adhere to the 2018 Taiwan's Daily Food Guide41- a consumption of 2.5-4 bowls (500- 800 g) of whole grains (one-third being refined), three to eight servings (300-800 g) of proteins (legume, beans, soy bean, fish, seafood, egg, or meat), 1.5-2 glasses (360-480 mL) of dairy products, three to five servings (300- 500 g) of vegetables, two to four servings (200-400 g) of fruits, four to eight servings of oils and nuts-three to seven table spoons (15-35 g) of oils and one serving (10 g) of nuts. The adequate amount was proportional to individual's estimated energy requirement. Coaching and peer support. One nurse investigator, one trained community health volunteer, and 6-7 participants formed a peer support group. Each group took a 12-hour course provided by the research team and the metabolic syndrome experts to learn about exercise, healthy diet, behavior change, communication skills, and methods of physical measurements (body weight, height, waist circumference, and blood pressure). To empower participants to meet the goal, the peers (nurses and community health volunteers) set the same goal, provided education, and shared experience to encourage participants by phone calls or LINE messages once weekly during the first six months and once monthly thereafter. Problem-solving. The most common problem encountered was the concern of the safety commuting to exercise sites on rainy days. The community health volunteers and the participants conferred to reach feasible alternatives, such as following the exercise videos shown on YouTube or digital video discs. Self-monitoring. The intervention participants were encouraged to visit nearby support sites monthly to monitor their body weight, body mass index, waist circumference, blood pressure, and fasting blood glucose. To monitor and reinforce healthy activities, each participant kept a health passport containing personal measurements recorded by the community health volunteers, and weekly exercise and dietary logs entered by crossing a checklist to allow for the low literacy of participants.”</td></tr>
<tr><td>Control/Comparator</td><td>“The attention-control arm received a health education leaflet about metabolic syndrome care.”</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 103
Intervention group/s: Intervention (n=53)

Comparator group: Control (n=50)</td></tr>
<tr><td>Mean age ± SD</td><td>60.6y (8.7)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Metabolic syndrome (i.e. two or more of the following define the presence of metabolic syndrome according to the International Diabetes Federation1: (1) triglycerides ≥ 150 mg/dL or specific treatment for this lipid abnormality; (2) high-density lipoprote</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 65.8
(9.5)

Intervention: 27
(3.4)

Intervention: 90.4
(8.6)</td><td>Control: 65.6
(12.2)

Control: 27
(4.2)

Control: 89.1
(9.3)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 63.5
(8.7)

Intervention: 26.1
(3)

Intervention: 87.8
(8.5)</td><td>Control: 66.2
(12.1)

Control: 27.3
(4.2)

Control: 89.5
(8.8)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Compliance was high, with 100% for nutrition courses, 80% for exercise classes (confirmed with self-reported assessment, see Table 2), and 90% for monthly self-monitoring, as approximated by community health volunteers.</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Cheng, 2013

Guideline record ID: 10113--1

Study characteristics		
Citation	Cheng, H. L., Griffin, H. J., Bryant, C. E., Rooney, K. B., Steinbeck, K. S., & O'Connor, H. T. (2013). Impact of diet and weight loss on iron and zinc status in overweight and obese young women. Asia Pacific Journal of Clinical Nutrition, 22(4), 574-582. https://doi.org/10.6133/apjcn.2013.22.4.08	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Impact of diet and weight loss on iron and zinc status in overweight and obese young women	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	"Healthy women aged 18-25 years with a measured BMI ≥27.5 kg/m2."	
Exclusion criteria	"Volunteers were ineligible if they had any haematological disorders, were anaemic (haemoglobin (Hb) <120 g/L) or vegetarian."	
Setting	Home	
Intervention	"The HP diet provided 32% protein; 41% carbohydrate; 25% fat; 12.2 mg iron; and 11.7 mg zinc (8.20 mg from animal sources) per day. Haem iron, estimated as 40% of total iron from meat, poultry and fish, was calculated at 1.90 and 0.40 mg/day for the HP and LP diets respectively. Both diet plans met the Australian estimated average requirement (EAR) for iron and zinc, but not the recommended dietary intake (RDI) for iron (HP: 68%; LP: 55%)."	
Control/Comparator	"The LP diet provided 20% protein; 58% carbohydrate; 21% fat; 9.90 mg iron; and 7.60 mg zinc (3.60 mg from animal sources). Haem iron, estimated as 40% of total iron from meat, poultry and fish, was calculated at 1.90 and 0.40 mg/day for the HP and LP diets respectively. Both diet plans met the Australian estimated average requirement (EAR) for iron and zinc, but not the recommended dietary intake (RDI) for iron (HP: 68%; LP: 55%). The LP diet also did not meet the RDI for zinc (95%)."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 71 Intervention group/s: HP diet (n=36) Comparator group: LP diet (n=35)	
Mean age ± SD	Reported for completers only (at 12 months), Intervention (HP diet): 22.5y (2.3); Control (LP diet): 22.1 (2.1)	
Sex	100.00% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>HP diet: 96.2
(8.9)

HP diet: 34.6
(3.4)</td><td>LP diet: 92.5
(11.6)

LP diet: 32.2
(3.6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of participants with <5% weight loss (%)
Proportion (%)

Proportion of participants with ≥10% weight loss
Proportion (%)</td><td>HP diet: 28.6%

HP diet: 42.9%</td><td>LP diet: 53.3%

LP diet: 26.7%</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (%)
Mean (SD)

Change in waist-circumference (cm)
Mean (SD)</td><td>HP diet: -9.79
(13)

HP diet: -7.9
(1.8)</td><td>LP diet: -4.56
(7.15)

LP diet: -2.4
(0.8)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>No significant urea/creatine ratio (UCR) difference was observed between the diets at baseline (HP: 33.5±7.43; LP: 30.6±6.94; p=0.194). At six months, UCR was significantly higher on the HP diet (HP: 38.4±9.67; LP: 30.5±7.31; p=0.023) which was consistent with the protein prescription. However, this difference was no longer significant at 12 months (HP: 35.0±7.40; LP: 33.7± 5.49; p=0.547), indicating reduced compliance.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Cheng, 2022

Guideline record ID: 10112

Study characteristics		
Citation	Cheng, A., Yeoh, E., Moh, A., Low, S., Tan, C. H., Lam, B., Sum, C. F., Subramaniam, T., & Lim, S. C. (2022). Roux-en-Y gastric bypass versus best medical treatment for type 2 diabetes mellitus in adults with body mass index between 27 and 32 kg/m2: a 5-year randomized controlled trial. Diabetes Research and Clinical Practice, 188, 109900. https://doi.org/10.1016/j.diabres.2022.109900	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Roux-en-Y gastric bypass versus best medical treatment for type 2 diabetes mellitus in adults with body mass index between 27 and 32 kg/m2: A 5-year randomized controlled trial	
Location	Singapore	
Trial name	N/A	
Methods		
Inclusion criteria	"The inclusion criteria were patients with established diagnosis of T2DM of duration ≤ 10 years, aged 21-65 years, BMI 27-32 kg/m2, HbA1c ≥ 8% (≥64 mmol/mol) despite treatment by the primary care physician, and at least one of the following co-morbidities on treatment: hypertension, hyperlipidaemia, micro/macroalbuminuria, diabetic nephropathy, or diabetic retinopathy. T2DM was managed according to the Singapore Ministry of Health Clinical Practice Guidelines for Management of Diabetes Mellitus [14]. Glucose lowering agents adopted included a wide range of oral medications (metformin, sulphonylurea, dipeptidyl peptidase-4 (DPP-4) inhibitors, α1-glucosidase inhibitor, SGLT2i, GLP1RA) and a wide range of basal-bolus insulin analogues."	
Exclusion criteria	"The exclusion criteria were a history of bariatric surgery or extensive upper abdominal surgery, pregnancy, nephropathy requiring dialysis, unfit for general anaesthesia or surgery, unwilling or possibly unable to adhere to the follow-up process, reluctant to be randomized into the two study groups, unstable psychiatric illness, or active substance abuse."	
Setting	Hospital	
Intervention	"Initial preoperative workup included, but was not limited to, consultation with surgeon, diabetologist, dietitian, physiotherapist, and psychologist; blood and urine tests, upper endoscopy, colonoscopy for over 50 years of age or otherwise indicated, sleep study, and abdominal ultrasound. Subjects underwent a standard laparoscopic RYGB with a 30-ml gastric pouch size, 10 mm gastrojejunostomy, 50-cm biliopancreatic limb, and 100-cm alimentary limb. Gastroenterostomy and jejunojejunostomy were performed using linear staples plus handsewn closure of enterostomy. Petersen's space and jejunal mesenteric defect were closed with non-absorbable sutures. A leak test was performed with air insufflation through an endoscope. Inpatient stay was usually 2 nights. On the first postoperative day, a barium swallow was performed. Oral fluid was permitted as soon as possible in small quantity until a normal barium swallow was reported. Oral medication was then reintroduced after adequate oral fluid was tolerated. In addition, visits by diabetologist, dietitian, and physiotherapist was conducted on day 1 post-surgery. Subjects were discharged the morning of post-operative day 2. Study visits were scheduled at week 2 and week 6 after surgery, then at 3, 6, 9, 12 months, then at 6-months intervals until the program ends. Each visit includes surgeon and diabetologist consult. Dietary and lifestyle intervention were more regular initially. Other visits were scheduled according to needs, with referral to other services as indicated."	
Control/Comparator	"All participants were assessed by a dietitian, endocrinologist, diabetes nurse educator, and physiotherapist. Initial consultation with diabetologist after randomization involved	

<table>
<tr><td></td><td>adjustment to existing glucose-lowering medications, including introduction of newer classes of glucose-lowering drugs (including GLP1RA and SGLT2i). An initial assessment of diet, individualized meal planning and counselling on best dietary practices based on the latest Singapore Ministry of Health Clinical Practice Guidelines for Management of Diabetes Mellitus and advice to engage in moderate intensity physical activity (minimum of 150 min/week) if deemed medically fit to do so, were also provided in the initial consultation. Clinic visits with diabetologists were scheduled every 3 months until the end of the program. Dietary and lifestyle interventions were more frequent during the first year. Other visits and consultations were scheduled as indicated.”</td></tr>
<tr><td>Treatment duration</td><td>5 years</td></tr>
<tr><td>Follow-up from baseline</td><td>5 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 26
Intervention group/s: RYGB (n=12)

Comparator group: Medical (n=14)</td></tr>
<tr><td>Mean age ± SD</td><td>44y (10)</td></tr>
<tr><td>Sex</td><td>65.38% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)

BMI (kg/m2) - Baseline
Mean (SD)

Waist circumference (cm) - Baseline
Mean (SD)</td><td>RYGB: 77.1
(9.5)

RYGB: 29.1
(1.6)

RYGB: 99.4
(7.3)</td><td>Medical: 78.4
(12.2)

Medical: 29.7
(1.6)

Medical: 99.3
(9.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in body weight (%) from baseline
Mean (SE)

Change in BMI (%) - from baseline
Mean (SE)

Change in waist circumference (%) from baseline
Mean (SE)</td><td>RYGB: -18.1
(3.5)

RYGB: -20.5
(2)

RYGB: -15.2
(1.8)</td><td>Medical: -2.8
(0.9)

Medical: -2.8
(1)

Medical: -3.4
(0.8)</td></tr>
</table>
</td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in body weight (%) from baseline Mean (SE)	RYGB: -15.7 (4.8)	Medical: -4.5 (2.3)
	Change in BMI (%) - from baseline Mean (SE)	RYGB: -18.6 (3.5)	Medical: -6.1 (2.5)
	Change in waist circumference (%) from baseline Mean (SE)	RYGB: -13.5 (5.7)	Medical: -2.7 (5.6)
Compliance with treatment	RYGB:50%; Medical: 50%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Christensen, 2012

Guideline record ID: 10115--1

Study characteristics		
Citation	Christensen, J. R., Overgaard, K., Carneiro, I. G., Holtermann, A., & Søgaard, K. (2012). Weight loss among female health care workers- a 1-year workplace based randomized controlled trial in the FINALE-health study. BMC Public Health, 12(1), 625. https://doi.org/10.1186/1471-2458-12-625	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight loss among female health care workers--a 1-year workplace based randomized controlled trial in the FINALE-health study	
Location	Denmark	
Trial name	FINALE-health	
Methods		
Inclusion criteria	"Female, overweight (i.e. BMI > 25 or body fat % > 33 for age 18-40 or > 34 for age > 40), and being health care worker or primarily working with elderly care."	
Exclusion criteria	Not reported	
Setting	Workplace	
Intervention	"The intervention lasted 12 months and consisted of two parts. The first part (0-3 months) focused on weight loss and included advice on dietary change based on the Danish Dietary recommendations, calorie counting, weight measurements, weight loss targets, strengthening exercises and initiating leisure time fitness exercise. The second part (3-12 months) focused on weight loss maintenance through further intervention with physical exercise and cognitive behavioral training"	
Control/Comparator	"monthly two-hour oral presentation during working hours. The twelve pre sentations were based on the Danish National Board of Health and the Ministry of Food, Agriculture and Fisher ies public websites and concerned the Danish Dietary recommendations and other health related topics."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 98 Intervention group/s: Intervention (n=54) Comparator group: Reference (n=44)	
Mean age ± SD	not reported	
Sex	100.00% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 84.2
(15.9)

Intervention: 30.7
(5.4)

Intervention: 100.1
(13.8)</td><td>Reference: 83
(14.4)

Reference: 30.4
(4.9)

Reference: 101.6
(12.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 78.4
(15.8)

Intervention: 28.5
(5.5)

Intervention: 96.1
(14.9)</td><td>Reference: 82.7
(14.6)

Reference: 30.3
(5.1)

Reference: 100
(13.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Christensen, 2013

Guideline record ID: 10116--1

Study characteristics		
Citation	Christensen, P., Frederiksen, R., Bliddal, H., Riecke, B. F., Bartels, E. M., Henriksen, M., Juul-Sørensen, T., Gudbergsen, H., Winther, K., Astrup, A., & Christensen, R. (2013). Comparison of three weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults. Obesity, 21(10), 1982-1990. https://doi.org/10.1002/oby.20413	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Comparison of three weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults	
Location	Denmark	
Trial name	Influence of Weight Loss or Exercise on Cartilage in Obese Knee Osteoarthritis Patients Trial (CAROT)	
Methods		
Inclusion criteria	"The participants were obese (defined as a body-mass index [BMI] > 30 kg/m2), more than 50 years of age and had primary knee OA diagnosed according to the American College of Rheumatology criteria."	
Exclusion criteria	"Exclusion criteria were lack of motivation to lose weight, inability to speak Danish, planned anti-obesity surgery, total knee alloplasty, and receiving pharmacologic therapy for obesity."	
Setting	University/research centre	
Intervention	"Initially all participants went through a 16-week intensive dietary weight loss intervention. The dietary weight loss approach applied in the CAROT trial for all participants was a combination of formula diet products, dietetic advice as well as focus on long-term lifestyle changes. In the intensive 16-week weight loss phase, participants were randomly assigned to either 8 weeks of low-energy diet (LED; 3,400 kJ/day [810 kcal/day]) or a very-low-energy diet (VLED; 1,743 kJ/ day [415 kcal/day]) in an all-provided formula-diet period in a supervised dietary program. Both dietary programs met all recommendations for daily intake of macronutrients, vitamins, and minerals. This was followed by an additional 8-week period of a hypo-energetic diet consisting of normal food plus two formula products daily (targeting 1,200 kcal/day in total). All participants were taught how to make diet plans with 5-6 small meals a day; the principles of the diet were in line with the guidelines for healthy eating issued by the Danish National Board of Health, i.e., low fat, low sugar, and high fiber intake. Second phase was 52 weeks where the participants were randomly assigned to either a continued dietary weight maintenance arm or knee exercise arm; D, Diet. The goal of the dietary intervention was to produce and maintain a weight loss of at least 10%, which has been found to be the magnitude of weight loss needed to achieve clinically relevant relief in disease symptoms in the knees (18). The focus of the dietary education was on long-term lifestyle changes and modifications. The education included self-monitoring of eating habits, dietetics, stimulus control, problem solving, and social support. Goals for body weight were advised to be in the range of BMI 24-29 kg/m2 . In the maintenance phase, the focus of the dietician included assisting participants who had reached their weight loss goals to maintain their weight loss, and providing counseling for participants who had a difficult time changing behavior and losing weight. Participants attended weekly sessions for approximately 1 h including weighing and provision of formula products (1 Cambridge Weight Plan product per day).; E, Exercise. The typical exercise intervention consisted of a warmup phase (10 min), a circuit training phase (45 min), and a cool down/stretching phase (5 min). The exercise intervention was divided into four periods of 12 weeks and one period of 4 weeks (total 52 weeks). The aim was to gradually translate the intervention from facility-based exercises to home-based exercises.	

	The participants alternated between attendance to exercise at the facility or performing the exercises at home. In this way, the participants were gradually going from supervised to unsupervised exercise. The aim of the intervention was to improve knee function and reduce pain. Functional weight-bearing exercises were applied, emulating activities of daily life-both light and more vigorous activities. The quality of the performance in each exercise was emphasized, and the level of training and progression was guided by the patient's performance."
Control/Comparator	"Initially all participants went through a 16-week intensive dietary weight loss intervention. The dietary weight loss approach applied in the CAROT trial for all participants was a combination of formula diet products, dietetic advice as well as focus on long-term lifestyle changes. In the intensive 16-week weight loss phase, participants were randomly assigned to either 8 weeks of low-energy diet (LED; 3,400 kJ/day [810 kcal/day]) or a very-low-energy diet (VLED; 1,743 kJ/ day [415 kcal/day]) in an all-provided formula-diet period in a supervised dietary program. Both dietary programs met all recommendations for daily intake of macronutrients, vitamins, and minerals. This was followed by an additional 8-week period of a hypo-energetic diet consisting of normal food plus two formula products daily (targeting 1,200 kcal/day in total). All participants were taught how to make diet plans with 5-6 small meals a day; the principles of the diet were in line with the guidelines for healthy eating issued by the Danish National Board of Health, i.e., low fat, low sugar, and high fiber intake. Second phase was 52 weeks where the participants were randomly assigned to the control group and received no further intervention."
Treatment duration	16 weeks
Follow-up from baseline	12 months
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 192 Intervention group/s: Diet (n=64); Exercise (n=64) Comparator group: Control (n=64)
Mean age ± SD	Diet: 63.0y (6.5); Exercise: 62.9y (5.8); Control: 61.7y (6.8)
Sex	80.73% female
Pre-existing medical condition	Knee osteoarthritis (OA)
Results	

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	Baseline waist circumference (cm) Mean (SD)	Diet: 112.5 (10.9) Exercise: 110 (10.9)	Control: 111.4 (11)
	Baseline weight (kg) Mean (SD)	Diet: 103.6 (14.8) Exercise: 101 (14)	Control: 105 (16.1)
	Baseline BMI (kg/m2) Mean (SD)	Diet: 37.6 (4.5) Exercise: 36.5 (4.4)	Control: 37.9 (5.3)

Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in waist circumference (cm) Mean (95% CIs)	Diet: -8.4 (-10.2---6.7) Exercise: --4.6 (-6.3--2.9)	Control: -7.0 (-8.7--5.3)
	Change in weight (kg) Mean (95% CIs)	Diet: -11.0 (-12.9--9.1) Exercise: --6.3 (-8.1--4.5)	Control: -8.3 (-10.1- -6.4)
	Change in BMI (kg/m2) Mean (95% CIs)	Diet: -4.1 (-4.7--3.4) Exercise: --2.3 (-3.0---1.7)	Control: -2.9 (-3.6- -2.3)
	Change in Fat mass, g Mean (95% CIs)	Diet: -8,985 (-10,569--7,401) Exercise: --4,797 (-6,398---3,195)	Control: -5,978 (-7,565- -4,391)
	Change in Fat mass % Mean (95% CIs)	Diet: -5.1 (-6.0- -4.1) Exercise: --2.4 (-3.4---1.4)	Control: -3.0 (-3.9- -2.0)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Clina, 2023

Guideline record ID: 12008--1

Study characteristics		
Citation	Clina, J. G., Sayer, R. D., Pan, Z., Cohen, C. W., McDermott, M. T., Catenacci, V. A., Wyatt, H. R., & Hill, J. O. (2023). High- and normal-protein diets improve body composition and glucose control in adults with type 2 diabetes: a randomized trial. Obesity, 31(8), 2021-2030. https://doi.org/https://doi.org/10.1002/oby.23815	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	High- and normal-protein diets improve body composition and glucose control in adults with type 2 diabetes: a randomized trial	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Participants were required to be at least 18 years old, have BMI ≥ 27 kg/m2, have had a T2D diagnosis within the past 6 years (documented physician diagnosis, fasting glucose ≥ 126 mg/dL, or hemoglobin A1c [HbA1c] ≥ 6.5%), be weight stable (±3 kg in the past 3 months), and be stable on all medications for the past 3 months. Regarding eligibility criteria for T2D diagnosis, participants enrolled were those who had a recent diagnosis as described earlier without meeting the threshold for fasting glucose or HbA1c if that participant was on medication to manage T2D, which would lower these values."	
Exclusion criteria	"Exclusion criteria were as follows: HbA1c ≥ 12%; current eating disorder (anorexia or bulimia); dependence on illicit drugs or alcohol; untreated hypothyroidism; currently using insulin or other drugs known to cause weight loss or gain (including glucagon-like peptide-1 or sodium/glucose cotransporter 2 medications, steroids, tricyclic antidepressants, chemotherapy, antipsychotics, or prescribed or over-the-counter weight loss agent); following a vegetarian or vegan diet; any illness or injury that would make it unsafe to follow a diet and/or exercise up to 70 minutes at a moderate intensity regularly; and women who were pregnant, lactating, trying to become pregnant, or who had been pregnant or lactating in the last 6 months."	
Setting	Home, University/research centre	
Intervention	"All participants followed the State of Slim (SOS) weight management program for the first 16 weeks of the program, which consisted of weekly group classes led by a trained coach. Participants received copies of the SOS book, copies of the course materials, and access to the online community. After the first 16 weeks, participants participated in the SOS Next Steps program, which consists of 18 biweekly group classes for the remainder of the intervention. The HP group, with instructions to consume ≥4 weekly servings of lean beef as the only source of red meat."	
Control/Comparator	"All participants followed the State of Slim (SOS) weight management program for the first 16 weeks of the program, which consisted of weekly group classes led by a trained coach. Participants received copies of the SOS book, copies of the course materials, and access to the online community. After the first 16 weeks, participants participated in the SOS Next Steps program, which consists of 18 biweekly group classes for the remainder of the intervention. The NP group, with instructions to not eat red meat for the duration of the study and to follow a modified SOS diet that reduced protein intake."	
Treatment duration	12 months	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 106
Intervention group/s: High protein diet (n=53)

Comparator group: Normal-protein diet (n=53)</td></tr>
<tr><td>Mean age ± SD</td><td>High-protein diet: 54.1y (12.0); Normal-protein diet: 55.4y (9.6)</td></tr>
<tr><td>Sex</td><td>75.47% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>T2D diagnosis within the past 6 years (documented physician diagnosis, fasting glucose ≥ 126 mg/dL, or hemoglobin A1c [HbA1c] ≥ 6.5%), be weight stable (±3 kg in the past 3 months), and be stable on all medications for the past 3 months.</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Percent fat mass - measured as a least-squares mean (SE)
Mean (SE)

Waist circumference (cm)
Mean (SE)

BMI (kg/m2)
Mean (SE)</td><td>High protein diet: 46.2
(0.8)

High protein diet: 118
(2)

High protein diet: 38.7
(1)</td><td>Normal-protein diet: 46.6
(0.8)

Normal-protein diet: 117
(2)

Normal-protein diet: 38.8
(1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Percent fat mass - measured as a least-squares mean (SE)
Mean (SE)

Waist circumference (cm)
Mean (SE)

BMI (kg/m2)
Mean (SE)</td><td>High protein diet: 41.9
(1.1)

High protein diet: 111
(2)

High protein diet: 35
(1)</td><td>Normal-protein diet: 42.8
(1.6)

Normal-protein diet: 109
(2)

Normal-protein diet: 34.4
(1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SE)</td><td>High protein diet: -10.2
(1.6)</td><td>Normal-protein diet: -12.7
(4.8)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Cohen, 2023

Guideline record ID: 10945--1

Study characteristics		
Citation	Cohen, T. R., Mak, I. L., Loiselle, S.-E., Kasvis, P., Hazell, T. J., Vanstone, C. A., Rodd, C., & Weiler, H. A. (2023). Changes in adiposity without impacting bone health in 9- to 12-year-old children with overweight and obesity after a one-year family-centered lifestyle behavior intervention. Childhood Obesity, 19(1), 46-56. https://doi.org/10.1089/chi.2022.0008	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Changes in Adiposity without Impacting Bone Health in Nine- to Twelve-Year-Old Children with Overweight and Obesity after a One-Year Family-Centered Lifestyle Behavior Intervention	
Location	Canada	
Trial name	McGill Youth Lifestyle Intervention with Food and Exercise (MY LIFE)	
Methods		
Inclusion criteria	"Eligibility in cluded 9- to 12-year-old children with no known illness, classified as overweight [85%-97%; BMI, +1 standard deviation (SD) scores], or with obesity [>97%; BMI +2 SD] according to the World Health Organization (WHO) criteria."	
Exclusion criteria	Not reported	
Setting	University/research centre	
Intervention	"Six registered dietitian-led sessions - sessions occurred at the end of the month for the first 5 months, then a final session at the end of the 8th month. The intervention used was based on Canadian dietary21 and PA guidelines,22 but were individualized for each family and included behavioral counseling. Principles of motivational interviewing techniques, such as engaging in reflective listening, shared decision making, and setting realistic goals were used."	
Control/Comparator	"Children randomized to CTRL were assessed every 3 months identical to the treatment group; after the 1-year study was completed they received the same interventions."	
Treatment duration	6 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 60 Intervention group/s: FCLI (n=30) Comparator group: Control (n=30)	
Mean age ± SD	11.1y (1.2)	
Sex	53.33% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	Body weight (kg) Mean (SD)	FCLI: 66.4 (15.3)	Control: 61.5 (15.8)
	Weight-for-age and -sex z-score Mean (SD)	FCLI: 2.14 (0.51)	Control: 1.92 (0.72)
	Waist Circumference (cm) Mean (SD)	FCLI: 95.3 (9.2)	Control: 93.6 (10.7)
	Waist Circumference (z-score) Mean (SD)	FCLI: 1.9 (0.2)	Control: 1.9 (0.3)
	BMI (kg/m2) Mean (SD)	FCLI: 27.7 (3.3)	Control: 27.8 (4.6)
	body mass index for age-and-sex Z-scores (BAZ) Mean (SD)	FCLI: 2.77 (0.49)	Control: 2.74 (0.74)
	Total body fat mass (kg) Mean (SD)	FCLI: 24.6 (7.2)	Control: 24.7 (7.6)
	Body fat percentage (%) Mean (SD)	FCLI: 36.8 (4.9)	Control: 39.2 (3.6)
	Fat mass index (kg/m2) Mean (SD)	FCLI: 10.4 (2.3)	Control: 10.9 (2.6)
	Truncal fat mass (kg) Mean (SD)	FCLI: 9.8 (3.3)	Control: 9.4 (2.9)
	Truncal percentage fat (%) Mean (SD)	FCLI: 33.4 (6)	Control: 34.9 (4.4)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Body weight (kg) Mean (SD)	FCLI: 73.3 (16.1)	Control: 70.2 (17.9)
	Weight-for-age and -sex z-score Mean (SD)	FCLI: 2.1 (0.54)	Control: 2.06 (0.63)
	Waist Circumference (cm) Mean (SD)	FCLI: 97.4 (9.4)	Control: 97.1 (10.3)
	Waist Circumference (z-score) Mean (SD)	FCLI: 1.8 (0.3)	Control: 1.8 (0.3)
	BMI (kg/m2) Mean (SD)	FCLI: 28.4 (3.8)	Control: 28.9 (4.9)
	body mass index for age-and-sex Z-scores (BAZ) Mean (SD)	FCLI: 2.59 (0.53)	Control: 2.69 (0.66)
	Total body fat mass (kg) Mean (SD)	FCLI: 26.6 (7.8)	Control: 27.9 (8.8)
	Body fat percentage (%) Mean (SD)	FCLI: 36.1 (5.9)	Control: 39.1 (4.1)
	Fat mass index (kg/m2)	FCLI: 10.4	Control: 11.4

	Mean (SD) Truncal fat mass (kg) Mean (SD) Truncal percentage fat (%) Mean (SD)	(2.7) FCLI: 10.2 (3.4) FCLI: 32.7 (6.8)	(2.9) Control: 10.3 (3.3) Control: 35.1 (4.7)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Coleman, 2017

Guideline record ID: 10754--1

Study characteristics		
Citation	Coleman, K. J., Caparosa, S. L., Nichols, J. F., Fujioka, K., Koebnick, C., McCloskey, K. N., Xiang, A. H., Ngor, E. W., & Levy, S. S. (2017). Understanding the capacity for exercise in post-bariatric patients. Obesity Surgery, 27(1), 51-58. https://doi.org/https://dx.doi.org/10.1007/s11695-016-2240-y	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Understanding the Capacity for Exercise in Post-Bariatric Patients	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"(1) Having had an initial bariatric procedure 6- 24 months prior to the date we began recruitment, (2) having no revisions of this procedure during this time, (3) having no conditions which would prevent them from doing moderate weight-bearing exercise, (4) living in San Diego county, and (5) planning to stay in the county for at least 1 year."	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"We began by adapting an exercise program designed specifically for people with poor functional fitness and/or arthritis to increase all aspects of fitness (aerobic endurance, strength, flexibility, and balance, with emphasis on dynamic balance and mobility). Mobility issues are often cited as barriers to exercise in these bariatric patients. We modified this curriculum to include a mastery learning approach to achieving the final goals of MVPA at least 150 min/week and to include the most enduring strategies for behavior change including self-monitoring, feedback, and goal setting, social support, modeling, and tailoring prescriptions and messages. Finally, we added a maintenance phase with booster exercise sessions and social support. These are all fundamental strategies for successful behavior change that are the foundation of all good exercise programs. Finally, there were a number of modifications we made to tailor the program specifically to post-bariatric patients in various phases of the weight loss trajectory (6-24 months after surgery). These included the concept of functional resistance exercise where patients were taught to use their body weight as the resistance challenge to the neuromuscular system and to focus on proper biomechanical movement during activities of daily living instead of adding a traditional resistance component like weight lifting or the use of resistance bands. This helped patients avoid further musculoskeletal injury in addition to assisting them to adapt to the postural and balance changes that were necessary with large amounts of weight loss. Another adaptation was teaching patients to do flexibility and strength exercises while standing or sitting in a chair instead of lying down, which was very uncomfortable for most participants because of excess skin and body fat. It was also difficult and awkward for patients to rise to a standing position from the floor. All exercises were tailored to the specific needs of each patient according to their abilities and patients were allowed to increase the frequency and intensity of activities as they mastered lower levels of exercise. All exercises had intensity/difficulty levels so that they could be done safely and consistently at home. Handouts with instructions for proper exercise technique were given to all participants for home use. We also incorporated discussions during the exercise class about specific nutritional considerations for exercise in postbariatric patients. These included being prepared for postprandial hypoglycemia, the importance of using vitamin and mineral supplements, and preparing for increases in appetite and the urge to overeat because they would burn the extra calories off. The final exercise prescription and program requirements were as follows: (1) attendance twice per week at a 60-min structured	

<table>
<tr><td></td><td>exercise class, (2) once per week phone counseling sessions to review progress, set new goals, and problem solve barriers to change, (3) wearing a pedometer daily, (4) reading the program curriculum, (5) and recording all out-of-class physical activity and daily pedometer counts in the 10,000 Steps™ website. The maintenance phase was designed to wean participants off the structure and requirements of the program by reducing class attendance to once per week and counseling sessions to once per month. The pedometer and website recording were made optional during maintenance”</td></tr>
<tr><td>Control/Comparator</td><td>“Regular post-operative care for bariatric patients included routine laboratory testing, weight assessment, and phone calls from nurse care managers that included guidance about dietary changes necessary throughout the post-operative period and counseling to encourage regular MVPA. Exercise counseling varied widely and did not contain any standardized recommendations. Phone calls and monitoring were done within the first 2 weeks of surgery, and then at 2 months, 6 months, and annually thereafter.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 51
Intervention group/s: Intervention (n=26)

Comparator group: Usual care control (n=25)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 52.0y (10.9); Control: 46.6y (12.0)</td></tr>
<tr><td>Sex</td><td>84.31% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2) - Baseline
Mean (SD)</td><td>Intervention: 90.8
(23)

Intervention: 32.7
(5.8)</td><td>Usual care control: 93.4
(19.8)

Usual care control: 33.1
(5.8)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>Intervention: 89
(21)</td><td>Usual care control: 94.6
(21.8)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Collins, 2011

Guideline record ID: 10122--1

Study characteristics		
Citation	Collins, C. E., Okely, A. D., Morgan, P. J., Jones, R. A., Burrows, T. L., Cliff, D. P., Colyvas, K., Warren, J. M., Steele, J. R., & Baur, L. A. (2011). Parent diet modification, child activity, or both in obese children: an RCT. Pediatrics, 127(4), 619-627. https://doi.org/10.1542/peds.2010-1518	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Parent Diet Modification, Child Activity, or Both in Obese Children: An RCT	
Location	Australia	
Trial name	Hunter Illawarra Kids Challenge Using Parent Support (HIKCUPS)	
Methods		
Inclusion criteria	"Children were being overweight, as defined by the International Obesity Taskforce cut points12; being aged 5.5 to 9.9 years; and being prepubertal (Tanner Stage I)."	
Exclusion criteria	"Exclusion criteria included being extremely obese (BMI z score 4), having syndromal obesity, having a chronic illness, or taking medications associated with weight change."	
Setting	Home, University/research centre	
Intervention	"Interventions The programs have been described previously.11 Briefly,the HIKCUPS study had 3 intervention arms: a parent-centered dietary-modification program (the Diet arm), a child-centered physical-activity skill-development program (the Activity arm), and a combination of both programs (the Activity Diet arm), each 6 months in duration and each withthefollowing 2 components: 1. A weekly 2-hour face-to-face session for 10 weeks that included homework activities designed to be completed in between face-to-face sessions; and then 2. A 3-month relapse-prevention program that reviewed short- to medium-term goals set by parents, by telephone, monthly for 3 months using a standardized procedure. Diet Program This program11 was based on the Health Belief Model13 and was delivered to parents by accredited practicing dietitians at each site. It incorporated goal setting, problem solving, role modeling, and positive reinforcement by parent(s) to facilitate changes in eating behaviors. ; Activity Diet Program This arm was a combination of both the diet-only and activity-only programs, with parents and children participating concurrently"	
Control/Comparator	"Activity Program This program14 was based on the Competence Motivation Theory15 and was facilitated by physical education teachers at each site. Face-to-face sessions aimed to improve child fundamental movement-skill proficiency, which was related to activity level at baseline,16 with parents participating in the first session and being encouraged to complete the homework activities weekly with their child. A refresher session was conducted 8 weeks after the face to-face program."	
Treatment duration	6 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 206 Intervention group/s: Diet (n=63); PA+Diet (n=70) Comparator group: PA (n=73)	

Mean age ± SD	Diet: 8.2 (1.2); Activity: 8.3 (1.0); Diet + Activity: 8.1 (1.2)
Sex	Not reported
Pre-existing medical condition	No pre-existing medical condition
Results	

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Weight (kg) Mean (SD)	Diet: 46.3 (8.6) PA+Diet: 45.5 (12.2)	PA: 48 (10.8)
BMI (kg/m2) Mean (SD)	Diet: 24.6 (3) PA+Diet: 24.3 (3.7)	PA: 25.2 (4.1)
BMI z score Mean (SD)	Diet: 2.8 (0.6) PA+Diet: 2.8 (0.7)	PA: 2.8 (0.7)
Waist circumference (cm) Mean (SD)	Diet: 76.4 (6.3) PA+Diet: 75.8 (10.6)	PA: 77.6 (9.9)
Waist circumference z score Mean (SD)	Diet: 3.1 (0.7) PA+Diet: 3.1 (1)	PA: 3.2 (1)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point

Variable	Intervention arm/s	Comparator
Weight change (kg) Mean (95% CIs)	Diet: -1.71 (-4.63-1.21) PA+Diet: -0.87 (-3.62-1.77)	PA: 0.42 (-2.39-3.24)
BMI change (kg/m2) Mean (95% CIs)	Diet: 0.73 (0.04) PA+Diet: 1.35 (0.76-1.93)	PA: 1.54 (0.92-2.16)
BMI z score change Mean (95% CIs)	Diet: -0.35 (-0.48--0.22) PA+Diet: -0.24 (-0.35--0.13)	PA: -0.19 (-0.3--0.07)
Waist circumference Mean (95% CIs)	Diet: 2.79 (0.73-4.85) PA+Diet: 5.62 (3.88-7.36)	PA: 5.04 (3.18-6.9)
Waist circumference z score change	Diet: -0.27 (-0.48--0.06)	PA: -0.08 (-0.27-0.11)

	Mean (95% CIs)	PA+Diet: 0.02 (-0.16-0.19)	
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data	West, D. S., Gorin, A. A., Subak, L. L., Foster, G., Bragg, C., Hecht, J., Schembri, M., Wing, R. R., & for the Program to Reduce Incontinence by Diet and Exercise (PRIDE) Research Group. (2011). A motivation-focused weight loss maintenance program is an effective alternative to a skill-based approach. International Journal of Obesity, 35(2), 259-269. https://doi.org/https://dx.doi.org/10.1038/ijo.2010.138		

N/A – Not applicable

Conroy, 2015

Guideline record ID: 10124--1

Study characteristics		
Citation	Conroy, M. B., Sward, K. L., Spadaro, K. C., Tudorascu, D., Karpov, I., Jones, B. L., Kriska, A. M., & Kapoor, W. N. (2015). Effectiveness of a physical activity and weight loss intervention for middle-aged women: healthy bodies, healthy hearts randomized trial. Journal of General Internal Medicine, 30(2), 207-213. https://doi.org/10.1007/s11606-014-3077-5	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effectiveness of a physical activity and weight loss intervention for middle-aged women: healthy bodies, healthy hearts randomized trial	
Location	USA	
Trial name	Healthy Bodies Healthy Hearts (HBHH)	
Methods		
Inclusion criteria	"Women aged 45-65 years, With a BMI ≥ 25 kg/m2 who were relatively physically inactive (less than one hour of PA per week), and receiving primary care at one of three UPMC practices."	
Exclusion criteria	"Unstable cardiac or pulmonary disease (e.g., recent myocardial infarction), poorly controlled hypertension (i.e., systolic blood pressure [SBP] ≥ 180), primary care physician (PCP) unwilling to allow moderate PA, and participant unable to perform moderate PA (i.e., unable to walk due to severe pain)."	
Setting	GP clinic	
Intervention	"IL groups were comprised of 12 weekly group sessions and were conducted in a conference room in the largest of the three primary care practices. The content focused on physical activity, diet, and stress relief adapted from a lifestyle intervention for premenopausal and postmenopausal women, as well as portions of the Diabetes Prevention Program (DPP). Participants were given PA and dietary goals similar to those given in the DPP, with target calorie and fat gram goals based on starting weight and a PA goal of at least 150 min of moderate PA per week. Participants were given a calorie-counter book, a pedometer, and sheets for tracking PA and diet. The sessions included 30 min discussions followed by 30 min of group-based, moderate-intensity PA. Mindfulness concepts were formally introduced through mindful eating and mindful PA sessions, and were integrated throughout the 12 week intervention."	
Control/Comparator	"SG participants received a 12-week, self-guided manual based on the American Heart Association's Choose to Move program20 at randomization, as well as a calorie-counter book and a pedometer. There was no interventionist contact with the SG group, but they had the contact information of study personnel for any questions or concerns."	
Treatment duration	12 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 98 Intervention group/s: Interventionist-led group (n=49) Comparator group: Self-led group (n=49)	

<table>
<tr><td>Mean age ± SD</td><td>Intervention: 53.8y (5.3); Control: 54.0y (5.6)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Interventionist-led group: 95 (18.8)

Interventionist-led group: 36.1 (6)

Interventionist-led group: 106.4 (12.3)</td><td>Self-led group: 89.6 (16.3)

Self-led group: 33.4 (5.4)

Self-led group: 105 (10.4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)

Change in waist circumference (cm)
Mean (SD)</td><td>Interventionist-led group: -1.4 (6.8)

Interventionist-led group: -0.4 (2.6)

Interventionist-led group: -1.6 (6.3)</td><td>Self-led group: -1.4 (3.8)

Self-led group: -0.7 (2.1)

Self-led group: -3.2 (7.1)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Conroy, 2019

Guideline record ID: 10123--1

Study characteristics		
Citation	Conroy, M. B., McTigue, K. M., Bryce, C. L., Tudorascu, D., Gibbs, B. B., Arnold, J., Comer, D., Hess, R., Huber, K., Simkin-Silverman, L. R., & Fischer, G. S. (2019). Effect of electronic health record-based coaching on weight maintenance: a randomized trial. Annals of Internal Medicine, 171(11), 777-784. https://doi.org/https://dx.doi.org/10.7326/M18-3337	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Electronic Health Record-Based Coaching on Weight Maintenance: A Randomized Trial	
Location	USA	
Trial name	Maintaining Activity and Nutrition through Technology-Assisted Innovation in Primary Care (MAINTAIN-pc)	
Methods		
Inclusion criteria	"Eligibility criteria included age 18 to 75 years, inten tional weight loss of at least 5% in the previous 2 years, access to an Internet-connected computer, and receipt of care from a UPMC PCP."	
Exclusion criteria	"Exclusion criteria included a med ical explanation for recent weight loss (for example, can cer), active preparation for bariatric surgery, bariatric surgery in the previous 5 years, or pregnancy."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs), University/research centre	
Intervention	"All participants received a 1-hour orientation on the EHR-based tracking tools (weight, diet, and physical activity tracking flow sheets) and basic information about healthy eating and safe physical activity. Partici pants were encouraged to log in daily and enter data on weight, diet, and physical activity. Those in the coaching group also received an introduction to the role of the coaches. Both groups received weekly re minders to enter information into the EHR-based tracking tools. Participants in the coaching group received 2 years of personalized health coaching through the EHR patient portal. Participants were assigned to a specific coach, who contacted the participants via the EHR weekly for 1 month, biweekly in months 2 to 6, monthly in months 7 to 12, and quarterly in months 13 to 24, for a total of 24 scheduled contacts. Coaching group par ticipants received brief questionnaires relevant to weight management, including a text field where they could discuss questions or barriers. On the basis of par ticipant responses and self-monitoring data in the EHR flow sheets, coaches wrote a brief personalized note with advice on questionnaire topics and responses to any queries or barriers mentioned by the participant."	
Control/Comparator	"All participants received a 1-hour orientation on the EHR-based tracking tools (weight, diet, and physical activity tracking flow sheets) and basic information about healthy eating and safe physical activity. Partici pants were encouraged to log in daily and enter data on weight, diet, and physical activity. Both groups received weekly reminders to enter information into the EHR-based tracking tools. Tracking group participants re ceived questionnaires related to general health promo tion (for example, vaccines) each quarter but received no feedback on questionnaire responses or flow sheet entries."	
Treatment duration	24 months	
Follow-up from baseline	24 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 194
Intervention group/s: Coaching Group (n=98)

Comparator group: Tracking Group (n=96)</td></tr>
<tr><td>Mean age ± SD</td><td>53.4y (12.2)</td></tr>
<tr><td>Sex</td><td>73.71% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Mean weight, kg
Mean (SD)

BMI (kg/m2)
Mean (SD)

waist circumference, cm
Mean (SD)</td><td>Coaching Group: 88.2
(18.7)

Coaching Group: 30.9
(5.7)

Coaching Group: 99.7
(13.9)</td><td>Tracking Group: 83.3
(19.2)

Tracking Group: 29.8
(6.1)

Tracking Group: 96.2
(16.8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Mean weight, kg
Mean (SD)

BMI (kg/m2)
Mean (SD)

waist circumference, cm
Mean (SD)</td><td>Coaching Group: 87.9
(17.9)

Coaching Group: 30.8
(5.4)

Coaching Group: 99.8
(14.3)</td><td>Tracking Group: 81.4
(15.1)

Tracking Group: 29.3
(5.4)

Tracking Group: 94.9
(14.7)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight
Mean (SE)

Change in BMI (kg/m2)
Mean (SE)

Waist circumference, cm
Mean (SE)</td><td>Coaching Group: 0.63
(0.6)

Coaching Group: 0.28
(0.22)

Coaching Group: -0.74
(0.7)</td><td>Tracking Group: 1.94
(0.62)

Tracking Group: 0.74
(0.22)

Tracking Group: 1.33
(0.7)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight
Mean (SE)

Change in BMI (kg/m2)
Mean (SE)

Waist circumference, cm
Mean (SE)</td><td>Coaching Group: 2.07
(0.62)

Coaching Group: 0.8
(0.22)

Coaching Group: 1.34
(0.73)</td><td>Tracking Group: 4.93
(0.63)

Tracking Group: 1.8
(0.23)

Tracking Group: 3.83
(0.74)</td></tr>
</table></td></tr>
</table>

Compliance with treatment	Flow sheet: 15.4%; weight reporting: 9.5%; Diet: 6.0%; PA: 11.9%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Cooper, 2010

Guideline record ID: 10125--1

Study characteristics		
Citation	Cooper, Z., Doll, H. A., Hawker, D. M., Byrne, S., Bonner, G., Eeley, E., O'Connor, M. E., & Fairburn, C. G. (2010). Testing a new cognitive behavioural treatment for obesity: a randomized controlled trial with three-year follow-up. Behaviour Research and Therapy, 48(8), 706-713. https://doi.org/https://dx.doi.org/10.1016/j.brat.2010.03.008	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Testing a new cognitive behavioural treatment for obesity: A randomized controlled trial with three-year follow-up	
Location	UK	
Trial name	N/A	
Methods		
Inclusion criteria	"They were eligible to take part if they met the following criteria: (1) female, (2) aged between 20 and 60 years, (3) body mass index (weight in kg/height in m2 ; BMI) between 30.0 and 39.9, (4) available for treatment for 44 weeks, and (5) willing to participate in the study. Those receiving treatment for hypertension or hypercholesterolemia were eligible to take part provided their condition had been stable on medication over the previous three months. Participants who reported binge eating were eligible to take part."	
Exclusion criteria	"The exclusion criteria were: (1) weight loss of 10% or more within the previous six months, (2) major medical or psychiatric illness (including Type I or Type II diabetes), (3) current psychiatric or psychological treatment, and (4) disorders or treatments known to affect eating, weight or metabolic rate, and disorders in which calorie or fat restriction are contraindicated."	
Setting	Clinic	
Intervention	"BT: BT was based on the Pittsburgh Behavioural Weight Control Manual. It was designed to represent the optimal behavioural treatment available at the time, adapted for use on an individual basis. The style of the treatment was that of modern behaviour therapy with the treatment being applied flexibly so as to match the individual's needs and progress. Well-established behavioural methods were used to help participants change their eating habits and activity level, the aim being that they restrict their energy intake to 1200 kcal daily. Between weeks 24 and 30, and again at week 36, the subject of weight maintenance was raised and participants were given the choice of either continuing to pursue further weight loss for the remainder of treatment or deciding to maintain their new lower weight.; CBT: The new form of CBT was designed to address certain psychological processes that had been hypothesized to interfere with successful weight maintenance. The goal of the new treatment was not only to produce weight loss but also to help people accept and value more modest changes in weight and appearance. The treatment was also designed to encourage the acquisition and practice of weight maintenance skills as these differ from those required to lose weight. The weight loss phase lasted for the first 24e30 weeks (during which participants were helped to restrict their energy intake to about 1500 kcal daily) with the remainder of treatment being devoted to the establishment of weight maintenance skills."	
Control/Comparator	"GSH: This treatment was based on the LEARN Programme for Weight Control (seventh edition)), a widely used weight loss program. The LEARN programme is designed to produce permanent change in five areas of life: lifestyle, exercise, attitudes, relationships and nutrition. Participants are asked to restrict their energy intake to 1200 kcal daily, make healthy food choices, and gradually increase their level of activity. GSH involved participants following the LEARN programme with a limited amount of guidance and	

<table>
<tr><td></td><td>support from a therapist. This mode of treatment delivery was based on our experience using guided self-help in the treatment of eating disorders.”</td></tr>
<tr><td>Treatment duration</td><td>BT: 44 weeks; CBT: 44 weeks; GSH: 24 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>46 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 150
Intervention group/s: BT (n=50); CBT (n=49)

Comparator group: GSH (n=51)</td></tr>
<tr><td>Mean age ± SD</td><td>41.49y (9.07)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>BT: 95.2
(11.15)
CBT: 92.34
(8.81)</td><td>GSH: 95.94
(9.18)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>BT: 86.46
(14.38)
CBT: 86.76
(11.21)</td><td>GSH: 92.97
(11.65)</td></tr>
<tr><td>Proportion with weight loss ≥5%
Proportion (%)</td><td>BT: 60.6%
CBT: 59.2%</td><td>GSH: 19.6%</td></tr>
<tr><td>Proportion with weight loss ≥10%
Proportion (%)</td><td>BT: 42.0%
CBT: 28.6%</td><td>GSH: 15.7%</td></tr>
<tr><td>Proportion with weight loss >5% at the end of treatment maintained over each successive follow-up point
Proportion (%)</td><td>BT: 58.0%
CBT: 55.1%</td><td>GSH: 15.7%</td></tr>
<tr><td>Proportion with weight loss >10% at the end of treatment maintained over each successive follow-up point
Proportion (%)</td><td>BT: 42.0%
CBT: 26.5%</td><td>GSH: 15.7%</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>BT: 91.99
(13.43)
CBT: 91.86
(10.69)</td><td>GSH: 95.9
(10.89)</td></tr>
</table>
</td></tr>
</table>

	Proportion with weight loss ≥5% Proportion (%)	BT: 38.0% CBT: 24.5%	GSH: 17.70%
	Proportion with weight loss ≥10% Proportion (%)	BT: 22.0% CBT: 8.2%	GSH: 7.80%
	Proportion with weight loss >5% at the end of treatment maintained over each successive follow-up point Proportion (%)	BT: 24.0% CBT: 16.3%	GSH: 7.80%
	Proportion with weight loss >10% at the end of treatment maintained over each successive follow-up point Proportion (%)	BT: 12.0% CBT: 2.0%	GSH: 5.90%
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Percentage weight change from baseline Mean (SD)	BT: -9.25 (9.77) CBT: -6.12 (6.71)	GSH: -3.07 (8.05)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Percentage weight change from baseline Mean (SD)	BT: -3.38 (8.27) CBT: -0.44 (7.01)	GSH: 0.05 (7.3)
Compliance with treatment	87.7%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Coppins, 2011

Guideline record ID: 10126--1

Study characteristics		
Citation	Coppins, D. F., Margetts, B. M., Fa, J. L., Brown, M., Garrett, F., & Huelin, S. (2011). Effectiveness of a multi-disciplinary family-based programme for treating childhood obesity (The Family Project). European Journal of Clinical Nutrition, 65(8), 903-909. https://doi.org/10.1038/ejcn.2011.43	
Design & type	Randomised controlled trial (RCT)	Crossover design
Title	Effectiveness of a multi-disciplinary family-based programme for treating childhood obesity (The Family Project)	
Location	UK	
Trial name	Family Project	
Methods		
Inclusion criteria	"Inclusion criteria were children aged 6-14 years with a BMI above the 91st centile. Children with intellectual disability were included if judged able to participate in the intervention activities."	
Exclusion criteria	Not reported	
Setting	School	
Intervention	"The intervention involved two Saturday morning workshops (8 h in total) held 1-2 weeks apart and attendance at two physical activity sessions of 1 h/week during term time throughout the 1-year intervention. Workshops took place in a school (4-12 participants plus 2-10 parents/guardians and siblings involved) and focused on healthy eating, physical activity, reducing sedentary behaviour, behaviour change and psychological well being. The physical activity sessions were led by physical activity instructors and included junior gym sessions (bikes and various weights), circuits, trampolining, rock climbing, table tennis, basketball, tennis, badminton, football and the bleep test. After 1 year, the intervention and waiting list control group crossed over with the waiting list control group receiving the intervention programme and the intervention group receiving no input."	
Control/Comparator	"After 1 year, the intervention and waiting list control group crossed over with the waiting list control group receiving the intervention programme and the intervention group receiving no input."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 65 Intervention group/s: Intervention/Control (n=35) Comparator group: Control/Intervention (n=30)	
Mean age ± SD	Intervention: 133.4 months; Control: 116.9 months	
Sex	66.15% female	

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (95% CIs)

Body mass index (kg/m2)
Mean (95% CIs)

Body mass index SDS
Mean (95% CIs)

Waist circumference (cm)
Mean (95% CIs)

Waist circumference SDS
Mean (95% CIs)</td><td>Intervention/Control: 63.3
(57.9-68.7)

Intervention/Control: 28
(26.7-29.3)

Intervention/Control: 2.7
(2.6-2.9)

Intervention/Control: 86.8
(83.3-90.4)

Intervention/Control: 3
(2.8-3.3)</td><td>Control/Intervention: 55.6
(48.6-62.5)

Control/Intervention: 26.9
(25-28.8)

Control/Intervention: 2.8
(2.5-3)

Control/Intervention: 85.7
(80.7-90.7)

Control/Intervention: 3.3
(3-3.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in weight (unadjusted), kg (baseline to 12 months)
Mean (95% CIs)

Change in waist circumference (cm) (unadjusted) (baseline to 12 months)
Mean (95% CIs)

Change in BMI SDS (unadjusted) (baseline to 12 months)
Mean (95% CIs)</td><td>Intervention/Control: 3.7
(1.6-5.8)

Intervention/Control: 3.4
(1.3)

Intervention/Control: -0.17
(-0.26--0.08)</td><td>Control/Intervention: 5.2
(3.1-7.3)

Control/Intervention: 5.2
(2.8-7.6)

Control/Intervention: -0.08
(-0.24-0.07)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Cornelius, 2016

Guideline record ID: 10127--1

Study characteristics		
Citation	Cornelius, T., Gettens, K., & Gorin, A. A. (2016). Dyadic dynamics in a randomized weight loss intervention. Annals of Behavioral Medicine, 50(4), 506-515. https://doi.org/https://dx.doi.org/10.1007/s12160-016-9778-8	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Dyadic Dynamics in a Randomized Weight Loss Intervention	
Location	USA	
Trial name	Lifestyle Eating and Activity Program (LEAP)	
Methods		
Inclusion criteria	"To be eligible, individuals had to be between 21-70 years old, have a body mass index (BMI) between 25-50 kg/m2, and have a household member willing to participate in the study as a support partner. These partners had to reside in the same home as the participant, be between 15-70 years old, have a BMI between 25- 50 kg/m2, and be interested in weight loss. With the exception of the lower age limit, the same inclusion and exclusion criteria applied to both participants and partners."	
Exclusion criteria	"Individuals were excluded from participation if they reported a heart condition, chest pain during periods of activity or rest, loss of consciousness, being unable to walk 2 blocks without stopping, current participation in another weight loss program and/or taking weight loss medication, current pregnancy or planning on becoming pregnant in the next 18 months, or any condition that in the judgment of the research team made it unlikely the individual would complete the study protocol (i.e., plans to relocate, substance abuse). Individuals endorsing joint problems, prescription medication usage, or other conditions that could limit exercise were required to obtain written physician consent to participate."	
Setting	Hospital, Home, University/research centre	
Intervention	"Group met weekly for 6 months and bimonthly for 12 months. The BWL + H condition aimed to target the individual plus the physical and social cues within their homes. BWL + H participants and their partners were given items to facilitate healthy choices in their homes (e.g., exercise equipment, portion plates, and mo tivational posters) and attended standard treatment together. Additionally, BWL + H aimed to modify the type and amount of food consumed, the availability of exercise equipment, and sedentary activities, and create positive models for healthy eating and exercise in the home by including partners in treatment"	
Control/Comparator	"Group met weekly for 6 months and bimonthly for 12 months. In the BWL group, only primary participants received treatment consisting of a standard calorie and fat-restricted diet (e.g., 1200-1800 kcals/day and 30 % fat, depending on initial weight) and a gradual increase in physical activity until participants reached >200 min of moderate-intensity physical activity per week. Standard treat ment also included training in behavioral weight loss skills such as self-monitoring, goal setting, cognitive restructuring, problem solving, and, later in the program, weight loss maintenance strategies. Participants were encouraged to share information regarding behavioral weight loss strategies with their partners, although partners were untreated."	
Treatment duration	18 months	
Follow-up from baseline	18 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 201
Intervention group/s: BWL plus H (n=102)

Comparator group: BWL (n=99)</td></tr>
<tr><td>Mean age ± SD</td><td>47.84y (13.08)</td></tr>
<tr><td>Sex</td><td>78.11% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Data could not be extracted</td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Data could not be extracted</td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Gorin, A. A., Raynor, H. A., Fava, J., Maguire, K., Robichaud, E., Trautvetter, J., Crane, M., & Wing, R. R. (2013). Randomized controlled trial of a comprehensive home environment-focused weight-loss program for adults. Health Psychology, 32(2), 128-137. https://doi.org/https://dx.doi.org/10.1037/a0026959</td></tr>
</table>

N/A – Not applicable

Cornelli, 2017

Guideline record ID: 10128--1

Study characteristics		
Citation	Cornelli, U., Belcaro, G., Recchia, M., & D'Orazio, N. (2017). Long-term treatment of overweight and obesity with polyglucosamine (PG L112): randomized study compared with placebo in subjects after caloric restriction. Current Developments in Nutrition, 1(10), e000919. https://doi.org/https://dx.doi.org/10.3945/cdn.117.000919	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-Term Treatment of Overweight and Obesity with Polyglucosamine (PG L112): Randomized Study Compared with Placebo in Subjects after Caloric Restriction	
Location	Italy	
Trial name	N/A	
Methods		
Inclusion criteria	"The inclusion criteria were as follows: 1) age between 25 and 65 y, 2) BMI (in kg/m2) range of .30 to,35, and 3) able to complete the food intake assessment (FIA) questionnaire correctly."	
Exclusion criteria	"The exclusion criteria were as follows: 1) inability to complete the FIA questionnaire and comply with the trial protocol criteria; 2) pregnancy or breastfeeding; 3) receiving treatments for BW reduction or metabolic syndrome; 4) alcohol abuse, drug abuse, or drug addiction; 5) cancer or malignant tumors; 6) known hypersensitivity reactions to crustaceans or any of the ingredients in the products; 7) pre-existence of chronic intestinal disease, such as constipation requiring medical treatment; 8) postoperative state after gastrointestinal surgery; 9) metabolic disorders or chronic malabsorption disorder; 10) current use of medications that decrease intestinal motility, such as opiates; and 11) long-term use of medications, with the exception of antihypertensive drugs."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"In addition to a 10% calorie restriction and an increase in physical activity (9 MET-h/wk), 1 group received treatment: PG (Formoline L112; manufactured by Certmedica International GmbH). Each patient took 2 tablets/d with the 2 meals containing the highest fat content, which meant 4 tablets/d with 400 mg PG L112. If the patients were receiving other treatments that consisted of lipophilic medications, they were asked to take them >2 h apart."	
Control/Comparator	"In addition to a 10% calorie restriction and an increase in physical activity (9 MET-h/wk), 1 group received placebo (PL): 2 x 2 tablets before the 2 main meals for 12 mo. Placebo consisted of excipients and gum arabic in the form of tablets that were identical to those of the PG group. Each patient took 2 tablets/d with the 2 meals containing the highest fat content, which meant 400 mg placebo. If the patients were receiving other treatments that consisted of lipophilic medications, they were asked to take them >2h apart."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 100 Intervention group/s: PG (n=50)	

<table>
<tr><td></td><td>Comparator group: PL (n=50)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>50.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>PG: 95.2
(6.73)

PG: 115.1
(8.65)

PG: 33.9
(1.03)</td><td>PL: 95.5
(8.07)

PL: 115.2
(8.71)

PL: 34.1
(1.03)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>PG: 83.1
(6.27)

PG: 101.8
(7.89)

PG: 29.6
(1.06)</td><td>PL: 87.5
(6.94)

PL: 105
(7.02)

PL: 31.3
(1.23)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in bodyweight (%)
Mean (SD)

Change in waist circumference (cm)
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)</td><td>PG: -12.7

PG: -11.6

PG: -12.7</td><td>PL: -7.8

PL: -8.8

PL: -8.2</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Coughlin, 2013

Guideline record ID: 10130--1

Study characteristics		
Citation	Coughlin, J. W., Gullion, C. M., Brantley, P. J., Stevens, V. J., Bauck, A., Champagne, C. M., Dalcin, A. T., Funk, K. L., Hollis, J. F., Jerome, G. J., Lien, L. F., Loria, C. M., Myers, V. H., & Appel, L. J. (2013). Behavioral mediators of treatment effects in the weight loss maintenance trial. Annals of Behavioral Medicine, 46(3), 369-381. https://doi.org/10.1007/s12160-013-9517-3	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Behavioral mediators of treatment effects in the weight loss maintenance trial	
Location	USA	
Trial name	Weight Loss Maintenance (WLM)	
Methods		
Inclusion criteria	"Inclusion criteria for entry to phase 1 of the Weight Loss Maintenance Trial 1 included: BMI between 25 and 45 kg/m2, taking medication for hypertension, dyslipidemia, or both; aged 25 or greater, and willingness to abstain from weight loss medications and bariatric surgery during the study. Randomization into phase 2 required a weight loss of at least 4 kg during phase 1."	
Exclusion criteria	"Exclusion criteria included active or recent cardiovascular disease, medication-treated diabetes mellitus, recent weight loss of >9 kg, weight loss surgery, and other medical or psychiatric conditions that were contraindications to study participation."	
Setting	Home, monthly individual contact with an interventionist face-toface individual sessions occurred approximately every 4th month and ranged from 45 to 60 min in duration	
Intervention	"All participants: In brief, phase 1 was a group-based behavioral intervention led by a trained interventionist over 20 sessions [6]. Intervention goals included 180 min/week of moderate-to-vigorous physical activity, reduced caloric intake, and adoption of the dietary approaches to stop hypertension (DASH) dietary program, which emphasizes eating fruits, vegetables, and low-fat dairy products while reducing total and saturated fat [14, 15].; Personal contact (PC): The personal contact arm of phase 2 included monthly individual contact with an interventionist, during which key components of phase 1 were reinforced. Most personal contact sessions were by phone and lasted from 5 to 15 min; face-toface individual sessions occurred approximately every 4th month and ranged from 45 to 60 min in duration. Personal contact sessions consisted of an update of progress, support from the interventionist, accountability for previous goals, and a discussion of barriers and successes; Interactive Technology (IT): Participants in the interactive technology arm had unlimited access to a projectspecific website designed to support weight loss maintenance. Participants were encouraged to login at least weekly to enter their current weight, caloric intake, and physical activity minutes. Features of the Interactive technology intervention included goal setting and action planning exercises, graphing of personal data over time, a bulletin board offering social support among participants, modules teaching problem solving and motivation, and automated e-mail and phone calls prompting login behavior after periods of no contact [7]. Unlike the personal contact intervention, the interactive technology intervention did not include personal feedback from or interaction with an interventionist."	
Control/Comparator	"Self-directed (SD): At randomization, those in the selfdirected arm received a printed lifestyle guideline with the phase 1 diet and physical activity goals. They met briefly with a study interventionist at the 12-month data collection visit."	
Treatment duration	30 months	

<table>
<tr><td>Follow-up from baseline</td><td>30 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 880
Intervention group/s: IT (n=301); PC (n=292)

Comparator group: SD (n=287)</td></tr>
<tr><td>Mean age ± SD</td><td>IT: 56.0y (8.5); PC:55.8y (9.1); SD: 56.0y (8.6)</td></tr>
<tr><td>Sex</td><td>61.70% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight at randomization (kg)
Mean (SD)</td><td>IT: 88.1
(15.2)
PC: 88.1
(17.1)</td><td>SD: 86.9
(15)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Mean (SD)</td><td>IT: 5.2
(5.8)
PC: 4
(5.3)</td><td>SD: 5.9
(6.3)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Coughlin, J. W., Brantley, P. J., Champagne, C. M., Vollmer, W. M., Stevens, V. J., Funk, K., Dalcin, A. T., Jerome, G. J., Myers, V. H., Tyson, C., Batch, B. C., Charleston, J., Loria, C. M., Bauck, A., Hollis, J. F., Svetkey, L. P., Appel, L. J., & the Weight Loss Maintenance Collaborative Research Group. (2016). The impact of continued intervention on weight: five-year results from the weight loss maintenance trial. Obesity, 24(5), 1046-1053. https://doi.org/https://dx.doi.org/10.1002/oby.21454</td></tr>
</table>

N/A – Not applicable

Coughlin, 2016

Guideline record ID: 10129--1

Study characteristics		
Citation	Coughlin, J. W., Brantley, P. J., Champagne, C. M., Vollmer, W. M., Stevens, V. J., Funk, K., Dalcin, A. T., Jerome, G. J., Myers, V. H., Tyson, C., Batch, B. C., Charleston, J., Loria, C. M., Bauck, A., Hollis, J. F., Svetkey, L. P., Appel, L. J., & the Weight Loss Maintenance Collaborative Research Group. (2016). The impact of continued intervention on weight: five-year results from the weight loss maintenance trial. Obesity, 24(5), 1046-1053. https://doi.org/https://dx.doi.org/10.1002/oby.21454	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The impact of continued intervention on weight: Five-year results from the weight loss maintenance trial	
Location	USA	
Trial name	Weight Loss Maintenance (WLM)	
Methods		
Inclusion criteria	"Participants were adults with a body mass index (BMI) of 25-45 kg/ m2 who were taking medication for hypertension and/or dyslipidemia."	
Exclusion criteria	"The primary criterion for randomization into Phase 2 was weight loss of at least 4 kg during Phase 1. All Phase 2 participants at participating sites were invited to continue into Phase 3."	
Setting	Home, every fourth month when they had a 45-60 min individual, face-to-face contact	
Intervention	"PC-Active and PC-Control: During Phase 2, PC participants had telephone contact with interventionists trained in motivational interviewing and behavioral weight management for 15 min/month, except every fourth month when they had a 45-60 min individual, face-to-face contact. Those randomized to PC-Active in Phase 3 attended four, weekly group sessions. After these sessions, PC-Active participants continued monthly phone contacts, employing the same contact schedule, format, and general content as in Phase 2. Each PC-Active contact began with a reported weight and a review of progress, including frequency of food diaries and self-weighing, minutes/week of exercise, and progress toward goals. PC-Controls received no further intervention after completing Phase 2"	
Control/Comparator	"Self-directed (SD) participants received printed lifestyle guidelines with diet and physical activity recommendations at the Phase 2 randomization visit and met briefly with a study interventionist after the 12-month data collection visit (15). They received no further instructions or visits during the remainder of Phases 2 or 3."	
Treatment duration	60 months	
Follow-up from baseline	60 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 414 Intervention group/s: PC-Active (n=98); PC-Control (n=98) Comparator group: SD (n=218)	
Mean age ± SD	PC-Active: 55.1y (9.1); PC-Control: 55.1y (9.2); SD: 55.4y(8.8)	

<table>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>PC-Active: 86
(15.8)
PC-Control: 88.5
(17.6)</td><td></td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>PC-Active: 30.8
(4.7)
PC-Control: 31.1
(4.7)</td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>PC-Active: 90.1
(16.9)
PC-Control: 92.1
(18.6)</td><td></td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>PC-Active: 32.3
(5.1)
PC-Control: 32.3
(5.1)</td><td></td></tr>
<tr><td>No more than 3% above weight at 2nd randomization - proportion with 95% CIs
Proportion (%)</td><td>PC-Active: 61
(51-71)
PC-Control: 64
(54-73)</td><td>SD: 65
(58-71)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>At or below entry weight (n) - proportion with 95% CIs
Proportion (%)</td><td>PC-Active: 75
(65-83)
PC-Control: 79
(69-86)</td><td>SD: 63
(56-69)</td></tr>
<tr><td>Maintained at least 4 kg loss from entry - proportion with 95% CIs
Proportion (%)</td><td>PC-Active: 36
(27-46)
PC-Control: 44
(34-54)</td><td>SD: 36
(30-43)</td></tr>
<tr><td>At least 5% below entry weight - proportion with 95% CIs
Proportion (%)</td><td>PC-Active: 37
(28-48)
PC-Control: 38
(29-49)</td><td>SD: 27
(21-34)</td></tr>
<tr><td>No more than 3% above weight at 1st randomization - proportion with 95% CIs
Proportion (%)</td><td>PC-Active: 37
(28-48)
PC-Control: 35
(26-45)</td><td>SD: 26
(20-32)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight gain (kg) (30 month-60 month period)</td><td>PC-Active: 1
(3.4)</td><td></td></tr>
</table>
</td></tr>
</table>

	Mean (SD)	PC-Control: 0.5 (6.1)	
Compliance with treatment	PC-Active: 77%		
Notes			
Additional included publications arising from this study that did not contribute additional data	Coughlin, J. W., Gullion, C. M., Brantley, P. J., Stevens, V. J., Bauck, A., Champagne, C. M., Dalcin, A. T., Funk, K. L., Hollis, J. F., Jerome, G. J., Lien, L. F., Loria, C. M., Myers, V. H., & Appel, L. J. (2013). Behavioral mediators of treatment effects in the weight loss maintenance trial. Annals of Behavioral Medicine, 46(3), 369-381. https://doi.org/10.1007/s12160-013-9517-3		

N/A – Not applicable

Courcoulas, 2020

Guideline record ID: 10132

Study characteristics		
Citation	Courcoulas, A. P., Gallagher, J. W., Neiberg, R. H., Eagleton, E. B., DeLany, J. P., Lang, W., Punchai, S., Gourash, W., & Jakicic, J. M. (2020). Bariatric surgery vs lifestyle intervention for diabetes treatment: 5-year outcomes from a randomized trial. The Journal of Clinical Endocrinology & Metabolism, 105(3), 866–876. https://doi.org/10.1210/clinem/dgaa006	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Bariatric Surgery vs Lifestyle Intervention for Diabetes Treatment: 5-Year Outcomes From a Randomized Trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Adults were eligible for enrollment if they were 25 to 55 years of age and had a BMI of 30 to 40 because these characteristics represent a high-priority subgroup for comparative effectiveness studies.11 Diagnosis of T2DM was confirmed by a documented fasting plasma glucose (FPG) level of 126 mg/dL or greater (to convert to millimoles per liter, multiply by 0.0555) and/or treatment with antidiabetics to include a broad spectrum of T2DM severity. For participants with grade I obesity, treatment with antidiabetics and permission from their treating physician were required to participate."	
Exclusion criteria	"Adults were excluded for prior weight loss surgery, impaired mental status, alcohol or other drug addiction, current smoking, pregnancy or planned pregnancy, inability to tolerate general anesthesia owing to poor health, type 1 diabetes mellitus, failed nutritional or psychological assessment, unwillingness to be randomized, inability to provide informed consent, or being deemed unlikely to comply with study visits or procedures."	
Setting	Hospital, Home	
Intervention	"The RYGB was performed with a standard retrocolicretrogastric technique using a linear stapled and hand-sewn gastrojejunal anastomosis. The LAGB was performed using 1 of 2 gastric banding devices (Allergan 10 or AP Standard LapBand; Allergan, Inc) with sutures to secure the gastric cardia and prevent slippage and placement of the infusion port on the anterior rectus muscle. Those participants undergoing surgical intervention were counseled on a diet program consistent with postbariatric surgery recommendations and were encouraged to exercise aminimum of 3 to 4 times per week and to focus on weightbearing aerobic activity. After the first year of follow-up, the postsurgical patients (RYGB and LAGB) were provided instruction on the behavioral changes for weight control that participants in the LWLI were taught during their year 1 intervention. The LLLI for all groups comprised an in-person session (approximately 30-40 minutes) and a brief telephone call (less than 10 minutes) per month plus regular refresher group meetings. At each meeting, a specific behavioral change concept related to weight loss was targeted. If a participant was unable to attend the in-person session, a telephone call was utilized, and relevant materials were mailed to the individual."	
Control/Comparator	"Participants randomized to the LWLI underwent a standard behavioral weight control program delivered using an inperson, individual format based on the intervention developed for the Diabetes Prevention Program20 and the Look AHEAD trial21 and adapted into a 12-month program for subjects with grades I to II obesity. During the initial 6 months of treatment, LWLI participants attended weekly in-person intervention sessions. During months 7 to 12, they attended inperson sessions in the first and third weeks of the month and received brief telephone contacts in the second and fourth weeks. Each session	

<table>
<tr><td></td><td>focused on a specific behavioral topic related to weight loss, eating, or exercise behaviors. Participants were provided with supplemental written materials and were asked to self-monitor body weight, eating, and exercise. All LWLI participants were prescribed an energy-restricted diet (1200-1800 kcal/d) and were provided meal plans, meal replacements, and calorie-counter books.Moderate-intensity exercise was prescribed 5 days each week beginning at 20 minutes per day and gradually progressing to at least 60 minutes per day, with bouts of activity encouraged to be longer than 10 minutes. The LLLI for all groups comprised an in-person session (approximately 30-40 minutes) and a brief telephone call (less than 10 minutes) per month plus regular refresher group meetings. At each meeting, a specific behavioral change concept related to weight loss was targeted. If a participant was unable to attend the in-person session, a telephone call was utilized, and relevant materials were mailed to the individual."</td></tr>
<tr><td>Treatment duration</td><td>5 years</td></tr>
<tr><td>Follow-up from baseline</td><td>5 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 61
Intervention group/s: RYGB (n=20); LAGB (n=21)

Comparator group: LWLI (n=20)</td></tr>
<tr><td>Mean age ± SD</td><td>47.3y (6.6)</td></tr>
<tr><td>Sex</td><td>81.97% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg) - Baseline
Mean (SE)</td><td>RYGB: 99.27
(2.99)
LAGB: 100.2
(3.06)</td><td>LWLI: 102
(3.19)</td></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SE)</td><td>RYGB: 35.67
(0.61)
LAGB: 35.58
(0.75)</td><td>LWLI: 35.75
(0.73)</td></tr>
<tr><td>Waist circumference (cm) - baseline
Mean (SE)</td><td>RYGB: 110.6
(1.83)
LAGB: 114.5
(2.59)</td><td>LWLI: 111.8
(2.13)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight change (kg) from baseline
Mean (SE)</td><td>RYGB: -28.7
(1.64)
LAGB: -17.6
(1.78)</td><td>LWLI: -7.52
(1.95)</td></tr>
</table>
</td></tr>
</table>

	% weight change from baseline Mean (SE) BMI (kg/m2) change from baseline Mean (SE) Waist circumference (cm) change from baseline Mean (SE)	 RYGB: -29.1 (1.62) LAGB: -17.6 (1.73) RYGB: -10.2 (0.57) LAGB: -6.13 (0.62) RYGB: -26.9 (1.58) LAGB: -16 (1.67)	 LWLI: -7.94 (1.92) LWLI: -2.4 (0.65) LWLI: -5.42 (1.8)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Weight change (kg) from baseline Mean (SE) % weight change from baseline Mean (SE) BMI (kg/m2) change from baseline Mean (SE) Waist circumference (cm) change from baseline Mean (SE)	RYGB: -24.9 (2.12) LAGB: -12.6 (2.01) RYGB: -25.2 (2.09) LAGB: -12.7 (1.98) RYGB: -8.75 (0.76) LAGB: -4.38 (0.71) RYGB: -18.9 (1.8) LAGB: -10.4 (1.75)	LWLI: -4.5 (2.51) LWLI: -5.14 (2.46) LWLI: -1.2 (0.85) LWLI: -6.02 (2.02)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Cox, 2021

Guideline record ID: 10134--1

Study characteristics		
Citation	Cox, D. J., Oser, T., Moncrief, M., Conaway, M., & McCall, A. (2021). Long-term follow-up of a randomized clinical trial comparing glycemic excursion minimization (GEM) to weight loss (WL) in the management of type 2 diabetes. BMJ Open Diabetes Research & Care, 9(2), e00240. https://doi.org/https://dx.doi.org/10.1136/bmjdrc-2021-002403	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-term follow-up of a randomized clinical trial comparing glycemic excursion minimization (GEM) to weight loss (WL) in the management of type 2 diabetes	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"GEM training involved four 90 min group sessions focused on reducing postnutrient glucose excursions (area under the curve) by the mechanisms of: (1) educating participants on the glycemic impact of different foods and activity choices, (2) diminishing BG elevations through moderate reduction of certain carbohydrates, and (3) hastening BG recovery by increasing postprandial and routine physical activity."	
Control/Comparator	"WL training involved six 60 min group sessions adapted from lessons in the Centers for Disease Control and Prevention's (CDC) 'Prevent T2' curriculum aimed at: (1) reducing caloric intake and (2) increasing moderate to vigorous physical activity."	
Treatment duration	3 months	
Follow-up from baseline	13 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= Not reported Intervention group/s: GEM (n=Not reported) Comparator group: WL (n=Not reported)	
Mean age ± SD	Not reported	
Sex	Not reported	
Pre-existing medical condition	T2DM for ≤10 years, an HbA1c ≥6.8% (51 mmol/mol), and were not using insulin	
Results		
Outcome measure at baseline	Variable / Intervention arm/s / Comparator ( ) / ( ) / ( )	

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>GEM: -1
(1.6)</td><td>WL: -0.9
(1.4)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Crespo, 2012

Guideline record ID: 10755--1

Study characteristics		
Citation	Crespo, N. C., Elder, J. P., Ayala, G. X., Slymen, D. J., Campbell, N. R., Sallis, J. F., McKenzie, T. L., Baquero, B., & Arredondo, E. M. (2012). Results of a multi-level intervention to prevent and control childhood obesity among Latino children: the Aventuras Para Ninos Study. Annals of Behavioral Medicine, 43(1), 84-100. https://doi.org/https://dx.doi.org/10.1007/s12160-011-9332-7	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Results of a multi-level intervention to prevent and control childhood obesity among Latino children: the Aventuras Para Ninos Study	
Location	USA	
Trial name	Aventuras para Niños	
Methods		
Inclusion criteria	"All schools in the target region were identified and screened for the following eligibility criteria: (1)Latino enrollment of at least 70%; (2) a defined attendance boundary (no charter or magnet schools); and (3) no other obesity prevention programs or additional physical education training for teachers within the past 4 years. Eligible families self-identified as Latino, had a child in kindergarten, first, or second grade who attended one of the 13 schools, had no major health problems that limited participation, lived within the school attendance boundaries, and intended to live in the area for at least 1 year."	
Exclusion criteria	Not reported	
Setting	Home, School	
Intervention	"Briefly, Family intervention included Promotora home visits, newsletters, recipe cards and goal setting. Based on Health Belief Model & Social Cognitive Theory. Promotoras discussed with participants ways to overcome barriers to healthy eating and physical activity, ways to prepare healthy meals in the home, benefits of promoting healthy eating and PA in their children, ways to set appropriate goals for the family and monitor healthy eating in the home, and modelling healthy eating. Visits were 1 per month for 7 months (over one school year). Key behaviours targeted during the discussions focused on increasing fruit, vegetable, and water consumption, increasing active play and decreasing sugar-sweetened beverages and TV viewing. Targeted environmental changes included having cut-up vegetables within a child's reach and moving a TV out of a child's bedroom, as well as contingency management such as rules and boundaries set by parents, discipline methods and use of positive reinforcement. Promotoras followed-up participants with booster calls (4 times over 2 years). Briefly, Community intervention included school playgrounds (improvements) and salad bars (implementation and improvement); community parks (improvements); Physical education equipment; implemented healthy children's menus at restaurants within a 1-mile radius; culturally appropriate media messages. All participating teachers were asked to place posters in the classroom and distribute newsletter about healthy eating to students; frequent produce buyer cards were distributed throughout the community (3 years) Posters for healthy eating."	
Control/Comparator	"The control condition consisted of measures only. Participants in the control condition were asked to maintain their regular lifestyles and to complete the yearly measurements."	
Treatment duration	1 year	
Follow-up from baseline	36 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 796
Intervention group/s: Family-Only (n=194); Family+Community (n=163); Community- Only (n=216)

Comparator group: Control (n=223)</td></tr>
<tr><td>Mean age ± SD</td><td>5.9y (0.9)</td></tr>
<tr><td>Sex</td><td>50.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of participants overweight
Proportion (%)

Proportion of participants Obese
Proportion (%)</td><td>Family-Only: 14.0%
Family+Community: 19.0%
Community-Only: 19.0%

Family-Only: 31.0%
Family+Community: 27.0%
Community-Only: 28.0%</td><td>Control: 18.0%

Control: 31.0%</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of participants overweight
Proportion (%)

Proportion of participants Obese
Proportion (%)</td><td>Family-Only: 17.0%
Family+Community: 17.0%
Community- Only: 19.0%

Family-Only: 29.0%
Family+Community: 27.0%
Community- Only: 26.0%</td><td>Control: 17.0%

Control: 33.0%</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of participants overweight
Proportion (%)

Proportion of participants Obese
Proportion (%)</td><td>Family-Only: 23.0%
Family+Community: 18.0%
Community-Only: 20.0%

Family-Only: 30.0%
Family+Community: 32.0%
Community-Only: 35.0%</td><td>Control: 13.00%

Control: 35.00%</td></tr>
</table>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Crespo, 2018

Guideline record ID: 10137--1

Study characteristics		
Citation	Crespo, N. C., Talavera, G. A., Campbell, N. R., Shadron, L. M., Behar, A. I., Slymen, D., Ayala, G. X., Wilfley, D., & Elder, J. P. (2018). A randomized controlled trial to prevent obesity among Latino paediatric patients. Pediatric Obesity, 13(11), 697-704. https://doi.org/https://dx.doi.org/10.1111/ijpo.12466	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A randomized controlled trial to prevent obesity among Latino paediatric patients	
Location	USA	
Trial name	Luces de Cambio/Lights of Change (Luces)	
Methods		
Inclusion criteria	"5 - 10 year olds, BMI between the 75th and 98.9th percentile, Other eligibility criteria for families were: 1) planning on living in the target area for the study duration, 2) ability to understand and read Spanish or English, 3) willing to be randomized into one of the two experimental conditions and 4) willing/able to attend the intervention classes if randomized to that condition."	
Exclusion criteria	"Exclusion criteria included: 1) children on a medically-prescribed restricted diet, 2) children with a condition that limits their ability to be physically active or that would affect growth or participation in the intervention, and 3) children who participated in other clinic-based overweight/obesity programs within the past year."	
Setting	GP clinic	
Intervention	"Luces emphasized changes in parenting behaviors and improving parent-provider communication to reduce child BMI and promote weight maintenance. The intervention targeted three child health behaviors (dietary behaviors, physical activity, and sedentary behaviors) and corresponding parenting behaviors (role modeling, parenting strategies, and restructuring the home environment). The culturally sensitive Luces program included individual, family, and community components in the context of the Mexican-derived culture of Southern California. A traffic light concept was the basis for the Luces program, where green activities (e.g., active play & family walks) and green foods and beverages (e.g., vegetables & water) were encouraged, while red activities (e.g., watching television) and red foods (e.g., sodas & chips) were discouraged. The components of the 12-month Luces program included: a) seven 1.5 - 2-hour group classes with parents and children led by trained bilingual Luces Lay Health Educators, held over 6-months (four classes the first two months and three classes between three to six months; b) two visits at the clinic with a clinic mid-level provider (MLP; physician assistant) once before and once after the seven group classes to reinforce key messages from the program; c) six scripted phone calls (averaging 10 minutes in length) with the Lay Health Educator (LHE) after each of the first six group classes to reinforce concepts taught in class; and d) six monthly group booster classes. The total contact time totaled 19.75 hours over the 12-month period."	
Control/Comparator	"The usual care condition consisted of standard clinical practices offered by pediatricians to pediatric patients with overweight/obesity (e.g., basic nutrition education, health education handouts, didactic education), including two one-on-one visits with a Health Educator, supplemented by follow-up visits with the patient's primary care physician when deemed clinically-appropriate. The total contact time for participants in the usual care condition ranged from 1.25 to 2.25 hours."	
Treatment duration	12 months	

<table>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 297
Intervention group/s: Luces Intervention (n=149)

Comparator group: Usual Care (n=148)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 98.0 (17.6) months; Control: 96.3 (19.6) months</td></tr>
<tr><td>Sex</td><td>49.83% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2) (ITT)
Mean (SD)</td><td>Luces Intervention: 20.7
(2.9)</td><td>Usual Care: 20.5
(2.8)</td></tr>
<tr><td>BMI percentile
Mean (SD)</td><td>Luces Intervention: 92.4
(5.9)</td><td>Usual Care: 91.8
(6.6)</td></tr>
<tr><td>BMI z-score
Mean (SD)</td><td>Luces Intervention: 1.57
(0.44)</td><td>Usual Care: 1.54
(0.46)</td></tr>
<tr><td>DXA Total % fat (per protocol)
Mean (SD)</td><td>Luces Intervention: 33.9
(7.5)</td><td>Usual Care: 31.4
(7.8)</td></tr>
<tr><td>DXA Trunk % fat (per protocol)
Mean (SD)</td><td>Luces Intervention: 34.7
(8.7)</td><td>Usual Care: 31.4
(9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2) (ITT)
Mean (SE)</td><td>Luces Intervention: 21.6
(0.2)</td><td>Usual Care: 21.5
(0.1)</td></tr>
<tr><td>BMI percentile
Mean (SE)</td><td>Luces Intervention: 91
(0.7)</td><td>Usual Care: 89.5
(0.6)</td></tr>
<tr><td>BMI z-score
Mean (SE)</td><td>Luces Intervention: 1.5
(0.03)</td><td>Usual Care: 1.46
(0.03)</td></tr>
<tr><td>DXA Total % fat (per protocol)
Mean (SE)</td><td>Luces Intervention: 34.2
(0.6)</td><td>Usual Care: 36.1
(0.5)</td></tr>
<tr><td>DXA Trunk % fat (per protocol)
Mean (SE)</td><td>Luces Intervention: 35.6
(0.7)</td><td>Usual Care: 37.4
(0.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Cummings, 2016

Guideline record ID: 10139--1

Study characteristics		
Citation	Cummings, D. E., Arterburn, D. E., Westbrook, E. O., Kuzma, J. N., Stewart, S. D., Chan, C. P., Bock, S. N., Landers, J. T., Kratz, M., Foster-Schubert, K. E., & Flum, D. R. (2016). Gastric bypass surgery vs intensive lifestyle and medical intervention for type 2 diabetes: the CROSSROADS randomised controlled trial. Diabetologia, 59(5), 945-953. https://doi.org/https://dx.doi.org/10.1007/s00125-016-3903-x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Gastric bypass surgery vs intensive lifestyle and medical intervention for type 2 diabetes: the CROSSROADS randomised controlled trial	
Location	USA	
Trial name	Calorie Reduction Or Surgery: Seeking to Reduce Obesity And Diabetes Study (CROSSROADS)	
Methods		
Inclusion criteria	"Age 25-64, with type 2 diabetes and a BMI 30-45 kg/m2."	
Exclusion criteria	"Candidates were considered ineligible if they had any of the following: pregnancy, cancer (except nonmelanoma skin cancer), ascites, peritoneal effusion, dementia, bipolar disorder, schizophrenia, cirrhosis, end-stage renal disease, human immunodeficiency virus, inflammatory bowel disease, diagnosed type 1 diabetes, diabetes secondary to a specific disease or glucocorticoid therapy, prior bariatric or major gastrointestinal surgery or organ transplantation. These exclusions were designed to eliminate patients who were at greater-than-average risk for complications, disease-related weight change or nonadherence to treatment and follow-up visits."	
Setting	Hospital, Home	
Intervention	"Participants randomised to surgery underwent a laparoscopic proximal RYGB, using an estimated 40 ml gastric pouch, 100-150 cm alimentary limb, a biliopancreatic limb that included 30-50 cm of jejunum beyond the ligament of Treitz, an antecolic/antegastric approach, and combined stapled and sutured technique. Surgical patients also underwent a 4-week pre-operative and 10-month postoperative behavioural treatment regimen. In the pre-operative phase, patients had weekly telephone-based appointments with a health educator and were required to attend 2-3 bariatric support group meetings. Patients continued to have phone appointments with their health educator for 10 months after surgery. The postoperative behavioural treatment programme focused on diet and nutrition counselling, behaviour modification and exercise recommendations. glycaemic index foods. In the second 6-month phase of the study, participants were contacted weekly by the dietitian via telephone or email, and were encouraged to attend monthly inperson group nutrition sessions. Diabetes-related medical care Medical care, including pharmaceutical diabetes treatment, was provided similarly in both groups by each participant's own primary care physician, based on guidelines of the American Diabetes Association (ADA) and European Association for the Study of Diabetes [26]. Study staff conducted quarterly chart reviews to ensure these guidelines were met. Hypertension and lipid-lowering medications were prescribed according to ADA guidelines using the following treatment goals: blood pressure ≤130/ 80 mmHg and LDL-cholesterol ≤2.6 mmol/l."	
Control/Comparator	"The ILMI The ILMI was a 12-month, in-person and telephone-based programme that included behaviour modification skills counselling, combined with training in diet and exercise change. Exercise intervention The focus of the exercise intervention was a gradual increase in brisk walking or other activities of similar moderate aerobic intensity over 12 months. Participants were asked to attend ≥3 exercise physiologist-supervised sessions per	

<table>
<tr><td></td><td>week at the FHCRC Prevention Center Exercise Testing and Training Center, a dedicated research gym, and they were asked to exercise an additional ≥2 days/week at home for the first 6 months. For the remaining 6 months, participants were asked to exercise ≥1 day/week at the Prevention Center and ≥4 days/week at home. In summary, they were directed to exercise ≥45 min/day, ≥5 days/week, for 1 year. Dietary intervention The dietary intervention was conducted by a research dietitian trained in behaviour modification. Each participant was required to attend weekly group nutrition sessions for the first 6 months. These sessions were based on DPP [24], with several modifications for our diabetic participants. Although reduced calorie intake and weight loss were strongly encouraged, participants were not given specific weight loss goals. Instead, the dietary intervention emphasised food quality by encouraging consumption of protein, fresh fruits and vegetables, and avoidance of processed foods. The programme advocated a slightly higher percentage of energy from protein and fat, combined with avoidance of high glycaemic index foods. In the second 6-month phase of the study, participants were contacted weekly by the dietitian via telephone or email, and were encouraged to attend monthly inperson group nutrition sessions. Diabetes-related medical care Medical care, including pharmaceutical diabetes treatment, was provided similarly in both groups by each participant's own primary care physician, based on guidelines of the American Diabetes Association (ADA) and European Association for the Study of Diabetes [26]. Study staff conducted quarterly chart reviews to ensure these guidelines were met. Hypertension and lipid-lowering medications were prescribed according to ADA guidelines using the following treatment goals: blood pressure ≤130/ 80 mmHg and LDL-cholesterol ≤2.6 mmol/l.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 32
Intervention group/s: Surgical (n=15)

Comparator group: ILMI (n=17)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 52.0y (8.3); Control 54.6y (6.3)</td></tr>
<tr><td>Sex</td><td>68.75% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2) - Baseline
Mean (SD)

Body fat %
Mean (SD)</td><td>Surgical: 108.8
(14.9)

Surgical: 38.3
(3.7)

Surgical: 47.6
(5.4)</td><td>ILMI: 112.8
(16.5)

ILMI: 37.1
(3.5)

ILMI: 46.1
(6.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (%)
Mean (SD)</td><td>Surgical: -25.8
(14.5)</td><td>ILMI: -6.4
(5.8)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Curtin, 2013

Guideline record ID: 10140--1

Study characteristics		
Citation	Curtin, C., Bandini, L. G., Must, A., Gleason, J., Lividini, K., Phillips, S., Eliasziw, M., Maslin, M., & Fleming, R. K. (2013). Parent support improves weight loss in adolescents and young adults with Down syndrome. The Journal of Pediatrics, 163(5), 1402-1408.e1401. https://doi.org/10.1016/j.jpeds.2013.06.081	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Parent support improves weight loss in adolescents and young adults with Down syndrome	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	“Participants with Down syndrome met the following inclusion criteria: age 13-26, body mass index (BMI) ≥ 85th percentile,7 IQ 45-70; written physician approval; and a parent willing to attend sessions.”	
Exclusion criteria	“Exclusion criteria included use of appetite-altering medications, chronic gastrointestinal illness, untreated thyroid disorders, uncontrolled seizure disorders, or orthopedic or cardiac conditions that would preclude physical activity participation.”	
Setting	University/research centre	
Intervention	“Nutrition and activity education+behaviorial intervention included the same nutrition and activity education activities (first 40 minutes) - taught basic nutritional concepts and exercises through simple verbal instruction, demonstrations, activities (e.g., games), and taste tests. Participants were taught to make food choices associated with their diet plans, emphasizing fruit, vegetable, and low-fat dairy consumption; correct portion sizes; and healthy snacking. Physical activity sessions taught exercises from the participants' plans. All 15 sessions provided 40 minutes of instruction with parents present, a 10-minute break, and 40 minutes of practice and taste tests with adolescent and young adult participants only. Parents attended the first 40 minutes and met separately as a group for informal support/discussion for the last 40 minutes. Followed by 40 minutes of group training with parents, conducted by a behavioral specialist who provided instruction on behavioral strategies such as diet/activity monitoring, modification of "stimulus control" conditions at home, daily/weekly goal setting, and positive reinforcement. Although not required to make personal changes, parents were encouraged to model, facilitate, and reinforce healthy eating/activity for their offspring.”	
Control/Comparator	“Nutrition and activity education taught basic nutritional concepts and exercises through simple verbal instruction, demonstrations, activities (e.g., games), and taste tests. Sessions were conducted by a dietitian and a therapeutic recreation specialist. Eight sessions covered nutrition, seven also addressed physical activity, and the final session was a potluck celebration dinner. Participants were taught to make food choices associated with their diet plans, emphasizing fruit, vegetable, and low-fat dairy consumption; correct portion sizes; and healthy snacking. Physical activity sessions taught exercises from the participants' plans. All 15 sessions provided 40 minutes of instruction with parents present, a 10-minute break, and 40 minutes of practice and taste tests with adolescent and young adult participants only. Parents attended the first 40 minutes and met separately as a group for informal support/discussion for the last 40 minutes.”	
Treatment duration	12 months	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 21
Intervention group/s: NAE+BI (n=11)

Comparator group: NAE (n=10)</td></tr>
<tr><td>Mean age ± SD</td><td>20.5y (3.2)</td></tr>
<tr><td>Sex</td><td>80.95% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Down Syndrome</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>NAE+BI: 79.2
(14.9)

NAE+BI: 35.8
(5.4)</td><td>NAE: 77.3
(16.5)

NAE: 36.5
(6.9)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Mean (SE)</td><td>NAE+BI: -1.9
(0.8)</td><td>NAE: 1.7
(0.8)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Fidelity checks revealed 100% adherence to the intervention protocol with the new treatment team in Wave 3</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Damaso, 2014

Guideline record ID: 10143--1

Study characteristics		
Citation	Dâmaso, A. R., da Silveira Campos, R. M., Caranti, D. A., de Piano, A., Fisberg, M., Foschini, D., de Lima Sanches, P., Tock, L., Lederman, H. M., Tufik, S., & de Mello, M. T. (2014). Aerobic plus resistance training was more effective in improving the visceral adiposity, metabolic profile and inflammatory markers than aerobic training in obese adolescents. Journal of Sports Sciences, 32(15), 1435-1445. https://doi.org/https://dx.doi.org/10.1080/02640414.2014.900692	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Aerobic plus resistance training was more effective in improving the visceral adiposity, metabolic profile and inflammatory markers than aerobic training in obese adolescents	
Location	Brazil	
Trial name	N/A	
Methods		
Inclusion criteria	"The inclusion criteria for the post-pubertal stage were based on the Tanner scale (five-stage) for boys and girls (Tanner & Whitehouse, 1976)."	
Exclusion criteria	"The exclusion criteria were endocrine diseases, chronic alcohol consumption, pregnancy and previous use of drugs such as anabolic- androgenic steroids or psychotropics, which may affect appetite regulation."	
Setting	Hospital, Research University	
Intervention	"Aerobic plus resistance training (AT+RT) AT + RT was performed three times per week for 1 year, including 30 min of AT and 30 min of resistance training per session. The order of the exercises was reversed at each training session: in one session, the participants began the training session with aerobic exercises, and in the subsequent session, they began with the resistance training. The AT mode was running performed on a motor-driven treadmill (Life Fitness®-Model TR 9700HR) at the heart rate intensity of the ventilatory threshold I (±4 rpm), according to the results of an initial oxygen uptake test for aerobic exercises (cycle-ergometer and treadmill). Physiologists controlled the heart rate, which was measured with a cardiometer at intervals of 5 min during all of the training sessions (Polar-Model® FS1dark blue). The exercise therapy was based on a previous protocol of the American College of Sports Medicine (ACSM, 2002; Kraemer et al., 2002). Resistance training was structured following the recommendations of the ACSM (Kraemer et al., 2002). The sequence of exercises used large muscle groups before small ones, multiple-joint exercises before single-joint exercises, and higher-intensity before lower-intensity exercises. Exercises included the bench press, the leg press, situps, lat pull-downs, hamstring curls, lower-back exercises, the military press, calf raises, arm curls and tricep pushdowns. The order of the exercises was strictly followed by the group. The optimal characteristics of strength-specific programmes include the use of concentric, eccentric and isometric muscle actions and the performance of bilateral and unilateral single- and multiple-joint exercises to improve the effects of training (Kraemer et al., 2002). The first 2 weeks of the resistance training programme were for adaptation to training and learning the movements (three sets of maximum 15-20 repetitions). Following this period, the training load was adjusted by inversely modifying the volume and intensity, decreasing the number of repetitions to between 6 and 20 for three sets. The intensity of AT + RT was quantified as a percentage of the one-repetition maximum (1-RM) and continued until volitional fatigue in each of the major muscle groups. These factors were adapted to the individual's habitual physical activity, physical function, health status, exercise responses and stated goals, as recommended for a universal screening Intra-abdominal fat in obese adolescents 1437 to enhance the safety of exercise (Foschini et al., 2010). The rest interval between series and	

<table>
<tr><td></td><td>exercises was as follows: 15-20 (repetitions maximum) = 45 s, 10-12 (repetitions maximum) = 1 min and 6-8 (repetitions maximum) = 1.5 min. Psychological therapy Psychological issues were assessed by validated questionnaires that took into account some of the psychological alterations caused by obesity, as described in the literature, including depression, eating disorders, anxiety, decreased self-esteem and body-image disorders. During the interdisciplinary therapy, the adolescents received psychological counselling for 1 h in a weekly group session. The psychologist discussed body image and eating disorders, such as bulimia and anorexia nervosa and binge eating disorders, as well as their signs, symptoms and health consequences; the relationship between feelings and food; and familial problems such as alcoholism and other issues. Individualised psychological therapy was recommended when weight in balance or poor dietary habits were found (Lofrano-Prado et al., 2011). Nutritional therapy Energy intake was set at the levels recommended by the dietary reference standard for participants with low levels of physical activity of the same age and gender as the participants who were following a balanced diet. No drugs or antioxidants were recommended. Once a week, the adolescents had a dietetics lesson; these lessons provided information on the food pyramid; diet record assessment; weight loss diets and miracle diets; food labels, dietetics, fat-free and low-calorie foods; fats (types, sources and substitute foods); fast food calories and nutritional composition; good nutritional choices on special occasions; healthy sandwiches; shakes and products to promote the weight loss; functional foods; and decisions regarding food choices. All of the patients received individual nutritional consultation during the intervention programme.”</td></tr>
<tr><td>Control/Comparator</td><td>“Aerobic training (AT) During the 1 year of therapy, the obese adolescents followed a personalised AT programme of 60-min sessions three times a week (180-min/week) under the supervision of a sports physiologist. For each participant, a programme was developed according to the results of an initial oxygen uptake test for aerobic exercises (cycle-ergometer and treadmill). The intensity was set at a workload corresponding to the ventilatory threshold I (50-70% of the oxygen uptake test). At the end of 6 weeks, aerobic tests were performed individually to assess the participants' physical capacities and to adjust the physical training intensity for each individual. During the aerobic sessions, the heart rate was monitored. The exercise programme was based on a protocol of the ACSM, 2002 (Kraemer et al., 2002) and adapted by Foschini et al. (2010).”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 116
Intervention group/s: AT+RT (n=61)

Comparator group: AT (n=55)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body Mass (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>AT+RT: 102.7
(14.7)

AT+RT: 36.7
(4.9)</td><td>AT: 98.3
(13.7)

AT: 35.7
(4.3)</td></tr>
</table>
</td></tr>
</table>

Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Body Mass (kg) Mean (SD) BMI (kg/m2) Mean (SD)	AT+RT: 90.4 (13.4) AT+RT: 31.9 (4.6)	AT: 89.5 (12.5) AT: 32.6 (4.5)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Body Mass change (kg) Mean (SD) BMI change (kg/m2) Mean (SD)	AT+RT: -12.3 (7.2) AT+RT: -4.7 (2.6)	AT: -8.8 (8.5) AT: -3.2 (3)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Das, 2021

Guideline record ID: 10146--1

Study characteristics		
Citation	Das, S. K., Bukhari, A. S., Taetzsch, A. G., Ernst, A. K., Rogers, G. T., Gilhooly, C. H., Hatch-McChesney, A., Blanchard, C. M., Livingston, K. A., Silver, R. E., Martin, E., McGraw, S. M., Chin, M. K., Vail, T. A., Lutz, L. J., Montain, S. J., Pittas, A. G., Lichtenstein, A. H., Allison, D. B., . . . Roberts, S. B. (2021). Randomized trial of a novel lifestyle intervention compared with the Diabetes Prevention Program for weight loss in adult dependents of military service members. The American Journal of Clinical Nutrition, 114(4), 1546-1559. https://doi.org/https://dx.doi.org/10.1093/ajcn/nqab259	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Randomized trial of a novel lifestyle intervention compared with the Diabetes Prevention Program for weight loss in adult dependents of military service members	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria included adult (≥18 y old) dependents of active-duty or retired military personnel; willingness to be randomly assigned; and a BMI (in kg/m2) ≥ 25 at screening."	
Exclusion criteria	"Exclusion criteria included pregnancy or lactation; prior weight loss surgery or eating disorder; >4.5 kg weight loss within 6 mo; >2 h/d of vigorous activity; any condition or medication use influencing food absorption; current moderate or severe depression; and current severe noncommunicable disease."	
Setting	US military installations	
Intervention	"Healthy weight for living (HWL): As with traditional health behavior change models, HWL (also called iDiet, www.theidiet.com) is informed by multiple theories of behavior change including goal-setting theory and SCT. However, a key difference between HWL and the DPP is that HWL uses a revised interpretation of SCT (28, 29) as one of its foundational underpinnings, in which reciprocal determinism is recognized to include biological factors as well as psychological factors, environmental factors, and behavior (30). This new biological focus is included on the grounds that hunger and food cravings are determinants of energy intake during weight loss and weight loss maintenance, and are driven at least in part by biological signals of nutrient sufficiency (6, 7, 31, 32). Therefore, in contrast to traditional interventions such as the DPP, which hardly mention hunger (18), HWL has a clear focus on managing hunger (6, 15) and reducing food cravings in tandem with increasing preferences for healthy food (7, 15, 33). HWL is also informed by the Transtheoretical Model of behavior change (9, 15, 34- 37), which emphasizes reducing participant burden. Although reducing participant burden is recognized in most theoretical models (38), traditional interventions use daily food logging as a central strategy, with the additional concomitant burden of increased physical activity. Finally, the health behavior change model for HWL differs from that of the DPP in emphasizing the development of intrinsic motivation (34). Intrinsic motivation refers to the tendency to perform activities for their inherent satisfaction rather than for separable consequences (35), and our new health behavior change model emphasizes developing healthier food preferences and active hunger management for the satisfaction and interest in doing them independent of weight loss, with weight loss viewed in part as the secondary consequence of these changes along with the extrinsic benefit of the weight loss. This approach differs from the DPP, which builds extrinsic motivation for weight loss, and dietary changes are positioned for their anticipated effects on weight rather than direct and immediate enjoyment of those changes. HWL had the same goals as the m-DPP for rate of weight loss, reduction in energy intake, and increase in physical activity and also addressed standard lifestyle topics. Major	

<table>
<tr><td></td><td>programmatic differences were the greater emphasis in HWL on actively managing hunger and satiety and developing preferences for healthy foods, and the use of portion-controlled self-selection menus rather than daily food logging to achieve a reduction in energy intake. The default dietary composition of HWL (15) was implemented as a core strategy to address hunger management (9) and was consistent with dietary patterns for long-term health (36). Specifically, default nutrient parameters were based on published studies indicating beneficial effects on hunger and/or satiety of high fiber (target > 14 g/1000 kcal), moderately high protein (25% energy), moderately low carbohydrate from predominantly lowglycemic-index sources (45% energy), and high food volume (40-44). In addition, flexible dietary ranges encompassing lowcarbohydrate to low-fat plant-based diets were supported when desired, assuming additive effects of beneficial dietary factors”</td></tr>
<tr><td>Control/Comparator</td><td>“modified Diabetes Prevention Program (m-DPP): The m-DPP implemented here used the Group Lifestyle Balance curriculum (27). Goal setting and daily food and activity logging are central features of this national program; additional components include planning, stimulus control, relapse recovery, flexible eating restraint, and increasing self-efficacy through incremental accomplishments. Participants and interventionists agree on daily goals for energy and fat intakes and physical activity to achieve 0.5-1.0 kg/wk weight loss with a 500- to 1000-kcal/d reduction in energy intake, 25% of energy from fat, and 150 min exercise/wk. Participants are expected to log food and activity daily and provide these logs to the interventionist for feedback each week. In this study, the m-DPP also included an individual midweek e-mail check-in with the interventionist and, except for the first 3 groups of participants, was implemented exclusively by videoconference (16) after an initial in-person meeting, similar to HWL. The midweek check-in made contact time equivalent across the interventions.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 238
Intervention group/s: HWL (n=121)
Comparator group: m-DPP (n=117)</td></tr>
<tr><td>Mean age ± SD</td><td>HWL: 42.4y (12.0); m-DPP: 39.1y (9.5)</td></tr>
<tr><td>Sex</td><td>98.32% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Baseline BMI (kg/m2)
Mean (SD)</td><td>HWL: 34.9
(6.4)</td><td>m-DPP: 34.5
(6.4)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight change (kg)
Mean (SE)

Weight change (%)
Mean (SE)

BMI change (kg/m2)
Mean (SE)</td><td>HWL: -7.46
(0.85)

HWL: -8.07
(0.93)

HWL: -2.77
(0.32)</td><td>m-DPP: -7.32
(0.87)

m-DPP: -7.61
(0.92)

m-DPP: -2.74
(0.32)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Daumit, 2013

Guideline record ID: 10147--1

Study characteristics		
Citation	Daumit, G. L., Dickerson, F. B., Wang, N.-Y., Dalcin, A., Jerome, G. J., Anderson, C. A. M., Young, D. R., Frick, K. D., Yu, A., Gennusa, J. V., III, Oefinger, M., Crum, R. M., Charleston, J., Casagrande, S. S., Guallar, E., Goldberg, R. W., Campbell, L. M., & Appel, L. J. (2013). A behavioral weight-loss intervention in persons with serious mental illness. The New England Journal of Medicine, 368(17), 1594-1602. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1214530	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A behavioral weight-loss intervention in persons with serious mental illness	
Location	USA	
Trial name	Achieving Healthy Lifestyles in Psychiatric Rehabilitation (ACHIEVE)	
Methods		
Inclusion criteria	"The eligibility criteria were minimal; we aimed to enroll a broad population that would be representative of persons with serious mental illness attending community mental health programs. The study population consisted of overweight or obese adults (≥18 years of age) who attended 1 of 10 community psychiatric rehabilitation programs in central Maryland or their affiliated out-patient mental health clinics."	
Exclusion criteria	"We excluded persons with a medical contraindication to weight loss, a cardiovascular event within the previous 6 months, an inability to walk, or an active alcohol-use or substance-use disorder."	
Setting	outpatient psychiatric rehabilitation programs	
Intervention	"The intervention was composed of three contact types: group weight-management sessions, individual weight-management sessions, and group exercise sessions. The goals for the intervention group included the following: reducing caloric intake by avoiding sugar-sweetened beverages and junk food (e.g., candy and high-fat snacks), eating five total servings of fruits and vegetables daily, choosing smaller portions and healthy snacks, and participating in moderate-intensity aerobic exercise. Group exercise started at a level appropriate for sedentary persons, with gradual increases in duration and intensity. Trained members of the study staff led all exercise classes for the first 6 months. Subsequently, a trained member of the rehabilitation-program staff offered some exercise session using a video specifically prepared for this trial."	
Control/Comparator	"Participants in the control group received standard nutrition and physical-activity information at baseline. Health classes were offered quarterly, with content unrelated to weight (e.g., cancer screening)."	
Treatment duration	18 months	
Follow-up from baseline	18 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 291 Intervention group/s: Intervention (n=144) Comparator group: Control (n=147)	

<table>
<tr><td>Mean age ± SD</td><td>45.3y (11.3)</td></tr>
<tr><td>Sex</td><td>50.17% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Serious Mental Illness</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 101.3
(21.5)

Intervention: 36
(7.2)</td><td>Control: 104
(20.7)

Control: 36.5
(7.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Absolute weight change (kg)
Mean (95% CIs)

Percent weight change (%)
Mean (95% CIs)

Absolute BMI change (kg/m2)
Mean (95% CIs)</td><td>Intervention: -3
(-4--2)

Intervention: -3.2
(-4.2--2.1)

Intervention: -1.1
(-1.4--0.7)</td><td>Control: -0.5
(-1.8-0.8)

Control: -0.6
(-1.9-0.6)

Control: -0.2
(-0.6-0.3)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Absolute weight change (kg)
Mean (95% CIs)

Percent weight change (%)
Mean (95% CIs)

Absolute BMI change (kg/m2)
Mean (95% CIs)

Change in waist circumference (cm)
Mean (95% CIs)</td><td>Intervention: -3.4
(-4.7--2.1)

Intervention: -3.8
(-5.3--2.4)

Intervention: -1.2
(-1.7--0.8)

Intervention: -2.2
(-3.8--0.7)</td><td>Control: -0.2
(-1.7-1.3)

Control: -0.4
(-1.7-0.9)

Control: -0.1
(-0.6-0.4)

Control: -0.4
(-1.9-1.2)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Davies, 2015

Guideline record ID: 10149--1

Study characteristics		
Citation	Davies, M. J., Bergenstal, R., Bode, B., Kushner, R. F., Lewin, A., Skjøth, T. V., Andreasen, A. H., Jensen, C. B., DeFronzo, R. A., & for the NN8022-1922 Study Group. (2015). Efficacy of liraglutide for weight loss among patients with type 2 diabetes: the SCALE Diabetes randomized clinical trial. JAMA, 314(7), 687-699. https://doi.org/https://dx.doi.org/10.1001/jama.2015.9676	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Efficacy of Liraglutide for Weight Loss Among Patients With Type 2 Diabetes: The SCALE Diabetes Randomized Clinical Trial	
Location	France; Germany; Israel; South Africa; Spain; Sweden; Turkey; England; Scotland	
Trial name	Satiety and Clinical Adiposity - Liraglutide Evidence (SCALE)	
Methods		
Inclusion criteria	"Eligible participants were overweight or obese (body mass index [BMI] ≥27.0, calculated as weight in kilograms divided by height in meters squared) adults (age ≥18 years) with a stable body weight (<5-kg change in the last 3 months), diagnosed with type 2 diabetes (hemoglobin A1c [HbA1c] level 7.0%-10.0%)6 treated with diet and exercise alone or in combination with 1 to 3 oral hypoglycemic agents (metformin, thiazolidinedione, sulfonylurea). Participants taking sulfonylurea were asked to reduce their dose by 50% to mitigate the risk of hypoglycemia."	
Exclusion criteria	"1. Treatment with GLP-1 receptor agonists (including liraglutide or exenatide), dipeptidyl peptidase-4 (DPP-4) inhibitors or insulin within the last 3 months 2. Treatment with any hypoglycemic agent(s) other than metformin, sulfonylurea and glitazone in the 3 months prior to screening 3. Recurrent major hypoglycemia or hypoglycemic unawareness as judged by the investigator 4. Use of any drug (except for metformin, sulfonylurea or glitazone), which in the investigator's opinion could interfere with glucose level (e.g. systemic corticosteroids) 5. Receipt of any other anti-diabetic investigational drug within 3 months prior to screening for this trial, or receipt of any investigational drugs not affecting diabetes within 1 month prior to screening for this trial 6. Known proliferative retinopathy or maculopathy requiring acute treatment, as judged by the investigator 7. Untreated or uncontrolled hypothyroidism/hyperthyroidism defined as thyroid-stimulating hormone (TSH) >6 mIU/L or <0.4 mIU/L 8. History of chronic pancreatitis or idiopathic acute pancreatitis 9. Obesity induced by other endocrinologic disorders (e.g. Cushing Syndrome) 10. Current or history of treatment with medications that may cause significant weight gain, within 3 months prior to screening for this trial, including systemic corticosteroids (except for a short course of treatment, ie, 7-10 days), tricyclic antidepressants, atypical antipsychotic and mood stabilizers (eg, imipramine, amitryptiline, mirtazapin, paroxetine, phenelzine, clorpromazine, thioridazine, clozapine, olanzapine, valproic acid and its derivatives, and lithium) 11. Diet attempts using herbal supplements or over-the-counter medications within 3 months prior to screening into this trial 12. Current participation in an organized weight reduction program (or within the last 3 months) and/or are currently using or have used within 3 months prior to screening for this trial: pramlintide, sibutramine, orlistat, zonisamide, topiramate or phenteremine (either by prescription or as part of a clinical trial) 13. Participation in a clinical trial within the last 3 months prior to screening for this trial 14. Previous surgical treatment for obesity (excluding liposuction if performed >1 year before trial entry) 15. Screening calcitonin value ≥50 ng/L 16. Familial or personal history of multiple endocrine neoplasia type 2 or familial medullary thyroid carcinoma 17. Personal history of non-familial medullary thyroid carcinoma 18. Simultaneous participation in any other clinical trial of an investigational drug 19. History of Major Depressive Disorder within the last 2 years 20. A patient health questionnaire -9 (PHQ-9) score of ≥15 21. History of other severe psychiatric disorders, eg, schizophrenia,	

	bipolar disorder 22. Any lifetime history of a suicide attempt 23. A history of any suicidal behavior in the last month prior to randomization 24. Any suicidal ideation of type 4 or 5 on the Columbia suicidality severity rating scale (C-SSRS) in the last month prior to randomization 25. Surgery scheduled for the trial duration period, except for minor surgical procedures, at the discretion of the investigator 26. Uncontrolled treated/untreated hypertension (systolic blood pressure ?160 mmHg and/or diastolic blood pressure ?100 mmHg). If white coat hypertension is suspected at the screening visit (visit 1) a repeated measurement at visit 2 prior to other trial related activities is allowed 27. Cancer (past or present except basal cell skin cancer or squamous cell skin cancer), which in the investigator's opinion could interfere with the results of the trial © 2015 American Medical Association. All rights reserved. 9 28. Known or suspected hypersensitivity to trial product(s) or related product(s) 29. Previous participation in the randomized phase of this trial. Re-screening is allowed once within the limits of the recruitment period 30. Known or suspected abuse of alcohol or narcotics 31. Language barrier, mental incapacity, unwillingness or inability to understand and be able to complete the mental health questionnaires in the provided language 32. Participants from the same house hold participating in the trial 33. Females of childbearing potential who are pregnant, breast-feeding or intend to become pregnant or are not using adequate contraceptive methods (adequate contraceptive measures as required by local law or practice) US: abstinence and the following methods: diaphragm with spermicide, condom with spermicide (by male partner), intrauterine device, sponge, spermicide, Norplant®, Depo-Provera® or oral contraceptives. Germany: adequate contraceptive measures are implants, injectables, combined oral contraceptives, hormonal IUD, sexual abstinence or vasectomized partner). UK: adequate contraceptive measures are defined as sterilization, intra-uterine device, oral contraceptives, consistent use of barrier methods, male sterilization or true abstinence 34. The receipt of any investigational product within 4 weeks prior to screening for this trial The following exclusion criteria were applicable to France in addition to the criteria listed above: Treatment with diet and exercise only, treatment with sulfonylurea as single agent therapy or glitazone as single agent therapy, unless the patient has metformin contraindication or metformin intolerance, treatment with triple oral antidiabetic therapy, abnormality of the thyroid identified during the physical examination at screening."
Setting	Unclear (trial was conducted between June 2011 and January 2013 at 126 sites in 9 countries)
Intervention	"Trial drug was administered once daily by subcutaneous injection using a modified insulin pen device (FlexPen; Novo Nordisk). The starting dose of the trial drug was 0.6 mg. It was escalated by increments of 0.6 mg weekly to the treatment dose. This occurred over 2 weeks for the 1.8-mg treatment dose and 4 weeks for the 3.0-mg treatment dose. Participants were encouraged to follow a diet containing a maximum of 30% of energy from fat, approximately 20% of energy from protein, and approximately 50% of energy from carbohydrates, with a 500-kcal/d deficit based on estimated total energy expenditure and exercise program. After an initial counseling session by a qualified dietician at randomization, participants were advised to increase their physical activity to at least 150 minutes of brisk walking per week and to reduce their daily energy intake to 500 kcal below their individualized daily total energy requirements based on multiplying their basal metabolic rate according to World Health Organization estimates by an 'average' activity factor of 1.3 (Sacks FM, Bray GA, Carey VJ, et al. Comparison of weight-loss diets with different compositions of fat, protein, and carbohydrates. N Engl J Med 2009; 360: 859-73). The recommended macronutrient distribution was 30% of energy from fat, 20% from protein, and 50% from carbohydrate. To encourage adherence, pedometers were provided and a 3-day food diary was dispensed for completion every second month. Counselling on diet and physical activity (either in a group or individually) was provided every month, with the exception of visits 15 and 16 (weeks 50 and 56), where visits were 6 weeks apart. Prandial plasma glucose (PPG) increment was determined using a supplied glucose meter as the mean of three plasma glucose increments across (before and 90 minutes after) each breakfast, lunch and dinner meal."

<table>
<tr><td>Control/Comparator</td><td>“Placebo was administered once daily by subcutaneous injection using a modified insulin pen device (FlexPen; Novo Nordisk). The starting dose of the trial drug was 0.6 mg. It was escalated by increments of 0.6 mg weekly to the treatment dose. This occurred over 2 weeks for the 1.8-mg treatment dose and 4 weeks for the 3.0-mg treatment dose. Participants were encouraged to follow a diet containing a maximum of 30% of energy from fat, approximately 20% of energy from protein, and approximately 50% of energy from carbohydrates, with a 500-kcal/d deficit based on estimated total energy expenditure and exercise program. After an initial counseling session by a qualified dietician at randomization, participants were advised to increase their physical activity to at least 150 minutes of brisk walking per week and to reduce their daily energy intake to 500 kcal below their individualized daily total energy requirements based on multiplying their basal metabolic rate according to World Health Organization estimates by an 'average' activity factor of 1.3 (Sacks FM, Bray GA, Carey VJ, et al. Comparison of weight-loss diets with different compositions of fat, protein, and carbohydrates. N Engl J Med 2009; 360: 859-73). The recommended macronutrient distribution was 30% of energy from fat, 20% from protein, and 50% from carbohydrate. To encourage adherence, pedometers were provided and a 3-day food diary was dispensed for completion every second month. Counselling on diet and physical activity (either in a group or individually) was provided every month, with the exception of visits 15 and 16 (weeks 50 and 56), where visits were 6 weeks apart. Prandial plasma glucose (PPG) increment was determined using a supplied glucose meter as the mean of three plasma glucose increments across (before and 90 minutes after) each breakfast, lunch and dinner meal. The placebo group was further subdivided into two groups, with different injection volumes corresponding to the different dose levels of liraglutide.”</td></tr>
<tr><td>Treatment duration</td><td>56 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>56 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 846
Intervention group/s: Liraglutide 3.0mg (n=423); Liraglutide 1.8mg (n=211)

Comparator group: Placebo (n=212)</td></tr>
<tr><td>Mean age ± SD</td><td>Liraglutide 3.0mg: 55.0y (10.8); Liraglutide 1.8mg: 54.9y (10.7); Placebo: 54.7y (9.8)</td></tr>
<tr><td>Sex</td><td>49.76% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Liraglutide 3.0mg: 105.7 (21.9)
Liraglutide 1.8mg: 105.8 (21)</td><td>Placebo: 106.5 (21.3)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Liraglutide 3.0mg: 37.1 (6.5)
Liraglutide 1.8mg: 37 (6.9)</td><td>Placebo: 37.4 (7.1)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Liraglutide 3.0mg: 118 (14.4)
Liraglutide 1.8mg: 117.5</td><td>Placebo: 117.3 (14)</td></tr>
</table>
</td></tr>
</table>

		(14.7)	

Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator

Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in weight (%) Mean (SD) Change in waist circumference (cm) Mean (SD) Change in BMI (kg/m2) Mean (SD)	Liraglutide 3.0mg: -5.9 Liraglutide 1.8mg: -4.6 Liraglutide 3.0mg: -6.1 (6.5) Liraglutide 1.8mg: -4.8 (5.6) Liraglutide 3.0mg: -2.2 (2.1) Liraglutide 1.8mg: -1.7 (2.1)	Placebo: -2 Placebo: -2.7 (5.4) Placebo: -0.8 (1.7)

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Davies, 2021

Guideline record ID: 10148--1

Study characteristics		
Citation	Davies, M., Færch, L., Jeppesen, O. K., Pakseresht, A., Pedersen, S. D., Perreault, L., Rosenstock, J., Shimomura, I., Viljoen, A., Wadden, T. A., & Lingvay, I. (2021). Semaglutide 2·4 mg once a week in adults with overweight or obesity, and type 2 diabetes (STEP 2): a randomised, double-blind, double-dummy, placebo-controlled, phase 3 trial. The Lancet, 397(10278), 971-984. https://doi.org/10.1016/S0140-6736(21)00213-0	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Semaglutide 2·4 mg once a week in adults with overweight or obesity, and type 2 diabetes (STEP 2): A randomised, double-blind, double-dummy, placebo-controlled, phase 3 trial	
Location	Argentina; Canada; Germany; Greece; India; Japan; Russia; South Africa; Spain; United Arab Emirates; United Kingdom; United States of America	
Trial name	Semaglutide Treatment Effect in People with Obesity (STEP 2)	
Methods		
Inclusion criteria	"Patients are eligible to be included in the trial only if all of the following criteria apply: 1. Informed consent obtained before any trial-related activities. Trial-related activities are any procedures that are carried out as part of the trial, including activities to determine suitability for the trial. 2. Male or female; age ≥18 years at the time of signing informed consent. 3. Body mass index (BMI) ≥27 kg/m2 . 4. History of at least one self-reported unsuccessful dietary effort to lose body weight. 5. Diagnosed with type 2 diabetes ≥180 days prior to the day of screening. 6. Patient treated with either: • Diet and exercise alone or stable treatment with metformin, sulfonylurea (SU), sodium-glucose cotransporter-2 inhibitors (SGLT2is), or glitazone as single-agent therapy; or • Up to 3 oral glucose-lowering drugs (metformin, SU, SGLT2i, or glitazone) according to local label. Any approved and marketed metformin, glitazone, SGLT2i, or SU product, or combination products are allowed. Treatment with oral agents should be stable (same drug[s], dose, and dosing frequency) for at least 90 days prior to screening. 7. Glycated haemoglobin (HbA1c) 7-10% (53-86 mmol/mol) (both inclusive). The criteria are assessed at the investigator's discretion unless otherwise stated."	
Exclusion criteria	"Patients are excluded from the trial if any of the following criteria apply: Diabetes-related: 1. Treatment with any medication for the indication of diabetes or obesity other than stated in the inclusion criteria within the past 90 days before screening. 2. Receipt of any other glucose-lowering investigational drug within 90 days prior to screening for this trial, or receipt of any investigational drugs not affecting diabetes within 30 days before screening for this trial. 3. Treatment with a glucagon-like peptide-1 receptor agonist within 180 days prior to screening. 4. Renal impairment measured as estimated glomerular filtration rate value of <30 mL/min/1·73 m2 (<60 mL/min/1·73 m2 in patients treated with SGLT2i) according to Chronic Kidney Disease Epidemiology Collaboration creatinine equation as defined by Kidney Disease: Improving Global Outcomes 2012 by the central laboratory at screening. 5. Uncontrolled and potentially unstable diabetic retinopathy or maculopathy, verified by a pharmacologically pupil-dilated fundus examination performed by an ophthalmologist or an equally qualified healthcare provider (e.g. optometrist) within the past 90 days before screening or in the period between screening and randomisation. Obesity-related: 6. A self-reported change in body weight of >5 kg (11 lbs) within 90 days before screening, irrespective of medical records. 7. Previous or planned (during the trial period) obesity treatment with surgery or a weight-loss device. However, the following are allowed: (1) liposuction and/or abdominoplasty, if performed >1 year before screening; (2) lap banding, if the band has been removed >1 year before screening; (3) intragastric balloon, if the balloon has been removed >1 year before screening; or (4) duodenal-jejunal bypass sleeve, if the sleeve has been removed >1 year before screening. 8. Uncontrolled thyroid disease, defined as thyroid-stimulating hormone >6·0 mIU/L or <0·4 mIU/L as	

	measured by central laboratory at screening. Mental health: 9. History of major depressive disorder within 2 years before screening. 10. Diagnosis of other severe psychiatric disorder (e.g. schizophrenia, bipolar disorder). 11. A score of ≥15 on the Patient Health Questionnaire-9 at screening. 12. A lifetime history of a suicidal attempt. 13. Suicidal behavior within 30 days before screening. 14. Suicidal ideation corresponding to type 4 or 5 on the Columbia-Suicide Severity Rating Scale within the past 30 days before screening. General safety: 15. Use of non-herbal Chinese medicine or other non-herbal local medicine with unknown/unspecified content within 90 days before screening. 16. Presence of acute pancreatitis within the past 180 days prior to the day of screening. 17. History or presence of chronic pancreatitis. 18. Calcitonin ≥100 ng/L as measured by the central laboratory at screening. 19. Personal or first-degree relative(s) history of multiple endocrine neoplasia type 2 or medullary thyroid carcinoma. 20. History of malignant neoplasms within the past 5 years prior to screening. Basal and squamous cell skin cancer and any carcinoma in situ are allowed. 21. Any of the following: myocardial infarction, stroke, hospitalisation for unstable angina, or transient ischemic attack within the past 60 days prior to screening. 22. Patient presently classified as being in New York Heart Association Class IV. 23. Surgery scheduled for the duration of the trial, except for minor surgical procedures, in the opinion of the investigator. 24. Known or suspected abuse of alcohol or recreational drugs. 25. Known or suspected hypersensitivity to trial product(s) or related products. 26. Previous participation in this trial. Participation is defined as signed informed consent. 27. Participation in another clinical trial within 90 days before screening. 28. Other patient(s) from the same household participating in any semaglutide trial. 29. Woman who is pregnant, breast-feeding, or intends to become pregnant, or is of child-bearing potential and not using a highly effective contraceptive method. 30. Any disorder, unwillingness, or inability, not covered by any of the other exclusion criteria, which in the investigator's opinion, might jeopardise the patient's safety or compliance with the protocol. The criteria are assessed at the investigator's discretion unless otherwise stated.”
Setting	Home
Intervention	“Patients received semaglutide 2·4 mg or semaglutide 1·0 mg once a week for 68 weeks, plus a lifestyle intervention, followed by 7 weeks without treatment. Semaglutide was started at 0·25 mg per week and escalated in a fixed-dose regimen every 4 weeks until the target dose was reached (ie, 2·4 mg or 1·0 mg in weeks 8-16; . The lifestyle intervention involved counselling on diet (500 kcal per day reduction relative to the estimated total daily energy expenditure calculated at time of random allocation) and physical activity (150 min per week-eg, walking or using the stairs). Counselling was provided by a dietitian or a similarly qualified health-care professional every fourth week, via in-person visit or telephone. Patients were instructed how to measure their physical activity and food intake, and were encouraged to keep a food and activity diary daily (using paper, an app, or another tool), which was reviewed during counselling sessions. The estimated total daily energy expenditure was calculated by multiplying the estimated basal metabolic rate with a physical activity amount value of 1-3.14 To mitigate risk of hypoglycaemia, patients on sulfonylureas were to reduce the dose by approximately 50% at treatment start, at the investigator's discretion. Patients could intensify glucose-lowering therapy as judged by the investigator according to local guidelines. Insulin was permitted only in cases of persistent hyperglycaemia (ie, fasting plasma glucose >15 mmol/L). Patients remained in the trial regardless of whether they discontinued treatment using the study drug.”
Control/Comparator	“Patients received placebo once a week for 68 weeks, plus a lifestyle intervention, followed by 7 weeks without treatment. The lifestyle intervention involved counselling on diet (500 kcal per day reduction relative to the estimated total daily energy expenditure calculated at time of random allocation) and physical activity (150 min per week-eg, walking or using the stairs). Counselling was provided by a dietitian or a similarly qualified health-care professional every fourth week, via in-person visit or telephone. Patients were instructed how to measure their physical activity and food intake, and were encouraged to keep a food and activity diary daily (using paper, an app, or another tool), which was reviewed during counselling sessions. The estimated total daily energy expenditure was calculated by multiplying the estimated basal metabolic rate with a physical activity amount value of 1-

<table>
<tr><td></td><td>3.14 To mitigate risk of hypoglycaemia, patients on sulfonylureas were to reduce the dose by approximately 50% at treatment start, at the investigator's discretion. Patients could intensify glucose-lowering therapy as judged by the investigator according to local guidelines. Insulin was permitted only in cases of persistent hyperglycaemia (ie, fasting plasma glucose >15 mmol/L). Patients remained in the trial regardless of whether they discontinued treatment using the study drug.”</td></tr>
<tr><td>Treatment duration</td><td>68 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>68 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 1210
Intervention group/s: Semaglutide 2.4 mg (n=404); Semaglutide 1.0mg (n=403)

Comparator group: Placebo (n=403)</td></tr>
<tr><td>Mean age ± SD</td><td>55y (11)</td></tr>
<tr><td>Sex</td><td>50.91% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes mellitus</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Semaglutide 2.4 mg: 99.9 (22.5)
Semaglutide 1.0mg: 99 (21.1)</td><td>Placebo: 100.5 (20.9)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Semaglutide 2.4 mg: 35.9 (6.4)
Semaglutide 1.0mg: 35.3 (5.9)</td><td>Placebo: 35.9 (6.5)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Semaglutide 2.4 mg: 114.5 (14.3)
Semaglutide 1.0mg: 113.9 (14)</td><td>Placebo: 115.5 (13.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Semaglutide 2.4 mg: 89.6 (21)
Semaglutide 1.0mg: 92.3 (20.7)</td><td>Placebo: 96.8 (20.3)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Semaglutide 2.4 mg: 32.3 (6.1)
Semaglutide 1.0mg: 32.9 (5.9)</td><td>Placebo: 34.6 (6.4)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Semaglutide 2.4 mg: 104.4 (14.7)
Semaglutide 1.0mg: 107.2 (14.6)</td><td>Placebo: 111 (13.7)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td>Change in weight (%)
Mean (SE)</td><td>Semaglutide 2.4 mg: -9.64 (0.4)
Semaglutide 1.0mg: -6.99 (0.4)</td><td>Placebo: -3.42 (0.4)</td></tr><tr><td>Change in waist circumference (cm)
Mean (SE)</td><td>Semaglutide 2.4 mg: -9.4 (0.4)
Semaglutide 1.0mg: -6.7 (0.4)</td><td>Placebo: -4.5 (0.4)</td></tr><tr><td>Change in weight (kg)
Mean (SE)</td><td>Semaglutide 2.4 mg: -9.7 (0.4)
Semaglutide 1.0mg: -6.9 (0.4)</td><td>Placebo: -3.5 (0.4)</td></tr><tr><td>Change in BMI (kg/m2)
Mean (SE)</td><td>Semaglutide 2.4 mg: -3.5 (0.1)
Semaglutide 1.0mg: -2.5 (0.1)</td><td>Placebo: -1.3 (0.1)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Davis, 2016

Guideline record ID: 10150--1

Study characteristics		
Citation	Davis, S. M., Myers, O. B., Cruz, T. H., Morshed, A. B., Canaca, G. F., Keane, P. C., & O'Donald, E. R. (2016). CHILE: outcomes of a group randomized controlled trial of an intervention to prevent obesity in preschool Hispanic and American Indian children. Preventive Medicine, 89, 162-168. https://doi.org/https://dx.doi.org/10.1016/j.ypmed.2016.05.018	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	CHILE: Outcomes of a group randomized controlled trial of an intervention to prevent obesity in preschool Hispanic and American Indian children	
Location	USA	
Trial name	Child Health Initiative for Lifelong Eating and Exercise (CHILE)	
Methods		
Inclusion criteria	"Head Start (HS) centers were eligible for the study if they had at least two classrooms, 15 or more 3-year-old children enrolled, a retention rate of at least 80% over 2 school years, a primarily Hispanic or AI student population, and a location in a nonmetropolitan community within 150 miles of the research center."	
Exclusion criteria	"HS centers housing other prekindergarten programs were excluded."	
Setting	School, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"(1) A nutrition and physical activity curriculum for the HS centers that was designed to provide children with repeated opportunities to taste a new fruit or vegetable and to add 30 minutes of physical activity to daily class activities; (2) quarterly professional development training for HS teachers and food service staff to provide assistance in implementing the CHILE intervention and information about physical activity and nutrition; (3) a component focused on integrating policy and behavior change in food purchasing, preparation, and serving by HS food service staff; (4) a family component consisting of take-home materials about nutrition and physical activity and family events reinforcing these messages twice during the school year; (5) a local grocery store component with the goal of increasing availability and visibility of healthier food options and providing recipes and nutrition-related information to families while shopping; and (6) a component that asked local healthcare providers to emphasize healthy eating and physical activity during routine patient visits and invited health professionals to attend CHILE family events to show support for the intervention."	
Control/Comparator	"Usual care."	
Treatment duration	19 months	
Follow-up from baseline	19 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 436 Intervention group/s: CHILE Intervention (n=226) Comparator group: Comparison (n=210)	
Mean age ± SD	not reported	

<table>
<tr><td>Sex</td><td>47.25% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of overweight/obesity in the primary cohort
Proportion (%)</td><td>CHILE Intervention: 32.7%</td><td>Comparison: 29.5%</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of overweight/obesity in the primary cohort
Proportion (%)</td><td>CHILE Intervention: 35.8%</td><td>Comparison: 57 (35.40%)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of overweight/obesity in the primary cohort
Proportion (%)</td><td>CHILE Intervention: 36.6%</td><td>Comparison: 39.58%</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Davy, 2017

Guideline record ID: 10151--1

Study characteristics		
Citation	Davy, B. M., Winett, R. A., Savla, J., Marinik, E. L., Baugh, M. E., Flack, K. D., Halliday, T. M., Kelleher, S. A., Winett, S. G., Williams, D. M., & Boshra, S. (2017). Resist diabetes: a randomized clinical trial for resistance training maintenance in adults with prediabetes. PLOS ONE, 12(2), e0172610. https://doi.org/https://dx.doi.org/10.1371/journal.pone.0172610	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Resist diabetes: A randomized clinical trial for resistance training maintenance in adults with prediabetes	
Location	USA	
Trial name	Resist Diabetes	
Methods		
Inclusion criteria	"Inclusion criteria included a sedentary lifestyle (defined as moderate PA <120 min/week or vigorous PA <60 minutes/week), overweight or obese weight status (BMI 25-39.9 kg/m2), and not having engaged in RT in the past 12 months. Individuals who appeared eligible following the online screening were required to obtain medical clearance from their personal physician and were scheduled for baseline testing to determine prediabetes status. Only those meeting prediabetes criteria were eligible to participate. Indivi duals taking commonly prescribed medications (e.g., hormone replacement therapy) were eligible for participation if they had been on a stable dose of the medication for greater than one year. Individuals with hypertension whose blood pressure (BP) was adequately controlled (i.e., <140/<90 mm Hg) with antihypertensive medications were permitted to participate."	
Exclusion criteria	"Exclusion criteria were as follows: current smokers, cardiovascular disease diagnosis, pul monary, liver or kidney disease, uncontrolled hypertension (BP>160/100 mmHg), diabetes or use of diabetes medications, conditions precluding RT such as major orthopedic injuries or musculoskeletal disabilities, and short-term use of any medications known to influence metab olism (e.g., beta blockers) or body weight (e.g., thyroid replacement, antidepressants)."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs), University/research centre	
Intervention	"All participants completed a 3-month initiation phase. Resistance training sessions were completed two times per week on nonconsecutive days, and were supervised by an American College of Sports Medicine-certified Personal Trainer in a laboratory/gym. This was followed by a 6 month RT transition and maintenance condition of Social Cognitive Theory (SCT)-based intervention delivered over nine transition sessions and nine brief maintenance sessions using interactive, self-regulation procedures (e.g., goal setting, monitoring, reporting, feedback, planning, problem solving) with tailored in-person and web-based feedback, Then 6 months of no contact."	
Control/Comparator	"All participants completed a 3-month initiation phase. Resistance training sessions were completed two times per week on nonconsecutive days, and were supervised by an American College of Sports Medicine-certified Personal Trainer in a laboratory/gym. Then 6 month maintentance phase consisting of a standard, usual care condition consisting of four transition and two brief maintenance sessions with SCT content (e.g., didactic instruction in problem solving) and generic web-based tracking of RT sessions. The 6 months of no contact."	

<table>
<tr><td>Treatment duration</td><td>9 months</td></tr>
<tr><td>Follow-up from baseline</td><td>15 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 159
Intervention group/s: SCT (n=79)

Comparator group: Standard (n=80)</td></tr>
<tr><td>Mean age ± SD</td><td>59.5y (5.4)</td></tr>
<tr><td>Sex</td><td>77.99% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Pre-diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Body fat percent (%)
Mean (SD)

Fat mass (kg)
Mean (SD)

Waist Circumference (cm)
Mean (SD)</td><td>SCT: 92.82
(13.3)

SCT: 32.98
(3.85)

SCT: 43.73
(6.89)

SCT: 40.35
(7.81)

SCT: 108.83
(10.36)</td><td>Standard: 93.89
(14.21)

Standard: 33.07
(3.71)

Standard: 43.82
(6.79)

Standard: 40.79
(8.43)

Standard: 109.75
(10.19)</td></tr>
</table>
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<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Body fat percent (%)
Mean (SD)

Fat mass (kg)
Mean (SD)

Waist Circumference (cm)
Mean (SD)</td><td>SCT: 91.65
(13.99)

SCT: 32.62
(3.94)

SCT: 42.75
(6.57)

SCT: 39.07
(8.22)

SCT: 106.49
(10.77)</td><td>Standard: 92.74
(13.51)

Standard: 32.63
(4.03)

Standard: 42.85
(7.08)

Standard: 39.25
(8.87)

Standard: 107.5
(10.79)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Within-group difference point estimate (Bonferroni 95% CI)</td><td>SCT: -0.58
(-1.61-0.46)</td><td>Standard: -0.82
(-1.84-0.2)</td></tr>
</table>
</td></tr>
</table>

	Change in BMI (kg/m2) Within-group difference point estimate (Bonferroni 95% CI) Change in body fat percent (%) Within-group difference point estimate (95% CI) Change in fat mass (kg) Within-group difference point estimate (95% CI) Change in waist circumference (cm) Within-group difference point estimate (95% CI)	SCT: -0.22 (-0.58-0.15) SCT: -0.47 (-0.99-0.06) SCT: -0.75 (-1.57-0.07) SCT: -2.86 (-4.22--1.49)	Standard: -0.27 (-0.64-0.09) Standard: -0.54 (-1.06--0.02) Standard: -0.86 (-1.66--0.06) Standard: -1.97 (-3.3--0.64)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

de Oliveira Maranhão Pureza, 2021

Guideline record ID: 10153--1

Study characteristics		
Citation	de Oliveira Maranhão Pureza, I. R., da Silva Junior, A. E., Silva Praxedes, D. R., Lessa Vasconcelos, L. G., de Lima Macena, M., Vieira de Melo, I. S., de Menezes Toledo Florêncio, T. M., & Bueno, N. B. (2021). Effects of time-restricted feeding on body weight, body composition and vital signs in low-income women with obesity: a 12-month randomized clinical trial. Clinical Nutrition, 40(3), 759-766. https://doi.org/10.1016/j.clnu.2020.06.036	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of time-restricted feeding on body weight, body composition and vital signs in low-income women with obesity: A 12-month randomized clinical trial	
Location	Brazil	
Trial name	N/A	
Methods		
Inclusion criteria	“Adult women (19-44 years old) in social vulnerability were included, classified in the economic class "C" or "D-E00, as determined by the Brazil Economic Classification Criterion (CCEB). For the definition of obesity, the presence of two of the following three criteria was adopted: Body Mass Index (BMI) > 30 kg/m2 and <45 kg/m2 ; waist circumference (WC) > 88 cm; and body fat percentage > 35% determined by electrical bioimpedance). Only women who had the desire to lose weight and who reported having a stable weight for at least one month before inclusion were included.”	
Exclusion criteria	“Women on chronic medication use (including antidia betics, antihypertensives, antiretrovirals, immunosuppressants, antidepressants, thyroid hormones, and diet pills), those who were in postmenopausal state, pregnant, breastfeeding, working in shifts or who have already undergone any surgical intervention for weight loss, were not included. Participants who became pregnant, needed to undergo any surgical procedure, or those who requested to be discontinued from the study were excluded.”	
Setting	University/research centre, obesity clinic of the Center for Recovery and Nutritional Education (CREN), linked to the Federal University of Alagoas	
Intervention	“A hypoenergetic diet and 12 h of Time Restricted Feeding (TRF)”	
Control/Comparator	“Hypoenergetic diet only.”	
Treatment duration	16 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 58 Intervention group/s: HD+TRF (n=31) Comparator group: HD (n=27)	
Mean age ± SD	Control: 31.03y (7.16); Intervention: 31.80y (6.96)	
Sex	100.00% female	

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (Kg/m2)
Mean (SD)

Waist Circumference (cm)
Mean (SD)</td><td>HD+TRF: 81.25
(13.51)

HD+TRF: 33.53
(4.53)

HD+TRF: 102.79
(10.75)</td><td>HD: 80.25
(9.4)

HD: 33.12
(3.63)

HD: 98.86
(9.61)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight at 12 months
Mean (95% CIs)

BMI at 12 months
Mean (95% CIs)

Waist Circumference (cm) at 12 months
Mean (95% CIs)</td><td>HD+TRF: 80.67
(75.24-86.1)

HD+TRF: 33.27
(31.45-35.09)

HD+TRF: 99.83
(95.47-104.2)</td><td>HD: 79.73
(75.63-83.82)

HD: 32.96
(31.16-34.75)

HD: 98.75
(94.88-102.63)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

de Vos, 2014

Guideline record ID: 10156--1

Study characteristics		
Citation	de Vos, B. C., Runhaar, J., & Bierma-Zeinstra, S. M. A. (2014). Effectiveness of a tailor-made weight loss intervention in primary care. European Journal of Nutrition, 53(1), 95-104. https://doi.org/https://dx.doi.org/10.1007/s00394-013-0505-y	
Design & type	Randomised controlled trial (RCT)	Factorial design
Title	Effectiveness of a tailor-made weight loss intervention in primary care	
Location	Netherlands	
Trial name	PRevention of knee Osteoarthritis in Overweight Females (PROOF)	
Methods		
Inclusion criteria	"Inclusion criteria were as follows: female gender, age 50-60 years, overweight (BMI C 27), free of knee osteoarthritis according to the ACR criteria [12], free of contraindications to MRI, free of rheumatic diseases and not using oral glucosamine during the past 6 months."	
Exclusion criteria	"Exclusion criteria were as follows: already consulted a physician, a physical therapist or an alternative health provider for knee pain possibly indicating osteoarthritis of the knee, presence of radiologic signs indicating knee osteoarthritis (KellgrenLawrence index of 2 or more), not being able to communicate in the Dutch language and presence of severely disabling comorbidity."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs), Visit a dietician and a physical therapist nearby their home address	
Intervention	"The relevant intervention consists of an individual tailormade intervention to reduce weight, which has been constructed in cooperation with the Dutch Society of Dieticians. As said, literature suggests the focus of any weight loss intervention should be on changing food patterns and habits in physical activity. The Health Council of the Netherlands also emphasizes the importance of these components [13]. To make the intervention easily applicable in everyday clinical practice, all participants were given the opportunity to visit a dietician and a physical therapist nearby their home address. All dieticians were trained in motivational interviewing [10]. At baseline, the participant discussed nutritional habits and physical activity patterns with a dietician. Based on the goal-setting theory of Strecher et al. [14] and the specific implement technique [15], they agreed on the intentions. Subsequently, the dietician composed the"	
Control/Comparator	"The participants in the control group have not received this active (i.e. initiated by the research group) intervention to reduce body weight, but were free to undertake any actions to lose weight at their own initiative. dividual tailor-made strategy to accomplish these goals. Primarily, a tailor-made advice was given for a low-fat or a low-calorie diet, or both, as well as for physical activity. During the first month, the participant had an appointment with the dietician once in every 2 weeks; during the consecutive period, the frequency of appointments was determined in dialogue by the dietician and the participant. These appointments were used to evaluate the plan and, if indicated, to adjust the plan. The total duration of these sessions was limited to a total of 4 h per year. No limit was set on the total period during which they were under treatment. Besides, the participants in the intervention group were given the opportunity to participate in physical activity classes. In these classes (groups of 12-16 persons) they tried a broad range of different low-intensive sport activities under the supervision of a physical therapist, such as Nordic walking, volleyball, bowling, salsa dancing, tai chi, softball, belly dance and modern dance. The aim of these lessons was to regain pleasure in physical activity and to find an activity which they could maintain for themselves for long-term continuation. Twenty group activities, one lesson of 1 h weekly, were spread over a period of half a year. Because	

<table>
<tr><td></td><td>participants in every group were recruited per general practice and lived in the same neighbourhood, continuation of activities together was stimulated in case they were interested. Both the dietician appointments and the physical activity lessons were free of cost to the participants in the intervention group.”</td></tr>
<tr><td>Treatment duration</td><td>30 months</td></tr>
<tr><td>Follow-up from baseline</td><td>2.5 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 407
Intervention group/s: Intervention (n=203)

Comparator group: Control (n=204)</td></tr>
<tr><td>Mean age ± SD</td><td>55.7y (3.2)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline Body weight (kg)
Mean (SD)

Baseline BMI (kg/m2)
Mean (SD)</td><td>Intervention: 88.2
(12.9)

Intervention: 32.2
(4.1)</td><td>Control: 89.2
(13.6)

Control: 32.2
(4.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td><Baseline body weight (%)
Proportion (%)

Lost >5 kg or >5 % of baseline body weight (%)
Proportion (%)</td><td>Intervention: 52

Intervention: 18.7</td><td>Control: 39

Control: 11</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td><Baseline body weight (%)
Proportion (%)

Lost >5 kg or >5 % of baseline body weight (%)
Proportion (%)</td><td>Intervention: 52

Intervention: 14.7</td><td>Control: 42

Control: 20.3</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change (kg)
Mean (SE)</td><td>Intervention: -0.6
(0.4)</td><td>Control: 0.6
(0.4)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change (kg)
Mean (SE)</td><td>Data could not be extracted</td><td>Data could not be extracted</td></tr>
</table>
</td></tr>
</table>

Compliance with treatment	Of these 203 participants, 79 % attended at least one physical activity lesson. Fifty-seven percentage of the participants attended seven classes or more. Mean attended lessons were 8 (SD 6)
Notes	
Additional included publications arising from this study that did not contribute additional data	Llauradó, E., Tarro, L., Moriña, D., Aceves-Martins, M., Giralt, M., & Solà, R. (2018). Follow-up of a healthy lifestyle education program (the EdAl study): four years after cessation of randomized controlled trial intervention. BMC Public Health, 18, 104. https://doi.org/10.1186/s12889-017-5006-0; Tarro, L., Llauradó, E., Albaladejo, R., Moriña, D., Arija, V., Solà, R., & Giralt, M. (2014). A primary-school-based study to reduce the prevalence of childhood obesity - the EdAl (Educació en Alimentació) study: a randomized controlled trial. Trials, 15, 58. https://doi.org/https://doi.org/10.1186/1745-6215-15-58

N/A – Not applicable

de Vos, 2016

Guideline record ID: 10157--1

Study characteristics		
Citation	de Vos, B. C., Runhaar, J., van Middelkoop, M., Krul, M., & Bierma-Zeinstra, S. M. (2016). Long-term effects of a randomized, controlled, tailor-made weight-loss intervention in primary care on the health and lifestyle of overweight and obese women. The American Journal of Clinical Nutrition, 104(1), 33-40. https://doi.org/https://dx.doi.org/10.3945/ajcn.116.133512	
Design & type	Randomised controlled trial (RCT)	Factorial design
Title	Long-term effects of a randomized, controlled, tailor-made weight-loss intervention in primary care on the health and lifestyle of overweight and obese women	
Location	Netherlands	
Trial name	PRevention of knee Osteoarthritis in Overweight Females (PROOF)	
Methods		
Inclusion criteria	"Inclusion criteria were female sex, age 50-60 y, overweight (BMI $27), free of knee osteoarthritis according to the clinical American College of Rheumatology criteria (23), free of contraindications to MRI, free of rheumatic diseases, and no use of oral glucosamine during the past 6 mo."	
Exclusion criteria	"Exclusion criteria were current consultation with a physician, a physiotherapist, or an alternative health provider for knee pain possibly indicating knee osteoarthritis; presence of radiologic signs indicating knee osteoarthritis (Kellgren Lawrence index of $2); inability to communicate in the Dutch language; and presence of severely disabling comorbidity. Recruitment took place between July 2006 and May 2009."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs), The dietitian, the physiotherapist, and the facilities to engage in sports were available close to the participants' homes.	
Intervention	"In short, participants in the intervention group met with a dietitian. After evaluation of current nutritional and physical activity habits, mutual agreement goals were set through the use of motivational interviewing (16). These goals were individually tailored and concerned both diet and physical activity. The first 3 appointments were biweekly; after that the frequency of visits was determined by mutual agreement. These meetings were limited to a total duration of 4 h/calendar year. Additionally, participants were invited to attend 20 weekly physical activity classes, supervised by a physiotherapist. These classes served as an exploration of low-intensive sport activities to find a sport the participants could enjoy and maintain until after the intervention. The dietitian, the physiotherapist, and the facilities to engage in sports were available close to the participants' homes to make the intervention more approachable and to stimulate mutual involvement between participants living in the same neighborhood. The dietitian and physiotherapist sessions were free of charge for the participants. The intervention lasted 2.5 y."	
Control/Comparator	"The participants in the control group did not receive an intervention, but they were free to undertake any health-promoting activities at their own initiative."	
Treatment duration	30 months	
Follow-up from baseline	80 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 407
Intervention group/s: Intervention (n=203)

Comparator group: Control (n=204)</td></tr>
<tr><td>Mean age ± SD</td><td>55.7y (3.2)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline Body weight (kg)
Mean (SD)

Baseline BMI (kg/m2)
Mean (SD)</td><td>Intervention: 88.2
(12.9)

Intervention: 32.2
(4.1)</td><td>Control: 89.2
(13.6)

Control: 32.5
(4.5)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Subjects who lost 5 kg or 5% of baseline weight, %
Odds Ratio (OR) and 95% CIs</td><td>Intervention: 1.62
(1.14-2.31)</td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change (kg) - Estimated differences in weight change between randomly assigned groups
Difference (95% CI)</td><td>Intervention: 1.22
(0.35-2.09)</td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Eleven percent of participants randomly assigned to the intervention never visited the dietitian, whereas 51% visited the dietitian $6 times. Twenty-one percent of the participants randomly assigned to the intervention did not attend any of the physical activity classes, and 57% attended $7 classes. Thirtytwo percent of the participants in the intervention group complied with both criteria and were considered compliant to the intervention.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Llauradó, E., Tarro, L., Moriña, D., Aceves-Martins, M., Giralt, M., & Solà, R. (2018). Follow-up of a healthy lifestyle education program (the EdAl study): four years after cessation of randomized controlled trial intervention. BMC Public Health, 18, 104. https://doi.org/10.1186/s12889-017-5006-0; Tarro, L., Llauradó, E., Albaladejo, R., Moriña, D., Arija, V., Solà, R., & Giralt, M. (2014). A primary-school-based study to reduce the prevalence of childhood obesity - the EdAl (Educació en Alimentació) study: a randomized controlled trial. Trials, 15, 58. https://doi.org/https://doi.org/10.1186/1745-6215-15-58</td></tr>
</table>

N/A – Not applicable

DeBar, 2012

Guideline record ID: 10160--1

Study characteristics		
Citation	DeBar, L. L., Stevens, V. J., Perrin, N., Wu, P., Pearson, J., Yarborough, B. J., Dickerson, J., & Lynch, F. (2012). A primary care-based, multicomponent lifestyle intervention for overweight adolescent females. Pediatrics, 129(3), e611-e620. https://doi.org/https://dx.doi.org/10.1542/peds.2011-0863	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A primary care-based, multicomponent lifestyle intervention for overweight adolescent females	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Female health plan members aged 12 to 17 years with an age- and gender-adjusted BMI≥90th percentile."	
Exclusion criteria	"Significant cognitive impairment or psychosis, severe obesity (BMI ≥45), use of medications known to affect body weight, and pregnancy."	
Setting	Large health maintenance organization	
Intervention	"16 group sessions for teens (weekly for the first 3 months, bi-weekly thereafter); In-session yoga; Dance Video Games & Play Stations provided to families as aid to meet physical activity targets; 12 group sessions for parents; Physician visits (baseline, post-treatment); Health education and psychoeducational materials"	
Control/Comparator	"Usual care participants received a packet ofmaterials, including outlines of evidence-based approaches to weight management for youth and adults, a parents' guide to help adolescents make healthy lifestyle changes, local resources for weight management and healthy activity, and suggested books and online materials on healthy lifestyle change. Usual care participants also metwith their PCPs at the study onset to encourage healthy lifestyle changes, although PCPs were not given the tailored patient assessment summaries described earlier in the intervention arm for use in their visit nor were usual care participants scheduled for a 6-month study-related session with their PCPs."	
Treatment duration	5 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 208 Intervention group/s: Intervention (n=105) Comparator group: Usual Care (n=103)	
Mean age ± SD	14.1 (1.4)	
Sex	100.00% female	
Pre-existing medical condition	No pre-existing medical condition	

<table>
<tr><td>Results</td><td colspan="3"></td></tr>
<tr><td>Outcome measure at baseline</td><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td>Weight (lb)
Mean (SD)

BMI percentile
Mean (SD)

BMI z score
Mean (SD)</td><td>Intervention: 189.68
(33.47)

Intervention: 97.09
(2.27)

Intervention: 2
(0.34)</td><td>Usual Care: 186.43
(34.49)

Usual Care: 97.1
(2.29)

Usual Care: 2
(0.33)</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td>Weight (lb)
Mean (SD)

BMI percentile
Mean (SD)

BMI z score
Mean (SD)</td><td>Intervention: 194.56
(38.2)

Intervention: 95.19
(6.79)

Intervention: 1.85
(0.46)</td><td>Usual Care: 193.5
(37.35)

Usual Care: 96.28
(3.31)

Usual Care: 1.92
(0.39)</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td>Change in BMI Z score
Mean</td><td>Intervention: -0.15</td><td>Usual Care: -0.08</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>Compliance with treatment</td><td colspan="3">Intervention - 86%; Control - 81%</td></tr>
<tr><td>Notes</td><td colspan="3"></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td colspan="3"></td></tr>
</table>

N/A – Not applicable

Debussche, 2012

Guideline record ID: 10161--1

Study characteristics		
Citation	Debussche, X., Rollot, O., Le Pommelet, C., Fianu, A., Le Moullec, N., Régnier, C., Boyer, M. C., Cogne, M., Bakiri, F., Schwager, J. C., & Favier, F. (2012). Quarterly individual outpatients lifestyle counseling after initial inpatients education on type 2 diabetes: the REDIA Prev-2 randomized controlled trial in Reunion Island. Diabetes & Metabolism, 38(1), 46-53. https://doi.org/https://dx.doi.org/10.1016/j.diabet.2011.07.002	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Quarterly individual outpatients lifestyle counseling after initial inpatients education on type 2 diabetes: the REDIA Prev-2 randomized controlled trial in Reunion Island	
Location	Reunion Island	
Trial name	Reunion Diabetes (REDIA) Prev-2	
Methods		
Inclusion criteria	"Men and non-pregnant women (≥ 18 years of age) with type 2 dia betes (defined as either non-insulin-requiring or insulin-treated, but with no insulin treatment within the first year of diagno sis), but with no contraindications to moderate physical activity (cardiopathy, uncontrolled high blood pressure, ischaemic or proliferative retinopathy, proteinuria, vegetative neuropathy and diabetic foot), were considered eligible for the study."	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"All patients completed a course of inpatients education by an education nurse, a dietitian and an exercise physiologist (1 to 2 hours sessions, with two to six patients per session) dedicated to the following topics: understanding diabetes, blood glucose goals and issues; the five food groups; reduction of dietary fats; physical activity; and prevention of foot complications. The sessions combined interactive lectures and focus group discussions. Physical activity workshops were also organized (10 min of stretching and warm-up exercises, then a 30 to 40 minutes walk, followed by assessments of blood pressure, blood glucose and heart rate), as well as cooking workshops. A brief introductory educational recall of the dietary and physical activity recommendations was followed by free discussion of the difficulties encountered in daily life in applying these recommendations, based on individual assessments, with culturally tailored goals set for personalized strategies to overcome barriers, and follow-ups including evaluation and problem-solving. The nurse assessed levels of physical activity, compliance with medication, and level of self-care for diabetic complications and management of daily stress. The dietitian assessed the patients' eating patterns. Creole-speaking educators trained in counseling techniques gave individual assessments of the patient's educational and other needs, and addressed the implementation of strategies for change. Postal and telephone reminders were used to maximize participation in the scheduled visits in the intervention group"	
Control/Comparator	"All patients completed a course of inpatients education by an education nurse, a dietitian and an exercise physiologist (1 to 2 hours sessions, with two to six patients per session) dedicated to the following topics: understanding diabetes, blood glucose goals and issues; the five food groups; reduction of dietary fats; physical activity; and prevention of foot complications. The sessions combined interactive lectures and focus group discussions. Physical activity workshops were also organized (10 min of stretching and warm-up exercises, then a 30 to 40 minutes walk, followed by assessments of blood pressure, blood glucose and heart rate), as well as cooking workshops. The controls were required to attend just one visit with a dietitian and nurse, 1 year after their initial hospitalization, for patients' education."	

<table>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 398
Intervention group/s: Intervention (n=206)

Comparator group: Control (n=192)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes (defined as either non-insulin-requiring or insulin-treated, but with no insulin treatment within the first year of diagnosis)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 27.9
(5)

Intervention: 97.8
(10.7)</td><td>Control: 28.1
(4.9)

Control: 98.7
(12.2)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in BMI (kg/m2)
Mean (SD)

Change in waist circumference (cm)
Mean (SD)</td><td>Intervention: 0.73
(1.77)

Intervention: 1.73
(5.46)</td><td>Control: 0.86
(1.91)

Control: 1.25
(8.27)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Demark-Wahnefried, 2012

Guideline record ID: 10166

Study characteristics		
Citation	Demark-Wahnefried, W., Morey, M. C., Sloane, R., Snyder, D. C., Miller, P. E., Hartman, T. J., & Cohen, H. J. (2012). Reach out to enhance wellness home-based diet-exercise intervention promotes reproducible and sustainable long-term improvements in health behaviors, body weight, and physical functioning in older, overweight/obese cancer survivors. Journal of Clinical Oncology, 30(19), 2354-2361. https://doi.org/https://dx.doi.org/10.1200/JCO.2011.40.0895	
Design & type	Randomised controlled trial (RCT)	Crossover design
Title	Reach out to enhance wellness home-based diet-exercise intervention promotes reproducible and sustainable long-term improvements in health behaviors, body weight, and physical functioning in older, overweight/obese cancer survivors	
Location	USA; Canada; UK	
Trial name	Reach Out to Enhance Wellness (RENEW)	
Methods		
Inclusion criteria	"Only individuals who were age ≥65 years, had body mass indices (BMI) of 25 to 40 kg/m2, and a previous diagnosis of breast, prostate, or colorectal cancer ≥5 years previously with no evidence of progressive disease or second malignancies were considered eligible. Participants also had to be sedentary (<150 minutes of moderate-to-vigorous PA a week), community dwelling, and mentally and physically able to participate in telephone interviews and unsupervised PA."	
Exclusion criteria	Not reported	
Setting	Home	
Intervention	"The RENEW intervention consisted of a personally tailored workbook and quarterly newsletters and telephone counseling with automated prompts (15 sessions and eight prompts over 12 months). The theoretically based intervention (Social Cognitive Theory and Transtheoretical Model) endorsed 15 minutes of strength-training exercise every other day, 30 minutes of endurance exercise each day, daily consumption of ≥seven servings (women) or ≥nine servings (men) of fruits and vegetables, restriction of saturated fat to less than 10% of energy intake, and modest weight loss of less than 0.5 kg/wk-recommendations consonant with the American Cancer Society and the US Dietary Guidelines for the prevention of commonly occurring diseases and promotion of overall health. The intervention was tailored on current and previous diet and PA behaviors and body weight; self-efficacy and stage of readiness to exercise regularly and eat a diet low in saturated fat and high in fruits and vegetables; and sex and cancer type. Participants also received a pedometer, variable resistance exercise bands, an exercise poster depicting six lower extremity strength exercises, Portion Doctor tableware to guide food consumption (Portion Health Products, St Augustine Beach, FL), and personalized record logs to self-monitor daily exercise and dietary intake. At 1-year follow-up, the immediate-intervention arm was discontinued from treatment and observed (to assess durability) for 1 year."	
Control/Comparator	"Participants wait-listed for 12 months then crossover to receive identical home-based diet-exercise intervention for 12 months."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 641
Intervention group/s: Immediate-intervention (n=319)

Comparator group: Delayed-intervention (n=322)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>Breast, prostate or colorectal cancer survivors</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SE)

BMI (kg/m2)
Mean (SE)</td><td>Immediate-intervention: 85.55 (0.85)

Immediate-intervention: 29.1 (0.2)</td><td>Delayed-intervention: 84.43 (0.82)

Delayed-intervention: 29.1 (0.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SE)

BMI (kg/m2)
Mean (SE)</td><td>Immediate-intervention: 83.09 (0.83)

Immediate-intervention: 28.2 (0.2)</td><td>Delayed-intervention: 83.49 (0.84)

Delayed-intervention: 28.8 (0.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Demark-Wahnefried, 2014

Guideline record ID: 10165A--MOTHERS

Study characteristics		
Citation	Demark-Wahnefried, W., Jones, L. W., Snyder, D. C., Sloane, R. J., Kimmick, G. G., Hughes, D. C., Badr, H. J., Miller, P. E., Burke, L. E., & Lipkus, I. M. (2014). Daughters and Mothers Against Breast Cancer (DAMES): main outcomes of a randomized controlled trial of weight loss in overweight mothers with breast cancer and their overweight daughters. Cancer, 120(16), 2522-2534. https://doi.org/10.1002/cncr.28761	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Daughters and Mothers Against Breast Cancer (DAMES): main outcomes of a randomized controlled trial of weight loss in overweight mothers with breast cancer and their overweight daughters	
Location	USA	
Trial name	Daughters And MothErS Against Breast Cancer (DAMES)	
Methods		
Inclusion criteria	"Women diagnosed with AJCC stage 0 to III breast cancer who had completed primary treatment but were within 5 years of diagnosis with no evidence of progressive disease or second primary tumors and who had a biological daughter who was aged 21 years were eligible. Dyad daughters had to have no previous diagnoses of cancer, with the exception of nonmelanoma skin cancer. Both mothers and daughters had to meet the following criteria: 1) a BMI of 25 kg/m2 to 39.9 kg/m2 ; 2) no preexisting medical condition(s) that would preclude adherence to an unsupervised exercise program (eg, untreated stage 3 hypertension, severe orthopedic conditions or being scheduled for a hip or knee replacement, paralysis, end-stage renal disease, dementia, unstable angina, history of a recent myocardial infarction, or congestive heart failure or pulmonary conditions requiring hospitalization or oxygen use within 6 months) or to a diet high in fruits and vegetables (ie, taking pharmacologic doses of warfarin); 3) ability to speak and write English and the completion of at least the sixth grade and thereby the ability to comprehend the intervention materials; 4) community dwelling in the United States, Puerto Rico, or Guam (regions in which there was visiting nurse coverage by Examination Management Services Inc [Scottsdale, Ariz]); 5) not currently exercising at least 150 minutes per week as assessed by the Leisure-Time Exercise Questionnaire of Godin et al17; and 6) not currently enrolled in a weight loss program."	
Exclusion criteria	Not reported	
Setting	Home	
Intervention	"Individual: All participants received materials promoting portion control and diets high in nutrients and low in energy as well as 150 minutes per week of aerobic exercise and twice-weekly strength training. However, interventions differed with respect to tailoring.Mothers and daughters assigned to this arm each received individually tailored print materials. For example, the ini tial workbook was not only personalized with the partici pant's name, but the initial pages also delineated individual weight goals and the kilocalorie levels required to achieve desired rates of weight loss using the Mifflin-St. Jeor equation (kcal/day 5 2161 1 10(wt) 1 6.25 (ht) 25(age)).29 In addition, the 3 major foods contributing the highest percentage of kilocalories to each participant's diet were identified from the dietary recalls performed at baseline, and individuals were either directed to lower-calorie substitutes or provided with guidance on portion control. Introductory pages also included tailored feed back on how current intakes of saturated fat and fruits and vegetables as well as physical activity compared with the national guidelines.; Team: All participants received materials promoting portion control and diets high in nutrients and low in energy as well as 150 minutes per week of aerobic exercise and twice-weekly strength training. However,	

<table>
<tr><td></td><td>interventions differed with respect to tailoring. Mothers and daughters assigned to the team-based intervention received information and supplies identical to those in the individual arm, but also received information on their other team member. Here, concepts of interdependence theory (ie, structuring goals to guide mother-daughter interactions to ultimately achieve outcomes) and the theory of communal coping (ie, cooperative problem-solving to deal with individual and common stressors) were drawn on to leverage the mother-daughter bond by encouraging effective communication between partners that would enhance their sense of confidence in planning, coordinating, and carrying forth strategies to increase mutual benefit.31,32 As an example, if a dyad member was charting success at meeting exercise goals, their next newsletter would provide positive reinforcement and also encourage them to share (in a helpful way) what had worked for them with their partner. Likewise, if a dyad member was experiencing a setback, they were provided with suggestions to get back on track and their partner was encouraged to provide them with helpful support”</td></tr>
<tr><td>Control/Comparator</td><td>“All participants received materials promoting portion control and diets high in nutrients and low in energy as well as 150 minutes per week of aerobic exercise and twice-weekly strength training. However, interventions differed with respect to tailoring. Mothers and daughters assigned to this arm received a copy of the National Cancer Institute brochure Facing Forward (NIH Publication No. 10-2424) and the American Insti tute for Cancer Research publication Facts on Weight Man agement and Cancer, which were included in their binder personalized with their name. Subsequent brochures were mailed on a bimonthly basis and included American Insti tute for Cancer Research brochures (New American Plate, A Healthy Weight for Life, Getting Active-Staying Active, and Moving Toward a Plant-based Diet) and pamphlets from the American Heart Association (Managing Your Weight and Cholesterol, Blood Pressure and Weight Tracker) and the American College of Sports Medicine (Fit Over 40). These brochures were accompanied by a cover letter that encour aged the participant to read the brochure and then place it in their binder for easy reference.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 136
Intervention group/s: INDIVIDUAL (n=50); TEAM (n=50)

Comparator group: CONTROL (n=36)</td></tr>
<tr><td>Mean age ± SD</td><td>Mothers: 61.3y (7.4); Daughters: 32.9y (1.4)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Mothers: Breast cancer survivors</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2) in mothers
Mean (SD)</td><td>INDIVIDUAL: 31.6
(3.4)
TEAM: 30.8
(3.3)</td><td>CONTROL: 30.7
(2.6)</td></tr>
<tr><td>Body weight (kg) in mothers
Mean (SD)</td><td>INDIVIDUAL: 83.2
(8.8)
TEAM: 82.6</td><td>CONTROL: 81.6
(9.3)</td></tr>
</table>
</td></tr>
</table>

		(13.4) INDIVIDUAL: 97.4 (8.9) TEAM: 96.1 (10.5)	 CONTROL: 94.7 (8.8)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	BMI (kg/m2) in mothers Mean (SD) Body weight (kg) in mothers Mean (SD) Waist circumference (cm) in mothers Mean (SD)	INDIVIDUAL: 30.1 (4) TEAM: 29.6 (2.9) INDIVIDUAL: 79.7 (10.2) TEAM: 78.8 (9.6) INDIVIDUAL: 90.7 (7.4) TEAM: 91.4 (8.4)	CONTROL: 30.4 (3.1) CONTROL: 80.7 (10.1) CONTROL: 93.7 (9.7)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in BMI in mothers Mean (SD) Change in body weight in mothers Mean (SD) Change in waist circumference, mothers Mean (SD)	INDIVIDUAL: -1.4 (1.72) TEAM: -0.74 (1.63) INDIVIDUAL: -3.77 (4.8) TEAM: -2.09 (4.3) INDIVIDUAL: -6.5 (6.7) TEAM: -3.7 (5.4)	CONTROL: -0.33 (1.12) CONTROL: -0.87 (2.97) CONTROL: -1 (3.7)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Individual: 30%; Team: 28%; Control: 43%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Demark-Wahnefried, 2014

Guideline record ID: 10165B--DAUGHTERS

Study characteristics		
Citation	Demark-Wahnefried, W., Jones, L. W., Snyder, D. C., Sloane, R. J., Kimmick, G. G., Hughes, D. C., Badr, H. J., Miller, P. E., Burke, L. E., & Lipkus, I. M. (2014). Daughters and Mothers Against Breast Cancer (DAMES): main outcomes of a randomized controlled trial of weight loss in overweight mothers with breast cancer and their overweight daughters. Cancer, 120(16), 2522-2534. https://doi.org/10.1002/cncr.28761	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Daughters and Mothers Against Breast Cancer (DAMES): main outcomes of a randomized controlled trial of weight loss in overweight mothers with breast cancer and their overweight daughters	
Location	USA	
Trial name	Daughters And MothErS Against Breast Cancer (DAMES)	
Methods		
Inclusion criteria	"Women diagnosed with AJCC stage 0 to III breast cancer who had completed primary treatment but were within 5 years of diagnosis with no evidence of progressive disease or second primary tumors and who had a biological daughter who was aged 21 years were eligible. Dyad daughters had to have no previous diagnoses of cancer, with the exception of nonmelanoma skin cancer. Both mothers and daughters had to meet the following criteria: 1) a BMI of 25 kg/m2 to 39.9 kg/m2 ; 2) no preexisting medical condition(s) that would preclude adherence to an unsupervised exercise program (eg, untreated stage 3 hypertension, severe orthopedic conditions or being scheduled for a hip or knee replacement, paralysis, end-stage renal disease, dementia, unstable angina, history of a recent myocardial infarction, or congestive heart failure or pulmonary conditions requiring hospitalization or oxygen use within 6 months) or to a diet high in fruits and vegetables (ie, taking pharmacologic doses of warfarin); 3) ability to speak and write English and the completion of at least the sixth grade and thereby the ability to comprehend the intervention materials; 4) community dwelling in the United States, Puerto Rico, or Guam (regions in which there was visiting nurse coverage by Examination Management Services Inc [Scottsdale, Ariz]); 5) not currently exercising at least 150 minutes per week as assessed by the Leisure-Time Exercise Questionnaire of Godin et al17; and 6) not currently enrolled in a weight loss program."	
Exclusion criteria	Not reported	
Setting	Home	
Intervention	"Individual: All participants received materials promoting portion control and diets high in nutrients and low in energy as well as 150 minutes per week of aerobic exercise and twice-weekly strength training. However, interventions differed with respect to tailoring.Mothers and daughters assigned to this arm each received individually tailored print materials. For example, the ini tial workbook was not only personalized with the partici pant's name, but the initial pages also delineated individual weight goals and the kilocalorie levels required to achieve desired rates of weight loss using the Mifflin-St. Jeor equation (kcal/day 5 2161 1 10(wt) 1 6.25 (ht) 25(age)).29 In addition, the 3 major foods contributing the highest percentage of kilocalories to each participant's diet were identified from the dietary recalls performed at baseline, and individuals were either directed to lower-calorie substitutes or provided with guidance on portion control. Introductory pages also included tailored feed back on how current intakes of saturated fat and fruits and vegetables as well as physical activity compared with the national guidelines.; Team: All participants received materials promoting portion control and diets high in nutrients and low in energy as well as 150 minutes per week of aerobic exercise and twice-weekly strength training. However,	

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<tr><td></td><td>interventions differed with respect to tailoring. others and daughters assigned to the team-based intervention received information and supplies identical to those in the individual arm, but also received information on their other team member. Here, concepts of interdependence theory (ie, structuring goals to guide mother-daughter interactions to ultimately achieve outcomes) and the theory of communal coping (ie, cooperative problem-solving to deal with individual and common stressors) were drawn on to leverage the mother-daughter bond by encouraging effective communication between partners that would enhance their sense of confidence in planning, coordinating, and carrying forth strategies to increase mutual benefit.31,32 As an example, if a dyad member was charting success at meeting exercise goals, their next newsletter would provide positive reinforcement and also encourage them to share (in a helpful way) what had worked for them with their partner. Likewise, if a dyad member was experiencing a setback, they were provided with suggestions to get back on track and their partner was encouraged to provide them with helpful support”</td></tr>
<tr><td>Control/Comparator</td><td>“All participants received materials promoting portion control and diets high in nutrients and low in energy as well as 150 minutes per week of aerobic exercise and twice-weekly strength training. However, interventions differed with respect to tailoring. Mothers and daughters assigned to this arm received a copy of the National Cancer Institute brochure Facing Forward (NIH Publication No. 10-2424) and the American Insti tute for Cancer Research publication Facts on Weight Man agement and Cancer, which were included in their binder personalized with their name. Subsequent brochures were mailed on a bimonthly basis and included American Insti tute for Cancer Research brochures (New American Plate, A Healthy Weight for Life, Getting Active-Staying Active, and Moving Toward a Plant-based Diet) and pamphlets from the American Heart Association (Managing Your Weight and Cholesterol, Blood Pressure and Weight Tracker) and the American College of Sports Medicine (Fit Over 40). These brochures were accompanied by a cover letter that encour aged the participant to read the brochure and then place it in their binder for easy reference.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 136
Intervention group/s: INDIVIDUAL (n=50); TEAM (n=50)

Comparator group: CONTROL (n=36)</td></tr>
<tr><td>Mean age ± SD</td><td>Mothers: 61.3y (7.4); Daughters: 32.9y (1.4)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Mothers: Breast cancer survivors</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2) in daughters
Mean (SD)</td><td>INDIVIDUAL: 32.5
(5)
TEAM: 32.6
(7.3)</td><td>CONTROL: 33.3
(5.7)</td></tr>
<tr><td>Body weight (kg) in daughters
Mean (SD)</td><td>INDIVIDUAL: 87.5
(14.5)
TEAM: 89.1</td><td>CONTROL: 93.1
(18.7)</td></tr>
</table>
</td></tr>
</table>

		(23.7) INDIVIDUAL: 95.9 (11.9) TEAM: 94.9 (14.5)	 CONTROL: 97.3 (12.9)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	BMI (kg/m2) in daughters Mean (SD)	INDIVIDUAL: 30.9 (5.7) TEAM: 31.4 (6.3)	CONTROL: 32.8 (5.5)
	Body weight (kg) in daughters Mean (SD)	INDIVIDUAL: 83.1 (16.5) TEAM: 85.8 (20)	CONTROL: 91.4 (17.7)
	Waist circumference (cm) in daughters Mean (SD)	INDIVIDUAL: 90.1 (13.6) TEAM: 90.8 (13.4)	CONTROL: 97.2 (13.2)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in BMI in daughters Mean (SD)	INDIVIDUAL: -1.38 (2.79) TEAM: -1.07 (2.81)	CONTROL: -0.97 (2.96)
	Change in body weight in daughters Mean (SD)	INDIVIDUAL: -3.65 (7.35) TEAM: -3.09 (8)	CONTROL: -2.78 (8.39)
	Change in waist circumference, daughters Mean (SD)	INDIVIDUAL: -5.3 (5.9) TEAM: -4.1 (6.9)	CONTROL: -1 (6.9)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Individual: 30%; Team: 28%; Control: 43%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Derosa, 2012

Guideline record ID: 11017--1

Study characteristics		
Citation	Derosa, G., Cicero, A. F., D'Angelo, A., Fogari, E., & Maffioli, P. (2012). Effects of 1-year orlistat treatment compared to placebo on insulin resistance parameters in patients with type 2 diabetes. Journal of Clinical Pharmacy & Therapeutics, 37(2), 187-195. https://doi.org/https://doi.org/10.1111/j.1365-2710.2011.01280.x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of 1-year orlistat treatment compared to placebo on insulin resistance parameters in patients with type 2 diabetes	
Location	Italy	
Trial name	N/A	
Methods		
Inclusion criteria	"Type 2 diabetes aged ‡18 of either sex according to the European Society of Cardiology and European Association for the Study of Diabetes Guidelines criteria,17 obese [body mass index (BMI) ‡30 kg/m2] 18 and with uncontrolled type 2 diabetes mellitus [glycated haemoglobin (HbA1c) >8Æ0%] on therapy with different oral hypoglycaemic agents or insulin."	
Exclusion criteria	"Patients were excluded if they had a history of ketoacidosis or had unstable or rapidly progressive diabetic retinopathy, nephropathy or neuropathy; impaired hepatic function [defined as plasma aminotransferase and/or gamma-glutamyltransferase level higher than the upper limit of normal (ULN) for age and sex], impaired renal function (defined as serum creatinine level higher than the ULN for age and sex) or severe anaemia. Patients with serious cardiovascular disease (CVD) (e.g. New York Heart Association class I-IV congestive heart failure or a history of myocardial infarction or stroke) or cerebrovascular conditions within 6 months prior to study enrolment were excluded. We also excluded patients with GI disorders or those who had major abdominal surgery within 6 months of study enrolment. Women who were pregnant or breast-feeding or of child-bearing potential and not taking adequate contraceptive precautions were also excluded."	
Setting	University/research centre	
Intervention	"Patients were assigned to receive in the randomized, doubleblind study, in addition to their current antidiabetic therapy, orlistat 360 mg (orlistat group) for 12 months. Subjects began a controlled-energy diet (near 600 Kcal daily deficit) based on American Heart Association recommendations19 that included 50% of calories from carbohydrates, 30% from fat (6% saturated) and 20% from proteins, with a maximum cholesterol content of 300 mg/day and 35 g/day of fibre. Patients were not treated with vitamins or mineral preparations during the study. Standard dietary advice was given by a dietitian and/or specialist doctor. The dietitian and/or specialist doctor periodically provided instruction on dietary intake recording procedures as part of a behaviour modification programme and then later used the subject's food diaries for counselling. Individuals were also encouraged to increase their physical activity by walking briskly for 20-30 min, 3-5 times per week, or by cycling. The recommended changes in physical activity throughout the study were assessed at each visit using the subject's activity diary."	
Control/Comparator	"Patients were assigned to receive in the randomized, doubleblind study, in addition to their current antidiabetic therapy, placebo (control group) for 12 months. Subjects began a controlled-energy diet (near 600 Kcal daily deficit) based on American Heart Association recommendations19 that included 50% of calories from carbohydrates, 30% from fat (6% saturated) and 20% from proteins, with a maximum cholesterol content of 300 mg/day and	

<table>
<tr><td></td><td>35 g/day of fibre. Patients were not treated with vitamins or mineral preparations during the study. Standard dietary advice was given by a dietitian and/or specialist doctor. The dietitian and/or specialist doctor periodically provided instruction on dietary intake recording procedures as part of a behaviour modification programme and then later used the subject's food diaries for counselling. Individuals were also encouraged to increase their physical activity by walking briskly for 20-30 min, 3-5 times per week, or by cycling. The recommended changes in physical activity throughout the study were assessed at each visit using the subject's activity diary.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 254
Intervention group/s: Orlistat (n=126)

Comparator group: Control (n=128)</td></tr>
<tr><td>Mean age ± SD</td><td>Orlistat: 53y (6); Control: 52y (5)</td></tr>
<tr><td>Sex</td><td>49.61% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Orlistat: 94.5
(9.6)

Orlistat: 33.1
(2.9)

Orlistat: 102
(6)</td><td>Control: 91.7
(8.7)

Control: 32.5
(2.3)

Control: 101
(5.5)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Orlistat: 85
(5.9)

Orlistat: 29.8
(1.2)

Orlistat: 95
(3)</td><td>Control: 89.1
(7.8)

Control: 31.6
(1.8)

Control: 99
(4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td></td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Derwig, 2022

Guideline record ID: 10756--1

Study characteristics		
Citation	Derwig, M., Tiberg, I., Björk, J., & Kristensson Hallström, I. (2022). Changes in perceived parental self-efficacy after a Child-Centred Health Dialogue about preventing obesity. Acta Paediatrica, 111(10), 1956-1965. https://doi.org/https://dx.doi.org/10.1111/apa.16453	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Changes in perceived parental self-efficacy after a Child-Centred Health Dialogue about preventing obesity	
Location	Sweden	
Trial name	N/A	
Methods		
Inclusion criteria	"The inclusion criteria were children born between January 2013 and August 2014, who were invited to their 4-year health visit and who had parents who were able to read and write Swedish."	
Exclusion criteria	"Children who were not brought to their 4-year health visit were excluded. We also excluded 30 children, because a newly recruited nurse had not been trained in the intervention."	
Setting	Swedish child health centres	
Intervention	"Children and parents allocated to the intervention group all received the 10-min structured universal part of the Child-Centred Health Dialogue at the 4-year health visit. If the child was classified as overweight or obesity by the nurse, the parents were offered a further 45-min targeted intervention called family guidance. This took place 1-3 weeks after the 4-year health visit. The conceptual framework was based on the concepts of child-centred care and health literacy and used 8 interactive age-appropriate illustrations, which covered the most important modifiable lifestyle behaviours, and the BMI growth chart to clarify the child's natural growth pattern. The intervention used a solution-based approach that focused on the child's health, and not their weight issues, to build relationships with the children and parents. It enabled the nurse to strengthen the child and parents' health literacy in everyday situations and increase the parents' self-efficacy when it came to promoting a healthy diet and physical activity. The aim was to decrease zBMI after the 4-year health visit in children with a positive zBMI at 4 years of age. Children with obesity were also referred to specialised care outside the primary care setting."	
Control/Comparator	"Children and parents allocated to the usual care group received the 4-year health visit according to that national Child Health Programme. It included an unstructured health dialogue with the parents identifying any children with overweight and obesity. The visit was guided by the Swedish digital National Handbook for Child Health Services (www.riksh andbo ken-bhv. se). Nurses delivering usual care may have used the illustrations developed for the intervention, as they were published in the National Handbook in Spring 2016, before the start of this study. However, they were not been trained in how to use them.15."	
Treatment duration	One off appointment conducted	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 1197
Intervention group/s: Intervention group (n=706)

Comparator group: Control group (n=491)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 4.0y (0.1) ; Control 4.1y (0.1)</td></tr>
<tr><td>Sex</td><td>51.80% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in BMI z-score (overweight children) Mean (SD)</td><td>Intervention group: -0.22 (0.4)</td><td>Control group: -0.02 (0.49)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>The drop-out rates at 12 months were 28.5% in the intervention group and 23.6% in the control group</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Díaz, 2010

Guideline record ID: 10171--1

Study characteristics		
Citation	Díaz, R. G., Esparza-Romero, J., Moya-Camarena, S. Y., Robles-Sardín, A. E., & Valencia, M. E. (2010). Lifestyle intervention in primary care settings improves obesity parameters among Mexican youth. Journal of the American Dietetic Association, 110(2), 285-290. https://doi.org/10.1016/j.jada.2009.10.042	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Lifestyle intervention in primary care settings improves obesity parameters among Mexican youth	
Location	Mexico	
Trial name	N/A	
Methods		
Inclusion criteria	"Age between 9 and 17 years, BMI 95th percentile based on the Centers for Disease Control and Prevention growth chart (15) or BMI 90th percentile with waist circumference 90th percentile (16), caregivers interested in weight control, and willingness to attend the group educational sessions."	
Exclusion criteria	"Glucose intolerance or type 2 diabetes, psychiatric disorders, any medical condition that would preclude participation in the study, the use of medication that affected weight, or involvement in a weight loss program or structured physical activity. Participants who had lost weight during the 4 months before the study were also excluded."	
Setting	Hospital, Primary Care	
Intervention	"Behavioral Curriculum. The behavior modification component of this lifestyle intervention was based on information contained in the workbook, Programa Cambia. This program was adapted from Mellin's Shapedown Program (17,18), including new culturally appropriate topics focused mainly on the health belief model (19,20), and a simple food guide developed by our group. This adaptation was based on two pilot interventions (Díaz RG, et al, unpublished data, January 2006), including 31 youths with overweight/obesity and their parents with different socioeconomic status. The first part of the program was focused mainly on children's perceptions of susceptibility, severity, benefits, and barriers. The second part of the program was centered on self-esteem, how to deal with emotions, communication skills, knowledge regarding body weight regulation, energy intake, nutrition, physical activity, and the use of behavior modification techniques. The program consisted of 12 consecutive, weekly, 2-hour group sessions in the clinic. Sessions were led by an RD with expertise in implementing the program. Each session included about 10 participants similar in age. Participants were asked to establish their own goals regarding physical activity, time spent in sedentary activities, and diet improvement. Goals were revised and renewed every session. Parents of participants received six education sessions and were encouraged to lose weight if they were overweight. For nutrition education and diet prescriptions for children, a simple food guide using different colors (red, yellow, and green) to designate different food groups was developed by our group (Health Nutrition Traffic Light). This tool uses the Mexican exchange list for meal planning (21) and integrated knowledge about the glycemic index of various foods. Fruits, vegetables, legumes, lowfat milk, lean meat/substitutes were assigned the color green, "highly recommended"; starches and fats were assigned the color yellow, "recommended but not exceeding"; and sweets, desserts, fast food, high-fat meat/substitutes, and high-fat milk were assigned the color red, "limit as much as possible." Foods with a high glycemic index were marked and the participants were encouraged to avoid these foods as much as possible. RD Consultations. Participants and their parents attended weekly consultations with the RD during the first 12 consecutive weeks of the study and monthly thereafter. Participants	

<table>
<tr><td></td><td>were given an individualized diet of 1,200 to 1,800 kcal/day, depending on their physical activity and weight status. The diets were flexible regarding macronutrients (22). Slow weight loss was promoted or weight maintenance was emphasized while height increased, with the goal of improving food habits, not implementing a rigid diet. Physician Consultations. Participants and their parents had monthly consultations of 10 to 15 minutes with a primary care physician. The physician only monitored BMI and blood pressure and encouraged the participants to adhere to the dietary recommendation given by the RD and the physical activity goals established in the behavior program.”</td></tr>
<tr><td>Control/Comparator</td><td>“Participants in the control group and their parents attended monthly consultations of 10 to 15 minutes in length with a primary care physician. Primary care physicians monitored BMI and encouraged youths to progressively perform 30 minutes of physical activity most days of the week, limiting sedentary time to 2 hours per day, and to follow a diet consistent with the Food Guide Pyramid (23). Physicians provided and instructed the participants and their parents how to use a color Food Guide Pyramid and a menu example. The original Food Guide Pyramid was adapted to include various traditional foods eaten in México. Parents were encouraged by physicians to adopt positive behaviors, for instance, reduction of sweetened beverages and increasing exercise and healthful foods to facilitate behavior change in their children. Primary Care Physician Recruitment and Training Primary care physicians who participated in the study consisted of five general practitioners and one pediatrician. This group attended a series of meetings (four to six sessions of 1.5 hours each) before the beginning of the intervention. The program included the revision and discussion of the clinical guidelines for obesity in children (23), a review of health consequences of obesity in youth, and the use of Epi Info software (version 3.3.2, 2005, Centers for Disease Control and Prevention, Atlanta, GA) for monitoring BMI and the study Food Guides. At the end of the program, all physicians answered satisfactorily an informal evaluation including 20 open questions regarding the topics mentioned above. Furthermore, physicians were provided with an algorithm to facilitate the visits. The same physicians participated in the two different group interventions and had a similar number of participants from each group.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 43
Intervention group/s: Lifestyle (n=21)

Comparator group: Control (n=22)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 11.6 (2.1); Control: 11.7 (2.2)</td></tr>
<tr><td>Sex</td><td>51.16% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) (per protocol)
Mean (SD)

BMI (per protocol)
Mean (SD)

BMI Z score (per protocol)</td><td>Lifestyle: 70.3
(17)

Lifestyle: 30.2
(5.4)

Lifestyle: 2.12</td><td>Control: 69.2
(15)

Control: 29.1
(4.2)

Control: 2.07</td></tr>
</table>
</td></tr>
</table>

	Mean (SD) Waist circumference (cm) (per protocol) Mean (SD) Body fat (kg) (per protocol) Mean (SD) Body fat (%) Mean (SD)	(0.37) Lifestyle: 97.5 (11.4) Lifestyle: 33.8 (10.5) Lifestyle: 47.7 (4)	(0.25) Control: 96.8 (9.7) Control: 33.4 (10.2) Control: 46.5 (4.8)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight (kg) (per protocol) Mean (SD) BMI (per protocol) Mean (SD) BMI Z score (per protocol) Mean (SD) Waist circumference (cm) (per protocol) Mean (SD) Body fat (kg) (per protocol) Mean (SD) Body fat (%) Mean (SD)	Lifestyle: 69.5 (16.1) Lifestyle: 28.4 (5.5) Lifestyle: 1.83 (0.5) Lifestyle: 91.3 (12.1) Lifestyle: 31.5 (11) Lifestyle: 44.6 (6.2)	Control: 74.8 (15.9) Control: 29.5 (4.7) Control: 1.97 (0.36) Control: 97.4 (11.8) Control: 34.7 (10.5) Control: 44.9 (5.5)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in weight (kg, per protocol) Mean (SD) Change in BMI (kg/m2) (per protocol) Mean (SD) Change in BMI Z score (per protocol) Mean (SD) Change in waist circumference (cm) (per protocol) Mean (SD) Change in body fat (kg) (per protocol) Mean (SD) Change in body fat (%) (per protocol) Mean (SD) Change in weight (mITT) Mean (95% CIs) Change in BMI (kg/m2) (mITT)	Lifestyle: -0.8 (5.2) Lifestyle: -1.8 (1.9) Lifestyle: -0.29 (0.24) Lifestyle: -6.2 (6.2) Lifestyle: -2.3 (4.8) Lifestyle: -3.1 (4.1) Lifestyle: 2.1 (-0.06-4.3) Lifestyle: -0.6	Control: 5.6 (5.9) Control: 0.4 (2.1) Control: -0.09 (0.23) Control: 0.6 (6.4) Control: 1.3 (5.3) Control: -1.7 (4.5) Control: 5.6 (3.5-7.7) Control: 0.6

	Mean (95% CIs)	(-1.4-0.2)	(-0.1-1.3)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	57%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Dixon, 2012

Guideline record ID: 10176--1

Study characteristics		
Citation	Dixon, J. B., Schachter, L. M., O'Brien, P. E., Jones, K., Grima, M., Lambert, G., Brown, W., Bailey, M., & Naughton, M. T. (2012). Surgical vs conventional therapy for weight loss treatment of obstructive sleep apnea: a randomized controlled trial. JAMA, 308(11), 1142-1149. https://doi.org/10.1001/2012.jama.11580	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Surgical vs conventional therapy for weight loss treatment of obstructive sleep apnea: a randomized controlled trial	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	"The inclusion criteria were patients aged 18 to 60 years, body mass index (calculated as weight in kilograms divided by height in meters squared) of 35 to 55, apnea-hypopnea index (AHI) of 20 events/hour or more diagnosed within the previous 6 months with recommendation to commence CPAP therapy,13 and at least 3 prior significant weight loss attempts."	
Exclusion criteria	"The exclusion criteria were previous bariatric surgery, obesity hypoventilation syndrome requiring bilevel positive airway pressure, and contraindications to bariatric surgery including cognitive impairment, drug or alcohol addiction, and significant cardiopulmonary, neurological, vascular, gastrointestinal, or neoplastic disease."	
Setting	Hospital, University/research centre	
Intervention	"Participants underwent 2 weeks of VLED to reduce liver size prior to placement of an LAGB within 1 month of randomization.17 Adjustments to band volume were made using standard clinical criteria. Patients in both programs had open access to a bariatric physician, sleep physician, and dietitian, and had their progress reviewed every 4 to 6 weeks throughout the 2 years. The management of OSA, the intensity, and nature of the lifestyle program were common to both groups."	
Control/Comparator	"This program delivered the best available medical practice for the treatment, education, and follow-up of severely obese patients with moderate to severe OSA. Dietary, physical activity, and behavioral programs were individualized. The advice regarding physical activity encouraged walking and 200 minutes/week of structured activity, including moderate-intensity aerobic activity and resistance exercise. Dietary advice was based on the Dietary Guidelines for Australian Adults and the Australian Guide to Healthy Eating and included a planned daily deficit of 500 kcal from estimated energy requirements. All participants were offered an initial intensive very low-energy diet (VLED) (Optifast, Nestle Australia) program, with the meal replacements provided. The VLED meal replacements continued to be available for further intensive, intermittent, or occasional use throughout the study."	
Treatment duration	2 years	
Follow-up from baseline	2 years	
Eligible outcome(s) reported	Weight for height growth chart	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 60
Intervention group/s: Surgery (n=30)

Comparator group: Conventional Care (n=30)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 47.4y (8.8); Control: 50.0y (8.2)</td></tr>
<tr><td>Sex</td><td>41.67% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Obstructive sleep apnea</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Surgery: 134.9
(22.1)

Surgery: 46.3
(6)</td><td>Conventional Care: 126
(19.3)

Conventional Care: 43.8
(4.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight at 2 years
Mean (95% CIs)

BMI (kg/m2)
Mean (SD)</td><td>Surgery: 107.1
(99-116)

Surgery: 36.6</td><td>Conventional Care: 121.8
(113-129)

Conventional Care: 42.3</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>% Weight loss
Mean (95% CIs)</td><td>Surgery: 20.6
(15.4-25.7)</td><td>Conventional Care: 2.9
(0.6-7.3)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Dorenbos, 2021

Guideline record ID: 10178--1

Study characteristics		
Citation	Dorenbos, E., Drummen, M., Adam, T., Rijks, J., Winkens, B., Martínez, J. A., Navas-Carretero, S., Stratton, G., Swindell, N., Stouthart, P., Mackintosh, K., Mcnarry, M., Tremblay, A., Fogelholm, M., Raben, A., Westerterp-Plantenga, M., & Vreugdenhil, A. (2021). Effect of a high protein/low glycaemic index diet on insulin resistance in adolescents with overweight/obesity-a PREVIEW randomized clinical trial. Pediatric Obesity, 16(1), e12702. https://doi.org/https://dx.doi.org/10.1111/ijpo.12702	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a high protein/low glycaemic index diet on insulin resistance in adolescents with overweight/obesity-A PREVIEW randomized clinical trial	
Location	Netherlands; Spain; UK	
Trial name	PREVention of diabetes through lifestyle intervention and population studies In Europe and around the World (PREVIEW)	
Methods		
Inclusion criteria	"Inclusion criteria were overweight/obesity (BMI z-score >1.0 SDS), increased IR (defined as HOMA-IR >2.0 for adolescents Tanner G/M stages ≥3 or any HOMA-IR for adolescents at Tanner stages 1-2) and signed informed consent from both parents and adolescents ≥12 years.2."	
Exclusion criteria	"Exclusion criteria included medical conditions or use of medication that might influence study outcomes (eg, T2DM, bariatric surgery and use of metformin) or compromise study adherence (eg, severe food intolerances or musculoskeletal diseases)."	
Setting	Home	
Intervention	"The first 8 weeks aimed at weight stabilization during growth. All participants received sample menus based on their estimated energy requirements, consisting of 15/55/30 energy percent (En%) protein/carbohydrate/ fat. The HP group received a sample menu with a target macronutrient composition of 25/45/30 En% protein/carbohydrate/ fat and a GI ≤ 50. All menus were tailored to the participant's estimated energy requirements. Upon request, further personalized tips were given taking for example, cultural traditions into account. In addition, in the perspective of pre-diabetes related health, participants were instructed to increase PA (in organized sports and daily movement)."	
Control/Comparator	"The first 8 weeks aimed at weight stabilization during growth. All participants received sample menus based on their estimated energy requirements, consisting of 15/55/30 energy percent (En%) protein/carbohydrate/ fat. The MP group received a sample menu with a macronutrient composition of 15/55/30 En% protein/carbohydrate/fat and a GI≥56. All menus were tailored to the participant's estimated energy requirements. Upon request, further personalized tips were given taking for example, cultural traditions into account. In addition, in the perspective of pre-diabetes related health, participants were instructed to increase PA (in organized sports and daily movement)."	
Treatment duration	104 weeks	
Follow-up from baseline	2 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 126
Intervention group/s: HP (n=68)

Comparator group: MP (n=58)</td></tr>
<tr><td>Mean age ± SD</td><td>HP: 13.7y (2.4); MP: 13.4y (2.0)</td></tr>
<tr><td>Sex</td><td>58.73% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)

BMI (kg/m2) - Baseline
Mean (SD)

BMI z-score (SD) - Baseline
Mean (SD)</td><td>HP: 80
(20.9)

HP: 30.1
(5.1)

HP: 3.1
(0.69)</td><td>MP: 75.7
(18.2)

MP: 29.3
(4.6)

MP: 2.97
(0.63)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)

Change in BMI (kg/m2)
Mean (95% CIs)

Change in BMI z-score (SD)
Mean (95% CIs)</td><td>HP: 8.3
(1.1-15.5)

HP: 1.3
(-1.1-3.6)

HP: -0.22
(-0.33--0.1)</td><td>MP: 10.6
(3.6-17.6)

MP: 2.3
(-0.3-4.9)

MP: -0.09
(-0.21-0.03)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)

Change in BMI (kg/m2)
Mean (95% CIs)

Change in BMI z-score (SD)
Mean (95% CIs)</td><td>HP: 4.4
(-1.5-10.4)

HP:-0.33
(-1.8-1.2)

HP: -0.16
(-0.36--0.04)</td><td>MP: 3.0
(-2.9-8.9)

MP: -0.5
(-1.8-0.8)

MP: -0.22
(-0.46-0.01)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>No compliance to the diets was observed</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Raben, A., Vestentoft, P. S., Brand-Miller, J., Jalo, E., Drummen, M., Simpson, L., Martinez, J. A., Handjieva-Darlenska, T., Stratton, G., Huttunen-Lenz, M., Lam, T., Sundvall, J., Muirhead, R., Poppitt, S., Ritz, C., Pietiläinen, K. H., Westerterp-Plantenga, M., Taylor, M. A., Navas-Carretero, S., . . . Fogelholm, M. (2021). The PREVIEW intervention study: results from a 3-year randomized 2 x 2 factorial multinational trial investigating the role of protein,</td></tr>
</table>

	glycaemic index and physical activity for prevention of type 2 diabetes. Diabetes, Obesity and Metabolism, 23(2), 324-337. https://doi.org/https://dx.doi.org/10.1111/dom.14219

N/A – Not applicable

Dowsey, 2022

Guideline record ID: 11073--1

Study characteristics		
Citation	Dowsey MM, Brown WA, Cochrane A, Burton PR, Liew D, Choong PF. Effect of Bariatric Surgery on Risk of Complications After Total Knee Arthroplasty: A Randomized Clinical Trial. JAMA Netw Open. 2022 Apr 1;5(4):e226722. doi: 10.1001/jamanetworkopen.2022.6722. PMID: 35420662; PMCID: PMC9011119.	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Bariatric Surgery on Risk of Complications After Total Knee Arthroplasty A Randomized Clinical Trial	
Location	Australia	
Trial name	The Arthroplasty and Bariatric Surgery (ABS) study	
Methods		
Inclusion criteria	"(i) Age ≤ 65 years at time of LAGB (ii) BMI ≥35 kg/m² (iii) On the surgical waiting list for primary TKA at SVHM (iv) Willing and able to cooperate in a long-term weight management programme."	
Exclusion criteria	"(i) Revision surgery or surgery for neoplastic disease (ii) Inability to provide informed consent (iii) A medical condition which in the opinion of the investigators makes the patient unsuitable for participation in the trial (iv) Previous oesophagogastric surgery such as fundoplication (v) Lack of acceptance of the randomisation process."	
Setting	Hospital	
Intervention	"Surgery was preceded by 2 weeks of a weight-loss program (Optifast) to reduce liver size before placement of the LAGB using the Allergan Health Lap-Band System. LAGB was performed at The Avenue Hospital as either a day procedure or as an overnight stay if medically indicated. Patients underwent a routine barium-enhanced esophagogram before discharge to assess for position of the band. Patients attended regular follow-up visits after LAGB, as described elsewhere,23 in which lifelong follow-up is intended. In brief, 3 to 5 visits are scheduled at 2-week to 4-week intervals, reducing to 3-week intervals, then 6-month intervals, and, ultimately, patients are seen once per year, at a minimum. Clinical visits involve LAGB adjustment to optimize satiety without inducing adverse symptoms. Education and advice regarding eating behavior, dietary intake, and lifestyle change are provided at each visit"	
Control/Comparator	"In line with standard practice, patients in the comparator TAU group underwent TKA with routine follow-up and were provided general weight management advice."	
Treatment duration	Surgical	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 82 Intervention group/s: LAGB (n=41) Comparator group: TAU (n=41)	
Mean age ± SD	LAGB: 58.7y (3.7); TAU: 57.0y (5.7)	

<table>
<tr><td>Sex</td><td>80.49% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Osteoarthritis</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body mass index (kg/m2)
Mean (SD)

Body weight (kg)
Mean (SD)</td><td>LAGB: 43.8
(4.8)

LAGB: 116.1
(18)</td><td>TAU: 43.6
(6.3)

TAU: 114
(15.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body mass index (kg/m2)
Mean (SD)

Body weight (kg)
Mean (SD)</td><td>LAGB: 36.5
(5.5)

LAGB: 96.6
(17.1)</td><td>TAU: 42.5
(6.6)

TAU: 111.5
(17)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>95%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Driehuis, 2012

Guideline record ID: 10181--1

Study characteristics		
Citation	Driehuis, F., Barte, J. C. M., ter Bogt, N. C. W., Beltman, F. W., Smit, A. J., van der Meer, K., & Bemelmans, W. J. E. (2012). Maintenance of lifestyle changes: 3-year results of the Groningen Overweight and Lifestyle study. Patient Education and Counseling, 88(2), 249-255. https://doi.org/https://dx.doi.org/10.1016/j.pec.2012.03.017	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Maintenance of lifestyle changes: 3-year results of the Groningen Overweight and Lifestyle study	
Location	Netherlands	
Trial name	Groningen Overweight And Lifestyle (GOAL)	
Methods		
Inclusion criteria	"Aged between 40 and 70 years, with a BMI between 25 and 40 kg/m2 and should have hypertension and/or dyslipidemia."	
Exclusion criteria	"Exclusion criteria were having diabetes mellitus, hypothyroidism, liver- or kidney disease, mental illness, addiction to alcohol and/or drugs, shortened life expectancy, current treatment for malignancy and being pregnant."	
Setting	GP clinic, Hospital	
Intervention	"In the first year the intervention contained four individual counseling meetings by a NP (1, 2, 3 and 8 months after baseline) and one feedback consultation by phone (5 months after baseline). In the second and third year subjects had one meeting with NP and received two feedback phone calls each year. In their counseling NPs were guided by a standardized computerized software program. This software program contained instructions on lifestyle counseling according to (inter)national guidelines"	
Control/Comparator	"The GP group was offered one GP consultation to discuss the results of baseline measurements and thereafter received usual care by a general practitioner according to national GP guidelines."	
Treatment duration	3 years	
Follow-up from baseline	3 years	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 338 Intervention group/s: Nurse practitioner group (n=162) Comparator group: General practitioner group (n=176)	
Mean age ± SD	NP Group: 55.5y (7.8); GP Group: 56.9y (7.8)	
Sex	52.96% female	
Pre-existing medical condition	Hypertension and/or dyslipidaemia	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2) - Baseline Mean (SD)

Weight (kg) - Baseline Mean (SD)</td><td>Nurse practitioner group: 29.4 (3)

Nurse practitioner group: 88.3 (12.1)</td><td>General practitioner group: 29.5 (3.6)

General practitioner group: 87.6 (13.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg) Mean (SD)</td><td>Nurse practitioner group: -1.4 (5.4)</td><td>General practitioner group: -1.0 (5.2)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>ter Bogt, N. C. W., Milder, I. E. J., Bemelmans, W. J. E., Beltman, F. W., Broer, J., Smit, A. J., & van der Meer, K. (2011). Changes in lifestyle habits after counselling by nurse practitioners: 1-year results of the Groningen Overweight and Lifestyle study. Public Health Nutrition, 14(6), 995-1000. https://doi.org/10.1017/S1368980010003708</td></tr>
</table>

N/A – Not applicable

Due, 2017

Guideline record ID: 10182--1

Study characteristics		
Citation	Due, A., Larsen, T. M., Mu, H., Hermansen, K., Stender, S., Toubro, S., Allison, D. B., & Astrup, A. (2017). The effect of three different ad libitum diets for weight loss maintenance: a randomized 18-month trial. European Journal of Nutrition, 56(2), 727-738. https://doi.org/10.1007/s00394-015-1116-6	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The effect of three different ad libitum diets for weight loss maintenance: a randomized 18-month trial	
Location	Denmark	
Trial name	N/A	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	University/research centre	
Intervention	"Prescribed ad libitum diets were (1) Moderate fat (35-45 E%), high in Mono-Unsaturated Fatty Acid (>20 E%) [MUFA], (2) Low Fat (20-30 E%) [LF]. Protein was similar (15 E%) in all three diets. The MUFA diet included more whole grain foods, nuts and legumes. Foods recommended to eat plenty of, eat less of, or restrict to a minimum in the respective groups have been described [10]. Differences in both the total amount of carbohydrate and specific food components supposedly resulted in low, medium glycaemic index and glycaemic load (GL) in MUFA, LF, respectively. Alcohol intake was recommended at a minimum, though consumption was allowed in accordance with Danish guidelines before August 2010, i.e. <14 units/week for women and <21 units/week for men (1 unit = 12 g alcohol). Subjects were instructed to maintain their habitual physical activity level throughout the study. To control dietary composition, the supermarket model was used [10, 11]. During the first 6 months study participants collected all foods (100 % of their energy needs) 1-3 times/ week free of charge. Food intake was permitted ad libitum and the energy content was not known by the subjects. During the following 12 months all subjects were provided freely with 20 % of their estimated calorie requirements (calculations based on body weight after weight loss, sex, age, and a moderate PAL factor of 1.4) [3]. All food items provided were characteristic of their respective diet [10], and the food items were picked up from the supermarket monthly. The subjects shopped the remaining 80 % of their foods in ordinary shops and supermarkets. To ensure high dietary compliance, all subjects received monthly individual face-to-face dietary counselling and encouragement from a dietician throughout this 12-month less strict intervention period. Additionally, fat biopsies and questionnaires were performed and used to monitor dietary compliance."	
Control/Comparator	"prescribed ad libitum diets were (3) Control (35 E% fat) with >15 E% saturated fatty acid [CTR]. Protein was similar (15 E%) in all three diets. the CTR included more added sugar than the other diets. Foods recommended to eat plenty of, eat less of, or restrict to a minimum in the respective groups have been described [10]. Differences in both the total amount of carbohydrate and specific food components supposedly resulted in high glycaemic index and glycaemic load (GL) in CTR diet. Alcohol intake was recommended at a minimum, though consumption was allowed in accordance with Danish guidelines before August 2010, i.e. <14 units/week for women and <21 units/week for men (1 unit = 12 g alcohol). Subjects were instructed to maintain their habitual physical activity level throughout the study. To control dietary composition, the supermarket model was used	

<table>
<tr><td></td><td>[10, 11]. During the first 6 months study participants collected all foods (100 % of their energy needs) 1-3 times/ week free of charge. Food intake was permitted ad libitum and the energy content was not known by the subjects. During the following 12 months all subjects were provided freely with 20 % of their estimated calorie requirements (calculations based on body weight after weight loss, sex, age, and a moderate PAL factor of 1.4) [3]. All food items provided were characteristic of their respective diet [10], and the food items were picked up from the supermarket monthly. The subjects shopped the remaining 80 % of their foods in ordinary shops and supermarkets. To ensure high dietary compliance, all subjects received monthly individual face-to-face dietary counselling and encouragement from a dietician throughout this 12-month less strict intervention period. Additionally, fat biopsies and questionnaires were performed and used to monitor dietary compliance."</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 125
Intervention group/s: MUFA (n=52); LF (n=48)

Comparator group: CTR (n=25)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (95% CIs)</td><td>MUFA: 81.9
(75.9-87.8)
LF: 85.7
(82.1-89.2)</td><td>CTR: 81.7
(76.3-87.1)</td></tr>
<tr><td>BMI (kg/m2)
Mean (95% CIs)</td><td>MUFA: 27.3
(26.4-28.6)
LF: 27.7
(26.9-28.6)</td><td>CTR: 27.1
(26.1-28.1)</td></tr>
<tr><td>Fat mass (kg)
Mean (95% CIs)</td><td>MUFA: 24.5
(20.9-28.2)
LF: 26.1
(23.1-29.2)</td><td>CTR: 23.5
(19.4-27.5)</td></tr>
<tr><td>Waist circumference
Mean (95% CIs)</td><td>MUFA: 92.3
(89.5-95)
LF: 93.8
(91.1-96.9)</td><td>CTR: 91.6
(87.2-96)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (95% CIs)</td><td>MUFA: 87.9
(79.8-96.1)
LF: 90.4
(86.1-94.7)</td><td>CTR: 87.9
(80.4-95.3)</td></tr>
<tr><td>BMI (kg/m2)</td><td>MUFA: 29</td><td>CTR: 29</td></tr>
</table>
</td></tr>
</table>

	Mean (95% CIs)	(27.4-30.7) LF: 29.4 (28.4-30.5)	(27.6-30.5)
	Fat mass (kg) Mean (95% CIs)	MUFA: 30.9 (25.9-35.9) LF: 32 (28.7-35.3)	CTR: 30.3 (26.2-34.4)
	Waist circumference Mean (95% CIs)	MUFA: 99.6 (94.1-105.1) LF: 100.5 (96.9-104)	CTR: 98.5 (93.1-103.9)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in weight (kg) Mean (95% CIs)	MUFA: 6.1 (2.2-9.9) LF: 4.7 (2.6-6.9)	CTR: 6.1 (3.3-9)
	Change in weight (%) Mean (95% CIs)	MUFA: 7.1 (2.6-11.5) LF: 5.6 (3-8.1)	CTR: 7.2 (4.1-10.3)
	Change in BMI (kg/m2) Mean (95% CIs)	MUFA: 1.7 (0.7-2.8) LF: 1.7 (1-2.4)	CTR: 2 (1.1-2.8)
	Change in fat mass (kg) Mean (95% CIs)	MUFA: 6.4 (3.7) LF: 5.9 (3.9-7.9)	CTR: 6.8 (5.1-8.6)
	Change in waist circumference (cm) Mean (95% CIs)	MUFA: 7.4 (3.5-11.2) LF: 6.6 (4.6-8.6)	CTR: 6.9 (2.9-10.9)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	51%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Duggan, 2019

Guideline record ID: 10757--1

Study characteristics		
Citation	Duggan, C., Tapsoba, J. d. D., Stanczyk, F., Wang, C.-Y., Schubert, K. F., & McTiernan, A. (2019). Long-term weight loss maintenance, sex steroid hormones, and sex hormone-binding globulin. Menopause, 26(4), 417-422. https://doi.org/10.1097/GME.0000000000001250	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-term weight loss maintenance, sex steroid hormones, and sex hormone-binding globulin	
Location	USA	
Trial name	Nutrition and Exercise for Women (NEW)	
Methods		
Inclusion criteria	"Postmenopausal women from the greater Seattle, WA area, aged 50-75 years, who were overweight or obese (BMI ≥25kg/m2, or ≥23kg/m2 for AsianAmerican women), and exercising <100min/week at moderate intensity or greater."	
Exclusion criteria	"Specific exclusion criteria included: diagnosed diabetes, fasting blood glucose ≥126mg/dl, or use of diabetes medications; use of postmenopausal hormone therapy within the prior 3 months; history of breast cancer or other serious medical condition(s); alcohol intake in excess of 2 drinks/day or current smoker; contraindication to participating in the diet or exercise intervention for any reason, including an abnormal exercise tolerance test, current or planned participation in another structured weight loss program, use of weight loss medications, or additional factors that might interfere with measurement of outcomes or with the success of the intervention (e.g., inability to attend facility-based sessions). Additional exclusion criteria for ancillary study: These additional exclusion criteria were: estrogen use during the trial (n=1); serum estradiol ≥ 42 pg/mL (n=13), testosterone ≥100 ng/dL (n=1), or SHBG ≥180 nmol/L (n=1)."	
Setting	Home, University/research centre	
Intervention	"Diet: The NEW dietary weight-loss intervention comprised our modification of the dietary component of the DPP (9) and the Look Action for Health in Diabetes (AHEAD) (13) lifestyle intervention programs, with the following goals: total daily energy intake of 1,200-2,000kcal/ day based on baseline weight, <30% daily energy intake from fat, and a 10% reduction in body weight by 6 months with maintenance thereafter to 12 months. Content of the dietary counseling sessions was modified to better fit our study population (less focus on diabetes or diabetes risk), and the frequency and type of sessions (individual vs. group) also varied from DPP and Look AHEAD. Women met individually with a study dietitian for personalized goal-setting on at least two occasions, followed by weekly meetings in groups of ~5-10 women, through the first 6 months. Thereafter (months 7-12), dietitians had contact with participants twice a month, including one face-to-face contact (individual or group session) and one additional contact via phone or email. Participants were permitted additional in-person sessions, phone, or email contacts beyond the 32 expected, if they or the dietician felt these would help to achieve intervention goals. This combination of individual and group-based approaches was used to maximize the benefits of targeted, personalized recommendations along with the social support and greater cost-effectiveness of a group setting. Women were asked to record all food eaten daily for at least 6 months, or until they reached their individual weight loss goal (10%). Food journals were collected by the dietitian and returned with feedback. Journaling, weekly weigh-ins, and session attendance were tracked to promote adherence to the diet intervention.; Exercise:Based on our previous exercise research in a similar population, the goal of the NEW exercise intervention was ≥45min of moderate-to-vigorous intensity exercise, 5	

<table>
<tr><td></td><td>days/week (225min/week) for 12 months (14,15). Participants attended at least three sessions/week at our study facility where they were supervised by an exercise physiologist, and exercised for their remaining sessions at home. The exercise training program began with a 15min session at 60-70% maximal heart rate (determined by baseline exercise treadmill testing) and progressed to the target 70-85% maximal heart rate for 45min by the 7th week after enrollment where it was maintained for the remainder of the study. Women wore Polar heart rate monitors (Polar Electro, Lake Success, NY) during facility exercise sessions to assist with attaining their target heart rate. In addition, during both facility and home sessions they recorded the mode and duration of exercise, and peak heart rate achieved. Facility-based exercise consisted of treadmill walking, stationary bicycling, and use of other aerobic machines; while a variety of home exercises were encouraged including walking/hiking, aerobics, and bicycling. A small amount of resistance training to strengthen joints and limit injury was recommended, though not required. Activities of at least four metabolic equivalents according to the Compendium of Physical Activities (16) such as brisk walking were counted toward the prescribed aerobic exercise target. Activity logs were reviewed weekly by study staff in order to monitor adherence. Participants who were not meeting exercise targets were contacted by staff to discuss barriers and approaches to increase activity. In addition, the dietitians and exercise physiologists met regularly with a clinical health psychologist experienced in lifestyle behavior change to discuss participant progress and refine behavior modification goals according to each participant's needs.; Diet+Exercise: Women randomized to the diet + exercise group received both the dietary weight loss and aerobic exercise interventions. They participated in separate groups for the dietary weight-loss intervention from women assigned to diet alone. Although the diet + exercise group could use the exercise facility at the same time as participants assigned to the exerciseonly group, they were instructed not to discuss the diet intervention”</td></tr>
<tr><td>Control/Comparator</td><td>“Women randomized to the control group were requested not to change their diet or exercise habits for the duration of the trial. At the end of 12 months, participants in the control group were offered four group nutrition classes and 8 weeks of facility exercise training with individualized guidance from an exercise physiologist, as an incentive to undergo randomization.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>30 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 352
Intervention group/s: Diet (n=118); Diet+Exercise (n=117)

Comparator group: Exercise (n=117)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% Change BMI (kg/m2)
Mean</td><td>Diet: -6.6
Diet+Exercise: -7.9</td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Foster-Schubert, K. E., Alfano, C. M., Duggan, C. R., Xiao, L., Campbell, K. L., Kong, A., Bain, C. E., Wang, C.-Y., Blackburn, G. L., & McTiernan, A. (2012). Effect of diet and exercise, alone or combined, on weight and body composition in overweight-to-obese postmenopausal women. Obesity, 20(8), 1628-1638. https://doi.org/https://dx.doi.org/10.1038/oby.2011.76</td></tr>
</table>

N/A – Not applicable

Duggins, 2010

Guideline record ID: 10186--1

Study characteristics		
Citation	Duggins, M., Cherven, P., Carrithers, J., Messamore, J., & Harvey, A. (2010). Impact of family YMCA membership on childhood obesity: a randomized controlled effectiveness trial. The Journal of the American Board of Family Medicine, 23(3), 323-333. https://doi.org/10.3122/jabfm.2010.03.080266	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Impact of family YMCA membership on childhood obesity: a randomized controlled effectiveness trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"5 to17 years old in at least the 85th body mass index (BMI) percentile were eligible."	
Exclusion criteria	"No exclusion criteria."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The treatment group was provided a 1-year, nocost family membership to any of 6 area YMCAs. The YMCAs were located in different quadrants of the city as well as a centralized location. Activities offered at all the YMCAs included in the study were aquatics such as swimming and water aerobics, a track for walking or jogging, and weights (for adolescents) in a variety of sizes. At the facility the entire family could participate in the same activities or different activities during the same family visit. The first visit to the YMCA was prescribed by the physician and scheduled with telephone reinforcement by study personnel within 2 weeks of study enrollment. At this initial visit the participant, family members, and a study co-coordinator met with YMCA staff, who provided an orientation and answered any questions or concerns. YMCA diaries were completed by the participant during each visit to the YMCA throughout the 12-month study duration. YMCA staff was alerted by their computer system when a participant visited, and they reminded the participant to fill out their diary before leaving. Every participant and their parents or guardians were scheduled to attend 4 nutrition classes, held after school and work hours, irrespective of their treatment group. These were project-exclusive, dietitian-led classes during which proper diet, nutrition, eating habits, and meal planning were discussed. Classes did not differentiate between those in the control and treatment groups, and the dietitian was given no indication of group assignment. The first class was scheduled within the 6 weeks after enrollment; the second class 1 week after the first class. A third nutrition class was scheduled during the 6-month visit and included preparation of healthy snacks for consumption. A fourth class was scheduled during the 9-month visit. Eating habits were surveyed at the first and the fourth class; perceptions of the project were elicited during the fourth class. Study-related physician visits and nutrition classes were provided at no cost to participants. At enrollment every family received a handbook from the Center for Disease Control and Prevention's program We Can!, or Ways to Enhance Children's Activity and Nutrition. This program was designed to help children 8 to 13 years old stay at a healthy weight through improving food choices, increasing physical activity, and reducing time spent on a computer or watching TV. Studyrelated visits were scheduled for all participants at 2 months, 4 months, 6 months, 9 months, and 12 months after enrollment to evaluate physical condition since the last appointment, provide emotional support and reassurance, and answer any questions"	
Control/Comparator	"Every participant and their parents or guardians were scheduled to attend 4 nutrition classes, held after school and work hours, irrespective of their treatment group. These	

<table>
<tr><td></td><td>were project-exclusive, dietitian-led classes during which proper diet, nutrition, eating habits, and meal planning were discussed. Classes did not differentiate between those in the control and treatment groups, and the dietitian was given no indication of group assignment. The first class was scheduled within the 6 weeks after enrollment; the second class 1 week after the first class. A third nutrition class was scheduled during the 6-month visit and included preparation of healthy snacks for consumption. A fourth class was scheduled during the 9-month visit. Eating habits were surveyed at the first and the fourth class; perceptions of the project were elicited during the fourth class. Study-related physician visits and nutrition classes were provided at no cost to participants. At enrollment every family received a handbook from the Center for Disease Control and Prevention's program We Can!, or Ways to Enhance Children's Activity and Nutrition. This program was designed to help children 8 to 13 years old stay at a healthy weight through improving food choices, increasing physical activity, and reducing time spent on a computer or watching TV. Studyrelated visits were scheduled for all participants at 2 months, 4 months, 6 months, 9 months, and 12 months after enrollment to evaluate physical condition since the last appointment, provide emotional support and reassurance, and answer any questions.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 66
Intervention group/s: Treatment (nutrition class + family YMCA) (n=36)

Comparator group: Control (nutrition class only) (n=30)</td></tr>
<tr><td>Mean age ± SD</td><td>Treatment: 10.6y (3.9); Control: 10.6y (3.4)</td></tr>
<tr><td>Sex</td><td>50.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI percentile
Median (range)</td><td>Treatment (nutrition class + family YMCA): 99
(91-99)</td><td>Control (nutrition class only): 99
(93-99)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in BMI percentile
Median (no spread reported)</td><td>Treatment (nutrition class + family YMCA): 0
(0-0)</td><td>Control (nutrition class only): 0
(0-0)</td></tr><tr><td>Change in BMI (kg/m2)
Mean (no spread reported)</td><td>Treatment (nutrition class + family YMCA): 10.2</td><td>Control (nutrition class only): 6.5</td></tr></table></td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Duncan, 2016

Guideline record ID: 10188--1

Study characteristics		
Citation	Duncan, S., Goodyear-Smith, F., McPhee, J., Grøntved, A., & Schofield, G. (2016). Family-centered brief intervention for reducing obesity and cardiovascular disease risk: a randomized controlled trial. Obesity, 24(11), 2311-2318. https://doi.org/https://dx.doi.org/10.1002/oby.21602	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Family-centered brief intervention for reducing obesity and cardiovascular disease risk: A randomized controlled trial	
Location	New Zealand	
Trial name	N/A	
Methods		
Inclusion criteria	"Aligned with national screening guidelines: (1) adults aged 35 to 65 years and (2) a 5-year CVD risk of at least 10% (2). Forty-three participants (13.4%) were recruited using the initial inclusion criteria. Four months after the commencement of the study (September 2010), the inclusion criteria were modified to increase recruitment rates: (1) adults aged 35 to 65 years, (2) a 5-year CVD risk of at least 7%, and/or (3) a body mass index (BMI) of at least 33 kg/m2 for participants younger than 50 years."	
Exclusion criteria	"Receipt of a CVD risk assessment in the previous 2 years."	
Setting	GP clinic, Primary health organizations	
Intervention	"Intervention participants received up to five home visits (approximately 60 min per visit) from a trained health promoter over a period of 8 to 16 weeks. Each participant was encouraged, where possible, to invite all family members to the home-based consultation session. Whether or not the patients received all five visits was dependent on their availability and willingness to arrange the visit. The number of visits each participant received was noted by the health promoter and given to the practice nurse at each clinic. The length of time between each home visit ranged from 1 to 4 weeks. The program delivered to the intervention group-named Healthy As (NZ slang)-was a complex model utilizing a combination of the "small-changes" approach and group motivational interviewing techniques to encourage physical activity and healthy eating. The smallchanges approach has been shown to be successful in reducing energy intake, increasing physical activity, and reducing weight when used in a treatment setting (16,17). Furthermore, there is evidence that motivational interviewing is an effective method for promoting behavior change (18,19), including when integrated with a BI approach (20). Typically, motivational interviewing is conducted in one-on-one sessions; however, motivational interviewing techniques have also been applied in group settings to facilitate behavior change through group communication and collaboration We therefore deemed the combination of group motivational interviewing and the small-changes approach as the ideal family-centered strategy to elicit sustained behavior change. The purpose of the Healthy As manual was to elicit small changes each week to three lifestyle areas: nutrition (every session), physical activity (every session), and "other" lifestyle behaviors (some sessions), while acknowledging that all families will have differing needs and offering alternative suggestions where appropriate. Common focus areas for physical activity included regular family walking, active transport, interrupting extended periods of sitting, and joining a sport or recreation club. Common focus areas for nutrition included reducing fat intake, increasing fruit and vegetable consumption, choosing healthy snacks, and breakfast consumption. The other lifestyle focus areas were determined on an individual basis and could include smoking cessation, reducing alcohol intake, or any other health-related behavior identified by the family. At each session, participants were asked to set	

<table>
<tr><td></td><td>personalized goals based on the small-changes approach that were reviewed at subsequent sessions. If the previous session goals were achieved, new goals would be set. If the goals had not been achieved, discussion was initiated to identify the barriers to goal progression and to develop strategies for overcoming them. Participants were encouraged to write down their plan to achieving their goals for a given session, to use specific, measureable goals (20 min more physical activity each day, rather than "more" physical activity each day), and to track their progress regularly. Ten health promoters from the three participating Primary Health Organisations attended an 8-h training session on group motivational interviewing techniques and program delivery that included background theory, examples, and simulation exercises. Additionally, they were provided with the Healthy As manual and resources including fridge magnets designed to support suggested weekly changes, Healthy Food Guides, park and recreational space brochures, a Diabetes Foundation of NZ DVD on making correct food choices when shopping, and pedometers to aid participants in increasing daily step counts (and therefore overall physical activity).”</td></tr>
<tr><td>Control/Comparator</td><td>“a CVD risk assessment and a family physician consultation to discuss the results of the assessment ("usual care" for patients who present with a 5- year CVD risk greater than 9%).”</td></tr>
<tr><td>Treatment duration</td><td>8-16 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 313
Intervention group/s: Intervention (n=154)

Comparator group: Control (n=159)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 53.1 (9.83); Control: 54.8 (8.48)</td></tr>
<tr><td>Sex</td><td>43.77% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Elevated 5-year cardiovascular disease (CVD) risk</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) (per protocol)
Mean (SD)

BMI (per protocol)
Mean (SD)

Waist circumference (cm) (per protocol)
Mean (SD)</td><td>Intervention: 96.3
(22)

Intervention: 33.8
(7.14)

Intervention: 106
(16.8)</td><td>Control: 91.6
(19.6)

Control: 31.8
(6.91)

Control: 103
(14.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) (per protocol)
Mean (SD)

BMI (per protocol)
Mean (SD)

Waist circumference (cm) (per protocol)</td><td>Intervention: 92
(20.6)

Intervention: 32.2
(6.75)

Intervention: 103
(16.2)</td><td>Control: 91.7
(18.7)

Control: 31.7
(6.83)

Control: 99.8
(14.2)</td></tr>
</table>
</td></tr>
</table>

	Mean (SD)		
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Intervention effect on BMI (ITT) Beta coefficient and 95% CIs Intervention effect on waist circumference (ITT) Beta coefficient and 95% CIs	Intervention: -0.633 (0.281-0.985) Intervention: 1.03 (-1.48-3.53)	
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	52.6%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Duncan, 2020

Guideline record ID: 10187--1

Study characteristics		
Citation	Duncan, M. J., Fenton, S., Brown, W. J., Collins, C. E., Glozier, N., Kolt, G. S., Holliday, E. G., Morgan, P. J., Murawski, B., Plotnikoff, R. C., Rayward, A. T., Stamatakis, E., Vandelanotte, C., & Burrows, T. L. (2020). Efficacy of a multi-component m-health weight-loss intervention in overweight and obese adults: a randomised controlled trial. International Journal of Environmental Research and Public Health, 17(17), 6200. https://doi.org/https://dx.doi.org/10.3390/ijerph17176200	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Efficacy of a Multi-component m-Health Weight-loss Intervention in Overweight and Obese Adults: A Randomised Controlled Trial	
Location	Australia	
Trial name	Move, Eat and Sleep	
Methods		
Inclusion criteria	"Inclusion criteria were age 18-65 years, a BMI between 25.0 and 40.0 kg/m2, and possession of an iOS/Android smartphone/tablet with internet access."	
Exclusion criteria	"Exclusion criteria were current use of an activity tracker for physical activity and/or sleep, current pregnancy, reported presence of a doctor-diagnosed sleep disorder, current use of medication to assist with sleep or weight management, presence of a condition which precluded activity, diet and/or sleep behaviour modification, weight loss ≥4.5 kg in last 3 months, intention to participate in another weight loss trial, previous weight loss surgery at any time, or current employment involving shift-work on a rotating roster."	
Setting	Home, University/research centre, Online; Smart phone app	
Intervention	"The Enhanced and Traditional group participants were provided with personalised dietary recommendations, and given access to the 'Balanced' smartphone app [6], an additional calorie counting platform (CalorieKing Wellness Solutions Inc" La Mesa, CA, USA), a set of body weight scales (Tanita HD-380), a Fitbit activity tracker (Fitbit Alta) and a participant handbook [6,21,22]. The intervention used behaviour change techniques (e.g., education, goal setting, self-monitoring, feedback on behaviour) to operationalise constructs from social cognitive and self-regulatory theories specifical to the target behaviours [23-25]. An overview of the intervention is provided in Supplementary Table S1. Participants received intervention content specific to their group allocation only. Educational materials detailing how behaviours related to weight loss and target weight loss (5% weight loss target) were provided via in-app content, email and SMS messages, a printed participant handbook, and in-person via a dietary counselling session. The handbook provided guidance on goal setting, action planning, stress management, healthy eating advice and body weight resistance training activities. The in-person counselling session followed a standardised protocol to provide personalised dietary advice based on assessment of their current dietary intake, as measured by the Australian Eating Survey® (FFQ) and personalised nutrition report (Australian Eating Survey® Version 2, University of Newcastle, Callaghan NSW, Australia) to improve overall diet quality in line with Australian Dietary Guidelines and the Australian Guide to Healthy Eating [26-29]. Participants were also provided with a personalised daily energy intake target to create an energy deficit of 2000 kJ based on the Mifflin-St Jeor equation [30]. Intervention group participants accessed the Balanced app to set goals and self-monitor weight and target behaviours (daily minutes of moderate-to-vigorous intensity physical activity, steps, resistance training, and the number of food goals achieved), and received dynamic feedback on performance relative to their goals [6]. Both intervention groups were also encouraged to self-monitor and receive feedback on overall diet quality [31] and energy intake (kilojoules/day) (CalorieKing website or the	

<table>
<tr><td></td><td>ControlMyWeight app by CalorieKing) [6]. The Enhanced group also received access to a sleep intervention via the app and participant handbook [6,21,22] that targeted a reduction in sleep timing variability, promoted sleep hygiene behaviours and provided stress management and relaxation techniques (e.g., progressive muscle relaxation, deep breathing exercises, and mindfulness). The Enhanced group could set goals and self-monitor and receive dynamic feedback on bed times/wake times, sleep quality and sleep hygiene behaviours [6,21,22]. Participants of both intervention groups received emailed weekly summaries of their behaviours in relation to their goals based on Balanced app entries, and weekly educational weight loss facts via SMS. Participants who stopped self-monitoring using the app (≥4/7 days/week) were sent an SMS to prompt re-engagement [6,21,22].”</td></tr>
<tr><td>Control/Comparator</td><td>Not reported</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 116
Intervention group/s: Enhanced (n=39); Traditional (n=41)

Comparator group: Control (n=36)</td></tr>
<tr><td>Mean age ± SD</td><td>44.5y (10.4)</td></tr>
<tr><td>Sex</td><td>70.69% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Enhanced: 90.8
(13.09)
Traditional: 88.91
(13.81)</td><td>Control: 92.5
(16.09)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Enhanced: 31.9
(4)
Traditional: 31.4
(3.8)</td><td>Control: 31.9
(3.9)</td></tr>
<tr><td>BMI 25.0-29.9
Proportion (%)</td><td>Enhanced: 28.2%
Traditional: 34.1%</td><td>Control: 27.8%</td></tr>
<tr><td>BMI 30.0-40.0
Proportion (%)</td><td>Enhanced: 71.8%
Traditional: 65.9%</td><td>Control: 72.2%</td></tr>
<tr><td>Waist Circumference (cm)
Mean (SD)</td><td>Enhanced: 99.5
(12.54)
Traditional: 99.61
(8.99)</td><td>Control: 99.72
(11.67)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Enhanced: 87.92
(14.95)
Traditional: 82.63
(13.86)</td><td>Control: 88.63
(16.85)</td></tr>
</table>
</td></tr>
</table>

	Waist Circumference (cm) Mean (SD)	Enhanced: 95.86 (10.3) Traditional: 94.68 (9.82)	Control: 95.79 (13.19)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Over the 12-month period, a total of 62 (77.5%) participants succumbed to non-usage attrition (Traditional = 29 (70.7%); Enhanced = 33 (84.6%)), and there was no statistically significant difference between intervention groups (HR = 1.26, 95% CI 0.77, 2.08, p = 0.360)		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Dutheil, 2013

Guideline record ID: 10189--1

Study characteristics		
Citation	Dutheil, F., Lac, G., Lesourd, B., Chapier, R., Walther, G., Vinet, A., Sapin, V., Verney, J., Ouchchane, L., Duclos, M., Obert, P., & Courteix, D. (2013). Different modalities of exercise to reduce visceral fat mass and cardiovascular risk in metabolic syndrome: the RESOLVE randomized trial. International Journal of Cardiology, 168(4), 3634-3642. https://doi.org/https://dx.doi.org/10.1016/j.ijcard.2013.05.012	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Different modalities of exercise to reduce visceral fat mass and cardiovascular risk in metabolic syndrome: the RESOLVE randomized trial	
Location	France	
Trial name	REverse metabolic SyndrOme by Lifestyle and Various Exercises (RESOLVE)	
Methods		
Inclusion criteria	"To be eligible, participants were: aged between 50 and 70 years, symptomatic of MetS [2], with a sedentary lifestyle, stable body weight and stable medical treatment over the previous 6 months, post-menopausal for women, no hepatic, renal, or psychiatric diseases, nor cardiovascular or endocrine diseases except those defining MetS, no HIV infection, no use of medications altering body weight (supplementary file), no restricted diet in the previous year, and with a satisfactory completion of a maximal exercise tolerance test (VO2 max)."	
Exclusion criteria	Not reported	
Setting	Home, participants stayed in a residential establishment	
Intervention	"Re-high-Resistance-moderate-endurance-performed 10 repetitions at 70% of one maximal repetition in resistance and 30% of VO2-peak for endurance training; rE-moderate-resistance(30%)-high-Endurance(70%); All participants followed the same restrictive diet. Participants attended lectures and workshops on the MetS taught by dieticians, physicians and coaches dealing with nutrition, cooking and exercise in order to maintain this lifestyle on returning home [18]. Daily throughout the residential program, the patients received both standard and personalized balanced meals prescribed by dieticians. Protein accounted for 15 to 20% of the total energy intake (1.2 g/kg/day to maintain protein homeostasis) [19], lipids 30 to 35%, and carbohydrates the remaining. Their total daily food intake was calculated to enable them to reach a negative energy balance of 500 kcal/day. The participants were coached daily individually [18], within the context of their assigned group. The same time (15-20 h/week) was spent by all groups in endurance (90 min daily) plus in resistance (90 min four days a week). Exercises differed only in intensity, from 30% to 70%. Participants' heart rate was monitored by Polar™ S810 with instantaneous recording and storage of heart rate values. Endurance training included aquagym, cycling and walking. Resistance training consisted of 8 exercises with free weights and traditional muscle building equipment. Each exercise was performed for three sets of 10 repetitions."	
Control/Comparator	"re-moderate-resistance(30%)-moderate-endurance(30%). All participants followed the same restrictive diet. Participants attended lectures and workshops on the MetS taught by dieticians, physicians and coaches dealing with nutrition, cooking and exercise in order to maintain this lifestyle on returning home [18]. Daily throughout the residential program, the patients received both standard and personalized balanced meals prescribed by dieticians. Protein accounted for 15 to 20% of the total energy intake (1.2 g/kg/day to maintain protein homeostasis) [19], lipids 30 to 35%, and carbohydrates the remaining. Their total daily food intake was calculated to enable them to reach a negative energy balance of 500 kcal/day. The participants were coached daily individually [18], within the	

<table>
<tr><td></td><td>context of their assigned group. The same time (15-20 h/week) was spent by all groups in endurance (90 min daily) plus in resistance (90 min four days a week). Exercises differed only in intensity, from 30% to 70%. Participants' heart rate was monitored by Polar™ S810 with instantaneous recording and storage of heart rate values. Endurance training included aquagym, cycling and walking. Resistance training consisted of 8 exercises with free weights and traditional muscle building equipment. Each exercise was performed for three sets of 10 repetitions.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 92
Intervention group/s: Re (n=30); rE (n=29)

Comparator group: re (n=33)</td></tr>
<tr><td>Mean age ± SD</td><td>59.4y (5.0)</td></tr>
<tr><td>Sex</td><td>56.52% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline weight (kg)
Mean (SD)</td><td>Re: 87.1
(11.8)
rE: 95.9
(13.2)</td><td>re: 91.4
(12.7)</td></tr>
<tr><td>Baseline waist circumference (cm)
Mean (SD)</td><td>Re: 99.8
(8.7)
rE: 104.4
(10.1)</td><td>re: 102.5
(9.1)</td></tr>
<tr><td>Central fat (g)
Mean (SD)</td><td>Re: 2986
(684)
rE: 3111
(675)</td><td>re: 3144
(714)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>% change in central fat
Mean (SD)</td><td>Re: -21.5
(16.5)
rE: -21.1
(16.3)</td><td>re: -12.7
(20.7)</td></tr>
<tr><td>% change in Body weight
Mean (SD)</td><td>Re: -5.9
(5.8)
rE: -8.4
(8.7)</td><td>re: -4.7
(6.7)</td></tr>
</table></td></tr>
</table>

	% change in fat mass Mean (SD) % change in waist circumference Mean (SD)	Re: -1.8 (1.5) rE: -2.1 (2.3) Re: -7.7 (6.6) rE: -9.5 (6.8)	re: -1.3 (1.3) re: -6.3 (5)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	The mean compliance scores of 54.6 ± 22.1% (Re), 52.7 ± 26.1% (rE) and 52.1 ± 18.1% (re)		
Notes			
Additional included publications arising from this study that did not contribute additional data	Tremblay, A., Dutheil, F., Drapeau, V., Metz, L., Lesour, B., Chapier, R., Pereira, B., Verney, J., Baker, J. S., Vinet, A., Walther, G., Obert, P., Courteix, D., & Thivel, D. (2019). Long-term effects of high-intensity resistance and endurance exercise on plasma leptin and ghrelin in overweight individuals: the RESOLVE Study. Applied Physiology, Nutrition, and Metabolism, 44(11), 1172-1179. https://doi.org/https://doi.org/10.1139/apnm-2019-0019		

N/A – Not applicable

Dutton, 2017

Guideline record ID: 10190--1

Study characteristics		
Citation	Dutton, G. R., Gowey, M. A., Tan, F., Zhou, D., Ard, J., Perri, M. G., & Lewis, C. E. (2017). Comparison of an alternative schedule of extended care contacts to a self-directed control: a randomized trial of weight loss maintenance. International Journal of Behavioral Nutrition and Physical Activity, 14, 107. https://doi.org/https://dx.doi.org/10.1186/s12966-017-0564-1	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Comparison of an alternative schedule of extended care contacts to a self-directed control: a randomized trial of weight loss maintenance	
Location	USA	
Trial name	Improving Weight Loss Maintenance Through Alternative Schedules of Treatment (ImWeL)	
Methods		
Inclusion criteria	"Inclusion criteria for the initial, 16-week program included a body mass index (BMI; kg/m2) between 28 and 45. Participants in this part of the study were those who had lost >/= 5% bodyweight in the initial program."	
Exclusion criteria	"If they had lost >4.5 kg and/or taken a weight loss medication in the past 6 months, had a medical condition for which weight loss or physical activity would be inadvisable, planned to relocate from the area in the next 18 months, were unable or unwilling to attend sessions, or were unwilling to accept random assignment."	
Setting	University/research centre	
Intervention	"Extended care interventions Clustered campaign maintenance program Consistent with other extended care programs [7, 30], the purpose was to maintain adherence, bolster motivation, and reinforce information previously discussed with a focus on the maintenance of healthy lifestyle behaviors. Sessions included some review of previouslylearned concepts and skills as well as incorporation of novel material pertaining to diet, physical activity, and behavior/motivation. The main focus of the extended care sessions was on the maintenance (rather than initial adoption) of healthy lifestyle behaviors associated with continued weight loss and/or weight loss maintenance and the avoidance of returning to less healthy behaviors. The unique feature of this maintenance program was the non-conventional schedule of delivery. Rather than an evenly-distributed, fixed-interval (e.g., monthly) schedule of contact, the program included 12 extended care group sessions divided into three intensive, 4-week campaigns. These occurred during months 7, 10, and 13 of the 16-month study (Table 1). Thus, the periodic episodes of frequent visits were separated by extended periods without contact. Session content of the three campaigns was organized to reflect themes, including overviews of dietary practices (sessions 1-4), physical activity (sessions 5-8), and behavioral and motivational strategies and relapse prevention (sessions 9-12). This schedule of several weekly meetings separated by extended periods with less frequent contact is consistent with the campaigns or refresher groups offered in the Look AHEAD trial during extended care [27]. During extended care, participants established weight goals mutually agreed upon by them and interventionists. Goals could include additional weight loss or weight maintenance, depending on individuals' progress, desired weight loss, and current BMI. Across all three campaigns, recommended behavioral goals for each participant included dietary and activity self-monitoring at least 3 days/week. In addition to self-monitoring goals, participants were encouraged to set campaign-specific dietary, physical activity, or behavioral/relapse prevention goals corresponding to specific session content (e.g., applying volumetric techniques to modify meals, identifying a new structured exercise to implement). Although general goals were provided to participants at each session,	

<table>
<tr><td></td><td>participants were encouraged to develop individualized action plans to tailor and implement each goal. Because the trial included only participants losing ≥5% of baseline weight, fewer groups were required to deliver extended care treatment than during the initial weight reduction program. Therefore, extended care participants were consolidated into new treatment groups at randomization, which included a combination of familiar and new group members. The same team of interventionists delivered the initial and extended care programs. To ensure fidelity to treatment delivery, all interventionists participated in initial training on the intervention protocol, which included structured facilitator guides and participant treatment materials. Although treatment fidelity was not formally assessed, all interventionists participated in ongoing weekly group supervision directed by the study PI, a licensed clinical psychologist with extensive experience in the delivery of behavioral weight management programs. Content of these group discussions indicated consistent protocol adherence."</td></tr>
<tr><td>Control/Comparator</td><td>"Self-directed program Participants in the self-directed program received printed intervention materials at the initiation of the 12- month extended care period. These materials were identical to those provided in the clustered campaign condition. Self-directed participants initially met with an interventionist to review the treatment materials and answer any questions about the extended care program. They were encouraged to continue using behavioral strategies for weight management including selfmonitoring and independently work through the written materials provided. The self-directed control group did not receive further in-person contacts with interventionists during the 12-month follow-up. If participants initiated contact with interventionists by telephone or email during the extended care period, the interventionist provided brief feedback, responded to questions or concerns, and referred participants back to the intervention materials provided at randomization."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 108
Intervention group/s: Clustered campaign group (n=52)

Comparator group: Self-directed group (n=56)</td></tr>
<tr><td>Mean age ± SD</td><td>51.64 (13.03)</td></tr>
<tr><td>Sex</td><td>95.37% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Proportion maintained ≥5% weight reductions Proportion (%)</td><td>Clustered campaign group: 62.2</td><td>Self-directed group: 54.9</td></tr><tr><td>Proportion achieving a weight loss of >= 7%</td><td>Clustered campaign group: 51.1</td><td>Self-directed group: 24.9</td></tr></table></td></tr>
</table>

	Proportion (%)		
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in weight (kg) Mean (SD)	Clustered campaign group: 0.35 (4.62)	Self-directed group: 2.4 (3.99)
	% Change in weight Mean (SD)	Clustered campaign group: 13.11 (57.51)	Self-directed group: 35.55 (61.85)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	87%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Eakin, 2014

Guideline record ID: 10191--1

Study characteristics		
Citation	Eakin, E. G., Winkler, E. A., Dunstan, D. W., Healy, G. N., Owen, N., Marshall, A. M., Graves, N., & Reeves, M. M. (2014). Living well with diabetes: 24-month outcomes from a randomized trial of telephone-delivered weight loss and physical activity intervention to improve glycemic control. Diabetes Care, 37(8), 2177-2185. https://doi.org/https://dx.doi.org/10.2337/dc13-2427	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Living well with diabetes: 24-month outcomes from a randomized trial of telephone-delivered weight loss and physical activity intervention to improve glycemic control	
Location	Australia	
Trial name	Living Well With Diabetes (LWWD)	
Methods		
Inclusion criteria	"Eligible patients (i.e. Those with a diagnosis of type 2 diabetes; age range 20-75 years; with a listed telephone number); Eligible patients were inactive (self-reported,5 days/ week of $30 min planned exercise) and/or overweight or obese (BMI $ 25.0 kg/m2), not using weight loss medi cations, and without previous or planned bariatric surgery."	
Exclusion criteria	Not reported	
Setting	Home	
Intervention	"Participants received a detailed workbook and up to 27 telephone calls over the 18 months (4 initial weekly calls; fortnightly calls for 5 months; monthly calls for 12 months) to support the initiation and maintenance of weight loss. The intervention followed a motivational interviewing approach, and emphasized behavior change strategies. These included the following: identifying the benefits of weight loss; setting goals for gradual changes to physical activity and dietary intake; self-monitoring progress; problem solving; using available supports; and focusing on achievements with appropriate rewards. Intervention targets for weight loss, physical activity, and dietary intake were consistent with management goals for type 2 diabetes, with the aim to reduce HbA1c level to <7%. Participants were encouraged to achieve moderate weight loss of 5-10% of initial body weight, an amount consistent with clinically meaningful disease prevention and management, with a loss of 1-2 kg/month. A target of at least 210 min/week (30 min every day) of moderate-intensity planned aerobic activity was recommended, consistent with the level of physical activity necessary to promote and maintain weight loss, along with resistance exercise (two to three sessions per week). Individualized advice was used to encourage participants to reduce daily energy intake by 2,000 kJ (~500 kcal) by following healthy eating principles, including following a low-fat diet (i.e., total fat <30% of energy; saturated fat <7% of energy) with sufficient dietary fiber (25 g/day for women; 30 g/day for men)."	
Control/Comparator	"Usual-care participants were mailed a brief summary of their results following each assessment, as well as standard, diabetes self-management education brochures. GPs in trial practices were not asked to change their management practices in any way and were involved only in participant recruitment."	
Treatment duration	18 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 302
Intervention group/s: Telephone counselling (n=151)

Comparator group: Usual care (n=151)</td></tr>
<tr><td>Mean age ± SD</td><td>58.0y (8.6)</td></tr>
<tr><td>Sex</td><td>43.71% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (Kg/m2)
Mean (SD)</td><td>Telephone counselling: 94.5 (18.7)

Telephone counselling: 33.1 (6.3)</td><td>Usual care: 95.3 (20.1)

Usual care: 33.2 (6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion (%) with weight gain ≥1%
Proportion (%)</td><td>Telephone counselling: 31.5</td><td>Usual care: 43.1</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion (%) with weight loss ≥5%
Proportion (%)

Proportion (%) with weight gain ≥1%
Proportion (%)</td><td>Telephone counselling: 21

Telephone counselling: 18.7</td><td>Usual care: 13.2

Usual care: 36.6</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (%)
Mean (95% CIs)

Change in waist circumference (cm)
Mean (95% CIs)</td><td>Telephone counselling: -1.08 (-1.89--0.28)

Telephone counselling: -1.68 (-2.69--0.67)</td><td>Usual care: 0.48 (-0.24-1.2)

Usual care: -0.45 (-1.35-0.45)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (%)
Mean (95% CIs)

Change in waist circumference (cm)
Mean (95% CIs)</td><td>Telephone counselling: -0.94 (-1.83--0.05)

Telephone counselling: -1.98 (-2.95--1.01)</td><td>Usual care: -0.09 (-0.83-0.65)

Usual care: -1.02 (-1.99--0.06)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>At the end of intervention, only a small percentage of the telephone counseling and usual-care groups, respectively, achieved program targets of ≥210 min/week MVPA (34.8% vs. 27.8%), and ≥2 MJ energy reduction (22.8% vs. 18.8%).</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from</td><td></td></tr>
</table>

this study that did not contribute additional data	

N/A – Not applicable

Eaton, 2016

Guideline record ID: 10192--1

Study characteristics		
Citation	Eaton, C. B., Hartman, S. J., Perzanowski, E., Pan, G., Roberts, M. B., Risica, P. M., Gans, K. M., Jakicic, J. M., & Marcus, B. H. (2016). A randomized clinical trial of a tailored lifestyle intervention for obese, sedentary, primary care patients. The Annals of Family Medicine, 14(4), 311-319. https://doi.org/https://dx.doi.org/10.1370/afm.1952	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A Randomized Clinical Trial of a Tailored Lifestyle Intervention for Obese, Sedentary, Primary Care Patients	
Location	USA	
Trial name	Choose to Lose	
Methods		
Inclusion criteria	"Participant inclusion criteria included being 18 to 80 years old with a BMI of at least 25 kg/m2 and the ability to read and speak English and provide informed consent."	
Exclusion criteria	"Exclusion criteria included having a family member already enrolled in the study and having a health condition that might make participation in a weight loss and exercise study unsafe."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"All participants met with a lifestyle counselor at baseline and set a weight loss goal of 10% over 6 months. They were given a structured meal plan dependent on their starting weight to support a 500 to 1,000 kcal reduced-calorie diet based on the Diabetes Prevention Program guidelines.35 Participants were encouraged to add 10 minutes of moderate-intensity activity most days of the week and to work up to engaging in 300 minutes of moderate physical activity per week by 6 months. Participants were given food and exercise self-monitoring diaries for the first 6 months. All participants also met with their lifestyle counselor at 6 and 12 months to review progress and set new goals as needed.Participants in the EI group received phone calls from the lifestyle counselor monthly for the first 6 months and bi-monthly for the next 6. For the first 12 months, they also received weekly mailings that included print materials, feedback on food and exercise logs, and 2 exercise-related DVDs. The mailings focused on participant motivation, weight loss, calorie and exercise goal attainment, journal compliance, food-related issues, and comorbid conditions. Four of these mailings were tailored nutrition reports based on information gathered on the counseling calls. Enhanced intervention participants also received monthly tailored exercise feedback reports for the first 12 months focused on processes of change, decisional balance, and self-efficacy. The reports were generated from a computer-based expert system in response to the participant's answers to monthly questionnaire items. In the maintenance phase during the second year, EI participants received tailored and non-tailored materials bi-weekly for the first 6 months and monthly for the last 6 months. They also received exercise feedback reports 4 times throughout the second year and 2 nutrition-related DVDs."	
Control/Comparator	"All participants met with a lifestyle counselor at baseline and set a weight loss goal of 10% over 6 months. They were given a structured meal plan dependent on their starting weight to support a 500 to 1,000 kcal reduced-calorie diet based on the Diabetes Prevention Program guidelines.35 Participants were encouraged to add 10 minutes of moderate-intensity activity most days of the week and to work up to engaging in 300 minutes of moderate physical activity per week by 6 months. Participants were given food and exercise self-monitoring diaries for the first 6 months. All participants also met with their lifestyle counselor at 6 and 12 months to review progress and set new goals as needed. In addition	

<table>
<tr><td></td><td>to the 3 face-to-face meetings with the lifestyle counselors, participants in the SI group received 5 pamphlets (3 in year 1 and 2 in year 2) produced by the National Institute for Diabetes and Digestive and Kidney Diseases on weight loss, physical activity, and healthy eating.”</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 211
Intervention group/s: Enhanced intervention (n=105)

Comparator group: Standard intervention (n=106)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 48.5y (11.9); Control: 48.6y (112.1)</td></tr>
<tr><td>Sex</td><td>79.15% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Enhanced intervention: 104.8 (21.6)

Enhanced intervention: 37.7 (6.5)</td><td>Standard intervention: 102.1 (18.7)

Standard intervention: 37.8 (6.7)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Mean (95% CIs)</td><td>Enhanced intervention: -5.4 (-6.9--3.9)</td><td>Standard intervention: -3.8 (-5.3--2.3)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Mean (95% CIs)</td><td>Enhanced intervention: -4.1 (-5.6--2.6)</td><td>Standard intervention: -4 (-5.5--2.5)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Both groups had high adherence for the face-to-face visits (2.8 of 3, on average) and for EI, high adherence with the phone calls; on average, 7 out of 8 calls were completed. Participants in the EI group mailed in an average of 14 food and exercise journals out of a possible 24 during the first 6 months. On average, EI participants received 3.8 of 4 individually tailored nutrition mailings over the first 6 months, which relied upon information gathered from monthly lifestyle phone calls. The individually tailored physical activity reports required completing a monthly mailed questionnaire and were sent on average 6 out of 13 possible times during year 1 and 1.4 out of 4 possible times during year 2.</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Epstein, 2023

Guideline record ID: 12009--1

Study characteristics		
Citation	Epstein, L. H., Wilfley, D. E., Kilanowski, C., Quattrin, T., Cook, S. R., Eneli, I. U., Geller, N., Lew, D., Wallendorf, M., Dore, P., Paluch, R. A., & Schechtman, K. B. (2023). Family-based behavioral treatment for childhood obesity implemented in pediatric primary care: a randomized clinical trial. JAMA, 329(22), 1947-1956. https://doi.org/10.1001/jama.2023.8061	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Family-Based Behavioral Treatment for Childhood Obesity Implemented in Pediatric Primary Care: A Randomized Clinical Trial	
Location	USA	
Trial name	Primary Care Pediatrics, Learning, Activity, and Nutrition With Families (PLAN)	
Methods		
Inclusion criteria	"Families with a child aged 6 through 12 years with overweight or obesity (>85th percentile body mass index [BMI]), a parent with overweight or obesity (BMI >25), and, when available, siblings aged 2 through 18 years with overweight or obesity. In addition to the aboveweight criteria, inclusion criteria included both the child and parent being interested in participating and having no dietary restrictions and the child to be living with the participating parent at least 50% of the time."	
Exclusion criteria	"Child-parent dyads were excluded if either was taking medication or had a health condition that altered growth or nutritional status, if either had unmanaged psychiatric illnesses or inability to engage in regular exercise, or if the parent planned to have weight loss surgery."	
Setting	GP clinic, Home	
Intervention	"The family-based treatment4,17 intervention includedmaterials that covered the Traffic LightEating (eTable 2 in Supplement 1) and Activity Plans, parenting and behavioral techniques, and facilitation of support in family and peer environments.18Familieswere seen in individual sessions that incorporated parent and childweigh-ins, review of eating and activity self-monitoring inhabit books, review ofweightchange and problem solving and goal setting for the next meeting in relationship to behavior change, and review of treatment manuals and handouts. The treatment was implemented by people with a variety of backgrounds, with the emphasis on individuals eitherhadmaster's degrees in psychology, counseling, or social work or were master's degree-level registered dietitians. Weekly meetingswere planned during the first 4 months as families learned the program, shifting to biweekly for 2 months and then tomonthly meetings. The goal was for families to attend 26 sessions during the 24-month intervention and follow-up period, but the frequency of sessions could be increased or decreased based on family progress in meeting weight, eating, physical activity, and parenting behavior goals or challenges in attending meetings. Recognizing that familiesmake changes in behavior at different rates, behavioral goals were based on demonstrating mastery of behavior and weight change and behavior change concepts.19 To ensure that coaches followed the protocol, they used checklists and had access to a family dashboard that provided cumulative behavior and weight changes to guide treatment sessions."	
Control/Comparator	"Pediatricians in both the intervention and usual care groups were advised to follow standard recommendations for the treatment of overweight and obesity in children and adolescents."	
Treatment duration	24 months	

<table>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n=Intervention group/s: Family-based treatment (n=Index children: 226; Parents: 226; Siblings: 54)

Comparator group: Usual Care (n=Index children: 226; Parents: 226; Siblings: 52)</td></tr>
<tr><td>Mean age ± SD</td><td>Index children: 9.8y (1.9); Parents: 41.4y (7.5); Siblings: 10.0y (3.7).</td></tr>
<tr><td>Sex</td><td>Family-based treatment, n females (%): Index children: 120 (53%); Parents: 196 (87%); Siblings: 30 (56%); Usual care, n females (%): Index children: 122 (54%); Parents: 192 (85%); Siblings: 30 (58%).</td></tr>
<tr><td>Pre-existing medical condition</td><td></td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Data could not be extracted.</td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Data could not be extracted.</td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Erickson, 2016

Guideline record ID: 10197--1

Study characteristics		
Citation	Erickson, Z. D., Mena, S. J., Pierre, J. M., Blum, L. H., Martin, E., Hellemann, G. S., Aragaki, D. R., Firestone, L., Lee, C., Lee, P., Kunkel, C. F., & Ames, D. (2016). Behavioral interventions for antipsychotic medication-associated obesity: a randomized, controlled clinical trial. The Journal of Clinical Psychiatry, 77(2), e183-e189. https://doi.org/https://dx.doi.org/10.4088/JCP.14m09552	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Behavioral interventions for antipsychotic medication-associated obesity: a randomized, controlled clinical trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"(1) DSM-IV-diagnosed SMI(schizophrenia, schizoaffective disorder, bipolar disorder, or posttraumatic stress disorder with psychotic symptoms), (2) an increase of ≥ 7% body weight or body mass index (BMI) > 25 while taking SGAs, and (3) age 18-70 years."	
Exclusion criteria	"Not matching inclusion criteria."	
Setting	Hospital	
Intervention	"The LB program (n = 60) consisted of 8 weekly education classes, dietary monitoring, recommendations for 30 minutes of exercise 5 days per week, and individual coaching on nutrition and healthy lifestyles. Core classes, derived from the DPP website,13 were followed by monthly booster classes for the remainder of the year. Subjects and/or caregivers maintained food and exercise diaries that were reviewed individually along with the subjects' individualized goals for the first 8 weeks and monthly thereafter until week 52. Subjects were quizzed at weeks 8, 26, and 52 about exercise and healthy eating habits. Small rewards (eg, $10 gift certificates) were provided for achieving weight loss and exercise goals. DPP instructions for fat and calorie restriction were recommended with a goal of achieving weight loss through a 500-calorie daily deficit. LB participants' caregivers also received support from program dietitians. Group exercise activities led by LB instructors were offered, but optional. Subjects were primarily guided by staff to exercise options within the VA clinics and the community."	
Control/Comparator	"Subjects randomized to UC (n = 62) were encouraged to exercise and eat healthy and were given publicly available,printed self-help materials regarding weight loss, exercise, and nutrition. Follow-up visits for weight measurement, data collection, and completion of questionnaires were scheduled at the same intervals as for LB subjects."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 108 Intervention group/s: Lifestyle Balance (n=60) Comparator group: Usual Care (n=48)	

<table>
<tr><td>Mean age ± SD</td><td>Intervention: 49.67 (6.9); Control: 49.58 (9.1)</td></tr>
<tr><td>Sex</td><td>11.11% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Diagnosed SMI ((schizophrenia, schizoaffective disorder, bipolar disorder, or posttraumatic stress disorder with psychotic symptoms)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline weight (kg)
Mean (SD)

Baseline BMI (kg/m2)
Mean (SD)</td><td>Lifestyle Balance: 105.3
(21)

Lifestyle Balance: 34.1
(5.3)</td><td>Usual Care: 106.7
(15.6)

Usual Care: 34.3
(4.8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean

Change in BMI (kg/m2)
Mean

Proportion who lost 5% body weight
Proportion (%)

Proportion who lost ≥7% weight
Proportion (%)</td><td>Lifestyle Balance: -4.6

Lifestyle Balance: -1.7

Lifestyle Balance: 33

Lifestyle Balance: 22</td><td>Usual Care: 0.6

Usual Care: 0.6

Usual Care: 19

Usual Care: 12</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>42%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Erickson, 2017

Guideline record ID: 10196--1

Study characteristics		
Citation	Erickson, Z. D., Kwan, C. L., Gelberg, H. A., Arnold, I. Y., Chamberlin, V., Rosen, J. A., Shah, C., Nguyen, C. T., Hellemann, G., Aragaki, D. R., Kunkel, C. F., Lewis, M. M., Sachinvala, N., Sonza, P. A., Pierre, J. M., & Ames, D. (2017). A randomized, controlled multisite study of behavioral interventions for veterans with mental illness and antipsychotic medication-associated obesity. Journal of General Internal Medicine, 32, 32-39. https://doi.org/https://dx.doi.org/10.1007/s11606-016-3960-3	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A Randomized, Controlled Multisite Study of Behavioral Interventions for Veterans with Mental Illness and Antipsychotic Medication-Associated Obesity	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	“Age 18-70 years old; diagnosis of mental illness per DSM-IV; APD treatment; BMI over 25 or weight gain over 7% on APDs; and medical and psychiatric stability, confirmed by chart reviews and primary care provider approval.”	
Exclusion criteria	“Hospitalizations within 30 days, substance abuse history without sobriety over the previous 90 days, and homelessness.”	
Setting	University/research centre	
Intervention	“Educational Materials and Group Classes. LB participants received RD-led classes and individual nutrition counseling. The LB curriculum included 16 topics (Table 2). The first 8 weeks, 60-min classes covered two topics per session. Monthly booster classes reinforced healthy behaviors for the remaining 10 months. Class size typically ranged from 1-4 people. Classes utilized multi-modal techniques including colored handouts, written materials, food models, poster images, and group discussions to accommodate visual, auditory, and kinesthetic learning styles. Concepts were reviewed with repetition to address potential cognitive barriers associated with mental illness.41 Individual Nutrition Counseling. Following each class, participants met RDs for 15 to 60 min of individualized nutrition counseling, depending on participants' needs and time availability. RDs addressed each participant's specific nutrition-related concerns and helped participants set and accomplish both short- and long-term goals. RDs provided a comprehensive nutrition assessment at the first session, including a 24-h food recall42 assessing participants' dietary intake. RDs also reviewed medical records and physical activity, stage of change,43 and cognitive ability. A discussion followed about specific food and activity goals to initiate behavior change. RDs used cognitive behavioral therapy techniques,44 motivational interviewing45, 46 and accountability tools, including food and activity journals. RDs reviewed these journals during participants' appointments. For data analysis, 24-h food recalls42 were used with journals to quantify food and beverage intake changes. These data were input into the USDA BSupertracker^ database47 and analyzed to assess behavioral changes. During groups and individual sessions, RDs encouraged change using positive affirmations and praise.41 To enhance motivation and adherence to the program, participants received rewards for meeting goals such as gift certificates, tote bags, and BHealthy Plates.^ Following the DPP's protocol BToolbox^ and the in-vivo approach to social skills training,48 RDs met with caregivers at 12 participants' residences to discuss dietary changes; they also taught healthy cooking classes and promoted walking groups. During semi-annual class field trips, RDs provided on-site education at restaurants and grocery stores.41 Once-daily meal replacement shakes were offered when basic food and exercise changeswere less effective in meeting weight loss goals; only 13 participants chose this option.”	

<table>
<tr><td>Control/Comparator</td><td>“UC participants met with research coordinators with a frequency and duration equivalent to individual LB counseling sessions. Anthropometric measures and vitals were recorded. Participants answered questionnaires about diet, exercise, and health. VA-approved self-help educational handouts on health issues were provided. Due to ethical concerns and participant request, 17 UC participants were allowed to begin the active treatment at month 6, and these 17 crossover (CO) participants were not included in any analysis after month 6.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 121
Intervention group/s: Lifestyle Balance (n=62)

Comparator group: Usual Care (n=59)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 51.9 (9.3); Control: 50.4 (9.0)</td></tr>
<tr><td>Sex</td><td>16.53% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Diagnosed mental illness</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Waist circumference (cm) Mean</td><td>Lifestyle Balance: -1.04</td><td>Usual Care: 0.25</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>53%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Estruch, 2019

Guideline record ID: 10203--1

Study characteristics		
Citation	Estruch, R., Martínez-González, M. A., Corella, D., Salas-Salvadó, J., Fitó, M., Chiva-Blanch, G., Fiol, M., Gómez-Gracia, E., Arós, F., Lapetra, J., Serra-Majem, L., Pintó, X., Buil-Cosiales, P., Sorlí, J. V., Muñoz, M. A., Basora-Gallisá, J., Lamuela-Raventós, R. M., Serra-Mir, M., Ros, E., & for the Predimed Study Investigators. (2019). Effect of a high-fat Mediterranean diet on bodyweight and waist circumference: a prespecified secondary outcomes analysis of the PREDIMED randomised controlled trial. The Lancet Diabetes & Endocrinology, 7(5), e6-e17. https://doi.org/https://dx.doi.org/10.1016/S2213-8587(19)30074-9	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a high-fat Mediterranean diet on bodyweight and waist circumference: a prespecified secondary outcomes analysis of the PREDIMED randomised controlled trial	
Location	Spain	
Trial name	Prevención con Dieta Mediterránea (PREDIMED)	
Methods		
Inclusion criteria	"Community-dwelling men (aged 55-80 years) and women (aged 60-80 years) who had either type 2 diabetes or at least three of the following cardiovascular risk factors: current smoking, hypertension (blood pressure >140/90 mmHg or treatment with antihypertensive drugs), high plasma LDL cholesterol concentration (≥4·14 mmol/L), low plasma HDL cholesterol concentration (<1·04 mmol/L for men and <1·30 mmol/L for women), overweight or obesity (BMI ≥25 kg/m²), or family history of premature coronary heart disease."	
Exclusion criteria	Not reported	
Setting	GP clinic	
Intervention	"Trained dietitians were responsible for all aspects of the behavioural intervention promoting the Mediterranean diet, as previously described.14 Briefly, on the basis of the initial assessment of individual scores of adherence to the Mediterranean diet with a 14-item questionnaire,18,19 dietitians gave personalised dietary advice to participants randomly assigned to the two Mediterranean diet interventions, with instructions directed to improve adherence by face-to-face intervention every 3 months by registered dietitians. The intended goals of the interventions were to increase fat intake to more than 40% of energy in the two Mediterranean diet groups. Participants in the two Mediterranean diet groups received at no cost either extravirgin olive oil (1 L per week for the participants' family needs as each participant should consume 50 mL a day) or 30 g of nuts per day (15 g of walnuts, 7·5 g of almonds, and 7·5 g of hazelnuts, with additional 1 kg sachets of mixed nuts every 3 months to account for family needs). Neither energy restriction nor increased physical activity was advised for any of the study groups. The duration of the trial was prespecified as 6 years; however, the Data and Safety Monitoring Board decided to stop the trial after analysing the results during the meeting done at year 5, according to prespecified rules to stop"	
Control/Comparator	"Participants assigned to the control diet received personal advice and written recommendations to reduce all types of dietary fat once a year; however, during the trial, this frequency of dietary advice in the control group was perceived as a limitation by reviewers, and the protocol was modified to increase the intensity and frequency of the intervention of the control group so that intervention in the three groups was similar. The change of the intervention was made on Oct 1, 2006, when 1626 participants were already included in the control group. The intended goals of the interventions were to reduce fat intake to less than 30% of energy in the control diet group. those in the control group were	

<table>
<tr><td></td><td>given small non-food gifts every 3 months (such as, books, kitchen clocks, spoons, etc). Neither energy restriction nor increased physical activity was advised for any of the study groups. The duration of the trial was prespecified as 6 years; however, the Data and Safety Monitoring Board decided to stop the trial after analysing the results during the meeting done at year 5, according to prespecified rules to stop.”</td></tr>
<tr><td>Treatment duration</td><td>5 years</td></tr>
<tr><td>Follow-up from baseline</td><td>5 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 7447
Intervention group/s: Mediterranean diet plus extra-virgin olive oil (n=2543); Mediterranean diet plus nuts (n=2454)

Comparator group: Control diet (n=2450)</td></tr>
<tr><td>Mean age ± SD</td><td>Mediterranean diet plus extra-virgin olive oil: 67.0y (6.2); Mediterranean diet plus nuts: 66.7y (6.1); Control diet: 67.3y (6.3)</td></tr>
<tr><td>Sex</td><td>57.50% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Either type 2 diabetes or at least three of the following cardiovascular risk factors: current smoking, hypertension (blood pressure >140/90 mmHg or treatment with antihypertensive drugs), high plasma LDL cholesterol concentration (≥4·14 mmol/L), low plasma HDL cholesterol concentration (<1·04 mmol/L for men and <1·30 mmol/L for women), overweight or obesity (BMI ≥25 kg/m²), or family history of premature coronary heart disease.</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Mediterranean diet plus extra-virgin olive oil: 76.7
(11.8)
Mediterranean diet plus nuts: 76.6
(11.9)</td><td>Control diet: 77
(12.2)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Mediterranean diet plus extra-virgin olive oil: 29.9
(3.7)
Mediterranean diet plus nuts: 29.7
(3.8)</td><td>Control diet: 30.2
(10.8)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Mediterranean diet plus extra-virgin olive oil: 100.2
(10.4)
Mediterranean diet plus nuts: 100.2
(10.5)</td><td>Control diet: 100.9
(10.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg; vs baseline)
Mean (95% CIs)</td><td>Mediterranean diet plus extra-virgin olive oil: -0.19
(-0.331--0.048)
Mediterranean diet plus nuts: 0.014
(-0.141-0.169)</td><td>Control diet: -0.231
(-0.398--0.064)</td></tr>
<tr><td>Change in waist circumference (cm; vs baseline)
Mean (95% CIs)</td><td>Mediterranean diet plus extra-virgin olive oil: -0.659
(-0.898--0.419)
Mediterranean diet plus nuts: -0.406
(-0.655--0.157)</td><td>Control diet: -0.447
(-0.729--0.166)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg; vs baseline)
Mean (95% CIs)</td><td>Mediterranean diet plus extra-virgin olive oil: -0.88
(-1.149--0.612)
Mediterranean diet plus nuts: -0.402
(-0.696--0.108)</td><td>Control diet: -0.604
(-0.904--0.304)</td></tr>
<tr><td>Change in waist circumference (cm; vs baseline)
Mean (95% CIs)</td><td>Mediterranean diet plus extra-virgin olive oil: 0.851
(0.427-1.275)
Mediterranean diet plus nuts: 0.372
(-0.123-0.868)</td><td>Control diet: 1.198
(0.677-1.719)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Interventions: 62%; Control: 60%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Evans, 2012

Guideline record ID: 10152A--FEMALES

Study characteristics		
Citation	Evans, E. M., Mojtahedi, M. C., Thorpe, M. P., Valentine, R. J., Kris-Etherton, P. M., & Layman, D. K. (2012). Effects of protein intake and gender on body composition changes: a randomized clinical weight loss trial. Nutrition & Metabolism, 9(1), 55. https://doi.org/10.1186/1743-7075-9-55	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of protein intake and gender on body composition changes: a randomized clinical weight loss trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Overweight or obese."	
Exclusion criteria	"BMI<26 kg/m2, body weight>140 kg (due to DXA scanning bed constraints), smoking, any existing medical conditions requiring medications that impact primary or secondary outcomes of the study, i.e. use of oral steroids or use of anti-depression medication."	
Setting	Community	
Intervention	"The PRO diet prescribed dietary protein at 1.6 g. kg -1.d-1 (~30 % of energy intake) with a carbohydrate/protein ratio <1.5 and dietary lipids ~30 % energy intake"	
Control/Comparator	"The CARB diet provided dietary protein equal to 0.8 g.kg-1.d-1 (~15 % of energy intake) with a carbohydrate/protein ratio>3.5 and total fat ~30 % of energy intake."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 130 Intervention group/s: PRO (n=66) Comparator group: CARB (n=64)	
Mean age ± SD	N/A	
Sex	55.38% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	FEMALE weight (kg) Mean (SD)	PRO: 85.1 (12)	CARB: 87.6 (11.4)
	FEMALE Whole body Fat (kg) Mean (SD)	PRO: 34.6 (7.5)	CARB: 36.8 (7.8)

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>FEMALE weight (kg)
Mean (SD)

FEMALE Whole body Fat (kg)
Mean (SD)</td><td>PRO: 77.6
(13.1)

PRO: 29.6
(7.9)</td><td>CARB: 85.9
(8.1)

CARB: 32.8
(7.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>FEMALE weight loss %
Mean (SD)</td><td>PRO: -9.5
(6)</td><td>CARB: -10.3
(6.1)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>64% (for PRO group), 45% (CARB group)</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Evans Ellen M; Mojtahedi Mina C; Thorpe Matthew P; Valentine Rudy J; Kris-Etherton Penny M; Layman Donald K, 2012

Guideline record ID: 10152B--MALES

Study characteristics		
Citation	Evans, E. M., Mojtahedi, M. C., Thorpe, M. P., Valentine, R. J., Kris-Etherton, P. M., & Layman, D. K. (2012). Effects of protein intake and gender on body composition changes: a randomized clinical weight loss trial. Nutrition & Metabolism, 9(1), 55. https://doi.org/10.1186/1743-7075-9-55	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of protein intake and gender on body composition changes: a randomized clinical weight loss trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Overweight or obese."	
Exclusion criteria	"BMI<26 kg/m2, body weight>140 kg (due to DXA scanning bed constraints), smoking, any existing medical conditions requiring medications that impact primary or secondary outcomes of the study, i.e. use of oral steroids or use of anti-depression medication."	
Setting	Community	
Intervention	"The PRO diet prescribed dietary protein at 1.6 g. kg -1.d-1 (~30 % of energy intake) with a carbohydrate/protein ratio <1.5 and dietary lipids ~30 % energy intake"	
Control/Comparator	"The CARB diet provided dietary protein equal to 0.8 g.kg-1.d-1 (~15 % of energy intake) with a carbohydrate/protein ratio>3.5 and total fat ~30 % of energy intake."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 130 Intervention group/s: PRO (n=66) Comparator group: CARB (n=64)	
Mean age ± SD	N/A	
Sex	55.38% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	MALE weight (kg) Mean (SD)	PRO: 100.2 (16.4)	CARB: 100.1 (10.8)
	MALE whole body fat (kg)	PRO: 28.7	CARB: 30.5

	Mean (SD)	(7.7)	(5.5)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	MALE weight (kg) Mean (SD) MALE whole body fat (kg) Mean (SD)	PRO: 90.2 (16.1) PRO: 21 (7.3)	CARB: 90.2 (16.1) CARB: 21.6 (4.6)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	MALE weight loss % Mean (SD)	PRO: -12.1 (7.6)	CARB: -9.8 (6.5)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	64% (for PRO group), 45% (CARB group)		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Everett, 2021

Guideline record ID: 10760--1

Study characteristics		
Citation	Everett, B., Salamonson, Y., Koirala, B., Zecchin, R., & Davidson, P. M. (2021). A randomized controlled trial of motivational interviewing as a tool to enhance secondary prevention strategies in cardiovascular disease (MICIS study). Contemporary Nurse, 57(1-2), 80-98. https://doi.org/10.1080/10376178.2021.1927774	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A randomized controlled trial of motivational interviewing as a tool to enhance secondary prevention strategies in cardiovascular disease (MICIS study)	
Location	Australia	
Trial name	Motivational interviewing as a tool to enhance secondary prevention strategies in cardiovascular disease (MICIS)	
Methods		
Inclusion criteria	"Patients commencing attendance at any of the 6-week outpatient CR programs (at three hospitals under Western Sydney Local Health District in Australia) during the data collection period (April 2006 to May 2007) were invited to participate in the study. Prospective participants were only approached after clinical staff had assessed their suitability and asked if they might be interested in the study. Fluency in, and ability to understand English was required to give informed consent, complete study instruments with minimal assistance, and participate in MI sessions."	
Exclusion criteria	"Patients were excluded from the study if they had not been cleared to exercise by their consulting cardiologist, had an uncontrolled arrhythmia, or cognitive impairment precluding completion of study instruments and participation in MI sessions."	
Setting	Hospital	
Intervention	"The intervention was supplemental to the usual care model of cardiac rehabilitation (CR), and consisted of two, 1-hour sessions of nurse-delivered Motivational interviewing (MI) over the first 2 weeks of a standard 6-week outpatient CR program, based on Miller and Rollnick's (Miller & Rollnick, 2002) conceptualization of MI occurring in two phases. Individuals attended MI sessions adjacent to their CR sessions."	
Control/Comparator	"Participants randomized to control group (usual care) attended the standard 6-week outpatient cardiac rehabilitation (CR) program of exercise, education, and risk factor modification based on best practice guidelines at the time."	
Treatment duration	6 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference	
Participant characteristics		
Number of participants	n= 110 Intervention group/s: Intervention (n=52) Comparator group: Control (n=58)	
Mean age ± SD	60.1y (10.6)	
Sex	28.18% female	

<table>
<tr><td>Pre-existing medical condition</td><td>cardiovascular disease</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference, cm
Mean (SD)

BMI (kg/m2)
Mean (SD)

Proportion of Overweight (25.0-29.9 kg/m2)
Proportion (%)

Proportion Obese (≥ 30.0 kg/m2)
Proportion (%)</td><td>Intervention: 103.1 (13.2)

Intervention: 29.9 (5.4)

Intervention: 39.0%

Intervention: 40.0%</td><td>Control: 98.5 (11.2)

Control: 28.3 (4.3)

Control: 43.0%

Control: 33.0%</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference, cm
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 101.1 (13.8)

Intervention: 30.8 (5.5)</td><td>Control: 97 (13.3)

Control: 29.1 (4.7)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
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<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Fagevik Olsen, 2022

Guideline record ID: 10204

Study characteristics		
Citation	Fagevik Olsén, M., Wiklund, M., Sandberg, E., Lundqvist, S., & Dean, E. (2022). Long-term effects of physical activity prescription after bariatric surgery: a randomized controlled trial. Physiotherapy Theory and Practice, 38(11), 1591-1601. https://doi.org/https://dx.doi.org/10.1080/09593985.2021.1885087	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-term effects of physical activity prescription after bariatric surgery: A randomized controlled trial	
Location	Sweden	
Trial name	N/A	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	"Not being fluent in Swedish or having concurrent cardiovascular, orthopedic, respiratory, rheumatologic, or neurologic conditions or injury that would limit participants' capacity to be physically active at a moderate-intensity level for at least 150 minutes/week."	
Setting	Hospital	
Intervention	"In addition to general information administered to the control group, patients in the intervention group (n = 57) received a PAP that was individually prescribed by the physical therapist based on patients' general multisystem assessment and their baseline PA, exercise, and preferences. Based on each patient's goals, the dose of PA in the written instruction included type of exercise, frequency, intensity, and duration (Garber et al., 2011; World Health Organization, 2010). Patients were to start with lowintensity aerobic exercise such as walking during the first three weeks post-operatively. Thereafter, the exercise dose parameters were progressed with the goal of reaching at least 150 minutes of moderately intense PA and exercise per week and maintaining it throughout the first year after surgery. Motivational interviewing strategies were used with goal setting and establishing the initial PAP, to encourage and enable patients to succeed in adhering to the program for one year, the duration of the study"	
Control/Comparator	"The patients in the control group (n = 64) received care that is standard in Sweden. Administered by physical therapists, this included general written and verbal information about the importance of PA and exercise and how to return to an optimal level after surgery."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 121 Intervention group/s: Intervention (n=57) Comparator group: Control (n=64)	
Mean age ± SD	Intervention: 39.7y (11.3); Control: 40.2y (10.8)	

<table>
<tr><td>Sex</td><td>79.34% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 121
(18.6)

Intervention: 43.5
(4.45)

Intervention: 130.3
(16.1)</td><td>Control: 125.8
(16.8)

Control: 43.1
(3.6)

Control: 130
(12.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 82.9
(15.2)

Intervention: 30
(4.3)

Intervention: 92
(13.7)</td><td>Control: 84.1
(16.3)

Control: 28.6
(3.9)

Control: 90.6
(12.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (%)
Mean (SD)

Change in BMI (%)
Mean (SD)

Change in waist circumference (%)
Mean (SD)</td><td>Intervention: -31
(8)

Intervention: -31
(8)

Intervention: -29
(9.2)</td><td>Control: -33.4
(8)

Control: -33.4
(8)

Control: -29.8
(9.1)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Fahs, 2013

Guideline record ID: 10205--1

Study characteristics		
Citation	Fahs, P. S., Pribulick, M., Williams, I. C., James, G. D., Rovynak, V., & Seibold-Simpson, S. M. (2013). Promoting heart health in rural women. The Journal of Rural Health, 29(3), 248-257. https://doi.org/10.1111/j.1748-0361.2012.00442.x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Promoting Heart Health in Rural Women	
Location	USA	
Trial name	Promoting Heart Health in Rural Women (PPH)	
Methods		
Inclusion criteria	"Women enrolled in this study had a Framingham score of ≤ 20 points and were between 35 and 65 years of age, with no history of coronary heart disease (CHD) or diabetes. Subjects who reported medications such as lipid lowering drugs or antihypertensives were included if they had been taking those medications for at least 1 year."	
Exclusion criteria	Not reported	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The Community Intervention (CI) consisted of an invitation, extended to all participants, to attend a community-visioning meeting; 1 meeting was held at each site. Meeting participants discussed ways to increase awareness of both female CVD and the local community resources available to women to improve their heart health. A directed round robin exercise elicited and prioritized ideas for new community-based interventions. The NY subjects requested a web-based listing of countywide accessible physical activity sites. The list of sites and photos was posted on the county health department webpage. The VA subjects chose to use an annual health fair organized and held at a primarily African American church as a means to improve heart health in that region. A community organization in each county was given $2,000 to implement each respective idea. Interventions were team developed, designed according to the 10 processes of change,15 and approved by a TM consultant (personal communication Sue Rossi, University of Rhode Island). Interventions were also designed to take into consideration the rural living environment using the Moos social-ecological perspective. Positive rural environmental factors built into interventions included identifying advantages of space and the cultural aspect of growing vegetables and fruits as well as using seasonal, locally grown foods in a heart healthy diet. Nurses providing the interventions received training on the staged matched interventions in a 2-day workshop."	
Control/Comparator	"The Community Intervention (CI) consisted of an invitation, extended to all participants, to attend a community-visioning meeting; 1 meeting was held at each site. Meeting participants discussed ways to increase awareness of both female CVD and the local community resources available to women to improve their heart health. A directed round robin exercise elicited and prioritized ideas for new community-based interventions. The NY subjects requested a web-based listing of countywide accessible physical activity sites. The list of sites and photos was posted on the county health department webpage. The VA subjects chose to use an annual health fair organized and held at a primarily African American church as a means to improve heart health in that region. A community organization in each county was given $2,000 to implement each respective idea. Interventions were team developed, designed according to the 10 processes of change,15 and approved by a TM consultant (personal communication Sue Rossi, University of Rhode Island). Interventions were also designed to take into consideration the rural living environment using the Moos social-ecological perspective. Positive rural environmental	

<table>
<tr><td></td><td>factors built into interventions included identifying advantages of space and the cultural aspect of growing vegetables and fruits as well as using seasonal, locally grown foods in a heart healthy diet. Nurses providing the interventions received training on the staged matched interventions in a 2-day workshop. In addition to the community interventions, subjects in the SMN+CI group were also visited 4 times by 1 of 12 Registered Nurses (RNs), using a book of possible interventions for up to 3 areas: diet, physical activity, and/or smoking. Subject and RN negotiated time and place of visit as well as which area(s) to address for each visit.”</td></tr>
<tr><td>Treatment duration</td><td>14 months</td></tr>
<tr><td>Follow-up from baseline</td><td>14 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 167
Intervention group/s: SMN + CI (n=85)

Comparator group: CI (n=82)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Waist circumference (inches)
Mean (SD)</td><td>SMN + CI: 31

SMN + CI: 38</td><td>CI: 30

CI: 37</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Waist circumference (inches)
Mean (SD)</td><td>SMN + CI: 30

SMN + CI: 38</td><td>CI: 30

CI: 36</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Fanning, 2022

Guideline record ID: 10206--1

Study characteristics		
Citation	Fanning, J., Rejeski, W. J., Leng, I., Barnett, C., Lovato, J. F., Lyles, M. F., & Nicklas, B. J. (2022). Intervening on exercise and daylong movement for weight loss maintenance in older adults: a randomized, clinical trial. Obesity, 30(1), 85-95. https://doi.org/10.1002/oby.23318	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Intervening on exercise and daylong movement for weight loss maintenance in older adults: A randomized, clinical trial	
Location	USA	
Trial name	Empowered with Movement to Prevent Obesity and Weight Regain (EMPOWER)	
Methods		
Inclusion criteria	"65-85 years who were classified as obese based on a BMI of 30-45 kg/m2. In addition to the age and BMI criteria, eligibility criteria included: 1) insufficiently active (i.e., no participation in regular resistance training and/or > 20 mins/day of aerobic exercise in past 6 months); 2) non-smoking for >1 year; 3) <5% weight change in past 6 months; and 4) no insulin-dependent or uncontrolled diabetes (fasting glucose >140 mg/dl), osteoporosis (self-reported or t-score < −2.3 on hip or spine DXA scan), cognitive impairment (Montreal Cognitive Assessment <22), or clinical evidence of depression, anemia, heart disease, cancer, liver, renal, or chronic pulmonary disease, uncontrolled hypertension (>160/90 mmHg), major physical impairment, or contraindication for exercise or weight loss. These criteria were selected to minimize the likelihood for adverse events related to dietary weight loss and/or participation in moderate-to-vigorous physical activity. Participants were also asked about their access to a personal smartphone device and willingness to use it in the study. Those without a device or without consistent access to mobile internet were provided with a smartphone for the duration of the study (33/183; 18%)."	
Exclusion criteria	Not reported	
Setting	Home, University/research centre	
Intervention	"All participants received a Fitbit Alta activity monitor at least two weeks prior to the start of the intervention, and the device was paired with a mobile health application that was tailored to each intervention arm (mHealth app; the EMPOWER Companion App)(23). The app facilitated contact between group members and research staff between intervention visits and was designed to facilitate self-monitoring of activity behaviors by providing group-specific visual feedback of Fitbit activity data, which is described further below. All participants underwent a diet intervention designed to elicit 7-10% WL from baseline body mass. Individual goals for caloric intake were prescribed to achieve an energy deficit of ~400 kcal/d from weight maintenance energy requirements (calculated as measured resting energy expenditure times an activity factor of 1.3). The macronutrient goal targeted an intake range of 25-30% from protein, 20-35% fat, and 45-55% carbohydrates. In the first 6 months of the study, considered to be the intensive phase, participants attended weekly in-person group sessions by treatment arm delivered by the registered dietitian (RD) and a staff member with expertise in behavioral interventions. The group sessions were designed using principles from social cognitive theory (24) and the group dynamics literature, (25) with an emphasis on developing self-regulatory skills, social support, nutritional knowledge, and an awareness of daily dietary patterns via mindful eating exercises and food tracking. Body weight was measured and recorded at all sessions. In addition, participants were asked to track their daily food and beverage intake and these logs were reviewed weekly by the RD. Participants were allowed to reduce their frequency of logging at the discretion of the RD. For the final month of the intensive phase, focus was placed on	

	transitioning toward self-management of WL, with an emphasis on continued self-monitoring and relapse prevention. During the transition phase of the study (months 7- 9) group sessions were held twice monthly and participants were asked to continue logging their food/beverage intake and body weight. Group sessions were not held during the maintenance phase (months 10-18), but monthly contact was maintained with participants, either by brief phone call or email, to encourage study retention. -Participants in the WL+SL and WL+EX+SL treatment arms aimed to indirectly reduce the presence of sustained sitting bouts by engaging in frequent bouts of physical activity. These sessions occurred in conjunction with the diet sessions and followed the same contact schedule to achieve treatment goals (weekly during the first 6 months and bimonthly during months 7-9). During the maintenance phase (months 10-18), the monthly phone call or email contact emphasized adherence to the SL goals. SitLess group content focused on optimizing patterns of movement such that a daily step goal was achieved by evenly distributing stepping throughout the day. This was monitored using the Companion mHealth app, which displayed progress toward step goals, and minutelevel Fitbit data were displayed on a daily timeline bar in near real time (see Online Supplemental Figure S1). Daily stepping goals were increased by approximately 25% each week in collaboration with an interventionist until a maintenance limit of 10,000 steps was achieved. See "Goal Setting and the Companion App" in the online supplement for more detail. Intervention leaders also provided guidance and motivation to achieve movement throughout the day at home (e.g., stand and complete light movement while watching television, finding a space to engage in mindful walking), and in the community (e.g., identify opportunities for active transport). Of note, we have retained the SitLess label here to align with previously published work,(23) but ongoing iterations of this project have adopted the phrasing of "day-long physical activity" to better reflect the nature of the intervention."
Control/Comparator	"All participants received a Fitbit Alta activity monitor at least two weeks prior to the start of the intervention, and the device was paired with a mobile health application that was tailored to each intervention arm (mHealth app; the EMPOWER Companion App)(23). The app facilitated contact between group members and research staff between intervention visits and was designed to facilitate self-monitoring of activity behaviors by providing group-specific visual feedback of Fitbit activity data, which is described further below. All participants underwent a diet intervention designed to elicit 7-10% WL from baseline body mass. Individual goals for caloric intake were prescribed to achieve an energy deficit of ~400 kcal/d from weight maintenance energy requirements (calculated as measured resting energy expenditure times an activity factor of 1.3). The macronutrient goal targeted an intake range of 25-30% from protein, 20-35% fat, and 45-55% carbohydrates. In the first 6 months of the study, considered to be the intensive phase, participants attended weekly in-person group sessions by treatment arm delivered by the registered dietitian (RD) and a staff member with expertise in behavioral interventions. The group sessions were designed using principles from social cognitive theory (24) and the group dynamics literature, (25) with an emphasis on developing self-regulatory skills, social support, nutritional knowledge, and an awareness of daily dietary patterns via mindful eating exercises and food tracking. Body weight was measured and recorded at all sessions. In addition, participants were asked to track their daily food and beverage intake and these logs were reviewed weekly by the RD. Participants were allowed to reduce their frequency of logging at the discretion of the RD. For the final month of the intensive phase, focus was placed on transitioning toward self-management of WL, with an emphasis on continued self-monitoring and relapse prevention. During the transition phase of the study (months 7- 9) group sessions were held twice monthly and participants were asked to continue logging their food/beverage intake and body weight. Group sessions were not held during the maintenance phase (months 10-18), but monthly contact was maintained with participants, either by brief phone call or email, to encourage study retention. Participants in the WL+EX and WL+EX+SL treatment arms aimed to perform structured aerobic exercise (treadmill walking) of moderate intensity for 4-5 days/week, progressing to a duration of 200 min/week. Participants were asked to attend center-based sessions for at least 3 days/week during the 6-month intensive phase and at least 1 day/week during the 3-month transition phase (months 7-9), exercising at home for the other 2-4 days/week. During the maintenance phase, the monthly phone call or email contact emphasized adherence to the

<table>
<tr><td></td><td>moderate-intensity exercise goal of 5-6 days/week to maintain a volume of 200 min/week. The supervised exercise sessions consisted of treadmill walking in which participants began with a 3-5 min warm-up at a slow pace before progressing to an intensity of 65-70% of their heart rate reserve (assessed during their baseline CPET). The exercise duration progressed to 40-50 min by the end of the 6th week and thereafter. Two heart rate readings were taken during each supervised session to monitor compliance to the prescribed intensity, and speed and grade were adjusted as necessary to ensure that participants exercised at their prescribed intensity. Each walking session ended with a 3-5 min cool-down followed by 5 min of large muscle flexibility stretches. Regarding exercise conducted outside of the center, participants received guidance on how to safely complete ground or treadmill walking, elliptical, or stationary cycling depending on availability. They were also advised to sustain moderate-intensity activity equivalent to a rating of 13-15 using Borg's Rating of Perceived Exertion (RPE). As a self-monitoring tool, participants were instructed to self-report their completion of their daily exercise bouts using the Companion mHealth app, wherein they checked "I Exercised Today". They were also able to view their participation in sustained bouts of activity of at least 10 minutes within a timeline bar in the app (see Online Supplemental Figure S1). For individuals in the WL+EX+SL condition, the EMPOWER Companion App integrated feedback and self-monitoring tools pertaining to both moving throughout the day and achieving exercise goals, and this is described in detail in the passage "Goal Setting and the Companion App" within the Online Supplement.”</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 120
Intervention group/s: WL + SL (n=41); WL + EX + SL (n=39)

Comparator group: WL + EX (n=40)</td></tr>
<tr><td>Mean age ± SD</td><td>70y (4.7)</td></tr>
<tr><td>Sex</td><td>81.67% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>WL + SL: 35.8
(3.8)
WL + EX + SL: 35.5
(3.7)</td><td>WL + EX: 34.9
(3.3)</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>WL + SL: 95.1
(14.3)
WL + EX + SL: 94.7
(10.2)</td><td>WL + EX: 91.6
(14.3)</td></tr>
<tr><td>Fat Mass (kg)
Mean (SD)</td><td>WL + SL: 45.3
(7.3)
WL + EX + SL: 44.6
(8)</td><td>WL + EX: 43
(5.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>WL + SL: 88.7
(14.3)</td><td>WL + EX: 87.2
(13.1)</td></tr>
</table>
</td></tr>
</table>

	Fat Mass (kg) Mean (SD)	WL + EX + SL: 89.8 (14.3) WL + SL: 41 (7.3) WL + EX + SL: 41.3 (0.8)	WL + EX: 41 (5.4)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Farinatti, 2016

Guideline record ID: 10208--1

Study characteristics		
Citation	Farinatti, P., Monteiro, W. D., & Oliveira, R. B. (2016). Long term home-based exercise is effective to reduce blood pressure in low income brazilian hypertensive patients: a controlled trial. High Blood Pressure & Cardiovascular Prevention, 23(4), 395-404. https://doi.org/10.1007/s40292-016-0169-9	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long Term Home-Based Exercise is Effective to Reduce Blood Pressure in Low Income Brazilian Hypertensive Patients: A Controlled Trial	
Location	Brazil	
Trial name	N/A	
Methods		
Inclusion criteria	"Patients diagnosed with hypertension were recruited from a public outpatient clinic at the Pedro Ernesto Hospital at the University of Rio de Janeiro State. A low income urban community was defined as population of interest in the present study, with the aim of reducing potential disparities in health status and access to health care across population sub-groups. Participants had never been treated for hypertension or had discontinued their therapy for at least six months before the experiment."	
Exclusion criteria	"(a) Bone, muscle or joint problems that limited or contraindicated the exercise practice; (b) uncontrolled diabetes, myocardial infarction, heart failure, ischemic heart disease, or unstable angina in the previous two years; (c) participation in other exercise program of any modality; (d) kidney disease (creatinine [1.5 mg/dL); (e) anemia (Hb \10 g/dl); (f) change in dose or class of hypotensive medication during the experimental protocol; (g) low adherence to the intervention program (fail to perform at least 75 % of the planned home-based exercise sessions)."	
Setting	Home	
Intervention	"Patients performed a home-based exercise program including light- to moderate-intensity walking at intensity corresponding to 60-85 % of maximum heart rate (HRmax) as estimated by 220 - age, with sessions of 30 min performed three times per week. Complementary stretching exercises were also performed three times per week. All patients underwent electrocardiography at rest and laboratory analyses, at least twice a year at the University hospital facilities. Additionally, anthropometric and fitness assessments were performed: body mass, height, waist and hip perimeters, skinfolds, trunk flexibility, and heart rate response to submaximal cycling exercise (aerobic efficiency). Subsequently, they were oriented by trained exercise instructors on how to control the walking intensity (checking HR by palpation of the radial artery), duration and frequency in the home-based exercise prescription. They also received instructions on how to properly perform selected stretching exercises. Participants assigned to home-based exercise group were reassessed every two months during 16 months for blood pressure, anthropometric, aerobic efficiency, and flexibility variables. In order to follow their progression and to adjust workloads to their new training status, they were asked to fill a form reporting the days they walked and 10-s HR measured every 10 min during the 30-min walk. Patients also reported the days in which stretching exercises were performed. The filled forms were used to determine the compliance to the exercise program."	
Control/Comparator	"Patients in the control group were reassessed only after 8 and 16 months, being recommended not to perform any kind of physical activity during the experimental period."	
Treatment duration	16 months	

<table>
<tr><td>Follow-up from baseline</td><td>16 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 74
Intervention group/s: Experimental group (n=35)

Comparator group: Control group (n=39)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 53y (11); Control: 48y (5)</td></tr>
<tr><td>Sex</td><td>51.35% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Hypertension</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Experimental group: 78.9
(9.9)

Experimental group: 30.5
(4.6)

Experimental group: 92.4
(9.6)</td><td>Control group: 76.2
(6.8)

Control group: 30.4
(4.5)

Control group: 95
(8.9)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)

Change in waist circumference (cm)
Mean (SD)</td><td>Experimental group: -5.4
(2)

Experimental group: -1.9
(0.7)

Experimental group: -6.1
(1.2)</td><td>Control group: 3.6
(0.2)

Control group: 0.3
(0.6)

Control group: 0.9
(0.4)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>83 ± 7%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Farpour-Lambert, 2019

Guideline record ID: 10209--1

Study characteristics		
Citation	Farpour-Lambert, N. J., Martin, X. E., Bucher Della Torre, S., von Haller, L., Ells, L. J., Herrmann, F. R., & Aggoun, Y. (2019). Effectiveness of individual and group programmes to treat obesity and reduce cardiovascular disease risk factors in pre-pubertal children. Clinical Obesity, 9(6), e12335. https://doi.org/https://dx.doi.org/10.1111/cob.12335	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effectiveness of individual and group programmes to treat obesity and reduce cardiovascular disease risk factors in pre-pubertal children	
Location	Switzerland	
Trial name	N/A	
Methods		
Inclusion criteria	“Prepubertal, BMI was >97th age- and genderspecific percentile according to the World Health Organization (WHO) references.”	
Exclusion criteria	“Tanner stage assessed by clinical examination (size of the breasts or testicular volume, and development of pubic hair) >1; (b) were involved in any weight control, physical activity, behavioural intervention or bariatric surgery; (c) had a family history of dyslipidaemia or essential hypertension; (d) took any medications or hormones that could affect cardiovascular function, body composition, lipid or glucose metabolism; (e) had an orthopaedic condition that limited physical activity; (f) had a genetic disorder or another chronic disease; and (g) received therapy for psychiatric problems.”	
Setting	Hospital	
Intervention	“The moderateintensity individually delivered intervention (treatment A) comprised 7 monthly 60-minute sessions with the child and his/her parent/s (at least the mother), which were conducted by a trained paediatrician (at 0, 3 and 6 months) and a dietician (at 1, 2, 4 and 5 months). Parents could choose a convenient appointment time which could be changed if unexpected events arose. Similar mastery approach and education manuals "Contrepoids" were used in both treatment arms, but topics were chosen according to family needs in individual care. The high-intensity group delivered intervention (treatment B) comprised 14 sessions (11 weekly then 3 monthly meetings, total 35 hours) over a 6-month period. Ideally both parents, but at least the mother, were asked to participate. Parental and child sessions were held separately. The parental group sessions consisted of 90 minutes with a dietician (at all sessions), a psychologist trained in cognitive behavioural therapy (at least four sessions) or a paediatrician experienced in therapeutic patient education. The child sessions consisted of 60 minutesutes with the same therapists. Each group included 10 to 12 children and their parents.Treatment groups A and B could participate in a 6-month after school moderate-to-vigorous physical activity training programme including two sessions of 60 minutes per week (total 44 hours between September-October and March-April), in addition to school physical education (135 minutes/week). Children who were already enrolled in a sports club (at least 60 minute/week 6 months/year) attended only one physical activity session per week at the Children's Hospital. One session per week was organized at the gym hall and the other one at the swimming pool, under close supervision of two physical education teachers. Training sessions included 40 minutes of aerobic exercise, 10 minutes of resistance training of the legs, arms and trunk and 10-minute of stretching. The intensity was progressively increased during the 6-month period, to reach intermittent vigorous intensities. During each session, physical education teachers discussed theoretical aspects of exercise such as discomfort, sweating and fatigue in relation to intensity, progress, self-esteem, benefits on health and well-being, leisure-time physical activity and active transport. Children and parents	

<table>
<tr><td></td><td>received a pedometer to assess and increase progressively their number of steps per day. The final goal was to do 10 000 steps per day for adults and 12 000 to 13 000 steps for children."</td></tr>
<tr><td>Control/Comparator</td><td>"Controls (group C) received standard care for 12 months, which included four 45-minute paediatric consultations (every 3 months) and instruction to maintain their current level of physical activity."</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 74
Intervention group/s: Group A: Individual delivery (n=21); Group B: Group delivery (n=31)
Comparator group: Group C: Control (n=22)</td></tr>
<tr><td>Mean age ± SD</td><td>Individual delivery: 9.5y (1.2); Group delivery: 9.7y (1.1); Control: 9.7y (1.0)</td></tr>
<tr><td>Sex</td><td>48.65% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Baseline total body fat (%)
Median (IQR)</td><td>Group A: Individual delivery:
41.4
(9.2)
Group B: Group delivery: 44.1
(4.1)</td><td>Group C: Control: 44
(5.2)</td></tr>
<tr><td>Baseline Weight (kg)
Median (IQR)</td><td>Group A: Individual delivery:
46.1
(16)
Group B: Group delivery: 50.2
(10.3)</td><td>Group C: Control: 47.9
(17.1)</td></tr>
<tr><td>Baseline BMI (kg/m2)
Median (IQR)</td><td>Group A: Individual delivery:
23.7
(4.7)
Group B: Group delivery: 25.8
(2.9)</td><td>Group C: Control: 24.8
(6)</td></tr>
<tr><td>Baseline BMI z (CDC)
Median (IQR)</td><td>Group A: Individual delivery:
2.1
(0.5)
Group B: Group delivery: 2.1
(0.3)</td><td>Group C: Control: 2
(0.5)</td></tr>
<tr><td>Baseline BMI z (WHO)
Median (IQR)</td><td>Group A: Individual delivery:
2.8
(0.7)
Group B: Group delivery: 2.8
(0.6)</td><td>Group C: Control: 2.7
(0.8)</td></tr>
<tr><td>Baseline waist circumference (cm)
Median (IQR)</td><td>Group A: Individual delivery:
79
(13)</td><td>Group C: Control: 80
(12)</td></tr>
</table>
</td></tr>
</table>

		Group B: Group delivery: 80 (12.5)	

Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator

Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Treatment effect on Body weight at 12 months, compared with control group (kg) Mean (95% CIs)	Group A: Individual delivery: 1.47 (-1.18 – 4.13) Group B: Group delivery: 0.90 (-3.31 -1.51)	
	Treatment effect on BMI at 12 months, compared with control group (kg/m2) Mean (95% CIs)	Group A: Individual delivery: 0.31 (-0.89 – 1.50) Group B: Group delivery: -0.77 (-1.86 -0.32)	
	Treatment effect on BMI z-score (CDC) at 12 months, compared with control group Mean (95% CIs)	Group A: Individual delivery: -0.02 (-0.15 – 0.11) Group B: Group delivery: -0.10 (-0.22 -0.01)	
	Treatment effect on BMI z-score (WHO) at 12 months, compared with control group Mean (95% CIs)	Group A: Individual delivery: 0.06 (-0.16 – 0.29) Group B: Group delivery: -0.09 (-0.29 -0.11)	
	Treatment effect on Waist circumference (cm) at 12 months, compared with control group Mean (95% CIs)	Group A: Individual delivery: -1.09 (-2.99 – 5.17) Group B: Group delivery: -1.77 (-5.59 -2.05)	
	Treatment effect on Total body fat (%) at 12 months, compared to control group Mean (95% CIs)	Group A: Individual delivery: -0.33 (-2.58 – 1.92) Group B: Group delivery: -1.65 (-3.75 –0.46)	

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator

Compliance with treatment	Individual delivery: 90%; Group delivery: 90%
Notes	

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Feigel-Guiller, 2015

Guideline record ID: 10211--1

Study characteristics		
Citation	Feigel-Guiller, B., Drui, D., Dimet, J., Zair, Y., Le Bras, M., Fuertes-Zamorano, N., Cariou, B., Letessier, E., Nobécourt-Dupuy, E., & Krempf, M. (2015). Laparoscopic gastric banding in obese patients with sleep apnea: a 3-year controlled study and follow-up after 10 years. Obesity Surgery, 25(10), 1886-1892. https://doi.org/https://dx.doi.org/10.1007/s11695-015-1627-5	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Laparoscopic Gastric Banding in Obese Patients with Sleep Apnea: A 3-Year Controlled Study and Follow-up After 10 Years	
Location	France	
Trial name	N/A	
Methods		
Inclusion criteria	"Aged 18- 65 years, had BMIs >35 kg/m2 2 months before study inclusion, and were receiving nocturnal NIV treatment for OSA and/or obesity-hypoventilation syndrome (OHS). OSA requiring NIV was defined by an AHI >30 events/h on polysomnography, and OHS requiring NIV was defined by a partial pressure of carbon dioxide in arterial blood (PaCO2) >6.5 kPa, according to French guidelines. NIV was provided using continuous positive airway pressure, bi-level positive airway pressure, or volumetric ventilation, as recommended by pulmonologists at the onset of the study."	
Exclusion criteria	"Patients with contraindications for surgery or severe eating disorders were excluded."	
Setting	Hospital, University/research centre	
Intervention	"Laparascopic adjustable gastric banding and were advised to consume a low-energy (5862 kJ [1400 kcal]/day) diet and to perform physical exercise"	
Control/Comparator	"Patients in both groups were advised to consume a low-energy (5862 kJ [1400 kcal]/day) diet and to perform physical exercise."	
Treatment duration	3 years	
Follow-up from baseline	10 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 63 Intervention group/s: LAGB (n=30) Comparator group: INC (n=33)	
Mean age ± SD	INC: 50.1y (7.4); LAGB: 46.9y (8.6)	
Sex	66.67% female	
Pre-existing medical condition	Obstructive Sleep Aponea OR Obesity-hyperventilation syndrome	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)

Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>LAGB: 132.1
(15)

LAGB: 135
(25.3)

LAGB: 48.8
(9.9)</td><td>INC: 126.6
(12.6)

INC: 123
(25.1)

INC: 44.4
(9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>LAGB: 115.5
(21.8)

LAGB: 41.5
(8.3)</td><td>INC: 116.4
(28.2)

INC: 41.7
(10.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>LAGB: 115.6
(18.8)

LAGB: 41
(6.5)</td><td>INC: 116.5
(17.8)

INC: 43.4
(6.6)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Excess weight loss (%)
Mean (SD)</td><td>LAGB: 15</td><td>INC: 15</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Excess weight loss (%)
Mean (SD)</td><td>LAGB: 33</td><td>INC: 2</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Fernandez-Ruiz, 2018

Guideline record ID: 10212--1

Study characteristics		
Citation	Fernández-Ruiz, V. E., Armero-Barranco, D., Paniagua-Urbano, J. A., Sole-Agusti, M., Ruiz-Sánchez, A., & Gómez-Marín, J. (2018). Short-medium-long-term efficacy of interdisciplinary intervention against overweight and obesity: randomized controlled clinical trial. International Journal of Nursing Practice, 24(6), e12690. https://doi.org/https://dx.doi.org/10.1111/ijn.12690	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Short-medium-long-term efficacy of interdisciplinary intervention against overweight and obesity: Randomized controlled clinical trial	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	"Overweight (BMI between 25.0 and 29.9 kg/m2) or obesity (BMI ≥ 30 kg/m2), as well as filling in a consent form."	
Exclusion criteria	"Comorbidities with other pathologies (depression, cancer, fibromyalgia, and others, which could interfere with the intervention)."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The experimental group underwent an interdisciplinary programme (I2AO2) with a comprehensive approach for the treatment of overweight and obesity for 12 months, and with postintervention re-evaluation (Figure 1). The project was created, developed, and coordinated by a research team of nurses outside the PHSM. It included new features that are not covered by the adult programme established in the PHSM, and it is based on publications that highlight the leadership of nurses, already recognized as the cornerstone of care (Steaban, 2016). The interdisciplinary team consisted of graduates in medicine, nursing, nutrition, psychology, and physical activity and sport science (SPAS). The intervention and the interdisciplinary staff were coordinated by nurses, under the theory of activity and interprofessional education (Kent, Francis-Cracknell & McDonald, 2016). Nurses were responsible for establishing the targets of the intervention, selecting the interdisciplinary team, and developing, along with them, the educational programme to be carried out during the intervention. Specifically, the role of nursing in the study was defined by the following activities: a. To create, develop, and coordinate the project. b. To coordinate the intervention and the interdisciplinary staff. c. To implement health education, maintaining a 60-minute monthly session focus on treating obesity and its comorbidities, enhancing changes of bad habits, and selecting and preparing healthy menus (12 total sessions). d. To be the nexus between the participants and the interdisciplinary staff. e. To evaluate the outcomes of the I2AO2 programme (Figure 2). The ongoing evaluation of the project, with a monthly meeting between all professionals, was established as a prerequisite. The nurses were present in all activities carried out by the different professionals, being the link between them and the patients, to clarify and resolve potential difficulties. The intervention conducted by the SPAS professional consisted of 4 weekly sessions of physical activity lasting 40 minutes; it began with stretching exercises (10 minutes) followed by 30 minutes of moderate aerobic work for all ages (20 minutes of fast treadmill walking or running at a slow pace) with a rest period at the end (208 total sessions). The sessions were conducted in 3 groups of 10 and a group of 7. The participation rate of the physical activity component was 88%. Participants with more than 35% of missed sessions would have been excluded from the intervention programme, but no one was excluded for this reason. Psychologists conducted a monthly 60-minute cognitive behavioural therapy (CBT) session, based on psychoeducation techniques	

<table>
<tr><td></td><td>(motivation), cognitive restructuring, problem solving (self-efficacy), and skills training, among others (12 sessions in total). The CBT component was created by the psychology team based on established theories and interventions, targeting the maintenance of the weight loss in the medium and long term. Sessions were individually targeted. The physician and nutritionist conducted the clinical and nutritional evaluation of the patient, to monitor drug-nutrient interactions and any imbalance or adverse reactions that may occur to the physical activity and the dietary management. Energy needs and nutritional assessments were calculated using the formula of Harris and Benedict (1919), and both professionals instructed on dietary management individually. The menus were produced from the ATP-III diet with a 300 kcal/day deficit, divided into 55% carbohydrates, less than 30% fat, 15% protein, and less than 150 mg/day cholesterol. Furthermore, the idea of consuming more vegetables and fruits was strengthened (Miguel et al., 2012)."</td></tr>
<tr><td>Control/Comparator</td><td>"Nothing."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 74
Intervention group/s: Experimental (n=37)

Comparator group: Control (n=37)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 59.4 (9.1); Control: 62.8 (8.9)</td></tr>
<tr><td>Sex</td><td>50.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight
Mean (SD)

BMI
Mean (SD)

Waist circumference
Mean (SD)</td><td>Experimental: 86.9
(11.4)

Experimental: 32.4
(3.8)

Experimental: 106.1
(9.3)</td><td>Control: 88.9
(13.1)

Control: 34.3
(4.5)

Control: 108.3
(8.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight
Mean (SD)

BMI
Mean (SD)

Waist circumference
Mean (SD)</td><td>Experimental: 80
(9.9)

Experimental: 29.8
(3.3)

Experimental: 97.8
(7.9)</td><td>Control: 88.7
(12.4)

Control: 34.2
(4.2)

Control: 108.5
(8.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
</table></td></tr>
</table>

12 months or closest time point	Change in weight Mean Change in BMI Mean Change in waist circumference Mean	Experimental: -6.9 Experimental: -2.6 Experimental: -8.3	Control: -0.2 Control: -0.1 Control: 0.1
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	100		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Fernández-Ruiz, 2021

Guideline record ID: 10214--1

Study characteristics		
Citation	Fernández-Ruiz, V. E., Solé-Agustí, M., Armero-Barranco, D., & Cauli, O. (2021). Weight loss and improvement of metabolic alterations in overweight and obese children through the I2AO2 family program: a randomized controlled clinical trial. Biological Research For Nursing, 23(3), 488-503. https://doi.org/10.1177/1099800420987303	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight Loss and Improvement of Metabolic Alterations in Overweight and Obese Children Through the I 2 AO 2 Family Program: A Randomized Controlled Clinical Trial	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	"A diagnosis of excess weight (85th percentile) or obesity (95th percentile) according to the WHO (2006)."	
Exclusion criteria	Not reported	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The EG completed the I2AO2 family interdisciplinary program for 9 months (academic year 2015/2016). Based on publications that highlight the leadership capacity of nurses (Chang et al., 2016; Nanri et al., 2012; Steinberger et al., 2009), this project was created, developed, and coordinated by a research team of nurses, mostly working in the Monteagudo healthcare services zone. The interdisciplinary team comprised physicians, nurses, nutritionists, psychologists, physical activity and sport sciences (CAFD in its Spanish acronym) professors, and a team of teachers, together forming what we termed the "health faculty." The I2AO2 family program focused on two fundamental pillars to treat excess weight or obesity and associated metabolic alterations in children and their guardians, namely nutritional treatment and physical activity. The study particularly focused on parent-child dyads. Furthermore, the program was complemented with a behavioral approach which encouraged responsibility among all the participants to maintain the acquired behaviors over time (Bawaked et al., 2018; Garcia- Silva et al., 2018). The nutritional approach followed the Mediterranean diet model (Trichopoulou et al., 2014), characterized by increased consumption of olive oil, whole grains, legumes, fruits, and vegetables, moderate intake of dairy products and fish, and reduced red meat intake. Because of the age of the children, we did not impose any caloric restrictions and relied only on establishing healthy nutrition based on the Mediterranean diet (Iaccarino-Idelson et al., 2017). Dietary changes were based on nutritional education for both the children and parents by using games, meal preparation, considering the preferences of the children, and always in a relaxed and playful environment. The program was conducted in kitchen facilities suitable for conducting a workshop at one of the schools and focused on producing healthy and attractive recipes for the whole family (over a total of 10 sessions). The physician and the nutritionist carried out the clinical and nutritional evaluation of the adults and monitored any possible drug-nutrient interactions. For the children, these functions were carried out by the pediatrician and the nutritionist. The objective was to monitor possible imbalances or adverse reactions that might occur in the context of dietary management. The CAFD professionals helped establish activities to intervene in sedentary lifestyles consisting of three weekly sessions of physical activity for 60 minutes; on 2 days the children exercised with their peers, and on the 3rd day they exercised with their guardians. The training sessions began with stretching exercises (10 minutes), followed by 30 minutes of ageadjusted aerobic work and 20 minutes of play with a break at the end (120 sessions in total). The sessions were conducted in four groups of 13 participants each,	

<table>
<tr><td></td><td>with an average participation rate of 88% in the physical training sessions. To maintain long term adherence to the healthy eating and physical exercise therapeutic strategies, they were combined with CBT. The psychological intervention aimed at the parents consisted of a monthly CBT session lasting 60 minutes, which was based on psychoeducation (motivation), cognitive restructuring, problem solving (self-efficacy), and skills training, among other techniques (for a total of 10 sessions). The CBT component was created by the psychology team based on previous theories and interventions (Ban˜os et al., 2019; Forcano et al., 2018) and aimed to maintain the healthy habits acquired over the medium and long-term. The sessions were always carried out with both the children and their guardians, with the latter being the driving force for change and for working on adherence. For the children in the EG, the pediatric psychologists also carried out a monthly CBT session lasting 60 minutes for a total of 10 sessions. This was based on positive reinforcement techniques and aimed to improve self-esteem, self-image, and motivation to change as well as providing, among others, tools for problem solving (self-efficacy) and skills training. As with the parents, the CBT component was created by the psychology team, and aimed to maintain the acquired healthy habits over the medium and long-term. The sessions were always conducted in a group setting, using the children as facilitators of change and work toward adherence. The therapy was not reinforced individually in any case.”</td></tr>
<tr><td>Control/Comparator</td><td>“Standard guidelines included in the Monteagudo public health zone community service program.”</td></tr>
<tr><td>Treatment duration</td><td>9 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 108
Intervention group/s: Experimental (n=54)

Comparator group: Control (n=54)</td></tr>
<tr><td>Mean age ± SD</td><td>9.1 (1.9)</td></tr>
<tr><td>Sex</td><td>54.63% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI Percentile
Mean (SD)

Waist circumference percentile
Mean (SD)

BMI (baseline)
Mean (SD)</td><td>Experimental: 96.53
(2.74)

Experimental: 96.14
(2.4)

Experimental: 23.53
(3.33)</td><td>Control: 97.1
(2.4)

Control: 95.74
(2.2)

Control: 24.41
(2.8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>94%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Fichtner, 2022

Guideline record ID: 10218--1

Study characteristics		
Citation	Fichtner, U. A., Armbruster, C., Bischoff, M., Maiwald, P., Sehlbrede, M., Tinsel, I., Brame, J., Kohl, J., König, D., Fuchs, R., Wurst, R., & Farin-Glattacker, E. (2022). Evaluation of an interactive web-based health program for weight loss -a randomized controlled trial. International Journal of Environmental Research and Public Health, 19(22), 15157. https://doi.org/https://dx.doi.org/10.3390/ijerph192215157	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Evaluation of an Interactive Web-Based Health Program for Weight Loss-A Randomized Controlled Trial	
Location	Germany	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were healthy persons of any sex, aged 18 years and older regardless of their health insurance. In case of pre-existing conditions or health impairments, subjects required a medical assessment for suitability in advance. Participation was only possible in one of the three coaches (smoking cessation, weight loss or increasing fitness); at the same time, however, members of the WLC could use modules of the fitness coach as well."	
Exclusion criteria	"Subjects who were participating in another study aiming to change health behavior towards the respective goal were not included. For the WLC, pregnant or breastfeeding women, individuals with a circumference > 200 cm or BMI > 40 kg/m2 or current underweight or underweight after a loss of 3 kg were excluded."	
Setting	Home	
Intervention	"All study participants were given access to a health goalspecific, web-based program. The IG is characterized by an interactive program with protocols, reactive algorithms, videos, health information, recipe suggestions and push messages. IG participants were recommended to use the WLC for 12 weeks, while individual action planning with adaptable intensity was implemented (weight loss goal of 3 or 5 kg within 12 weeks)."	
Control/Comparator	"All study participants were given access to a health goal specific, web-based program. The CG was enabled to use the noninteractive information web platform without any personalized feedback."	
Treatment duration	12 weeks	
Follow-up from baseline	15 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 3031 Intervention group/s: Intervention group (n=1514) Comparator group: Control group (n=1517)	
Mean age ± SD	Not reported	
Sex	Not reported	

<table>
<tr><td></td><td></td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intervention group: 86.4
(16.1)</td><td>Control group: 86.1
(15.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intervention group: 85.1
(17.5)</td><td>Control group: 84.1
(15.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (%)
Mean (SD)</td><td>Intervention group: 2.6
(7.2)</td><td>Control group: 2
(6.8)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Fisher, 2012

Guideline record ID: 10220--1

Study characteristics		
Citation	Fisher, G., Hunter, G. R., & Gower, B. A. (2012). Aerobic exercise training conserves insulin sensitivity for 1 yr following weight loss in overweight women. Journal of Applied Physiology, 112(4), 688-693. https://doi.org/https://dx.doi.org/10.1152/japplphysiol.00843.2011	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Aerobic exercise training conserves insulin sensitivity for 1 yr following weight loss in overweight women	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"BMI 27 and 30 kg/m2, premenopausal, age 21-46 yr, sedentary (no more than one time per week regular exercise)."	
Exclusion criteria	"Presumably - smoking, abnormal menstrual cycles, poor overal health, abnormal glucose tolerance as documented by 2h postprandial blood glucose levels after an oral glucose load, use of oral contraceptives, use of medications known to affect body composition."	
Setting	University/research centre	
Intervention	"For Diet + Aerobic training group: Aerobic training entailed continuous walking/ jogging on a treadmill, commencing with a warm-up of 3 min, and 3-5 min of stretching. During the first week of training, the subjects performed 20 min of continuous exercise at 67% maximum heart rate. Each week after the 1st week, duration and intensity increased so that by the beginning of the 8th wk, subjects exercised continuously at 80% of maximum heart rate for 40 min. Subjects were encouraged to increase intensity (either speed or grade) when average exercise heart rate was consistently below 80% of maximum. After the exercise session, subjects cooled down for 3-5 min with gradually decreasing exercise intensity. All food was furnished during weight loss and consisted of 800 kcal/day that were 20-22% fat, 18-22% protein, and 58-62% carbohydrate. Subjects picked up food at the General Clinical Research Center (GCRC) twice weekly and were instructed to remain on the 800 kcal/day diet until a BMI of 25 kg/m2 was reached. Time needed to reach the goal of a 25 kg/m2 BMI was variable with a mean of 154 61 days. However, no differences between the groups was found (P 0.2) Subjects were evaluated three times, at baseline in the overweight state (213 subjects were assessed at baseline), following weight loss (BMI 25 kg/m2; 126 subjects reached the target BMI), and 1 yr following the weight loss (97 subjects returned for the 1-yr post weight loss evaluation). During the 1 yr following weight loss, subjects were given instructions on a balanced diet that focused on low-density food intake according to EatRight Weight Management Program principles (31). For Diet + Resistance Training: All food was furnished during weight loss and consisted of 800 kcal/day that were 20-22% fat, 18-22% protein, and 58-62% carbohydrate. Subjects picked up food at the General Clinical Research Center (GCRC) twice weekly and were instructed to remain on the 800 kcal/day diet until a BMI of 25 kg/m2 was reached. Time needed to reach the goal of a 25 kg/m2 BMI was variable with a mean of 154 61 days. However, no differences between the groups was found (P 0.2) Subjects were evaluated three times, at baseline in the overweight state (213 subjects were assessed at baseline), following weight loss (BMI 25 kg/m2; 126 subjects reached the target BMI), and 1 yr following the weight loss (97 subjects returned for the 1-yr post weight loss evaluation). During the 1 yr following weight loss, subjects were given instructions on a balanced diet that focused on low-density food intake according to EatRight Weight Management Program principles (31). After a warm-up on the treadmill or cycle ergometer for 5 min and 3-5 min of stretching, subjects performed	

<table>
<tr><td></td><td>the following exercises: squats, leg extension, leg curl, elbow flexion, triceps extension, lateral pull-down, bench press, military press, lower back extension, and bent leg sit-ups. One set of 10 repetitions was performed during the first 4 wk, after which two sets of 10 repetitions were performed for each exercise with 2-min rest between sets. The training was progressive with intensity based on 80% of the maximum weight that an individual lifted one time (1 RM). Strength was evaluated every 3 wk, and adjustments in training resistance were made based on the most current 1 RM in both the weight loss and 1-yr weight maintenance phases. In both the aerobic and resistance exercise groups, subjects were expected to train 3 days/wk during the weight loss and 2 days/wk during 1-yr follow up."</td></tr>
<tr><td>Control/Comparator</td><td>"All food was furnished during weight loss and consisted of 800 kcal/day that were 20-22% fat, 18-22% protein, and 58-62% carbohydrate. Subjects picked up food at the General Clinical Research Center (GCRC) twice weekly and were instructed to remain on the 800 kcal/day diet until a BMI of 25 kg/m2 was reached. Time needed to reach the goal of a 25 kg/m2 BMI was variable with a mean of 154 61 days. However, no differences between the groups was found (P 0.2) Subjects were evaluated three times, at baseline in the overweight state (213 subjects were assessed at baseline), following weight loss (BMI 25 kg/m2; 126 subjects reached the target BMI), and 1 yr following the weight loss (97 subjects returned for the 1-yr post weight loss evaluation). During the 1 yr following weight loss, subjects were given instructions on a balanced diet that focused on low-density food intake according to EatRight Weight Management Program principles (31)."</td></tr>
<tr><td>Treatment duration</td><td>5.1 months (average)</td></tr>
<tr><td>Follow-up from baseline</td><td>17.1 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 213
Intervention group/s: Diet + Aerobic Training (n=80); Diet + Resistance Training (n=80)

Comparator group: Diet Only (n=53)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Diet + Aerobic Training: 75
(6)
Diet + Resistance Training: 78
(8)</td><td>Diet Only: 79
(8)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Diet + Aerobic Training: 28
(1)
Diet + Resistance Training: 28
(1)</td><td>Diet Only: 28
(1)</td></tr>
<tr><td>Body fat %
Mean (SD)</td><td>Diet + Aerobic Training: 46
(3)
Diet + Resistance Training: 45
(4)</td><td>Diet Only: 45
(3)</td></tr>
<tr><td>Lean Mass kg</td><td>Diet + Aerobic Training: 42</td><td>Diet Only: 44.7</td></tr>
</table>
</td></tr>
</table>

	Mean (SD)	(3.3) Diet + Resistance Training: 44.1 (4.5)	(3.6)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	46%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Fitzgibbon, 2010

Guideline record ID: 10222--1

Study characteristics		
Citation	Fitzgibbon, M. L., Stolley, M. R., Schiffer, L., Sharp, L. K., Singh, V., & Dyer, A. (2010). Obesity reduction black intervention trial (ORBIT): 18-month results. Obesity, 18(12), 2317-2325. https://doi.org/https://dx.doi.org/10.1038/oby.2010.47	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Obesity reduction black intervention trial (ORBIT): 18-month results	
Location	USA	
Trial name	Obesity Reduction Black Intervention Trial (ORBIT)	
Methods		
Inclusion criteria	"To be eligible for the study, a potential participant was required to have a BMI, calculated as weight in kilograms divided by height in meters squared, between 30 and 50, to be female, self-identified as African American or black, between the ages of 30 and 65 years, able to participate in an activity program requiring 30min of uninterrupted moderate activity, and able to attend class sessions."	
Exclusion criteria	"Women were excluded if they were unable to exercise because of emphysema, chronic bronchitis, or asthma; if they used a cane, walker, or wheelchair for mobility; if they were planning to move out of the area; if they had been treated for cancer (excluding skin cancer other than melanoma) in the past 5 years; if they were participating in a formal weight-loss program or taking weight-loss medications prescribed by a doctor; if they were pregnant, nursing, or planning a pregnancy; or if they were using illegal drugs or consuming >2 alcoholic drinks per day on a daily basis."	
Setting	University/research centre	
Intervention	"The 6-month weight-loss intervention was conducted in a group format by trained interventionists. The class met twice weekly on the university campus. The women were weighed weekly. The weight-loss goal for the first 6 months was 7% of initial body weight, which would then be maintained throughout the 12-month maintenance intervention. The recommended rate for weight loss was ~1-2 lb per week. All participants were taught behavioral strategies such as self-monitoring, and stimulus and portion control to help with both weight loss and weight-loss maintenance. All participants were encouraged to adopt a low-fat, high-fiber diet with increased fruit and vegetable consumption and decreased caloric intake. In feedback sessions conducted during the development of the intervention, former participants in our weight-loss trials said that they wanted a program that could be integrated into their lives and the lives of family members. Therefore, highly structured meal plans and meal replacements were not included in the intervention. Participants were encouraged to increase their physical activity. Self-monitoring of both food and activity were taught, and women were given pedometers and encouraged to walk ≥10,000 steps a day. The intervention was tailored to the individual primarily by feedback on their self-monitoring logs. Between sessions, the interventionists reviewed the logs and were then able to provide more structured and individual guidance on healthier food choices, food preparation techniques, and portion sizes. Participants were also offered a monthly motivational interviewing (MI) session by trained interventionists that addressed either diet or physical activity. MI sessions were conducted face-to-face or over the phone, and each session lasted ~20-30min. The group facilitators did not use MI during the group meetings. The 12-month weight-loss maintenance intervention emphasized structuring one's life in a way that supported maintenance of weight-loss behaviors. However, for many of the women who had lost minimal weight during the 6-month weightloss intervention, weight loss continued to be a goal. In months 7-12, the group met twice weekly and each member received monthly MI sessions. The topic of each group session	

<table>
<tr><td></td><td>was chosen by a participant, which allowed for the material to remain responsive to the needs of the group members and provided them with a sense of ownership. In months 13-15, the group met once weekly for an exercise class, and women continued to receive monthly MI. Finally, in months 16-18, there were no face-to-face group meetings, but women continued to receive monthly MI. Because the majority of the women were still trying to lose weight during the maintenance period of the study, the MI component did not change substantially over the course of the intervention. During MI sessions, interventionists and participants continued to work on building motivation and commitment and focused on relevant target behaviors (e.g., problem foods and barriers to being physically active). Throughout the 12-month maintenance period, participants received newsletters every other month, which reinforced concepts related to health behavior change."</td></tr>
<tr><td>Control/Comparator</td><td>"Women in the control group received newsletters that covered general health and safety topics on a weekly basis throughout the 6-month period. A staff member telephoned control participants once a month to allow participants to ask questions or express concerns about the information contained in the weekly newsletters. This staff member was not an interventionist and was not trained in MI. Women in the control group received monthly newsletters that covered general health and safety topics throughout the 12-month weight-maintenance period. Control group participants also continued to receive monthly phone calls from staff who were not trained in MI."</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 213
Intervention group/s: Intervention (n=107)

Comparator group: Control (n=106)</td></tr>
<tr><td>Mean age ± SD</td><td>46.0y (8.4)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 103.9
(15.7)

Intervention: 38.7
(5.5)</td><td>Control: 105.9
(17.4)

Control: 39.8
(5.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Proportion (%) at or below baseline weight
Proportion (%)</td><td>Intervention: 104.6
(15.8)

Intervention: 38.9
(5.5)

Intervention: 58</td><td>Control: 105.6
(18.1)

Control: 39.7
(5.9)

Control: 40</td></tr>
</table>
</td></tr>
</table>

	Proportion (%) at least 4kg below baseline weight Proportion (%) Proportion (%) at least 5% below baseline weight Proportion (%)	Intervention: 27 Intervention: 24	Control: 19 Control: 12
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in weight (kg) Mean (SD) Change in BMI (kg/m2) Mean (SD)	Intervention: -2.26 (7.42) Intervention: -0.86 (2.79)	Control: 0.51 (5.69) Control: 0.22 (2.07)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Fitzgibbon, 2020

Guideline record ID: 10223--1

Study characteristics		
Citation	Fitzgibbon, M. L., Tussing-Humphreys, L., Schiffer, L., Smith-Ray, R., Marquez, D. X., DeMott, A. D., Berbaum, M. L., & Hughes, S. L. (2020). Fit and Strong! Plus: twelve and eighteen month follow-up results for a comparative effectiveness trial among overweight/obese older adults with osteoarthritis. Preventive Medicine, 141, 106267. https://doi.org/10.1016/j.ypmed.2020.106267	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Fit and Strong! Plus: Twelve and eighteen month follow-up results for a comparative effectiveness trial among overweight/obese older adults with osteoarthritis	
Location	USA	
Trial name	Fit and Strong! Plus	
Methods		
Inclusion criteria	"The study definition of LE OA was based on self-reported pain or stiffness: pain in or around one or both knees or hips on most days in the past month and/or pain or stiffness in or around hips, knees ankles, feet or lower back on most days of at least 1 month during the last 6 months. Eligible participants were 60 or older and had a BMI of 25-50 kg/m2 ."	
Exclusion criteria	Not reported	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The interventions were both 90 min in length and were both conducted three times per week for eight weeks, for a total of 24 sessions. The initial 60 min of both interventions consist of stretching, low-impact aerobics, and strength training, with a primary focus on the lower extremities. Following each 60-min PA session, the F &S! group participated in a 30-min health education session that in cluded topics such as using PA to manage OA symptoms and exercising safely with OA. The curriculum for F&S! Plus retained the core physical activity and OA material included in standard F&S!. Sixteen weight and diet-related topics were added to F&S! Plus, with weight loss and diet quality concepts included in 22 of the 24 sessions. The diet quality information followed the Group Lifestyle Balance curriculum, adapted from the Diabetes Prevention Program and the 2010-2015 Dietary Guidelines for Americans and USDA My-Plate eating plan. Content was designed to produce 5% weight loss at 6 months and improve diet quality. To gether, the curriculum, homework, and weekly weight checks were designed to enhance social support (e.g., group problem solving) and self-regulation (e.g., goal setting, planning, self-monitoring) to build self-efficacy for weight loss and improve overall diet quality. The boosters sought to help participants continue to adhere to their dietary and physical activity goals. Maintenance of behavior was reinforced in months 3-18 in both groups through telephone reinforcement sessions in months 4, 8, and 15. The health educators who conducted these sessions were trained in motivational interviewing techniques, and separate educators were assigned to F&S! and F&S! Plus"	
Control/Comparator	"The interventions were both 90 min in length and were both conducted three times per week for eight weeks, for a total of 24 sessions. The initial 60 min of both interventions consist of stretching, low-impact aerobics, and strength training, with a primary focus on the lower extremities. Following each 60-min PA session, the F &S! group participated in a 30-min health education session that in cluded topics such as using PA to manage OA symptoms and exercising safely with OA. Maintenance of behavior was reinforced in months 3-18 in both groups through telephone reinforcement sessions in months 4, 8, and 15. The health educators who conducted these sessions were trained in motivational interviewing techniques, and separate educators were assigned to F&S! and F&S! Plus."	

<table>
<tr><td>Treatment duration</td><td>8 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 413
Intervention group/s: F&S! Plus (n=203)

Comparator group: F&S! (n=210)</td></tr>
<tr><td>Mean age ± SD</td><td>67.9y (5.9)</td></tr>
<tr><td>Sex</td><td>85.96% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>LE Osteoarthritis: self-reported pain or stiffness: pain in or around one or both knees or hips on most days in the past month and/or pain or stiffness in or around hips, knees ankles, feet or lower back on most days of at least 1 month during the last</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SE)</td><td>F&S! Plus: 93.1
(1.1)</td><td>F&S!: 93.7
(1.1)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SE)</td><td>F&S! Plus: 34.7
(0.4)</td><td>F&S!: 35
(0.4)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SE)</td><td>F&S! Plus: 113.9
(0.5)</td><td>F&S!: 111.8
(0.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SE)</td><td>F&S! Plus: 91.4
(1.1)</td><td>F&S!: 92.8
(1.1)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SE)</td><td>F&S! Plus: 31.1
(0.4)</td><td>F&S!: 34.7
(0.4)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SE)</td><td>F&S! Plus: 111.2
(0.7)</td><td>F&S!: 111.4
(0.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SE)</td><td>F&S! Plus: 91.8
(1.2)</td><td>F&S!: 92.8
(1.2)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SE)</td><td>F&S! Plus: 34.2
(0.4)</td><td>F&S!: 34.7
(0.4)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SE)</td><td>F&S! Plus: 111.9
(0.7)</td><td>F&S!: 110.4
(0.6)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SE)</td><td>F&S! Plus: -1.7
(0.3)</td><td>F&S!: -0.9
(0.3)</td></tr>
<tr><td>Change in weight (%)
Mean (SE)</td><td>F&S! Plus: -1.8</td><td>F&S!: -1</td></tr>
<tr><td>Change in BMI (kg/m2)</td><td>F&S! Plus: -0.6</td><td>F&S!: -0.3</td></tr>
</table>
</td></tr>
</table>

	Mean (SE) Change in BMI (%) Mean (SE) Change in waist circumference (cm) Mean (SE) Change in waist circumference (%) Mean (SE)	(0.1) F&S! Plus: -1.9 F&S! Plus: -2.7 (0.6) F&S! Plus: -2.4	(0.1) F&S!: -0.9 F&S!: -0.4 (0.6) F&S!: -0.3
Change in outcome measure from baseline to final follow-up/endpoint	Variable Change in weight (kg) Mean (SE) Change in weight (%) Mean (SE) Change in BMI (kg/m2) Mean (SE) Change in BMI (%) Mean (SE) Change in waist circumference (cm) Mean (SE) Change in waist circumference (%) Mean (SE)	Intervention arm/s F&S! Plus: -1.3 (0.3) F&S! Plus: -1.4 F&S! Plus: -0.5 (0.1) F&S! Plus: -1.4 F&S! Plus: -2 (0.5) F&S! Plus: -1.8	Comparator F&S!: -0.9 (0.3) F&S!: -1 F&S!: -0.3 (0.1) F&S!: -0.9 F&S!: -1.4 (0.5) F&S!: -1.2
Compliance with treatment	Not reported.		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Fjeldsoe, 2019

Guideline record ID: 10224

Study characteristics		
Citation	Fjeldsoe, B. S., Goode, A. D., Phongsavan, P., Bauman, A., Maher, G., Winkler, E., Job, J., & Eakin, E. G. (2019). Get Healthy, Stay Healthy: evaluation of the maintenance of lifestyle changes six months after an extended contact intervention. JMIR mHealth and uHealth, 7(3), e11070. https://doi.org/https://dx.doi.org/10.2196/11070	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Get Healthy, Stay Healthy: Evaluation of the Maintenance of Lifestyle Changes Six Months After an Extended Contact Intervention	
Location	Australia	
Trial name	Get Healthy, Stay Healthy (GHSH)	
Methods		
Inclusion criteria	"Participants completing GHS between August 2012 and February 2013 were eligible to join the GHSH trial if they had no intention of re-enrolling in GHS coaching, were not involved in other GHS evaluation substudies, and owned a mobile phone."	
Exclusion criteria	Not reported	
Setting	Home	
Intervention	"The "Get Healthy, Stay Healthy" (GHSH) intervention was an extended contact program delivered via text messages for 6 months following completion of an initial 6-month community-wide lifestyle telephone coaching program called "Get Healthy Service" (GHS). The GHSH-extended contact intervention was delivered via individually tailored text messages. Tailoring data were collected during an initial and an interim telephone call (around 12 weeks), during which participants worked with a trained coach to set a 12-week weight goal (weight maintenance or further weight loss) and two 12-week goals for physical activity and/or dietary behavior change, with targets consistent with national guidelines. For each behavioral goal (diet and/or physical activity), participants were asked to identify rewards for reaching their goal, expected benefits, preparatory behaviors for goal attainment, barriers and solutions, and a person who could support them to reach their goals. Participants selected their desired number of text messages (from 3-13 per fortnight), timing of texts (eg, 6 am), and type of texts. Overall, 4 types of texts targeted different behavior change strategies, each with different permitted frequencies: prompts to self-monitor weight (once per fortnight), goal checks for behavioral goals (from once per fortnight to once per week for each goal), real-time behavioral prompts (from none to 4 per fortnight for each goal), and goal resets for weight and behavioral goals (1 in week 6 and 1 in week 18). At 12 weeks, participants received a second telephone call from their coach to update their tailoring goals and preferences."	
Control/Comparator	"An initial 6-month community-wide lifestyle telephone coaching program called "Get Healthy Service" (GHS) was conducted. To minimize trial attrition, control participants were posted brief written feedback of results following each assessment. The control group received no other contact."	
Treatment duration	12 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 228
Intervention group/s: GHSH (n=114)

Comparator group: Control (n=114)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 55.5y (12.3); Control: 51.2y (11.9)</td></tr>
<tr><td>Sex</td><td>66.67% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>GHSH: 29.3
(5.8)

GHSH: 82.8
(19.4)

GHSH: 98.9
(15.4)</td><td>Control: 29.6
(6.3)

Control: 83.6
(18.9)

Control: 99.6
(14.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)

Change in waist circumference (cm)
Mean (95% CIs)</td><td>GHSH: 0.75
(-0.25-1.74)

GHSH: -1.78
(-3--0.55)</td><td>Control: -0.41
(-1.22-0.4)

Control: -1.41
(-2.8--0.02)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Fontana, 2016

Guideline record ID: 10226--1

Study characteristics		
Citation	Fontana, L., Villareal, D. T., Das, S. K., Smith, S. R., Meydani, S. N., Pittas, A. G., Klein, S., Bhapkar, M., Rochon, J., Ravussin, E., Holloszy, J. O., & the Calerie Study Group. (2016). Effects of 2-year calorie restriction on circulating levels of IGF-1, IGF-binding proteins and cortisol in nonobese men and women: a randomized clinical trial. Aging Cell, 15(1), 22-27. https://doi.org/https://dx.doi.org/10.1111/acel.12400	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of 2-year calorie restriction on circulating levels of IGF-1, IGF-binding proteins and cortisol in nonobese men and women: a randomized clinical trial	
Location	USA	
Trial name	Comprehensive Assessment of Long-Term Effects of Reducing Intake of Energy (CALERIE)	
Methods		
Inclusion criteria	"Inclusion Criteria: Age must be between 21-50 (inclusive) for men and 21-47 (inclusive) for women Body mass index (BMI) must be greater than or equal to 22 and less than 28 Female participants must use acceptable forms of contraception (barrier method, oral contraceptive, intra-uterine device, or similar) and be willing to continue using such a method while enrolled in the study."	
Exclusion criteria	"Exclusion Criteria: History or clinical manifestation of cardiovascular disease or an elevated blood pressure (greater than 140/90 mm Hg) Abnormal resting ECG History or clinical manifestation of diabetes History or clinical manifestation of cholelithiasis (the presence or formation of gallstones in the gallbladder or bile ducts) History of anaphylaxis, severe allergies, or asthma History or clinical manifestation of any other significant metabolic, hematologic, pulmonary, cardiovascular, gastrointestinal, neurologic, immune, hepatic, renal, urologic disorders, or cancer that, in opinion of the investigator, would make the candidate ineligible for the study History of stomach or intestinal surgery (except appendectomy) or major abdominal, thoracic or non-peripheral vascular surgery within one year prior to the randomization date Any disease or condition that seriously affects body weight and/or body composition Potassium level above the upper limit of normal at the screening visit confirmed by a test repeated within two weeks Hemoglobin, hematocrit, RBC, or iron level below the lower limit of normal at the screening visit confirmed by a test repeated within two weeks Evidence of active liver disease or ALT levels above 1.5 times the upper limit of normal Practice a vegan dietary lifestyle History or clinical manifestation of any eating disorder Any history of pharmacologic treatment for a psychiatric disorder within one year prior to the randomization date or a history of more than one episode of a pharmacologic treatment for a psychiatric disorder within lifetime History of drug or alcohol abuse (up to 14 drinks a week are allowed) within the past two years BDI (Beck Depression Inventory) score of 20 or higher at screening or baseline Treatment with steroids for more than a month within five years prior to the randomization date, or short-term (less than a month) treatment with steroids within six months prior to the randomization date Regular use of other medications, except contraceptives Participated in the CALERIE Phase 1 studies Lost or gained 3 kg or more over the past six months A volunteer must be either a never-smoker of tobacco products or an ex-smoker who quit completely at least 12 months prior to the screening visit Donated blood within 30 days prior to the randomization date Concurrent participation in any other interventional study Breast-feeding or pregnant women or women intending to become pregnant before the scheduled end of the intervention Engaged in a regular program of physical fitness involving some kind of heavy physical activity (e.g., jogging, running or riding fast on a bicycle for 30 minutes or more) five or more times per week over the past year Unwilling to be assigned at random to the CR or control intervention. Unwilling or unable to adhere to the rigors of the CR intervention over the entire two-year intervention period. Unable or	

<table>
<tr><td></td><td>unwilling to discontinue dietary supplements or adhere to the alcohol consumption restrictions during the study. Unwilling or unable to adhere to the rigors of the data collection and clinical evaluation schedule over the entire two-year period follow-up period.”</td></tr>
<tr><td>Setting</td><td>University/research centre</td></tr>
<tr><td>Intervention</td><td>“Behavioral: Caloric Restriction (CR) Participants follow a diet with 25% fewer calories than calculated at baseline over a period of 24 months”</td></tr>
<tr><td>Control/Comparator</td><td>“Participants continue their current diet for 24 months.”</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 218
Intervention group/s: Calorie restriction (n=143)

Comparator group: Ad libitum (n=75)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 38.0y (7.34); Control: 37.9y (6.94)</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Weight (kg)

Change in BMI (kg/m2)

Change in % Body fat

Change in Fat mass (kg)

Change in Fat-free mass (kg)</td><td>Calorie restriction: 72
(0.8)

Calorie restriction: 25.2
(0.2)

Calorie restriction: 32.9
(0.5)

Calorie restriction: 23.5
(0.4)

Calorie restriction: 48.5
(0.8)</td><td>Ad libitum: 71.5
(1)

Ad libitum: 25.1
(0.2)

Ad libitum: 33.6
(0.8)

Ad libitum: 23.8
(0.6)

Ad libitum: 47.6
(1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Weight (kg)
Mean (SE)

Change in BMI (kg/m2)
Mean (SE)</td><td>Calorie restriction: -8.4
(0.3)

Calorie restriction: -2.9
(0.1)</td><td>Ad libitum: -0.7
(0.4)

Ad libitum: -0.2
(0.1)</td></tr>
</table>
</td></tr>
</table>

	Change in % Body fat Mean (SE) Change in Fat mass (kg) Mean (SE) Change in Fat-free mass (kg) Mean (SE)	Calorie restriction: -5.5 (0.2) Calorie restriction: -6.1 (0.2) Calorie restriction: -2.2 (0.1)	Ad libitum: -0.47 (0.3) Ad libitum: -0.34 (0.3) Ad libitum: -0.3 (0.2)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in Weight (kg) Mean (SE) Change in BMI (kg/m2) Mean (SE) Change in % Body fat Mean (SE) Change in Fat mass (kg) Mean (SE) Change in Fat-free mass (kg) Mean (SE)	Calorie restriction: -7.5 (0.4) Calorie restriction: -2.6 (0.1) Calorie restriction: -4.6 (0.3) Calorie restriction: -5.3 (0.3) Calorie restriction: -2.2 (0.2)	Ad libitum: 0.1 (0.5) Ad libitum: 0.1 (0.2) Ad libitum: 0.13 (0.3) Ad libitum: 0.38 (0.4) Ad libitum: -0.2 (0.2)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data	Murphy, J. C., McDaniel, J. L., Mora, K., Villareal, D. T., Fontana, L., & Weiss, E. P. (2012). Preferential reductions in intermuscular and visceral adipose tissue with exercise-induced weight loss compared with calorie restriction. Journal of Applied Physiology, 112(1), 79-85. https://doi.org/https://dx.doi.org/10.1152/japplphysiol.00355.2011		

N/A – Not applicable

Forman, 2013

Guideline record ID: 10228

Study characteristics		
Citation	Forman, E. M., Butryn, M. L., Juarascio, A. S., Bradley, L. E., Lowe, M. R., Herbert, J. D., & Shaw, J. A. (2013). The mind your health project: a randomized controlled trial of an innovative behavioral treatment for obesity. Obesity, 21(6), 1119-1126. https://doi.org/10.1002/oby.20169	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The mind your health project: a randomized controlled trial of an innovative behavioral treatment for obesity	
Location	USA	
Trial name	Mind Your Health (MYH)	
Methods		
Inclusion criteria	"Required to have a BMI between 27 and 40 kg/m2, be 21-65 years of age, and have the ability to engage in PA."	
Exclusion criteria	"Individuals were excluded from participation if they had a medical or psychiatric condition that may have limited their ability to comply with the behavioral recommendations of the program or posed a risk to the participant during weight loss; were pregnant or planning to become pregnant in next 18 months; reported recently beginning a course of or changing the dosage of prescription medications that can cause a significant change in weight or appetite; or were participating in or planning to participate in another weight loss program in the next 18 months."	
Setting	Unclear (reatment was group-based and held weekly during weeks 1-20 and bi-weekly in weeks 21-40, for a total of 30, 75-min sessions.)	
Intervention	"Shared components of treatment. The SBT and ABT treatment manuals shared many components. The nutritional education, expectations for daily self-monitoring of calorie intake, and prescriptions for a balanced-deficit diet were identical (1200-1500 kcal/day for most participants, depending on weight, and 25% of calories from fat). The progression of PA goals (i.e., gradual increase to 200 min/week of brisk walking or the equivalent by week 22) and expectations for self-monitoring structured and lifestyle activity (in minutes per day and with a pedometer, respectively) also were identical. Stimulus control, behavior shaping, behavior analysis, and relapse prevention strategies were taught. Participants learned to identify triggers for overeating and barriers to PA and engage in problem solving to address these. Interventionists also encouraged participants to obtain social support for behavioral changes. ABT-only components. ABT was behavioral at its core, but with a heavy focus on acceptance- and commitment-based strategies designed to facilitate participants' dietary and PA adherence. The novel components were adapted in large part from the treatment descriptions by Hayes and colleagues.11 Strategies were designed to operate on three key factors of noncompliance: erosion of commitment, distress intolerance, and mindless eating. Consistent with principles of ACT11 and intrinsic motivation theory,27 ABT emphasized that participants must choose weight-related goals that emanate from freely chosen, personal life values (e.g., health). A structured process for the identification of such life values was followed. Participants were helped to recognize the connections between these values and day-to-day eating and PA behaviors. These strategies were integrated into the treatment materials through hand-outs, tip-sheets, and problem-solving techniques. Participants were helped to appreciate that commitment to difficult behavioral goals, especially those that contain sustained exposure to unpleasant experiential states, is only likely to be maintained when one connects psychologically with life values important enough and meaningful enough to make such an effort and sacrifice worthwhile. The intervention also helped participants be aware of their moment-by-moment behavior	

	choices and to increase the likelihood they reflect one's ultimate goals (or values), rather than a more immediate wish to decrease an aversive state. The intervention aimed to help participants recognize that eatingrelated mental experiences (urges to eat, hunger, cravings, deprivation, and eating visualizations) are bound to occur with high intensity and frequency in today's obesogenic environment, and generally cannot be suppressed or controlled, and that their attempts to control these experiences were often ineffectual or even counterproductive. A core component of ABT was the teaching of skills to improve tolerance of aversive internal states that include eating-related states as well as affective states such as boredom, sadness, and anxiety. Similarly, participants were helped to better tolerate PA-related distress (e.g., through in-group moderate PA and simultaneous mindful awareness of the sensations generated). Participants were helped to recognize that attempts to modify aversive states (i.e., experiential avoidance related to intolerance of distress) is often associated with food intake since eating is a method of altering the internal experience, as well as with the cessation or avoidance of PA. Experiential acceptance was framed as a more adaptive alternative since it need not involve unhealthy eating nor avoidance of activity, and skills to enhance willingness to experience unpleasant states were taught. One such skill is ''urge surfing''28 in which participants are trained to ''ride'' (i.e., to observe from a distance without acting on or attempting to change) their eating-related urges. A related skill crucial to the ABT program is ''defusion,'' that is, the ability to distance oneself from thoughts and feelings to see them as ''merely'' transient psychological experiences that need not be believed, acted on, controlled, or suppressed. The notion of uncoupling internal experiences and externalized behaviors was heavily emphasized. To facilitate the acquisition of defusion and uncoupling, simple demonstrations were performed, such as exposure to food cues designed to provoke thoughts (e.g., ''That will taste so wonderful, I can always make up for the calories later'') and feelings (e.g., powerful urge to eat the food) that usually lead to unhealthy eating. Simultaneously, participants practiced distancing themselves from these thoughts and feelings (e.g., explicitly recognizing a thought and its status as merely a thought) in a way that enhances willingness to experience the thoughts/feelings thereby reducing the necessity of acting (i.e., eating) to alter them. An important component of ABT was training in experiential awareness. The intervention incorporated mindfulness training designed to help individuals increase awareness of their perceptual, cognitive, and affective experiences. Metaphors and experiential exercises were utilized to train participants to become more present-centered and aware, thereby reducing the likelihood that they would engage in ''mindless'' behaviors. The intervention had a major focus on helping participants more consistently make ''mindful'' and deliberate behavioral (i.e., eating and PA) choices. Participants learned to attend to behaviors, thoughts, and feelings that triggered weight regain in the past.”
Control/Comparator	“Shared components of treatment. The SBT and ABT treatment manuals shared many components. The nutritional education, expectations for daily self-monitoring of calorie intake, and prescriptions for a balanced-deficit diet were identical (1200-1500 kcal/day for most participants, depending on weight, and 25% of calories from fat). The progression of PA goals (i.e., gradual increase to 200 min/week of brisk walking or the equivalent by week 22) and expectations for self-monitoring structured and lifestyle activity (in minutes per day and with a pedometer, respectively) also were identical. Stimulus control, behavior shaping, behavior analysis, and relapse prevention strategies were taught. Participants learned to identify triggers for overeating and barriers to PA and engage in problem solving to address these. Interventionists also encouraged participants to obtain social support for behavioral changes. SBT-only components. The SBT manual was based on existing behavioral treatment manuals for obesity, especially the LEARN and Diabetes Prevention Program weight loss and maintenance protocols.25,26 Components of SBT not included in ABT were introduction of the traditional cognitive-behavioral model, which indicates that changing the content of one's thoughts can produce behavior change; cognitive restructuring; building self-efficacy and positive self-esteem; and learning to cope with food cravings by distracting from and psychologically confronting cravings.”
Treatment duration	40 weeks

<table>
<tr><td>Follow-up from baseline</td><td>16 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 128
Intervention group/s: ABT (n=74)

Comparator group: SBT (n=54)</td></tr>
<tr><td>Mean age ± SD</td><td>45.69y (12.81)</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>ABT: 34.43
(3.63)</td><td>SBT: 33.64
(3.65)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (%)
Mean (SD)</td><td>ABT: 10.17
(8.36)</td><td>SBT: 10.17
(8.36)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>ABT 77%; SBT 70.4% (attended the vast majority (i.e., 25 or more) of the 30 scheduled groups)</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Forman, 2019

Guideline record ID: 10230--1

Study characteristics		
Citation	Forman, E. M., Manasse, S. M., Butryn, M. L., Crosby, R. D., Dallal, D. H., & Crochiere, R. J. (2019). Long-term follow-up of the mind your health project: acceptance-based versus standard behavioral treatment for obesity. Obesity, 27(4), 565-571. https://doi.org/https://dx.doi.org/10.1002/oby.22412	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-Term Follow-up of the Mind Your Health Project: Acceptance-Based versus Standard Behavioral Treatment for Obesity	
Location	USA	
Trial name	Mind Your Health II (MYH)	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	“Exclusion criteria included severe medical or psychiatric conditions, conditions that precluded adherence to the exercise prescription of the program, recent (i.e., within the last 3 months) change in dosage of weight-influencing medications, pregnancy or plans to become pregnant within the study period, recent (i.e., within the last 6 months) weight loss of greater than 5% of one's body weight, or a binge eating disorder diagnosis.”	
Setting	unclear (25 closed-group sessions, each lasting 75 minutes, with groups consisting of 10 to 14 participants)	
Intervention	“Participants received one of two manualized treatments across 25 closed-group sessions, each lasting 75 minutes, with groups consisting of 10 to 14 participants. Groups were led by doctoral-level clinicians experienced in delivering behavioral weight-loss treatments, with interventionists leading an equal number of SBT and ABT groups. Participants across conditions (SBT and ABT) were assigned the same balance-deficit diet and physical activity prescription. In addition, in both groups, behavioral skills such as stimulus control and problem solving were taught and emphasized. ABTunique principles included selection of goals that align with personal values, acceptance of reduced pleasure (and, slightly less so, increased discomfort) when seeking weight loss in an obesogenic society, and recognition of the benefit inherent in understanding cues that influence eating and physical activity behavior. In addition, the ABT group stressed a "Control What You Can and Accept What You Can't" framework to help participants identify aspects of their life that can and should be changed (e.g., their behaviors) versus those that cannot and those toward which direct attempts to control may be futile (e.g., involuntary urges).”	
Control/Comparator	“Participants received one of two manualized treatments across 25 closed-group sessions, each lasting 75 minutes, with groups consisting of 10 to 14 participants. Groups were led by doctoral-level clinicians experienced in delivering behavioral weight-loss treatments, with interventionists leading an equal number of SBT and ABT groups. Participants across conditions (SBT and ABT) were assigned the same balance-deficit diet and physical activity prescription. In addition, in both groups, behavioral skills such as stimulus control and problem solving were taught and emphasized. However, elements that were unique to SBT included content related to the cognitive behavioral model, cognitive restructuring, bolstering of self-efficacy and selfesteem, and distraction-based coping techniques.”	
Treatment duration	12 months	
Follow-up from baseline	36 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 190
Intervention group/s: ABT (n=100)

Comparator group: SBT (n=90)</td></tr>
<tr><td>Mean age ± SD</td><td>51.64y (0.73)</td></tr>
<tr><td>Sex</td><td>82.11% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (%)
Mean (SD)</td><td>ABT: -4.7%
(10.1%)</td><td>SBT: 3.3
(8.2)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Foster, 2010

Guideline record ID: 10232--1

Study characteristics		
Citation	Foster, G. D., Wyatt, H. R., Hill, J. O., Makris, A. P., Rosenbaum, D. L., Brill, C., Stein, R. I., Mohammed, B. S., Miller, B., Rader, D. J., Zemel, B., Wadden, T. A., Tenhave, T., Newcomb, C. W., & Klein, S. (2010). Weight and metabolic outcomes after 2 years on a low-carbohydrate versus low-fat diet: a randomized trial. Annals of Internal Medicine, 153(3), 147-157. https://doi.org/https://dx.doi.org/10.7326/0003-4819-153-3-201008030-00005	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight and metabolic outcomes after 2 years on a low-carbohydrate versus low-fat diet: a randomized trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Age 18 to 65 years, body mass index of 30 to 40 kg/m2, and body weight less than 136 kg."	
Exclusion criteria	"We excluded study applicants if they had serious medical illnesses, such as type 2 diabetes; took lipid-lowering medications; were pregnant or lactating; or took medications that affect body weight, including antiobesity agents. Participants with blood pressures of 140/90 mm Hg or more were excluded regardless of whether they were treated."	
Setting	University/research centre	
Intervention	"All participants received comprehensive, in-person group behavioral treatment (13, 14) weekly for 20 weeks, every other week for 20 weeks, and then every other month for the remainder of the 2-year study period. Each treatment session lasted 75 to 90 minutes. The Appendix (available at www.annals.org) provides details of the treatment. Topics included self-monitoring, stimulus control, and relapse management. All participants were prescribed the same level of physical activity (principally walking), beginning at week 4, with 4 sessions of 20 minutes each and progressing by week 19 to 4 sessions of 50 minutes each. Group sessions reviewed participants' completion of their eating and activity records, as well as other skill builders. Participants in both groups were instructed to take a daily multivitamin supplement (provided by the study). Approximately half of the participants (n 153) were assigned to a low-carbohydrate diet, which limited carbohydrate intake but allowed unrestricted consumption of fat and protein. During the first 12 weeks of treatment, participants were instructed to limit carbohydrate intake to 20 g/d in the form of low-glycemic index vegetables. After the first 12 weeks, participants gradually increased carbohydrate intake (5 g/d per week) by consuming more vegetables, a limited amount of fruits, and eventually small quantities of whole grains and dairy products, until a stable and desired weight was achieved. They followed guidelines described in Dr. Atkins' New Diet Revolution (15) but were not provided with a copy of the book. Participants were instructed to focus on limiting carbohydrate intake and to eat foods rich in fat and protein until they were satisfied. The primary behavioral target was to limit carbohydrate intake."	
Control/Comparator	"All participants received comprehensive, in-person group behavioral treatment (13, 14) weekly for 20 weeks, every other week for 20 weeks, and then every other month for the remainder of the 2-year study period. Each treatment session lasted 75 to 90 minutes. The Appendix (available at www.annals.org) provides details of the treatment. Topics included self-monitoring, stimulus control, and relapse management. All participants were prescribed the same level of physical activity (principally walking), beginning at week 4, with 4 sessions of 20 minutes each and progressing by week 19 to 4 sessions of 50 minutes each. Group sessions reviewed participants' completion of their eating and activity records,	

<table>
<tr><td></td><td>as well as other skill builders. Participants in both groups were instructed to take a daily multivitamin supplement (provided by the study). The remaining 154 participants were assigned to consume a low-fat diet, which consisted of limiting energy intake to 1200 to 1500 kcal/d for women and 1500 to 1800 kcal/d for men, with approximately 55% of calories from carbohydrate, 30% from fat, and 15% from protein. Participants were instructed to limit calorie intake, with a focus on decreasing fat intake. However, limiting overall energy intake (kcal/d) was the primary behavioral target."</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 307
Intervention group/s: Low-carbohydrate diet (n=153)

Comparator group: Low-fat diet (n=154)</td></tr>
<tr><td>Mean age ± SD</td><td>45.5y (9.7)</td></tr>
<tr><td>Sex</td><td>67.75% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Fat mass (kg)
Mean (SD)</td><td>Low-carbohydrate diet: 103.3 (15.5)

Low-carbohydrate diet: 36.1 (3.59)

Low-carbohydrate diet: 40 (7.6)</td><td>Low-fat diet: 103.5 (14.4)

Low-fat diet: 36.1 (3.46)

Low-fat diet: 40.4 (7.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)

Change in fat mass (kg)
Mean (95% CIs)</td><td>Low-carbohydrate diet: -10.87 (-12.1--9.67)

Low-carbohydrate diet: -7.83 (-7.89--6.14)</td><td>Low-fat diet: 10.81 (-12.4-9.28)

Low-fat diet: -7.29 (-8.55--6.03)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)

Change in fat mass (kg)
Mean (95% CIs)</td><td>Low-carbohydrate diet: -6.34 (-8.06--4.63)

Low-carbohydrate diet: -3.99 (-5.5--2.79)</td><td>Low-fat diet: -7.37 (-9.1--5.63)

Low-fat diet: -3.84 (-5.03--2.64)</td></tr>
</table>
</td></tr>
</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Foster, 2012

Guideline record ID: 10231--1

Study characteristics		
Citation	Foster, G. D., Shantz, K. L., Vander Veur, S. S., Oliver, T. L., Lent, M. R., Virus, A., Szapary, P. O., Rader, D. J., Zemel, B. S., & Gilden-Tsai, A. (2012). A randomized trial of the effects of an almond-enriched, hypocaloric diet in the treatment of obesity. The American Journal of Clinical Nutrition, 96(2), 249-254. https://doi.org/https://dx.doi.org/10.3945/ajcn.112.037895	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A randomized trial of the effects of an almond-enriched, hypocaloric diet in the treatment of obesity	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Age of 18 to 75 y and a BMI of 27-40."	
Exclusion criteria	"Uncontrolled hypertension (defined as a blood pressure .180/ 100 mm Hg), established cardiovascular disease or an inflammatory condition (eg, lupus), diabetes or use of antihyperglycemic medications, dyslipidemia requiring prescription drug therapy as defined by the National Cholesterol Education Program Adult Treatment Panel III guidelines (23), or any known allergy or sensitivity to nuts. Additional exclusion criteria were the use of medications known to affect body weight or a weight loss of 5 kg in the preceding 6 mo."	
Setting	Hospital, University/research centre	
Intervention	"Participants were provided two 28-g packages of almonds (;24 almonds per package) to consume daily throughout the study, which were distributed at their group meetings. Over the first 5 wk of treatment, participants received whole, raw almonds only. At week 6, roasted almonds were introduced and, over time, a variety of isocaloric, flavored almonds were used. This group was instructed to abstain from alternative nut consumption. The primary behavioral targets were adherence to the total energy intake goal and consumption of 56 g almonds/d. During the first week of treatment, all participants were instructed to maintain their usual eating and activity habits. Thereafter, all participants were prescribed an LCD providing 1200-1500 kcal/d for women and 1500-1800 kcal/d for men. Beginning in week 4, participants in both groups were encouraged to walk for 20 min 4 times/wk, progressing to 50 min 4 times/wk by week 19. Additionally, both groups were instructed in traditional behavioral methods of weight control, such as self-monitoring and stimulus control (24, 25). Groups met weekly for 20 wk, biweekly for the next 20 wk, and every 6 wk for the remainder of 18 mo."	
Control/Comparator	"During the first week of treatment, all participants were instructed to maintain their usual eating and activity habits. Thereafter, all participants were prescribed an LCD providing 1200-1500 kcal/d for women and 1500-1800 kcal/d for men. Beginning in week 4, participants in both groups were encouraged to walk for 20 min 4 times/wk, progressing to 50 min 4 times/wk by week 19. Additionally, both groups were instructed in traditional behavioral methods of weight control, such as self-monitoring and stimulus control (24, 25). Groups met weekly for 20 wk, biweekly for the next 20 wk, and every 6 wk for the remainder of 18 mo. These participants were instructed to abstain from the consumption of nuts (eg, peanuts, peanut butter, cashews, macadamia nuts, walnuts, and pistachios). The primary behavioral target was adherence to the total energy intake goal."	
Treatment duration	18 months	

<table>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 123
Intervention group/s: Almond-enriched diet (n=61)

Comparator group: Nut-free diet (n=62)</td></tr>
<tr><td>Mean age ± SD</td><td>46.8y (12.4)</td></tr>
<tr><td>Sex</td><td>91.06% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight, kg
Mean (SD)

Fat mass (kg)
Mean (SD)</td><td>Almond-enriched diet: 94
(13.1)

Almond-enriched diet: 37.8
(7.4)</td><td>Nut-free diet: 91.5
(11.9)

Nut-free diet: 37.6
(7.4)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight
Mean (SE)

Change in fat mass kg
Mean (SE)</td><td>Almond-enriched diet: -3.7
(1)

Almond-enriched diet: -3
(0.8)</td><td>Nut-free diet: -5.9
(1)

Nut-free diet: -4
(0.8)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>77%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Foster-Schubert, 2012

Guideline record ID: 10233--1

Study characteristics		
Citation	Foster-Schubert, K. E., Alfano, C. M., Duggan, C. R., Xiao, L., Campbell, K. L., Kong, A., Bain, C. E., Wang, C.-Y., Blackburn, G. L., & McTiernan, A. (2012). Effect of diet and exercise, alone or combined, on weight and body composition in overweight-to-obese postmenopausal women. Obesity, 20(8), 1628-1638. https://doi.org/https://dx.doi.org/10.1038/oby.2011.76	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of diet and exercise, alone or combined, on weight and body composition in overweight-to-obese postmenopausal women	
Location	USA	
Trial name	Nutrition and Exercise in Women (NEW)	
Methods		
Inclusion criteria	"Postmenopausal women from the greater Seattle, WA area, aged 50-75 years, who were overweight or obese (BMI ≥25kg/m2, or ≥23kg/m2 for AsianAmerican women), and exercising <100min/week at moderate intensity or greater."	
Exclusion criteria	"Specific exclusion criteria included: diagnosed diabetes, fasting blood glucose ≥126mg/dl, or use of diabetes medications; use of postmenopausal hormone therapy within the prior 3 months; history of breast cancer or other serious medical condition(s); alcohol intake in excess of 2 drinks/day or current smoker; contraindication to participating in the diet or exercise intervention for any reason, including an abnormal exercise tolerance test, current or planned participation in another structured weight loss program, use of weight loss medications, or additional factors that might interfere with measurement of outcomes or with the success of the intervention (e.g., inability to attend facility-based sessions)."	
Setting	Home, University/research centre	
Intervention	"Diet: The NEW dietary weight-loss intervention comprised our modification of the dietary component of the DPP (9) and the Look Action for Health in Diabetes (AHEAD) (13) lifestyle intervention programs, with the following goals: total daily energy intake of 1,200-2,000kcal/ day based on baseline weight, <30% daily energy intake from fat, and a 10% reduction in body weight by 6 months with maintenance thereafter to 12 months. Content of the dietary counseling sessions was modified to better fit our study population (less focus on diabetes or diabetes risk), and the frequency and type of sessions (individual vs. group) also varied from DPP and Look AHEAD. Women met individually with a study dietitian for personalized goal-setting on at least two occasions, followed by weekly meetings in groups of ~5-10 women, through the first 6 months. Thereafter (months 7-12), dietitians had contact with participants twice a month, including one face-to-face contact (individual or group session) and one additional contact via phone or email. Participants were permitted additional in-person sessions, phone, or email contacts beyond the 32 expected, if they or the dietician felt these would help to achieve intervention goals. This combination of individual and group-based approaches was used to maximize the benefits of targeted, personalized recommendations along with the social support and greater cost-effectiveness of a group setting. Women were asked to record all food eaten daily for at least 6 months, or until they reached their individual weight loss goal (10%). Food journals were collected by the dietitian and returned with feedback. Journaling, weekly weigh-ins, and session attendance were tracked to promote adherence to the diet intervention.; Exercise:Based on our previous exercise research in a similar population, the goal of the NEW exercise intervention was ≥45min of moderate-to-vigorous intensity exercise, 5 days/week (225min/week) for 12 months (14,15). Participants attended at least three sessions/week at our study facility where they were supervised by an exercise physiologist, and exercised for their remaining sessions at home. The exercise training program began	

<table>
<tr><td></td><td>with a 15min session at 60-70% maximal heart rate (determined by baseline exercise treadmill testing) and progressed to the target 70-85% maximal heart rate for 45min by the 7th week after enrollment where it was maintained for the remainder of the study. Women wore Polar heart rate monitors (Polar Electro, Lake Success, NY) during facility exercise sessions to assist with attaining their target heart rate. In addition, during both facility and home sessions they recorded the mode and duration of exercise, and peak heart rate achieved. Facility-based exercise consisted of treadmill walking, stationary bicycling, and use of other aerobic machines; while a variety of home exercises were encouraged including walking/hiking, aerobics, and bicycling. A small amount of resistance training to strengthen joints and limit injury was recommended, though not required. Activities of at least four metabolic equivalents according to the Compendium of Physical Activities (16) such as brisk walking were counted toward the prescribed aerobic exercise target. Activity logs were reviewed weekly by study staff in order to monitor adherence. Participants who were not meeting exercise targets were contacted by staff to discuss barriers and approaches to increase activity. In addition, the dietitians and exercise physiologists met regularly with a clinical health psychologist experienced in lifestyle behavior change to discuss participant progress and refine behavior modification goals according to each participant's needs.; Diet+Exercise: Women randomized to the diet + exercise group received both the dietary weight loss and aerobic exercise interventions. They participated in separate groups for the dietary weight-loss intervention from women assigned to diet alone. Although the diet + exercise group could use the exercise facility at the same time as participants assigned to the exerciseonly group, they were instructed not to discuss the diet intervention”</td></tr>
<tr><td>Control/Comparator</td><td>“Women randomized to the control group were requested not to change their diet or exercise habits for the duration of the trial. At the end of 12 months, participants in the control group were offered four group nutrition classes and 8 weeks of facility exercise training with individualized guidance from an exercise physiologist, as an incentive to undergo randomization.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 439
Intervention group/s: Diet (n=118); Exercise (n=117); Diet+Exercise (n=117)

Comparator group: Control (n=87)</td></tr>
<tr><td>Mean age ± SD</td><td>Diet: 58.1y(6.0); Exercise: 58.1y(5.0); Diet+Exercise: 58.0y(4.5); Control: 57.4y(4.4)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)</td><td>Diet: 84
(11.8)
Exercise: 83.7
(12.3)
Diet+Exercise: 82.5
(10.8)

Diet: 31</td><td>Control: 84.2
(12.5)

Control: 30.7</td></tr>
</table>
</td></tr>
</table>

	Mean (SD)	(3.9) Exercise: 30.7 (3.7) Diet+Exercise: 31 (4.3)	(3.9)
	Waist circumference (cm) Mean (SD)	Diet: 94.6 (10.2) Exercise: 95.1 (10.1) Diet+Exercise: 93.7 (9.9)	Control: 94.8 (10.2)
	Body fat (kg) Mean (SD)	Diet: 39.7 (8.1) Exercise: 39.9 (8.2) Diet+Exercise: 39.4 (7.9)	Control: 40.1 (8.5)
	Body fat (%) Mean (SD)	Diet: 47 (4.3) Exercise: 47.3 (4.1) Diet+Exercise: 47.4 (4.5)	Control: 47.3 (4.4)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight (kg) Mean (SD)	Diet: 76.9 (13.4) Exercise: 81.7 (12.4) Diet+Exercise: 73.6 (11.5)	Control: 83.5 (12.3)
	BMI (kg/m2) Mean (SD)	Diet: 28.4 (4.6) Diet+Exercise: 29.9 (3.8) Diet+Exercise: 27.6 (4.5)	Control: 30.5 (4.1)
	Waist circumference (cm) Mean (SD)	Diet: 90.2 (11.5) Exercise: 93.1 (9.8) Diet+Exercise: 86.7 (11.6)	Control: 95.7 (9.6)
	Body fat (kg) Mean (SD)	Diet: 33.6 (10) Exercise: 37.8 (8.7) Diet+Exercise: 31.2 (9.5)	Control: 39.7 (8.7)
	Body fat (%) Mean (SD)	Diet: 42.8 (6.6) Exercise: 45.7 (4.9) Diet+Exercise: 41.5 (7)	Control: 47.1 (5.2)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>%Weight change
Mean</td><td>Diet: -8.5
Exercise: -2.4
Diet+Exercise: -10.8</td><td>Control: -0.8</td></tr>
<tr><td>% BMI change
Mean</td><td>Diet: -8.6
Exercise: -2.4
Diet+Exercise: -10.8</td><td>Control: -0.7</td></tr>
<tr><td>% change waist circumference
Mean</td><td>Diet: -4.7
Exercise: -2.1
Diet+Exercise: -7.5</td><td>Control: 1</td></tr>
<tr><td>% Change Body fat (kg)
Mean</td><td>Diet: -15.6
Exercise: -5.3
Diet+Exercise: -20.8</td><td>Control: -1</td></tr>
<tr><td>% Change Body Fat %
Mean</td><td>Diet: -8.9
Exercise: -3.3
Diet+Exercise: -12.4</td><td>Control: -0.3</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Diet-alone and diet + exercise groups, women attended an average of 27-diet behavior change sessions (86%). Women randomized to exercise alone achieved on average 80% of the target 225min/week aerobic exercise over the 12-month trial, whereas women randomized to diet + exercise achieved 85%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Duggan, C., Tapsoba, J. d. D., Stanczyk, F., Wang, C.-Y., Schubert, K. F., & McTiernan, A. (2019). Long-term weight loss maintenance, sex steroid hormones, and sex hormone-binding globulin. Menopause, 26(4), 417-422. https://doi.org/10.1097/GME.0000000000001250</td></tr>
</table>

N/A – Not applicable

Franklin, 2022

Guideline record ID: 10234--1

Study characteristics		
Citation	Franklin, K. A., Lindberg, E., Svensson, J., Larsson, C., Lindahl, B., Mellberg, C., Sahlin, C., Olsson, T., & Ryberg, M. (2022). Effects of a palaeolithic diet on obstructive sleep apnoea occurring in females who are overweight after menopause-a randomised controlled trial. International Journal of Obesity, 46(10), 1833-1839. https://doi.org/https://dx.doi.org/10.1038/s41366-022-01182-4	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of a palaeolithic diet on obstructive sleep apnoea occurring in females who are overweight after menopause-a randomised controlled trial	
Location	Sweden	
Trial name	N/A	
Methods		
Inclusion criteria	"Postmenopausal, non-smoking, body mass index >27 kg/m2, healthy and free from medication, except for three women with well-controlled hypertension treated with an angiotensin-converting enzyme inhibitor."	
Exclusion criteria	Not reported	
Setting	Hospital, Home	
Intervention	"The palaeolithic diet was based on lean meat, fish, eggs, vegetables, fruits, berries and nuts. Additional fat sources were avocado, rapeseed oil and olive oil. Dairy products, cereals, added salt, refined fats and sugar were excluded. The diet aimed at 30% of energy intake from protein, 40% of energy intake from fat, with a recommended high intake of mono- and polyunsaturated fatty acids, and 30% of energy intake from carbohydrate. One dietician per dietary group held 12 group sessions. Four cooking classes and four follow-up sessions were held during the first 6 months, followed by group meetings at 6, 12, 18 and 24 months. Participants were recommended to eat the advised food at three main meals and two snacks a day. Food intake was ad libitum for both diets, meaning that women could eat as much as they liked, without restriction. Recipes, written instructions and suggestions of food for breakfast, lunch and dinner were given during the 12 group sessions. The group sessions consisted of information on how to prepare and cook meals and dishes in the intervention diet. The sessions also included information about dietary effects on health, body weight and how to maintain behavioural changes. The group session on behavioural change was devoted to a discussion of different aspects of motivation, including group discussions of benefits and difficulties changing diet. Adherence to the diet intervention was monitored using self-reported 4-day food records at study start, monthly during the first 6 months and at 9, 12, 18 and 24 months"	
Control/Comparator	"The control diet according to the official Nordic Nutritional Recommendations was based on low-fat and high-fibre products, aiming at a daily intake of 15% energy intake from protein, 25-30% energy intake from fat and 55-60% energy intake from carbohydrates. One dietician per dietary group held 12 group sessions. Four cooking classes and four follow-up sessions were held during the first 6 months, followed by group meetings at 6, 12, 18 and 24 months. Participants were recommended to eat the advised food at three main meals and two snacks a day. Food intake was ad libitum for both diets, meaning that women could eat as much as they liked, without restriction. Recipes, written instructions and suggestions of food for breakfast, lunch and dinner were given during the 12 group sessions. The group sessions consisted of information on how to prepare and cook meals and dishes in the intervention diet. The sessions also included information about dietary effects on health, body weight and how to maintain behavioural changes. The group	

<table>
<tr><td></td><td>session on behavioural change was devoted to a discussion of different aspects of motivation, including group discussions of benefits and difficulties changing diet. Adherence to the diet intervention was monitored using self-reported 4-day food records at study start, monthly during the first 6 months and at 9, 12, 18 and 24 months.”</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 70
Intervention group/s: Palaeolithic diet (n=35)

Comparator group: Control diet (n=35)</td></tr>
<tr><td>Mean age ± SD</td><td>60y (58-61)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (95% CIs)</td><td>Palaeolithic diet: 86.2
(82.7-89.8)</td><td>Control diet: 85.3
(81.7-89)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (95% CIs)</td><td>Palaeolithic diet: 79
(74.9-83.1)</td><td>Control diet: 81.4
(77.1-85.6)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Mellberg, C., Sandberg, S., Ryberg, M., Eriksson, M., Brage, S., Larsson, C., Olsson, T., & Lindahl, B. (2014). Long-term effects of a Palaeolithic-type diet in obese postmenopausal women: a 2-year randomized trial. European Journal of Clinical Nutrition, 68(3), 350-357. https://doi.org/10.1038/ejcn.2013.290</td></tr>
</table>

N/A – Not applicable

French, 2011

Guideline record ID: 10235--1

Study characteristics		
Citation	French, S. A., Gerlach, A. F., Mitchell, N. R., Hannan, P. J., & Welsh, E. M. (2011). Household obesity prevention: Take Action—a group-randomized trial. Obesity, 19(10), 2082-2088. https://doi.org/https://dx.doi.org/10.1038/oby.2010.328	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Household obesity prevention: Take Action--a group-randomized trial	
Location	USA	
Trial name	Take Action	
Methods		
Inclusion criteria	"Eligibility criteria included: (i) at least one child ages ≥5 years and two HH members ages ≥12 years; (ii) residence in a private house or apartment within 20 miles of the university; (iii) HH TV viewing weekly average of ≥10h per person; (iv) no HH members with dietary, medical, psychological, or physical limitations that would prevent their participation in intervention activities; and (v) willingness to be randomized to active intervention or control group."	
Exclusion criteria	Not reported	
Setting	Home, University/research centre	
Intervention	"The intervention program was 1 year in duration and included 6 monthly face-to-face group sessions, monthly newsletters, and 12 home-based activities. Group sessions were held at the University of Minnesota monthly for the first 6 months of the intervention. Two trained research intervention staff led each session. Three to five Households (HHs) attended each session and remained as a group for the six sessions. All HH members age ≥12 years were encouraged to attend and participate. Sessions were 2h in length, held on a weekday evening, included behavioral education, interactive activities, 20-30min of PA, and a healthy snack. HHs received a $25 gift card for a local grocery store chain for each session attended. Behavioral strategies, including goal setting, self-monitoring, and positive reinforcement, were used to promote and support behavior changes at the HH and individual level. HHs were encouraged to set goals for each of the target behavior areas. In addition to HH-level goals, each individual member was encouraged to set his or her personal behavioral goals for each of the target behaviors. HH-level goals were defined, tracked, and posted at home on a goal sheet. Individual behavioral goals and behaviors were tracked using an individual behavioral self-monitoring booklet. Home activities were designed to reinforce behavioral messages addressed at the previous group session, and to encourage parents to discuss the behaviors with any HH members not present at the group intervention session. Home activity instructions and materials were included with each monthly newsletter and were completed over the course of 2-3 weeks by the HH as a group. Incentives were provided for each home activity completed and included items such as gift cards for local discount stores, sports balls, and hand-weight sets. Each intervention HH was given a digital scale at the first group session. Adults were instructed to self-weigh daily to monitor their body weight. Adults were explicitly instructed not to weigh their children or adolescents because weight gain is normal and expected during childhood and adolescence. At the beginning of the study, a TV limiting device was attached to every TV in the HH. The purpose of the device was to assist HHs with meeting TV viewing reduction goals. The TV limiting device provided an objective method to limit TV viewing by all HH members during the intervention period. Research staff visited each HH following the first group session to attach the devices to the HH TVs. Devices were programmed to allow only the number of hours of TV viewing that HHs selected as the weekly HH viewing limit. After	

<table>
<tr><td></td><td>the limit was reached, the TV limiting device disabled the TV until the start of the next week. Goals recommended by study staff were 50% reduction from the HH baseline TV viewing hours per week. One or more individual pin codes could be programmed into the device. The devices remained on the HH TVs for the 12-month study duration unless HH requested otherwise. Intervention staff telephoned each intervention HH monthly between sessions. Email also was used to maintain regular contact with intervention HHs. The purpose of these contacts was to provide support for the behavior changes being made by HHs. Intervention staff queried the adult HH contact person about progress and problems, assisted with problem solving when needed, and reinforced progress on HH behavior changes”</td></tr>
<tr><td>Control/Comparator</td><td>“Control HHs received no intervention.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= Not reported
Intervention group/s: Intervention (n=45 (number of households reported only))

Comparator group: Control (n=45 (number of households reported only))</td></tr>
<tr><td>Mean age ± SD</td><td>41y</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2) (adults only) Mean</td><td>Intervention: 28.81</td><td>Control: 29.64</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2) (adults only) Mean</td><td>Intervention: 28.78</td><td>Control: 29.88</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Over 73% of the 45 intervention HHs attended at least four of six face-to-face group sessions and completed half or more of the home activities. About 20% of HHs had perfect attendance and home activity completion rates. Within-HH attendance, or the average percent of eligible HH members who attended each session, was 59%. Two-thirds (68%) of HHs had 50% or more HH members attending sessions, and one-third of HHs had 75% or</td></tr>
</table>

	more HH members attending sessions. TV-limiting devices were placed in 93% of intervention HHs. The average duration the devices were kept attached to the TVs was 10.6 months. Monitors were programmed to a weekly mean of 29.8h (range 11-70), a 44% reduction from baseline (52.8h weekly).
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

French, 2018

Guideline record ID: 10236A--1

Study characteristics		
Citation	French, S. A., Sherwood, N. E., Veblen-Mortenson, S., Crain, A. L., JaKa, M. M., Mitchell, N. R., Hotop, A. M., Berge, J. M., Kunin Batson, A. S., Truesdale, K., Stevens, J., Pratt, C., & Esposito, L. (2018). Multicomponent obesity prevention intervention in low-income preschoolers: primary and subgroup analyses of the NET-Works randomized clinical trial, 2012-2017. American Journal of Public Health, 108(12), 1695-1706. https://doi.org/https://dx.doi.org/10.2105/AJPH.2018.304696	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Multicomponent Obesity Prevention Intervention in Low-Income Preschoolers: Primary and Subgroup Analyses of the NET-Works Randomized Clinical Trial, 2012-2017	
Location	USA	
Trial name	NET-Works	
Methods		
Inclusion criteria	"A child was eligible for the study if the child 1. Was aged between 2 and 4 years, 2. Had no medical problems that would preclude study participation, 3. Did not use any medications that would affect the child's growth, 4. Had body mass index (BMI) greater than or equal to the 50th percentile according to Centers for Disease Control and Prevention age and sex reference standards, 5. Had a family income of less than $65 000 per year, 6. Had a parent who agreed to participate in the study and did not plan to move out of the state in the next 3 years, 7. Had a parent who was willing and able to complete the evaluation measures and participate in intervention activities, and 8. Had a parent who spoke English or Spanish."	
Exclusion criteria	Not reported	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Trained professionals with a minimum of a bachelor's degree and several years of experience working with families and children conducted the home visiting and parentingclass components. Home visits were about 1 hour in duration and were planned for monthly intervals with telephone check-in calls between home visits. Motivational interviewing and behavior change models were used as the intervention foundation. Parenting classes were held weekly for 12 weeks in the communities where the families resided. Efforts were made to accommodate family schedules. The study provided or reimbursed transportation. Referrals to community resources were designed to support parent and family use of food and physical activity resources in their neighborhood and were implemented through the home visits, parenting classes, and check-in calls."	
Control/Comparator	"A primary care provider intervention component was included for both intervention and usual care groups. Providers were trained to discuss child BMI with the parent at the annual well-child visit, by using a study-provided pamphlet with the child's BMI percentile and messages about healthful eating and physical activity for the child. In addition, parents randomized to the comparison condition received quarterly postcards that focused on child development and school readiness."	
Treatment duration	36 months	
Follow-up from baseline	36 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 1068
Intervention group/s: NET-Works (n=530)

Comparator group: Usual Care (n=538)</td></tr>
<tr><td>Mean age ± SD</td><td>Children: 3.4y (0.7); Parents: 31.4y (6.4)</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Parent BMI (kg/m2)
Mean (SD)</td><td>NET-Works: 30.3
(6.7)</td><td>Usual Care: 29.9
(7.4)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Parent BMI (kg/m2)
Mean (SD)</td><td>NET-Works: 30.9
(6.6)</td><td>Usual Care: 30.2
(7.6)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Parent BMI (kg/m2)
Mean (SD)</td><td>NET-Works: 31.1
(6.7)</td><td>Usual Care: 30.7
(7.5)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

French, 2018

Guideline record ID: 10236B--1

Study characteristics		
Citation	French, S. A., Sherwood, N. E., Veblen-Mortenson, S., Crain, A. L., JaKa, M. M., Mitchell, N. R., Hotop, A. M., Berge, J. M., Kunin Batson, A. S., Truesdale, K., Stevens, J., Pratt, C., & Esposito, L. (2018). Multicomponent obesity prevention intervention in low-income preschoolers: primary and subgroup analyses of the NET-Works randomized clinical trial, 2012-2017. American Journal of Public Health, 108(12), 1695-1706. https://doi.org/https://dx.doi.org/10.2105/AJPH.2018.304696	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Multicomponent Obesity Prevention Intervention in Low-Income Preschoolers: Primary and Subgroup Analyses of the NET-Works Randomized Clinical Trial, 2012-2017	
Location	USA	
Trial name	NET-Works	
Methods		
Inclusion criteria	"A child was eligible for the study if the child 1. Was aged between 2 and 4 years, 2. Had no medical problems that would preclude study participation, 3. Did not use any medications that would affect the child's growth, 4. Had body mass index (BMI) greater than or equal to the 50th percentile according to Centers for Disease Control and Prevention age and sex reference standards, 5. Had a family income of less than $65 000 per year, 6. Had a parent who agreed to participate in the study and did not plan to move out of the state in the next 3 years, 7. Had a parent who was willing and able to complete the evaluation measures and participate in intervention activities, and 8. Had a parent who spoke English or Spanish."	
Exclusion criteria	Not reported	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Trained professionals with a minimum of a bachelor's degree and several years of experience working with families and children conducted the home visiting and parentingclass components. Home visits were about 1 hour in duration and were planned for monthly intervals with telephone check-in calls between home visits. Motivational interviewing and behavior change models were used as the intervention foundation. Parenting classes were held weekly for 12 weeks in the communities where the families resided. Efforts were made to accommodate family schedules. The study provided or reimbursed transportation. Referrals to community resources were designed to support parent and family use of food and physical activity resources in their neighborhood and were implemented through the home visits, parenting classes, and check-in calls."	
Control/Comparator	"A primary care provider intervention component was included for both intervention and usual care groups. Providers were trained to discuss child BMI with the parent at the annual well-child visit, by using a study-provided pamphlet with the child's BMI percentile and messages about healthful eating and physical activity for the child. In addition, parents randomized to the comparison condition received quarterly postcards that focused on child development and school readiness."	
Treatment duration	36 months	
Follow-up from baseline	36 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 534
Intervention group/s: NET-Works (n=265)

Comparator group: Usual Care (n=269)</td></tr>
<tr><td>Mean age ± SD</td><td>3.4y (0.7)</td></tr>
<tr><td>Sex</td><td>50.90% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Proportion with BMI ≥95th percentile (%)- Child Proportion (%)</td><td>NET-Works: 24.9</td><td>Usual Care: 20.5</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Proportion with BMI ≥95th percentile (%)- Child Proportion (%)</td><td>NET-Works: 24.8</td><td>Usual Care: 24.1</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Proportion with BMI ≥95th percentile (%)- Child Proportion (%)</td><td>NET-Works: 28.9</td><td>Usual Care: 31.8</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

French, 2023

Guideline record ID: 12010--1

Study characteristics		
Citation	French, S. A., Kunin-Batson, A. S., Sherwood, N. E., Berge, J. M., & Shanley, R. (2023). NET-Works paediatric obesity prevention trial: 66 month outcomes. Pediatric Obesity, 18(8), e13055. https://doi.org/https://doi.org/10.1111/ijpo.13055	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	NET-Works paediatric obesity prevention trial: 66 month outcomes	
Location	USA	
Trial name	NET-Works	
Methods		
Inclusion criteria	"A parent-child dyad was eligible for the study if the child: (1) was age 2-4 years; (2) had no medical problems that would preclude study participation; (3) did not use any medications that would affect the child's growth; (4) had a body mass index >=50th percentile according to the Centers for Disease Control and Prevention age and sex reference standards15; (5) had a family income of <US$65,000 per year; (6) had a parent who agreed to participate in the study and did not plan to move out of the state in the next 3 years; (7) had a parent who was willing and able to complete the evaluation measures and participate in the intervention."	
Exclusion criteria	Not reported	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The NET-Works intervention was a multisetting, multicomponent, community-based paediatric obesity prevention intervention that targeted parents of 2-4 year old children with low-income and diverse racial and ethnic identities. The intervention settings and components were selected based on social-ecological theory,16 previous research,17-19 and potential for dissemination and sustainability.2,9 The intervention program components included home visiting, community-based parenting classes, and telephone check-in calls. Trained interventionists with a minimum of a bachelor's degree and several years of experience working with families and children conducted the home visiting and parenting class intervention components. Interventionists were trained in Motivational Interviewing skills. Behaviour change models were the intervention foundation and basis for the development of intervention materials, emphasizing the idea of parent as the agent of change for their child's eating and activity routines. Home visiting and parenting class curricula were designed to be synergistic. Goal setting, behavioural tracking, reinforcement for behaviour change, and change in the home environment were strategies used to shape healthful family routines around food choices, portion sizes, screen time limits, physical activity, and healthy child development. Referrals to community resources were designed to support parent and family use of food and physical activity resources in their neighbourhood and were implemented through the home visits, parenting classes, and check-in calls Families in the NET-Works intervention received an average of 35.4 intervention contacts over 3 years (year 1: 15.5 contacts; year 2: 10.9 contacts; year 3: 8.6 contacts). On average, families participated in 18.3 home visits, 9.3 parenting classes, and 7.4 telephone check-in calls."	
Control/Comparator	"Parents in the control group received quarterly postcards about healthy child development and school readiness. Cohort retention was 92.3% at 36 months (95.9% in the comparison group and 88.7% in the intervention group, $p < 0.05$; see Figure 1)."	
Treatment duration	3 years	

<table>
<tr><td>Follow-up from baseline</td><td>66 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td></td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 534
Intervention group/s: NET-Works (n=265)

Comparator group: Usual care (n=269)</td></tr>
<tr><td>Mean age ± SD</td><td>3.4y (0.6)</td></tr>
<tr><td>Sex</td><td>50.94% female</td></tr>
<tr><td>Pre-existing medical condition</td><td></td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Data could not be extracted</td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Data could not be extracted</td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Friedenreich, 2011

Guideline record ID: 10240--1

Study characteristics		
Citation	Friedenreich, C. M., Woolcott, C. G., McTiernan, A., Terry, T., Brant, R., Ballard-Barbash, R., Irwin, M. L., Jones, C. A., Boyd, N. F., Yaffe, M. J., Campbell, K. L., McNeely, M. L., Karvinen, K. H., & Courneya, K. S. (2011). Adiposity changes after a 1-year aerobic exercise intervention among postmenopausal women: a randomized controlled trial. International Journal of Obesity, 35(3), 427-435. https://doi.org/10.1038/ijo.2010.147	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Adiposity changes after a 1-year aerobic exercise intervention among postmenopausal women: a randomized controlled trial	
Location	USA	
Trial name	Alberta Physical Activity and Breast Cancer Prevention (ALPHA)	
Methods		
Inclusion criteria	"Specific eligibility criteria included age 50-74 years, postmenopausal, no previous cancer diagnosis, no major comorbidities, acceptable baseline fitness test, sedentary (<90 min of weekly exercise or, if between 90 and 120 min, having a VO2max level <34 ml kg-1min-1), able to do unrestricted physical activity, normal blood lipid and hormone levels, BMI between 22 and 40 kg m2, nonsmoker, <14 drinks per week of alcohol, no medications or exogenous hormones that might influence estrogen metabolism and not currently or planning to undertake a weight loss program."	
Exclusion criteria	Not reported	
Setting	Home, University/research centre	
Intervention	"The exercise prescription was moderate-to-vigorous intensity aerobic exercise for at least 45 min on 5 days per week for 1 year. At least three sessions per week were facility based with on-site exercise trainers and the remaining sessions were home based. Participants wore heart rate monitors (Polar A3, Polar Electro Oy, Kempele, Finland) to ensure that at least half of their total workout time was at 70-80% of their heart rate reserve. They were instructed to warm up for 5 min, cool down for 5-10 min and stretch. The prescription ramped up over the first 3 months starting with three weekly sessions of 15-20 min at 50-60% of the heart rate reserve. Within these general parameters, the program was individualized to the age and fitness level of each participant. Several methods were used to increase success in meeting the exercise prescription, including scheduling of all facility-based sessions and telephone follow-up of missed sessions, plans for vacations and return after illness or injury, group sessions to permit interaction between participants, a comprehensive educational package highlighting issues of relevance to women starting an exercise program, incentives that were awarded when program milestones were reached, regular newsletters and a study website. Both exercise and control participants were instructed not to change their usual diet."	
Control/Comparator	"Women in the control group were asked to maintain their regular lifestyle. Both exercise and control participants were instructed not to change their usual diet."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		

Number of participants	n= 320 Intervention group/s: Exercisers (n=160) Comparator group: Controls (n=160)
Mean age ± SD	Intervention: 61.2y (5.4); Control: 60.6y (5.7)
Sex	100.00% female
Pre-existing medical condition	No pre-existing medical condition
Results	

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Weight (kg) Mean (SD)	Exercisers: 75.6 (13)	Controls: 76.3 (12.7)
BMI (kg/m2) Mean (SD)	Exercisers: 29.1 (4.5)	Controls: 29.2 (4.3)
Waist circumference (cm) Mean (SD)	Exercisers: 88.8 (10.6)	Controls: 110.6 (10.1)
Total body fat (kg) Mean (SD)	Exercisers: 30.9 (8.2)	Controls: 31.3 (8.6)
Body fat (%) Mean (SD)	Exercisers: 42.2 (4.9)	Controls: 42.4 (5.7)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator
Proportion (%) with weight loss ≥5% Proportion (%)	Exercisers: 28	Controls: 14
Proportion (%) with weight loss >3% to <5% Proportion (%)	Exercisers: 16	Controls: 6
Proportion (%) with weight loss +/-3% Proportion (%)	Exercisers: 47	Controls: 68
Proportion (%) with weight gain >3% Proportion (%)	Exercisers: 8	Controls: 12

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point

Variable	Intervention arm/s	Comparator
Change in weight (kg) Mean (95% CIs)	Exercisers: -2.3 (-2.9--1.7)	Controls: -0.5 (-1-0.1)
Change in BMI (kg/m2) Mean (95% CIs)	Exercisers: -0.9 (-1.1)	Controls: -0.2 (-0.4-0.1)
Change in waist circumference (cm) Mean (95% CIs)	Exercisers: -2.2 (-3--1.5)	Controls: -0.1 (-0.7-0.9)
Change in total body fat (kg) Mean (95% CIs)	Exercisers: -2.4 (-2.8--1.9)	Controls: -0.5 (-0.8-0)

	Change in total body fat (%) Mean (95% CIs)	Exercisers: -2 (-2.4--1.5)	Controls: -0.2 (-0.5-0.1)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	23% reported >150 min per week of physical activity during the intervention		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Friedenreich, 2015

Guideline record ID: 10238--1

Study characteristics		
Citation	Friedenreich, C. M., Neilson, H. K., O'Reilly, R., Duha, A., Yasui, Y., Morielli, A. R., Adams, S. C., & Courneya, K. S. (2015). Effects of a high vs moderate volume of aerobic exercise on adiposity outcomes in postmenopausal women: a randomized clinical trial. JAMA Oncology, 1(6), 766-776. https://doi.org/https://dx.doi.org/10.1001/jamaoncol.2015.2239	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of a High vs Moderate Volume of Aerobic Exercise on Adiposity Outcomes in Postmenopausal Women: A Randomized Clinical Trial	
Location	USA	
Trial name	Breast Cancer and Exercise Trial in Alberta (BETA)	
Methods		
Inclusion criteria	"Eligible women were postmenopausal, aged 50 to 74 years, had a body mass index (BMI) (calculated as weight in kilograms divided by height in meters squared) of 22 to 40, were inactive (≤120 min/wk or no more than 3 d/wk moderate intensity recreational activity less than 30 minutes/session; baseline estimated maximum oxygen consumption [V˙ O2max] no more than 34.5 mL/kg/min or, if estimated V˙ O2max was 34.6-37.0 mL/kg/min, 7-day accelerometer count less than 10 000 steps/d), and had no previous cancer diagnosis except nonmelanoma skin cancer and no major comorbid condition or recent reconstructive surgery. Women could maintain acceptable heart and lung function in a submaximal treadmill test, were nonusers of exogenous hormones or drugs affecting estrogen metabolism, nonsmokers, consumed no more than 2 drinks of alcohol/d, English speaking, not intending to be away longer than 4 weeks consecutively (8 weeks total) during the intervention, and not participating in or planning a weight loss program."	
Exclusion criteria	Not reported	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs), University/research centre	
Intervention	"Exercise volume was increased gradually over a 12-week ramp-up period. The goal by week 13 was to attain 5 d/wk aerobic exercise for 60 minutes (high volume) per session, achieving 65% to 75% maximum heart rate reserve for at least half of each workout (fitness levels were reassessed every 3 months).Women received Polar FT4 heart rate monitors (Polar Electro) to use in each supervised or unsupervised session. From weeks 13 through 52, women were prescribed supervised sessions 3 d/wk (Westside Recreation Centre, Calgary, or the Behavioral Medicine Fitness Centre, University of Alberta, Edmonton) and unsupervised home-based exercise 2 d/wk."	
Control/Comparator	"Exercise volume was increased gradually over a 12-week ramp-up period. The goal by week 13 was to attain 5 d/wk aerobic exercise for 30 minutes (moderate volume) per session, achieving 65% to 75% maximum heart rate reserve for at least half of each workout (fitness levels were reassessed every 3 months).Women received Polar FT4 heart rate monitors (Polar Electro) to use in each supervised or unsupervised session. From weeks 13 through 52, women were prescribed supervised sessions 3 d/wk (Westside Recreation Centre, Calgary, or the Behavioral Medicine Fitness Centre, University of Alberta, Edmonton) and unsupervised home-based exercise 2 d/wk."	
Treatment duration	12 months	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 400
Intervention group/s: High volume exercise (n=200)

Comparator group: Moderate volume exercise (n=200)</td></tr>
<tr><td>Mean age ± SD</td><td>Moderate Volume Exercise (Control): 59y (29.5); High Volume Exercise (Intervention): 71y (35.5)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Baseline Weight (kg)
Mean (SD)</td><td>High volume exercise: 77.3
(13)</td><td>Moderate volume exercise: 77.4
(13)</td></tr>
<tr><td>Baseline BMI (kg/m2)
Mean (SD)</td><td>High volume exercise: 29.1
(4.4)</td><td>Moderate volume exercise: 29.4
(4.4)</td></tr>
<tr><td>Baseline Waist Circumference (cm)
Mean (SD)</td><td>High volume exercise: 98.7
(11)</td><td>Moderate volume exercise: 98.6
(10.8)</td></tr>
<tr><td>Baseline Body Fat (%)
Mean (SD)</td><td>High volume exercise: 40.5
(5.8)</td><td>Moderate volume exercise: 40.7
(5.9)</td></tr>
<tr><td>Total Fat Mass (kg)
Mean (SD)</td><td>High volume exercise: 30.8
(8.6)</td><td>Moderate volume exercise: 31
(8.7)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in Weight (kg)
Least-squares mean (95% CI)</td><td>High volume exercise: -2.52
(-3.19--1.85)</td><td>Moderate volume exercise: -1.79
(-2.46--1.11)</td></tr>
<tr><td>Change in BMI
Least square mean (95% CI)</td><td>High volume exercise: -1.05
(-1.31--0.8)</td><td>Moderate volume exercise: -0.7
(-0.95--0.44)</td></tr>
<tr><td>Change in Waist circumference (cm)
Least square mean (95% CIs)</td><td>High volume exercise: -5.66
(-6.61--4.71)</td><td>Moderate volume exercise: -4.37
(-5.33--3.41)</td></tr>
<tr><td>Change in Body Fat (%)
Least square mean (95% CIs)</td><td>High volume exercise: -2.2
(-2.6--1.7)</td><td>Moderate volume exercise: -1.2
(-1.7--0.7)</td></tr>
</table>
</td></tr>
</table>

	Change in Total Fat Mass (kg) Least square mean (95% CIs)	High volume exercise: -2.41 (-2.97--1.85)	Moderate volume exercise: -1.45 (-2.01--0.89)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Median (interquartile range) adherence for the moderate and high-volume groups was 129 (106-138) and 228 (156- 262) min/wk		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Fuller, 2013

Guideline record ID: 10242--1

Study characteristics		
Citation	Fuller, N. R., Pearson, S., Lau, N. S., Wlodarczyk, J., Halstead, M. B., Tee, H.-P., Chettiar, R., & Kaffes, A. J. (2013). An intragastric balloon in the treatment of obese individuals with metabolic syndrome: a randomized controlled study. Obesity, 21(8), 1561-1570. https://doi.org/10.1002/oby.20414	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	An intragastric balloon in the treatment of obese individuals with metabolic syndrome: A randomized controlled study	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligible subjects were obese individuals aged between 18 and 60 years, who had had a BMI of 30-40 kg/m2 for a minimum of 2 years, and who had provided written informed consent. All had failed supervised weight reduction programs (including diet and exercise), and had the metabolic syndrome (MS) as defined by the Third Report of the National Cholesterol Education Program's Adult Treatment Panel (ATP III) Criteria (25)."	
Exclusion criteria	"Exclusion criteria included any condition which would increase the risks associated with endoscopy and/or insertion of the IGB, inflammatory disease of the gastrointestinal (GI) tract, upper GI bleeding conditions, history or symptoms of oesophageal or GI motility disorders, large hiatus hernia (>5 cm in diameter), structural abnormality of the GI tract, prior gastric surgery or insertion of an IGB, or major surgery within previous three months, cerebrovascular or cardiopulmonary disease, uncontrolled blood pressure (160/95 mmHg), epilepsy, type 1 diabetes, undiagnosed thyroid disease or hypothyroidism in which the dose of thyroxine replacement had not been stable for at least three months, hepatic or renal insufficiency, psychiatric disorder, or a pregnancy. Subjects were not permitted to take prescription or non-prescription medication or supplements with known effects on appetite or weight, or take aspirin, non-steroidal antiinflammatory agents (NSAIDs), anticoagulants, or other gastric irritants. Subjects with a history of alcoholism or drug abuse were excluded as were those with a history of weight loss of greater than 5 kg. Enrolment in any formal weight loss program within the 3 months prior to screening was also an exclusion criterion."	
Setting	University/research centre	
Intervention	"The same behavioral modification program was employed for both groups, based on the Type 2 Diabetes Lifestyle Intervention Program (26). During the baseline visit, the study dietitian/exercise physiologist (NRF) provided each subject with a written guide as to the specific types of foods and the quantities which could be consumed, in addition to a tailored exercise program. Each subject also received a pedometer and was encouraged to walk at least 10,000 steps daily. Baseline Visit (IGB insertion). After the baseline evaluations, subjects in the IGBG were taken to the endoscopy center (SDS) for the IGB insertion. Individuals with no contraindications identified on a preceding endoscopy had the IGB inserted using the standard protocol (27). A volume of 450-700 ml of saline was inserted into each IGB, with the volume predicated on the pre-treatment subjects BMI and stomach anatomy. In this study, the entire insertion procedure took on average 13 min per subject. The subjects were informed of all symptoms of deflation, gastrointestinal obstruction, ulceration, and other complications which might occur post-insertion and were advised to contact the investigators immediately if such symptoms occurred. Anti-emetics and antispasmodic drugs were prescribed for 5-7 days during the post-insertion period, with a proton pump inhibitor taken daily from 1 to 2 weeks prior to insertion and continued	

<table>
<tr><td></td><td>while the IGB was in situ. Subjects were instructed to remain inactive for 3 days post-insertion and to comply with a transitional diet up to day 20 to minimize post-procedure discomfort, prior to commencing their behavioral modification program. Month 6 Visit (IGB removal). The standard removal protocol was observed (27). The subjects were subsequently followed for a further six months after IGB extraction (ex-IGB group; ''Ex-IGBG'').”</td></tr>
<tr><td>Control/Comparator</td><td>“The same behavioral modification program was employed for both groups, based on the Type 2 Diabetes Lifestyle Intervention Program (26). During the baseline visit, the study dietitian/exercise physiologist (NRF) provided each subject with a written guide as to the specific types of foods and the quantities which could be consumed, in addition to a tailored exercise program. Each subject also received a pedometer and was encouraged to walk at least 10,000 steps daily. After the Baseline visit, all subjects in the CG commenced their prescribed behavioral modification program of diet and exercise, and this was continued over the 12 months of the study.”</td></tr>
<tr><td>Treatment duration</td><td>Intervention: 18 months; Control 12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 66
Intervention group/s: IGB Group (n=31)

Comparator group: Control Group (n=35)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention (IGB group): 43.4y (9.4); Control group: 48.1 (7.3)</td></tr>
<tr><td>Sex</td><td>66.67% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>IGB Group: 104.6
(14.8)

IGB Group: 36
(2.7)

IGB Group: 115.4
(10.9)</td><td>Control Group: 103.4
(13.9)

Control Group: 36.7
(2.9)

Control Group: 115.2
(8.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (%)
Mean (SD)

Change in weight (kg)
Mean (SD)</td><td>IGB Group: -9.2

IGB Group: -9.4</td><td>Control Group: -5.2

Control Group: -5.3</td></tr>
</table>
</td></tr>
</table>

	Change in waist circumference (cm) Mean (SD) Change in BMI (kg/m2) Mean (SD) Excess weight loss (%) Mean (SD)	IGB Group: -11.1 IGB Group: -3.4 IGB Group: 32.7	Control Group: -6.4 Control Group: -1.9 Control Group: 17.8
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Fuller, 2014

Guideline record ID: 10243--1

Study characteristics		
Citation	Fuller, N. R., Williams, K., Shrestha, R., Ahern, A. L., Holzapfel, C., Hauner, H., Jebb, S. A., & Caterson, I. D. (2014). Changes in physical activity during a weight loss intervention and follow-up: a randomized controlled trial. Clinical Obesity, 4(3), 127-135. https://doi.org/https://dx.doi.org/10.1111/cob.12057	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Changes in physical activity during a weight loss intervention and follow-up: a randomized controlled trial	
Location	Australia; UK; Germany	
Trial name	N/A	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	GP clinic, Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The CP promotes weight loss through a hypo-energetic, balanced diet based on healthy eating habits, increased physical activity and behavioural changes, primarily by providing group support. Weight loss goals were selfselected with input from the group leader, and participants were encouraged to attend weekly meetings for a 'weigh-in' and group discussion that included behavioural and motivational counselling. The plan promoted a 500-calorie deficit per day, with the aim of 0.5-1.0 kilogram of weight loss per week."	
Control/Comparator	"SC was delivered by primary care professionals at the participant's local general practice. Professionals delivering this intervention were provided with, and encouraged to use, national clinical guidelines for treatment (11) and were made aware of available patient literature with reference to advice on weight loss."	
Treatment duration	12 months	
Follow-up from baseline	2 years	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= Not reported Intervention group/s: Commercial programme (n=Not reported in this article) Comparator group: Standard care (n=Not reported in this article)	
Mean age ± SD	47.4y (12.9)	
Sex	Not reported	
Pre-existing medical condition	No pre-existing medical condition	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data	Jebb, S. A., Ahern, A. L., Olson, A. D., Aston, L. M., Holzapfel, C., Stoll, J., Amann-Gassner, U., Simpson, A. E., Fuller, N. R., Pearson, S., Lau, N. S., Mander, A. P., Hauner, H., & Caterson, I. D. (2011). Primary care referral to a commercial provider for weight loss treatment versus standard care: a randomised controlled trial. The Lancet, 378(9801), 1485-1492. https://doi.org/https://dx.doi.org/10.1016/S0140-6736(11)61344-5		

N/A – Not applicable

Gabriel, 2011

Guideline record ID: 10245--1

Study characteristics		
Citation	Gabriel, K. K. P., Conroy, M. B., Schmid, K. K., Storti, K. L., High, R. R., Underwood, D. A., Kriska, A. M., & Kuller, L. H. (2011). The impact of weight and fat mass loss and increased physical activity on physical function in overweight, postmenopausal women: results from the Women on the Move Through Activity and Nutrition study. Menopause, 18(7), 759-765. https://doi.org/https://dx.doi.org/10.1097/gme.0b013e31820acdcc	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The impact of weight and fat mass loss and increased physical activity on physical function in overweight, postmenopausal women: results from the Women on the Move Through Activity and Nutrition study	
Location	USA	
Trial name	Women on the Move through Activity and Nutrition (WOMAN)	
Methods		
Inclusion criteria	"Eligible women were between the ages of 52 and 62 years, had a BMI of 25-39.9kg/m2, waist circumference >80cm diameter, BP <140/90mmHg, with or without antihypertensive therapy, not on lipid-lowering drug therapy, LDL cholesterol (LDL-C) between 100 and 160 mg% and no history of CVD."	
Exclusion criteria	Not reported	
Setting	University/research centre	
Intervention	"The intervention was primarily group-based and was facilitated by a multidisciplinary team of nutritionists, exercise physiologists, and psychologists. Contact was frequent throughout the program with 40 visits during the first year and a minimum of 12 monthly visits in year 2 and beyond. Dietary goals for the intervention (Lifestyle Change) group were to reduce the saturated fat to <7% of total energy or <10g/day, reduction in total energy intake to 1,300 cal or 1,500 cal when baseline body weight was >175 lbs to support a 10% loss of weight and a decrease in waist circumference. They were also encouraged to increase the use of foods high in soluble fiber and nutrient-dense, high-volume, low-caloric foods such as fruits, vegetables, and whole grains. Also, during the first year of the intervention consumption of functional foods such as stanol esther containing margarines, soy products and n-3 fatty acids from fish were encouraged. The physical activity component of the lifestyle intervention began after the first 6 months of group initiation. It was a stepped care approach to reach 150min/week of moderate intensity physical activity as the standard minimum goal for all women. Women who reached the minimum goal were then encouraged to increase to 180min and then to 240min/week. Resistance training of large skeletal muscle groups was also encouraged to facilitate beneficial body composition changes and bone health."	
Control/Comparator	"The Health Education group had a series of six seminars during the first year of participation and then several times per year through 36 months. Most of these sessions focused on women's health and not specifically on CV risk factors."	
Treatment duration	30 months	
Follow-up from baseline	48 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 508
Intervention group/s: Lifestyle Change (n=253)

Comparator group: Health Education (n=255)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 56.9y (2.94); Control: 57.1y (2.94</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (lbs)
Mean (SD)</td><td>Lifestyle Change: 179.1 (25.3)</td><td>Health Education: 181.3 (25.3)</td></tr>
<tr><td>Body mass index, kg/m
Mean (SD)</td><td>Lifestyle Change: 30.6 (3.8)</td><td>Health Education: 30.9 (3.8)</td></tr>
<tr><td>Waist Circumference, cm
Mean (SD)</td><td>Lifestyle Change: 105.5 (11.2)</td><td>Health Education: 106.3 (11.2)</td></tr>
<tr><td>Whole Body Fat Mass (kg)
Mean (SD)</td><td>Lifestyle Change: 33.1 (7.1)</td><td>Health Education: 33.7 (7.1)</td></tr>
<tr><td>Trunk Fat Mass (kg)
Mean (SD)</td><td>Lifestyle Change: 15.9 (3.9)</td><td>Health Education: 16.2 (3.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (lbs)
Mean (SD)</td><td>Lifestyle Change: 172.6 (26.9)</td><td>Health Education: 180.6 (26.9)</td></tr>
<tr><td>Body mass index, kg/m
Mean (SD)</td><td>Lifestyle Change: 29.5 (4.2)</td><td>Health Education: 30.9 (4.2)</td></tr>
<tr><td>Waist Circumference, cm
Mean (SD)</td><td>Lifestyle Change: 98.3 (11.4)</td><td>Health Education: 102.2 (11.4)</td></tr>
<tr><td>Whole Body Fat Mass (kg)
Mean (SD)</td><td>Lifestyle Change: 32.7 (7.7)</td><td>Health Education: 34.1 (7.7)</td></tr>
<tr><td>Trunk Fat Mass (kg)
Mean (SD)</td><td>Lifestyle Change: 15.9 (4.4)</td><td>Health Education: 16.7 (4.4)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	Kuller, L. H., Pettee Gabriel, K. K., Kinzel, L. S., Underwood, D. A., Conroy, M. B., Chang, Y., Mackey, R. H., Edmundowicz, D., Tyrrell, K. S., Buhari, A. M., & Kriska, A. M. (2012). The Women on the Move Through Activity and Nutrition (WOMAN) study: final 48-month results. Obesity, 20(3), 636-643. https://doi.org/https://dx.doi.org/10.1038/oby.2011.80

N/A – Not applicable

Gadde, 2011

Guideline record ID: 11025--1

Study characteristics		
Citation	Gadde, K. M., Allison, D. B., Ryan, D. H., Peterson, C. A., Troupin, B., Schwiers, M. L., & Day, W. W. (2011). Effects of low-dose, controlled-release, phentermine plus topiramate combination on weight and associated comorbidities in overweight and obese adults (CONQUER): a randomised, placebo-controlled, phase 3 trial. The Lancet, 377(9774), 1341-1352. https://doi.org/https://doi.org/10.1016/S0140-6736(11)60205-5	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of low-dose, controlled-release, phentermine plus topiramate combination on weight and associated comorbidities in overweight and obese adults (CONQUER): a randomised, placebo-controlled, phase 3 trial	
Location	USA	
Trial name	CONQUER trial	
Methods		
Inclusion criteria	"Inclusion criteria were two or more of the following comorbidities at baseline: systolic blood pressure 140-160 mm Hg (130-160 mm Hg in patients with diabetes), diastolic blood pressure 90-100 mm Hg (85-100 mm Hg in patients with diabetes), or taking at least two antihypertensive drugs; concentration of triglycerides 2·26-4·52 mmol/L or using at least two lipid-lowering drugs; concentration of fasting blood glucose greater than 5·55 mmol/L, blood glucose greater than 7·77 mmol/L at 2 h after oral glucose load during oral glucose tolerance test, or diagnosed type 2 diabetes managed with lifestyle changes or metformin monotherapy; and waist circumference of at least 102 cm for men or at least 88 cm for women."	
Exclusion criteria	"Exclusion criteria included blood pressure greater than 160/100 mm Hg, a concentration of fasting glucose greater than 13·32 mmol/L or triglycerides greater than 4·52 mmol/L at randomisation, type 1 diabetes, use of antidiabetic drugs other than metformin, history of nephrolithiasis, recurrent major depression, presence or history of suicidal behaviour or ideation with intent to act, and current substantial depressive symptoms (Patient Health Questionnaire [PHQ-9]21 total score ≥10). Antidepressant drugs (but not tricyclic antidepressant drugs and monoamine oxidase inhibitors) were allowed if the dose was stable for 3 months."	
Setting	University/research centre	
Intervention	"Once-daily, controlled-release combination of phentermine 7·5 mg plus topiramate 46·0 mg, and once-daily controlledrelease combination of phentermine 15·0 mg plus topiramate 92·0 mg for 56 weeks with standardised counselling for diet and lifestyle modification. All patients had dose titration during the initial 4 weeks, starting at phentermine 3·75 mg plus topiramate 23·00 mg, or placebo, with weekly increases in phentermine (3·75 mg) plus topiramate (23·00 mg) until the achievement of the assigned doses, which were then maintained for 52 weeks. At baseline, each patient was provided with a LEARN manual,22 advised to implement lifestyle changes as appropriate, and given instructions to reduce their caloric intake by 500 kcal/day. Progress was discussed with study staff during monthly visits."	
Control/Comparator	"Once-daily treatment with placebo for 56 weeks with standardised counselling for diet and lifestyle modification. At baseline, each patient was provided with a LEARN manual,22 advised to implement lifestyle changes as appropriate, and given instructions to reduce their caloric intake by 500 kcal/day. Progress was discussed with study staff during monthly visits."	

<table>
<tr><td>Treatment duration</td><td>56 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>56 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 2487
Intervention group/s: Phentermine 7·5 mg plus topiramate 46·0 mg (n=498); Phentermine 15·0 mg plus topiramate 92·0 mg (n=995)

Comparator group: Placebo (n=994)</td></tr>
<tr><td>Mean age ± SD</td><td>Phentermine 7·5 mg plus topiramate 46·0mg: 51.1y (10.43); Phentermine 15·0 mg plus topiramate 92·0mg: 51.0y (10.65); Placebo: 51.2y (10.25)</td></tr>
<tr><td>Sex</td><td>69.84% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)</td><td>Phentermine 7.5 mg plus topiramate 46.0 mg: 102.6 (18.2)
Phentermine 15.0 mg plus topiramate 92.0 mg: 103 (17.6)</td><td>Placebo: 103.3 (18.1)</td></tr>
<tr><td>Waist circumference (cm) - Baseline
Mean (SD)</td><td>Phentermine 7.5 mg plus topiramate 46.0 mg: 112.6 (12.5)
Phentermine 15.0 mg plus topiramate 92.0 mg: 113.2 (12.2)</td><td>Placebo: 113.4 (12.2)</td></tr>
<tr><td>Fat mass (kg) - Baseline
Mean (SD)</td><td>Phentermine 7.5 mg plus topiramate 46.0 mg: 43.6 (9.3)
Phentermine 15.0 mg plus topiramate 92.0 mg: 39.5 (8.8)</td><td>Placebo: 40.4 (7.5)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
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<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in body weight (%)
Mean (95% CIs)</td><td>Phentermine 7.5 mg plus topiramate 46.0 mg: -7.8 (-8.5--7.1)
Phentermine 15.0 mg plus topiramate 92.0 mg: -9.8 (-10.4--9.3)</td><td>Placebo: -1.2 (-1.8--0.7)</td></tr>
<tr><td>Change in body weight (kg)
Mean (95% CIs)</td><td>Phentermine 7.5 mg plus topiramate 46.0 mg: -8.1 (-8.9--7.4)</td><td>Placebo: -1.4 (-2--0.8)</td></tr>
</table></td></tr>
</table>

	Change in waist circumference (cm) Mean (95% CIs) Change in Fat mass (kg) Mean (SD)	Phentermine 15.0 mg plus topiramate 92.0 mg: -10.7 (-11.3--10.1) Phentermine 7.5 mg plus topiramate 46.0 mg: -7.6 (-8.4--6.9) Phentermine 15.0 mg plus topiramate 92.0 mg: -9.2 (-9.8--8.6) Phentermine 7.5 mg plus topiramate 46.0 mg: -7 (4.6) Phentermine 15.0 mg plus topiramate 92.0 mg: -8.1 (7.1)	Placebo: -2.4 (-3--1.8) Placebo: -1.3 (3.8)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Gade, 2015

Guideline record ID: 10246--1

Study characteristics		
Citation	Gade, H., Friborg, O., Rosenvinge, J. H., Småstuen, M. C., & Hjelmesæth, J. (2015). The impact of a preoperative cognitive behavioural therapy (CBT) on dysfunctional eating behaviours, affective symptoms and body weight 1 year after bariatric surgery: a randomised controlled trial. Obesity Surgery, 25(11), 2112-2119. https://doi.org/https://dx.doi.org/10.1007/s11695-015-1673-z	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Impact of a Preoperative Cognitive Behavioural Therapy (CBT) on Dysfunctional Eating Behaviours, Affective Symptoms and Body Weight 1 Year after Bariatric Surgery: A Randomised Controlled Trial	
Location	Norway	
Trial name	N/A	
Methods		
Inclusion criteria	"All patients who were invited to participate in the study were already accepted for bariatric surgery."	
Exclusion criteria	"Patients suffering from drug and/or alcohol addiction."	
Setting	Hospital	
Intervention	"During the 4 months prior to surgery, patients in both treatment arms were offered up to three voluntary consultations from either a medical doctor, a dietician, a nurse or a physical therapist tailored to the patients' individual needs. The CBT intervention has been described in more detail elsewhere [28], but this 10-week treatment condition consisted of learning to recognise triggers of DE, i.e. identifying how automatic thoughts and dysfunctional cognitions, negative moods and overeating are interrelated. Moreover, weekly home-work tasks were used to break the DE-patterns which are a common problem for patients suffering from extreme obesity. Thus, the main purpose of the intervention was to improve selfmonitoring and self-regulation of eating behaviour. Some individual adjustments during the course of therapy were allowed to accommodate for the fact that some patients spent more time working on obtaining more regularity in eating, whilst others addressed cognitive negative self-talk in order to reduce emotionally triggered eating behaviour. In the year following the surgery, all patients were invited to attend one group session with a clinical nutritionist and another with a physical therapist. The patients were additionally offered two individual consultations with a physician."	
Control/Comparator	"During the 4 months prior to surgery, patients in both treatment arms were offered up to three voluntary consultations from either a medical doctor, a dietician, a nurse or a physical therapist tailored to the patients' individual needs. In the year following the surgery, all patients were invited to attend one group session with a clinical nutritionist and another with a physical therapist. The patients were additionally offered two individual consultations with a physician."	
Treatment duration	10 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 102
Intervention group/s: Intervention (n=50)

Comparator group: Control (n=52)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg) - Baseline Mean (SD)</td><td>Intervention: 129.5 (17.2)</td><td>Control: 127.7 (19.2)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% Change in body weight Mean</td><td>Intervention: -30.9</td><td>Control: -31.2</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Hjelmesæth, J., Rosenvinge, J. H., Gade, H., & Friborg, O. (2019). Effects of cognitive behavioral therapy on eating behaviors, affective symptoms, and weight loss after bariatric surgery: a randomized clinical trial. Obesity Surgery, 29(1), 61-69. https://doi.org/https://dx.doi.org/10.1007/s11695-018-3471-x</td></tr>
</table>

N/A – Not applicable

Gallè, 2017

Guideline record ID: 10251--1

Study characteristics		
Citation	Gallè, F., Di Onofrio, V., Romano Spica, V., Mastronuzzi, R., Russo Krauss, P., Belfiore, P., Buono, P., & Liguori, G. (2017). Improving physical fitness and health status perception in community-dwelling older adults through a structured program for physical activity promotion in the city of Naples, Italy: a randomized controlled trial. Geriatrics & Gerontology International, 17(10), 1421-1428. https://doi.org/10.1111/ggi.12879	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Improving physical fitness and health status perception in community-dwelling older adults through a structured program for physical activity promotion in the city of Naples, Italy: A randomized controlled trial	
Location	Italy	
Trial name	N/A	
Methods		
Inclusion criteria	"Patients were eligible if they were aged >60 years, typically sedentary (classified according to the World Health Organization guidelines for physical activity)18 and did not show severe psychological or physical diseases; only individuals physically suited for PA were enrolled, on the basis of medical certification."	
Exclusion criteria	Not reported	
Setting	GP clinic, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The PA program consisted of 1-h sessions carried out twice a week. Each session included exercises for respiration, muscle trophism, coordination, equilibrium, orientation, osteomuscular mobility and discussion about health education topics. After 10-min of warm-up including walking or marching, progressive resistance training for all of the major muscle groups and balance training were carried out. The last 10min included upper body and lower body flexibility exercises. Booklets regarding PA practice were distributed to all the participants."	
Control/Comparator	"At the start of the study, control patients were advised to be more physically active during a brief counseling session: physicians discussed with them the health benefits of PA and the opportunities to be physically active every day following the existing recommendations.18,19 Booklets regarding PA practice were distributed to all the participants."	
Treatment duration	1 year	
Follow-up from baseline	1 year	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 160 Intervention group/s: Intervention (n=80) Comparator group: Control (n=80)	
Mean age ± SD	71y (6)	

<table>
<tr><td>Sex</td><td>93.75% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Intervention: 27.9
(1.6)</td><td>Control: 28.3
(1.5)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Intervention: 25.1
(1.9)</td><td>Control: 27.8
(1.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Garcia-Silva, 2024

Guideline record ID: 12011--1

Study characteristics		
Citation	Garcia-Silva, J., Borrego, I. R. S., Navarrete, N. N., Peralta-Ramirez, M. I., Águila, F. J., & Caballo, V. E. (2024). Efficacy of cognitive-behavioural therapy for lifestyle modification in metabolic syndrome: a randomised controlled trial with a 18-months follow-up. Psychology & Health, 39(2), 195-215. https://doi.org/https://doi.org/10.1080/08870446.2022.2055023	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Efficacy of cognitive-behavioural therapy for lifestyle modification in metabolic syndrome: a randomised controlled trial with a 18-months follow-up	
Location	Spain	
Trial name	PROMETS	
Methods		
Inclusion criteria	"The inclusion criteria of the study was related to the MetS diagnosis. Specifically, men and women, between 25 and 65years of age, with a waist circumference (WC) >88 cm for women and >102 cm for men, as well as two or more of the following characteristics: A) blood pressure (BP): systolic ≥130 mmHg and diastolic ≥85 mmHg; B) fasting glucose level ≥110mg / dL; C) triglycerides: ≥150 mg/dL; D) HDL cholesterol ≤40 mg/dL in men and ≤50 mg/dL in women."	
Exclusion criteria	"Exclusion criteria were: having diagnosis of advanced osteoarthritis, active inflammatory diseases, severe psychiatric disorders and/or significant cognitive impairment assessed through the Mini-Mental State Examination (MMSE) (Lobo et al., 2002), and being illiterate."	
Setting	University/research centre	
Intervention	"Specifically, the intervention used in EG includes different modules in addition to cognitive-behavioral intervention, such as changes in lifestyle, related to healthy eating, physical exercise and psychoeducation on MetS (Figure 1). The multimodal intervention includes sessions in psychology, as well as information and recommendations for lifestyle change according to the NAOS Strategy, (2011). The training was performed by a psychologist in a face-to-face group format, with a maximum of 12 patients per group, during 12 weekly sessions lasting 90minutes (4 therapy groups). The objective of this intervention was to provide information about the disease as well as to provide the patients with cognitive strategies for both lifestyle change and adherence to the proposed therapeutic measures (Figure 2). All sessions were audio recorded and some of the sessions were observed by a clinical psychologist. This last procedure was adopted in order to guarantee technical quality in accordance to session's aims. As far as pharmacological treatment is concerned, both groups have maintained their usual treatment during the intervention."	
Control/Comparator	"The CG received usual care and attended workshops for healthy lifestyle. The intervention for the CG consisted of workshops with basic information about MetS and its associated cardiovascular risk. In this workshop, standard therapeutic measures were presented in accordance with the NAOS Strategy, (2011) for healthy eating and physical exercise (the importance of eating breakfast, eating fruits and vegetables, fibre, fish, drinking water, reducing salt and fat intake, being active and doing sports, as well as maintaining adequate weight). These workshops lasted 90 minutes and were delivered for groups of approximately 10 to 15 people, totalling 4 subgroups. As far as pharmacological treatment is concerned, both groups have maintained their usual treatment during the intervention."	
Treatment duration	12 weeks	

<table>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Weight for height growth chart, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 76
Intervention group/s: EG (n=45)

Comparator group: CG (n=31)</td></tr>
<tr><td>Mean age ± SD</td><td>55.67y (7.39)</td></tr>
<tr><td>Sex</td><td>52.63% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Metabolic syndrome: two or more of the following characteristics: A) blood pressure (BP): systolic ≥130 mmHg and diastolic ≥85 mmHg; B) fasting glucose level ≥110mg / dL; C) triglycerides: ≥150 mg/dL; D) HDL cholesterol ≤40 mg/dL in men and ≤50 mg/dL in w</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference, cm
Mean (SD)

Weight, kg
Mean (SD)

BMI
Mean (SD)</td><td>EG: 112.94
(10.15)

EG: 89.49
(15.81)

EG: 32.84
(4.42)</td><td>CG: 105.68
(10.98)

CG: 80.95
(14.97)

CG: 30.73
(3.63)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference, cm
Mean (SD)

Weight, kg
Mean (SD)

BMI
Mean (SD)</td><td>EG: 110
(1.53)

EG: 86.86
(15.34)

EG: 31.88
(0.64)</td><td>CG: 104.93
(2.49)

CG: 80.38
(2.69)

CG: 30.51
(0.67)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight, kg
Mean (95% CIs)

Change in BMI, kg
Mean (95% CIs)

Change in waist circumference, cm
Mean (95% CIs)</td><td>EG: -2.633
(-4.322--0.943)

EG: -0.915
(-1.494--0.335)

EG: -2.944
(-5.09--0.798)</td><td>CG: -0.565
(-1.896-0.767)

CG: -0.212
(-0.718-0.293)

CG: -0.046
(-0.685--0.023)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>The results showed an increase in the EG for adherence to the Mediterranean diet (B=1.064; 95%CI 0.560, 1.568; p = .0001)</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Garvey, 2012

Guideline record ID: 11028--1

Study characteristics		
Citation	Garvey, W. T., Ryan, D. H., Look, M., Gadde, K. M., Allison, D. B., Peterson, C. A., Schwiers, M., Day, W. W., & Bowden, C. H. (2012). Two-year sustained weight loss and metabolic benefits with controlled-release phentermine/topiramate in obese and overweight adults (SEQUEL): a randomized, placebo-controlled, phase 3 extension study. The American Journal of Clinical Nutrition, 95(2), 297-308. https://doi.org/https://doi.org/10.3945/ajcn.111.024927	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Two-year sustained weight loss and metabolic benefits with controlled-release phentermine/topiramate in obese and overweight adults (SEQUEL): a randomized, placebo-controlled, phase 3 extension study	
Location	USA	
Trial name	SEQUEL Study	
Methods		
Inclusion criteria	"Inclusion and exclusion criteria for CONQUER required subjects to have a BMI (in kg/m2) of 27 and 45 as well as 2 weight-related comorbidities, as previously described in detail (17). To continue into the SEQUEL extension study, female subjects of childbearing potential were required to continue contraception in the form of a doublebarrier method, stable hormonal contraception plus single barrier, or tubal ligation."	
Exclusion criteria	"Exclusion criteria included having a BMI 22 at the completion of the CONQUER study, continuously not taking the study drug for .4 wk at the completion of the CONQUER study, developing a condition during the CONQUER study that would interfere with compliance or attainment of study measures, or participating in another formal weight-loss program."	
Setting	University/research centre	
Intervention	"Study drugs and placebo were administered as capsules that were identical in size and appearance. Eligible subjects maintained their originally assigned once-daily treatment from the CONQUER study (2:1:2 randomization for 7.5 mg phentermine/46 mg controlled release topiramate (7.5/46), or 15 mg phentermine/92 mg controlled release topiramate (15/92) (17)All subjects continued to receive standardized diet and lifestyle-modification counseling based on the LEARN (Lifestyle, Exercise, Attitudes, Relationships, and Nutrition) program (18)"	
Control/Comparator	"Study drugs and placebo were administered as capsules that were identical in size and appearance. Eligible subjects maintained their originally assigned once-daily treatment from the CONQUER study (2:1:2 randomization for placebo All subjects continued to receive standardized diet and lifestyle-modification counseling based on the LEARN (Lifestyle, Exercise, Attitudes, Relationships, and Nutrition) program (18)."	
Treatment duration	108 weeks	
Follow-up from baseline	108 weeks	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 675 Intervention group/s: PHEN/TPM CR 7.5/46 (n=153); PHEN/TPM CR 15/92 (n=295)	

<table>
<tr><td></td><td>Comparator group: Placebo (n=227)</td></tr>
<tr><td>Mean age ± SD</td><td>PHEN/TPM CR 7.5/46: 52.2y (10.6); PHEN/TPM CR 15/92: 51.2y (10.4); Placebo: 52.7y (9.8)</td></tr>
<tr><td>Sex</td><td>66.37% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)

Waist circumference (cm) - Baseline
Mean (SD)</td><td>PHEN/TPM CR 7.5/46: 102.2 (18.4)
PHEN/TPM CR 15/92: 101.9 (18.9)

PHEN/TPM CR 7.5/46: 112.9 (12.3)
PHEN/TPM CR 15/92: 112.2 (12.3)</td><td>Placebo: 101.1 (18.9)

Placebo: 113 (12.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in body weight (%)
Mean

Change in body weight (kg)
Mean

Change in waist circumference (cm)
Mean</td><td>PHEN/TPM CR 7.5/46: -9.3
PHEN/TPM CR 15/92: -10.5

PHEN/TPM CR 7.5/46: -9.6
PHEN/TPM CR 15/92: -10.9

PHEN/TPM CR 7.5/46: -9.8
PHEN/TPM CR 15/92: -10.6</td><td>Placebo: -1.8

Placebo: -2.1

Placebo: -3.6</td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Garvey, 2020

Guideline record ID: 10254--1

Study characteristics		
Citation	Garvey, W. T., Birkenfeld, A. L., Dicker, D., Mingrone, G., Pedersen, S. D., Satylganova, A., Skovgaard, D., Sugimoto, D., Jensen, C., & Mosenzon, O. (2020). Efficacy and safety of liraglutide 3.0 mg in individuals with overweight or obesity and type 2 diabetes treated with basal insulin: the SCALE Insulin randomized controlled trial. Diabetes Care, 43(5), 1085-1093. https://doi.org/10.2337/dc19-1745	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Efficacy and Safety of Liraglutide 3.0 mg in Individuals With Overweight or Obesity and Type 2 Diabetes Treated With Basal Insulin: The SCALE Insulin Randomized Controlled Trial	
Location	Canada; Germany; Israel; Italy; Turkey; Mexico; USA	
Trial name	Satiety and Clinical Adiposity - Liraglutide Evidence (SCALE)	
Methods		
Inclusion criteria	"Eligible individuals were aged ≥18 years with a BMI of ≥27 kg/m2, stable body weight (maximum 5 kg self-reported weight change within 90 days before screening), diagnosed with type 2 diabetes with an HbA1c≥6.0 to ≤10% (42-86 mmol/mol) at screening, and receiving stable treatment with any basal insulin (≥90 days; no requirement for minimum or maximum dose) and ≤2 OADs."	
Exclusion criteria	"Individuals were excluded if they had type 1 diabetes, recurrent severe hypoglycemic episodes within the last year, or use of dipeptidyl peptidase 4 inhibitors, GLP-1 receptor agonists, bolus insulin, or medications known to induce significant weight change in the previous 90 days. Other exclusion criteria included a recent history of cardiovascular event; history of medullary thyroid carcinoma or multiple endocrine neoplasia type 2; pregnancy, breast-feeding, or intention to become pregnant; or a history of pancreatitis."	
Setting	Hospital, University/research centre	
Intervention	"Liraglutide 3.0 mg was administered once daily by subcutaneous injection. During the first 4 weeks postrandomization, the dose was escalated by 0.6 mg weekly to reach the maintenance dose of 3.0 mg. A 4-week follow-up period was included after the 56-week treatment period. To promote individual retention and improve data quality, individuals were permitted to stop and restart the study drug without re-escalating the dose, or with re-escalation if three consecutive doses had been missed. IBT consisted of a hypocaloric diet, increased physical activity, and behavioral therapy delivered in frequent counseling sessions and is described in detail elsewhere (21) and in the Supplementary Data. Individuals attended a total of 23 individual or group counseling sessions during the 56-week period, delivered bya registereddietitianor similarly qualified health care professional."	
Control/Comparator	"placebo was administered once daily by subcutaneous injection. During the first 4 weeks postrandomization, the dose was escalated by 0.6 mg weekly to reach the maintenance dose of 3.0 mg. A 4-week follow-up period was included after the 56-week treatment period. To promote individual retention and improve data quality, individuals were permitted to stop and restart the study drug without re-escalating the dose, or with re-escalation if three consecutive doses had been missed. IBT consisted of a hypocaloric diet, increased physical activity, and behavioral therapy delivered in frequent counseling sessions and is described in detail elsewhere (21) and in the Supplementary Data. Individuals attended a total of 23 individual or group counseling sessions during the 56-week period, delivered bya registereddietitianor similarly qualified health care professional."	

<table>
<tr><td>Treatment duration</td><td>56 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>56 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 396
Intervention group/s: Liraglutide 3.0mg (n=198)

Comparator group: Placebo (n=198)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention (liraglutide 3.0mg): 55.9y (11.3); Control (placebo): 57.6y (10.4)</td></tr>
<tr><td>Sex</td><td>52.27% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)

BMI (kg/m2) - Baseline
Mean (SD)

waist circumference (cm) - Baseline
Mean (SD)</td><td>Liraglutide 3.0mg: 100.6 (20.8)

Liraglutide 3.0mg: 35.9 (6.5)

Liraglutide 3.0mg: 114.8 (13.7)</td><td>Placebo: 98.9 (19.9)

Placebo: 35.3 (5.8)

Placebo: 114.2 (13.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of individuals achieving =>5% weight loss, % Proportion (%)

Proportion of individuals achieving =>10% weight loss % Proportion (%)</td><td>Liraglutide 3.0mg: 51.8

Liraglutide 3.0mg: 22.8</td><td>Placebo: 24

Placebo: 6.6</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (%)
Mean

Change in waist circumference (cm)
Mean</td><td>Liraglutide 3.0mg: -5.8

Liraglutide 3.0mg: -5.3</td><td>Placebo: -1.5

Placebo: -2.6</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Garvey, 2022

Guideline record ID: 11026--1

Study characteristics		
Citation	Garvey, W. T., Batterham, R. L., Bhatta, M., Buscemi, S., Christensen, L. N., Frias, J. P., Jódar, E., Kandler, K., Rigas, G., Wadden, T. A., Wharton, S., & the STEP 5 Study Group. (2022). Two-year effects of semaglutide in adults with overweight or obesity: the STEP 5 trial. Nature Medicine, 28(10), 2083-2091. https://doi.org/https://doi.org/10.1038/s41591-022-02026-4	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Two-year effects of semaglutide in adults with overweight or obesity: the STEP 5 trial	
Location	USA; Canada; Hungary; Italy; Spain	
Trial name	STEP 5	
Methods		
Inclusion criteria	"Inclusion Criteria: Male or female, age more than or equal to 18 years at the time of signing informed consent, Body mass index (BMI) more than or equal to 30 kg/m^2 or more than or equal to 27 kg/m^2 with the presence of at least one of the following weight-related comorbidities (treated or untreated): hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease, History of at least one self-reported unsuccessful dietary effort to lose body weight."	
Exclusion criteria	"Exclusion criteria: HbA1c more than or equal to 48 mmol/mol (6.5%) as measured by the central laboratory at screening, A self-reported change in body weight more than 5 kg (11 lbs) within 90 days before screening irrespective of medical records."	
Setting	GP clinic, University/research centre	
Intervention	"Participants will receive semaglutide 2.4 mg during 104-week treatment period in addition to a reduced-calorie diet and increased physical activity"	
Control/Comparator	"Participants will receive placebo (semaglutide) during 104-week treatment period in addition to a reduced-calorie diet and increased physical activity."	
Treatment duration	2 years	
Follow-up from baseline	2 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 304 Intervention group/s: Semaglutide (n=152) Comparator group: Placebo (n=152)	
Mean age ± SD	Semaglutide: 47.3y (11.7); Placebo: 47.4y (10.3)	
Sex	77.63% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Body weight, kg
Mean (SD)

Body mass index, kg m-2
Mean (SD)

Waist circumference, cm
Mean (SD)</td><td>Semaglutide: 105.6
(20.8)

Semaglutide: 38.6
(6.7)

Semaglutide: 115.8
(14.3)</td><td>Placebo: 106.5
(23.1)

Placebo: 38.5
(7.2)

Placebo: 115.7
(15.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>≥5% weight loss at week 104
Proportion (%)

≥10% weight loss at week 104
Proportion (%)

≥15% weight loss at week 104
Proportion (%)

≥20% weight loss at week 104
Proportion (%)</td><td>Semaglutide: 77.1%

Semaglutide: 61.8%

Semaglutide: 52.1%

Semaglutide: 36.1%</td><td>Placebo: 34.40%

Placebo: 13.30%

Placebo: 7.00%

Placebo: 2.30%</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Body weight change from baseline to week 104, %
Mean (SE)

Waist circumference-change from baseline to week 104, cm
Mean (SE)

Body weight change from baseline to week 104, %
Mean (SE)

Body mass index-change from baseline to week 104, kg m-2
Mean (SE)</td><td>Semaglutide: -15.2
(0.9%)

Semaglutide: -14.4
(0.9)

Semaglutide: -16.1
(1)

Semaglutide: -5.9
(0.4)</td><td>Placebo: -2.6
(1.1)

Placebo: -5.2
(1.2)

Placebo: -3.2
(1.2)

Placebo: -1.6
(0.6)</td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Garvey, 2023

Guideline record ID: 11070--1

Study characteristics		
Citation	Garvey, W. T., Frias, J. P., Jastreboff, A. M., le Roux, C. W., Sattar, N., Aizenberg, D., Mao, H., Zhang, S., Ahmad, N. N., Bunck, M. C., Benabbad, I., Zhang, X. M., & for the SURMOUNT-2 investigators. (2023). Tirzepatide once weekly for the treatment of obesity in people with type 2 diabetes (SURMOUNT-2): a double-blind, randomised, multicentre, placebo-controlled, phase 3 trial. The Lancet, 402(10402), 613-626. https://doi.org/https://doi.org/10.1016/S0140-6736(23)01200-X	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Tirzepatide once weekly for the treatment of obesity in people with type 2 diabetes (SURMOUNT-2): a double-blind, randomised, multicentre, placebo-controlled, phase 3 trial	
Location	Argentina; Brazil; India; Japan; Russia; Taiwan; USA	
Trial name	SURMOUNT-2	
Methods		
Inclusion criteria	"Have Type 2 Diabetes (T2DM) with HbA1c ≥7% to ≤10% at screening, on stable therapy for the last 3 months prior to screening. T2DM may be treated with diet/exercise alone or any oral glycemic-lowering agent (as per local labeling) EXCEPT dipeptidyl peptidase 4 (DPP-4) inhibitors or glucagon like peptide-1 receptor agonists (GLP-1 RAs) Have a BMI of ≥27 kg/m² Are overweight or have obesity Have a history of at least 1 self-reported unsuccessful dietary effort to lose body weight Are at least 18 years of age and age of majority per local laws and regulations."	
Exclusion criteria	"Type 1 diabetes mellitus, history of ketoacidosis or hyperosmolar state/coma or any other types of diabetes except T2DM Have at least 2 confirmed fasting self-monitoring blood glucose (SMBG) values >270 mg/dL(on 2 nonconsecutive days) prior to Visit 3 Have proliferative diabetic retinopathy OR diabetic macular edema OR non-proliferative diabetic retinopathy that requires acute treatment Have self-reported change in body weight >5kg within 3 months prior to screening Have had a history of chronic or acute pancreatitis Change in body weight greater than 5 kg within 3 months prior to starting study Obesity induced by other endocrinologic disorders or monogenetic or syndromic forms of obesity Family or personal history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN-2) History of significant active or unstable major depressive disorder (MDD) or other severe psychiatric disorder within the last 2 years Any lifetime history of a suicide attempt."	
Setting	Hospital, University/research centre	
Intervention	"10 or 15 mg Tirzepatide administered subcutaneously (SC)"	
Control/Comparator	"Placebo administered subcutaneously."	
Treatment duration	72 weeks	
Follow-up from baseline	72 weeks	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 938 Intervention group/s: Tirzepatide 10 mg (n=312); Tirzepatide 15 mg (n=311) Comparator group: Placebo (n=315)	

Mean age ± SD	54.2y (10.6)
Sex	50.75% female
Pre-existing medical condition	Type 2 diabetes
Results	

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Body weight, kg Mean (SD)	Tirzepatide 10 mg: 100.9 (20.9) Tirzepatide 15 mg: 99.6 (20.1)	Placebo: 101.7 (22.3)
BMI Mean (SD)	Tirzepatide 10 mg: 36 (6.4) Tirzepatide 15 mg: 35.7 (6.1)	Placebo: 36.6 (7.3)
Waist circumference, cm Mean (SD)	Tirzepatide 10 mg: 114.2 (14.1) Tirzepatide 15 mg: 114.6 (13.1)	Placebo: 116 (15.7)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator
Participants with weight reduction ≥5% Proportion (%)	Tirzepatide 10 mg: 79.0% Tirzepatide 15 mg: 83.0%	Placebo: 102 (32%)
Participants with weight reduction ≥10% Proportion (%)	Tirzepatide 10 mg: 61.0% Tirzepatide 15 mg: 65.0%	Placebo: 30 (9%)
Participants with weight reduction ≥15% Proportion (%)	Tirzepatide 10 mg: 40.0% Tirzepatide 15 mg: 48.0%	Placebo: 8 (3%)
Participants with weight reduction ≥20% Proportion (%)	Tirzepatide 10 mg: 22.0% Tirzepatide 15 mg: 31.0%	Placebo: 3 (1%)
Participants with weight reduction ≥25% Proportion (%)	Tirzepatide 10 mg: 9.0% Tirzepatide 15 mg: 15.0%	Placebo: 1 (<1%)

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point

Variable	Intervention arm/s	Comparator
Percent change in weight, % Mean (SE)	Tirzepatide 10 mg: -12.8 (0.6) Tirzepatide 15 mg: -14.7 (0.5)	Placebo: -3.2 (0.5)
Change in waist circumference, cm Mean (SE)	Tirzepatide 10 mg: -10.8 (0.6) Tirzepatide 15 mg: -13.1 (0.5)	Placebo: -3.3 (0.5)
Mean change in BMI, kg/m2 Mean (SE)	Tirzepatide 10 mg: -4.7 (0.2) Tirzepatide 15 mg: -5.4 (0.2)	Placebo: -1.2 (0.2)

	Change in bodyweight, kg Mean (SE)	Tirzepatide 10 mg: -12.9 (0.6) Tirzepatide 15 mg: -14.8 (0.5)	Placebo: -3.2 (0.5)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Georgoulis, 2023

Guideline record ID: 12012--1

Study characteristics		
Citation	Georgoulis, M., Yiannakouris, N., Kechribari, I., Lamprou, K., Perraki, E., Vagiakis, E., & Kontogianni, M. D. (2023). Sustained improvements in the cardiometabolic profile of patients with obstructive sleep apnea after a weight-loss Mediterranean diet/lifestyle intervention: 12-month follow-up (6 months post-intervention) of the "MIMOSA" randomized clinical trial. Nutrition, Metabolism & Cardiovascular Diseases, 33(5), 1019-1028. https://doi.org/https://doi.org/10.1016/j.numecd.2023.02.010	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Sustained improvements in the cardiometabolic profile of patients with obstructive sleep apnea after a weight-loss Mediterranean diet/lifestyle intervention: 12-month follow-up (6 months post-intervention) of the "MIMOSA" randomized clinical trial	
Location	Greece	
Trial name	MIMOSA	
Methods		
Inclusion criteria	"The study population consisted of 180 adult males and females with overweight/obesity who visited the Center of Sleep Disorders of "Evangelismos" Hospital, Athens, Greece for clinical evaluation and sleep testing and were diagnosed with moderate/severe OSA [apnea-hypopnea index (AHI) 15events/h] based on an attended overnight in-hospital polysomnography."	
Exclusion criteria	"Patients with mild OSA (AHI <15 events/h), normal bodyweight [body mass index (BMI) <25kg/m2], other sleep disorders (e.g., central sleep apnea or chronic insomnia), other chronic diseases (e.g., diabetes mellitus, cardiovascular disease, chronic kidney disease, liver disease, psychiatric disease and cancer), and those who reported recent (within 6 months) changes in lifestyle habits (significant weight loss or change in habitual dietary intake, physical activity level and sleep pattern) were excluded."	
Setting	Hospital, Home	
Intervention	"For the first 6 months of the study, participants of all three study groups were prescribed with auto CPAP therapy to be used daily during night sleep as standard care. To evaluate compliance, CPAP use (h/d based on device memory data) was recorded by participants in self-monitoring print forms. Intervention arms participated in an intensive, dietitian-led behavioral intervention, which was structured in seven 1-h group counselling sessions and aimed at weight loss (5-10% of baseline bodyweight) and improving dietary habits according to the Mediterranean diet [15]. Participants in the MLG received additional counselling for physical activity [16] and optimal sleep duration [17],and were educated on sleep hygiene."	
Control/Comparator	"For the first 6 months of the study, participants of all three study groups were prescribed with auto CPAP therapy to be used daily during night sleep as standard care. To evaluate compliance, CPAP use (h/d based on device memory data) was recorded by participants in self-monitoring print forms. Additionally, the SCG was solely provided with brief written healthy lifestyle advice."	
Treatment duration	6 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 180
Intervention group/s: Mediterranean Diet Group (n=59); Mediterranean Lifestyle Group (n=59)

Comparator group: Standard Care Group (n=62)</td></tr>
<tr><td>Mean age ± SD</td><td>49y (10)</td></tr>
<tr><td>Sex</td><td>25.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Moderate/severe Obstructive Sleep Apnea [apnea-hypopnea index (AHI) 15 events/h].</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight, kg
Mean (SD)</td><td>Mediterranean Diet Group: 108
(24)
Mediterranean Lifestyle Group: 108
(20)</td><td>Standard Care Group: 111
(22)</td></tr>
<tr><td>BMI, kg/m2
Mean (SD)</td><td>Mediterranean Diet Group: 34.8
(5.9)
Mediterranean Lifestyle Group: 35.5
(5.6)</td><td>Standard Care Group: 35.8
(6.3)</td></tr>
<tr><td>Waist circumference, cm
Mean (SD)</td><td>Mediterranean Diet Group: 118
(17)
Mediterranean Lifestyle Group: 117
(14)</td><td>Standard Care Group: 118
(14)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight, kg
Mean (SD)</td><td>Mediterranean Diet Group: 100
(22)
Mediterranean Lifestyle Group: 99
(16)</td><td>Standard Care Group: 111
(20)</td></tr>
<tr><td>BMI, kg/m2
Mean (SD)</td><td>Mediterranean Diet Group: 32.4
(5.3)
Mediterranean Lifestyle Group: 32.4
(4.5)</td><td>Standard Care Group: 35.9
(6)</td></tr>
<tr><td>Waist circumference, cm
Mean (SD)</td><td>Mediterranean Diet Group: 112
(14)
Mediterranean Lifestyle Group: 112
(10)</td><td>Standard Care Group: 117
(16)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
</table>
</td></tr>
</table>

12 months or closest time point			
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported.		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Gepner, 2018

Guideline record ID: 10255--1

Study characteristics		
Citation	Gepner, Y., Shelef, I., Schwarzfuchs, D., Zelicha, H., Tene, L., Yaskolka Meir, A., Tsaban, G., Cohen, N., Bril, N., Rein, M., Serfaty, D., Kenigsbuch, S., Komy, O., Wolak, A., Chassidim, Y., Golan, R., Avni-Hassid, H., Bilitzky, A., Sarusi, B., . . . Shai, I. (2018). Effect of distinct lifestyle interventions on mobilization of fat storage pools: CENTRAL magnetic resonance imaging randomized controlled trial. Circulation, 137(11), 1143-1157. https://doi.org/https://dx.doi.org/10.1161/CIRCULATIONAHA.117.030501	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Distinct Lifestyle Interventions on Mobilization of Fat Storage Pools: CENTRAL Magnetic Resonance Imaging Randomized Controlled Trial	
Location	Israel	
Trial name	CENTRAL	
Methods		
Inclusion criteria	"Abdominal obesity was the main inclusion criteria (waist circumference [WC] >102 cm for men and >88 cm for women) or dyslipidemia (serum triglycerides >150 mg/dL and high-density-lipoprotein cholesterol [HDL-c] <40 mg/dL for men and <50 mg/dL for women)."	
Exclusion criteria	"Exclusion criteria were serum creatinine ≥2 mg/dL; impaired liver function (≥3-fold the upper level of alanine amino transferase and aspartate amino transferase); active cancer, pregnancy, or lactation; being physically active (>3 hoursper week) or unable to take part in PA; or participation in another trial."	
Setting	Workplace	
Intervention	"Both diets aimed for moderate, long-term weight loss with restricted intake of trans fats and refined carbohydrates and increased intake of vegetables. Lunch, typically the main meal in this population, was adjusted to the specific diet groups and was provided by the workplace cafeteria. The 18-month dietary intervention included a 90-minute nutritional session in the workplace with clinical dietitians every week during the first month, and every month thereafter, in equal format between the 2 dietary groups. The MED/LC diet combined the Med and LC diets described in our previous weight loss trial.33 The diet restricted carbohydrate intake to <40 g/day in the first 2 months (induction phase), and thereafter a gradual increase ≤70 g/day, and increased protein and fat intake, according to the MED diet. The MED/LC diet was rich in vegetables and legumes and low in red meat, with poultry and fish replacing beef and lamb. This group was also provided 28g of walnuts per day (160 Kcal/84% fat, mostly omega-3 α-linolenic acid) starting from the 3rd month. Starting after the first 6 months of dietary intervention, participants who were randomized to added PA received a free supervised gym membership for the following 12 months. The intervention included monthly 60-minute educational workshops and training group sessions at the gym directed by certified fitness instructors who were blinded to the assigned diets. The exercise program included 3 sessions per week of mostly aerobic training. In the first month, participants started with 20 minutes of aerobic training at 65% maximum heart rate and 10 minutes of resistance training. Exercise was gradually increased to 45 minutes of aerobic training at 80% of maximum heart rate and 15 minutes of resistance training. The resistance training increased from 1 set of weights with 60% of the maximum weight to 2 sets with 80% of the maximum weight and included leg extension, leg curl, elbow flexion, triceps extension, lateral pull-down, lower back extension, and bent leg sit-ups."	
Control/Comparator	"Both diets aimed for moderate, long-term weight loss with restricted intake of trans fats and refined carbohydrates and increased intake of vegetables. Lunch, typically the main	

<table>
<tr><td></td><td>meal in this population, was adjusted to the specific diet groups and was provided by the workplace cafeteria. The 18-month dietary intervention included a 90-minute nutritional session in the workplace with clinical dietitians every week during the first month, and every month thereafter, in equal format between the 2 dietary groups. For the LF diet, the aim was to limit total fat intake to 30% of calories, with ≤10% of saturated fat and ≤300 mg of cholesterol per day, and to increase dietary fiber. Participants were counseled to consume whole grains, vegetables, fruits, and legumes and to limit their consumption of additional fats, sweets, and high-fat snacks.”</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 259
Intervention group/s: MED/LC PA+ (n=66); MED/LC PA- (n=63); LF PA+ (n=63)

Comparator group: LF PA- (n=67)</td></tr>
<tr><td>Mean age ± SD</td><td>47.8y (9.3)</td></tr>
<tr><td>Sex</td><td>11.97% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in waist circumference Mean (SD)</td><td>MED/LC PA+: -5.2 (6.1)</td><td>LF PA-: -2.5 (6.5)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>86%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Gerards, 2015

Guideline record ID: 10256--1

Study characteristics		
Citation	Gerards, S. M. P. L., Dagnelie, P. C., Gubbels, J. S., van Buuren, S., Hamers, F. J. M., Jansen, M. W. J., van der Goot, O. H. M., de Vries, N. K., Sanders, M. R., & Kremers, S. P. J. (2015). The effectiveness of lifestyle triple P in the Netherlands: a randomized controlled trial. PLOS ONE, 10(4), e0122240. https://doi.org/https://dx.doi.org/10.1371/journal.pone.0122240	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The effectiveness of lifestyle triple P in the Netherlands: a randomized controlled trial	
Location	Netherlands	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligible participants were parent-child triads. Parents of children aged between 4 and 8 yearswere eligible for participation if their child was considered to be overweight or obese at inclu-sion, based on the BMI, using the international sex- and age-specific cut-off points proposedby Cole et al [19]. Furthermore, eligible parents were living in the southern part of Limburg,and were able to communicate in Dutch. Parents who agreed to participate and who bothsigned the informed consent form were included in the study."	
Exclusion criteria	Not reported	
Setting	Public health services	
Intervention	"Parents who were assigned to the intervention condition received the Lifestyle Triple P intervention, a 14-week intervention comprising ten 90-minute parental group sessions and four individual 15-30 minute telephone sessions. Both parents were invited to attend the group sessions. The intervention was delivered to parents-only. The group sessions took place at three different locations of the Public Health Services in South Limburg (Maastricht, Heerlen and Geleen). Per location, two intervention groups of parents were formed, the group size ranged from 5 to 10 parents. Lifestyle Triple P is an intervention strategy consisting of active skills training methods based on self-regulation principles. Parents were instructed on a range of nutrition, physical activity and positive parenting strategies. Individual telephone sessions provided parents individual support in implementing the strategies at home. The intervention was led by three different Lifestyle Triple P facilitators. These health professionals have been accredited after attending an official 3-day Triple P training course and an additional Lifestyle Triple P day. The intervention materials consisted of a parent workbook, a recipe book, and an active games booklet, all translated from English into Dutch for the current study, by Triple P International. The Lifestyle Triple P intervention was developed by the University of Queensland in Brisbane, Australia [21]. For a more detailed description of the intervention we refer to an earlier publication [18]."	
Control/Comparator	"Parents who were assigned to the control condition received two brochures (one on healthy nutrition and physical activity and one on positive parenting), as well as a short knowledge quiz via the Internet (sent via email) including tailored advice and suggestions for active exercises at home."	
Treatment duration	14 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 86
Intervention group/s: Lifestyle Triple P intervention (n=44)

Comparator group: Control condition (n=42)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 7.14 (1.55); Control: 7.29 (1.31)</td></tr>
<tr><td>Sex</td><td>55.81% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI z-score
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Lifestyle Triple P intervention:
1.82
(0.83)

Lifestyle Triple P intervention:
67.3
(8.37)</td><td>Control condition: 1.86
(0.74)

Control condition: 68.76
(8.68)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in BMI-z score from baseline to 12 months
Mean (SD)

Change in waist circumference from baseline to 12 months
Mean (SD)</td><td>Lifestyle Triple P intervention:
0.05
(0.26)

Lifestyle Triple P intervention:
3.88
(2.99)</td><td>Control condition: -0.08
(0.27)

Control condition: 3.44
(3.46)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Gessler, 2021

Guideline record ID: 10258--1

Study characteristics		
Citation	Gessler, N., Willems, S., Steven, D., Aberle, J., Akbulak, R. O., Gosau, N., Hoffmann, B. A., Meyer, C., Sultan, A., Tilz, R., Vogler, J., Wohlmuth, P., Scholz, S., Gunawardene, M. A., Eickholt, C., & Lüker, J. (2021). Supervised Obesity Reduction Trial for AF ablation patients: results from the SORT-AF trial. EP Europace, 23(10), 1548-1558. https://doi.org/10.1093/europace/euab122	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Supervised Obesity Reduction Trial for AF ablation patients: results from the SORT-AF trial	
Location	Germany	
Trial name	Supervised Obesity Reduction Trial for AF Ablation Patients (SORT-AF)	
Methods		
Inclusion criteria	"To be enrolled in the SORT-AF study, patients had to have symptomatic AF (paroxysmal or persistent AF) with indication for AF ablation and a body mass index (BMI) between 30 and 40."	
Exclusion criteria	"Main exclusion criteria were previous ablation therapy, longstanding persistent atrial fibrillation (continuous episodes >12 months), contraindication for anticoagulation, manifest hyperthyroidism or hypothyroidism, and diseases or conditions prohibiting physical activity."	
Setting	Hospital	
Intervention	"In addition to usual care, patients in group 1 were enrolled in a structured weight reduction programme with medical attendance twice a month, regular nutrition advice as well as assistance for physical training for the duration of 6 months, as recommended by current guidelines. A nutrition log which each patient kept for 2 months monitored patient's adherence to energy reduction. Details of nutrition advice included two steps: Healthy mix of food with reduction of energy of 500-800 kcal per day; and stabilization of weight: Lessons for healthy nutrition according to current guidelines. Physical training included 8 x 60min aquatraining and 8 x 60min cardio and weight training, with participants keeping an activity log for and learns to improve physical activity in everyday life. Psychosomatic treatment involved 8 x 90min cognitive behaviour therapy sessions (first individual, then the remainder in groups)"	
Control/Comparator	"Usual care without weight reduction program."	
Treatment duration	6 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 133 Intervention group/s: Intervention (n=67) Comparator group: Control (n=66)	
Mean age ± SD	60y (10)	
Sex	38.35% female	

<table>
<tr><td>Pre-existing medical condition</td><td>Symptomatic AF (paroxysmal or persistent AF) with indication for AF ablation</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 111
(18)

Intervention: 34.9
(2.6)</td><td>Control: 110
(17)

Control: 34.8
(3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 106
(16)

Intervention: 33.4
(3.6)</td><td>Control: 109
(18)

Control: 33.4
(3.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
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<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>With regard to group 1, non-compliance to intervention (structured weight reduction programme) was 19% at 3 months, 21% at 6 months, and 33% at 12 months of follow-up.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Gilcharan Singh, 2020

Guideline record ID: 10259--1

Study characteristics		
Citation	Gilcharan Singh, H. K., Chee, W. S. S., Hamdy, O., Mechanick, J. I., Lee, V. K. M., Barua, A., Mohd Ali, S. Z., & Hussein, Z. (2020). Eating self-efficacy changes in individuals with type 2 diabetes following a structured lifestyle intervention based on the transcultural Diabetes Nutrition Algorithm (tDNA): a secondary analysis of a randomized controlled trial. PLOS ONE, 15(11), e0242487. https://doi.org/https://dx.doi.org/10.1371/journal.pone.0242487	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Eating self-efficacy changes in individuals with type 2 diabetes following a structured lifestyle intervention based on the transcultural Diabetes Nutrition Algorithm (tDNA): A secondary analysis of a randomized controlled trial	
Location	Malaysia	
Trial name	N/A	
Methods		
Inclusion criteria	"Patients, aged 30-65 years, with body mass index (BMI) of >23 kg/m2, and A1C >7% were recruited. Eligible patients were not treated with insulin and had optimized pharmacotherapy for T2D management, with no changes in pharmacotherapy within the past 3 months prior to the study."	
Exclusion criteria	"We excluded patients who were pregnant, nursing, or with a history of serious illness or diabetes-related complications. Written informed consent was obtained from all patients before enrollment."	
Setting	GP clinic	
Intervention	"Patients who were randomized to receive tDNA care underwent initial risk stratification based on the Malaysian tDNA algorithm [7]. A structured low calorie meal plan of 1200 kcal/ day for female and 1500 kcal/day for male patients was prescribed using natural foods, with the incorporation of one or two servings of a diabetes-specific formula as meal replacements, (Glucerna SR, Abbott Nutrition, USA) as well as physical activity of >=150 min/week to create a deficit in the calorie intake and aid weight loss. Education about lifestyle modification was provided using a tDNA toolkit, consisting of a flip chart on healthy eating, 14-day meal plans, and culturally adapted information on physical activity and exercise. Patients were further randomized to receive either motivational interviewing (tDNA-MI) or conventional counseling (tDNA-CC) to promote adherence to the lifestyle recommendations. The MI counseling provided is a collaborative, patient-centered counseling style for eliciting behavior change by helping patients explore self-motivational statements towards positive behavior and resolve ambivalence by expressing empathy through reflective listening, avoiding argument and direct confrontation, developing discrepancy between patients' goals or values and their current behavior, adjusting to patient resistance, and supporting self-efficacy and optimism [38]. The conventional counseling was counselor-driven rather than patient-driven focusing on empathetic listening, education, persuasion, and encouragement [8]. Patients receiving tDNA care were followed-up monthly during the initial 6 months of intervention and subsequently every 3 months during the passive follow-up for a period of 6 months"	
Control/Comparator	"Patients randomized into UC group received care based on the Malaysian clinical practice guidelines for T2D [39]. A conventional low calorie diet plan of 1200 kcal/day for female and 1500 kcal/day for male patients was prescribed using normal foods, with standard diabetes support and lifestyle education to promote lifestyle change, calorie intake reduction, and aid weight loss. Patients were counseled by the dietitian based on individualized care using the similar conventional counseling technique to facilitate positive	

<table>
<tr><td></td><td>behavioral change toward weight loss. Patients receiving the UC were followed-up every 3 months throughout the one year study period.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 230
Intervention group/s: tDNA-MI (n=58); tDNA-CC (n=57)

Comparator group: UC (n=115)</td></tr>
<tr><td>Mean age ± SD</td><td>tDNA-MI: 54y (7); tDNA-CC: 53y (6); UC: 53y (6)</td></tr>
<tr><td>Sex</td><td>62.17% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes (T2D)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>tDNA-MI: 78.3
(20.9)
tDNA-CC: 74.6
(16)</td><td>UC: 75.8
(18.6)</td></tr>
<tr><td>Body mass index (kg/m2)
Mean (SD)</td><td>tDNA-MI: 30.7
(8.2)
tDNA-CC: 29.4
(7.3)</td><td>UC: 28.9
(6.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight
Mean (SE)</td><td>tDNA-MI: -4.8
(0.3)
tDNA-CC: -2.9
(0.3)</td><td>UC: -0.6
(0.2)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Gillison, 2015

Guideline record ID: 10260--1

Study characteristics		
Citation	Gillison, F., Stathi, A., Reddy, P., Perry, R., Taylor, G., Bennett, P., Dunbar, J., & Greaves, C. (2015). Processes of behavior change and weight loss in a theory-based weight loss intervention program: a test of the process model for lifestyle behavior change. International Journal of Behavioral Nutrition and Physical Activity, 12, 2. https://doi.org/https://dx.doi.org/10.1186/s12966-014-0160-6	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Processes of behavior change and weight loss in a theory-based weight loss intervention program: a test of the process model for lifestyle behavior change	
Location	England	
Trial name	Waste the Waist	
Methods		
Inclusion criteria	"People aged 40-74 with a body mass index (BMI) of 28 Kg/m2 - 45 Kg/m2 and with high cardiovascular risk. High cardiovascular risk was defined as any combination of a) a ten-year cardiovascular risk score of 20% or more (calculated from clinical data using either the Framingham or QRISK2 algorithm), b) impaired glucose regulation defined as either a 2-hour glucose of 7.8 to 11.0 mmol/l (Impaired Glucose Tolerance) or a fasting plasma glucose of 6.1 to 6.9 mmol/l (Impaired Fasting Glycaemia), c) having hypertension, hypercholesterolemia, family history of diabetes or heart disease, history of gestational diabetes, or polycystic ovary syndrome."	
Exclusion criteria	"People with existing heart disease or type 2 diabetes, people who were pregnant or currently using weight loss drugs, people not fluent in English, people with terminal illness and anyone who, in their General Practitioner's opinion, had other co-morbidities which would prevent engagement with the intervention."	
Setting	GP clinic, Hospital, Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The GGT DPP intervention was adapted for the local population through a systematic process of design and adaptation [28], resulting in the addition of 13 techniques and practical adjustments to reflect the needs of the patient population and local context [23]. New materials were developed for lifestyle coaches and participants to reflect the adaptations made. The intervention comprised a series of nine 2-hour long group sessions involving 8 to 12 participants, facilitated by a pair of lifestyle coaches. As social support has been demonstrated to be beneficial in facilitating weight loss [27], participants were invited to bring along a partner if they wished. Each session comprised a series of short sections to elicit and exchange ideas (e.g., about the importance of exercise, risks of excess weight, healthy eating etc.) using patient-centered counseling techniques [42]. Group activities were designed to teach key facts about diet and physical activity, in addition to the skills of action/coping planning, selfmonitoring and problem-solving. Early sessions focused on the skills and information required to adopt a new behavior, and later sessions introduced discussions more relevant to the maintenance of behavior, such as dealing with stress and challenging situations, and how to maintain motivation if weight loss 'plateaus'. Sessions also encouraged emotional self-regulation, and included a cognitive behavioral therapy technique for impulse control. The main focus of sessions was to equip participants with a better understanding of what a healthy lifestyle is and why it is important, to encourage them towards the continued use of self-regulatory activities (goal-setting, self-monitoring of behavior and weight, reviewing progress, problem-solving and review of goals) and to help them to better understand the process of behavior change over the long term. At the start and end of each session participants were reminded of the program's two key	

<table>
<tr><td></td><td>messages designed to encourage sustainable lifestyle change; (i) small changes can make a big difference to your weight and your health, and (ii) aim for a lifestyle that is both healthy and enjoyable (make changes that you can live with). Participants were provided with a handbook including information for reference, and were given "take away" tasks each week; these usually included implementing action plans set during session time”</td></tr>
<tr><td>Control/Comparator</td><td>“Usual care.”</td></tr>
<tr><td>Treatment duration</td><td>9 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 108
Intervention group/s: Intervention group (n=55)

Comparator group: Control group (n=53)</td></tr>
<tr><td>Mean age ± SD</td><td>65.2y (7.0)</td></tr>
<tr><td>Sex</td><td>33.33% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>Intervention group: 96.63 (13.96)</td><td>Control group: 97.57 (12.84)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>Intervention group: 92.98 (14.1)</td><td>Control group: 95.67 (12.39)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Greaves, C., Gillison, F., Stathi, A., Bennett, P., Reddy, P., Dunbar, J., Perry, R., Messom, D., Chandler, R., Francis, M., Davis, M., Green, C., Evans, P., & Taylor, G. (2015). Waste the waist: a pilot randomised controlled trial of a primary care based intervention to support lifestyle change in people with high cardiovascular risk. International Journal of Behavioral Nutrition and Physical Activity, 12, 1. https://doi.org/https://dx.doi.org/10.1186/s12966-014-0159-z</td></tr>
</table>

N/A – Not applicable

Glasgow, 2012

Guideline record ID: 10261--1

Study characteristics		
Citation	Glasgow, R. E., Kurz, D., King, D., Dickman, J. M., Faber, A. J., Halterman, E., Woolley, T., Toobert, D. J., Strycker, L. A., Estabrooks, P. A., Osuna, D., & Ritzwoller, D. (2012). Twelve-month outcomes of an Internet-based diabetes self-management support program. Patient Education and Counseling, 87(1), 81-92. https://doi.org/https://dx.doi.org/10.1016/j.pec.2011.07.024	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Twelve-month outcomes of an Internet-based diabetes self-management support program	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	“25-75 years of age, diagnosis of type 2 diabetes, body mass index (BMI) of 25 kg/m2 or greater, and at least one other risk factor for heart disease (e.g., hypertension, smoking, hyperlipidemia). Additional inclusion criteria were access to a telephone and at least biweekly access to the Internet, ability to read and write in English or Spanish, and ability to perform mild to moderate exercise. Participants were individually randomized via a computer program developed by our computer programmer and statistician.”	
Exclusion criteria	Not reported	
Setting	Home, unclear (an invitation to attend three group visits with other participants in the same study condition)	
Intervention	“CASM participants were given access to the ''My Path to Healthy Life''/''Mi Camino A La Vida Sana'' website and instructed in log-in, navigation, and usage procedures by a research staff member. Participants were asked to select initial, easily achievable goals in each of three areas: medication adherence, physical activity, and food choices. They recorded their progress on these three daily goals using the tracking section of the website and received immediate feedback on success in meeting their goals over the past 7 days. The website, described in detail elsewhere [28], included a graphic display of the patient's hemoglobin A1c, blood pressure, and cholesterol results; a moderated forum; and community resources (e.g., healthful recipes, printable handouts) for diabetes self-management and healthful lifestyles, as well as features to enhance user engagement, such as rotating quiz questions and motivational tips. After 6 weeks, participants created personalized ''action plans'' for medication taking, healthy eating, and physical activity. For each of the three areas, users identified barriers to achieving the goal(s) they had selected, and then chose from a list of problemsolving strategies to overcome those barriers [29]. Each user's action plan summary was available for easy reference and revision. In addition to the website, CASM participants received periodic motivational calls and prompting using a computer-based telephone system that initiated outbound calls, received inbound calls, and collected data. 2.1.2. CASM+ CASM+ participants received all aspects of the CASM intervention with the addition of two follow-up calls from an interventionist, and an invitation to attend three group visits with other participants in the same study condition. The two extra follow-up calls occurred 2 and 8 weeks after the initial visit to answer any intervention-related questions and troubleshoot problems with the website or self-management goals, and to discuss the participant's action plans, respectively. The first call was from a research project staff member and the second call to coordinate with the patients more general diabetes management goals was from a KPCO diabetes care coordinator. The 120-min group sessions focused on (1) healthy eating, interacting with one's physician and using community resources and (2) maintenance enhancement through the use of analyzing personal behavior chains related to relapse [30]. The first group session for CASM+	

<table>
<tr><td></td><td>participants, scheduled after their action plans were created, focused on healthful eating, and was led by a nutritionist. The meeting included information on healthful restaurant eating behaviors and grocery shopping tips. The second group visit was designed to supplement the Behavior Chain exercise introduced to enhance maintenance of the CASM+ intervention. The Behavior Chain Activity was designed to help participants understand that lapses in healthful eating, physical activity, and medication-taking practices usually result from a chain of behaviors leading up to the lapse. The Behavior Chain links may be thought of as high-risk situations in which unhealthful behaviors may be substituted for healthful ones. To prevent future lapses, the activity was designed to help participants identify their links, and then develop strategies for each link in their own Behavior Chain. The third group meeting was led by a bilingual family physician to educate participants about community diabetes resources and how to obtain maximum benefit from their doctor visits."</td></tr>
<tr><td>Control/Comparator</td><td>"EUC provided computer-based health risk appraisal feedback and recommended preventive care behaviors using the same contact schedule as the CASM conditions, but did not include the key intervention procedures."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 463
Intervention group/s: CASM (n=169); CASM+ (n=162)

Comparator group: EUC (n=132)</td></tr>
<tr><td>Mean age ± SD</td><td>58.4y (9.2)</td></tr>
<tr><td>Sex</td><td>49.89% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes mellitus and at least one other risk factor for heart disease (e.g., hypertension, smoking, hyperlipidemia)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SE)</td><td>CASM: 34.4
(0.5)
CASM+: 35.3
(0.5)</td><td>EUC: 34.8
(0.6)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SE)</td><td>CASM: 34.2
(0.5)
CASM+: 35.1
(0.6)</td><td>EUC: 34.9
(0.6)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Glaysher, 2021

Guideline record ID: 10262--1

Study characteristics		
Citation	Glaysher, M. A., Ward, J., Aldhwayan, M., Ruban, A., Prechtl, C. G., Fisk, H. L., Chhina, N., Al-Najim, W., Smith, C., Klimowska-Nassar, N., Johnson, N., Falaschetti, E., Goldstone, A. P., Miras, A. D., Byrne, J. P., Calder, P. C., & Teare, J. P. (2021). The effect of a duodenal-jejunal bypass liner on lipid profile and blood concentrations of long chain polyunsaturated fatty acids. Clinical Nutrition, 40(4), 2343-2354. https://doi.org/https://dx.doi.org/10.1016/j.clnu.2020.10.026	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The effect of a duodenal-jejunal bypass liner on lipid profile and blood concentrations of long chain polyunsaturated fatty acids	
Location	UK	
Trial name	EndoBarrier	
Methods		
Inclusion criteria	"Male and female patients, aged 18e65 years with a BMI 30e50 kg/m2 and a confirmed diagnosis of T2DM for at least 1 year, who had inadequate glycaemic control and were on oral anti-hyperglycaemic medications."	
Exclusion criteria	Not reported	
Setting	Hospital, University/research centre	
Intervention	"At visit 4 (0 weeks), participants who had been randomised to receive the EndoBarrier device had it endoscopically implanted under a general anaesthetic. The nickel titanium alloy anchor was deployed in the first part of the duodenum and the 60 cm impermeable, highly-flexible fluoropolymer sleeve was unfurled under fluoroscopic guidance. The implant is open at both ends to allow for passage of undigested chyme from the stomach into the midjejunum and prohibits nutrient absorption along its length by creating a barrier between the partially digested food and the absorptive surface of the small intestine. The Endobarrier was implanted for 12 months but is completely reversible and so could be removed at any time. If relevant, subjects had their dose of sulphonylurea medication reduced by 50% at the time of EndoBarrier implant to avoid potential hypoglycaemic episodes and all patients in the Endobarrier group were prescribed a proton pump inhibitor (PPI; Omeprazole 40 mg twice daily). The device was removed at visit 11 (12 months) under sedation or general anaesthetic and participants were followed up for a further 12 months. all patients across both groups were prescribed a liquid diet for the 7 days before and 13 days after the intervention visit (visit 4). The liquid diet was guided by a specialist dietitian and comprised of 125 mL Fortisip Compact drinks (Nutricia, UK): 5 per day for males, 4 per day for females, containing per 100 mL: 240 kcal, 9.6 g protein (16% total energy), 29.7 g carbohydrate (49% total energy), 15 g sugars, 9.3 g fat (35% total energy; 2.7 g of PUFAs). Patients were also allowed to consume sugarfree squashes, smooth/clear soup (1 medium bowl per day), tea or coffee without sugar, or unsweetened puree. All patients were regularly reviewed by a specialist dietitian. Participants were recommended to consume between 1200 and 1500 kcal each day for women and between 1500 and 1800 kcal for men. In accordance with standard dietary practice, participants were advised: to eat 5 meals per day; to control their portion sizes and intake of carbohydrates/starchy foods; to increase their intake of low glycaemic index and high protein foods, as well as vegetables; and to reduce their intake of alcohol and of foods high in fat and sugar. Participants were advised to include 150 min per week of moderate intensity and 75 min per week of vigorous intensity aerobic activity and muscle strengthening activities on more than 2 days a week."	

<table>
<tr><td>Control/Comparator</td><td>“All patients across both groups were prescribed a liquid diet for the 7 days before and 13 days after the intervention visit (visit 4). The liquid diet was guided by a specialist dietitian and comprised of 125 mL Fortisip Compact drinks (Nutricia, UK): 5 per day for males, 4 per day for females, containing per 100 mL: 240 kcal, 9.6 g protein (16% total energy), 29.7 g carbohydrate (49% total energy), 15 g sugars, 9.3 g fat (35% total energy; 2.7 g of PUFAs). Patients were also allowed to consume sugarfree squashes, smooth/clear soup (1 medium bowl per day), tea or coffee without sugar, or unsweetened puree. All patients were regularly reviewed by a specialist dietitian and participants in the control arm of the trial had an additional review by the dietitian in place of the DJBL implantation and removal. Participants were recommended to consume between 1200 and 1500 kcal each day for women and between 1500 and 1800 kcal for men. In accordance with standard dietary practice, participants were advised: to eat 5 meals per day; to control their portion sizes and intake of carbohydrates/starchy foods; to increase their intake of low glycaemic index and high protein foods, as well as vegetables; and to reduce their intake of alcohol and of foods high in fat and sugar. Participants were advised to include 150 min per week of moderate intensity and 75 min per week of vigorous intensity aerobic activity and muscle strengthening activities on more than 2 days a week.”</td></tr>
<tr><td>Treatment duration</td><td>11.5 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 140
Intervention group/s: Endobarrier (n=70)

Comparator group: Control (n=70)</td></tr>
<tr><td>Mean age ± SD</td><td>Endobarrier: 51.6y (7.8); Control: 52.3y (8.3)</td></tr>
<tr><td>Sex</td><td>45.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Confirmed diagnosis of T2DM for at least 1 year, who had inadequate glycaemic control and were on oral anti-hyperglycaemic medications</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Endobarrier: 107.8
(17.1)

Endobarrier: 37
(5)</td><td>Control: 103.6
(13.9)

Control: 35.4
(3.7)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Endobarrier: 94.9
(14.9)

Endobarrier: 32.7
(4.3)</td><td>Control: 97.2
(14.6)

Control: 33.3
(4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Total body weight loss (kg)
Mean (SD)</td><td>Endobarrier: -12.2
(6.6)</td><td>Control: -6.2
(6.3)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>12 months or closest time point</td><td><table><tr><td>Total body weight loss (%)
Mean (SD)</td><td>Endobarrier: -11.3
(5.3)</td><td>Control: -6
(5.7)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Gómez, 2016

Guideline record ID: 10264--1

Study characteristics		
Citation	Gómez, V., Woodman, G., & Abu Dayyeh, B. K. (2016). Delayed gastric emptying as a proposed mechanism of action during intragastric balloon therapy: results of a prospective study. Obesity, 24(9), 1849-1853. https://doi.org/https://doi.org/10.1002/oby.21555	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Delayed gastric emptying as a proposed mechanism of action during intragastric balloon therapy: Results of a prospective study	
Location	USA	
Trial name	IB-005	
Methods		
Inclusion criteria	"Eligible subjects were adults (ages 18-65), with BMI of ≥30 and ≤40 kg/m2 and a history of obesity for at least 2 years with failed conservative weight loss attempts, such as supervised diet, exercise, and behavioral modification programs."	
Exclusion criteria	"Exclusion criteria included history of foregut or gastrointestinal surgery, gastrointestinal obstruction, large hiatal hernia, history of esophageal or gastric motility disorder, inflammatory bowel disease, a positive blood test for Helicobacter pylori at screening, allergies to egg/strawberry/gluten (food products in the scintigraphy meal), pregnancy, and inability to provide informed consent."	
Setting	Hospital	
Intervention	"Participants were randomly assigned to placement of the Orbera IGB (Apollo Endosurgery, Austin, TX) for 6 months in addition to a lifestyle intervention program (LIP) for 12 months. Placement of the IGB was performed in an ambulatory endoscopy suite under general anesthesia. The deflated Orbera IGB preloaded on a catheter was advanced transorally into the stomach under endoscopic guidance. Once in the stomach the balloon was filled with 550 mL of saline solution through an external portion of the catheter. Once inflated, the catheter and gastroscope were removed. The IGB remained in place for 6 months. Removal was performed endoscopically, under anesthesia, by puncturing the balloon with a needle cannula and withdrawing the saline, then grasping and extracting the collapsed device through the mouth. Post-IGB placement, subjects were instructed to remain on a full liquid diet for the first week, then advance to pureed foods the second week, and then introduce regular-consistency foods the third week. The LIP incorporated the following elements: a low-calorie (1,000-1,500 calories/day) diet, daily food and exercise diary, nutritionally balanced eating plan, encouragement to exercise, and emphasis on behavioral change during a total of 21 visits (9 visits in months 1-6, 12 visits in months 7-12) over the 1-year study."	
Control/Comparator	"Participants were randomly assigned to lifestyle intervention program (LIP) alone for 12 months The LIP incorporated the following elements: a low-calorie (1,000-1,500 calories/day) diet, daily food and exercise diary, nutritionally balanced eating plan, encouragement to exercise, and emphasis on behavioral change during a total of 21 visits (9 visits in months 1-6, 12 visits in months 7-12) over the 1-year study."	
Treatment duration	Intervention: 18 months; Control: 12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 29
Intervention group/s: IGB (n=15)

Comparator group: Control (n=14)</td></tr>
<tr><td>Mean age ± SD</td><td>IGB: 38.1y (8.8); Control: 38.2y (8.78)</td></tr>
<tr><td>Sex</td><td>89.66% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Weight (lbs)
Mean (SD)</td><td>IGB: 34.7
(3.42)

IGB: 216.3
(39.4)</td><td>Control: 35.6
(2.84)

Control: 222.6
(23.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Total body weight loss (%)
Mean (SD)</td><td>IGB: -10.6
(7.9)</td><td>Control: -3.3
(5)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Gomez-Marcos, 2018

Guideline record ID: 10265--1

Study characteristics		
Citation	Gomez-Marcos, M. A., Patino-Alonso, M. C., Recio-Rodriguez, J. I., Agudo-Conde, C., Romaguera-Bosch, M., Magdalena-Gonzalez, O., Gomez-Arranz, A., Mendizabal-Gallastegui, N., Angel Fernandez-Diez, J., Gomez-Sanchez, L., Maderuelo-Fernandez, J. A., Rodriguez-Sanchez, E., Garcia-Ortiz, L., & on behalf the EVIDENT Investigators. (2018). Short- and long-term effectiveness of a smartphone application for improving measures of adiposity: a randomised clinical trial - EVIDENT II study. European Journal of Cardiovascular Nursing, 17(6), 552-562. https://doi.org/https://dx.doi.org/10.1177/1474515118761870	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Short- and long-term effectiveness of a smartphone application for improving measures of adiposity: A randomised clinical trial - EVIDENT II study	
Location	Spain	
Trial name	EVIDENT II	
Methods		
Inclusion criteria	"Those aged between 18 and 70 years who did not meet any exclusion criteria and who provided informed consent were included in this study."	
Exclusion criteria	"Exclusion criteria included being over 70 years of age, being unable to exercise or follow the heart-healthy diet or meeting any of the exclusion criteria of the EVIDENT I project (known coronary or cerebrovascular atherosclerotic disease; heart failure; moderate or severe chronic obstructive pulmonary disease; musculoskeletal disease that limited walking; advanced respiratory, renal or hepatic disease; severe mental disease; or oncological disease treated or diagnosed in the last 5 years)."	
Setting	GP clinic, Home	
Intervention	"Counselling on nutrition and PA. All subjects received an individual 30-minute counselling session in which a nurse provided standardised advice on PA and the benefits of the Mediterranean diet (15 minutes each). In order to make the intervention more effective, they also received an information brochure to take home.25,26 PA counselling consisted of an individual 15-minute visit during which the beneficial effects of PA on health were explained. Patients were encouraged to engage in at least 30 minutes of moderate activity 5 days a week, or 20 minutes of vigorous activity 3 days a week, or walking at least 10,000 steps a day. The first part of the PA counselling focused on the benefits of physical exercise on cardiovascular health, while the intensities of different types of PA were explained during the second part. The last part was dedicated to answering questions and clarifying doubts. Nutrition counselling consisted of an individual 15-minute visit that provided nutritional advice focused on improving adherence to the Mediterranean diet. In the first part, the general idea behind the Mediterranean diet was explained. The second part of the session focused on explaining the basic nutrient groups and their differences using brief and clear messages. The last part of the interview was dedicated to answering questions and clarifying doubts. Specific intervention with the app. IG participants (advice plus app) were lent a smartphone for 3 months. A researcher trained the participants in the use of the app designed to promote the Mediterranean diet and increase PA. In the initial visit, they were trained for 15 minutes on use of the app, which they would be using daily for the next 3 months. Subjects were instructed on how to correctly record their daily food intake (breakfast, lunch, afternoon snack and dinner) and any PA performed without the mobile phone. One week after the device was delivered, a separate visit took place to confirm that the app was being used correctly and to clarify emerging doubts about its use. The smartphone was returned at the 3-month follow-up visit, which was common to both groups. The smartphone app was designed by software engineers in collaboration with	

<table>
<tr><td></td><td>dieticians and PA experts. It has a simple and user-friendly interface for daily recording of both portions of food eaten and PA performed. The user's portion logs were used by the app, which applies standardised criteria to assess the quantity and quality of the food eaten each day. The app generated a detailed report on the composition of the diet and the calories consumed. PA was recorded by a pedometer included in the smartphone application. The app analysed activity logged by the subject that took place when the device could not be used (e.g. swimming) and generated an additional report on all PA performed. After a daily analysis, the app generated a plan of recommendations for the following days with the aim of improving eating habits and increasing the PA so as to reach the target of 10,000 steps per day."</td></tr>
<tr><td>Control/Comparator</td><td>"Counselling on nutrition and PA. All subjects received an individual 30-minute counselling session in which a nurse provided standardised advice on PA and the benefits of the Mediterranean diet (15 minutes each). In order to make the intervention more effective, they also received an information brochure to take home.25,26 PA counselling consisted of an individual 15-minute visit during which the beneficial effects of PA on health were explained. Patients were encouraged to engage in at least 30 minutes of moderate activity 5 days a week, or 20 minutes of vigorous activity 3 days a week, or walking at least 10,000 steps a day. The first part of the PA counselling focused on the benefits of physical exercise on cardiovascular health, while the intensities of different types of PA were explained during the second part. The last part was dedicated to answering questions and clarifying doubts. Nutrition counselling consisted of an individual 15-minute visit that provided nutritional advice focused on improving adherence to the Mediterranean diet. In the first part, the general idea behind the Mediterranean diet was explained. The second part of the session focused on explaining the basic nutrient groups and their differences using brief and clear messages. The last part of the interview was dedicated to answering questions and clarifying doubts."</td></tr>
<tr><td>Treatment duration</td><td>3 months</td></tr>
<tr><td>Follow-up from baseline</td><td>15 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 833
Intervention group/s: Counselling + app (n=415)

Comparator group: counselling only (n=418)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention (counselling + app): 51.44y (12.11); Control (counselling only): 52.33 (12.00)</td></tr>
<tr><td>Sex</td><td>62.06% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Counselling + app: 28.1
(5.1)

Counselling + app: 95.1
(12.9)</td><td>Counselling only: 27.6
(4.6)

Counselling only: 94.7
(12.6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in BMI (kg/m2)
Mean (95% CIs)

Change in waist circumference (cm)
Mean (95% CIs)</td><td>Counselling + app: 0.082
(-0.06-0.224)

Counselling + app: -0.718
(-2.35--0.017)</td><td>Counselling only: 0.145
(0.008-0.282)

Counselling only: 0.025
(-0.05-0.055)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Gómez-Pardo, 2016

Guideline record ID: 10266--1

Study characteristics		
Citation	Gómez-Pardo, E., Fernández-Alvira, J. M., Vilanova, M., Haro, D., Martínez, R., Carvajal, I., Carral, V., Rodríguez, C., de Miguel, M., Bodega, P., Santos-Beneit, G., Peñalvo, J. L., Marina, I., Pérez-Farinós, N., Dal Re, M., Villar, C., Robledo, T., Vedanthan, R., Bansilal, S., & Fuster, V. (2016). A comprehensive lifestyle peer group-based intervention on cardiovascular risk factors: the randomized controlled Fifty-Fifty Program. Journal of the American College of Cardiology, 67(5), 476-485. https://doi.org/10.1016/j.jacc.2015.10.033	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A Comprehensive Lifestyle Peer Group-Based Intervention on Cardiovascular Risk Factors: The Randomized Controlled Fifty-Fifty Program	
Location	Spain	
Trial name	Fifty-Fifty Study	
Methods		
Inclusion criteria	"Eligible participants were 25 to 50 years of age with at least 1 of the following risk factors: hypertension (blood pressure [BP] $140/90 mm Hg or receiving treatment), overweight or obese (body mass index $25 kg/m2), smoking, or physical inactivity (<=150 min/week)."	
Exclusion criteria	Not reported	
Setting	Multicenter	
Intervention	"Enrolled participants were entered in a run-in training period consisting of 6 workshops on core lifestyle and risk factor education related to: motivation to change, physical activity, healthful diet, smoking cessation, stress management, and self-control of BP. Once this process was completed, participants were randomized 1:1 to a peer-based intervention versus self-management, stratified according to sex. Intervention participants were randomly assigned to small PGs composed of approximately 10 subjects, 2 of whom were selected to be peer educators or leaders (22). Health and psychology professionals led each group through a group dynamics education session, aimed at assessing group members for leadership, availability for the peer educator role, and clear understanding of the intervention. Each peer educator attended a 3-h session on relevant health and health promotion information, leadership, and communication skills. A holistic approach was used, including physical, nutritional, and psychological aspects of lifestyle change, aimed at improving the associated risk factors (11,23). Armed with these skills, the peer educators then engaged their peers in conversations about the issues of concern, seeking to promote health-enhancing knowledge and skills (24). The goal was for each group to identify potential barriers and determinants of lifestyle improvement and subsequently take actions to reduce their CVD risk. Additional midterm training was provided to reinforce the group and increase adherence (25). This training consisted of a 3-h motivational session led by the psychologist for refreshing peer supporters on their skills and allowing the sharing of learned concepts (26) (Table 1). PG meetings were held on a monthly basis, and each meeting lasted 60 to 90 min. During the monthly meetings, each participant explained the improvements in healthy habits and difficulties during the last month; group leaders and participants were supposed to support, encourage, and help. Each leader monitored the progress of the group members. The activities involved in the group dynamics included, of their own choice, group discussions, roleplaying, brainstorming, relaxation techniques, menu design, joint sporting activities, and others. At each meeting, participants addressed emotion management, problem resolution, relapse prevention, diet control, and physical activity engagement. Through these reflections, participants proposed achievable goals that would improve their lifestyle. To promote management of risk factors, members of the IG were provided with a health handbook containing information on evidence-based	

<table>
<tr><td></td><td>prevention; these handbooks were also to be used for recording the participants' lifestyle behavior, health parameters, and immediate goals at each meeting (27,28).”</td></tr>
<tr><td>Control/Comparator</td><td>“Enrolled participants were entered in a run-in training period consisting of 6 workshops on core lifestyle and risk factor education related to: motivation to change, physical activity, healthful diet, smoking cessation, stress management, and self-control of BP. Once this process was completed, participants were randomized 1:1 to a peer-based intervention versus self-management, stratified according to sex. The control group (CG) went through these initial 6 workshops only, and no further support was organized during the intervention.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 543
Intervention group/s: Intervention group (n=266)

Comparator group: Control group (n=277)</td></tr>
<tr><td>Mean age ± SD</td><td>42y (6)</td></tr>
<tr><td>Sex</td><td>71.27% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (95% CIs)

Waist circumference (cm)
Mean (95% CIs)</td><td>Intervention group: 30.5
(29.7-31.2)

Intervention group: 100.7
(97.8-103.6)</td><td>Control group: 29.9
(29-30.7)

Control group: 99.2
(96.2-102.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (95% CIs)

Waist circumference (cm)
Mean (95% CIs)</td><td>Intervention group: 30.2
(29.4-31)

Intervention group: 99.7
(95.9-103.5)</td><td>Control group: 29.8
(28.9-30.7)

Control group: 98.8
(95-102.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>To assess a potential dose-response effect of the PG intervention and of the total program, differences in FBS between participants attending >=7 PG sessions (high adherence) versus</td></tr>
</table>

	participants attending <7 PG sessions (low adherence) were also explored (n = 251). High adherence: n = 128; Low adherence; n = 123.
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Gong, 2014

Guideline record ID: 10267--1

Study characteristics		
Citation	Gong, L., Yuan, F., Teng, J., Li, X., Zheng, S., Lin, L., Deng, H., Ma, G., Sun, C., & Li, Y. (2014). Weight loss, inflammatory markers, and improvements of iron status in overweight and obese children. The Journal of Pediatrics, 164(4), 795-800.e792. https://doi.org/https://dx.doi.org/10.1016/j.jpeds.2013.12.004	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight loss, inflammatory markers, and improvements of iron status in overweight and obese children	
Location	China	
Trial name	Nutrition-based comprehensive intervention study on childhood obesity (NISCOC)	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	School	
Intervention	“Four components of intervention: physical activity (One physical activity training class for teachers, Under the guidance of trained teachers, children participated in the "Happy 10" campaign,* which consisted either of 2 times/day with 10 min of physical activity/time or of 1 time/day with 20 min of physical activity/time. This campaign also encouraged after-school physical activities.); nutrition education (Four lectures about nutrition and health for teachers, One class per month (8 times/year) with organized essay competitions on nutrition and nutrition-knowledge contests, Ten classes about the relationship between nutrition, physical activity, and health. These 40-min classes were held on a monthly basis. Children were provided with nutrition handbooks); food service personnel (Four lectures about nutrition, Cooking oil consumption was reduced by decreasing the preparation of fried foods. Additionally, school meals were frequently monitored by nutritionists); parents (Three lectures about nutrition and health. Parents were provided with nutrition brochures, Parents were provided with a limited amount of cooking oil.)”	
Control/Comparator	“Children in the control group received no intervention.”	
Treatment duration	1 year	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 326 Intervention group/s: Intervention (n=160) Comparator group: Control (n=166)	
Mean age ± SD	Intervention: 8.8y (1.3); Control: 8.9y (1.3)	
Sex	34.97% female	
Pre-existing medical condition	No pre-existing medical condition	

<table>
<tr><td>Results</td><td></td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Body mass index-for-age z-scores
Mean (SD)</td><td>Intervention: 40.8
(8.9)

Intervention: 69.6
(8.8)

Intervention: 21.5
(2.6)

Intervention: 2
(1.1)</td><td>Control: 41.7
(8.3)

Control: 70.2
(9.6)

Control: 21.7
(2.6)

Control: 2
(1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Body mass index-for-age z-scores
Mean (SD)</td><td>Intervention: 45.5
(9.1)

Intervention: 72.6
(9.7)

Intervention: 21.9
(2.5)

Intervention: 1.6
(0.9)</td><td>Control: 47.6
(9.4)

Control: 74.2
(10.4)

Control: 22.6
(2.8)

Control: 2
(1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)

Change in waist circumference (cm)
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)

Change in Body mass index-for-age z-scores
Mean (SD)</td><td>Intervention: 4.7
(3.4)

Intervention: 3
(5.2)

Intervention: 0.4
(1.6)

Intervention: -0.4
(0.7)</td><td>Control: 5.9
(3.3)

Control: 4
(5.2)

Control: 0.9
(1.5)

Control: -0.1
(0.6)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Goodwin, 2014

Guideline record ID: 10269--1

Study characteristics		
Citation	Goodwin, P. J., Segal, R. J., Vallis, M., Ligibel, J. A., Pond, G. R., Robidoux, A., Blackburn, G. L., Findlay, B., Gralow, J. R., Mukherjee, S., Levine, M., & Pritchard, K. I. (2014). Randomized trial of a telephone-based weight loss intervention in postmenopausal women with breast cancer receiving letrozole: the LISA Trial. Journal of Clinical Oncology, 32(21), 2231-2239. https://doi.org/10.1200/JCO.2013.53.1517	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Randomized Trial of a Telephone-Based Weight Loss Intervention in Postmenopausal Women With Breast Cancer Receiving Letrozole: The LISA Trial	
Location	Canada	
Trial name	Lifestyle Intervention in Adjuvant Treatment of Early Breast Cancer (LISA)	
Methods		
Inclusion criteria	"Postmenopausal women diagnosed with T1-3N0-3M0 breast cancer during the previous 36 months who had received definitive surgery, were currently receiving letrozole, and had a body mass index (BMI) 24 to 40 kg/m2 were eligible. After June 2008, women with BMI more than 40 kg/m2 were included, and those with N3 disease were excluded. Chemotherapy (if given) must have been completed 4 weeks previously. Participants were required to be fluent in English or French."	
Exclusion criteria	"Women with a life expectancy of less than 5 years, self-reported inability to walk two or more blocks, insulin requiring diabetes, medical comorbidity that precluded com pliance with the intervention, serious psychiatric disorders, recurrence of breast cancer (locoregional or distant), or history of other invasive cancers were ineligible."	
Setting	Home	
Intervention	"Both study arms received mailed information on healthy living obtained from public sources (Canadian Cancer Society, Health Canada, and similar organizations) at random assignment and at 1 year. The content addressed healthy diets, physical activity, breast cancer, compliance with therapy, osteoporosis, and other general medical issues. Women also received a 2-year subscription to the Canadian Health Magazine, vetted by the Canadian Medical Association. Women allocated to the individual lifestyle intervention (LI) arm also participated in a 2-year telephone-based intervention patterned on the DPP. Goals included 10% weight loss (1 to 2 lbs per week) to a BMI not less than 21 kg/m2 ; calorie reduction to attain a 500 to 1,000 kcal daily deficit, with initial recommended daily intake of 1,250, 1,500, or 1,750 kcal and reduction infat to approximately 20% of calories and increased intake of fruits, vegetables, and grains; a gradual increase in moderate-intensity aerobic physical activity (walking for the majority of participants) to 150 to 200 minutes per week; and behavioral change-motivation, relapse prevention, reducing emotional distress, time management, and overcoming barriers.Participants received a workbook that provided detailed information regarding each call. Calls lasted 30 to 60 minutes and were scripted, semistructured, and standardized; they involved a review of progress and problems since the previous call and setting of goals (diet, activity, behavioral) to be addressed before the next call. Lifestyle coaches individualized the intervention as necessary and highlighted problem solving and motivation."	
Control/Comparator	"Both study arms received mailed information on healthy living obtained from public sources (Canadian Cancer Society, Health Canada, and similar organizations) at random assignment and at 1 year. The content addressed healthy diets, physical activity, breast cancer, compliance with therapy, osteoporosis, and other general medical issues. Women	

<table>
<tr><td></td><td>also received a 2-year subscription to the Canadian Health Magazine, vetted by the Canadian Medical Association.”</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 338
Intervention group/s: Individualised lifestyle intervention (n=171)

Comparator group: Mail-based intervention (n=167)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 61.6y (6.7); Control: 60.4y (7.8)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>T1-3N0-3M0 breast cancer during the previous 36 months</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Individualised lifestyle intervention: 82.7 (15.3)</td><td>Mail-based intervention: 81.2 (14.5)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Individualised lifestyle intervention: 31.4 (5)</td><td>Mail-based intervention: 31.1 (5.3)</td></tr>
<tr><td>BMI (kg/m2)
Median (range)</td><td>Individualised lifestyle intervention: 30.7 (24-60.7)</td><td>Mail-based intervention: 30.4 (24-55.2)</td></tr>
<tr><td>BMI 24 to <30kg/m2
Mean (SD)</td><td>Individualised lifestyle intervention: 72.3 (6.4)</td><td>Mail-based intervention: 71 (6.4)</td></tr>
<tr><td>BMI ≥30kg/m2
Mean (SD)</td><td>Individualised lifestyle intervention: 90.4 (15.4)</td><td>Mail-based intervention: 89.7 (13.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)</td><td>Individualised lifestyle intervention: -4.5 (5.4)</td><td>Mail-based intervention: -0.6 (5.7)</td></tr>
<tr><td>Change in weight (%)
Mean (SD)</td><td>Individualised lifestyle intervention: -5.5 (6.4)</td><td>Mail-based intervention: -0.7 (6.6)

Mail-based intervention: 0</td></tr>
</table>
</td></tr>
</table>

	Change in BMI 24 to <30kg/m2 Mean (SD) Change in BMI 24 to <30kg/m2 (%) Mean (SD) Change in BMI ≥30kg/m2 Mean (SD) Change in BMI ≥30kg/m2 (%) Mean (SD)	Individualised lifestyle intervention: -3.6 (4.6) Individualised lifestyle intervention: -5 (6.3) Individualised lifestyle intervention: -5.3 (5.8) Individualised lifestyle intervention: -5.9 (6.5)	(3.5) Mail-based intervention: 0 (5) Mail-based intervention: -1.2 (7.1) Mail-based intervention: -1.4 (7.8)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in weight (kg) Mean (SD) Change in weight (%) Mean (SD) Change in BMI 24 to <30kg/m2 Mean (SD) Change in BMI 24 to <30kg/m2 (%) Mean (SD) Change in BMI ≥30kg/m2 Mean (SD) Change in BMI ≥30kg/m2 (%) Mean (SD)	Individualised lifestyle intervention: -3.1 (6.2) Individualised lifestyle intervention: -3.6 (7.7) Individualised lifestyle intervention: -1.5 (6.1) Individualised lifestyle intervention: -2 (8.6) Individualised lifestyle intervention: -4.3 (6) Individualised lifestyle intervention: -5 (6.6)	Mail-based intervention: -0.3 (5.3) Mail-based intervention: -0.4 (6.4) Mail-based intervention: -0.4 (4.6) Mail-based intervention: -0.6 (6.3) Mail-based intervention: -0.2 (5.9) Mail-based intervention: -0.3 (6.7)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Gorin, 2013

Guideline record ID: 10270--1

Study characteristics		
Citation	Gorin, A. A., Raynor, H. A., Fava, J., Maguire, K., Robichaud, E., Trautvetter, J., Crane, M., & Wing, R. R. (2013). Randomized controlled trial of a comprehensive home environment-focused weight-loss program for adults. Health Psychology, 32(2), 128-137. https://doi.org/https://dx.doi.org/10.1037/a0026959	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Randomized controlled trial of a comprehensive home environment-focused weight-loss program for adults	
Location	USA	
Trial name	Lifestyle Eating and Activity Program (LEAP)	
Methods		
Inclusion criteria	"To be eligible, individuals had to be between 21 and 70 years old, have abody mass index (BMI) between 25 and 50 kg/m2, and have ahousehold member willing to participate in the study as a supportpartner. These partners had to reside in the same home as the partic-ipant, be between 15 and 70 years old, have a BMI between 25 and50 kg/m2, and be interested in weight loss. With the exception of thelower age limit, the same inclusion and exclusion criteria applied toboth participants and partners. Individuals endorsing joint problems, prescriptionmedication usage, or other conditions that could limit exercise wererequired to obtain written physician consent to participate."	
Exclusion criteria	"Individuals were excluded from par-ticipation if they reported a heart condition, chest pain during periodsof activity or rest, loss of consciousness, being unable to walk twoblocks without stopping, current participation in another weight-lossprogram and/or taking weight-loss medication, current pregnancy orplanning on becoming pregnant in the next 18 months, or any con-dition that in the judgment of the research team made it unlikely theindividual would complete the study protocol (i.e., plans to relocate,substance abuse)."	
Setting	GP clinic, Home	
Intervention	"Common elements of BWL and BWLH: Both condi-tions had weekly group meetings for 6 months followed bybiweekly meetings for 12 months. Interventionists had an ad-vanced degree in nutrition, exercise physiology, or behavioralpsychology, and experience providing weight-loss treatment.Dietary and exercise prescriptions and behavior-change skillswere modeled after recent trials (Look AHEAD ResearchGroup, 2006; Subak et al., 2009), with the exception that mealreplacement products were not provided. To achieve the 10%weight-loss goal, all participants were placed on a standard caloric and fat-restricted diet (e.g., 1200-1800 kcals/day and30% fat, depending on initial weight), and given sample mealplans and a calorie guidebook. Participants were instructed togradually increase their physical activity until they achieved 200 min of moderate-intensity, physical activity per week.Brisk walking was encouraged, and participants were allowedto accumulate exercise minutes via multiple short bouts orlonger continuous bouts. Participants received a pedometer,with the goal of reaching 10,000 steps per day (Wilde, Sidman,& Corbin, 2001). Participants in both conditions received in-struction in core behavioral skills. They were provided withdaily diaries and instructed to record all food and beverageintake, the corresponding calories and fat grams, minutes ofphysical activity, daily steps, and their weight. Interventionistsprovided written feedback weekly. Participants were taughtbasic skills in stimulus control, problem solving, goal setting,cognitive restructuring, and relapse prevention. The focus oftreatment shifted to weight-loss maintenance in the lattermonths of the program. Keys to long-term success were re-viewed and participants were taught a problem-solving ap-proach (Perri et al., 2001). Treatment components specific to the BWL H condition.BWL H targeted the individualplusphysical and social cues withintheir homes.	

	Although many BWL H strategies have been used inprior weight-loss programs with some success (e.g., Black et al.,1990; Jakicic et al., 1999), a unique element of this study is thatBWL H offered these components in a comprehensive treatmentpackage that simultaneously manipulated physical and social aspectswithin participants' households. BWL H components aimed tomodify the type and amount of food consumed, the availability ofexercise equipment and sedentary activities, the saliency of the consequences of eating and activity choices, and to create a positivemodel for healthy eating and exercise in the home.Modifying the type and amount of food consumed in thehome.Once a month, BWL H participants were instructed toparticipate in a "cabinet cleanout" exercise. A checklist of high-calorie, high-fat foods (e.g., potato chips) was provided and partici-pants were instructed to search for these items in their homes andremove them if found. A complementary "filling up with fit foods"exercise was completed monthly. Participants were provided with achecklist of foods that were consistent with their dietary prescription(e.g., oatmeal) and encouraged to have these items at home to pro-mote dietary adherence. To increase cues for healthy food choices,participants were provided a low-calorie cookbook, a subscription toa healthy recipe magazine and motivational posters related to healthyeating. To limit portions and decrease passive overeating, participantswere given serving-size-appropriate dishware and glasses (e.g., 8 oz.glasses), a food scale, and a set of measuring cups and spoons. Finally,to limit impulse purchases while grocery shopping, participants wereencouraged to use a commercially available online grocery orderingand home food delivery service (Gorin, Raynor, Niemeier, & Wing,2007). Participants paid for their own groceries and were reimbursed for the delivery fee. Modifying the availability of exercise equipment and seden-tary activities in the home.BWL H participants wereprovided with a treadmill or stationary bicycle for home use. Toreduce home-based sedentary activity, BWL H participantswere asked to restrict their television viewing to one location in thehome and to decrease the overall amount of time spent watchingtelevision. The intervention staff outfitted each television in thehome with a TV Allowance (Mindmaster, Inc., Miami, FL), aprogrammable device often used in childhood obesity programs(Gorin et al., 2006; Robinson, 1999) that provided participantswith objective feedback about their weekly viewing habits.BWL H participants were also provided a subscription to anexercise-related magazine, exercise videotapes, resistance bands,and motivational posters to further increase cues for physicalactivity.Increasing the saliency of the consequences of eating andexercise choices.BWL H participants were given a digitalbody weight scale and a full length mirror. They were instructed toplace these items in a prominent location in their home to serve asdaily cues to self-weigh and to limit overeating and engage inphysical activity. Creating a positive model for healthy eating and exercise inthe home.During the screening process, all participants wererequired to identify another member from their home who was alsooverweight and willing to participate in the program. In BWL H, these partners were encouraged to attend all weight-loss groupsand make the same diet and exercise changes as the participants.Partners were given a 10% weight-loss goal, expected to use thesame behavioral tools, and model healthy eating and exercise behaviors in the home.”
Control/Comparator	“N/A.”
Treatment duration	12 months
Follow-up from baseline	18 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 201 Intervention group/s: BWL+H (n=102) Comparator group: BWL (n=99)
Mean age ± SD	48.9 (10.5)

<table>
<tr><td>Sex</td><td>78.11% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SE)

Baseline BMI (kg/m2)
Mean (SD)</td><td>BWL+H: 101.2
(2.1)

BWL+H: 36.7
(6.2)</td><td>BWL: 101.7
(2.2)

BWL: 36.1
(6.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight from baseline (kg)
Mean (SE)</td><td>BWL+H: -7.3
(1)</td><td>BWL: -5.5
(1)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Cornelius, T., Gettens, K., & Gorin, A. A. (2016). Dyadic dynamics in a randomized weight loss intervention. Annals of Behavioral Medicine, 50(4), 506-515. https://doi.org/https://dx.doi.org/10.1007/s12160-016-9778-8</td></tr>
</table>

N/A – Not applicable

Gotfredsen, 2021

Guideline record ID: 10271--1

Study characteristics		
Citation	Gotfredsen, J. L., Hoppe, C., Andersen, R., Andersen, E. W., Landberg, R., Overvad, K., & Tetens, I. (2021). Effects of substitution dietary guidelines targeted at prevention of IHD on dietary intake and risk factors in middle-aged Danish adults: the Diet and Prevention of Ischemic Heart Disease: a Translational Approach (DIPI) randomised controlled trial. British Journal of Nutrition, 126(8), 1179-1193. https://doi.org/10.1017/S0007114520005164	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of substitution dietary guidelines targeted at prevention of IHD on dietary intake and risk factors in middle-aged Danish adults: the Diet and Prevention of Ischemic Heart Disease: a Translational Approach (DIPI) randomised controlled trial	
Location	Denmark	
Trial name	Diet and Prevention of Ischemic Heart Disease: a Translational Approach (DIPI)	
Methods		
Inclusion criteria	"The inclusion criteria were age between 30 and 65 years and one or more of the self-assessed risk factors for IHD at screening: overweight or obesity (BMI ≥25 kg/m2), waist circumference ≥ 80 cm for women and ≥ 94 cm for men and/or physical inactivity defined as being moderately physically active during leisure time for 15 min or less per week."	
Exclusion criteria	"Exclusion criteria were current smoking, pregnancy or plans to become pregnant within the next 12 months, breast-feeding, history of CVD, type 2 diabetes, chronic diseases/disorders that could affect the results of the study (chronic diseases reported by participants were evaluated by the physician responsible), drug abuse within the last 12 months, regular alcohol consumption > 14 units/week for women or > 21 units/week for men (one unit equals 12 g of pure alcohol), allergies or intolerance of the food groups included in the Danish DG, consumption of dietary supplements with high doses of nutrients that could have a potential effect on IHD risk factors (e.g. fish oils) and/or no access to a computer or the Internet."	
Setting	Home, University/research centre	
Intervention	"The SUB DG group received five DG formulated as advice on which specific foods to substitute for what. The SUB DG were targeted IHD and based on the scientific evidence for a relationship between specific foods and IHD outcomes found to be convincing or probable during a systematic literature update of the Danish OFF DG the previous year. Futher, the SUB DG were based on insights to the habitual dietary intake of the general population leading to a priority to emphasise fish rather than meat. Also, the SUB DG on coarse vegetables instead of fine vegetables' were based on previous calculations that showed that unless vegetables had a high content of dietary fibre (DF) (DF > 2 g/100 g), the average dietary intake of DF would be insufficient in relation to the Dietary Reference Values (NNR2012). The OFF DG group received the OFF Danish ten DG on food, beverages, and physical activity that were based on convincing or probable evidence for a relationship between dietary intake and all non-communicable diseases relevant in the Danish context, on knowledge of the Danish dietary habits and the Nordic Nutrition Recommendations 2012."	
Control/Comparator	"The HAB group received no dietary advice."	
Treatment duration	6 months	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 219
Intervention group/s: SUB (Substitution Dietary Guidelines) (n=74); OFF (Official Dietary Guidelines) (n=72)

Comparator group: HAB (Habitual diet) (n=73)</td></tr>
<tr><td>Mean age ± SD</td><td>HAB: 51.0y (p25-p25 = 42.0-55.0); SUB: 51.0 (p25-p25 = 42.3-57.0); OFF: 52.5 (p25-p25 = 45.0-58.0)</td></tr>
<tr><td>Sex</td><td>58.90% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline
Median (IQR)</td><td>SUB (Substitution Dietary Guidelines): 82.2
(74.2-88.8)
OFF (Official Dietary Guidelines): 80.7
(70.5-91.8)</td><td>HAB (Habitual diet): 85.2
(71.8-90.8)</td></tr>
<tr><td>BMI (kg/m2) - Baseline
Median (IQR)</td><td>SUB (Substitution Dietary Guidelines): 27
(25.6-29.2)
OFF (Official Dietary Guidelines): 26.8
(24.6-29.4)</td><td>HAB (Habitual diet): 26
(24.2-29.3)</td></tr>
<tr><td>Waist circumference (cm) - Baseline
Median (IQR)</td><td>SUB (Substitution Dietary Guidelines): 92.3
(86.8-98.2)
OFF (Official Dietary Guidelines): 94.1
(83.1-99.2)</td><td>HAB (Habitual diet): 92.3
(85.7-99.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - between group difference (SUB vs HAB)
Mean (95% CIs)</td><td>SUB (Substitution Dietary Guidelines): -0.19
(-1.4-1.03)
OFF (Official Dietary Guidelines): -0.47
(-1.68-0.73)</td><td></td></tr>
<tr><td>BMI (kg/m2) - between group difference (SUB vs HAB)
Mean (95% CIs)</td><td>SUB (Substitution Dietary Guidelines): -0.06
(-0.47-0.35)
OFF (Official Dietary Guidelines): -0.17
(-0.58-0.23)</td><td></td></tr>
</table>
</td></tr>
</table>

	Waist circumference (cm) - between group difference (SUB vs HAB) Mean (95% CIs)	SUB (Substitution Dietary Guidelines): -0.92 (-2.33-0.48) OFF (Official Dietary Guidelines): -0.08 (-1.49-1.32)	
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported.		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Gram, 2010

Guideline record ID: 10272--1

Study characteristics		
Citation	Gram, B., Christensen, R., Christiansen, C., & Gram, J. (2010). Effects of nordic walking and exercise in type 2 diabetes mellitus: a randomized controlled trial. Clinical Journal of Sport Medicine, 20(5), 355-361. https://doi.org/10.1227/NEU.0b013e3181e56e0a	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of nordic walking and exercise in type 2 diabetes mellitus: a randomized controlled trial	
Location	Denmark	
Trial name	N/A	
Methods		
Inclusion criteria	“The eligibility criteria were type 2 diabetes for more than 1 year, HbA1c in the range of 7% to 10 %, body mass index .25 kg/m2, age in the range of 25 to 80 years, and stable antidiabetic treatment for at least 3 months before inclusion.”	
Exclusion criteria	“Participants with symptomatic heart disease (NYHA 2-4) ischemia in lower extremities, myocardial infarction within the past 3 months, and severe lung disease were excluded.”	
Setting	NORDIC WALKING: outdoor and forest paths; EXERCISE PRESCRIPTION: unclear (The participants had supervised training sessions, and access to ergometer cycles, rowing machines, step machines, and strength training machines (for chest and leg, upper back, and	
Intervention	“For both intervention groups, EP and NW, the exercise intervention lasted for 4 months. During the first 2 months, the participants trained twice a week, and during the final 2 months, they trained once a week. Each supervised session lasted 45 minutes and included a 10-minute warm-up, 30 minutes of exercise/Nordic walking, and a 5-minute cooldown. Both groups were instructed and supervised by a physiotherapist. During the intervention period, the physiotherapist emphasized and instructed the participants to increase their physical activity outside of the training sessions. At the end of the intervention period, all participants were given information on physical training opportunities available in their neighborhood and individually tailored advice. Each participant was guided to take the initiative to find suitable forms of training in the follow-up period. There was no obligation to provide information about potential training activities to the instructors. The intensity and duration of the intervention were based on an existing training concept provided to people with lifestyle disease. Furthermore, the intention was to design a program that was realistic for the lifestyle of patients with type 2 diabetes rather than to create a high-intensity training program that would be implemented for only a temporary period EXERCISE PRESCRIPTION GROUP: The training program was individually tailored and included both strength training and aerobic exercise. Training was individualized on the basis of a cycle test at inclusion, the participant's physical capacity, and his/her goals expressed during an interview with the physiotherapist. The participants had access to ergometer cycles, rowing machines, step machines, and strength training machines (for chest and leg, upper back, and knee extension and flexion). Training intensity was individually based; however, participants had to work continuously for a minimum of 30 minutes at a workload of at least moderate intensity (.40% of Vo_ 2max). The exercise intensity was not measured directly, but ''rate of perceived exertion'' was used as the minimum intensity (Borg scale 13-14; ''It is quite an effort; you feel tired but can continue.'').16 Each participant was interviewed 3 times by the physiotherapist using a structured interview at weeks 0, 8, and 16, then assisted with goal setting, and provided with advice about training and exercise. Four months after the supervised training intervention, all participants were contacted and interviewed in the same way as before.	

	NORDINC WALKING GROUP: All the training for the NW group was conducted outdoors on forest paths. Walking distance and intensity were individually based. The participants were instructed to walk at a speed of at least moderate intensity (.40% of V_ O2max) continuously for a minimum of 30 minutes. They received the same instructions as the EP group. All the participants were issued with the same type of walking sticks (Exel Trainer Pro; ESB Sports Oy, Kitee, Finland) until the end of the study (1 year), with stick length adjusted according to individual body height. Four months after the supervised intervention ended, all the participants were contacted and interviewed about their physical activity."
Control/Comparator	"Control subjects received no supervised training but got the diabetes outpatient clinic's standard written information on exercise as a part of the treatment for type 2 diabetes and were, like other patients with type 2 diabetes in the clinic, advised to be physically active at inclusion."
Treatment duration	12 months
Follow-up from baseline	12 months
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 68 Intervention group/s: Nordic Walking (n=22); Exercise Percription (n=24) Comparator group: Control group (n=22)
Mean age ± SD	Nordic walking: 62y (10); Exercise Prescription: 59y (10); Control: 61y (10)
Sex	45.59% female
Pre-existing medical condition	Type 2 diabetes mellitus
Results	

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Weight, kg Mean (SE)	Nordic Walking: 88.9 (14.3) Exercise Prescription: 93.6 (14.8)	Control group: 99 (15)
BMI, kg/m2 Mean (SE)	Nordic Walking: 31.4 (4.3) Exercise Prescription: 32.4 (4.1)	Control group: 32.8 (4)
Waist circumference, cm Mean (SE)	Nordic Walking: 109 (11) Exercise Prescription: 110 (10)	Control group: 113 (10)
fat tissue mass, kg Mean (SE)	Nordic Walking: 29.6 (7) Exercise Prescription: 31 (7.9)	Control group: 32.5 (7.6)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator
Weight, kg Mean (SE)	Nordic Walking: 87.1 (3.3) Exercise Prescription: 92.5 (3.2)	Control group: 98.8 (3.2)

	BMI, kg/m2 Mean (SE) Waist circumference, cm Mean (SE) Fat tissue mass, kg Mean (SE)	Nordic Walking: 30.9 (0.9) Exercise Prescription: 31.8 (0.9) Nordic Walking: 108 (2) Exercise Prescription: 108 (2) Nordic Walking: 28.9 (1.6) Exercise Prescription: 30.6 (1.7)	Control group: 32.6 (0.9) Control group: 112 (2) Control group: 33.6 (1.9)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Nordic Walking: 54.5%; Exercise Prescription: 50%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Greaves, 2015

Guideline record ID: 10273--1

Study characteristics		
Citation	Greaves, C., Gillison, F., Stathi, A., Bennett, P., Reddy, P., Dunbar, J., Perry, R., Messom, D., Chandler, R., Francis, M., Davis, M., Green, C., Evans, P., & Taylor, G. (2015). Waste the waist: a pilot randomised controlled trial of a primary care based intervention to support lifestyle change in people with high cardiovascular risk. International Journal of Behavioral Nutrition and Physical Activity, 12, 1. https://doi.org/https://dx.doi.org/10.1186/s12966-014-0159-z	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Waste the waist: a pilot randomised controlled trial of a primary care based intervention to support lifestyle change in people with high cardiovascular risk	
Location	UK	
Trial name	Waste the Waist	
Methods		
Inclusion criteria	"People aged 40-74 with a body mass index (BMI) of 28Kg/m2 or more and with high cardiovascular risk. High cardiovascular risk was defined as any combination of a) a ten-year cardiovascular risk score of 20% or more using either the Framingham [30] or QRISK2 algorithm [15] (these algorithms calculate the risk of future cardiovascular events from clinical data on BMI, blood pressure, cholesterol and other cardiovascular risk factors) b) Impaired Glucose Regulation, defined as either a 2-hour glucose of 7.8 to 11.0 mmol/l (Impaired Glucose Tolerance) or a fasting plasma glucose of 6.1 to 6.9 mmol/l (Impaired Fasting Glycaemia) c) having hypertension, hypercholesterolemia, family history of diabetes or heart disease, history of gestational diabetes, or polycystic ovary syndrome."	
Exclusion criteria	"People with existing heart disease, type 2 diabetes or BMI > 45; people who were pregnant or currently using weight loss drugs; people not fluent in English; people with terminal illness and anyone who, in their General Practitioner's opinion had other co-morbidities which would prevent engagement with the intervention."	
Setting	GP clinic, Hospital, Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The development of the "Waste the Waist" intervention is described elsewhere [27] and the intervention content is described in detail in Additional file 2. Briefly, the intervention aimed to encourage weight loss by increasing physical activity, reducing intake of total and saturated fat, increasing fibre intake and other dietary changes (such as reducing portion sizes). Targets were set by participants, but we presented the health benefits of 5% weight loss and of 150 mins per week of moderate activity and suggested that these should be minimum long-term targets for health gain. The intervention was based on the Australian "Greater Green Triangle" (GGT) Programme [42], but we extended the intervention and its theoretical model (the Health Action Process Approach [43]) to include a greater emphasis on social support, self-monitoring and relapse management and the use of coping plans [27]. The intervention processes (Figure 1) involved a) increasing motivation (perceived importance of healthy lifestyle, self-efficacy for achieving healthy lifestyle, perceived risk and outcome expectations); b) making a specific action plan (including plans for social support and for overcoming barriers (coping plans)) and c) supporting maintenance through repeated 'self-regulatory cycles' of feedback/reflection, use of self-monitoring and relapse prevention techniques and revision of action plans. There was also a strong emphasis on empowering participants to develop autonomous motivation and to practice skills for lifestyle behaviour change. To promote sustainability of weight loss we advised participants to make a series of small, achievable changes, rather than dramatic, unsustainable changes. We encouraged participants to prioritise ideas for change that	

<table>
<tr><td></td><td>would not detract from their enjoyment of food (for dietary changes) or that would be enjoyable or easy to build into a routine (for physical activity) [47]. The Waste the Waist intervention was delivered in local community venues (e.g. community halls, meeting rooms in GP practices after hours). The intervention consisted of four 120-minute group based sessions in the first month to support initial behaviour change, then five 90-minute maintenance support sessions at 1.5, 2, 4, 6 and 9 months after the first session. The total contact time was therefore 13.5 hours spread over 9 months. Groups consisted of 8-12 participants, facilitated by two lifestyle coaches. Participants also received usual GP care."</td></tr>
<tr><td>Control/Comparator</td><td>"Participants in the control group were posted a standard pack of written information on cardiovascular risk and the effects of diet and physical activity on such risk, in addition to their usual GP care. In the Bath and North and East Somerset area where the study took place, usual care for people with high cardiovascular risk varied considerably, but a number of exercise-on-referral and slimming-on-referral schemes were available and self-referral to commercial weight loss programmes was also possible. Support and encouragement for weight by GPs and practice nurses was also possible, but this was unlikely to consist of more than simple, brief advice. After the collection of 12 month data the control group were offered a condensed (two session) version of the intervention."</td></tr>
<tr><td>Treatment duration</td><td>9 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td>Participant characteristics</td><td></td></tr>
<tr><td>Number of participants</td><td>n= 108
Intervention group/s: Intervention group (n=55)

Comparator group: Control group (n=53)</td></tr>
<tr><td>Mean age ± SD</td><td>65.1y (7.0)</td></tr>
<tr><td>Sex</td><td>30.56% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td>Results</td><td></td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline weight (kg)
Mean (SD)

Baseline BMI (kg/m2)
Mean (SD)

Baseline waist (kg)
Mean (SD)</td><td>Intervention group: 96.6
(14)

Intervention group: 33
(3.2)

Intervention group: 110
(10.7)</td><td>Control group: 97.6
(12.8)

Control group: 32.3
(3)

Control group: 110
(8.8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
</table></td></tr>
</table>

12 months or closest time point	Weight change (kg) Mean (SD) Waist circumference (cm) adjusted mean difference between groups Mean (95% CIs) BMI (kg/m2) adjusted mean difference between groups Mean (95% CIs)	Intervention group: -3.65 (5.22) Intervention group: -2.18 (-4.43-0.06) Intervention group: -0.51 (-1.28-0.26)	Control group: -1.9 (6.69)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Participants attended between zero and nine sessions (median = 7), with 70% of participants attending 5 or more of the 9 sessions. Attendance tapered off over time, particularly after session 6 (the attendance rates from sessions 1 to 9 respectively were 86%, 80%, 79%, 75%, 73%, 74%, 55%, 59%, 64%)		
Notes			
Additional included publications arising from this study that did not contribute additional data	Gillison, F., Stathi, A., Reddy, P., Perry, R., Taylor, G., Bennett, P., Dunbar, J., & Greaves, C. (2015). Processes of behavior change and weight loss in a theory-based weight loss intervention program: a test of the process model for lifestyle behavior change. International Journal of Behavioral Nutrition and Physical Activity, 12, 2. https://doi.org/https://dx.doi.org/10.1186/s12966-014-0160-6		

N/A – Not applicable

Green, 2015

Guideline record ID: 10274--1

Study characteristics		
Citation	Green, C. A., Yarborough, B. J. H., Leo, M. C., Yarborough, M. T., Stumbo, S. P., Janoff, S. L., Perrin, N. A., Nichols, G. A., & Stevens, V. J. (2015). The STRIDE weight loss and lifestyle intervention for individuals taking antipsychotic medications: a randomized trial. The American Journal of Psychiatry, 172(1), 71-81. https://doi.org/https://doi.org/10.1176/appi.ajp.2014.14020173	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The STRIDE weight loss and lifestyle intervention for individuals taking antipsychotic medications: a randomized trial	
Location	USA	
Trial name	STRIDE	
Methods		
Inclusion criteria	"We included adults (age >18) taking antipsychotic agents for >30 days prior to enrollment and with a body mass index (BMI) >27. Planned BMI inclusion criteria (>25 to <45) were adjusted after pilot results and following safety consultations with clinicians after individuals with a BMI over 44.9 asked to participate."	
Exclusion criteria	"Study exclusion criteria included current or currently planning pregnancy/breastfeeding, inpatient psychiatric hospitalization within <30 days (deferred participation was allowed), history of or currently planning bariatric surgery, history of cancer (past 2 years), heart attack or stroke within 6 months, and cognitive impairment that might interfere with consenting/participation."	
Setting	GP clinic, The study took place in Pacific Northwest community mental health centers (Cascadia Behavioral Healthcare and LifeWorks Northwest) and a not-for-profit integrated health system (Kaiser Permanente Northwest)	
Intervention	"STRIDE's core was a series of weekly 2-hour group meetings with 20 minutes of physical activity, delivered over 6 months. Participants were taught to keep records of 1) food, beverages, and calories consumed; 2) serv ings of fruits, vegetables, and low-fat dairy products; 3) fiber and fat intake; 4) daily minutes exercised; and 5) nightly hours slept. Goals included $25 minutes of moderate physical ac tivity per day, primarily through walking; increased fruit, vegetable, and low-fat dairy consumption; and improved sleep quality. Food and other monitoring records were used to assess progress and identify barriers to lifestyle change. The intervention relied on engaging sessions and small-group ac tivities to facilitate acquisition and practice of behavioral self management and problem-solving skills and to foster social support and program ownership. Core components included increasing awareness of health-related practices through self monitoring, creating personalized plans, reducing energy intake by reducing portions, increasing consumption of low calorie density foods, increasing physical activity, managing high-risk eating situations, graphing progress, and addressing effects of mental health on change efforts. Maintenance intervention. The maintenance phase included 6 months of group sessions focused on maintaining weight loss through problem solving and motivational enhance ment. Sessions were supplemented with monthly individual telephone sessions with group leaders. Contacts were col laborative, discussed lifestyle change efforts, and included guided problem solving."	
Control/Comparator	"usual care."	
Treatment duration	6 months	

<table>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 200
Intervention group/s: STRIDE (n=104)

Comparator group: Usual Care (n=96)</td></tr>
<tr><td>Mean age ± SD</td><td>47.2y (10.6)</td></tr>
<tr><td>Sex</td><td>72.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>serious mental illnesses</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

Body mass index (kg/m2)
Mean (SD)</td><td>STRIDE: 108.6
(27.2)

STRIDE: 38.3
(9.1)</td><td>Usual Care: 106.6
(22.7)

Usual Care: 38.2
(7.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>12 month Change in Weight (kg) time-by-group coefficients Coefficients and confidence intervals

Change in BMI at 12 months (time-by-group coefficients) Coefficients and confidence intervals

Change in weight (%)
Mean</td><td>STRIDE: -2.6
(-5.14--0.07)

STRIDE: -0.97
(-1.88--0.06)

STRIDE: -4.5</td><td>

Usual Care: -1.7</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Grilo, 2022

Guideline record ID: 10277--1

Study characteristics		
Citation	Grilo, C. M., Ivezaj, V., Duffy, A. J., & Gueorguieva, R. (2022). 24-month follow-up of randomized controlled trial of guided-self-help for loss-of-control eating after bariatric surgery. International Journal of Eating Disorders, 55(11), 1521-1531. https://doi.org/https://dx.doi.org/10.1002/eat.23804	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	24-Month follow-up of randomized controlled trial of guided-self-help for loss-of-control eating after bariatric surgery	
Location	USA	
Trial name	Loss of Control Eating Following Weight Loss Surgery	
Methods		
Inclusion criteria	"Eligibility criteria included age 18-65 years and recurrent (≥once weekly/ past 28 days) LOC-eating, defined as feeling unable to stop/control an eating episode regardless of quantity."	
Exclusion criteria	"Exclusion criteria included taking medications known to effectively influence eating/weight, current substance dependence or severe psychiatric illness (psychosis, bipolar, suicidality) requiring acute care determined by clinical interviewing and the administration of a structured diagnostic interview (MINI International Neuropsychiatric Interview, version 7.0; Sheehan et al., 1998)."	
Setting	Not reported	
Intervention	"Guided-Self-Help Cognitive-Behavioral Therapy (gshCBT) followed protocols (Grilo & Masheb, 2005) used previously in RCTs for BED that were adapted specifically for patients following bariatric surgery. The gshCBT was delivered via six individual sessions (25-30 min) over 12 weeks and was keyed to a self-care manual along with standard bariatric nutrition education provided to participants. The gshCBT teaches patients how to assess and modify maladaptive eating-related behaviors and thinking hypothesized to maintain the disordered eating. Clinicians' "guidance" includes support while addressing patients' questions about the CBT model, helping patients plan achievable behavioral steps, and learn cognitive-restructuring exercises, and emphasizing/reinforcing the importance of self-monitoring and problem-solving. Guided-Self-Help Behavioral Weight Loss (gshBWL) followed manualized protocols (Grilo & Masheb, 2005) used previously for RCTs for BED. The gshBWL which was based initially on the LEARN (lifestyle, exercise, attitudes, relationships, and nutrition) patient self-care program was adapted specifically for patients following bariatric surgery. The gshBWL was delivered via six individual sessions (25-30 min) over 12 weeks and was keyed to a self-care manual along with standard bariatric nutrition education provided to participants. The gshBWL teaches patients how to plan and make gradual and modest lifestyle changes during the challenging postoperative period. Clinicians' guidance includes support while helping patients reestablish acceptable eating and nutrition patterns given the restrictions of surgery, gradually/safely increasing physical activity, and problem-solving social/interpersonal contexts needed to sustain the lifestyle changes."	
Control/Comparator	"The CON condition comprised standard care at the Yale bariatric center-ofexcellence delivered by allied-health clinicians including support groups and nutrition education following guidelines (Busetto et al., 2018; Mechanick et al., 2009). All participants had access to the bariatric center's standard care; however, participants assigned to CON condition were referred to the bariatric center's clinicians and resources by the study research-clinicians who were assigned to them to perform monthly assessments; this was	

<table>
<tr><td></td><td>intended clinically to provide support and increase accountability, and methodologically as a partial "control-for-attention."."</td></tr>
<tr><td>Treatment duration</td><td>12 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 84
Intervention group/s: gshBWL (n=60)

Comparator group: CON (n=24)</td></tr>
<tr><td>Mean age ± SD</td><td>45.6y (10.9)</td></tr>
<tr><td>Sex</td><td>141.67% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight
Mean (SD)

BMI
Mean (SD)</td><td>gshBWL: 218.1
(47.8)

gshBWL: 35.5
(6.2)</td><td>CON: 215.7
(64)

CON: 35.8
(9.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight
Mean (SD)

BMI
Mean (SD)</td><td>gshBWL: 218.7
(43.2)

gshBWL: 35.6
(5.6)</td><td>CON: 223
(72)

CON: 36.9
(10.6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight
Mean (SD)

BMI
Mean (SD)</td><td>gshBWL: 229.4
(47.2)

gshBWL: 37.7
(6.6)</td><td>CON: 235
(76.6)

CON: 38.7
(11.3)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>percent total weight loss (%TWL)
Mean (SD)</td><td>gshBWL: 2.1
(7.5)</td><td>CON: 3.9
(6.9)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>percent total weight loss (%TWL)
Mean (SD)</td><td>gshBWL: 7
(10.5)</td><td>CON: 8.2
(9.3)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Guo, 2015

Guideline record ID: 10286--1

Study characteristics		
Citation	Guo, H., Zeng, X., Zhuang, Q., Zheng, Y., & Chen, S. (2015). Intervention of childhood and adolescents obesity in Shantou city. Obesity Research & Clinical Practice, 9(4), 357-364. https://doi.org/10.1016/j.orcp.2014.11.006	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Intervention of childhood and adolescents obesity in Shantou city	
Location	China	
Trial name	N/A	
Methods		
Inclusion criteria	"Students in grade 3-5 with BMI for age growth charts and the table of cut-off points of the charts adjusted by the CDC. Students classed in the overweight or obese range and their parents were included in the study."	
Exclusion criteria	"Students with malnutrition, students in grades 1, 2 and 6, secondary obesity students and students who used to have diseases that are known to affect habitus, insulin sensitivity, physical activity and diet intake were excluded."	
Setting	School	
Intervention	"An hour long nutrition education lectures were given to intervention school students monthly, which were consisted of 40 min of teaching and 20 min of interaction including questions asking and homework assignments. After the lectures, brochures designed according to Chinese residents dietary guidelines were dispense to disseminate the knowledge of healthy diet. The general principles of diet intervention are intake of the least amount of calories and fat and getting the maximum nutri- tional value. Exercise session According to the advice of WHO, all the interven- tion school students were guided to have moderate to vigorous activity for at least 60 min with most of which is aerobic exercise [12]. Students took part in a 1-h session of exercise and activities with the intent to help establishing regular, safe and effective exercise pattern so as to work out a suit- able plan. Students were motivated to exercise at 70-80% of their maximal heart rate. Psychological intervention session An hour long psychological health education and consultation lectures were given to intervention school students monthly. The educations and con- sultations were given by psychiatrist. Based on the all the characteristics of the children and adoles- cents mental development, all the lectures were guided by Social Cognitive Theory (SCT) [13], the most influential healthy behaviour changing theory. Fun activity session During summer and winter vacation, there were 1-2 outdoor activities held in contesting form. Telephone follow-up Telephone follow-up was conducted once every two weeks during the intervention trial."	
Control/Comparator	"No intervention."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 41 Intervention group/s: Intervention (n=26)	

<table>
<tr><td></td><td>Comparator group: Control (n=15)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>39.02% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight kg
Mean (SD)</td><td>Intervention: 44.13
(7.13)</td><td>Control: 44.88
(8.49)</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Intervention: 22.18
(2.13)</td><td>Control: 22.05
(2.57)</td></tr>
<tr><td>BMI Z-score
Mean (SD)</td><td>Intervention: 1.56
(0.33)</td><td>Control: 1.45
(0.35)</td></tr>
<tr><td>BMI Percentile
Mean (SD)</td><td>Intervention: 93.04
(4.04)</td><td>Control: 91.62
(4.31)</td></tr>
<tr><td>Waist-circumference
Mean (SD)</td><td>Intervention: 76.39
(7.24)</td><td>Control: 75.35
(8.01)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight kg
Mean (SD)</td><td>Intervention: 50.35
(8.18)</td><td>Control: 50.51
(8.95)</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Intervention: 22.95
(2.53)</td><td>Control: 23.16
(2.39)</td></tr>
<tr><td>BMI Z-score
Mean (SD)</td><td>Intervention: 1.47
(0.44)</td><td>Control: 1.48
(0.31)</td></tr>
<tr><td>BMI Percentile
Mean (SD)</td><td>Intervention: 91.13
(7.4)</td><td>Control: 92.15
(4.49)</td></tr>
<tr><td>Waist-circumference
Mean (SD)</td><td>Intervention: 77.77
(7.24)</td><td>Control: 77.6
(6.82)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>88.5%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Gupta, 2023

Guideline record ID: 12013--1

Study characteristics		
Citation	Gupta, A., Kaur, J., Shukla, G., Bhullar, K. K., Lamo, P., KC, B., Agarwal, A., Srivastava, A. K., & Sharma, G. (2023). Effect of yoga-based lifestyle and dietary modification in overweight individuals with sleep apnea: a randomized controlled trial (ELISA). Sleep Medicine, 107, 149-156. https://doi.org/https://doi.org/10.1016/j.sleep.2023.04.020	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of yoga-based lifestyle and dietary modification in overweight individuals with sleep apnea: A randomized controlled trial (ELISA)	
Location	India	
Trial name	ELISA	
Methods		
Inclusion criteria	"Patients between 30 and 70 years of age with a baseline BMI between 23 kg/m2 and 39.9 kg/m2 (obesity grades 1, 2) whose diagnostic overnight polysomnography (PSG) showed an AHI >5/ hour were included in the study."	
Exclusion criteria	"Patients who were on a regular structured exercise or yoga programme were not included. Preg nant women, patients with a history of previous upper airway surgery, patients with severe cardiac morbidity, hyperthyroidism, malignancy, or any other chronic illness that could alter body weight (kidney and liver disease), as well as those on systemic corticosteroid treatment, were excluded. Morbidly obese (BMI >40 kg/m2) patients and those contemplating metabolic surgery were also excluded."	
Setting	University/research centre	
Intervention	"Following randomization, patients received interventions ac cording to their group allocation. All patients received dietary modification and regular exercise recommendations as standard care. Patients enrolled in the Yoga group additionally received the OYM at the Center for Integrative Medicine and Research, (CIMR). All included patients had a 30-45-min initial consultation with the dietician to discuss their current diet as well as the suggested dietary programme of the study. All patients were provided with a list of high protein and low glycaemic index foods used as a staple diet in India. The food consumed on a regular basis in our part of the world is known as the staple Indian diet. It consists of wheat and rice as a source of carbohydrates; pulses, legumes and lean meat as a source of protein; mustard oil and clarified butter as a source of fat; and seasonal vegetables. Carbohydrates, proteins, and fats constituted 55-60%, 15%-20% and 25% of the overall value of daily calories, respectively, in the modified diet. Additionally, all patients were also educated on the principles of healthy eating [33]. A diet plan with calorie, protein, and fat distribution was provided, with emphasis on low-calorie foods, fruits, vegetables, and a low-fat diet. This was followed by reassessment after intervals of 6 months and 1 year. At each visit, the dietitian reviewed the continuously patient-maintained food and physical activity log. Counselling related to the restriction of calorie intake and the importance of physical activity was provided to all participants. The OYM consisted of 3 components asanas (postures), pra nayama (breathing techniques), and dhyana (meditation) for at least 45 min/day (Supplementary Table 1). Yoga based lifestyle guidelines (Yama & Niyama) were also advised [27]. All Patients were trained for OYM at our centre (CIMR), and a detailed in struction yoga booklet was given to every patient to practise at home. All participants were allowed to take weekly online yoga classes conducted by Yoga experts at CIMR. The exercise was recommended by the treating physician as a part of standard care according to WHO Asian guidelines for physical activity. Participants were also advised to practise 45e60 min of moderate activity per day or 150 min/week of brisk walking, jogging, cycling,	

<table>
<tr><td></td><td>or aerobic exercises as per individual capability, at least 5 days a week [34]. This was reinforced during counselling for diet modification and OYM administration.”</td></tr>
<tr><td>Control/Comparator</td><td>“Following randomization, patients received interventions ac cording to their group allocation. All patients received dietary modification and regular exercise recommendations as standard care. All included patients had a 30e45-min initial consultation with the dietician to discuss their current diet as well as the suggested dietary programme of the study. All patients were provided with a list of high protein and low glycaemic index foods used as a staple diet in India. The food consumed on a regular basis in our part of the world is known as the staple Indian diet. It consists of wheat and rice as a source of carbohydrates; pulses, legumes and lean meat as a source of protein; mustard oil and clarified butter as a source of fat; and seasonal vegetables. Carbohydrates, proteins, and fats constituted 55-60%, 15%-20% and 25% of the overall value of daily calories, respectively, in the modified diet. Additionally, all patients were also educated on the principles of healthy eating [33]. A diet plan with calorie, protein, and fat distribution was provided, with emphasis on low-calorie foods, fruits, vegetables, and a low-fat diet. This was followed by reassessment after intervals of 6 months and 1 year. At each visit, the dietitian reviewed the continuously patient-maintained food and physical activity log. Counselling related to the restriction of calorie intake and the importance of physical activity was provided to all participants. The exercise was recommended by the treating physician as a part of standard care according to WHO Asian guidelines for physical activity. Participants were also advised to practise 45e60 min of moderate activity per day or 150 min/week of brisk walking, jogging, cycling, or aerobic exercises as per individual capability, at least 5 days a week [34]. This was reinforced during counselling for diet modification and OYM administration.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 37
Intervention group/s: Indian Diet + Yoga (n=18)

Comparator group: Indian Diet (n=19)</td></tr>
<tr><td>Mean age ± SD</td><td>45.9y ± 9.9y</td></tr>
<tr><td>Sex</td><td>27.03% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Sleep apnea</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Indian Diet + Yoga: 86.1
(13.2)

Indian Diet + Yoga: 32.8
(5.3)</td><td>Indian Diet: 90.4
(11.9)

Indian Diet: 32.6
(4.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body Weight (kg)
Mean (SD)

Number of patients >6% weight loss</td><td>Indian Diet + Yoga: 79.8
(11.7)

Indian Diet + Yoga: 66.7%</td><td>Indian Diet: 85.8
(11.4)

Indian Diet: 26.3%</td></tr>
</table>
</td></tr>
</table>

	Proportion (%) BMI (kg/m2) Mean (SD)	 Indian Diet + Yoga: 30.5 (5.1)	 Indian Diet: 30.9 (3.8)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	% change in weight at 12 months Mean (SD)	Indian Diet + Yoga: 7.1 (3.6)	Indian Diet: 5 (3.9)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Compliance was ensured by maintaining food diaries and physical activity records. Every week, the patient reported their food log through an online/telephonic interview and verbal feed back. Treatment compliance was noted and the dietary intake of patients using the NIN(ICMR) food composition table was calcu lated [35] by the dietician at the in person visit at 1, 6 and 12 months. OYM compliance (in -person and Online sessions) was assessed by logs, verbal feedback, and attendance maintained by research nurses at CIMR, AIIMS.		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Gussenhoven, 2013

Guideline record ID: 10287--1

Study characteristics		
Citation	Gussenhoven, A. H. M., van Wier, M. F., Bosmans, J. E., Dekkers, J. C., & van Mechelen, W. (2013). Cost-effectiveness of a distance lifestyle counselling programme among overweight employees from a company perspective, ALIFE@Work: a randomized controlled trial. Work, 46(3), 337-346. https://doi.org/10.3233/WOR-121555	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Cost-effectiveness of a distance lifestyle counselling programme among overweight employees from a company perspective, ALIFE@Work: A randomized controlled trial	
Location	Netherlands	
Trial name	ALIFE@Work	
Methods		
Inclusion criteria	"Inclusion criteria of this study were: 1) BMI 25 kg/m2, 2) paid employment of at least 8 hours a week, 3) adequate knowledge of the Dutch language, 4) access to Internet and skilled in using it, and 5) at least 18 years of age."	
Exclusion criteria	"Employees were excluded for the following reasons: pregnancy, diagnosis or treatment of cancer, and any other disorder that would make physical activity impossible."	
Setting	Hospital, Home	
Intervention	"Both intervention groups received a lifestyle intervention programme. This programme was based on cognitive behavioural theory. An essential part of the programme was coaching by a personal counsellor. This counsellor, with a higher degree in nutrition or human movement studies, was trained by the research team and a trainer to apply the principles of the programme. The intervention consisted of ten modules that provided information on nutrition and physical activity, and taught techniques for changing behaviour (e.g. self-monitoring) [7]. After finishing each module, participants were contacted by their counsellor. The phone group received the programme in written form and was contacted by phone. The Internet group had access to an online website and was counselled via e-mail. Counselling was provided for a period of six months and was discontinued if the participant declined contact. All groups, including the control group, received selfhelp materials about physical activity and nutrition, published by The Netherlands Heart Foundation. Employees in the control group received only these materials and no counselling. At baseline the materials were briefly explained to the employee by the research personnel."	
Control/Comparator	"All groups, including the control group, received selfhelp materials about physical activity and nutrition, published by The Netherlands Heart Foundation. Employees in the control group received only these materials and no counselling. At baseline the materials were briefly explained to the employee by the research personnel."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 1386 Intervention group/s: Phone (n=462); Internet (n=464)	

<table>
<tr><td></td><td>Comparator group: Control (n=460)</td></tr>
<tr><td>Mean age ± SD</td><td>43.3y (8.6)</td></tr>
<tr><td>Sex</td><td>32.97% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Baseline weight (kg)
Mean (SD)</td><td>Phone: 92
(14)
Internet: 91.3
(14.1)</td><td>Control: 91.5
(13.5)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Body weight change (kg) - Phone group vs control group
Mean (95% CIs)</td><td>Phone: -0.2
(-1.1-1.6)
Internet: -0.8
(-0.8-2.5)</td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>van Wier, M. F., Dekkers, J. C., Hendriksen, I. J. M., Heymans, M. W., Ariëns, G. A. M., Pronk, N. P., Smid, T., & van Mechelen, W. (2011). Effectiveness of phone and e-mail lifestyle counseling for long term weight control among overweight employees. Journal of Occupational and Environmental Medicine, 53(6), 680-686. https://doi.org/10.1097/JOM.0b013e31821f2bbb</td></tr>
</table>

N/A – Not applicable

Habib-Mourad, 2020

Guideline record ID: 10764

Study characteristics		
Citation	Habib-Mourad, C., Ghandour, L. A., Maliha, C., Dagher, M., Kharroubi, S., & Hwalla, N. (2020). Impact of a three-year obesity prevention study on healthy behaviors and BMI among Lebanese schoolchildren: findings from Ajyal Salima program. Nutrients, 12(9), 2687. https://doi.org/10.3390/nu12092687	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Impact of a Three-Year Obesity Prevention Study on Healthy Behaviors and BMI among Lebanese Schoolchildren: Findings from Ajyal Salima Program	
Location	Lebanon	
Trial name	N/A	
Methods		
Inclusion criteria	“Public and private primary schools were conveniently sampled. Both private and public schools were chosen to ensure the inclusion of a diverse group of students with various socioeconomic statuses (SES), since middle- to high-income families in Lebanon tend to enroll their children in private schools with high annual tuition fees, whereas lower income families tend to send their children to public schools for a nominal fee.all classrooms in grades 4 and 5 (aged 8-12 years).”	
Exclusion criteria	“No information.”	
Setting	School	
Intervention	“Students in intervention schools received the program components for two consecutive academic years (within eight months each year). Twelve nutrition education interactive activities were delivered in the classroom during the first academic year and six complementary activities were delivered during the second academic year. The third year was the washout year (no intervention was administered).The intervention focused on the promotion of healthy eating and active lifestyle. Its specific objectives included increasing fruit and vegetable consumption to at least five a day as well as breakfast and healthy snacks intake; controlling high-energy dense foods and beverages consumption; encouraging regular physical activity; and reducing time spent in sedentary activities to less than two-hours a day. The intervention was based on the constructs of social cognitive theory [19], and comprised three coordinated components. The first component consisted of culturally appropriate classroom sessions using fun and interactive activities delivered once a week by teachers who had received a 'training of trainers (ToT)' workshop on all program components, as well as hands-on coaching on all educational activities by the research team. The intervention sessions provided appropriate nutrition education in a simple and fun layout. Each session consisted of two sections; 10 to 15 min of discussion, information and interaction about the topic of the week followed by 30 min of activity: game and/or food preparation. A set of attractive visual aids were distributed to students; the kit consisted of posters, pamphlets, activity booklets, cards and board games. The second component involved parents included meetings, health fairs, where the program was introduced to families and to assist them in creating a supportive environment at home for healthy lifestyle behaviors. Healthy meals were offered following the meetings. Take-home packets summarizing the major points covered during the educational sessions were also sent home along with some food samples and recipes. The goal of the take home pamphlets was to address non-compliance and poor attendance of parents' school meetings. The third component included a food service intervention targeting the school shops and the lunch boxes sent by the family.”	

<table>
<tr><td>Control/Comparator</td><td>“Students in the control schools did not receive any intervention through the entire three-year study period. After completion of the study, students in the control schools were offered the opportunity to receive the intervention.”</td></tr>
<tr><td>Treatment duration</td><td>2 years</td></tr>
<tr><td>Follow-up from baseline</td><td>3 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 1239
Intervention group/s: Intervention (n=698)

Comparator group: Control (n=541)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 9.81y (0.68); Control 10.13y (0.68)</td></tr>
<tr><td>Sex</td><td>31.23% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Odds of being overweight/obese post-intervention - intervention vs control
Odds Ratio (OR) and 95% CIs</td><td>Intervention: 0.79 (0.47-1.32)</td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Haire-Joshu, 2018

Guideline record ID: 10291--1

Study characteristics		
Citation	Haire-Joshu, D., Schwarz, C. D., Steger-May, K., Lapka, C., Schechtman, K., Brownson, R. C., & Tabak, R. G. (2018). A randomized trial of weight change in a national home visiting program. American Journal of Preventive Medicine, 54(3), 341-351. https://doi.org/10.1016/j.amepre.2017.12.012	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A Randomized Trial of Weight Change in a National Home Visiting Program	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria included female participants, aged between 18 and 45 years, overweight or obese (BMI 25-45 kg/m2), having at least one preschool-aged child at risk for overweight (BMI percentile ≥60%)24 living in the home, plans to continue in the PAT program for >2 years, and able to give informed consent."	
Exclusion criteria	"Exclusion criteria included women who were currently pregnant or planned to become pregnant in the next 24 months, unable to speak English, current enrollment in a weight loss program, undergoing treatment for diabetes or eating disorders, or inability to engage in a walking program."	
Setting	Home	
Intervention	"Intervention participants received HEALTH, which embedded a lifestyle intervention derived from DPP within the standard PAT curriculum. Participants were entitled to receive up to 36 visits over 24 months; however, the actual number of visits was based on need. Formative research with PAT staff assured lifestyle content was consistent with organizational mission, practice, and funding requirements. These factors were important to address to assure the sustainability and scalability of the embedded intervention. Intervention content was simplified to address specific lifestyle behaviors most likely to impact calorie intake, including limiting intake of sugar sweetened beverages, substituting fruits and vegetables for high caloric snacks, limiting portion sizes, increasing physical activity by walking 30 minutes per day, and decreasing sedentary activity, such as TV viewing. PAT parent-child activities were incorporated into HEALTH content. Social Cognitive Theory guided the adaptation of behavior change content to address intrapersonal (e.g., self-assessment, reinforcement), interpersonal (e.g., observational learning/parental modeling), and home environments (e.g., number of TVs, food access). This approach assured HEALTH met PAT requirements for reimbursement"	
Control/Comparator	"Participants in usual care received the standard PAT program for parents of preschoolers, who can be eligible for up to 25, hour long visits but receive an average of 10 visits per year. Parent educators provide support for parents while delivering a curriculum designed to assure school readiness through promotion of parent-child communication, child development, and family well-being. The curriculum also includes information on general health principles (e.g., accident prevention) but does not address maternal or family obesity related lifestyle change."	
Treatment duration	24 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	

<table>
<tr><td colspan="4">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td colspan="3">n= 230
Intervention group/s: Intervention (n=114)

Comparator group: Usual care (n=116)</td></tr>
<tr><td>Mean age ± SD</td><td colspan="3">32y (6)</td></tr>
<tr><td>Sex</td><td colspan="3">100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td colspan="3">No pre-existing medical condition</td></tr>
<tr><td colspan="4">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td colspan="3"><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intervention: 92.6
(15.9)</td><td>Usual care: 93
(15.3)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intervention: 34.4
(5.3)</td><td>Usual care: 34.5
(5.3)</td></tr>
<tr><td>Obesity category - Overweight
Proportion (%)</td><td>Intervention: 20.0%</td><td>Usual care: 20.0%</td></tr>
<tr><td>Obesity category - Obese I
Proportion (%)</td><td>Intervention: 40.0%</td><td>Usual care: 36.0%</td></tr>
<tr><td>Obesity category - Obese II
Proportion (%)</td><td>Intervention: 20.0%</td><td>Usual care: 29.0%</td></tr>
<tr><td>Obesity category - Obese III
Proportion (%)</td><td>Intervention: 21.0%</td><td>Usual care: 15</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Intervention: 110.5
(12.9)</td><td>Usual care: 111.1
(12.4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td colspan="3"><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intervention: 91.5
(16.9)</td><td>Usual care: 95.3
(16)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intervention: 34.1
(5.9)</td><td>Usual care: 35.4
(5.7)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Intervention: 109.6
(13.5)</td><td>Usual care: 113.1
(11.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td colspan="3"><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intervention: 91.3
(16.8)</td><td>Usual care: 97.2
(16.5)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intervention: 33.9
(5.6)</td><td>Usual care: 36
(5.9)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Intervention: 108.5
(13.9)</td><td>Usual care: 115.3
(13.1)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td colspan="3"><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Achieving 5% weight loss
Proportion (%)</td><td>Intervention: 18.0%</td><td>Usual care: 10.00%</td></tr>
</table></td></tr>
</table>

	Change in BMI (kg/m2) Mean (SD) Change in weight (kg) Mean (SD) Change in waist circumference from baseline (cm) Mean (SD)	Intervention: -0.1 (2.4) Intervention: -0.7 (6.2) Intervention: -0.7 (9.8)	Usual care: 0.8 (1.8) Usual care: 2.1 (4.8) Usual care: 2.1 (8.4)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Achieving 5% weight loss Proportion (%) Change in BMI (kg/m2) Mean (SD) Change in weight (kg) Mean (SD) Change in waist circumference from baseline (cm) Mean (SD)	Intervention: 26.0% (0.0%) Intervention: -0.5 (3.1) Intervention: -1.5 (8.3) Intervention: -2.5 (9.1)	Usual care: 11.00% Usual care: 1.3 (2.9) Usual care: 3.2 (7.6) Usual care: 3.8 (10.6)
Compliance with treatment	Intervention participants completed significantly more home visits than usual care (23 [SD=9] vs 13 [SD=6] visits, p<0.0001); the average length of visits did not differ (63 minutes [SD=11] vs 63 minutes [SD=11], p=0.17).		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Hajek, 2021

Guideline record ID: 10292--1

Study characteristics		
Citation	Hajek, P., Przulj, D., Pesola, F., McRobbie, H., Peerbux, S., Phillips-Waller, A., Bisal, N., & Myers Smith, K. (2021). A randomised controlled trial of the 5:2 diet. PLOS ONE, 16(11), e0258853. https://doi.org/https://dx.doi.org/10.1371/journal.pone.0258853	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A randomised controlled trial of the 5:2 diet	
Location	England	
Trial name	N/A	
Methods		
Inclusion criteria	"Adults with a BMI≥30kg/m2(or ≥28kg/m2, with co-morbidities) aged 18years and older who wanted to lose weight."	
Exclusion criteria	"Exclusion criteria included pregnancy, breastfeeding, using insulin, history of eating disorders, currently taking medication prescribed by a psychiatrist, BMI>45kg/m2, currently using the 5:2 diet, currently involved in other research, more than 5% bodyweight lost in the last 6 months, and unable to follow instructions and fill in forms in English."	
Setting	University/research centre	
Intervention	"Self-help format of the 5:2 diet (5:2SH). Participants received a leaflet on restricting their caloric intake to 500 kcal for women and 600 kcal for men, and on doing this on two non-consecutive days a week, with examples of meals containing the required amount of calories, and pointers to additional online support for 5:2 dieters. An advisor explained the programme and answered questions. Participants were also provided with the same leaflet about local resources for exercise that was given out with SBA. The individual session took approximately 20 minutes. Group support format of the 5:2 diet (5:2G). Participants received the 5:2SH intervention, but in addition were invited to attend six group support sessions (in weeks 1-6), each lasting one hour. Sessions were moderated by advisors. Participants were weighed and reported on their experience over the past week, whether they managed to adhere to the plan, whether they cook or use pre-prepared food on the fasting days, how they cope with hunger, etc. The focus of the sessions was on participants' sharing their experience and maintaining motivation to carry on with 5:2. Participants were also encouraged to join an internet forum to report on their 5:2 adherence and weight change, and discuss their experience with other participants."	
Control/Comparator	"Standard Brief Advice (SBA). Participants received a copy of the British Heart Foundation guides 'Facts Not Fads' and 'Get Active, Stay Active' plus the NHS 'Change 4 Life' series of booklets and a leaflet listing local resources for exercise. An advisor explained the programme, went over the key advice and tips in the written materials (e.g. portion control, food diaries, 'eat-well' plate, avoiding unnecessary snacks etc.), and answered questions. The individual session took approximately 20 minutes."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 300
Intervention group/s: 5:2SH (n=100); 5:2G (n=100)

Comparator group: SBA (n=100)</td></tr>
<tr><td>Mean age ± SD</td><td>48y (13)</td></tr>
<tr><td>Sex</td><td>66.33% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight kg
Median (IQR)

BMI
Median (IQR)</td><td>5:2SH: 92
(85-104)
5:2G: 95
(86-105)

5:2SH: 33.4
(31.7-37.7)
5:2G: 34
(31.7-37.7)</td><td>SBA: 95
(84-105)

SBA: 34
(30.7-37.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight, kg
Mean (SD)</td><td>5:2SH: -1.9
(4.9)
5:2G: -2.6
(4.6)</td><td>SBA: -1.8
(5.7)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>6 Weeks 81%; 6months; 34%; 12 months; 17%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Halle, 2021

Guideline record ID: 10293--1

Study characteristics		
Citation	Halle, M., Röhling, M., Banzer, W., Braumann, K. M., Kempf, K., McCarthy, D., Schaller, N., Predel, H. G., Scholze, J., Führer-Sakel, D., Toplak, H., Berg, A., & ACOORH study group. (2021). Meal replacement by formula diet reduces weight more than a lifestyle intervention alone in patients with overweight or obesity and accompanied cardiovascular risk factors-the ACOORH trial. European Journal of Clinical Nutrition, 75(4), 661-669. https://doi.org/https://dx.doi.org/10.1038/s41430-020-00783-4	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Meal replacement by formula diet reduces weight more than a lifestyle intervention alone in patients with overweight or obesity and accompanied cardiovascular risk factors-the ACOORH trial	
Location	Germany; Austria; England; France	
Trial name	Almased Concept against Overweight and Obesity and Related Health Risk (ACOORH)	
Methods		
Inclusion criteria	"Individuals without diabetes; aged 21-65 years; with a BMI of 27-35 kg/m2; a waist circumference (WC) of ≥88 cm (≥102 cm) for females (males); and, in addition, at least one of the following co-morbidities: (1) fasting blood glucose (FBG) 100-125 mg/dl, (2) triglycerides 150-400 mg/dl, (3) high-density lipoprotein (HDL)-cholesterol (HDL-C) < 40 mg/dl, or (4) untreated systolic (diastolic) blood pressure 140-160 (90-100) mmHg or anti-hypertensive medication. In the present predefined subanalysis, only patients with prediabetes (HbA1c: 5.7-6.4% [39-46 mmol/mol]) were considered."	
Exclusion criteria	"(i) Diabetes mellitus (FBG ≥ 126 mg/dl; HbA1c ≥ 6.5% (≥48 mmol/mol) or diabetes-related medical history (e.g., medical records or antidiabetic drugs)); (ii) total body weight > 141 kg; (iii) acute infections; (iv) chronic diseases such as cancer, chronic obstructive pulmonary disease, asthma, dementia, chronic gut diseases, psychoses, liver cirrhosis, nephropathy, and kidney insufficiency with glomerular filtration rate < 30 mL/min/1.73 m2; (v) plans to relocate to an area not served by the ACOORH; (vi) smoking cessation or planned smoking cessation during the study; (vii) drugs for active weight reduction; (viii) pregnancy or breast-feeding; and (ix) known intolerance with components of the used formula diet."	
Setting	Home, Centre specialising in lifestyle and nutritional counselling, exercise intervention, as well as obesity therapy	
Intervention	"Participants of both groups received quarterly lifestyle manuals containing information on healthy diet (limiting sweets, eating three times/day, being careful about the amount and composition of carbohydrates, eating whole-grain foods, fruits and vegetables, eating less fat, and limiting consumption of alcohol) as well as healthy behavior and were instructed to increase physical activity, but without further specifications regarding energy consumption and were equipped with telemetric scales and pedometers. In addition, the INT group was provided with the liquid soy-yoghurt-honey-based meal replacement AlmasedVitalkost® (protein content: 53.3% (83% soy-protein-isolate, and 17% milk protein), glycemic index: 27, energy per 100 g powder: 1507 kJ (360 kcal), Almased-WellnessGmbH, Bienenbüttel, Germany for the first 26 weeks and received an accompanying booklet containing information about preparing and applying the liquid formula diet and general advices about low-carbohydrate, low-glycemic and protein-rich meals. Participants were asked to replace breakfast, lunch, and dinner with 1 g powder/kg normal body weight (defined as height in cm-100) per meal dissolved in 250 mL water during the first week (~1200 kcal). Participants were further recommended to add 2-3 teaspoons (9-12 g) of safflower oil or rapeseed oil to the meal replacement. Energy-free beverages like water or unsweetened tea were allowed to be consumed ad libitum. No additional food was permitted. During	

<table>
<tr><td></td><td>weeks 2-4, participants replaced breakfast and dinner with the formula diet and ate a low-carbohydrate lunch (150-200 g of fish or meat, 500 g vegetables, and up to 50 g of carbohydrates from wholegrain bread or brown rice). The low-carbohydrate approach had to be continued in weeks 5-26 (1300-1500 kcal/day). Starting from week 5, participants of the INT group were instructed to preferably replace dinner with the formula diet. After 26-week follow-up, a cook book on low-carbohydrate meals and healthy cooking was provided to the INT group participants and they were advised to continue replacing one meal per day until the 52-week follow-up. All booklet records were evaluated at each visit by study nurses and used for nutritional and lifestyle counselling."</td></tr>
<tr><td>Control/Comparator</td><td>"Participants of both groups received quarterly lifestyle manuals containing information on healthy diet (limiting sweets, eating three times/day, being careful about the amount and composition of carbohydrates, eating whole-grain foods, fruits and vegetables, eating less fat, and limiting consumption of alcohol) as well as healthy behavior and were instructed to increase physical activity, but without further specifications regarding energy consumption, and were equipped with telemetric scales and pedometers. CON-Group participants received no further intervention."</td></tr>
<tr><td>Treatment duration</td><td>52 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>52 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 463
Intervention group/s: INT-group (n=308)

Comparator group: CON-group (n=155)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 51y (10); Control: 50y (10)</td></tr>
<tr><td>Sex</td><td>64.36% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Prediabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline Crude weight (kg)
Mean (SD)

Baseline BMI (kg/m2)
Mean (SD)

Baseline Waist circumference (cm)
Mean (SD)</td><td>INT-group: 92
(14)

INT-group: 31.7
(2.4)

INT-group: 106
(10)</td><td>CON-group: 94
(12)

CON-group: 31.5
(2.4)

CON-group: 107
(8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change (kg)
Mean (95% CIs)</td><td>INT-group: -4.4
(-5--3.8)</td><td>CON-group: -2.7
(-3.4--2)</td></tr>
</table>
</td></tr>
</table>

12 months or closest time point	Waist circumference change (cm) Mean (95% CIs)	INT-group: -4.4 (-5.2--3.7)	CON-group: -3.6 (-4.7--2.6)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Hanvold, 2019

Guideline record ID: 10296--1

Study characteristics		
Citation	Hanvold, S. E., Vinknes, K. J., Løken, E. B., Hjartåker, A., Klungsøyr, O., Birkeland, E., Risstad, H., Gulseth, H. L., Refsum, H., & Aas, A.-M. (2019). Does lifestyle intervention after gastric bypass surgery prevent weight regain? A randomized clinical trial. Obesity Surgery, 29(11), 3419-3431. https://doi.org/https://dx.doi.org/10.1007/s11695-019-04109-7	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Does Lifestyle Intervention After Gastric Bypass Surgery Prevent Weight Regain? A Randomized Clinical Trial	
Location	Norway	
Trial name	N/A	
Methods		
Inclusion criteria	"Patients who underwent laparoscopic RYGB from January 2006 to July 2009 at this hospital."	
Exclusion criteria	Not reported	
Setting	Hospital, Home	
Intervention	"In additional to usual care, 16 group meetings in the current intervention were offered over a 2-y period. The meetings lasted for 2 h and had 12-15 participants. Clinical dietitians or master students in clinical nutrition were responsible for leading the sessions, which included measurements of body weight, a lecture on a given topic, group work and/or an assignment, and 30 min with supervised physical activity. The meetings were based on the Norwegian Directorate of Health's recommendations regarding level of physical activity and diet. Dietary topics that were discussed were healthy food choices, meal frequency, portion size, and energy density. The participants were advised to choose food items labelled with the Keyhole symbol, which is used in the Nordic countries to help consumers identify healthier options. The participants were also advised to decrease time spent on sedentary activity, and they were recommended ≥ 150 min/wk with moderate activity or ≥ 75 min/wk with high activity, in accordance with Norwegian and WHO recommendations. The physical activity session varied between Nordic walking, climbing stairs, and strength training, depending on the weather. A psychologist attended two meetings (talking about self-esteem, body image, and behavioural strategies), an activity coach attended two meetings (guiding the participants in the use of Nordic walking and use of pedometer), and an experienced user from the Patient Education Resource Centre attended one meeting (informing about self-help groups)."	
Control/Comparator	"Usual care consisting of three follow-up consultations with a clinical dietitian or a doctor on the first year followed by annual consultations on the next 4 years)."	
Treatment duration	2 years	
Follow-up from baseline	2 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 165 Intervention group/s: LIG (n=85) Comparator group: UCG (n=80)	

<table>
<tr><td>Mean age ± SD</td><td>Intervention: 45.3y (8.8); Control: 46.1y (8.5)</td></tr>
<tr><td>Sex</td><td>74.55% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Crude body weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Total weight loss (kg)
Mean (SD)

Total weight loss (%)
Mean (SD)</td><td>LIG: 91.2
(17.8)

LIG: 31
(5)

LIG: 39
(13)

LIG: 29.9
(8.8)</td><td>UCG: 89.1
(17)

UCG: 30.7
(4.7)

UCG: 38.4
(11.8)

UCG: 30.1
(7.4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Crude body weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Total weight loss (kg)
Mean (SD)

Total weight loss (%)
Mean (SD)</td><td>LIG: 95.4
(19.2)

LIG: 32.4
(5.3)

LIG: 34.8
(13.4)

LIG: 26.6
(9.8)</td><td>UCG: 93
(18.5)

UCG: 32
(5.5)

UCG: 34.6
(14.2)

UCG: 27
(9.8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change (kg)
Mean (SD)

BMI Change (kg/m2)
Mean (SD)

Weight change (%)
Mean (SD)</td><td>LIG: 4.2
(6.4)

LIG: 1.5
(2.2)

LIG: 4.9
(7.4)</td><td>UCG: 3.9
(8.1)

UCG: 1.4
(2.9)

UCG: 4.6
(9.2)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>59%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Hao, 2019

Guideline record ID: 10297A--1

Study characteristics		
Citation	Hao, M., Han, W., & Yamauchi, T. (2019). Short-term and long-term effects of a combined intervention of rope skipping and nutrition education for overweight children in Northeast China. Asia Pacific Journal of Public Health, 31(4), 348-358. https://doi.org/https://doi.org/10.1177/1010539519848275	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Short-Term and Long-Term Effects of a Combined Intervention of Rope Skipping and Nutrition Education for Overweight Children in Northeast China	
Location	China	
Trial name	N/A	
Methods		
Inclusion criteria	“Children aged 9 to 12 years were determined to be overweight or obese based on China's body mass index (BMI) classification criterion.”	
Exclusion criteria	Not reported	
Setting	School	
Intervention	“Exercise intervention: This study chose skipping rope, which has relatively high METs (METs = 10.0)11 and the effects can be achieved in a short amount of time. The exercise intervention involved 30 minutes of rope skipping on the school sports grounds every morning before class. The 30-minute exercise was divided into the following 3phases. The first phase lasted 10 minutes, and the students were asked to skip rope as fast as they could. In the next 10 minutes, boys and girls were grouped by 2 and skipped rope at the same time, playing the game of "who skips for the longest time and who skips the most." Because of cumulative fatigue, in the last 10 minutes, in one group, one skipped rope and the other watched and counted to play a game of ropeskipping competition. In addition to the intervention, the students had two 45-minute physical education classes each week.; Nutrition Education: A textbook widely used in China18 was adopted by a local nutritionist to give a 45-minute lecture about nutrition education once a week for 2 months (8 lectures, 6 hours in total). The textbook covers the following content areas: characteristics of growth and development of children and juveniles (chapter 1); nutritional requirements of children and juveniles (chapter 2); daily diet plan (chapter 3); how to use Western fast food and beverages (chapter 4); nutrition for special periods (chapter 5); developing good dietary habits (chapter 6); common dietary mistakes (chapter 7); nutrition, exercise, and disease (chapter 8); common problems and countermeasures (Chapter 9); and recommendations (chapter 10). Specific to the intervention, the lecture included content on nutritional status and growth (chapter 1) and mentioned the importance of exercise (chapter 8). We combined the content from chapters 5 and 6. We also combined the content from chapters 9 and 10 in one lesson since one of the chapters had less content. Thus, the 10 chapters were covered in 8 lectures.”	
Control/Comparator	“No intervention.”	
Treatment duration	2 months	
Follow-up from baseline	14 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 229
Intervention group/s: E (n=57); N (n=60); EN (n=56)

Comparator group: C (n=56)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>45.41% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Girls BMI (kg/m2)
Mean (SD)</td><td>E: 22.6
(2.1)
N: 23
(2.4)
EN: 22.8
(2.2)</td><td>C: 22.7
(2)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Girls BMI (kg/m2)
Mean (SD)</td><td>E: 21.9
(2.2)
N: 22.2
(2.1)
EN: 21.9
(2.3)</td><td>C: 22.9
(1.8)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Hao, 2019

Guideline record ID: 10297B--1

Study characteristics		
Citation	Hao, M., Han, W., & Yamauchi, T. (2019). Short-term and long-term effects of a combined intervention of rope skipping and nutrition education for overweight children in Northeast China. Asia Pacific Journal of Public Health, 31(4), 348-358. https://doi.org/https://doi.org/10.1177/1010539519848275	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Short-Term and Long-Term Effects of a Combined Intervention of Rope Skipping and Nutrition Education for Overweight Children in Northeast China	
Location	China	
Trial name	N/A	
Methods		
Inclusion criteria	“Children aged 9 to 12 years were determined to be overweight or obese based on China's body mass index (BMI) classification criterion.”	
Exclusion criteria	Not reported	
Setting	School	
Intervention	“Exercise intervention: This study chose skipping rope, which has relatively high METs (METs = 10.0)11 and the effects can be achieved in a short amount of time. The exercise intervention involved 30 minutes of rope skipping on the school sports grounds every morning before class. The 30-minute exercise was divided into the following 3phases. The first phase lasted 10 minutes, and the students were asked to skip rope as fast as they could. In the next 10 minutes, boys and girls were grouped by 2 and skipped rope at the same time, playing the game of "who skips for the longest time and who skips the most." Because of cumulative fatigue, in the last 10 minutes, in one group, one skipped rope and the other watched and counted to play a game of ropeskipping competition. In addition to the intervention, the students had two 45-minute physical education classes each week.; Nutrition Education: A textbook widely used in China18 was adopted by a local nutritionist to give a 45-minute lecture about nutrition education once a week for 2 months (8 lectures, 6 hours in total). The textbook covers the following content areas: characteristics of growth and development of children and juveniles (chapter 1); nutritional requirements of children and juveniles (chapter 2); daily diet plan (chapter 3); how to use Western fast food and beverages (chapter 4); nutrition for special periods (chapter 5); developing good dietary habits (chapter 6); common dietary mistakes (chapter 7); nutrition, exercise, and disease (chapter 8); common problems and countermeasures (Chapter 9); and recommendations (chapter 10). Specific to the intervention, the lecture included content on nutritional status and growth (chapter 1) and mentioned the importance of exercise (chapter 8). We combined the content from chapters 5 and 6. We also combined the content from chapters 9 and 10 in one lesson since one of the chapters had less content. Thus, the 10 chapters were covered in 8 lectures.”	
Control/Comparator	“No intervention.”	
Treatment duration	2 months	
Follow-up from baseline	14 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 125
Intervention group/s: E (n=32); N (n=33); EN (n=31)

Comparator group: C (n=29)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>100.00% male</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Boys BMI (kg/m2)
Mean (SD)</td><td>E: 23.2
(2.7)
N: 23.2
(2.6)
EN: 23.2
(2.8)</td><td>C: 23.2
(2.5)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Boys BMI (kg/m2)
Mean (SD)</td><td>E: 22.5
(2.8)
N: 22.5
(2.6)
EN: 21.9
(2.7)</td><td>C: 23
(2)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Hardcastle, 2013

Guideline record ID: 10298

Study characteristics		
Citation	Hardcastle, S. J., Taylor, A. H., Bailey, M. P., Harley, R. A., & Hagger, M. S. (2013). Effectiveness of a motivational interviewing intervention on weight loss, physical activity and cardiovascular disease risk factors: a randomised controlled trial with a 12-month post-intervention follow-up. International Journal of Behavioral Nutrition and Physical Activity, 10, 40. https://doi.org/https://doi.org/10.1186/1479-5868-10-40	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effectiveness of a motivational interviewing intervention on weight loss, physical activity and cardiovascular disease risk factors: a randomised controlled trial with a 12-month post-intervention follow-up	
Location	UK	
Trial name	N/A	
Methods		
Inclusion criteria	"Participants needed to be aged 18-65 years and needed to exhibit at least one of the following CVD risk factors; excess weight (BMI of 28 or more, based on a value used in the recruiting GP practice), hypertension (SBP/DBP at least 150/90 mmHg), or hypercholesterolemia (at least 5.2 mmol.l-1)."	
Exclusion criteria	Not reported	
Setting	Health centre	
Intervention	"All participants received a standard leaflet that provided information on exercise and nutrition. Participants randomly allocated to the motivational interviewing (MI) intervention (treatment) were then given an appointment for their first face-to-face consultation with a physical activity specialist or registered dietician, with the opportunity to meet on up to four further occasions, for 20 to 30 mins, within the following 6-months. The counselling sessions were delivered by one trained physical activity specialist and one trained registered dietician. A patient-centred, tailored counselling intervention using was adopted incorporating principles and strategies from MI, integrated with a stage-matched approach [45]. Key strategies and techniques were used that adhere to the 'spirit' of MI [29]. Consistent with the underpinning 'spirit' of MI, personal motives to change (physical activity or diet) were identified by the patient and not imposed by the practitioner. The focus was on exploring ambivalence and eliciting self-directed 'change talk' [21]. Typical strategies adopted by the counselors to build motivation in those ambivalent about behavior change included agenda setting, exploration of the pros and cons, importance and confidence rulers. Strategies for those sufficiently motivated to change included strengthening commitment to change and negotiating a change plan"	
Control/Comparator	"Patients randomised to the minimal intervention group did not receive any MI counselling sessions. These participants were informed that they were part of a trial and received standard written information, in the form of a glossy A3 sized, double-sided poster that folded into an A5 leaflet on physical activity and diet produced by the Milton Keynes Primary Care Trust as a resource for health promotion. The leaflet includes lifestyle guidelines such as consuming five portions of fruit and vegetables per day, recommended fat intake and a recommendation to be physically active for 30 minutes, at least five times a week. The leaflet also lists the physiological and psychological benefits of increased physical activity. Finally, the leaflet included a food and physical activity quiz and advice depending upon scores."	
Treatment duration	6 months	

<table>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 334
Intervention group/s: Intervention (n=203)

Comparator group: Control (n=131)</td></tr>
<tr><td>Mean age ± SD</td><td>50.22y (0.58)</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)

Bodyweight (kg)
Mean (SD)</td><td>Intervention: 33.66
(5.12)

Intervention: 93.64
(15.93)</td><td>Control: 33.37
(4.47)

Control: 91.38
(16.88)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)

Bodyweight (kg)
Mean (SD)</td><td>Intervention: 33.68
(4.77)

Intervention: 94.12
(15.66)</td><td>Control: 34.04
(4.88)

Control: 92.75
(17.37)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>12%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Harris, 2017

Guideline record ID: 10765--1

Study characteristics		
Citation	Harris, L., Hankey, C., Jones, N., Pert, C., Murray, H., Tobin, J., Boyle, S., & Melville, C. (2017). A cluster randomised control trial of a multi-component weight management programme for adults with intellectual disabilities and obesity. British Journal of Nutrition, 118(3), 229-240. https://doi.org/10.1017/S0007114517001933	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A cluster randomised control trial of a multi-component weight management programme for adults with intellectual disabilities and obesity	
Location	Scotland	
Trial name	N/A	
Methods		
Inclusion criteria	"Participants were eligible to take part if they were diagnosed with intellectual disabilities (all level of intellectual disabilities were included, mild to profound), adults (≥18 years), obese (BMI ≥30 kg/m2), ambulatory, not currently on a prescribed or restricted diet (e.g. for phenylketonuria or diabetes) and had not intentionally lost weight of >3 kg in the previous 3 months."	
Exclusion criteria	"Participants were excluded if they had the following genetic syndromes; Prader-Willi syndrome, Cohen syndrome or Bardet-Biedl syndrome, taking medication for the purpose of losing weight (either prescribed or over the counter) and individuals who were pregnant or became pregnant during the study."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"TAKE 5 components To achieve a healthy sustainable weight loss of 0·5-1·0 kg/week participants followed a personalised EDD with a deficit of 2510 kJ/d (600 kcal/d)(2,3). Daily energy intake was calculated based on total energy requirements minus 2510 kJ/d (600 kcal/d). Participants total energy requirements were calculated based on their BMR (using the Mifflin St. Jeor equation)(28) multiplied by a physical activity level of 1·3(29). Quantitative dietary intake was from a specified number of portions based on the EatWell Plate(30) and based on recommendations of a healthy balanced diet. In the weight maintenance phase, a personalised diet was advised based on the estimated energy requirements to maintain body weight. The physical activity component was based on guidance of the benefits of being physically active and followed consensus guidelines on physical activity programmes for beginners(31). Participants were supported to gradually increase their participation in physical activity towards aiming to achieve health recommendations on the duration and intensity of physical activity(32,33). This was achieved by setting physical activity goals based on the participants' current level of physical activity, abilities and their preferred form of physical activity. Physical activity goals were individualised for each participant and focused on three types of physical activity: (1) Lifestyle physical activity: physical activity that could be performed in the home environment such as housework, walking up stairs and following the interactive you can do it DVD. (2) Walking: based on baseline average steps per day, individuals were encouraged to set targets to progressively increase walking behaviour and used pedometers to monitor step counts. (3) Sport and exercise: information was given to each participant on local leisure facilities and clubs with accessible sports and exercise groups/classes(16). Behaviour change techniques The most powerful behaviour change techniques shown to support changes in body weight (goal setting, self-monitoring, review of goals and feedback) were used in every session(2,3,34). Specific, Measurable, Relevant, and Time-specific (SMART)(35) goals were set relevant to individual dietary habits and physical activity levels. Participants were encouraged to monitor their food intake (to the specified number of	

	portions of the EDD) and physical activity, in diaries with support from carers. Diaries were reviewed and used to monitor progress, identify potential barriers to change and discuss progress to achieve goals. Weight maintenance To maintain body weight loss participants were encouraged with support from carers, where appropriate, to maintain the healthy lifestyle habits from phase one. Dietary intake followed the same dietary principles used to support weight loss, without an energy deficit of 2510 kJ/d (600 kcal/d). Instead, dietary plans aimed to ensure a euenergetic dietary prescription and intake. Individuals were encouraged to build on the levels of physical activity they achieved in the first 6 months and continue to aim to meet clinical recommendations. Behaviour change techniques used in the weight loss phase were continued to be used flexibly. Specific approaches, in particular, relapse prevention/coping planning and barrier identification/ problem solving were used to prevent large fluctuations in body weight. Weekly self-monitoring of body weight was encouraged as this has been shown to be influential in maintaining body weight.(36) Regular self-monitoring also helped to implement this behaviour as part of their routine in order to facilitate weight maintenance after the programme had finished. Carers were invited to attend sessions to help with communication or where necessary the implementation of behaviour change techniques, for example, goal setting and self-monitoring of the participants' physical activity or dietary intake. The level of carer involvement was dependent on the individual needs and abilities of participants and ranged from minimal support for example assistance with completing food diaries or encouraging participation in physical activity, to 24-h support in preparing and cooking all meals and actively assisting the participant to go for a walk."
Control/Comparator	"Waist Winners Too components WWToo was developed from the original mainstream Waist Winners weight management programme by a partnership group of health professionals, NHS Dietitians, Learning Disabilities Nursing, Health Improvement and Glasgow Life. For the purpose of this study, the format was adapted from the original community group programme with eight weekly sessions to an individualised programme, delivered on a one-to-one basis. Participants in this comparator programme received the same number of sessions as participants in the TAKE 5. The dietary component of the programme focused on a health education approach. This was based on the principles of a healthy balanced diet. Non-quantitative dietary advice was provided based on the EatWell Plate(30). Food and drink was categorised as 'healthy' such as fruit and vegetables, 'unhealthy' such as food high in fat and sugar, and other 'healthy' foods such as carbohydrates and dairy products which were advised to be consumed in portion-controlled amounts. Physical activity was discussed based on current public health recommendations on increasing activity and reducing sedentary behaviour(3). At each session, participants reviewed their current participation in physical activity and set new goals to increase physical activity levels. The focus of the programme session was to provide educational information on healthy lifestyle behaviours which was achieved by the inclusion of behaviour change techniques. The primary techniques included in each session were goal setting (diet and physical activity goals), self-monitoring (of weight, diet and physical activity) and feedback on performance. To retain participants to the study for the same duration period as those allocated to TAKE 5, a weight maintenance phase for WWToo was developed. Each session focused on the retention of knowledge delivered in the first phase of the programme. Support was also provided for continued monitoring of diet, physical activity and body weight and an opportunity for questions related to maintaining body weight addressed. Carers were invited to attend sessions to help with communication or where necessary the implementation of behaviour change techniques, for example, goal setting and self-monitoring of the participants' physical activity or dietary intake. The level of carer involvement was dependent on the individual needs and abilities of participants and ranged from minimal support for example assistance with completing food diaries or encouraging participation in physical activity, to 24-h support in preparing and cooking all meals and actively assisting the participant to go for a walk."
Treatment duration	12 months
Follow-up from baseline	12 months

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 50
Intervention group/s: TAKE 5 (n=26)

Comparator group: WWToo (n=24)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 40.6y (15.0); Control: 43.6y (14.0)</td></tr>
<tr><td>Sex</td><td>64.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Intellectual disabilities (all level of intellectual disabilities were included, mild to profound)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline weight (kg)
Mean (SD)

Baseline BMI (kg/m2)
Mean (SD)

Baseline waist circumference (cm)
Mean (SD)</td><td>TAKE 5: 102.3
(25.4)

TAKE 5: 40.2
(6.8)

TAKE 5: 121.9
(14)</td><td>WWToo: 104.1
(28.9)

WWToo: 41.2
(8.1)

WWToo: 122.2
(16.1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss =>5 % (mITT)
Proportion (%)</td><td>TAKE 5: 50.0%</td><td>WWToo: 20.8%</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg) (mITT)
Mean (95% CIs)

Change in weight (%) (mITT)
Mean (95% CIs)

Change in BMI (kg/m2) (mITT)
Mean (95% CIs)

Change in waist circumference (cm) (mITT)
Mean (95% CIs)</td><td>TAKE 5: -3.55
(-5.59--1.52)

TAKE 5: -3.8
(-5.86--1.74)

TAKE 5: -1.48
(-2.29--0.66)

TAKE 5: -3.6
(-5.99--1.21)</td><td>WWToo: -1.66
(-3.69-0.38)

WWToo: -1.22
(-3.28-0.83)

WWToo: -0.59
(-1.41-0.23)

WWToo: -1.83
(-4.24-0.58)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from</td><td></td></tr>
</table>

this study that did not contribute additional data	

N/A – Not applicable

Harvie, 2019

Guideline record ID: 10300

Study characteristics		
Citation	Harvie, M., Pegington, M., McMullan, D., Bundred, N., Livingstone, K., Campbell, A., Wolstenholme, J., Lovato, E., Campbell, H., Adams, J., Speed, S., Morris, J., Howell, S., & Howell, A. (2019). The effectiveness of home versus community-based weight control programmes initiated soon after breast cancer diagnosis: a randomised controlled trial. British Journal of Cancer, 121, 443-454. https://doi.org/https://dx.doi.org/10.1038/s41416-019-0522-6	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The effectiveness of home versus community-based weight control programmes initiated soon after breast cancer diagnosis: a randomised controlled trial	
Location	UK	
Trial name	N/A	
Methods		
Inclusion criteria	"There were no age, weight or treatment restrictions since we were assessing the general applicability of the interventions in all patients diagnosed with early Breast Cancer."	
Exclusion criteria	"Major physical/psychiatric conditions which would limit compliance to a diet and physical activity (PA) programme, diabetes requiring insulin or regularly taking medication known to affect body composition, e.g. daily glucocorticoids or were treated with neoadjuvant chemotherapy or endocrine therapy."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Received the written advice described above and individualised diet and PA advice from one of the trial dietitians and the physical activity specialist mainly by telephone after an initial face to face consultation. Diet advice included individualised food portion lists to follow a Mediterranean diet to meet estimated energy requirements for weight maintenance or an energy restriction 25% below estimated energy requirements for weight loss as described previously.22 Physical activity advice promoted a gradual increase towards the above targets for aerobic, resistance and arm mobility exercises which were tailored to the individual. Women were asked to estimate and report the intensity of PA using the rate of perceived exertion scale.24 Initial advice was given face to face in the main recruiting breast unit at Wythenshawe Hospital. The intensive 12 weeks of the programme included six fortnightly 20-min phone calls from their allocated trial dietitian to check compliance to diet and PA targets and address individual problems. This was followed by a mailed summary of goals and recommendations discussed. Women also received six fortnightly mailings which covered the same issues as the community programme. These were received on the weeks between the calls to maintain weekly contact throughout the 12- week programme; Supervised community-based group programme ('community'). This group received identical written and face to face advice as the 'home' group, but were also asked to attend 12 weekly PA and dietary education sessions in one of five different community locations across Greater Manchester. Each session included 30 min of moderate intensity aerobic PA and 10 min of resistance and flexibility PA, followed by a 30-min diet and behaviour change education session (Supplementary Table 1). Women were monitored throughout the class to ensure that they were exercising at a moderate level (50-80% age-adjusted heart rate maximum by pulse checks and rating of perceived exertion). In addition, women were asked to undertake four aerobic and one resistance PA sessions/week at home to meet their weekly goals. The home and community programmes used established behavioural techniques, i.e. goal setting, self-monitoring of weight and waist (weekly), diet (6 monthly food diaries), PA (daily pedometer), stress and time management, relapse prevention, and overcoming	

<table>
<tr><td></td><td>barriers.25 Both groups received booster phone calls from their allocated dietitian to reinforce advice, problem solve and monitor compliance at 4, 6 and 9 months. All study participants including the control group received a three month trial newsletter to encourage retention to the trial.”</td></tr>
<tr><td>Control/Comparator</td><td>“Standard written advice ('control'). This group received a comprehensive booklet which explained the importance of weight control (i.e. ≥ 5% weight loss in overweight/obese and prevention of weight gain in normal-weight subjects) and physical activity (PA) after diagnosis for overall health and wellbeing, and the possible effects on BC outcome. It recommended a healthy Mediterranean type diet (45% energy from low glycaemic index carbohydrates, 30% from fat, 15% monounsaturated, 7% from saturated, 8% from polyunsaturated fat, 25% from lean protein foods, 5-7 portions fruit and vegetables/day) as described previously,21,22 at least 150 min/week of moderate intensity aerobic PA, two sessions of resistance PA per week and arm mobility exercise in accordance with national guidelines,23 and standard advice for dealing with gastrointestinal and fatigue side effects for women receiving chemotherapy.”</td></tr>
<tr><td>Treatment duration</td><td>12 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 409
Intervention group/s: Home (n=134); Community (n=137)

Comparator group: Control (n=138)</td></tr>
<tr><td>Mean age ± SD</td><td>Home: 54.6y (11.2); Community: 54.0y (9.2); Control: 55.3y (10.5)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Breast Cancer</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline BMI >25-29.99 (kg/m2)
Proportion (%)</td><td>Home: 41.8
Community: 35.8</td><td>Control: 27.5</td></tr>
<tr><td>Baseline BMI >30 (kg/m2)
Proportion (%)</td><td>Home: 20.9
Community: 24.1</td><td>Control: 30.4</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Home: 71
(13.9)
Community: 71.9
(13.5)</td><td>Control: 72.5
(16.1)</td></tr>
<tr><td>DXA Body fat (kg)
Mean (SD)</td><td>Home: 27.3
(8.1)
Community: 27.7
(8.5)</td><td>Control: 27.9
(10.1)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Home: 94.2
(13.3)
Community: 94.7
(12.9)</td><td>Control: 95.6
(15.6)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight change (kg)
Mean (95% CIs)</td><td>Home: -1.5
(-2.2--0.8)
Community: -1.6
(-2.3--0.9)</td><td>Control: 0.8
(0.1-1.5)</td></tr><tr><td>DXA Body fat change (kg)
Mean (95% CIs)</td><td>Home: -1.2
(-1.7--0.6)
Community: -0.9
(-1.5--0.4)</td><td>Control: 0.5
(-0.7-1)</td></tr><tr><td>Waist circumference change (cm)
Mean (95% CIs)</td><td>Home: -1.7
(-2.6--0.8)
Community: -2.1
(-3--1.3)</td><td>Control: 0.4
(-0.5-1.2)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Home: 85%; Community: 64%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Hébert, 2013

Guideline record ID: 10303--1

Study characteristics		
Citation	Hébert, J. R., Wirth, M., Davis, L., Davis, B., Harmon, B. E., Hurley, T. G., Drayton, R., Murphy, E. A., Shivappa, N., Wilcox, S., Adams, S. A., Brandt, H. M., Blake, C. E., Armstead, C. A., Steck, S. E., & Blair, S. N. (2013). C-reactive protein levels in African Americans: a diet and lifestyle randomized community trial. American Journal of Preventive Medicine, 45(4), 430-440. https://doi.org/10.1016/j.amepre.2013.05.011	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	C-reactive protein levels in African Americans: a diet and lifestyle randomized community trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Churches were recruited in the Midlands of South Carolina (within 40 miles of the University of South Carolina-Columbia campus). A variety of recruitment methods were used, including word of mouth; media (TV and radio); and community liaisons with connections to area churches. These churches were invited to an information session that provided the specifics of the research. Each prospective church was oriented during an educational forum prior to signing a Memorandum of Agreement (MOA). Following the forum, participants were enrolled, screened, and asked to identify a partner to support them in their efforts to participate in the project. Each church pastor selected three lay health leaders, who constituted the Church Education Team (CET) that facilitated the study. Their duties included promotion of the study within the church, recruitment of individuals, reminders of clinical visits, and leading the intervention. Eligible individuals within each church were aged ≥30 years and had no reported cancer diagnosis or unstable comorbidities that might limit participation in the intervention. Lay leaders and participants received small incentives throughout the study. The number of subjects included in the analyses from each church ranged from five to 22, with a mean of ~12 subjects per church."	
Exclusion criteria	Not reported	
Setting	Church	
Intervention	"Design of the Healthy Eating and Active Living in the Spirit (HEALS) intervention was based on insights and experience from other successful studies conducted by the current authors over the past 20 years.6,24 This included an intensive 12-week healthy diet and physical activity program combined with stress reduction. Materials were modified to meet individuals' and churches' needs and goals within a structure that included: (1) cooking classes and recipes; (2) tips for increasing physical activity level as part of one's daily routine; (3) suggestions for stress reduction; and (4) assistance tracking basic measurements such as weight and blood pressure. The second phase of the intervention included monthly boosters for an additional 9 months to reinforce and expand on topics introduced in the first, 12-week, phase. Self-awareness and goal setting were central features of all modules. Social-ecologic models25,26 provided the framework for the intervention approach. The PEN-3 (individual influence [perceptions, enablers, and nurturers]; cultural influence (positive, exotic, and negative); and health education [person, extended family, neighborhood]) cultural identity model was used to guide the formative stages of culturally tailoring study protocols.27 Strategies from Social Cognitive Theory28 and the Transtheoretical Model29 were used in conjunction with PEN-3 to guide intervention messages delivered to individual members of the congregation and church leaders."	

<table>
<tr><td>Control/Comparator</td><td>“No intervention.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 159
Intervention group/s: Intervention (n=80)

Comparator group: Control (n=79)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 54.2y (10.8); Control: 57.5y (9.6)</td></tr>
<tr><td>Sex</td><td>79.87% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Baseline BMI (kg/m2)
Mean (SD)</td><td>Intervention: 33.6
(7.6)</td><td>Control: 32.6
(6.3)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Least-squares mean (95% CI)</td><td>Intervention: 32.6
(31.9-33.2)</td><td>Control: 33.2
(32.5-33.8)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>60%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Herrera-Espiñeira, 2022

Guideline record ID: 10305--1

Study characteristics		
Citation	Herrera-Espiñeira, C., Martínez-Cirre, M. d. C., López-Morales, M., Lozano-Sánchez, A., Rodríguez-Ruíz, A., Salmerón-López, L. E., Gómez-Crespo, M. I., & Expósito-Ruíz, M. (2022). Hospital intervention to reduce overweight with educational reinforcement after discharge: a multicenter randomized clinical trial. Nutrients, 14(12), 2499. https://doi.org/10.3390/nu14122499	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Hospital Intervention to Reduce Overweight with Educational Reinforcement after Discharge: A Multicenter Randomized Clinical Trial	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	“Inclusion criteria were age ≥18 years with BMI ≥ 25 kg/m2 at hospital admission (Virgen de las Nieves University Hospital, Granada; Baza Regional Hospital; Motril Regional Hospital; and University Hospital of Ceuta).”	
Exclusion criteria	“Exclusion criteria were: diagnosis of diabetes before or during hospitalization; cognitive/physical status hampering completion of questionnaires or fulfillment of physical exercise or dietary recommendations even with the assistance of a caregiver, according to the criteria of the principal collaborating nurse; pre-admission weight-loss diet controlled by nutritionist/endocrinologist; the receipt of major surgery during the hospital stay; and the refusal of consent to participation. Diabetics were specifically excluded to avoid interference with or influence from the multidisciplinary plan for diabetes of the regional health ministry.”	
Setting	Hospital	
Intervention	“In a one-to-one session on the day before their discharge, the patient (with caregiver when necessary) received advice on healthy eating and physical activity and on the potential repercussions of overweight on health. The session lasted 10-15 min, and a tablet was used for audiovisual support [23]. The session was called "Education of the 4 Cs", the initials of the Spanish words for Buying, Cooking, Eating, and Walking (Comprar, Cocinar, Comer, and Caminar), which comprised the four main components of the session (Supplementary File S2). Relevant points were reinforced during follow-up phone calls in the intervention group alone (see below). At 3, 6, and 12 months post-discharge, a single psychologist contacted all participants by phone to record their weight and BP measurements and administer the questionnaires. At these follow-up sessions, participants in the intervention group received reinforcement of the information given in the educational session based on a comparison between the patient's questionnaire findings and previous results”	
Control/Comparator	“Received a leaflet containing advice on diet and exercise for weight loss.”	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 273
Intervention group/s: Intervention (n=141)

Comparator group: Control (n=132)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>45.79% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline BMI (kg/m2)
Median (IQR)

Weight at discharge (kg)
Median (IQR)

Weight after discharge (kg)
Mean (SD)</td><td>Intervention: 31.2
(28.7-35.2)

Intervention: 84
(75.5-99)

Intervention: 87.87
(20.51)</td><td>Control: 30.9
(28.7-34.7)

Control: 84
(75.2-99)

Control: 84.98
(20.31)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight after discharge (kg)
Mean (SD)</td><td>Intervention: 84.72
(17.58)</td><td>Control: 81.25
(18.45)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Hersey, 2012

Guideline record ID: 10306--1

Study characteristics		
Citation	Hersey, J. C., Khavjou, O., Strange, L. B., Atkinson, R. L., Blair, S. N., Campbell, S., Hobbs, C. L., Kelly, B., Fitzgerald, T. M., Kish-Doto, J., Koch, M. A., Munoz, B., Peele, E., Stockdale, J., Augustine, C., Mitchell, G., Arday, D., Kugler, J., Dorn, P., . . . Britt, M. (2012). The efficacy and cost-effectiveness of a community weight management intervention: a randomized controlled trial of the health weight management demonstration. Preventive Medicine, 54(1), 42-49. https://doi.org/https://dx.doi.org/10.1016/j.ypmed.2011.09.018	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The efficacy and cost-effectiveness of a community weight management intervention: a randomized controlled trial of the health weight management demonstration	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligible participants were TRICARE Prime non-active-duty beneficiaries, aged 18 to 64, with a body mass index (BMI) of 25 to 50, living in four Midwestern states."	
Exclusion criteria	"Exclusions were minimal (e.g., pregnancy, eating disorders, and active cancer-see Appendix A); however, provider approval was required for enrollment if beneficiaries were taking medication for diabetes or high blood pressure, or had a heart condition or disability that limited their ability to be physically active."	
Setting	Home	
Intervention	"The intervention included a manual (bookHEALTH), tip sheets, and an associated eHEALTH Web site to help participants develop these skills. In addition, participants were asked to submit, via the Internet or a teleHEALTH hotline, a weekly self-assessment reporting weight, food intake, and physical activity. Randomized controlled trial group 1 (RCT1) participants received the bookHEALTH manual and eHEALTH tools (the basic Internet component of the intervention). RCT2 added an interactive version of eHEALTH that provided tailored computerized feedback whenever participants submitted weekly assessments.RCT3 added telephonic coaching support provided by trained health lifestyle coaches every 2 weeks alternating between a telephone call (typically 15 to 20 minutes) and a personalized e-mail. The lifestyle coaches were B.A.- and Master's-level staff who underwent additional 2-week training and received weekly supervision from clinical psychologists. The coaches used motivational interviewing (Miller and Rollnick, 2002) to help participants solve problems and reinforce successes. In addition, TRICARE Management Activity (TMA) offered all participants coverage of provider-prescribed, Food and Drug Administration-approved weight loss medications during their initial study year; however, fewer than 4% of participants reported that they took weight loss medications during the study"	
Control/Comparator	"The intervention included a manual (bookHEALTH), tip sheets, and an associated eHEALTH Web site to help participants develop these skills. In addition, participants were asked to submit, via the Internet or a teleHEALTH hotline, a weekly self-assessment reporting weight, food intake, and physical activity. Randomized controlled trial group 1 (RCT1) participants received the bookHEALTH manual and eHEALTH tools (the basic Internet component of the intervention)."	
Treatment duration	12 months	
Follow-up from baseline	15-18 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 1755
Intervention group/s: RCT2 (n=579); RCT3 (n=578)

Comparator group: RCT1 (n=598)</td></tr>
<tr><td>Mean age ± SD</td><td>46.7y</td></tr>
<tr><td>Sex</td><td>73.62% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>RCT2: 100.6
(18.8)
RCT3: 101.1
(19.1)</td><td>RCT1: 99.9
(17.7)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>RCT2: 97
(19)
RCT3: 95.3
(19.2)</td><td>RCT1: 96
(19.2)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>RCT2: 96.9
(19.1)
RCT3: 95
(19.5)</td><td>RCT1: 95.9
(18.6)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>98.8%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Hershey, 2023

Guideline record ID: 12014

Study characteristics		
Citation	Hershey, M. S., Chang, C.-R., Sotos-Prieto, M., Fernandez-Montero, A., Cash, S. B., Christophi, C. A., Folta, S. C., Muegge, C., Kleinschmidt, V., Moffatt, S., Mozaffarian, D., & Kales, S. N. (2023). Effect of a nutrition intervention on mediterranean diet adherence among firefighters: a cluster randomized clinical trial. JAMA Network Open, 6(8), e2329147. https://doi.org/10.1001/jamanetworkopen.2023.29147	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a Nutrition Intervention on Mediterranean Diet Adherence Among Firefighters: A Cluster Randomized Clinical Trial	
Location	USA	
Trial name	Feeding America	
Methods		
Inclusion criteria	"Inclusion criteria included age of 18 years or older; regular assignment to a specific fire station; medical examination data within the last 2 years; and full, modified, or restricted duty or administrative staff status."	
Exclusion criteria	"Exclusion criteria included no fire department medical examination recorded in the last 2 years, age younger than 18 years, or inability to give informed consent."	
Setting	Workplace	
Intervention	"From baseline through 12 months of follow-up, the Mediterranean nutrition intervention group was instructed to follow a Mediterranean diet using multicomponent nutrition intervention strategies. Education was provided via an online platform, which contained brochures on Mediterranean diet recommendations, a firefighter-specific Mediterranean diet pyramid, grocery shopping tips, sample recipes, video interviews with exemplary firefighters practicing the Mediterranean diet, and access to additional resources, such as chef-led cooking demonstrations in fire station kitchens"	
Control/Comparator	"Usual diet."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 484 Intervention group/s: Mediterranean nutrition intervention (n=240) Comparator group: Control (n=244)	
Mean age ± SD	Control: 46.28y (7.74y); Intervention: 45.12y (8.53y)	
Sex	5.58% female	
Pre-existing medical condition		
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Mediterranean nutrition intervention: 29.92
(4.4)

Mediterranean nutrition intervention: 98.27
(12.48)</td><td>Control: 30.14
(4.43)

Control: 101.16
(12.48)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Mediterranean nutrition intervention: 29.57
(4.26)

Mediterranean nutrition intervention: 98.38
(11.93)</td><td>Control: 30.2
(4.69)

Control: 101.55
(12.56)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Hinderliter, 2014

Guideline record ID: 10307--1

Study characteristics		
Citation	Hinderliter, A. L., Sherwood, A., Craighead, L. W., Lin, P.-H., Watkins, L., Babyak, M. A., & Blumenthal, J. A. (2014). The long-term effects of lifestyle change on blood pressure: one-year follow-up of the ENCORE study. American Journal of Hypertension, 27(5), 734-741. https://doi.org/https://dx.doi.org/10.1093/ajh/hpt183	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Long-Term Effects of Lifestyle Change on Blood Pressure: One-Year Follow-Up of the ENCORE Study	
Location	USA	
Trial name	Exercise and Nutrition Interventions for Cardiovascular Health (ENCORE)	
Methods		
Inclusion criteria	"Persons were eligible if they were aged >35 years, had a body mass index of 25-39.9 kg/ m2, were sedentary, and had a BP of 130-160/80-99mm Hg."	
Exclusion criteria	"Exclusion criteria included clinical or laboratory evidence of cardiac disease, chronic kidney disease, or diabetes."	
Setting	Hospital	
Intervention	"After randomization, participants entered a 2-week controlled feeding period during which they were provided meals according to their assigned dietary patterns (DASH diet, reduced calorie DASH diet, or control diet). Additional details of the study diets are described in a previous publication.4 After the initial 2 weeks of controlled feeding, participants were instructed to maintain the DASH diet either with (DASH-WM) or without (DASH-A) weight loss. DASH diet alone. Participants in the DASH-A condition met weekly with the study nutritionist in small group sessions to discuss the DASH diet and receive feedback on their adherence to the diet. The goal of the weekly sessions was to assist participants in learning how to buy and prepare the appropriate foods, to enhance their motivation to choose to eat those foods, and to overcome obstacles to following the diet. DASH plus weight management. Participants in the DASH-WM condition received the same instruction in the DASH diet as the DASH-A group, but their small group sessions also included a weekly cognitive behavioral weight loss intervention and supervised exercise sessions 3 times per week. The cognitive behavioral weight loss intervention was based on cognitive behavioral strategies10 and included appetite awareness training, a self-monitoring strategy in which individuals learn to identify internal cues of moderate hunger and fullness and to use these cues to guide their eating behavior.11 The supervised exercise routine consisted of 10 minutes of warm-up exercises, 30 minutes of biking and/ or walking or jogging at 70%-85% of the initial heart rate reserve, and 5 minutes of cool-down exercises."	
Control/Comparator	"Participants in the Usual Care condition were asked to maintain their usual dietary and exercise habits for the 4 months of the intervention."	
Treatment duration	4 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 144
Intervention group/s: DASH-WM (n=49); DASH-A (n=46)

Comparator group: Usual Care (n=49)</td></tr>
<tr><td>Mean age ± SD</td><td>52.0y (10)</td></tr>
<tr><td>Sex</td><td>67.36% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

Baseline BMI (kg/m2)
Mean (SD)</td><td>DASH-WM: 93.9
(14)
DASH-A: 93
(14)

DASH-WM: 33.5
(4.4)
DASH-A: 32.8
(3.4)</td><td>Usual Care: 92.6
(15)

Usual Care: 33
(3.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>DASH-WM: 86.7
DASH-A: 91.9</td><td>Usual Care: 91.8</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Hintze, 2018

Guideline record ID: 10308--1

Study characteristics		
Citation	Hintze, L. J., Messier, V., Lavoie, M.-È., Brochu, M., Lavoie, J.-M., Prud'homme, D., Rabasa-Lhoret, R., & Doucet, É. (2018). A one-year resistance training program following weight loss has no significant impact on body composition and energy expenditure in postmenopausal women living with overweight and obesity. Physiology & Behavior, 189, 99-106. https://doi.org/https://dx.doi.org/10.1016/j.physbeh.2018.03.014	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A one-year resistance training program following weight loss has no significant impact on body composition and energy expenditure in postmenopausal women living with overweight and obesity	
Location	Canada	
Trial name	Montreal Ottawa New Emerging Team (MONET)	
Methods		
Inclusion criteria	"The inclusion criteria were as follows: 1) body mass index ≥ 27 kg/m2, 2) cessation of menstruation for > 1 year and a follicle-stimulating hormone level ≥ 30 U/l, 3) non-smokers, 4) low to moderate alcohol consumption (< 2 drinks/day), 5) free of known inflammatory disease, 6) no use of hormone replacement therapy, and 7) physical activity levels (< 2 h/week of structured exercise)."	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"The 1-year RT weight loss maintenance intervention was performed weekly on 3 non-consecutive days for the first 6 months and on 2 nonconsecutive days for the last 6 months. There is evidence in the literature demonstrating that RT practiced twice a week should be sufficient to promote healthy improvements in post menopausal women [28,29]. Accordingly, we opted to decrease the training frequency from 3 to 2 times a week in order to increase exercise compliance in our sample. The intensity of the RT was set approximately at 70-80% of 1-repetition maximum (1RM). Each training session included a warm-up period which consisted of low intensity walking on a treadmill for 10 min. Each exercise session was individually monitored for proper technique and optimal progression. The RT program consisted of the following exercises: 1) leg press; 2) chest press; 3) lateral pull downs; 4) shoulder press; 5) arm curls; and 6) triceps extensions. These exercises provided a RT for the major muscle groups of the body. Each participant was given a target load range and attempted to keep each set (n = 3-4) within the target range by adjusting the load to allow for the prescribed number of repetitions (n = 10-12). Resting periods were 1-1.5 min between sets. The exercise program was developed based on the ACMS guidance for RT [30] and it was supervised by qualified personal trainers. The nutritional intervention for both groups consisted of monthly meetings with a registered dietitian. The total daily caloric intake was recommended to each participant (control and RT) and it was calculated based on their individual daily EE requirements measured by indirect calorimetry and by doubly labelled water (DLW) obtained from the measurements performed after the weight loss phase. All participants were encouraged to maintain their caloric intake based on their daily energy needs, with a macronutrient composition corresponding to 55%, 30%, and 15% of energy intake from carbohydrates, fats, and proteins, respectively. However, no individual meal plans were provided"	
Control/Comparator	"The nutritional intervention for both groups consisted of monthly meetings with a registered dietitian. The total daily caloric intake was recommended to each participant (control and RT) and it was calculated based on their individual daily EE requirements	

<table>
<tr><td></td><td>measured by indirect calorimetry and by doubly labelled water (DLW) obtained from the measurements performed after the weight loss phase. All participants were encouraged to maintain their caloric intake based on their daily energy needs, with a macronutrient composition corresponding to 55%, 30%, and 15% of energy intake from carbohydrates, fats, and proteins, respectively. However, no individual meal plans were provided.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 54
Intervention group/s: Resistance training (n=25)

Comparator group: Control (n=29)</td></tr>
<tr><td>Mean age ± SD</td><td>58.3y (4.8)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Resistance training: 76.9
(14.1)</td><td>Control: 79.1
(14.1)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Resistance training: 29.9
(4.2)</td><td>Control: 30.1
(4)</td></tr>
<tr><td>Fat Mass (kg)
Mean (SD)</td><td>Resistance training: 31.8
(8.6)</td><td>Control: 33.3
(10)</td></tr>
<tr><td>Peripheral Fat Mass (kg)
Mean (SD)</td><td>Resistance training: 16
(4.3)</td><td>Control: 16.4
(5)</td></tr>
<tr><td>Central Fat Mass (kg)
Mean (SD)</td><td>Resistance training: 14.8
(4.9)</td><td>Control: 15.2
(4.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Resistance training: 78.2
(15.3)</td><td>Control: 80
(14.3)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Resistance training: 30.4
(4.9)</td><td>Control: 30.5
(4.2)</td></tr>
<tr><td>Fat Mass (kg)
Mean (SD)</td><td>Resistance training: 32.6
(9.7)</td><td>Control: 34.6
(9.7)</td></tr>
<tr><td>Peripheral Fat Mass (kg)
Mean (SD)</td><td>Resistance training: 16.9
(5.2)</td><td>Control: 16.8
(4.6)</td></tr>
<tr><td>Central Fat Mass (kg)
Mean (SD)</td><td>Resistance training: 14.8
(4.8)</td><td>Control: 16.2
(5.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>64%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Hjelmesaeth, 2019

Guideline record ID: 10309--1

Study characteristics		
Citation	Hjelmesæth, J., Rosenvinge, J. H., Gade, H., & Friborg, O. (2019). Effects of cognitive behavioral therapy on eating behaviors, affective symptoms, and weight loss after bariatric surgery: a randomized clinical trial. Obesity Surgery, 29(1), 61-69. https://doi.org/https://dx.doi.org/10.1007/s11695-018-3471-x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of Cognitive Behavioral Therapy on Eating Behaviors, Affective Symptoms, and Weight Loss After Bariatric Surgery: a Randomized Clinical Trial	
Location	Norway	
Trial name	N/A	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"Briefly, all patients were offered voluntary consultations from either a medical doctor, a dietician, a nurse, or a physical therapist tailored to the patients' individual needs. In the psychological treatment arm, each patient received an additional individual 10-week CBT intervention. This intervention focused on self-monitoring to identify triggers of dysfunctional eating behaviors in order to improve regulation of eating as well as the breaking of the interrelationship between eating behaviors, negative mood, and dysfunctional cognitions"	
Control/Comparator	"Usual care."	
Treatment duration	10 weeks	
Follow-up from baseline	4 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 102 Intervention group/s: Intervention (n=50) Comparator group: Control (n=52)	
Mean age ± SD	Not reported	
Sex	Not reported	
Pre-existing medical condition	No pre-existing medical condition	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	Baseline BMI (kg/m2) (only those with 4 year follow up data)	Intervention: 43.6 (4.5)	Control: 43.5 (4.4)

	Mean (SD) BMI (kg/m2) Mean (95% CIs)	 Intervention: 42.2 (41.8-42.5)	 Control: 43.6 (43.1-44.1)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	BMI (kg/m2) Mean (95% CIs)	Intervention: 30 (28.9-31.1)	Control: 29.5 (28.5-30.6)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	BMI (kg/m2) Mean (95% CIs)	Intervention: 32 (30.3-33.8)	Control: 31.7 (30.3-33.2)
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data	Gade, H., Friborg, O., Rosenvinge, J. H., Småstuen, M. C., & Hjelmesæth, J. (2015). The impact of a preoperative cognitive behavioural therapy (CBT) on dysfunctional eating behaviours, affective symptoms and body weight 1 year after bariatric surgery: a randomised controlled trial. Obesity Surgery, 25(11), 2112-2119. https://doi.org/https://dx.doi.org/10.1007/s11695-015-1673-z		

N/A – Not applicable

Hoerster, 2022

Guideline record ID: 10310--1

Study characteristics		
Citation	Hoerster, K. D., Hunter-Merrill, R., Nguyen, T., Rise, P., Barón, A. E., McDowell, J., Donovan, L. M., Gleason, E., Lane, A., Plumley, R., Schooler, M., Schuttner, L., Collins, M., Au, D. H., & Ma, J. (2022). Effect of a remotely delivered self-directed behavioral intervention on body weight and physical health status among adults with obesity: the D-ELITE randomized clinical trial. JAMA, 328(22), 2230-2241. https://doi.org/https://dx.doi.org/10.1001/jama.2022.21177	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a Remotely Delivered Self-directed Behavioral Intervention on Body Weight and Physical Health Status Among Adults With Obesity: The D-ELITE Randomized Clinical Trial	
Location	USA	
Trial name	D-ELITE	
Methods		
Inclusion criteria	"Primary care measured BMI ≥30 and <45 kg/m2 and BMI measured in prior week indicating obesity; Able to participate fully in all study protocol/procedures including informed consent; Access to DVD player or internet."	
Exclusion criteria	"Inability to speak, read, or understand English; Pregnant, lactating, or planning to become pregnant during the study period; Participating in active weight loss intervention including use of prescription weight-loss medications in the past 3 months, current participation in group or individual weight loss programs provided by trained personnel, had/have plans for bariatric surgery during the study period; Expected weight loss because of alternate explanations, such as from illness; High variability in weight due to fluctuations in volume status (ascites - liver disease, chronic heart failure); Safety and/or adherence concerns due to severe physical or mental health issues or life expectancy <24 months; Participation in other intervention studies."	
Setting	VA Primary care clinic	
Intervention	"Self-directed interventions provide materials and resources to patients to use on their own at their own pace. Coach contact was minimal, aside from a 1-time orientation by telephone to review materials and set initial goals, biweekly standardized reminders, and asneeded messages. Participants were encouraged to selfmonitor exercise, nutrition consumption, and weight using a free online tracker (MyFitnessPal.com) or paper booklets. Some participants received coaching messages through the online platform. Handout and coaching message content were independent of the online platform. Participants who used the online platform could access its features (eg, recipes, nutrition analysis, reminders, community message boards), but doing so was not encouraged. The core curriculum (months 1-3) was delivered via weekly videos that were approximately 25 minutes long (DVD or streaming) and included self-study handouts. Topics included self-monitoring skills, portion control, lifestyle change benefits, problem solving, and motivation. Months 4 through 12 focused on continued self-monitoring for gradual weight loss and maintenance and for increased exercise, guided by 10 self-study handouts. This postcore curriculum was based on core topics such as engaging in exercise, monitoring nutrition, managing stress, decreasing sedentary time, reviewing progress, and setting new goals.Participants in both groups received care as usual, as well as a scale and water bottle."	
Control/Comparator	"Participants in both groups received care as usual, as well as a scale and water bottle. Control participants received no additional support."	
Treatment duration	12 months	

<table>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 511
Intervention group/s: Self-directed behavioral intervention (n=254)

Comparator group: Usual Care (n=257)</td></tr>
<tr><td>Mean age ± SD</td><td>57.4y (13.9)</td></tr>
<tr><td>Sex</td><td>45.21% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>Self-directed behavioral intervention: 102.7</td><td>Usual Care: 101.9</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>Self-directed behavioral intervention: 99.8
(15.8)</td><td>Usual Care: 101
(15)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>Self-directed behavioral intervention: 103.2
(14.5)</td><td>Usual Care: 101.4
(13.8)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Mean (SD)</td><td>Self-directed behavioral intervention: -2.5
(6.8)</td><td>Usual Care: -0.4
(5.7)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>61%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Hojan, 2017

Guideline record ID: 10311--1

Study characteristics		
Citation	Hojan, K., Kwiatkowska-Borowczyk, E., Leporowska, E., & Milecki, P. (2017). Inflammation, cardiometabolic markers, and functional changes in men with prostate cancer. A randomized controlled trial of a 12-month exercise program. Polish Archives of Internal Medicine, 127(1), 25-35. https://doi.org/https://dx.doi.org/10.20452/pamw.3888	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Inflammation, cardiometabolic markers, and functional changes in men with prostate cancer. A randomized controlled trial of a 12-month exercise program	
Location	Poland	
Trial name	N/A	
Methods		
Inclusion criteria	"The enrollment criteria were as follows: histologically confirmed diagnosis of high--risk or intermediate--risk PCa,22 ADT (LH- -analogue, 10.8 mg every 3 months) scheduled for a total period of 36 months (3 to 5 months prior to RT, during and after completion), patients before RT (a total dose of 76 Gy in 38 fractions),2,3 good general condition (in Eastern Cooperative Oncology Group, performance status 0-1), and minimum 18 years of age."	
Exclusion criteria	"Patients with distant metastases and/or disease progression resulting in RT or the introduction of chemotherapy; with insufficiently controlled arterial hypertension or cardiac diseases resulting in circulation failure (heart failure above class II according to the New York Heart Association classification) or uncontrolled asthma; with insufficiently controlled metabolic diseases or endocrine, rheumatic, and absorption disorders, as well as other tumors; with preexisting bone metastases at high risk for fracture; or with a psychiatric illness or dementia or organic brain disease."	
Setting	Hospital	
Intervention	"All exercise training sessions in the exercise group consisted of 5 exercise sessions/wk for 8 weeks (during RT-between assessments I and II), and 3 d/wk for the next 10 months. The physical activities were performed either individually (strength training performed with the assistance of a physiotherapist) or in groups (exercises on treadmills or cycle ergometers, supervised by a therapist) and took place at a rehabilitation department. During RT, optional progressive exercise training included brisk walking, running indoors or on a treadmill, various cycling activities (30 min), and 25-minute resistance exercises (2 sets of 8 repetitions of 5 different exercises: bicep curl, triceps extension, leg extension, leg curl, and abdominal crunch) at 70% to 75% of their estimated one--repetition maximum.23 All activities lasted approximately 65 to 70 minutes. The workout consisted of a 5--minute warm--up and 55 minutes of physical activity, followed by a 5--minute relaxation period. The physical activity was moderate, with a maximal heart rate of 65% to 70% (220--age). After RT, the exercise group performed a very similar exercise program 3 times/wk (ie, 1 day of exercise and 1 day of rest), but 1.5 h/d in our department. Exercise sessions consisted of 5 minutes of light warm--up and stretching, 40 minutes of middle--impact aerobics, 35 minutes of resistance training, and a 10--minute cool--down including relaxation. The prescribed aerobic intensity was 70% to 80% of heart rate reserve."	
Control/Comparator	"Patients randomized to the control group received usual care and physical activity according to recommendations.21 Clinicians provided medical clearance prior to the patients' involvement in the study. Patients in this group were given standard physical activity recommendations and were instructed via printed materials to perform 30 minutes of moderate physical activity 5 d/wk (150 min/wk). Patients randomized to this group were	

<table>
<tr><td></td><td>instructed not to begin any formal physical activities and perform usual daily activity at home.”</td></tr>
<tr><td>Treatment duration</td><td>8 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 72
Intervention group/s: Exercise (n=36)

Comparator group: Control (n=36)</td></tr>
<tr><td>Mean age ± SD</td><td>66.23y (4.94)</td></tr>
<tr><td>Sex</td><td>100.00% male</td></tr>
<tr><td>Pre-existing medical condition</td><td>Prostate cancer</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Exercise: 83.58
(8.8)

Exercise: 26.42
(2.8)</td><td>Control: 83.33
(6.7)

Control: 29.25
(3.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Exercise: 85.82
(9.9)

Exercise: 28.95
(3.11)</td><td>Control: 92.32
(15.6)

Control: 30.7
(3.57)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Holt, 2019

Guideline record ID: 10313--1

Study characteristics		
Citation	Holt, R. I. G., Gossage-Worrall, R., Hind, D., Bradburn, M. J., McCrone, P., Morris, T., Edwardson, C., Barnard, K., Carey, M. E., Davies, M. J., Dickens, C. M., Doherty, Y., Etherington, A., French, P., Gaughran, F., Greenwood, K. E., Kalidindi, S., Khunti, K., Laugharne, R., . . . Wright, S. (2019). Structured lifestyle education for people with schizophrenia, schizoaffective disorder and first-episode psychosis (STEPWISE): randomised controlled trial. The British Journal of Psychiatry, 214(2), 63-73. https://doi.org/https://dx.doi.org/10.1192/bjp.2018.167	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Structured lifestyle education for people with schizophrenia, schizoaffective disorder and first-episode psychosis (STEPWISE): randomised controlled trial	
Location	UK	
Trial name	The STructured lifestyle Education for People WIth SchizophrEnia, schizoaffective disorder and first episode psychosis programme (STEPWISE)	
Methods		
Inclusion criteria	“Adults (≥18 years) with a clinical diagnosis of schizophrenia, schizoaffective disorder (ICD-10 codes F20, F25) or first-episode psychosis (defined as <3 years since presentation to mental health services).13 The Operational Criteria Checklist (OPCRIT+) was completed using case-note review to assess whether the clinical diagnosis matched an objective measure of psychiatric illness.14 All participants had been prescribed an antipsychotic for ≥1 month and were able and willing to participate in a group education programme. Participants had a body mass index (BMI) ≥25 kg/m2 (≥23 kg/m2 for South Asian and Chinese backgrounds) or expressed concern about their weight.”	
Exclusion criteria	“People were excluded if they had a physical illness that could seriously reduce their life expectancy or ability to participate, that would independently have an impact on metabolic measures and weight, for example Cushing syndrome, or were currently pregnant or less than 6 months postpartum. High levels of psychiatric symptoms, as judged by the principal investigator, which could seriously affect participation and ability to put into practice the learning from the intervention sessions were a further exclusion criterion. People with significant alcohol or substance misuse, a primary diagnosis of psychotic depression, mania or intellectual disability (also known as learning disability in UK health services) were excluded. People currently (or within the past 3 months) engaged in a weight-management programme or unable to speak and read English were also excluded.”	
Setting	NHS Mental Health Trusts	
Intervention	“STEPWISE took place over approximately 12 months. Groups of participants (median 6, range 3-11) attended a foundation course of four weekly 2.5-hour group sessions delivered by two trained facilitators (Fig. 1(b)). This was followed by 1:1 support contact, mostly by telephone, lasting about 10 min, approximately every 2 weeks for the remainder of the intervention period. A trained facilitator carried out the support contact to promote behaviour change and continued engagement. Further 2.5-hour group-based booster sessions took place at approximately 4, 7 and 10 months after randomisation giving a total intervention duration of ∼25.5 h. All sessions started at lunchtime with the provision of a healthy lunch. After an initial introduction, participants were invited to 'share their story'. This provided the facilitators with feedback on what changes the person had made and what remained challenging. The facilitators used a non-judgemental style to encourage openness, problem-solving and sharing successful strategies. Specific changes and challenges were recorded so that the participants could refer back to their individualised solutions. The next part was entitled 'Taking control of your weight' to reinforce the focus	

<table>
<tr><td></td><td>of the intervention. Each session covered one or two aspects of how lifestyle changes could help the participants take control of their weight. Four topics covered diet whereas two focused on physical activity. A facilitative approach, as opposed to a didactic teaching style, was used to enable participants to discuss their beliefs about weight and explore their own solutions. The final section was devoted to action planning, when the participants developed their own individualised goals and solutions. As the participants departed, they were given supporting tools to reinforce the key messages of the session. ach centre had four to six trained facilitators to maintain consistency across sessions and support contact”</td></tr>
<tr><td>Control/Comparator</td><td>“As no consistent lifestyle education programme was offered across sites,15 we provided printed advice on lifestyle and the risks associated with weight gain for all participants. We recorded whether participants attended other weight-management or physical activity programmes outside the trial.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 412
Intervention group/s: Intervention (n=207)

Comparator group: Control (n=205)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 40.0y (11.3); Control: 40.1y (11.5)</td></tr>
<tr><td>Sex</td><td>49.03% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Schizophrenia, schizoaffective disorder (ICD-10 codes F20, F25) or first-episode psychosis (defined as <3 years since presentation to mental health services)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intervention: 105.2
(22.2)</td><td>Control: 102.1
(22.1)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intervention: 36.1
(7.2)</td><td>Control: 35.3
(7.2)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Intervention: 117.8
(15.6)</td><td>Control: 116.1
(17.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intervention: 104.1
(21.1)</td><td>Control: 101.3
(23.7)</td></tr>
<tr><td>Maintained or lost weight (%)
Proportion (%)</td><td>Intervention: 58.7</td><td>Control: 50.9</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intervention: 35.6
(7.2)</td><td>Control: 34.8
(7.3)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Intervention: 116.4
(16.1)</td><td>Control: 114
(17.7)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change (%)
Mean (SD)</td><td>Intervention: -0.5
(7.9)</td><td>Control: -0.5
(8.3)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Horie, 2016

Guideline record ID: 10317--1

Study characteristics		
Citation	Horie, N. C., Serrao, V. T., Simon, S. S., Gascon, M. R. P., dos Santos, A. X., Zambone, M. A., del Bigio de Freitas, M. M., Cunha-Neto, E., Marques, E. L., Halpern, A., de Melo, M. E., Mancini, M. C., & Cercato, C. (2016). Cognitive effects of intentional weight loss in elderly obese individuals with mild cognitive impairment. The Journal of Clinical Endocrinology & Metabolism, 101(3), 1104-1112. https://doi.org/10.1210/jc.2015-2315	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Cognitive Effects of Intentional Weight Loss in Elderly Obese Individuals With Mild Cognitive Impairment	
Location	Brazil	
Trial name	N/A	
Methods		
Inclusion criteria	“NR.”	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	“Received conventional care with nutritional counseling for 12 months". "All patients were advised to engage in physical activity according to "The global recommendations on physical activity for health" from the World Health Organization (12); briefly, they should do at least 150 minutes of moderate-intensity aerobic physical activity or walking throughout the week, or if limited due to health conditions, they should be as physically active as their abilities and conditions allow. All patients received conventional medical care, which was provided through consultation with a geriatrician approximately every 2 months and which focused on control of comorbidities. Half of the patients received additionally nutritional counseling in groups conducted by nutritionists (26 to 28 1-hour meetings held over the course of 12 mo) that aimed to promote healthy eating habits and weight loss through caloric restriction. The group meetings included advice on eating a diet rich in fiber, fruits, vegetables, and whole grains and included at least 1 g/kg of weight of protein per day, with a recommended calorie deficit of approximately 500 kcal/d (or to a minimum of 1200 kcal/d), and the meetings also included lectures on food composition, meal preparation, eating habits, and self-monitoring techniques."”	
Control/Comparator	“"received conventional care without nutritional counseling for 12 months". "All patients were advised to engage in physical activity according to "The global recommendations on physical activity for health" from the World Health Organization (12); briefly, they should do at least 150 minutes of moderate-intensity aerobic physical activity or walking throughout the week, or if limited due to health conditions, they should be as physically active as their abilities and conditions allow. All patients received conventional medical care, which was provided through consultation with a geriatrician approximately every 2 months and which focused on control of comorbidities.".”	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 80
Intervention group/s: Intensive (n=40)

Comparator group: Conventional (n=40)</td></tr>
<tr><td>Mean age ± SD</td><td>68.1y (4.9)</td></tr>
<tr><td>Sex</td><td>83.75% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Mild cognitive impairment</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in BMI (kg/m2)
Mean (95% CIs)</td><td>Intensive: -2.1
(-4.8-0.7)</td><td>Conventional: -1.3
(-4.1-1.4)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Howden, 2013

Guideline record ID: 10320--1

Study characteristics		
Citation	Howden, E. J., Leano, R., Petchey, W., Coombes, J. S., Isbel, N. M., & Marwick, T. H. (2013). Effects of exercise and lifestyle intervention on cardiovascular function in CKD. Clinical Journal of the American Society of Nephrology, 8(9), 1494-1501. https://doi.org/10.2215/CJN.10141012	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of Exercise and Lifestyle Intervention on Cardiovascular Function in CKD	
Location	Australia	
Trial name	LANDMARK III	
Methods		
Inclusion criteria	"Patients were eligible for inclusion if they were aged 18-75 years, had moderate CKD (estimated GFR [eGFR] 25-60 ml/min per 1.73 m2), and had one or more uncontrolled cardiovascular risk factors such as BP exceeding target, overweight (body mass index [BMI] .25 kg/m2), poor diabetic control (hemoglobin A1c .7%), or lipids exceeding target."	
Exclusion criteria	"Intervention for or symptomatic coronary artery disease (within 3 months), current heart failure (New York Heart Association class III and IV) or significant valvular heart disease, pregnant or planning to become pregnant, and life expectancy or anticipated time to dialysis or transplant,6 months."	
Setting	Chronic Kidney Disease clinic	
Intervention	"In addition to usual care, cardiovascular risk factor management was provided by a multidisciplinary clinic (including a CKD nurse practitioner, dietitian, exercise physiologist, diabetic educator, psychologist, and social worker) and targeted risk factors to national guidelines (15,16). The exercise training component involved 150 minutes of moderate intensity exercise per week, with 8 weeks of training supervised by an accredited clinical exercise physiologist. Patients attended gym sessions two to three times per week. The sessions included a warm-up, 20-30 minutes of aerobic activity using a treadmill, stationary bike, or rowing ergometer, and whole-body resistance training with machines and free weights. On completion of the gym-based training, patients began a home-based program and were provided a booklet depicting resistance exercise using Thera-Bands and a Swiss ball. Regular contact was maintained via telephone and Email. Participants were questioned on their ability to maintain the prescribed exercise; if they identified difficulty, they were encouraged to attend gym-based refresher visits. Patients performed exercise at a moderate intensity, with perceived exertion of 11-13 on the 20-point Borg scale (17), and progression was tailored individually. Lifestyle intervention involved 4 weeks of group behavior and lifestyle modification facilitated by a dietitian and psychologist. The program focused on sustainable diet and behavior change to assist with weight loss. The dietitian therapy complied with the Evidence-Based Practice Guidelines for Nutritional Management of CKD for patients with eGFR between 25 and 60 ml/min per 1.73 m2."	
Control/Comparator	"The control group received standard nephrologic care, which included review by a nephrologist, recommended lifestyle modification but no specific information or education, and referral to an allied health professional on an ad hoc basis."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 72
Intervention group/s: Exercise Training and Lifestyle Intervention Group (n=36)

Comparator group: Control Group (n=36)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 60.2y (9.7); Control: 62.0y (8.4)</td></tr>
<tr><td>Sex</td><td>37.50% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Moderate CKD (estimated GFR [eGFR] 25-60 ml/min per 1.73 m2) with one or more uncontrolled cardiovascular risk factors</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist (cm)
Mean (SD)</td><td>Exercise Training and Lifestyle Intervention Group: 92.6 (22.5)

Exercise Training and Lifestyle Intervention Group: 32.5 (6.8)

Exercise Training and Lifestyle Intervention Group: 106.9 (18.5)</td><td>Control Group: 92.7 (24.1)

Control Group: 33 (8)

Control Group: 107.6 (17.9)</td></tr>
</table>
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<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change (kg)
Mean (SD)

BMI change (kg/m2)
Mean (SD)

Waist change (cm)
Mean (SD)</td><td>Exercise Training and Lifestyle Intervention Group: -1.8 (4.2)

Exercise Training and Lifestyle Intervention Group: -0.6 (1.4)

Exercise Training and Lifestyle Intervention Group: -1.4 (5.5)</td><td>Control Group: 0.7 (3.7)

Control Group: 0.3 (1.4)

Control Group: 1.6 (5)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Hu, 2015

Guideline record ID: 10888--1

Study characteristics		
Citation	Hu, T., Yao, L., Reynolds, K., Whelton, P. K., Niu, T., Li, S., He, J., & Bazzano, L. A. (2015). The effects of a low-carbohydrate diet vs. a low-fat diet on novel cardiovascular risk factors: a randomized controlled trial. Nutrients, 7(9), 7978-7994. https://doi.org/10.3390/nu7095377	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Effects of a Low-Carbohydrate Diet vs. a Low-Fat Diet on Novel Cardiovascular Risk Factors: A Randomized Controlled Trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Men and women 22-75 years of age with a body mass index of 30 to 45 kg/m2 who lived in the Greater New Orleans Area."	
Exclusion criteria	"Individuals who had type 2 diabetes, CVD or chronic renal disease at baseline were excluded, as were those who were currently using prescription weight-loss medications, undergoing weight loss surgery, or had experienced significant weight loss within six months of study entry."	
Setting	University/research centre	
Intervention	"Participants followed a low-carbohydrate diet where net carbohydrate intake (total carbohydrate minus total fiber) was restricted to<40 grams/day. Participants met with a dietitian in weekly individual counseling sessions for the first month, followed by small group counseling sessions every other week for the subsequent five months, and then monthly for the last six months. Individual sessions lasted 1 h and included supportive counseling and dietary instructions in the form of recipes. Group sessions were held separately for participants in the low-fat and low-carbohydrate groups but participants received the same dietary behavioral curriculum, which included identical information on dietary fiber intake and education on the different types of fat with an emphasis on the benefits of monounsaturated fats and recommendations to limit or eliminate trans-fats. Behavioral counseling also emphasized portion control and change in eating patterns. An optional daily low-carbohydrate or low-fat meal replacement (bar or shake) was provided to participants in each group for the duration of the intervention. Participants were counseled to maintain their baseline levels of physical activity, which was assessed using validated measures at each clinical visit"	
Control/Comparator	"Participants followed a low-fat diet which restricted total fat to <30% of daily energy, with <7% from saturated fat (consistent with national guidelines)Participants met with a dietitian in weekly individual counseling sessions for the first month, followed by small group counseling sessions every other week for the subsequent five months, and then monthly for the last six months. Individual sessions lasted 1 h and included supportive counseling and dietary instructions in the form of recipes. Group sessions were held separately for participants in the low-fat and low-carbohydrate groups but participants received the same dietary behavioral curriculum, which included identical information on dietary fiber intake and education on the different types of fat with an emphasis on the benefits of monounsaturated fats and recommendations to limit or eliminate trans-fats. Behavioral counseling also emphasized portion control and change in eating patterns. An optional daily low-carbohydrate or low-fat meal replacement (bar or shake) was provided to participants in each group for the duration of the intervention. Participants were	

<table>
<tr><td></td><td>counseled to maintain their baseline levels of physical activity, which was assessed using validated measures at each clinical visit.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 148
Intervention group/s: Low carbohydrate diet (LCD) (n=75)

Comparator group: Low fat diet (LFD) (n=73)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention (LCD): 45.8y (9.9); Control (LCD): 47.8y (10.4)</td></tr>
<tr><td>Sex</td><td>88.51% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>Low carbohydrate diet (LCD): 96.3
(12.7)</td><td>Low fat diet (LFD): 97.9
(13.5)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Predicted mean change in body weight
Mean (95% CIs)</td><td>Low carbohydrate diet (LCD): -5.3
(-6.8--3.8)</td><td>Low fat diet (LFD): -1.8
(-3.3--0.3)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Hunter, 2010

Guideline record ID: 10324--1

Study characteristics		
Citation	Hunter, G. R., Brock, D. W., Byrne, N. M., Chandler-Laney, P. C., Del Corral, P., & Gower, B. A. (2010). Exercise training prevents regain of visceral fat for 1 year following weight loss. Obesity, 18(4), 690-695. https://doi.org/https://dx.doi.org/10.1038/oby.2009.316	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Exercise training prevents regain of visceral fat for 1 year following weight loss	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	“Healthy premenopausal women, with BMI between 27 and 30kg/m2." "All subjects were nonsmokers, of overall good health, and had normal menstrual cycles. Normal glucose tolerance was documented by 2-h postprandial blood glucose levels after an oral glucose load. None of the subjects used oral contraceptives at the time of enrollment into the study or medications known to affect body composition."."	
Exclusion criteria	Not reported	
Setting	Home, General Clinical Research Center (GCRC)	
Intervention	“During the 1 year following weight loss, subjects were given instructions on a balanced diet that focused on low-density food intake according to EatRight Weight Management Program principles (30)." "Aerobic training entailed continuous walking/jogging on a treadmill, commencing with a warm-up of 3 min and 3-5 min of stretching. During the first week of training, the subjects performed 20 min of continuous exercise at 67% maximum heart rate. Each week after the 1st week, duration and intensity increased so that by the beginning of the 8th week, subjects exercised continuously at 80% of maximum heart rate for 40 min. Subjects were encouraged to increase intensity (either speed or grade) when average exercise heart rate was consistently below 80% of maximum heart rate during both the weight loss and 1-year weight maintenance phases. After the exercise session, subjects cooled down for 3-5 min with gradually decreasing exercise intensity."; Resistance training group: "After a warm-up on the treadmill or bike ergometer for 5 min and 3-5 min of stretching, subjects performed the following exercises: squats, leg extension, leg curl, elbow flexion, triceps extension, lateral pull-down, bench press, military press, lower back extension, and bent leg sit-ups. One set of 10 repetitions was performed during the first 4 weeks, after which two sets of 10 repetitions were performed for each exercise with 2-min rest between sets. The training was progressive with intensity based on 80% of the maximum weight that an individual lifted one time (1 RM). Strength was evaluated every 3 weeks, and adjustments in training resistance were made based on the most current 1 RM in both the weight loss and 1-year weight maintenance phases. In both the aerobic and resistance exercise groups, subjects were expected to train 3 days/week during the weight loss and 2 days/week during the 1-year weight maintenance phase.”	
Control/Comparator	“"During the 1 year following weight loss, subjects were given instructions on a balanced diet that focused on low-density food intake according to EatRight Weight Management Program principles (30)."."	
Treatment duration	1 year + weight loss period	
Follow-up from baseline	1 year + weight loss period	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 69
Intervention group/s: Diet and aerobic exercise (n=18); Diet and resistance exercise (n=21)

Comparator group: Diet only (n=30)</td></tr>
<tr><td>Mean age ± SD</td><td>Diet and aerobic exercise: 34.7y (8.4); Diet and resistance training: 34.1y (7.2); Diet only: 34.8y (5.6)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Diet and aerobic exercise: 62.8 (5.2)
Diet and resistance exercise: 66 (8.3)</td><td>Diet only: 65 (5.7)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Diet and aerobic exercise: 23.5 (1)
Diet and resistance exercise: 23.9 (1)</td><td>Diet only: 23.9 (1.1)</td></tr>
<tr><td>% Fat
Mean (SD)</td><td>Diet and aerobic exercise: 31.8 (3.6)
Diet and resistance exercise: 32.7 (5.5)</td><td>Diet only: 33.7 (4.8)</td></tr>
<tr><td>Waist circumference
Mean (SD)</td><td>Diet and aerobic exercise: 74.3 (5.2)
Diet and resistance exercise: 75.6 (5.5)</td><td>Diet only: 77 (5.7)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Diet and aerobic exercise: 65.9 (7.1)
Diet and resistance exercise: 69.9 (8.0)</td><td>Diet only: 71.4 (7.5)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Diet and aerobic exercise: 24.7 (2.0)
Diet and resistance exercise: 25.3 (1.5)</td><td>Diet only: 26.5 (2.0)</td></tr>
<tr><td>% Fat
Mean (SD)</td><td>Diet and aerobic exercise: 35.2 (6.0)
Diet and resistance exercise: 37.1 (5.9)</td><td>Diet only: 39.0 (5.0)</td></tr>
</table>
</td></tr>
</table>

	Waist circumference Mean (SD)	Diet and aerobic exercise: 76.2 (6.6) Diet and resistance exercise: 78.5 (5.7)	Diet only: 82.5 (7.8)
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in weight (kg) Mean (SD)	Diet and aerobic exercise: 3.1 Diet and resistance exercise: 3.9	Diet only: 6.4
	Change in BMI (kg/m2) Mean (SD)	Diet and aerobic exercise: 1.2 Diet and resistance exercise: 1.2	Diet only: 2.6
	Change in % fat Mean (SD)	Diet and aerobic exercise: 3.4 Diet and resistance exercise: 4.4	Diet only: 5.3
	Change in waist circumference (cm) Mean (SD)	Diet and aerobic exercise: 1.9 Diet and resistance exercise: 2.9	Diet only: 5.3
Compliance with treatment			
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Hystad, 2013

Guideline record ID: 10328--1

Study characteristics		
Citation	Hystad, H. T., Steinsbekk, S., Ødegård, R., Wichstrøm, L., & Gudbrandsen, O. A. (2013). A randomised study on the effectiveness of therapist-led v. self-help parental intervention for treating childhood obesity. British Journal of Nutrition, 110(6), 1143-1150. https://doi.org/https://dx.doi.org/10.1017/S0007114513000056	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A randomised study on the effectiveness of therapist-led v. self-help parental intervention for treating childhood obesity	
Location	Norway	
Trial name	N/A	
Methods		
Inclusion criteria	“Children who were referred by their general practitioner to outpatient obesity treatment at St Olav University Hospital, Trondheim, Norway, in 2005-8, were assessed for eligibility. The inclusion criteria were as follows: age 7-12 years; BMI z-scores >=2; participation of at least one parent; the ability to participate in a group setting.”	
Exclusion criteria	“Families were excluded if the obese child was mentally retarded, if there was an organic cause of obesity or if the child used medication that may interfere with growth or weight control.”	
Setting	Hospital	
Intervention	“Reduced child adiposity was targeted through gradual changes that the families could manage to maintain over time, based on international and Norwegian recommendations(8,9). The focus of both the TLG and SHG interventions was to establish regular mealtimes, increase the intake of fruits, vegetables and other high-fibre food, reduce the intake of added sugar and fat, conduct at least 1 h of moderate physical activity per d and reduce sedentary behaviour gradually, towards a maximum of 2 h per d. The main focus of the TLG sessions was to enhance the parents' competence to accomplish the targeted lifestyle changes. A detailed treatment manual was devised. A total of ten sessions were conducted with the following topics: expectancies and goal setting; communication about obesity, diet and physical activity; daily physical activity; everyday dietary habits; mastery and motivation; guidance and setting boundaries; the role of siblings and the social network; parent's history of diet and physical activity; self-concept and body image; vacations and birthday parties. In brief, each group session was led by two therapists, and each session included the following: a presentation of the topic of the session followed by a group discussion; a discussion of the homework assignment for the present session; in some sessions also a role play on the topic of the session. A series of written material, such as 'fridge notes', home activity sheets and goal attainment sheets, was developed. . Both the TLG and SHG consisted of parents from four to six families. All children, regardless of their parents' group affiliation, participated in age-matched groups of six to twelve children led by a clinical dietitian and a physiotherapist. The aim was for the children to gain positive experiences related to physical activity and healthy eating, and the psychosocial consequences of being obese were addressed in a session led by a psychologist. All families attended five individual counselling sessions with a clinical dietitian and a physiotherapist to discuss the family's progress and to define new goals. The design of the study was based on the findings from pilot studies from 2003 to 2005, suggesting that it was preferable to have an intensive phase of 6 months at the beginning of the intervention period followed by a longer and less intensive phase of 18 months (S Steinsbekk and R Ødega°rd, unpublished results). The TLG, SHG and children's groups met simultaneously every second week for ten sessions during the first 6 months. During this 6-month period, each family	

<table>
<tr><td></td><td>also met monthly for individual counselling. Over the remaining 18 months of the 24-month intervention, the groups met five times at the hospital, and four individual family counselling sessions were conducted. Each of the fifteen group sessions lasted 2 h, while each of the ten individual family counselling sessions lasted 30 min.”</td></tr>
<tr><td>Control/Comparator</td><td>“The SHG were based on the principle of mutual help, derived from the participants' own experiences and knowledge. A health professional attended the two first and the last meeting to organise the group and facilitate group rules, but did not offer any education or guidance regarding how to reduce adiposity. . Both the TLG and SHG consisted of parents from four to six families. All children, regardless of their parents' group affiliation, participated in age-matched groups of six to twelve children led by a clinical dietitian and a physiotherapist. The aim was for the children to gain positive experiences related to physical activity and healthy eating, and the psychosocial consequences of being obese were addressed in a session led by a psychologist. All families attended five individual counselling sessions with a clinical dietitian and a physiotherapist to discuss the family's progress and to define new goals. The design of the study was based on the findings from pilot studies from 2003 to 2005, suggesting that it was preferable to have an intensive phase of 6 months at the beginning of the intervention period followed by a longer and less intensive phase of 18 months (S Steinsbekk and R Ødega°rd, unpublished results). The TLG, SHG and children's groups met simultaneously every second week for ten sessions during the first 6 months. During this 6-month period, each family also met monthly for individual counselling. Over the remaining 18 months of the 24-month intervention, the groups met five times at the hospital, and four individual family counselling sessions were conducted. Each of the fifteen group sessions lasted 2 h, while each of the ten individual family counselling sessions lasted 30 min.”</td></tr>
<tr><td>Treatment duration</td><td>2 years</td></tr>
<tr><td>Follow-up from baseline</td><td>2 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 96
Intervention group/s: Therapist-led groups (n=46)

Comparator group: Self-help groups (n=50)</td></tr>
<tr><td>Mean age ± SD</td><td>10.2 (1.7)</td></tr>
<tr><td>Sex</td><td>45.83% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body fat (%)
Mean (SD)

BMI z-score
Mean (SD)</td><td>Therapist-led groups: 40.4 (3.8)

Therapist-led groups: 3 (0.51)</td><td>Self-help groups: 40.6 (4)

Self-help groups: 3 (0.36)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body fat (%)
Mean (SD)

BMI z-score
Mean (SD)</td><td>Therapist-led groups: 35.7 (5.6)

Therapist-led groups: 2.78 (0.56)</td><td>Self-help groups: 36.2 (5.6)

Self-help groups: 2.81 (0.44)</td></tr>
</table>
</td></tr>
</table>

Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Body fat (%) Mean (SD) BMI z-score Mean (SD)	Therapist-led groups: 35.6 (6.3) Therapist-led groups: 2.82 (0.59)	Self-help groups: 35.6 (6.4) Self-help groups: 2.83 (0.51)
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Ikramuddin, 2013

Guideline record ID: 10769--1

Study characteristics		
Citation	Ikramuddin, S., Korner, J., Lee, W.-J., Connett, J. E., Inabnet, W. B., Billington, C. J., Thomas, A. J., Leslie, D. B., Chong, K., Jeffery, R. W., Ahmed, L., Vella, A., Chuang, L.-M., Bessler, M., Sarr, M. G., Swain, J. M., Laqua, P., Jensen, M. D., & Bantle, J. P. (2013). Roux-en-Y gastric bypass vs intensive medical management for the control of type 2 diabetes, hypertension, and hyperlipidemia: the Diabetes Surgery Study randomized clinical trial. JAMA, 309(21), 2240-2249. https://doi.org/10.1001/jama.2013.5835	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Roux-en-Y gastric bypass vs intensive medical management for the control of type 2 diabetes, hypertension, and hyperlipidemia: the Diabetes Surgery Study randomized clinical trial	
Location	USA; Taiwan	
Trial name	Diabetes Surgery Study (DSS)	
Methods		
Inclusion criteria	"Key inclusion criteria were the following: age 30-67, under a doctor's care for type 2 diabetes for at least 6 months prior to recruitment; a HbA1c ≥ 8.0% at the time of entry; and a serum C-peptide level > 1.0 ng/ml 90 minutes after a liquid mixed meal of Ensure ® (250 calories, 6 g fat/40 g carbohydrate/9 g protein). Participants had a BMI of 30.0-39.9 kg/ m2 and were willing to accept randomization to either treatment arm and follow the full treatment protocol. Additional criteria included the absence of conditions that would contraindicate surgery, such as serious cardiovascular disease, previous gastrointestinal surgery, psychological concerns, or history of malignancy."	
Exclusion criteria	Not reported	
Setting	Hospital, Home	
Intervention	"Laparoscopic Roux-en-Y Gastric Bypass: Participants randomized to the RYGB group were placed on a low-calorie diet with meal replacements 2 weeks prior to the operation. The laparoscopic RYGB technique was standardized across all sites and was performed with construction of a 20 ml lesser curvature gastric pouch, a 100 cm biliopancreatic limb, and an antecolic 150 cm Roux limb with closure of all mesenteric defects. On postoperative day 1, RYGB participants underwent a routine upper gastrointestinal (UGI) contrast study and were started on a clear liquid diet if the study showed no leak. Participants were typically discharged on postoperative day 2. At home, participants remained on a clear liquid diet for one week and were advanced gradually to pureed and then to solid foods as tolerated. RYGB participants were advised to progressively increase their level of moderate-intensity physical activity (such as walking) to a total of 325 minutes per week. Both groups met regularly with a trained interventionist to discuss strategies for facilitating weight management and increasing physical activity, including self-monitoring, stimulus control, problem solving, social support, cognitive behaviour modification, recipe modification, eating away from home and relapse prevention. Counselling sessions were comprised of 24 weekly meetings over the first 6 months, bi-weekly meetings between months 7 and 9, and monthly meetings between months 10 and 12. The lifestyle intervention protocol was similar for participants in both treatment arms. RYGB participants, however, delayed initiation of the lifestyle intervention until they could tolerate solid foods (typically about 3-4 months after surgery), did not have calorie ceilings during the period of rapid weight loss, and received additional instruction regarding food volume and adequate protein intake. Medications for control of glycemia, dyslipidemia, and blood pressure were reduced or discontinued in RYGB participants immediately after surgery because of fluid and caloric	

	decreases early postoperatively and were restarted as necessary to accomplish treatment goals."
Control/Comparator	"Intensive Medical Management: LS/IMM consisted of two components - lifestyle modification designed to produce maximum achievable weight loss, and medications to control glycemia and cardiovascular disease risk factors while facilitating weight loss. Only U.S. Food and Drug Administration approved medications were used. Lifestyle Modification: The study lifestyle intervention was modelled on recent successful clinical trials, particularly the Diabetes Prevention Program (DPP)12 and Look AHEAD.2 Participants were instructed to weigh themselves and to record eating and exercise behaviours on a daily basis. Both groups were advised to progressively increase their level of moderate-intensity physical activity (such as walking) to a total of 325 minutes per week. LS/IMM participants were given calorie intake targets of 1,200, 1,500 or 1,800 kilocalories per day, depending on body weight, with the goal of producing a weight loss of 1-2 pounds per week. Portion-controlled diets using meal replacements, structured menus and calorie counting were encouraged to help participants stay within calorie limits. Both groups met regularly with a trained interventionist to discuss strategies for facilitating weight management and increasing physical activity, including self-monitoring, stimulus control, problem solving, social support, cognitive behavior modification, recipe modification, eating away from home and relapse prevention. Counseling sessions were comprised of 24 weekly meetings over the first 6 months, bi-weekly meetings between months 7 and 9, and monthly meetings between months 10 and 12. The lifestyle intervention protocol was similar for participants in both treatment arms. Medications: Follow-up evaluations were scheduled monthly for 6 months and at least quarterly thereafter. When the lifestyle intervention did not produce adequate weight loss, Ikramuddin et al. Page 4 JAMA. Author manuscript; available in PMC 2014 June 05. NIH-PA Author Manuscript NIH-PA Author Manuscript NIH-PA Author Manuscript orlistat could be added to the treatment program. Sibutramine was also used for weight management until it was withdrawn from the U.S. market. Medications for glycemic control were added in the following order: 1) metformin, 2) a glucagon-like peptide-1 analog (GLP-1) or dipeptidyl peptidase 4 inhibitor (DPP-4), 3) sulfonylurea or pioglitazone, and 4) insulin. LDL cholesterol control was pursued with HMG-CoA reductase inhibitors first, followed by ezetimibe if necessary. Blood pressure medications were used in the following order: 1) angiotensin converting enzyme inhibitor (ACE) or angiotensin receptor blocker (ARB), 2) diuretic, 3) beta blocker, and 4) additional agents as necessary. The first approach to reducing elevated triglycerides was control of hyperglycemia; however, if triglycerides remained > 300 mg/dl, fenofibrate or fish oil was added. Smoking cessation was strongly recommended for all participants. An ACE or ARB was provided for all participants with micro- or macro-albuminuria. Aspirin (81-100 mg daily) was added consistent with evolving recommendations from the ADA and when not otherwise contraindicated. Vitamin and mineral supplements were prescribed for all patients based on routine testing; RYGB participants were prescribed additional calcium, iron, vitamin D and vitamin B12 supplements regardless of routine tests. The same medication treatment goals and algorithms were used for all participants with some qualifications. Occasionally, a participant refused or did not tolerate recommended medications or was controlled using medications differing from the algorithm and initiated prior to study entry."
Treatment duration	12 months
Follow-up from baseline	12 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 120 Intervention group/s: RYGB (n=60) Comparator group: LS/IMM (n=60)

<table>
<tr><td>Mean age ± SD</td><td>49y</td></tr>
<tr><td>Sex</td><td>60.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI (kg/m2)
Mean (95% CIs)</td><td>RYGB: 34.9
(34.2-35.7)</td><td>LS/IMM: 34.3
(33.5-35.1)</td></tr>
<tr><td>Weight (kg)
Mean (95% CIs)</td><td>RYGB: 98.8
(95.2-102)</td><td>LS/IMM: 97.9
(93.6-102)</td></tr>
<tr><td>Waist Circumference (cm)
Mean (95% CIs)</td><td>RYGB: 114
(111-116)</td><td>LS/IMM: 113
(110-116)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI (kg/m2)
Mean (95% CIs)</td><td>RYGB: 25.8
(24.9-26.7)</td><td>LS/IMM: 31.6
(30.6-32.6)</td></tr>
<tr><td>Weight (kg)
Mean (95% CIs)</td><td>RYGB: 73
(69.5-76.5)</td><td>LS/IMM: 90.1
(85.7-94.5)</td></tr>
<tr><td>Waist Circumference (cm)
Mean (95% CIs)</td><td>RYGB: 90
(87-93)</td><td>LS/IMM: 105
(102-108)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Percent Weight Change (%)
Mean (95% CIs)</td><td>RYGB: -26
(-28--24)</td><td>LS/IMM: -7.9
(-9.9--5.8)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Ikramuddin, S., Billington, C. J., Lee, W.-J., Bantle, J. P., Thomas, A. J., Connett, J. E., Leslie, D. B., Inabnet, W. B., III, Jeffery, R. W., Chong, K., Chuang, L.-M., Sarr, M. G., Jensen, M. D., Vella, A., Ahmed, L., Belani, K., Schone, J. L., Olofson, A. E., Bainbridge, H. A., . . . Korner, J. (2015). Roux-en-Y gastric bypass for diabetes (the Diabetes Surgery Study): 2-year outcomes of a 5-year, randomised, controlled trial. The Lancet Diabetes & Endocrinology, 3(6), 413-422. https://doi.org/https://dx.doi.org/10.1016/S2213-8587(15)00089-3; Ikramuddin, S., Korner, J., Lee, W.-J., Bantle, J. P., Thomas, A. J., Connett, J. E., Leslie, D. B., Inabnet, W. B., 3rd, Wang, Q., Jeffery, R. W., Chong, K., Chuang, L.-M., Jensen, M. D., Vella, A., Ahmed, L., Belani, K., Olofson, A. E., Bainbridge, H. A., & Billington, C. J. (2016). Durability of addition of Roux-en-Y gastric bypass to lifestyle intervention and medical management in achieving primary treatment goals for uncontrolled type 2 diabetes in mild to moderate obesity: a randomized control trial. Diabetes Care, 39(9), 1510-1518. https://doi.org/https://dx.doi.org/10.2337/dc15-2481</td></tr>
</table>

N/A – Not applicable

Ikramuddin, 2015

Guideline record ID: 10768--1

Study characteristics		
Citation	Ikramuddin, S., Billington, C. J., Lee, W.-J., Bantle, J. P., Thomas, A. J., Connett, J. E., Leslie, D. B., Inabnet, W. B., III, Jeffery, R. W., Chong, K., Chuang, L.-M., Sarr, M. G., Jensen, M. D., Vella, A., Ahmed, L., Belani, K., Schone, J. L., Olofson, A. E., Bainbridge, H. A., . . . Korner, J. (2015). Roux-en-Y gastric bypass for diabetes (the Diabetes Surgery Study): 2-year outcomes of a 5-year, randomised, controlled trial. The Lancet Diabetes & Endocrinology, 3(6), 413-422. https://doi.org/https://dx.doi.org/10.1016/S2213-8587(15)00089-3	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Roux-en-Y gastric bypass for diabetes (the Diabetes Surgery Study): 2-year outcomes of a 5-year, randomised, controlled trial	
Location	USA; Taiwan	
Trial name	Diabetes Surgery Study (DSS)	
Methods		
Inclusion criteria	"Key inclusion criteria included HbA1c of 8·0% (64 mmol/mol) or higher despite at least 6 months care from a doctor for type 2 diabetes, BMI 30·0-39·9 kg/m2, age 30-67 years, and a willingness and ability to accept random assignment and follow the full treatment protocol."	
Exclusion criteria	"Exclusion criteria included any cardiovascular event (such as myocardial infarction or stroke) in the previous 6 months, or current evidence of congestive heart failure or angina pectoris."	
Setting	Hospital, Home	
Intervention	"The Roux-en-Y surgical technique was standardised across all sites and done with construction of a 20 mL lesser curvature gastric pouch, and a 100 cm biliopancreatic limb. All surgeons committed to following this protocol, which was reviewed at an onsite meeting. The technical skill of each surgeon was assessed by personal observation of the principal surgeon. The study surgeons did all postoperative surgical interventions. The lifestyle and medical management intervention protocol for 12-24 months was similar in both treatment groups."	
Control/Comparator	"The lifestyle and medical management intervention was modelled on successful clinical trials, especially the Diabetes Prevention Program14 and the Look AHEAD trial protocol.15 Participants were instructed to weigh themselves and record eating and exercise behaviours daily, and advised to progressively increase their amount of moderate-intensity physical activity (such as walking) to 325 min per week. Participants met regularly with a dietitian or registered nurse to discuss strategies for weight management and increasing physical activity, including self-monitoring, stimulus control, problem-solving, social support, cognitive behaviour modification, recipe modification, eating away from home, and relapse prevention. Counselling sessions consisted of 24 meetings (one per week) during the first 6 months, one meeting every 2 weeks between months 7 and 9, one meeting per month between months 10 and 15, then one meeting every 3 months either up to 24 months or until a total of 40 modules were completed. The lifestyle and medical management intervention protocol for 12-24 months was similar in both treatment groups. The intervention was provided without charge, except New York participants were required by law to make standard insurance copayments for medicines. Minor modifications were made to the interventions in the USA versus Taiwan to account for differences in language and culture. Visits with an endocrinologist took place each month for 6 months, then every 3 months (or monthly if not at goal) for the next 6 months, then every 3 months through the second year. Medicines for glycaemic control were added or reintroduced in the	

<table>
<tr><td></td><td>following order: metformin, a glucagon-like peptide-1 agonist or dipeptidyl peptidase-4 inhibitor, sulfonylurea or pioglitazone, and insulin. We pursued control of LDL cholesterol with 3- hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitors first, then ezetimibe if necessary. Blood pressure medicines were used in the following order: angiotensin-converting enzyme inhibitors or angiotensin receptor II blockers, diuretics, β blockers, and additional agents as necessary. If triglyceride concentrations remained higher than 3·39 mmol/L after hyperglycaemia was controlled, fenofibrate or fish oil were added to participants' diets. Smoking cessation was strongly recommended for all. An angiotensinconverting enzyme inhibitor or angiotensin receptor II blocker was provided for participants with microalbuminuria or macro-albuminuria. Aspirin (81-100 mg daily) was added, consistent with evolving recommendations from the ADA, when not contra indicated. Medicines approved by the US Food and Drug Administration for long-term obesity treatment were used. By protocol, participants in the gastric bypass group were prescribed a multivitamin and other supplements, including calcium, iron, vitamin D, and vitamin B12, irrespective of routine test results, to prevent nutritional deficiencies. All patients received routine testing for nutritional deficiencies and supplements were adjusted as necessary."</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 120
Intervention group/s: Roux-en-Y gastric bypass (n=60)

Comparator group: Lifestyle management (n=60)</td></tr>
<tr><td>Mean age ± SD</td><td>Gastric bypass: 49y (9); Lifestyle management: 49y (8)</td></tr>
<tr><td>Sex</td><td>60.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Roux-en-Y gastric bypass: 34.9 (3)</td><td>Lifestyle management: 34.3 (3.1)</td></tr>
<tr><td>Baseline Waist circumference (cm)
Mean (SD)</td><td>Roux-en-Y gastric bypass: 114 (10)</td><td>Lifestyle management: 113 (12)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Roux-en-Y gastric bypass: 26 (5.2)</td><td>Lifestyle management: 31.7 (5.4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Roux-en-Y gastric bypass: 26.5 (5.4)</td><td>Lifestyle management: 31.8 (6.7)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss (%)
Mean (SD)</td><td>Roux-en-Y gastric bypass: 25.6 (13.3)</td><td>Lifestyle management: -7.5 (12.2)</td></tr>
</table></td></tr>
</table>

<table>
<tr><td>12 months or closest time point</td><td><table>
<tr><td>Reduction in waist circumference (%) Mean (SD)</td><td>Roux-en-Y gastric bypass: -23.9 (14.8)</td><td>Lifestyle management: -8.3 (14.7)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss (%) Mean (SD)</td><td>Roux-en-Y gastric bypass: -23.8 (13.9)</td><td>Lifestyle management: -7.3 (14.9)</td></tr>
<tr><td>Reduction in waist circumference (%) Mean (SD)</td><td>Roux-en-Y gastric bypass: -22.9 (15.8)</td><td>Lifestyle management: -8 (15.8)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Ikramuddin, S., Korner, J., Lee, W.-J., Connett, J. E., Inabnet, W. B., Billington, C. J., Thomas, A. J., Leslie, D. B., Chong, K., Jeffery, R. W., Ahmed, L., Vella, A., Chuang, L.-M., Bessler, M., Sarr, M. G., Swain, J. M., Laqua, P., Jensen, M. D., & Bantle, J. P. (2013). Roux-en-Y gastric bypass vs intensive medical management for the control of type 2 diabetes, hypertension, and hyperlipidemia: the Diabetes Surgery Study randomized clinical trial. JAMA, 309(21), 2240-2249. https://doi.org/10.1001/jama.2013.5835; Ikramuddin, S., Korner, J., Lee, W.-J., Bantle, J. P., Thomas, A. J., Connett, J. E., Leslie, D. B., Inabnet, W. B., 3rd, Wang, Q., Jeffery, R. W., Chong, K., Chuang, L.-M., Jensen, M. D., Vella, A., Ahmed, L., Belani, K., Olofson, A. E., Bainbridge, H. A., & Billington, C. J. (2016). Durability of addition of Roux-en-Y gastric bypass to lifestyle intervention and medical management in achieving primary treatment goals for uncontrolled type 2 diabetes in mild to moderate obesity: a randomized control trial. Diabetes Care, 39(9), 1510-1518. https://doi.org/https://dx.doi.org/10.2337/dc15-2481</td></tr>
</table>

N/A – Not applicable

Ikramuddin, 2016

Guideline record ID: 10330--1

Study characteristics		
Citation	Ikramuddin, S., Korner, J., Lee, W.-J., Bantle, J. P., Thomas, A. J., Connett, J. E., Leslie, D. B., Inabnet, W. B., 3rd, Wang, Q., Jeffery, R. W., Chong, K., Chuang, L.-M., Jensen, M. D., Vella, A., Ahmed, L., Belani, K., Olofson, A. E., Bainbridge, H. A., & Billington, C. J. (2016). Durability of addition of Roux-en-Y gastric bypass to lifestyle intervention and medical management in achieving primary treatment goals for uncontrolled type 2 diabetes in mild to moderate obesity: a randomized control trial. Diabetes Care, 39(9), 1510-1518. https://doi.org/https://dx.doi.org/10.2337/dc15-2481	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Durability of Addition of Roux-en-Y Gastric Bypass to Lifestyle Intervention and Medical Management in Achieving Primary Treatment Goals for Uncontrolled Type 2 Diabetes in Mild to Moderate Obesity: A Randomized Control Trial	
Location	US; Taiwan	
Trial name	Diabetes Surgery Study (DSS)	
Methods		
Inclusion criteria	“The complete list of inclusion and exclusion criteria has been published (13). Briefly, key inclusion criteria included HbA1c $8.0% despite at least 6 months under a provider's care for type 2 diabetes, BMI 30.0-39.9 kg/m2, C-peptide .1.0 ng/mL, and stated willingness and ability to accept randomization and follow the full treatment protocol.”	
Exclusion criteria	Not reported	
Setting	Hospital, Home	
Intervention	“The 2-year lifestyle intervention was based on protocols from two successful clinical trials: the Diabetes Prevention Program (DPP) and the Look AHEAD (Action for Health in Diabetes) study (15,16). Over the first 12 months the median number of lifestyle modules delivered was 32 for lifestyle-medical management intervention and 27 for gastric bypass. Between 12 and 24 months the median number of modules was five and seven for lifestyle-medical management intervention and gastric bypass, respectively. Visits with an endocrinologist occurred monthly for 6 months, then quarterly (or monthly if not at ADA treatment goal) for the next 6 months, and then quarterly through the second year. The intensive medical management protocol for both treatment groups aimed to optimize drug therapy to control hyperglycemia, cholesterol, and hypertension. After 24 months, all study interventions ceased and patients returned to usual care with their primary physician. Each subject's primary physician received a letter describing the study, the subject's current status, medications, and goals of care. The primary physicians also received recommendations about medications and information about the need for nutritional supplementation as appropriate. The study coordinator contacted participants at 30 months to maintain their connection with the study and to obtain interimdata on adverse events. Study endocrinologists evaluated patients during a clinic visit at 36 months but did not modify medications. The visit included a collection of blood pressure, weight, and waist circumference data and laboratory studies. Participants were encouraged to increase medication compliance, nutritional supplementation, and dietary control if adherence was deemed to be an issue. Gastric bypass was laparoscopically performed in a standardized fashion with construction of a 20-mL lesser curvature gastric pouch and a 100-cm biliopancreatic limb. Study surgeons performed all postoperative surgical interventions (13,17). The following is from an original paper describing the protocol in more detail: "The lifestyle-medical management pro-tocol consisted of 2 components-lifestyle modification designed to pro-duce maximum achievable weight lossand medications to control glycemiaand cardiovascular disease risk factorswhile facilitating weight loss. OnlyUS Food	

	and Drug Administration-approved medications were used." "Both groupswere advised to progressively increasetheir level of moderate-intensity physi-cal activity (such as walking) to a totalof 325 minutes per week. All lifestyle-medical management participants weregiven calorie intake targets of 1200, 1500,or 1800 kilocalories per day, dependingon body weight, with the goal of pro-ducing a weight loss of 1 to 2 pounds perweek. Portion-controlled diets using mealreplacements, structured menus, andcalorie counting were encouraged to helpparticipants stay within calorie limits.Both groups met regularly with atrained interventionist to discuss strat-egies for facilitating weight manage-ment and increasing physical activity,including self-monitoring, stimuluscontrol, problem solving, social sup-port, cognitive behavior modification,recipe modification, eating away fromhome, and relapse prevention. Coun-seling sessions comprised 24 weeklymeetings over the first 6 months, bi-weekly meetings between months 7 and9, and monthly meetings betweenmonths 10 and 12.The lifestyle intervention protocolwas similar for participants in bothtreatment groups. Patients assigned tothe gastric bypass group, however, de-layed initiation of the lifestyle inter-vention until they could tolerate solidfoods (typically about 3 to 4 months af-ter surgery), did not have calorie ceil-ings during the period of rapid weightloss, and received additional instruc-tion regarding food volume and ad-equate protein intake.Medications.When the interven-tion did not produce adequate weightloss among those in the lifestyle-medical management group, orlistatcould be added to the treatment pro-gram. Sibutramine was also used forweight management until it was with-drawn from the US market."”
Control/Comparator	“The 2-year lifestyle intervention was based on protocols from two successful clinical trials: the Diabetes Prevention Program (DPP) and the Look AHEAD (Action for Health in Diabetes) study (15,16). Over the first 12 months the median number of lifestyle modules delivered was 32 for lifestyle-medical management intervention and 27 for gastric bypass. Between 12 and 24 months the median number of modules was five and seven for lifestyle-medical management intervention and gastric bypass, respectively. Visits with an endocrinologist occurred monthly for 6 months, then quarterly (or monthly if not at ADA treatment goal) for the next 6 months, and then quarterly through the second year. The intensive medical management protocol for both treatment groups aimed to optimize drug therapy to control hyperglycemia, cholesterol, and hypertension. After 24 months, all study interventions ceased and patients returned to usual care with their primary physician. Each subject's primary physician received a letter describing the study, the subject's current status, medications, and goals of care. The primary physicians also received recommendations about medications and information about the need for nutritional supplementation as appropriate. The study coordinator contacted participants at 30 months to maintain their connection with the study and to obtain interimdata on adverse events. Study endocrinologists evaluated patients during a clinic visit at 36 months but did not modify medications. The visit included a collection of blood pressure, weight, and waist circumference data and laboratory studies. Participants were encouraged to increase medication compliance, nutritional supplementation, and dietary control if adherence was deemed to be an issue. The following is from an original paper describing the protocol in more detail: "The lifestyle-medical management pro-tocol consisted of 2 components-lifestyle modification designed to pro-duce maximum achievable weight lossand medications to control glycemiaand cardiovascular disease risk factorswhile facilitating weight loss. OnlyUS Food and Drug Administration-approved medications were used." "Both groupswere advised to progressively increasetheir level of moderate-intensity physi-cal activity (such as walking) to a totalof 325 minutes per week. All lifestyle-medical management participants weregiven calorie intake targets of 1200, 1500,or 1800 kilocalories per day, dependingon body weight, with the goal of pro-ducing a weight loss of 1 to 2 pounds perweek. Portion-controlled diets using mealreplacements, structured menus, andcalorie counting were encouraged to helpparticipants stay within calorie limits.Both groups met regularly with atrained interventionist to discuss strat-egies for facilitating weight manage-ment and increasing physical activity,including self-monitoring, stimuluscontrol, problem solving, social sup-port, cognitive behavior modification,recipe modification, eating away fromhome, and relapse prevention. Coun-seling sessions comprised 24 weeklymeetings over the first 6 months, bi-weekly meetings between months 7 and9, and monthly meetings betweenmonths 10 and 12.The lifestyle intervention

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<tr><td></td><td>protocolwas similar for participants in bothtreatment groups. Patients assigned tothe gastric bypass group, however, de-layed initiation of the lifestyle inter-vention until they could tolerate solidfoods (typically about 3 to 4 months af-ter surgery), did not have calorie ceil-ings during the period of rapid weightloss, and received additional instruc-tion regarding food volume and ad-equate protein intake.Medications.When the interven-tion did not produce adequate weightloss among those in the lifestyle-medical management group, orlistatcould be added to the treatment pro-gram. Sibutramine was also used forweight management until it was with-drawn from the US market."."</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>36 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 119
Intervention group/s: RYGB + Lifestyle/medical management (n=60)

Comparator group: Lifestyle/medical management (n=59)</td></tr>
<tr><td>Mean age ± SD</td><td>RYGB + Lifestyle/medical management: 49 (9); Lifestyle/medical management: 49(8)</td></tr>
<tr><td>Sex</td><td>60.50% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>RYGB + Lifestyle/medical management: 34.9
(3)

RYGB + Lifestyle/medical management: 114
(10)</td><td>Lifestyle/medical management: 34.3
(3.1)

Lifestyle/medical management: 113
(12)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Weight (kg) at 12 and 24 months
Mean (SD)</td><td>RYGB + Lifestyle/medical management: 26
(5.3)

RYGB + Lifestyle/medical management: 73.5
(19.8)</td><td>Lifestyle/medical management: 31.7
(5.5)

Lifestyle/medical management: 90.6
(24.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Weight (kg) at 12 and 24 months
Mean (SD)</td><td>RYGB + Lifestyle/medical management: 27.7
(5.8)

RYGB + Lifestyle/medical management: 77.9
(20.9)</td><td>Lifestyle/medical management: 32.1
(6.8)

Lifestyle/medical management: 92.1
(29.2)</td></tr>
</table>
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<tr><td>Change in outcome measure from baseline to</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
</table>
</td></tr>
</table>

12 months or closest time point	Change in weight (%) Mean (SD)	RYGB + Lifestyle/medical management: -25.5 (13.5)	Lifestyle/medical management: -7.3 (12.5)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in weight (%) Mean (SD)	RYGB + Lifestyle/medical management: -21 (14.5)	Lifestyle/medical management: -6.3 (16.1)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data	Ikramuddin, S., Korner, J., Lee, W.-J., Connett, J. E., Inabnet, W. B., Billington, C. J., Thomas, A. J., Leslie, D. B., Chong, K., Jeffery, R. W., Ahmed, L., Vella, A., Chuang, L.-M., Bessler, M., Sarr, M. G., Swain, J. M., Laqua, P., Jensen, M. D., & Bantle, J. P. (2013). Roux-en-Y gastric bypass vs intensive medical management for the control of type 2 diabetes, hypertension, and hyperlipidemia: the Diabetes Surgery Study randomized clinical trial. JAMA, 309(21), 2240-2249. https://doi.org/10.1001/jama.2013.5835; Ikramuddin, S., Billington, C. J., Lee, W.-J., Bantle, J. P., Thomas, A. J., Connett, J. E., Leslie, D. B., Inabnet, W. B., III, Jeffery, R. W., Chong, K., Chuang, L.-M., Sarr, M. G., Jensen, M. D., Vella, A., Ahmed, L., Belani, K., Schone, J. L., Olofson, A. E., Bainbridge, H. A., . . . Korner, J. (2015). Roux-en-Y gastric bypass for diabetes (the Diabetes Surgery Study): 2-year outcomes of a 5-year, randomised, controlled trial. The Lancet Diabetes & Endocrinology, 3(6), 413-422. https://doi.org/https://dx.doi.org/10.1016/S2213-8587(15)00089-3		

N/A – Not applicable

Iłowiecka, 2021

Guideline record ID: 10770--1

Study characteristics		
Citation	Iłowiecka, K., Glibowski, P., Skrzypek, M., & Styk, W. (2021). The long-term dietitian and psychological support of obese patients who have reduced their weight allows them to maintain the effects. Nutrients, 13(6), 2020. https://doi.org/10.3390/nu13062020	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Long-Term Dietitian and Psychological Support of Obese Patients Who Have Reduced Their Weight Allows Them to Maintain the Effects	
Location	Poland	
Trial name	N/A	
Methods		
Inclusion criteria	"Obese patients from the Lublin region, Poland, were recruited from a 3-year intervention study. After 12 months of weight loss process (personalised diet, encouraged to do PA, unlimited dietitian support) n=36 entered phase 2 (the current study). Original paper reference:doi: 10.3390/app10175830 . Inclusion criteria for that study were: age 18-50, obesity grade 0 according to the American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) classification [24], and readiness to comply with energy-restricted diet principles."	
Exclusion criteria	"Not participating in 12 month study. Original exclusion criteria from Banach paper: The exclusion criteria were: occurrence of obesity complications listed in the AACE/ACE classification, other metabolic and autoimmune disorders, infectious diseases during the study period, pregnancy, lactation, taking medications that may affect body weight, lactose intolerance, and allergy to cow's milk."	
Setting	University/research centre	
Intervention	"SG was invited to participate in group and individual meetings conducted by a qualified dietitian and a psychologist. The main assumptions in this stage comprised regular dietary education, in particular focusing on the most practical information of balanced nutrition, and psychological support. Based on the acquired knowledge, the participants were expected to become independent in weight loss maintenance without applying a strict nutritional plan. Teaching them correct eating habits was a priority in this phase. Ph2 was based on regular (at least once a month) group meetings where patients had the opportunity to acquire new knowledge and exchange experience. If applicable, there was also a possibility of individual sessions with a psychologist or dietitian (without a chance of obtaining a diet plan). The topics discussed during Ph2 included the assumptions of the Ten Top Tips (TTT) method, "which encouraged daily repetition of ten behaviors proposed to create a negative energy balance and subsequent weight loss. The behaviors included: (1) keep to a meal routine, (2) eat reduced-fat foods, (3) walk 10,000 steps a day, (4) pack a healthy snack, (5) check food labels, (6) watch portion sizes, (7) stand up for 10 min in every hour, (8) choose low-calorie drinks, (9) be mindful when eating, and (10) eat five portions of fruit and vegetables a day". Additionally, the discussed topics were related to the basic guidelines of balanced nutrition, rational purchasing, healthy substitutes for popular products, knowledge of portion size, valuable tips for holidays and family celebrations, or most common mistakes during weight loss. The psychological part was based on psychoeducation and some elements of integrating cognitive behavioral therapy (CBT) and motivational interviewing (MI), which might be effective methods in obesity reduction. CBT is traditionally recognized as the best-established long-term perspective treatment for obesity. Ph2 used some CBT assumptions, i.e., self-monitoring goal setting, stimulus control, contingency management, skills for increasing social support, problem-solving, and relapse prevention. The COVID-19 pandemic made it challenging to conduct an experiment,	

<table>
<tr><td></td><td>and the lockdown made it impossible to continue direct meetings. For this reason, Ph2 was continued via the Internet. The participants were receiving thematic newsletters or nutrition pamphlets related to weight control. They were also communicating and supporting each other (e.g., by exchanging photos of meals, recipes, or pieces of information about the effects) using a popular communicator.”</td></tr>
<tr><td>Control/Comparator</td><td>“CG did not receive any dietary care.”</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 36
Intervention group/s: Supported group (SG) (n=18)

Comparator group: Control group (CG) (n=18)</td></tr>
<tr><td>Mean age ± SD</td><td>35.58y (9.85)</td></tr>
<tr><td>Sex</td><td>61.11% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Bodyweight (kg)
Mean (SD)</td><td>Supported group (SG): 97.52 (14.79)</td><td>Control group (CG): 101.02 (22.51)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Supported group (SG): 32.97 (3.29)</td><td>Control group (CG): 33.82 (4.88)</td></tr>
<tr><td>WC (cm)
Mean (SD)</td><td>Supported group (SG): 100.7 (11.5)</td><td>Control group (CG): 101.67 (15.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Bodyweight (kg)
Mean (SD)</td><td>Supported group (SG): 100.04 (15.62)</td><td>Control group (CG): 106.33 (23.9)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Supported group (SG): 33.85 (3.7)</td><td>Control group (CG): 35.6 (5.23)</td></tr>
<tr><td>WC (cm)
Mean (SD)</td><td>Supported group (SG): 102.94 (13.81)</td><td>Control group (CG): 109.5 (17.77)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Bodyweight (kg)
Mean (SD)</td><td>Supported group (SG): 2.52 (8.4)</td><td>Control group (CG): 5.31 (4.62)</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (SD)</td><td>Supported group (SG): 0.88 (2.85)</td><td>Control group (CG): 1.78 (1.41)</td></tr>
<tr><td>Change in WC (cm
Mean (SD)</td><td>Supported group (SG): 2.3 (7)</td><td>Control group (CG): 7.83 (5.97)</td></tr>
</table>
</td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Inoue, 2015

Guideline record ID: 10773--1

Study characteristics		
Citation	Inoue, D. S., De Mello, M. T., Foschini, D., Lira, F. S., De Piano Ganen, A., Da Silveira Campos, R. M., De Lima Sanches, P., Silva, P. L., Corgosinho, F. C., Rossi, F. E., Tufik, S., & Dâmaso, A. R. (2015). Linear and undulating periodized strength plus aerobic training promote similar benefits and lead to improvement of insulin resistance on obese adolescents. Journal of Diabetes and its Complications, 29(2), 258-264. https://doi.org/https://dx.doi.org/10.1016/j.jdiacomp.2014.11.002	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Linear and undulating periodized strength plus aerobic training promote similar benefits and lead to improvement of insulin resistance on obese adolescents	
Location	Brazil	
Trial name	N/A	
Methods		
Inclusion criteria	"A total of 80 post-puberty (Tanner & Whitehouse, 1976) obese adolescents ([BMI > 95th percentile on the Centers for Disease Control and Prevention reference growth charts) (Center for Disease Control & Prevention, 1999) were enrolled in the program (AT n = 40; LP n = 20; and DUP n = 20). However, only 45 adolescents, aged 15 to 18 years (16.28 ± 1.34), including 28 girls and 17 boys, completed the whole year of therapy and were included in this study (Table 1)."	
Exclusion criteria	"Exclusion criteria were as follows: other metabolic or endocrine diseases; chronic alcohol consumption; previous use of drugs such as anabolic-androgenic steroids or psychotropic which may affect appetite regulation; and pregnancy."	
Setting	No information where recruited from	
Intervention	"The present study compares the effectiveness of three types of physical training for obesity control in adolescents submitted to a long-term interdisciplinary therapy. The aim of the interdisciplinary program consists in promoting changes in their sedentary lifestyle and nutritional habits through clinical therapy (once a month), physical exercise (three times a week), nutritional and psychological counselling (once a week). The subjects were randomized in three groups (Table 1). The exercises were performed three times a week, under the supervision of a sport professional. The aerobic training in all groups was done at the cardiac frequency intensity of the Ventilatory Threshold I (VTI) (± 4 bpm) on a motor-driven treadmill (Life Fitness® - Model TR 9700HR) or a cycle ergometer (Life Fitness® - Model 9500HR). The predominant aerobic training group (AT) was initiated with 14 weeks performing 60 minutes of aerobic exercises only. From 14 to 26 weeks the adolescents performed 30 minutes of aerobic plus 30 minutes of strength training non-periodizated with (in addition to) sub-maximal repetitions (SR: load = about 25% less of RM). Linear periodization group (LP) was divided in three mesocycles lasting eight weeks. In the first mesocycle the participants performed 30 minutes of aerobic plus strength training of three sets of 15-20 maximal repetition (RM). In the second, there is 30 minutes of aerobic plus strength training of three sets of 10-12 RM. In the third, there is 30 minutes of aerobic plus strength training of three sets of 6-8RM (Table 2). Daily undulating periodization group (DUP) performed three different loads in the same week. On Mondays, the participants trained 30 minutes of aerobic plus strength training with three sets of 15-20 RM; on Wednesdays, 30 minutes of aerobic plus strength training with three sets of 10-12RM; and on Fridays, 30 minutes of aerobic plus strength training with three sets of 6-8RM on all of the intervention period (Table 2)."	

<table>
<tr><td>Control/Comparator</td><td>“Aerobic group aerobic training (aerobic activities and some strength training); nutritional therapy, psych therapy, endocrinologist.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 45
Intervention group/s: Linear periodization (n=13); Daily undulating periodization (n=12)

Comparator group: Aerobic training (n=20)</td></tr>
<tr><td>Mean age ± SD</td><td>16.28y (1.34)</td></tr>
<tr><td>Sex</td><td>62.22% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight
Mean (SE)</td><td>Linear periodization: 99.4
(3.8)
Daily undulating periodization: 107.9
(3.3)</td><td>Aerobic training: 99.7
(3.1)</td></tr>
<tr><td>BMI
Mean (SE)</td><td>Linear periodization: 36.4
(1.6)
Daily undulating periodization: 38.2
(1.3)</td><td>Aerobic training: 35.1
(0.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight
Mean (SE)</td><td>Linear periodization: 88.5
(3.2)
Daily undulating periodization: 91.5
(3.3)</td><td>Aerobic training: 90.6
(3)</td></tr>
<tr><td>BMI
Mean (SE)</td><td>Linear periodization: 32.2
(1.3)
Daily undulating periodization: 32.1
(1.5)</td><td>Aerobic training: 31.8
(1.1)</td></tr>
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</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
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<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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Compliance with treatment	7 dropped out of LP group (35%) and 8 dropped out of DUP group (14%). Note 50% of aerobic training (control group) dropped out - 20 completed out of 40.
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Iqbal, 2010

Guideline record ID: 10774--1

Study characteristics		
Citation	Iqbal, N., Vetter, M. L., Moore, R. H., Chittams, J. L., Dalton-Bakes, C. V., Dowd, M., Williams-Smith, C., Cardillo, S., & Wadden, T. A. (2010). Effects of a low-intensity intervention that prescribed a low-carbohydrate vs. a low-fat diet in obese, diabetic participants. Obesity, 18(9), 1733-1738. https://doi.org/10.1038/oby.2009.460	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of a Low-intensity Intervention That Prescribed a Low-carbohydrate vs. a Low-fat Diet in Obese, Diabetic Participants	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were persons with type 2 diabetes, age ≥18 years, with a BMI ≥30 kg/m2. Diabetes was defined as a pre-existing clinical diagnosis or by the use of insulin or oral antidiabetic medications."	
Exclusion criteria	"Exclusion criteria included serum creatinine concentration >1.5 mg/dl (133 µmol/l), urine albumin-to-creatinine ratio >200 µg/mg, an HbA1c <6.0% or >12.0%, hypoglycemic or hyperglycemic episodes within the past month requiring external assistance, weight loss ≥5% in the past 3 months, participation in a weight-loss program, or the use of weight-loss medications."	
Setting	GP clinic, outpatient endocrinology, cardiology, and general medicine clinics at the Philadelphia Veterans Affairs Medical Center.	
Intervention	"Diabetic participants were randomly assigned to a low-carbohydrate diet (<30 g/day) Low-carbohydrate condition. Participants were provided weekly group nutrition education sessions for the first month, and monthly sessions thereafter through the end of 24 months. Participants in the low-carbohydrate condition were provided with the CalorieKing Calorie, Fat, and Carbohydrate Counter (Family Health Publications, Costa Mesa, CA) to help them achieve their target carbohydrate intake of 30 g/day. Thirty grams of carbohydrate was specifically chosen as the target intake, a goal we had used in our previous study (1). Although the glycemic index was not specifically discussed, participants were encouraged to select whole grain products and foods with a high fiber content. Participants were not instructed to restrict their total fat or caloric intake, although general advice was provided on the various types of dietary fat. They were encouraged to consume healthy fats (e.g., monounsaturated and polyunsaturated) and to minimize the intake of saturated and trans fats. Urinary or plasma ketones were not measured to evaluate dietary adherence. All participants were encouraged to engage in at least 30min of moderate activity at least five times per week and were given pedometers."	
Control/Comparator	"Diabetic participants were randomly assigned to a low fat diet (<or=30% of calories from fat with a deficit of 500 kcal/day). Participants were provided weekly group nutrition education sessions for the first month, and monthly sessions thereafter through the end of 24 months. Participants assigned to the low-fat group were given an individualized "fat budget" and a calorie goal, which were based on the participant's height, weight, and target calorie intake (with a deficit of 500 kcal daily to promote weight loss). In order to facilitate monitoring of fat and calories, participants in this condition were also provided with the CalorieKing Calorie, Fat, and Carbohydrate Counter. Participants received extensive education about the various types of dietary fats. Heart-healthy fats were emphasized, and participants were instructed to consume <7% of total calories from saturated fats (in accordance with the American Heart Association guidelines). Participants were specifically	

<table>
<tr><td></td><td>instructed to consume <300 mg of dietary cholesterol daily. Participants were also encouraged to increase their intake of fruits and vegetables. All participants were encouraged to engage in at least 30min of moderate activity at least five times per week and were given pedometers.”</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 144
Intervention group/s: Low CHO (n=70)

Comparator group: Low fat (n=74)</td></tr>
<tr><td>Mean age ± SD</td><td>59.4y (9.2)</td></tr>
<tr><td>Sex</td><td>10.42% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Persons with type 2 diabetes, Diabetes was defined as a pre-existing clinical diagnosis or by the use of insulin or oral antidiabetic medications.</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg) - Baseline Mean (SD)</td><td>Low CHO: 115.5 (16.7)</td><td>Low fat: 118.3 (21.3)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg) Mean (SE)</td><td>Low CHO: -1.3</td><td>Low fat: -1.2</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg) Mean (SE)</td><td>Low CHO: -1.5</td><td>Low fat: -0.2</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Jago, 2011

Guideline record ID: 10333--1

Study characteristics		
Citation	Jago, R., McMurray, R. G., Drews, K. L., Moe, E. L., Murray, T., Pham, T. H., Venditti, E. M., & Volpe, S. L. (2011). HEALTHY intervention: fitness, physical activity, and metabolic syndrome results. Medicine & Science in Sports & Exercise, 43(8), 1513-1522. https://doi.org/10.1249/MSS.0b013e31820c9797	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	HEALTHY Intervention: Fitness, Physical Activity, and Metabolic Syndrome Results	
Location	USA	
Trial name	HEALTHY	
Methods		
Inclusion criteria	"Middle school student body is at least 50% minority (defined as African American, Hispanic/Latino, and/or Native American) and/or greater than 50% eligible for free or reduced lunch. Middle school annual school-wide attrition from all causes is <= 25% (estimate determined from data provided by the school). Middle school expected cohort size at end of study is at least 50 per school determined by applying 50% anticipated enrollment rate and annual school-wide attrition rate over 3 years. Student able to participate in the school's standard PE program. Student's parent/guardian has provided informed consent for the child to participate in data collection and evaluation procedures. Student has provided informed assent to participate in data collection and evaluation procedures."	
Exclusion criteria	"None."	
Setting	School	
Intervention	"The overall focus of the intervention was on helping students to consume a healthier diet and engage in increased physical activity. The intervention had four integrated components. The first component was a change in the total school food environment, with the nutritional quality of food and beverages provided during school breakfast and lunch periods improved. The second component was a program of peer-led, teacher-facilitated learning activities known as FLASH (Fun Learning Activities for Student Health). Five FLASH modules were implemented over five semesters of the HEALTHY study. Each module contained sessions that were designed to be delivered on a weekly basis to foster self-awareness, knowledge, decision-making skills, and peer involvement for health behavior change. The third component was a social marketing campaign that had a different theme for each semester of the intervention. The five themes were water consumption, encouraging physical activity instead of sedentary time, high-quality versus lowquality food, energy balance, and life choices. Each theme was supported by branding, posters, and messaging that was prominently displayed and reinforced across the school. The fourth element was a revised, more active, physical education (PE) curriculum. The PE curriculum was designed to facilitate higher student participation in the lessons and spend more time engaged in moderate to vigorous physical activity (MVPA) during PE lessons. PE teachers were trained in how to deliver the new program by an expert teacher. Schools also received around $10,000 of equipment and a teacher assistant to facilitate small group activities that were intended to increase activity time during the sessions."	
Control/Comparator	"Control group activities were limited to recruitment and data collection only."	
Treatment duration	2.5 years	
Follow-up from baseline	2.5 years	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 4063
Intervention group/s: HEALTHY multicomponent intervention (n=2060)

Comparator group: Control (n=2003)</td></tr>
<tr><td>Mean age ± SD</td><td>11.3y (0.6)</td></tr>
<tr><td>Sex</td><td>52.40% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Proportion of participants with waist circumference ≥90th percentile (6th grade=pre, 8th grade=post) (All participants) Proportion (%)</td><td>HEALTHY multicomponent intervention: 29.8%</td><td>Control: 29.3%</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Proportion of participants with waist circumference ≥90th percentile (6th grade=pre, 8th grade=post) (All participants) Proportion (%)</td><td>HEALTHY multicomponent intervention: 21.6%</td><td>Control: 23.0%</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Jakicic, 2011

Guideline record ID: 10338--1

Study characteristics		
Citation	Jakicic, J. M., Otto, A. D., Lang, W., Semler, L., Winters, C., Polzien, K., & Mohr, K. I. (2011). The effect of physical activity on 18-month weight change in overweight adults. Obesity, 19(1), 100-109. https://doi.org/https://dx.doi.org/10.1038/oby.2010.122	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The effect of physical activity on 18-month weight change in overweight adults	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Subjects were 18-55 years of age, had a BMI of 25.0-29.9kg/m2, and reported being sedentary, which was defined as <3 days per week of <20min per day of structured exercise."	
Exclusion criteria	"Exclusion criteria included a medical condition that prohibited participation in prescribed levels of PA, a history of coronary heart disease, a medical condition that may affect body weight, taking medication that would affect body weight (i.e., Synthroid) or blood pressure (i.e., β-blocker), or recent weight loss of ≥10 pounds over the prior 12 months."	
Setting	Home, Research University	
Intervention	"Moderate Physical Activity dose (MOD-PA): MOD-PA participated in a behavioral intervention to promote progression and maintenance of 150min/week of structured PA by week 12, with the goal to sustain this dose of activity for the remainder of the 18-month intervention. Subjects were encouraged to spread the PA over a period of at least 5 days per week and to engage in bouts of PA that were at least 10min in duration. Intensity was prescribed as moderate to vigorous, which was defined as 55-85% of age-predicted maximal heart rate or 11-15 on the 15-point rating of perceived exertion scale. For months 1-6, subjects attended weekly behavioral intervention sessions to promote the adoption of this dose of PA, with each month consisting of three weekly group sessions and one individual session with their assigned PA counselor. During months 7-18, subjects attended two group intervention sessions per month combined with two telephone calls per month with their assigned counselor so that weekly contact was sustained throughout the 18-month intervention session. The counselor followed a structured script for the telephone intervention calls, with the goal to complete this call in ≤10min.Each intervention session was supplemented with a written lesson that highlighted the key points of the behavioral session. During each session, subjects were encouraged to exercise on-site with the intervention staff, with an additional supervised session offered on the weekends during months 1-3 to facilitate the initial adoption of the prescribed dose of PA. All remaining PA was performed under nonsupervised conditions. Subjects were provided guidance on healthy eating behaviors consistent with a balanced nutritional diet, but an energy restricted diet was not provided or encouraged. Subjects received a monthly newsletter that included general health information along with pertinent information related to the logistics of the study.; High Physical Activity dose (HIGH-PA): HIGH-PA received an 18-month intervention that was virtually identical to the intervention described for MOD-PA. However, HIGH-PA was prescribed PA that progressed from 100 to 300min/week, with the dose of PA increasing by 25min/week at 4-week intervals."	
Control/Comparator	"Self-help (SELF): self-help group (SELF) only attended assessment visits at 0, 6, 12, and 18 months, with no additional intervention contact provided by the staff. Subjects received a PA self-help manual (Active Living Every Day) (17), along with the same monthly newsletter provided to the MOD-PA and HIGH-PA groups. This SELF intervention is modeled after prior	

<table>
<tr><td></td><td>intervention (18), and was also intended to maintain contact to enhance retention of subjects in this group across the 18-month study period.”</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 269
Intervention group/s: MOD-PA (n=82); HIGH-PA (n=98)

Comparator group: SELF (n=89)</td></tr>
<tr><td>Mean age ± SD</td><td>44.4y (8.4)</td></tr>
<tr><td>Sex</td><td>91.45% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>MOD-PA: 74.1
(8.3)
HIGH-PA: 74.5
(8.3)</td><td>SELF: 73.9
(7.9)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>MOD-PA: 27.1
(1.7)
HIGH-PA: 27
(1.6)</td><td>SELF: 27.1
(1.7)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>MOD-PA: 91.4
(7.9)
HIGH-PA: 90.5
(8.4)</td><td>SELF: 89.3
(8.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>MOD-PA: 73.5
(8.5)
HIGH-PA: 73
(8.7)</td><td>SELF: 72.8
(8.6)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>MOD-PA: 26.9
(2)
HIGH-PA: 26.5
(2.1)</td><td>SELF: 26.7
(2.2)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>MOD-PA: 90.2
(8.9)
HIGH-PA: 87.8
(10.1)</td><td>SELF: 88.1
(8.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>MOD-PA: 73.5
(8.7)
HIGH-PA: 73.5
(9.2)</td><td>SELF: 73.2
(8.5)</td></tr>
<tr><td>BMI (kg/m2)</td><td>MOD-PA: 26.9</td><td>SELF: 26.9</td></tr>
</table>
</td></tr>
</table>

	Mean (SD) Waist circumference (cm) Mean (SD)	(2) HIGH-PA: 26.7 (2.4) MOD-PA: 90.6 (9.4) HIGH-PA: 89.4 (10)	(2.1) SELF: 88.4 (8.8)
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Jakicic, 2012

Guideline record ID: 10342--1

Study characteristics		
Citation	Jakicic, J. M., Tate, D. F., Lang, W., Davis, K. K., Polzien, K., Rickman, A. D., Erickson, K., Neiberg, R. H., & Finkelstein, E. A. (2012). Effect of a stepped-care intervention approach on weight loss in adults: a randomized clinical trial. JAMA, 307(24), 2617-2626. https://doi.org/https://dx.doi.org/10.1001/jama.2012.6866	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a stepped-care intervention approach on weight loss in adults: a randomized clinical trial	
Location	US	
Trial name	Step-Up	
Methods		
Inclusion criteria	"Eligibility included body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) between 25 and less than 40 and age between 18 and 55 years."	
Exclusion criteria	"Ineligibility included history of cardiovascular disease, presence of a metabolic condition that might affect weight, presence of a medical condition that would contraindicate diet and exercise, taking medication that would affect weight or heart rate response to exercise, sustained weight loss of 4.5 kg or greater within the past 6 months, regular participation in physical activity equivalent of 20 minutes per day or longer on 3 or more days per week over the prior 6 months, recent pregnancy (within 6 months), or current or planned pregnancy within the subsequent 18 months."	
Setting	Hospital	
Intervention	"The SBWI and STEP groups were prescribed identical diet and physical activity recommendations. The diet was prescribed to reduce energy intake and dietary fat consumption. Energy intake was prescribed at 1200 kcal/d for participants weighing 90 kg or less, 1500 kcal/d for participants weighing more than 90 kg, or 1800 kcal/d for participants weighing 113 kg or more. Prescribed kilocalories per day were adjusted downward for participants if the mean weight loss was less than 0.9 kg per week, the participant had a BMI of 25 or greater, and if the participant expressed a desire to continue to lose weight. Prescribed kilocalories per day were adjusted upward in 100 kcal/d increments each week when further weight loss was not indicated (BMI 25) or when the participant expressed to the intervention staff that they no longer desired to lose additional weight. Meal plans were provided to assist with adoption of dietary recommendations. Participants were instructed to self-monitor food intake in a weekly diary, and interventionists provided feedback to the participant in an attempt to maximize adherence to prescribed dietary goals. The SBWI group returned diaries at intervention sessions, whereas the STEP group returned diaries at in-person sessions but otherwise returned diaries via postal mail. Prescribed physical activity progressed to 300 minutes per week by the end of week 24, with participants encouraged to maintain this dose for the remainder of the 18 months. Intensity was prescribed as moderate to vigorous. 14 Participants were instructed to self-monitor their physical activity in a weekly diary that was reviewed by the interventionists and feedback was provided to the participant in an attempt to maximize adherence to the prescribed physical activity recommendations. The SBWI participants received group-based intervention sessions throughout the 18-month intervention. Sessions were weekly for months 1 through 6, twice per month during months 7 through 12, and once per month during months 13 through 18. Participants were offered a brief individual make-up session if a group session was missed. Sessions focused on improving knowledge related to adoption and maintenance of eating and activity behaviors to	

	promote weight loss, and strategies to facilitate long-term behavioral change such as barrier identification, problem solving, mastery experiences for self-efficacy, and others."
Control/Comparator	"The SBWI and STEP groups were prescribed identical diet and physical activity recommendations. The diet was prescribed to reduce energy intake and dietary fat consumption. Energy intake was prescribed at 1200 kcal/d for participants weighing 90 kg or less, 1500 kcal/d for participants weighing more than 90 kg, or 1800 kcal/d for participants weighing 113 kg or more. Prescribed kilocalories per day were adjusted downward for participants if the mean weight loss was less than 0.9 kg per week, the participant had a BMI of 25 or greater, and if the participant expressed a desire to continue to lose weight. Prescribed kilocalories per day were adjusted upward in 100 kcal/d increments each week when further weight loss was not indicated (BMI 25) or when the participant expressed to the intervention staff that they no longer desired to lose additional weight. Meal plans were provided to assist with adoption of dietary recommendations. Participants were instructed to self-monitor food intake in a weekly diary, and interventionists provided feedback to the participant in an attempt to maximize adherence to prescribed dietary goals. The SBWI group returned diaries at intervention sessions, whereas the STEP group returned diaries at in-person sessions but otherwise returned diaries via postal mail. Prescribed physical activity progressed to 300 minutes per week by the end of week 24, with participants encouraged to maintain this dose for the remainder of the 18 months. Intensity was prescribed as moderate to vigorous. 14 Participants were instructed to self-monitor their physical activity in a weekly diary that was reviewed by the interventionists and feedback was provided to the participant in an attempt to maximize adherence to the prescribed physical activity recommendations. . STEP was identical in content to SBWI. However, for the STEP group, contact frequency, contact type, and other weight loss strategies were modified depending on the achievement of specific weight loss goals at 3-month intervals. Weight loss goals were 5% at 3 months, 7% at 6 months, 10% at 9 months, and remained at 10% at 12, 15, and 18 months. While the goal at 9 months and beyond was to achieve a 10% weight loss, participants were encouraged to continue to lose weight if they desired and there were no contraindications to further weight loss. Participants in the STEP group started at step 1 and progressed to the next intervention step only if the weight loss goal was not achieved. Intervention steps are briefly described below and appear in FIGURE 1. Step 1: participants were offered a monthly group intervention session. During weeks that a session was not scheduled, lessons that were identical to what was provided to the SBWI group were mailed, and participants submitted their weekly self-monitoring diaries by mail. Step 2: continued with step 1 and received a 10-minute telephone intervention contact once per month. Step 3: continued with step 2 and received a second 10-minute telephone contact each month. Step 4: continued with step 3 and received 1 individual in-person intervention contact per month. Step 5: continued with step 4 and were provided meal replacement shakes and bars to replace 1 meal and 1 snack per day. Step 6: continued with step 5 but replaced 1 of the telephone contacts with a second individual session per month."
Treatment duration	18 months
Follow-up from baseline	18 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 363 Intervention group/s: Stepped-care weight loss intervention (STEP) (n=198) Comparator group: Standard behavioral weight loss intervention (SBWI) (n=165)
Mean age ± SD	42.20y (9.03)
Sex	82.64% female

Pre-existing medical condition	No pre-existing medical condition
Results	
Outcome measure at baseline	

Variable	Intervention arm/s	Comparator
Body weight (baseline) Least square Mean (95% CIs)	STEP: 92.7 (90.8-94.6)	SBWI: 93.1 (91-95.2)
BMI (baseline) Least square Mean (95% CIs)	STEP: 33 (32.4-33.5)	SBWI: 33 (32.4-33.6)
Waist circumference (baseline) Least square Mean (95% CIs)	STEP: 107.1 (105.6-108.6)	SBWI: 106.5 (104.9-108.2)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point

Variable	Intervention arm/s	Comparator
Body weight (change) Least square Mean (95% CIs)	STEP: -7.5 (-8.5--6.5)	SBWI: -9.1 (-10.2--8.1)
BMI (change) Least square Mean (95% CIs)	STEP: -2.7 (-3--2.3)	SBWI: -3.2 (-3.6--2.9)
Waist circumference (change) Least square Mean (95% CIs)	STEP: -9.6 (-10.8--8.3)	SBWI: -10.4 (-11.9--9)

Change in outcome measure from baseline to final follow-up/endpoint

Variable	Intervention arm/s	Comparator
Body weight (change) Least square Mean (95% CIs)	STEP: -6.2 (-7.3--5.2)	SBWI: -7.6 (-8.7--6.5)
BMI (change) Least square Mean (95% CIs)	STEP: -2.21 (-2.58--1.84)	SBWI: -2.67 (-3.06--2.28)
Waist circumference (change) Least square Mean (95% CIs)	STEP: -9.2 (-10.4--8)	SBWI: -10 (-11.4--8.5)

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Jakicic, 2015

Guideline record ID: 10339

Study characteristics		
Citation	Jakicic, J. M., Rickman, A. D., Lang, W., Davis, K. K., Gibbs, B. B., Neiberg, R., & Marcus, M. D. (2015). Time-based physical activity interventions for weight loss: a randomized trial. Medicine & Science in Sports & Exercise, 47(5), 1061-1069. https://doi.org/https://dx.doi.org/10.1249/MSS.0000000000000482	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Time-based physical activity interventions for weight loss: a randomized trial	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"A BMI of >25.0 to <40.0 kg/m2 and age between 18 and 55 yr."	
Exclusion criteria	"History of cardiovascular disease, presence of a metabolic condition that might affect body weight (e.g., diabetes mellitus, hypothyroid), presence of a medical condition that would preclude reducing energy intake or increasing physical activity, taking medication that would affect body weight (e.g., thyroid medication, psychotropic medication) or heart rate response to exercise (e.g., A blocker), sustained weight loss of Q5% within the past 12 months, regular participation in physical activity (Q20 minIdj1 for Q3 dIwkj1) over the prior 6 months. Moreover, women who had been pregnant in the past 6 months, were currently pregnant, or were planning on becoming pregnant in the subsequent 18 months were excluded from participation."	
Setting	Research University	
Intervention	"Subjects in ADOPT received all of the components described previously for SBWP. In addition, subjects received additional intervention strategies over the initial 9 months of the intervention aimed at enhancing compliance with the recommended dose of physical activity. These included telephone contacts (months 1-3), supervised physical activity sessions (months 1-6), and physical activity campaigns (months 4-9). The timing of these intervention strategies is illustrated in Figure 1. The additional telephone contact involved a biweekly 10-min telephone call from a member of the intervention staff; these were in addition to the in-person group intervention visit for weeks 1-12. The interventionist followed a structured script for the telephone intervention calls, with the goal to complete this call in e10 min. The focus of the call was to identify existing or anticipated barriers to the participant's physical activity behaviors and to identify strategies for overcoming these barriers. During weeks 1-24, subjects in ADOPT were encouraged to participate in a supervised session with the intervention staff, in conjunction with attending a group intervention meeting. These sessions involved the use of cardiovascular training equipment (treadmills and stationary cycles) located in the Physical Activity and Weight Management Research Center or an outdoor walk. A minimum of 30 min per session was encouraged. All remaining exercise for this study was performed under nonsupervised conditions. During months 4-9, subjects in ADOPT participated in two 12-wk campaigns to promote physical activity. These campaigns involved the use of pedometers to promote daily and weekly step goals consistent with the prescribed dose of exercise. Examples of campaigns included ''10,000 Steps,'' where subjects were encouraged to achieve 10,000 steps per day, or other campaigns that had a regional or seasonal theme.; MAINTAIN. Subjects in MAINTAIN received all of the components described previously for SBWP. In addition, subjects received the ADOPT intervention strategies, but these were implemented across the full 18 months of intervention, in contrast to the 9-month period utilized in the ADOPT intervention. Specifically, telephone intervention contacts were provided during months 4-6; supervised physical activity sessions, in conjunction with behavioral group sessions, were	

<table>
<tr><td></td><td>provided during months 7-12; and physical activity campaigns were provided during months 13-18”</td></tr>
<tr><td>Control/Comparator</td><td>“SBWP. Subjects in SBWP were instructed to attend groupbased intervention sessions throughout the 18-month intervention. Sessions were conducted weekly for months 1-6 and every other week during months 7-18. Sessions were scheduled for approximately 45 min and were led by an interventionist trained in health psychology, nutrition, or exercise. These sessions were modeled after sessions as previously described (7,9,11,12). The dietary intervention included instructions to reduce energy intake and dietary fat consumption and is based on dietary interventions implemented in other weight loss studies (9,11,12,14). Energy intake was prescribed at 1200 kcalIdj1 for subjects weighing e90 kg (e200 lb) or 1500 kcalIdj1 for subjects weighing 990 kg (9200 lb). Dietary fat intake was prescribed at 20%-30% of total energy intake. Meal plans were provided along with a published reference for calorie and fat composition of popular foods. Subjects were instructed to self-monitor food intake in a weekly diary provided to them. Completed diaries were reviewed by the interventionists, and feedback was provided to the subjects to maximize adherence to the dietary recommendations of the study. We also prescribed structured periods of physical activity, which progressed from an initial duration of 100 minIwkj1 to 150 minIwkj1 on week 5, and to 200 minIwkj1 on week 9, with subjects encouraged to maintain physical activity for at least 200 minIwkj1 for the remainder of the 18-month intervention period. Subjects were encouraged to distribute activity over 5 dIwkj1, with the minimum duration of any bout of activity lasting Q10 min. We have previously demonstrated that this physical activity prescription is effective for enhancing physical activity participation (7). Moderate to vigorous physical activity intensity was prescribed and defined as 11-15 on the 15-point RPE scale (21). Similar to dietary intake, subjects were instructed to self-monitor physical activity in a weekly diary that was reviewed and annotated by the interventionists.”</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 213
Intervention group/s: ADOPT (n=71); MAINTAIN (n=71)

Comparator group: SBWP (n=71)</td></tr>
<tr><td>Mean age ± SD</td><td>43.20y (8.55)</td></tr>
<tr><td>Sex</td><td>71.36% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SE)</td><td>ADOPT: 94.1
(1.7)
MAINTAIN: 94.2
(1.7)</td><td>SBWP: 91.5
(1.7)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SE)</td><td>ADOPT: 33.3
(0.4)
MAINTAIN: 33.1
(0.4)</td><td>SBWP: 32.7
(0.4)</td></tr>
</table>
</td></tr>
</table>

Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight change (kg) Mean (SE) BMI change (kg/m2) Mean (SE)	ADOPT: -7.6 (1.2) MAINTAIN: -11 (1.2) ADOPT: -2.7 (0.4) MAINTAIN: -3.8 (0.4)	SBWP: -7.8 (1.1) SBWP: -2.7 (0.4)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Jakicic, 2016

Guideline record ID: 10336--1

Study characteristics		
Citation	Jakicic, J. M., Davis, K. K., Rogers, R. J., King, W. C., Marcus, M. D., Helsel, D., Rickman, A. D., Wahed, A. S., & Belle, S. H. (2016). Effect of wearable technology combined with a lifestyle intervention on long-term weight loss: the IDEA randomized clinical trial. JAMA, 316(11), 1161-1171. https://doi.org/10.1001/jama.2016.12858	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Wearable Technology Combined With a Lifestyle Intervention on Long-term Weight Loss: The IDEA Randomized Clinical Trial	
Location	US	
Trial name	Innovative Approaches to Diet, Exercise and Activity (IDEA)	
Methods		
Inclusion criteria	"18-35 years of age; intending to be available for a 24 month intervention; an active cellular telephone that is capable of receiving text messaging; a computer and internet connectivity that can be used for the BodyMedia Fit system; body mass index (BMI) between 25.0-39.9 kg/m2; the ability to provide medical clearance to participate in this study from their primary care physician; the ability to complete the baseline graded exercise test, and clearance from the study physician to participate in this study after reviewing the results from this study."	
Exclusion criteria	"Unable to provide informed consent; household member on study staff; past or planned (within the next 24 months) weight loss surgery (e.g. gastric bypass, lap band, or liposuction); current participation in a commercial weight loss program (e.g. Weight Watcher's, Jenny Craig); current or planned enrollment in another diet/PA/weight loss intervention study; report regular use of systemic steroids, prescription weight loss drugs. "Regular use" is defined as "taking this medication most days of the week for the previous month". Current treatment for eating disorder; cardiovascular event (heart attack, stroke, episode of heart failure, or revascularization procedure) within the last 6 months; current treatment for malignancy (other than non-melanoma skin cancer); currently pregnant or gave birth within the last 6 months, currently lactating or breastfeeding within the last 3 months, actively planning pregnancy within the next 24 months; investigator discretion; currently taking medication that would affect heart rate or blood pressure responses to exercise (e.g., beta blockers) Report losing >5% of current body weight in the previous 6 months; currently treated for psychological issues, or taking psychotropic medications within the previous 6 months; report taking medication that could affect metabolism or change body weight; current treatment for diabetes mellitus."	
Setting	University/research centre	
Intervention	"Subjects in this group will participate in a weight loss intervention that includes technology enhancements. These enhancements will include the addition of intervention specific targeted and tailored text messaging and the BodyMedia Fit System® beginning at Month 7. At month 7 subjects in EWLI will also receive the same targeted study-related text messages provided to SBWP that otherwise would have been provided in paper format."	
Control/Comparator	"Subjects in this group will receive our standard behavioral weight control program that is delivered in an in-person group-based format. At month 7 subjects will also be given access to a study website to monitor eating and activity behaviors, and to have electronic access to standardized intervention materials. At month 7 subjects will also receive targeted study-related text messages that otherwise would have been provided in paper format."	
Treatment duration	24 months	

<table>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 470
Intervention group/s: Technology-enhanced weight loss intervention (n=237)

Comparator group: Standard behavioral weight loss intervention (n=233)</td></tr>
<tr><td>Mean age ± SD</td><td>not reported</td></tr>
<tr><td>Sex</td><td>71.06% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight, kg (baseline)
Median (IQR)</td><td>Technology-enhanced weight loss intervention: 90.6 (80.8-101.9)</td><td>Standard behavioral weight loss intervention: 88.5 (79.2-101.2)</td></tr>
<tr><td>BMI (baseline)
Median (IQR)</td><td>Technology-enhanced weight loss intervention: 31.5 (28.2-34.3)</td><td>Standard behavioral weight loss intervention: 30.9 (28.7-34.2)</td></tr>
<tr><td>Fat mass, kg (baseline)
Mean (95% CIs)</td><td>Technology-enhanced weight loss intervention: 37.2 (35.7-38.7)</td><td>Standard behavioral weight loss intervention: 36.8 (35.4-38.3)</td></tr>
<tr><td>Body fat, % (baseline)
Least squares mean (95% CI)</td><td>Technology-enhanced weight loss intervention: 38.8 (37.8-39.7)</td><td>Standard behavioral weight loss intervention: 38.9 (38-39.8)</td></tr>
<tr><td>Tissue body fat, % (baseline)
Least squares mean (95% CI)</td><td>Technology-enhanced weight loss intervention: 40 (39-40.9)</td><td>Standard behavioral weight loss intervention: 40.2 (39.2-41.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight, kg (change from baseline)
Least squares mean (95% CI)</td><td>Technology-enhanced weight loss intervention: -6.7 (-7.6--5.8)</td><td>Standard behavioral weight loss intervention: -8.3 (-9.2--7.4)</td></tr>
<tr><td>BMI (change from baseline)
Least squares mean (95% CI)</td><td>Technology-enhanced weight loss intervention: -2.1 (-2.9--1.4)</td><td>Standard behavioral weight loss intervention: -2.8 (-3.5--2)</td></tr>
<tr><td>Fat mass, kg (change from baseline)
Least squares mean (95% CI)</td><td>Technology-enhanced weight loss intervention: -5.7 (-6.5--4.9)</td><td>Standard behavioral weight loss intervention: -7 (-7.7--6.2)</td></tr>
<tr><td>Body fat, % (change from baseline)</td><td>Technology-enhanced weight loss intervention: -3.7</td><td>Standard behavioral weight loss intervention: -4.6</td></tr>
</table>
</td></tr>
</table>

	Least squares mean (95% CI) Tissue body fat, % (change from baseline) Least squares mean (95% CI)	(-4.2--3.2) Technology-enhanced weight loss intervention: -3.7 (-4.2--3.2)	(-5.2--4.1) Standard behavioral weight loss intervention: -4.7 (-5.2--4.2)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Weight, kg (change from baseline) Least squares mean (95% CI) BMI (change from baseline) Least squares mean (95% CI) Fat mass, kg (change from baseline) Least squares mean (95% CI) Body fat, % (change from baseline) Least squares mean (95% CI) Tissue body fat, % (change from baseline) Least squares mean (95% CI)	Technology-enhanced weight loss intervention: -3.5 (-4.5--2.6) Technology-enhanced weight loss intervention: -1.1 (-1.9--0.3) Technology-enhanced weight loss intervention: -3.4 (-4.3--2.6) Technology-enhanced weight loss intervention: -2.4 (-3--1.9) Technology-enhanced weight loss intervention: -2.4 (-3--1.9)	Standard behavioral weight loss intervention: -5.9 (-6.8--5) Standard behavioral weight loss intervention: -1.8 (-2.6--1) Standard behavioral weight loss intervention: -5.1 (-6--4.3) Standard behavioral weight loss intervention: -3.5 (-4--3) Standard behavioral weight loss intervention: -3.5 (-4.1--3)
Compliance with treatment	not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Jakicic, 2022

Guideline record ID: 10340--1

Study characteristics		
Citation	Jakicic, J. M., Rogers, R. J., Lang, W., Gibbs, B. B., Yuan, N., Fridman, Y., & Schelbert, E. B. (2022). Impact of weight loss with diet or diet plus physical activity on cardiac magnetic resonance imaging and cardiovascular disease risk factors: Heart Health Study randomized trial. Obesity, 30(5), 1039-1056. https://doi.org/10.1002/oby.23412	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Impact of weight loss with diet or diet plus physical activity on cardiac magnetic resonance imaging and cardiovascular disease risk factors: Heart Health Study randomized trial	
Location	US	
Trial name	Heart Health Study (HHS)	
Methods		
Inclusion criteria	"Eligibility included being aged 18 to 55 years and within a BMI range of 25 to <40."	
Exclusion criteria	"Ineligibility criteria included the following: (1) self-reporting ≥60 min/wk of structured moderate-to-vigorous PA (MVPA); (2) weight loss of ≥5% within the prior 6 months or a history of bariatric surgery; (3) history of cardiometabolic disease, diabetes mellitus, or cancer; (4) taking medication that could affect heart rate or blood pressure; (5) taking medication that could influence weight; (6) treatment for psychological conditions that included medication or counseling; (7) currently pregnant, pregnant within the prior 6 months, or planning a pregnancy within the next 12 months; (8) planning on geographical relocation outside of the region within 12 months; (9) inability to comply with the components of the interventions; and/or (10) had a contraindication that would prohibit magnetic resonance imaging scanning."	
Setting	University/research centre	
Intervention	"All of the interventions received the same prescribed diet. Calorie intake was prescribed at 1,200 kcal/d; 1,500 kcal/d; and 1,800 kcal/d for participants who weighed <90.7 kg; ≥90.7 kg to <113.4 kg; and ≥113.4 kg, respectively. Dietary fat intake was prescribed at 20% to 30% of total calorie intake, with specific amounts of other nutrients (e.g., carbohydrates, protein, sodium, added sugars, etc) not prescribed. The DIET+MODPA and DIET+HIGHPA groups were prescribed PA that started at 100 min/wk and progressed by 25 min/wk in 4-week intervals until achieving a prescribed dose of 150 min/wk for the DIET+MODPA group or 250 min/wk for the DIET+HIGHPA group. All activity was non-supervised, and participants were instructed to engage in PA similar to brisk walking or other modes that were consistent with MVPA for periods of ≥10 minutes to achieve the prescribed amount of PA."	
Control/Comparator	"All of the interventions received the same prescribed diet. Calorie intake was prescribed at 1,200 kcal/d; 1,500 kcal/d; and 1,800 kcal/d for participants who weighed <90.7 kg; ≥90.7 kg to <113.4 kg; and ≥113.4 kg, respectively. Dietary fat intake was prescribed at 20% to 30% of total calorie intake, with specific amounts of other nutrients (e.g., carbohydrates, protein, sodium, added sugars, etc) not prescribed. The DIET group was instructed to maintain their PA across the 12- month intervention."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 383
Intervention group/s: DIET+HIGHPA (n=127); DIET+MODPA (n=129)

Comparator group: DIET (n=127)</td></tr>
<tr><td>Mean age ± SD</td><td>45.6y (8.0)</td></tr>
<tr><td>Sex</td><td>79.37% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Baseline Weight (kg)
Mean (SD)</td><td>DIET+HIGHPA: 91
(13.1)
DIET+MODPA: 89.9
(13.5)</td><td>DIET: 91.8
(14.5)</td></tr>
<tr><td>Baseline BMI (kg/m2)
Mean (SD)</td><td>DIET+HIGHPA: 32.2
(4)
DIET+MODPA: 32.3
(3.8)</td><td>DIET: 32.6
(3.5)</td></tr>
<tr><td>Fat mass (kg) - Baseline
Mean (95% CIs)</td><td>DIET+HIGHPA: 39.6
(38.5-40.8)
DIET+MODPA: 38.6
(37.6-39.6)</td><td>DIET: 39.3
(38.4-40.2)</td></tr>
<tr><td>Body Fat (%) - Baseline
Mean (95% CIs)</td><td>DIET+HIGHPA: 43.5
(42.7-44.2)
DIET+MODPA: 42.6
(41.8-43.4)</td><td>DIET: 43.1
(42.5-43.7)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in Weight (kg)
Mean (95% CIs)</td><td>DIET+HIGHPA: -9.4
(-10.8--8)
DIET+MODPA: -10.1
(-11.5--8.8)</td><td>DIET: -9.4
(-10.8--8)</td></tr>
<tr><td>Weight change from Baseline (%)
Mean (95% CIs)</td><td>DIET+HIGHPA: -10.3
(-11.8--8.9)
DIET+MODPA: -11
(-12.4--9.5)</td><td>DIET: -10.2
(-11.7--8.8)</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (95% CIs)</td><td>DIET+HIGHPA: -3.3
(-3.8--2.8)
DIET+MODPA: -3.6
(-4.1--3.1)</td><td>DIET: -3.3
(-3.8--2.8)</td></tr>
<tr><td>Change in Fat Mass (kg)
Mean (95% CIs)</td><td>DIET+HIGHPA: -8.1
(-9.2--6.9)
DIET+MODPA: -8.3
(-9.5--7.2)</td><td>DIET: -7.8
(-8.9--6.6)</td></tr>
</table>
</td></tr>
</table>

	Change in Percent Body Fat (%) Mean (95% CIs)	DIET+HIGHPA: -5.2 (-6.1--4.4) DIET+MODPA: -5.3 (-6.2--4.5)	DIET: -5.1 (-5.9--4.2)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Jakobsen, 2017

Guideline record ID: 10343--1

Study characteristics		
Citation	Jakobsen, A. S., Speyer, H., Nørgaard, H. C. B., Karlsen, M., Birk, M., Hjorthøj, C., Mors, O., Krogh, J., Gluud, C., Pisinger, C., & Nordentoft, M. (2017). Effect of lifestyle coaching versus care coordination versus treatment as usual in people with severe mental illness and overweight: two-years follow-up of the randomized CHANGE trial. PLOS ONE, 12(10), e0185881. https://doi.org/https://dx.doi.org/10.1371/journal.pone.0185881	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of lifestyle coaching versus care coordination versus treatment as usual in people with severe mental illness and overweight: Two-years follow-up of the randomized CHANGE trial	
Location	Denmark	
Trial name	CHANGE	
Methods		
Inclusion criteria	"The participants were 18+ years old, and diagnosed according to the ICD-10 with schizophrenia (F20), schizoaffective disorder (F25), or persistent delusional disorder (F22)-confirmed at initial assessment by the Schedules for Clinical Assessment in Neuropsychiatry (SCAN)[10]-and with a waist circumference above the cut-off points for substantial risk of metabolic complications suggested by the WHO[11] (102 cm for men and 88 cm for women)."	
Exclusion criteria	"Patients were excluded if they were currently pregnant or unable to give written informed consent."	
Setting	GP clinic, Home	
Intervention	"The CHANGE intervention consisted of one year of affiliation with a CHANGE coach, who was a healthcare professional (physiotherapists, occupational therapists, or dieticians) with clinical experience in psychiatry and with special training in smoking cessation, healthy dieting, and monitoring and treatment of lifestyle diseases. Lifestyle coaching was based on the transtheoretical model (stages of change), motivational interviewing, and used an assertive approach. The latter involved the coach offering at least one personal meeting per week or home visit of variable duration, often one hour, besides phone calls, test messages, and e-mails. The coaches aimed to motivate and support the participants in finding realistic and attractive options for daily-life physical activity, healthy dietary choices (involving purchasing of food and cooking sessions), and-where relevant-smoking cessation. Each coach was assigned a maximum of 15 participants. All contacts with participants were registered by the lifestyle coaches. Besides the above mentioned intervention, the CHANGE intervention included care coordination and continued treatment as usual as described below. After 12 months of the CHANGE intervention all participants received treatment as usual. Care coordination consisted of one year of being affiliated to a care coordinator who was a special trained psychiatric nurse, facilitating contact for the participants to the primary care sector in order to secure optimal treatment of physical health problems. Symptoms of cardiovascular disease, diabetes, or obstructive pulmonary disease were main focuses. The care coordinator offered personal meetings, assistance at visits to the participants general practitioner, home visits, phone calls, and text-message contact with participant, and adjusted the frequency according to the individual need. The care coordinator to participant ratio was 1:40 and as for the CHANGE intervention all contacts with participants were registered by the care coordinator. The care coordination included continued treatment as usual as described below. After 12 months of the care coordination intervention all participants received treatment as usual."	

<table>
<tr><td>Control/Comparator</td><td>“The participants randomised to treatment as usual received no extra lifestyle counselling or treatment of physical disorders besides what is offered from the public health care system. All people in Denmark have affiliation to a general practitioner with free consultation when needed. People with severe mental illness are treated in secondary mental health service, and people treated with antipsychotics receive at least yearly mandatory screening of metabolic risk factors. All patients retained contact with their usual general practitioner, who monitors and treats somatic diseases.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>2 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 428
Intervention group/s: CHANGE intervention (n=138); Care coordination (TECHNICALLY A TRUE CONTROL) (n=142)

Comparator group: Treatment as usual (n=148)</td></tr>
<tr><td>Mean age ± SD</td><td>38.6 y (12.4)</td></tr>
<tr><td>Sex</td><td>56.07% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Severe mental illness - ICD-10 with schizophrenia (F20), schizoaffective disorder (F25), or persistent delusional disorder (F22)-confirmed at initial assessment by the Schedules for Clinical Assessment in Neuropsychiatry (SCAN)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (Kg)
Mean (SD)</td><td>CHANGE intervention: 105.9 (22.2)
Care coordination: 103.7 (22.1)</td><td>Treatment as usual: 104.9 (22.1)</td></tr><tr><td>Body mass index
Mean (SD)</td><td>CHANGE intervention: 35.6 (8.6)
Care coordination: 34.4 (8.7)</td><td>Treatment as usual: 34.4 (8.6)</td></tr><tr><td>Waist circumference (cm)
Mean (SD)</td><td>CHANGE intervention: 114.8 (17)
Care coordination: 114.9 (17.1)</td><td>Treatment as usual: 117 (16.8)</td></tr><tr><td>Proportion achieving min 5% weight loss at 2 years
Proportion (%)</td><td>CHANGE intervention: 25.4%
Care coordination: 19.7%</td><td>Treatment as usual: 16.9%</td></tr><tr><td>Proportion achieving min 10% weight loss at 2 years
Proportion (%)</td><td>CHANGE intervention: 11.6%
Care coordination: 11.3%</td><td>Treatment as usual: 8.8%</td></tr><tr><td>Percentage Min 5% weight gain at 2 years
Proportion (%)</td><td>CHANGE intervention: 20.3%
Care coordination: 20.4%</td><td>Treatment as usual: 21.6%</td></tr></table></td></tr>
</table>

	Percentage Min 10% weight gain at 2 years Proportion (%)	CHANGE intervention: 12.3% Care coordination: 6.3%	Treatment as usual: 8.8%
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	42.8% of participants in the CHANGE group attended at least 50% of the planned sessions. Mean attendance was 24.6 sessions (SD 14.5, range 0-70).		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Janicke, 2019

Guideline record ID: 10344A--PARENT

Study characteristics		
Citation	Janicke, D. M., Lim, C. S., Perri, M. G., Mathews, A. E., Bobroff, L. B., Gurka, M. J., Parish, A., Brumback, B. A., Dumont-Driscoll, M., & Silverstein, J. H. (2019). Featured article: behavior interventions addressing obesity in rural settings: the E-FLIP for Kids trial. Journal of Pediatric Psychology, 44(8), 889-901. https://doi.org/10.1093/jpepsy/jsz029	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Featured Article: Behavior Interventions Addressing Obesity in Rural Settings: The E-FLIP for Kids Trial	
Location	US	
Trial name	E-FLIP for Kids	
Methods		
Inclusion criteria	“Children were between the ages of 8 and 12 years, with a BMI at or above the 85th percentile for age and sex (Kuczmarski et al., 2000).”	
Exclusion criteria	“Families were excluded if the child had a developmental delay, the caregiver was above 75 years of age, or the child or parent was using prescription weight loss drugs or was enrolled in another weight loss program.”	
Setting	Cooperative Extension Service (CES) offices in rural communities (Janicke et al., 2008). The CES is a partnership among the U.S. Department of Agriculture, land-grant universities, and county government that delivers educational programs and research-base	
Intervention	“For all three conditions, weekly group sessions were held for the first eight weeks, then every two weeks for the next eight weeks, and then monthly for the last eight months. Sessions occurred weekday evenings starting at 6 p.m. and lasted 90min. Families were provided with $10 per treatment session attended as compensation for travel. Childcare was available at meetings for all three intervention conditions. Interventions were delivered by participating Family and Consumer Sciences (FCS) agents and 4-H Youth Development agents (n¼17) at each county CES office, in collaboration with members from the research team (postdoctoral psychologist and graduate students in psychology) (n¼10). Interventionists were allocated to an intervention group in each county based on weeknight availability. The FCS and 4-H agents had a Bachelor's or Master's degrees, often with a concentration in nutrition or youth development. Each parent group was led by two interventionists, while each child group was led by two separate interventionists. Interventionists received 12 hr of training before the intervention led by the study PI and participated in 30 min of weekly supervision. Training included discussion of session content, as well as practice and role-play exercises in goal setting, problem solving, addressing resistance to change and facilitating group discussion. Treatment manuals for the participants and group leaders were developed during the pilot study and updated and expanded for use in the current study. Sessions were recorded via audio tape to allow the investigator to monitor each interventionist's performance and assess treatment fidelity. . FB and PO Behavioral Interventions The FB and PO interventions and assessment methodology were very similar to those used in the previous pilot (Boutelle et al., 2011), with the main exception that additional sessions (sessions 13-20) were developed to focus on maintenance of behavior changes, and new measures were added to assess parent health behaviors and child glycated hemoglobin (HbA1c). The FB and PO interventions were grounded in social cognitive theory (Bandura 1998; Baranowski, Perry, & Parcel, 2002; Coppock et al., 2014). Consistent with this theory, the interventions helped families acquire behavioral weight management skills to better regulate their dietary intake and physical activity behaviors and create a healthier home environment. Additionally, parents were taught key behavior management skills to help them motivate and support their child to	

	make healthy choices including shaping, differential reinforcement, restructuring the physical environment, self-monitoring of behavior, modeling, goal setting, feedback on behavior, problem solving, and social support. Changes in dietary habits were addressed via a modified version of the Stoplight Diet (Epstein & Squires, 1998). Child and parent participants in both treatment conditions were encouraged to monitor everything they ate, but were not required to record energy or macronutrient values. For families that struggled with completing these monitoring logs, an abbreviated log was provided in which they could track the number of servings of "red" foods (i.e., highfat/ high sugar foods) and "green" foods (i.e., fruits and vegetables) consumed per day. Parents and group leaders worked together to set individualized physical activity and dietary goals, which included limiting the consumption of "red" foods and increasing the consumption of "green" foods. Children and parents in both behavioral arms were provided with pedometers to wear daily and encouraged to gradually increase their daily steps. In the parent group, parents reviewed and discussed weekly progress implementing change strategies, and participated in knowledge and skill training related to nutrition, physical activity, and behavior management strategies. In the FB intervention, parent and child dyads participated in simultaneous but separate groups. The child group sessions included review of progress during the previous week, a physical activity to demonstrate strategies to keep active, and preparation of a healthy snack. At the end of sessions, children and parents worked together to develop goals and action plans. In the PO intervention, only the participating parent(s) attended group meetings. Steps and material covered were the same as those in the FB intervention. In addition, parents role-played setting goals with their children and were encouraged to work with their children at home to help them monitor health behaviors and set goals."
Control/Comparator	"For all three conditions, weekly group sessions were held for the first eight weeks, then every two weeks for the next eight weeks, and then monthly for the last eight months. Sessions occurred weekday evenings starting at 6 p.m. and lasted 90min. Families were provided with $10 per treatment session attended as compensation for travel. Childcare was available at meetings for all three intervention conditions. Interventions were delivered by participating Family and Consumer Sciences (FCS) agents and 4-H Youth Development agents (n¼17) at each county CES office, in collaboration with members from the research team (postdoctoral psychologist and graduate students in psychology) (n¼10). Interventionists were allocated to an intervention group in each county based on weeknight availability. The FCS and 4-H agents had a Bachelor's or Master's degrees, often with a concentration in nutrition or youth development. Each parent group was led by two interventionists, while each child group was led by two separate interventionists. Interventionists received 12 hr of training before the intervention led by the study PI and participated in 30 min of weekly supervision. Training included discussion of session content, as well as practice and role-play exercises in goal setting, problem solving, addressing resistance to change and facilitating group discussion. Treatment manuals for the participants and group leaders were developed during the pilot study and updated and expanded for use in the current study. Sessions were recorded via audio tape to allow the investigator to monitor each interventionist's performance and assess treatment fidelity. ."
Treatment duration	1 year
Follow-up from baseline	24 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles
Participant characteristics	
Number of participants	n= 249 Intervention group/s: Parent-only (PO) (n=78); Family-based (FB) (n=88) Comparator group: Health education condition (HEC) (n=83)
Mean age ± SD	PO: 10.3 (1.3); FB: 10.4 (1.5); HEC: 10.4 (1.4)

<table>
<tr><td>Sex</td><td>54.62% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Parent BMI (kg/m2)
Mean (SD)</td><td>Parent-only (PO): 33.7
(7.1)
Family-based (FB): 36.7
(8.8)</td><td>Health education condition (HEC): 34.3
(7.6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Parent BMI (kg/m2)
Mean (SD)</td><td>Parent-only (PO): 33.8
(7.9)
Family-based (FB): 35.1
(8.3)</td><td>Health education condition (HEC): 34.7
(8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Parent BMI (kg/m2)
Mean (SD)</td><td>Parent-only (PO): 35.3
(7.9)
Family-based (FB): 35.5
(8.4)</td><td>Health education condition (HEC): 34.5
(8.7)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Parent BMI (change from baseline)
Least square means (95% CI)</td><td>Parent-only (PO): -0.43
(-0.94-0.08)
Family-based (FB): -0.69
(-1.19--0.2)</td><td>Health education condition (HEC): -0.19
(-0.66-0.28)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Parent BMI (change from baseline)
Least square means (95% CI)</td><td>Parent-only (PO): 0.55
(-0.13-1.23)
Family-based (FB): -0.96
(-1.63--0.29)</td><td>Health education condition (HEC): 0.11
(-0.54-0.76)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>There was a significant difference in attendance across conditions for both core sessions (FB = 65.1%, PO = 66.2%, HEC = 75.6%; p=.035) and maintenance sessions (FB = 37.1%, PO = 37.0, HEC = 52.9%; p=.011), with higher attendance in the HEC relative to the behavioral treatments.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Janicke, 2019

Guideline record ID: 10344B--CHILD

Study characteristics		
Citation	Janicke, D. M., Lim, C. S., Perri, M. G., Mathews, A. E., Bobroff, L. B., Gurka, M. J., Parish, A., Brumback, B. A., Dumont-Driscoll, M., & Silverstein, J. H. (2019). Featured article: behavior interventions addressing obesity in rural settings: the E-FLIP for Kids trial. Journal of Pediatric Psychology, 44(8), 889-901. https://doi.org/10.1093/jpepsy/jsz029	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Featured Article: Behavior Interventions Addressing Obesity in Rural Settings: The E-FLIP for Kids Trial	
Location	US	
Trial name	E-FLIP for Kids	
Methods		
Inclusion criteria	"Children were between the ages of 8 and 12 years, with a BMI at or above the 85th percentile for age and sex (Kuczmarski et al., 2000)."	
Exclusion criteria	"Families were excluded if the child had a developmental delay, the caregiver was above 75 years of age, or the child or parent was using prescription weight loss drugs or was enrolled in another weight loss program."	
Setting	Cooperative Extension Service (CES) offices in rural communities (Janicke et al., 2008). The CES is a partnership among the U.S. Department of Agriculture, land-grant universities, and county government that delivers educational programs and research-base	
Intervention	"For all three conditions, weekly group sessions were held for the first eight weeks, then every two weeks for the next eight weeks, and then monthly for the last eight months. Sessions occurred weekday evenings starting at 6 p.m. and lasted 90min. Families were provided with $10 per treatment session attended as compensation for travel. Childcare was available at meetings for all three intervention conditions. Interventions were delivered by participating Family and Consumer Sciences (FCS) agents and 4-H Youth Development agents (n¼17) at each county CES office, in collaboration with members from the research team (postdoctoral psychologist and graduate students in psychology) (n¼10). Interventionists were allocated to an intervention group in each county based on weeknight availability. The FCS and 4-H agents had a Bachelor's or Master's degrees, often with a concentration in nutrition or youth development. Each parent group was led by two interventionists, while each child group was led by two separate interventionists. Interventionists received 12 hr of training before the intervention led by the study PI and participated in 30 min of weekly supervision. Training included discussion of session content, as well as practice and role-play exercises in goal setting, problem solving, addressing resistance to change and facilitating group discussion. Treatment manuals for the participants and group leaders were developed during the pilot study and updated and expanded for use in the current study. Sessions were recorded via audio tape to allow the investigator to monitor each interventionist's performance and assess treatment fidelity. . FB and PO Behavioral Interventions The FB and PO interventions and assessment methodology were very similar to those used in the previous pilot (Boutelle et al., 2011), with the main exception that additional sessions (sessions 13-20) were developed to focus on maintenance of behavior changes, and new measures were added to assess parent health behaviors and child glycated hemoglobin (HbA1c). The FB and PO interventions were grounded in social cognitive theory (Bandura 1998; Baranowski, Perry, & Parcel, 2002; Coppock et al., 2014). Consistent with this theory, the interventions helped families acquire behavioral weight management skills to better regulate their dietary intake and physical activity behaviors and create a healthier home environment. Additionally, parents were taught key behavior management skills to help them motivate and support their child to	

	make healthy choices including shaping, differential reinforcement, restructuring the physical environment, self-monitoring of behavior, modeling, goal setting, feedback on behavior, problem solving, and social support. Changes in dietary habits were addressed via a modified version of the Stoplight Diet (Epstein & Squires, 1998). Child and parent participants in both treatment conditions were encouraged to monitor everything they ate, but were not required to record energy or macronutrient values. For families that struggled with completing these monitoring logs, an abbreviated log was provided in which they could track the number of servings of "red" foods (i.e., highfat/ high sugar foods) and "green" foods (i.e., fruits and vegetables) consumed per day. Parents and group leaders worked together to set individualized physical activity and dietary goals, which included limiting the consumption of "red" foods and increasing the consumption of "green" foods. Children and parents in both behavioral arms were provided with pedometers to wear daily and encouraged to gradually increase their daily steps. In the parent group, parents reviewed and discussed weekly progress implementing change strategies, and participated in knowledge and skill training related to nutrition, physical activity, and behavior management strategies. In the FB intervention, parent and child dyads participated in simultaneous but separate groups. The child group sessions included review of progress during the previous week, a physical activity to demonstrate strategies to keep active, and preparation of a healthy snack. At the end of sessions, children and parents worked together to develop goals and action plans. In the PO intervention, only the participating parent(s) attended group meetings. Steps and material covered were the same as those in the FB intervention. In addition, parents role-played setting goals with their children and were encouraged to work with their children at home to help them monitor health behaviors and set goals."
Control/Comparator	"For all three conditions, weekly group sessions were held for the first eight weeks, then every two weeks for the next eight weeks, and then monthly for the last eight months. Sessions occurred weekday evenings starting at 6 p.m. and lasted 90min. Families were provided with $10 per treatment session attended as compensation for travel. Childcare was available at meetings for all three intervention conditions. Interventions were delivered by participating Family and Consumer Sciences (FCS) agents and 4-H Youth Development agents (n¼17) at each county CES office, in collaboration with members from the research team (postdoctoral psychologist and graduate students in psychology) (n¼10). Interventionists were allocated to an intervention group in each county based on weeknight availability. The FCS and 4-H agents had a Bachelor's or Master's degrees, often with a concentration in nutrition or youth development. Each parent group was led by two interventionists, while each child group was led by two separate interventionists. Interventionists received 12 hr of training before the intervention led by the study PI and participated in 30 min of weekly supervision. Training included discussion of session content, as well as practice and role-play exercises in goal setting, problem solving, addressing resistance to change and facilitating group discussion. Treatment manuals for the participants and group leaders were developed during the pilot study and updated and expanded for use in the current study. Sessions were recorded via audio tape to allow the investigator to monitor each interventionist's performance and assess treatment fidelity. ."
Treatment duration	1 year
Follow-up from baseline	24 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles
Participant characteristics	
Number of participants	n= 249 Intervention group/s: Parent-only (PO) (n=78); Family-based (FB) (n=88) Comparator group: Health education condition (HEC) (n=83)
Mean age ± SD	PO: 10.3 (1.3); FB: 10.4 (1.5); HEC: 10.4 (1.4)

<table>
<tr><td>Sex</td><td>54.62% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Child BMI z-score (kg/m2)
Mean (SD)</td><td>Parent-only (PO): 2.2
(0.4)
Family-based (FB): 2.1
(0.4)</td><td>Health education condition (HEC): 2.2
(0.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Child BMI z-score (kg/m2)
Mean (SD)</td><td>Parent-only (PO): 2.2
(0.4)
Family-based (FB): 2.1
(0.5)</td><td>Health education condition (HEC): 2.1
(0.4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Child BMI z-score (kg/m2)
Mean (SD)</td><td>Parent-only (PO): 2.2
(0.4)
Family-based (FB): 2.1
(0.5)</td><td>Health education condition (HEC): 2.1
(0.4)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Child BMI (change from baseline)

Mean (95% CIs)
Child BMI z-score
Mean (95% CIs)</td><td>Parent-only (PO): 1.25
(0.81-1.69)
Family-based (FB): 1.41
(0.98-1.84)

Parent-only (PO): -0.03
(-0.08-0.01)
Family-based (FB): -0.02
(-0.06-0.02)</td><td>Health education condition (HEC): 1.11
(0.7-1.51)

Health education condition (HEC): -0.06
(-0.1--0.02)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Child BMI (change from baseline)
Mean (95% CIs)

Child BMI z-score
Mean (95% CIs)</td><td>Parent-only (PO): 2.86
(2.15-3.56)
Family-based (FB): 2.91
(2.22-3.6)

Parent-only (PO): -0.01
(-0.08-0.06)
Family-based (FB): -0.03
(-0.1-0.04)</td><td>Health education condition (HEC): 2.28
(1.62-2.94)

Health education condition (HEC): -0.09
(-0.15--0.02)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>There was a significant difference in attendance across conditions for both core sessions (FB = 65.1%, PO = 66.2%, HEC = 75.6%; p=.035) and maintenance sessions (FB = 37.1%, PO = 37.0, HEC = 52.9%; p=.011), with higher attendance in the HEC relative to the behavioral treatments..</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Jansson, 2013

Guideline record ID: 10346

Study characteristics		
Citation	Jansson, S. P., Engfeldt, P., Magnuson, A., Lohse PT, G., & Liljegren, G. (2013). Interventions for lifestyle changes to promote weight reduction, a randomized controlled trial in primary health care. BMC Research Notes, 6, 213. https://doi.org/https://dx.doi.org/10.1186/1756-0500-6-213	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Interventions for lifestyle changes to promote weight reduction, a randomized controlled trial in primary health care	
Location	Sweden	
Trial name	N/A	
Methods		
Inclusion criteria	“Adult patients between 18 and 70 years of age who consulted or were in care for overweight/obesity with or without type 2 diabetes, hypertension, CVD, coronary heart disease (CHD), dyslipidemia, gallstone, or musculoskeletal disorders.”	
Exclusion criteria	“Patients were not eligible if they were already taking part in another weight control program, understood the Swedish language poorly, were mentally ill, or had an alcohol or drug abuse problem. Neither were they eligible if they had a physical disability preventing intensified physical activity or were pregnant at study start.”	
Setting	GP clinic, Home	
Intervention	“Patients in the intervention group had regular appointments five times over the first two years with both a study nurse and a study physiotherapist. In addition, the study nurse and the physiotherapist contacted the patient by telephone four times during study months 6, 9, 15 and 21 (Figure 1). This contact was to encourage patients to comply with the advice given and answer patient questions. At the appointments with the nurse, written and illustrated information of the "plate model" was distributed to the patients and the content described in detail. Moreover, questions were answered and food advice repeated. They were also given a diary in which their physical activity was to be recorded and handed over to the physiotherapist at the check-ups. At the appointments with the physiotherapist a personalized program of regular exercise was designed and continuously adjusted for each participant. At these appointments the study nurse checked blood pressure, height, weight, waist circumference, calculated BMI, and performed blood tests for estimation of glucose and lipid levels. The basis of energy restriction given was the "platemodel", well known in Sweden, which illustrates the relative proportions of different food groups, in relation to which food of adequate composition and amount was demonstrated to the patient [14]. The model emphasizes that the two main daily meals (lunch and dinner) should contain no more than 25% meat, fish, chicken, eggs, beans, or other vegetarian protein alternatives. The rest of each meal should contain 25% potatoes, pasta or bread and 50% vegetables or fruit. It was recommended that water be the meal time drink. At breakfast, a sandwich and a bowl of yoghurt along with tea or coffee was recommended. Between meals, a fruit or a small sandwich was allowed [15]. This gives an energy intake where 10-15% comes from protein, no more than 30% from fat and the rest from carbohydrates. The advice emphasized an important aspect of the "plate model", namely to limit the amount of food at each meal. No second helpings or snacks between meals were allowed.”	
Control/Comparator	“In the control group the ordinary information used at the PHCC by members of the ordinary staff (doctor, nurse and physiotherapist) on the importance of a diet of adequate composition, reducing the total energy intake, and regular physical activity for weight control was given. Food advice was also based on the "plate-model" with the same	

<table>
<tr><td></td><td>composition as in the intervention group. The written information on the "plate-model" was given to the patients with no further discussion on the content. Patients in the control group had a check-up with a nurse after one month of compliance with the advice, and a repetition of what had been said at the start. At three months the nurse and the physiotherapist phoned the patients to encourage patients to comply with the advice given.”</td></tr>
<tr><td>Treatment duration</td><td>21 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 133
Intervention group/s: Intervention (n=67)

Comparator group: Control (n=66)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 45y (13); Control: 49y (13)</td></tr>
<tr><td>Sex</td><td>72.18% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Initial weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 97.7
(13.7)

Intervention: 33.8</td><td>Control: 95
(13.4)

Control: 33.6</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of Patients achieving minimum 5% weight loss (%)
Proportion (%)

Weight change (kg)
Mean (95% CIs)</td><td>Intervention: 26.6

Intervention: -2.5
(-4--1)</td><td>Control: 18.3

Control: -0.8
(-2.3-0.8)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Janus, 2012

Guideline record ID: 10347--1

Study characteristics		
Citation	Janus, E. D., Best, J. D., Davis-Lameloise, N., Philpot, B., Hernan, A., Bennett, C. M., O'Reilly, S., Carter, R., Vartiainen, E., Dunbar, J. A., & Melbourne Diabetes Prevention Study research group. (2012). Scaling-up from an implementation trial to state-wide coverage: results from the preliminary Melbourne Diabetes Prevention Study. Trials, 13, 152. https://doi.org/https://dx.doi.org/10.1186/1745-6215-13-152	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Scaling-up from an implementation trial to state-wide coverage: results from the preliminary Melbourne Diabetes Prevention Study	
Location	Australia	
Trial name	preliminary Melbourne Diabetes Prevention Study (pMDPS)	
Methods		
Inclusion criteria	"Individuals between 50 and 75 years at high T2DM risk were eligible to participate. High risk was defined as scoring 15 or above on the AUSDRISK tool, a 10-item questionnaire assessing T2DM risk [8]. Scores 15 to 19, and 20 and above respectively result in approximately one in seven and one in three developing T2DM within 5 years."	
Exclusion criteria	"Exclusion criteria were diagnosed diabetes, cancer, severe mental illness, substance abuse, recent myocardial infarction, pregnancy, difficulty with spoken and written English, belonging to a cultural group for whom the AUSDRISK test is not calibrated [8] and other household members involved in study."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The intervention was a series of six structured group sessions. The first five sessions were at 2-week intervals and the final sixth session was 8 months after the first [1]. . Certified and accredited Life! facilitators (trained health professionals such as nurses or diabetes educators) delivered the intervention. A physiotherapist or exercise physiologist and a dietitian co-facilitated sessions three and four, respectively [9,10]. The Finnish Diabetes Prevention Study goals were used [4]: no more than 30% energy from fat; no more than 10% energy from saturated fat; at least 15 g/1,000 kcal fibre; at least 30 minutes/day moderate intensity physical activity; and at least 5% body weight reduction. Processes and detailed goals for lifestyle change were individually tailored using a problem-solving and goalsetting approach."	
Control/Comparator	"Control subjects continued with usual care provided by their general practitioner and were subsequently offered the Life! programme after 12 months."	
Treatment duration	Life!: 8 months; Control: 12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Weight for height growth chart	
Participant characteristics		
Number of participants	n= 80 Intervention group/s: Diabetes prevention programme (Life!) (n=38) Comparator group: Usual care (n=42)	
Mean age ± SD	Life!: 64.2y (7.5); Usual care: 65.0y (6.0)	

<table>
<tr><td>Sex</td><td>66.25% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2) (baseline)
Mean (SD)</td><td>Diabetes prevention programme (Life!): 31.4 (4.82)</td><td>Usual care: 30.1 (4.19)</td></tr>
<tr><td>Weight (kg) (baseline)
Mean (SD)</td><td>Diabetes prevention programme (Life!): 87.2 (12.5)</td><td>Usual care: 81.8 (14.4)</td></tr>
<tr><td>Waist (cm) (baseline)
Mean (SD)</td><td>Diabetes prevention programme (Life!): 106.5 (8.35)</td><td>Usual care: 101.7 (11.52)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (SE)</td><td>Diabetes prevention programme (Life!): -0.98 (0.26)</td><td>Usual care: -0.21 (0.12)</td></tr>
<tr><td>Change in weight (kg)
Mean (SE)</td><td>Diabetes prevention programme (Life!): -2.65 (0.72)</td><td>Usual care: -0.6 (0.33)</td></tr>
<tr><td>Change in waist (cm)
Mean (SE)</td><td>Diabetes prevention programme (Life!): -7.45 (1.15)</td><td>Usual care: -4.02 (0.95)</td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
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<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Jarvholm, 2023

Guideline record ID: 10947--1

Study characteristics		
Citation	Järvholm, K., Janson, A., Peltonen, M., Neovius, M., Gronowitz, E., Engström, M., Laurenius, A., Beamish, A. J., Dahlgren, J., Sjögren, L., & Olbers, T. (2023). Metabolic and bariatric surgery versus intensive non-surgical treatment for adolescents with severe obesity (AMOS2): a multicentre, randomised, controlled trial in Sweden. The Lancet Child & Adolescent Health, 7(4), 249-260. https://doi.org/https://doi.org/10.1016/S2352-4642(22)00373-X	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Metabolic and bariatric surgery versus intensive non-surgical treatment for adolescents with severe obesity (AMOS2): a multicentre, randomised, controlled trial in Sweden	
Location	Sweden	
Trial name	Adolescent Morbid Obesity Surgery 2 (AMOS2)	
Methods		
Inclusion criteria	"Patients were eligible for inclusion if they were aged 13-16 years, with a BMI of at least 35 kg/m², and had attended treatment for obesity for at least 1 year, including at least 6 months at a specialised paediatric obesity unit.24 Participants were required to pass assessments by a paediatric psychologist and a paediatrician, have a Tanner pubertal stage of at least 3, and were required to show a positive attitude to long-term follow-up."	
Exclusion criteria	"Exclusion criteria included monogenic or syndromic obesity, major psychiatric illness, regular self-induced vomiting, ongoing substance use, severe pervasive developmental disorder, and previous major gastrointestinal surgery."	
Setting	Hospital, University/research centre	
Intervention	"Metabolic and bariatric surgery (MBS)"	
Control/Comparator	"intensive non-surgical treatment: low-calorie diet (880 calories per day) for 8 weeks, multi-professional lifestyle treatment aiming for a balanced diet with approximately 1500 calories per day and a physical activity plan meeting the recommendations of 60 min moderate-to-vigorous intensity daily activity and reduced sedentary behaviour. At least monthly minimum 1-h interactions with the treatment team were scheduled during the first year, and every 4-6 weeks during the second year."	
Treatment duration	24 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 50 Intervention group/s: Metabolic and bariatric surgery group (n=25) Comparator group: Intensive non-surgical treatment group (n=25)	
Mean age ± SD	Intervention: 15·6y (1·1); Control: 15·9y (0·8)	
Sex	74.00% female	

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Bodyweight, kg
Mean (95% CIs)</td><td>Metabolic and bariatric surgery group: 124.3 (116.8-131.7)</td><td>Intensive non-surgical treatment group: 120.9 (113.4-128.4)</td></tr>
<tr><td>BMI, kg/m²
Mean (95% CIs)</td><td>Metabolic and bariatric surgery group: 42.9 (40.8-45)</td><td>Intensive non-surgical treatment group: 42.3 (40.2-44.4)</td></tr>
<tr><td>BMI, kg/m² (SD score)
Mean (95% CIs)</td><td>Metabolic and bariatric surgery group: 3.5 (3.3-3.6)</td><td>Intensive non-surgical treatment group: 3.4 (3.3-3.6)</td></tr>
<tr><td>Waist circumference, cm
Mean (95% CIs)</td><td>Metabolic and bariatric surgery group: 120.2 (114.8-125.5)</td><td>Intensive non-surgical treatment group: 123.9 (118.5-129.2)</td></tr>
</table>
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<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Bodyweight, kg
Mean (95% CIs)</td><td>Metabolic and bariatric surgery group: 88.4 (79.7-97)</td><td>Intensive non-surgical treatment group: 121.3 (112.5-130)</td></tr>
<tr><td>BMI, kg/m²
Mean (95% CIs)</td><td>Metabolic and bariatric surgery group: 30.2 (27.6-32.9)</td><td>Intensive non-surgical treatment group: 42.1 (39.4-44.7)</td></tr>
<tr><td>BMI, kg/m² (SD score)
Mean (95% CIs)</td><td>Metabolic and bariatric surgery group: 2.1 (1.9)</td><td>Intensive non-surgical treatment group: 3.3 (3.1-3.6)</td></tr>
<tr><td>Waist circumference, cm
Mean (95% CIs)</td><td>Metabolic and bariatric surgery group: 93.4 (87.3-99.6)</td><td>Intensive non-surgical treatment group: 121.6 (115.2-128)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight change (%)
Mean (95% CIs)</td><td>Metabolic and bariatric surgery group: -28.7% (-33.6%--23.8%)</td><td>Intensive non-surgical treatment group: 0.4 (-4.6-5.4)</td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Jastreboff, 2022

Guideline record ID: 11071--1

Study characteristics		
Citation	Jastreboff, A. M., Aronne, L. J., Ahmad, N. N., Wharton, S., Connery, L., Alves, B., Kiyosue, A., Zhang, S., Liu, B., Bunck, M. C., Stefanski, A., & for the SURMOUNT-1 Investigators. (2022). Tirzepatide once weekly for the treatment of obesity. The New England Journal of Medicine, 387(3), 205-216. https://doi.org/10.1056/NEJMoa2206038	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Tirzepatide Once Weekly for the Treatment of Obesity	
Location	Argentina; Brazil; India; Japan; Russia; Taiwan; USA	
Trial name	SURMOUNT-1	
Methods		
Inclusion criteria	"Adults who were 18 years of age or older, with a body-mass index (BMI, the weight in kilograms divided by the square of the height in meters) of 30 or more, or a BMI of 27 or more and at least one weight-related complication (e.g., hyperten sion, dyslipidemia, obstructive sleep apnea, or cardiovascular disease), and who reported one or more unsuccessful dietary effort to lose weight were eligible to participate."	
Exclusion criteria	"Key exclusion criteria were diabetes, a change in body weight of more than 5 kg within 90 days before screening, pre vious or planned surgical treatment for obesity, and treatment with a medication that promotes weight loss within 90 days before screening."	
Setting	University/research centre	
Intervention	"Participants were randomly assigned in a 1:1:1:1 ratio to receive tirzepatide at a dose of 5 mg, 10 mg, or 15 mg or placebo, administered subcutaneously once weekly for 72 weeks as an adjunct to lifestyle inter vention. Lifestyle intervention included regular lifestyle counseling sessions, delivered by a dieti tian or a qualified health care professional, to help the participants adhere to healthful, bal anced meals, with a deficit of 500 calories per day, and at least 150 minutes of physical activity per week"	
Control/Comparator	"Participants were randomly assigned to a placebo, administered subcutaneously once weekly for 72 weeks as an adjunct to lifestyle inter vention. Lifestyle intervention included regular lifestyle counseling sessions, delivered by a dieti tian or a qualified health care professional, to help the participants adhere to healthful, bal anced meals, with a deficit of 500 calories per day, and at least 150 minutes of physical activity per week."	
Treatment duration	72 weeks	
Follow-up from baseline	72 weeks	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 2539 Intervention group/s: Tirzepatide 5mg (n=630); Tirzepatide10mg (n=636); Tirzepatide 15mg (n=630) Comparator group: Placebo (n=643)	
Mean age ± SD	44.9y (12.5)	
Sex	67.51% female	

Pre-existing medical condition	No pre-existing medical condition		
Results			
Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	Body weight - kg Mean (SD)	Tirzepatide 5mg: 102.9 (20.71) Tirzepatide10mg: 105.8 (23.32) Tirzepatide 15mg: 105.6 (22.92)	Placebo: 104.8 (21.37)
	Mean body-mass index Mean (SD)	Tirzepatide 5mg: 37.4 (6.63) Tirzepatide10mg: 38.2 (7.01) Tirzepatide 15mg: 38.1 (6.69)	Placebo: 38.2 (6.89)
	Waist circumference - cm Mean (SD)	Tirzepatide 5mg: 113.2 (14.25) Tirzepatide10mg: 114.8 (15.8) Tirzepatide 15mg: 114.4 (15.59)	Placebo: 114 (14.92)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight reduction of 5% or more at week 72 - percentage of participants Proportion (%)	Tirzepatide 5mg: 85.1 (81.6-88.6) Tirzepatide10mg: 88.9 (85.9-91.9) Tirzepatide 15mg: 90.9 (88-93.8)	Placebo: 34.5 (29.8-39.2)
	Weight reduction of 10% or more at week 72 - percentage of participants Proportion (%)	Tirzepatide 5mg: 68.5 (64.5-72.5) Tirzepatide10mg: 78.1 (74.4-81.7) Tirzepatide 15mg: 83.5 (80-86.9)	Placebo: 18.8 (14.9-22.7)
	Weight reduction of 15% or more at week 72 - percentage of participants Proportion (%)	Tirzepatide 5mg: 48 (43.9-52.1) Tirzepatide10mg: 66.6 (62.6-70.6) Tirzepatide 15mg: 70.6 (66.7-74.5)	Placebo: 8.8 (5.9)
	Weight reduction of 20% or more at week 72 - percentage of participants Proportion (%)	Tirzepatide 5mg: 30 (26.4-33.6) Tirzepatide10mg: 50.1 (46-54.2) Tirzepatide 15mg: 56.7 (52.6-60.8)	Placebo: 3.1 (1.1-5.1)
	Weight reduction of 25% or more at week 72 - percentage of participants Proportion (%)	Tirzepatide 5mg: 15.3 (12.5-18.1) Tirzepatide10mg: 32.3 (28.5-36.1) Tirzepatide 15mg: 36.2 (32.3-40.1)	Placebo: 1.5 (0.1-2.9)

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Percentage change in body weight
Mean (95% CIs)

Change in waist circumference - cm
Mean (SE)</td><td>Tirzepatide 5mg: -15
(-15.9--14.2)
Tirzepatide10mg: -19.5
(-20.4--18.5)
Tirzepatide 15mg: -20.9
(-21.8--19.9)

Tirzepatide 5mg: -14
(-14.9--13.1)
Tirzepatide10mg: -17.7
(-18.7--16.8)
Tirzepatide 15mg: -18.5
(-19.3--17.6)</td><td>Placebo: -3.1
(-4.3--1.9)

Placebo: -4
(-5.1--2.8)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Jebb, 2011

Guideline record ID: 10349--1

Study characteristics		
Citation	Jebb, S. A., Ahern, A. L., Olson, A. D., Aston, L. M., Holzapfel, C., Stoll, J., Amann-Gassner, U., Simpson, A. E., Fuller, N. R., Pearson, S., Lau, N. S., Mander, A. P., Hauner, H., & Caterson, I. D. (2011). Primary care referral to a commercial provider for weight loss treatment versus standard care: a randomised controlled trial. The Lancet, 378(9801), 1485-1492. https://doi.org/https://dx.doi.org/10.1016/S0140-6736(11)61344-5	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Primary care referral to a commercial provider for weight loss treatment versus standard care: a randomised controlled trial	
Location	Australia; Germany; UK	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligible participants were adults (aged ≥18 years) with a body-mass index (BMI) of 27-35 kg/m² who had at least one additional risk factor for obesity-related disease. Risk factors included central adiposity (waist circumference >88 cm in women or >102 cm in men); type 2 diabetes without insulin treatment; family history of diabetes; previous gestational diabetes; impaired glucose tolerance or impaired fasting glycaemia, mild to moderate dyslipidaemia (defi ned by national guidelines), or treatment for dyslipidaemia; treatment for hyper tension; polycystic ovarian syndrome or infertility without apparent cause other than weight; lower-limb osteo arthritis; or abdominal hernia."	
Exclusion criteria	"People were excluded if they met any of the following criteria: weight loss of 5 kg or more in the previous 3 months; history of a clinically diagnosed eating disorder; orthopaedic limitations preventing participation in regular physical activity; untreated thyroid disease or more than one change in thyroid treatment in the previous 6 months; receiving treatment with eff ects on weight or appetite; gastro intestinal disorders; previous surgical procedure for weight loss; major surgery in the previous 3 months; pregnancy or lactation; insulin-treated diabetes; diabetes diagnosis in the previous 6 months; glycated haemoglobin (HbA1c) of at least 75 mmol/mol (9·0%); heart problems in the previous 3 months; uncontrolled hypertension; new prescription drug for a chronic disorder in the previous 3 months or change in dose in the previous 1 month; history or presence of cancer, with the exception of completely resected basal or squamous cell carcinoma if treatment completed 6 months before enrolment or if treatment was stable; or participation in another clinical trial in the previous 30 days."	
Setting	GP clinic, Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Participants in the commercial programme group received free access to weekly community-based Weight Watchers meetings for 12 months. They were requested not to mention their participation in the study to the group leader or other attendees. This commercial programme promotes a hypoenergetic, balanced diet based on healthyeating principles, increased physical activity, and group support. Weight loss goals are self-selected with input from the group leader, and participants are encouraged to attend weekly meetings for a weigh-in and group discussion, behavioural counselling, and motivation. Participants were able to access internet-based systems to monitor their food intake, activity, and weight change; to participate in community discussion boards; and to access a library of information, recipes, and meal ideas."	
Control/Comparator	"Participants in the standard care group received weight loss advice from a primary care professional at their local general practitioner (GP) practice. Professionals delivering this	

<table>
<tr><td></td><td>intervention were provided with, and encouraged to use, Australian, German, and UK national clinical guidelines for treatment, and were made aware of information providing advice about weight loss.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 772
Intervention group/s: Commercial programme (n=377)

Comparator group: Standard care (n=395)</td></tr>
<tr><td>Mean age ± SD</td><td>Commercial programme: 46.5y (13.5); Standard care: 48.2y (12.2)</td></tr>
<tr><td>Sex</td><td>86.53% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline weight (kg)
Mean (SD)

Baseline waist circumference (cm)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Commercial programme: 86.9 (11.6)

Commercial programme: 100 (9.2)

Commercial programme: 31.5 (2.6)</td><td>Standard care: 86.5 (11.5)

Standard care: 99.9 (9.3)

Standard care: 31.3 (2.6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Bodyweight change (kg)
Mean (SE)

Waist circumference change (cm)
Mean (SE)</td><td>Commercial programme: -5.06 (0.31)

Commercial programme: -5.6 (0.37)</td><td>Standard care: -2.25 (0.21)

Standard care: -3.16 (0.28)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
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<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	Fuller, N. R., Williams, K., Shrestha, R., Ahern, A. L., Holzapfel, C., Hauner, H., Jebb, S. A., & Caterson, I. D. (2014). Changes in physical activity during a weight loss intervention and follow-up: a randomized controlled trial. Clinical Obesity, 4(3), 127-135. https://doi.org/https://dx.doi.org/10.1111/cob.12057

N/A – Not applicable

Jelalian, 2010

Guideline record ID: 10350--1

Study characteristics		
Citation	Jelalian, E., Lloyd-Richardson, E. E., Mehlenbeck, R. S., Hart, C. N., Flynn-O'Brien, K., Kaplan, J., Neill, M., & Wing, R. R. (2010). Behavioral weight control treatment with supervised exercise or peer-enhanced adventure for overweight adolescents. The Journal of Pediatrics, 157(6), 923-928.e921. https://doi.org/https://dx.doi.org/10.1016/j.jpeds.2010.05.047	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Behavioral weight control treatment with supervised exercise or peer-enhanced adventure for overweight adolescents	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligibility requirements included age between 13 and 16 years, between 30% and 90% overweight as defined with reference to median BMI for age and sex, at least one parent available to participate, and English speaking."	
Exclusion criteria	"Adolescents were excluded when they met the criteria for a major psychiatric disorder, were already enrolled in a weight loss program, or had a condition that prevented them from following the diet or physical activity prescription."	
Setting	Hospital, Home	
Intervention	"Cognitive Behavioural Therapy with peer-enhanced adventure therapy (CBT+PEAT): Both group-based interventions included 16 one-hour weekly sessions, with parents and adolescents attending separate concurrent meetings, followed by 4 biweekly maintenance sessions. Adolescents were prescribed a balanced deficit diet (1400-1600 calories) and asked to gradually increase physical activity to an ideal of 60 minutes on most days of the week. Treatment groups consisted of didactic material and educational activities illustrating a range of behavioral topics (eg, self-monitoring, motivation for weight loss, goal setting, stimulus control, and relapse prevention). Treatment groups were led by master- and doctoral-level psychologists with experience in adolescent weight management and a registered dietician. The content of co-occurring parent meetings paralleled that for adolescents. Parents were also provided guidance on implementing family-level change and supporting positive eating and physical activity habits in their adolescents. After completion of the 20 group sessions, periodic (ie, bimonthly) activities were scheduled to encourage continued participant involvement with the study through the end of 12 months. Activities were offered to adolescents in both treatment conditions at separate times and included events such as apple picking, bowling, and miniature golf. In addition to the CBT intervention aforementioned, adolescents participated in additional weekly activity sessions. Peer-Enhanced Adventure Therapy The peer-based activity session consisted of an initial ''warmup'' activity that included physical activity, followed by the primary challenge for the group, processing of the activity, and establishing weekly personal activity goals. Similar to Outward Bound adventure therapy, group activities consisted of both physical and mental challenges that were aimed at development of social skills, problem-solving abilities, and self-confidence. A more detailed description of the adventure therapy component is provided elsewhere"	
Control/Comparator	"Cognitive-behavioural treatment with exercise (CBT+EXER): Activities for the supervised exercise intervention included use of treadmills, stationary bicycles, and other aerobic activities selected by participants, including dance videos and brisk walking within the clinic setting. The format for each session followed the same sequence, beginning with a brief warm-up period, progressing to approximately 35 minutes of sustained physical activity,	

<table>
<tr><td></td><td>and ending with a wrap-up period consisting of ''cool down'' and review of weekly physical activity goals.”</td></tr>
<tr><td>Treatment duration</td><td>16 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 118
Intervention group/s: CBT+PEAT (n=62)

Comparator group: CBT+EXER (n=56)</td></tr>
<tr><td>Mean age ± SD</td><td>171.92 months (12.19)</td></tr>
<tr><td>Sex</td><td>67.80% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (lb)
Mean (SD)</td><td>CBT+PEAT: 187.04
(30.91)</td><td>CBT+EXER: 187.78
(31.17)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>CBT+PEAT: 31.49
(3.55)</td><td>CBT+EXER: 31.33
(3.1)</td></tr>
<tr><td>z-BMI
Mean (SD)</td><td>CBT+PEAT: 1.63
(0.4)</td><td>CBT+EXER: 1.61
(0.35)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>CBT+PEAT: 103.94
(9.61)</td><td>CBT+EXER: 103.04
(9.2)</td></tr>
</table>
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<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (lb)
Mean (SD)</td><td>CBT+PEAT: 183.67
(29.45)</td><td>CBT+EXER: 187.74
(34.82)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>CBT+PEAT: 30.31
(3.91)</td><td>CBT+EXER: 30.58
(3.77)</td></tr>
<tr><td>z-BMI
Mean (SD)</td><td>CBT+PEAT: 1.46
(0.5)</td><td>CBT+EXER: 1.5
(0.52)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>CBT+PEAT: 101.14
(10.66)</td><td>CBT+EXER: 101.18
(10.72)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
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<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
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</table>

Compliance with treatment	CBT+PEAT and CBT+EXER attended an average of 83% of sessions
Notes	
Additional included publications arising from this study that did not contribute additional data	Lloyd-Richardson, E. E., Jelalian, E., Sato, A. F., Hart, C. N., Mehlenbeck, R., & Wing, R. R. (2012). Two-year follow-up of an adolescent behavioral weight control intervention. Pediatrics, 130(2), e281-e288. https://doi.org/https://dx.doi.org/10.1542/peds.2011-3283

N/A – Not applicable

Jenkins, 2017

Guideline record ID: 10351--1

Study characteristics		
Citation	Jenkins, D. J. A., Boucher, B. A., Ashbury, F. D., Sloan, M., Brown, P., El-Sohemy, A., Hanley, A. J., Willett, W., Paquette, M., de Souza, R. J., Ireland, C., Kwan, N., Jenkins, A., Pichika, S. C., & Kreiger, N. (2017). Effect of current dietary recommendations on weight loss and cardiovascular risk factors. Journal of the American College of Cardiology, 69(9), 1103-1112. https://doi.org/10.1016/j.jacc.2016.10.089	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Current Dietary Recommendations on Weight Loss and Cardiovascular Risk Factors	
Location	Canada	
Trial name	N/A	
Methods		
Inclusion criteria	"18 years or older, English speaking, and had body mass index (BMI) >25 kg/m2 . Individuals or families were recruited if at least 1 family member had BMI >25 kg/m2, and blood pressure and thyroid medications (thyroxin) dosages, if taken, were stable for at least 1 month prior to starting the study."	
Exclusion criteria	"Exclusion criteria included pregnancy or breastfeeding; actively following a special diet or weight-loss program; major surgery or a cardiovascular event in the previous 6 months; diabetes, liver disease, renal failure, cancer (except nonmelanoma skin cancer), inflammatory bowel disease or major chronic inflammatory diseases; acute or chronic infections, irritable bowel syndrome; peanut or nut allergy; or a blood pressure >145/95 mm Hg on more than one occasion."	
Setting	Home	
Intervention	"Advice only: The first treatment group received additional dietary advice weekly for the first month and monthly for the following 5 months as 20- to 30-min telephone interviews with individual participants or the families' primary shopper or cook. The advice addressed benefits, strategies for change, and barriers to change for each participating family member. Participants were encouraged to increase intake of fruit, vegetables, whole grain cereals, to reduce meat and sweets, and to increase consumption of cholesterol-lowering functional foods including soy foods, nuts, and viscous fiber sources such as oats and barley. ; Food Only: A second treatment group received a weekly food basket (Food Share, Toronto, Ontario) for 6 months, reflecting the advice given to the first treatment group but did not receive dietary advice.; Food and Advice: The third treatment group received both the weekly food basket and dietary advice. All members of the same family were expected to follow the same treatment. Exercise patterns were recorded but no additional advice was given"	
Control/Comparator	"Participants received a copy of Health Canada's Food Guide. No further advice was given to the control group."	
Treatment duration	6 months	
Follow-up from baseline	18 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 919
Intervention group/s: Food Only (n=148); Advice Only (n=145); Food and Advice (n=140)

Comparator group: Control (n=486)</td></tr>
<tr><td>Mean age ± SD</td><td>44.7y</td></tr>
<tr><td>Sex</td><td>77.26% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (95% CIs)</td><td>Food Only: 89.2
(86.3-92.2)
Advice Only: 86.2
(83.3-89.1)
Food and Advice: 89.6
(86.6-92.6)</td><td>Control: 88
(86.5-89.5)</td></tr>
<tr><td>BMI (kg/m2)
Mean (95% CIs)</td><td>Food Only: 32.6
(31.6-33.5)
Advice Only: 31.7
(30.8-32.7)
Food and Advice: 32.7
(31.7-33.7)</td><td>Control: 32.5
(32-33)</td></tr>
<tr><td>Waist circumference (cm)
Mean (95% CIs)</td><td>Food Only: 102.3
(99.8-104.8)
Advice Only: 100.6
(98.3-102.8)
Food and Advice: 101.9
(99.5-104.3)</td><td>Control: 101.2
(100-102.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (95% CIs)</td><td>Food Only: 87.9
(85.1-90.8)
Advice Only: 85.2
(82.3-88.1)
Food and Advice: 88.9
(85.7-92.1)</td><td>Control: 87.2
(85.7-88.8)</td></tr>
<tr><td>BMI (kg/m2)
Mean (95% CIs)</td><td>Food Only: 32.2
(31.3-33.1)
Advice Only: 31.4
(30.4-32.4)
Food and Advice: 32.4
(31.3-33.4)</td><td>Control: 32.3
(31.7-32.8)</td></tr>
<tr><td>Waist circumference (cm)
Mean (95% CIs)</td><td>Food Only: 100.6
(98.1-103.1)
Advice Only: 99.3
(96.9-101.7)
Food and Advice: 100.9
(98.1-103.6)</td><td>Control: 99.7
(98.4-101.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change (kg)
Mean (95% CIs)</td><td>Food Only: -1.3
(-2.3--0.3)
Advice Only: -1</td><td>Control: -0.8
(-1.3--0.2)</td></tr>
</table>
</td></tr>
</table>

		(-1.8--0.1) Food and Advice: -0.7 (-1.8)	
	BMI change (kg/m2) Mean (95% CIs)	Food Only: -0.4 (-0.8-0) Advice Only: -0.3 (-0.8-0.1) Food and Advice: -0.3 (-0.7-0.1)	Control: -0.2 (-0.4--0.1)
	Waist circumference change (cm) Mean (95% CIs)	Food Only: -1.7 (-2.9--0.6) Advice Only: -1.3 (-2.4--0.1) Food and Advice: -1 (-2.4-0.4)	Control: -1.5 (-2.3--0.7)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Jiang, 2017

Guideline record ID: 10354--1

Study characteristics		
Citation	Jiang, X., Fan, X., Wu, R., Geng, F., & Hu, C. (2017). The effect of care intervention for obese patients with type II diabetes. Medicine, 96(42), e7524. https://doi.org/https://dx.doi.org/10.1097/MD.0000000000007524	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The effect of care intervention for obese patients with type II diabetes	
Location	China	
Trial name	N/A	
Methods		
Inclusion criteria	“Male or female patients of nonchildbearing potential; adult group with age range 18 to 70 years; the BMI ≥30 kg/m2.”	
Exclusion criteria	“Patients with diabetes complications such as diabetic nephropathy and diabetic foot, diabetes other than type 2, or other severe visceral organ disease were excluded from our study. In addition, the patients with psychological disorders would also be excluded from the current investigation.”	
Setting	Hospital, Home	
Intervention	“Patients received conventional treatment, including taking diabetes medications and monitoring their blood glucose, blood pressure. In addition to the conventional treatment, patients in the intervention group received dietary intervention, exercise intervention, and psychology intervention. The dietary intervention mainly included dietary evaluation by the program-registered dietitians, receiving a hypocaloric meal plan, using diabetes-specific meal replacement for breakfast and lunch. All meal plans were low in glycemic index and low in sodium (<2300mg/day). On the basis of each participant's health status and exercise capacity, an individualized exercised plan was designed by doctor and patients. The intensity level of exercise was set above the minimum required improve patients' current exercise capacity but below a level that might evoke abnormal clinical symptoms. The exercise intervention included a balanced mix of aerobic exercise, resistance exercise, and core stability training. Patients were instructed to progress gradually from 20minutes, 4 days/ week to 60minutes, 5 to 6 days/week. Clinical psychologist or a social worker was invited to conduct group behavioral support sessions including basic mental health knowledge and the effects of medication on the behavior of those who suffering from illness. Patients were provided with handouts as reminders, and they were taught of self-monitoring of eating and exercise, behavioral goal setting, cognitive restructuring, assertive communication skills, and relapse prevention. The group sessions were performed once a month; besides, the patients received psychological guidance every 2 weeks through telephone.”	
Control/Comparator	“Patients received conventional treatment, including taking diabetes medications and monitoring their blood glucose, blood pressure.”	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 126
Intervention group/s: IG (n=63)

Comparator group: CG (n=63)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 56.3y (5.2); Control: 57.1y (5.5)</td></tr>
<tr><td>Sex</td><td>48.41% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>T2DM</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>IG: 90.5
(11.3)

IG: 32.6
(2.4)</td><td>CG: 92.1
(12.2)

CG: 34.1
(3.1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>IG: 82.1
(10.6)

IG: 28.5
(2.6)</td><td>CG: 88.4
(12.6)

CG: 32.6
(3.5)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Jiskoot, 2020

Guideline record ID: 10355--1

Study characteristics		
Citation	Jiskoot, G., Timman, R., Beerthuizen, A., Dietz de Loos, A., Busschbach, J., & Laven, J. (2020). Weight reduction through a cognitive behavioral therapy lifestyle intervention in PCOS: the primary outcome of a randomized controlled trial. Obesity, 28(11), 2134-2141. https://doi.org/https://dx.doi.org/10.1002/oby.22980	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight Reduction Through a Cognitive Behavioral Therapy Lifestyle Intervention in PCOS: The Primary Outcome of a Randomized Controlled Trial	
Location	Netherlands	
Trial name	N/A	
Methods		
Inclusion criteria	"Women were eligible if they 1) were diag nosed with PCOS according to the Rotterdam 2003 consensus criteria, 2) had BMI > 25 kg/m2, 3) were between 18 and 38 years old, and 4) wished to become pregnant."	
Exclusion criteria	"Women with an inadequate command of the Dutch language, severe mental illness, obesity with another somatic cause, ovar ian tumors that lead to androgen excess, or adrenal diseases were not eligible for the study."	
Setting	GP clinic, Hospital, Home	
Intervention	"The 1-year multidisciplinary LS program aimed to 1) change cogni tions, 2) improve dietary habits, 3) encourage and promote physical activity, and 4) activate social support. It consisted of 20 CBT group sessions of 2.5 hours over the course of 1 year. CBT component were self-monitoring, realistic and achievable goal setting, developing new coping skills to han dle or prevent relapses, and promotion of alternative behaviors during critical emotional situations or negative mood states. The Dutch Food Guide was used as a guideline for a healthy diet and daily amounts of food groups. No caloric restriction was advised. Physical therapists encouraged participants to plan exercise as part of their daily routine. Half of the participants in the LS group received additional support by tailored SMS after 3 months of the LS program. Participants sent weekly self-monitored information regarding their diet, physical activity, and emotions by SMS to the psychologist. Participants received feedback on their messages to provide social support, encourage positive behavior, and empower behavioral strategies. Also, participants received two messages per week addressing eating behavior (self-monitoring, barriers, binge eating, eating pace, emotional eating, food choices, portions, planning, preparation, stimulus control, social eating, sugar-sweet ened beverages) and physical activity (motivation, fun facts, sedentary behavior)."	
Control/Comparator	"Participants in the CAU group received CAU, which included short, unstructured consultations with their treating physician at baseline and four consultations that were combined with the 3-, 6-, 9-, and 12-month study measurements. They were encouraged by their treating physician to lose weight through publicly available services (i.e., diets, visiting a dietitian, going to the gym, or participating in public programs such as Weight Watchers). The treating physician also mentioned the risk of overweight for both mother and child as well as the relation between overweight and fertility."	
Treatment duration	12 months	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 183
Intervention group/s: Lifestyle intervention without SMS (n=63); Lifestyle intervention with SMS (n=60)

Comparator group: Care as usual (n=60)</td></tr>
<tr><td>Mean age ± SD</td><td>29.1y (4.4)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Polycystic ovary syndrome (PCOS)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight estimates
Mean</td><td>Lifestyle intervention without SMS: 91.7
Lifestyle intervention with SMS: 96.5</td><td>Care as usual: 89.5</td></tr>
<tr><td>BMI estimates
Mean</td><td>Lifestyle intervention without SMS: 33.9
Lifestyle intervention with SMS: 34.7</td><td>Care as usual: 32.7</td></tr>
<tr><td>Waist circumference estimate
Mean</td><td>Lifestyle intervention without SMS: 100.1
Lifestyle intervention with SMS: 102.9</td><td>Care as usual: 100.4</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight estimates
Mean</td><td>Lifestyle intervention without SMS: 87
Lifestyle intervention with SMS: 88.7</td><td>Care as usual: 87.2</td></tr>
<tr><td>BMI estimates
Mean</td><td>Lifestyle intervention without SMS: 32.3
Lifestyle intervention with SMS: 31.9</td><td>Care as usual: 31.8</td></tr>
<tr><td>Waist circumference estimate
Mean</td><td>Lifestyle intervention without SMS: 96.3
Lifestyle intervention with SMS: 94.8</td><td>Care as usual: 94.9</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Estimate weight change
Mean</td><td>Lifestyle intervention without SMS: -4.65
Lifestyle intervention with SMS: -7.87</td><td>Care as usual: -2.32</td></tr>
<tr><td>Percent change in weight
Mean</td><td>Lifestyle intervention without SMS: -5.1</td><td>Care as usual: -2.6</td></tr>
</table>
</td></tr>
</table>

		Lifestyle intervention with SMS: -8.1	
	Estimate BMI change Mean	Lifestyle intervention without SMS: -1.69 Lifestyle intervention with SMS: -2.8	Care as usual: -0.85
	Percent change in BMI Mean %	Lifestyle intervention without SMS: -5 Lifestyle intervention with SMS: -8.1	Care as usual: -2.6
	Estimate waist circumference change Mean	Lifestyle intervention without SMS: -3.79 Lifestyle intervention with SMS: -8.13	Care as usual: -5.56
	Percent waist circumference change Mean %	Lifestyle intervention without SMS: -3.8 Lifestyle intervention with SMS: -7.9	Care as usual: -5.5

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Johansen, 2017

Guideline record ID: 10356

Study characteristics		
Citation	Johansen, M. Y., MacDonald, C. S., Hansen, K. B., Karstoft, K., Christensen, R., Pedersen, M., Hansen, L. S., Zacho, M., Wedell-Neergaard, A.-S., Nielsen, S. T., Iepsen, U. W., Langberg, H., Vaag, A. A., Pedersen, B. K., & Ried-Larsen, M. (2017). Effect of an intensive lifestyle intervention on glycemic control in patients with type 2 diabetes: a randomized clinical trial. JAMA, 318(7), 637-646. https://doi.org/https://dx.doi.org/10.1001/jama.2017.10169	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of an Intensive Lifestyle Intervention on Glycemic Control in Patients With Type 2 Diabetes: A Randomized Clinical Trial	
Location	Denmark	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were type 2 diabetes diagnosed less than 10 years, body mass index (BMI; calcu lated as weight in kilograms divided by height in meters squared) of 25 to 40, and taking 2 or fewer glucose-lowering medications."	
Exclusion criteria	"Exclusion criteria were HbA1c level greater than 9%, insulin-dependence, or presence of 1 or more of the following complications: diabetic retinopathy, macroalbumin uria (urine albumin-creatinine ratio ≥300 mg/g) or nephropa thy (plasma creatinine ≥1.47 mg/dL [to convert to µmol/L, multiply by 88.4])."	
Setting	Hospital, Home	
Intervention	"All participants received standard care that included medical counseling, education in type 2 diabetes, and lifestyle advice by the study nurse at baseline and every 3months for 12months. The treatment target for glycemic control was 6.5% for HbA1c level, and if this target was reached, the glucose-lowering medication dose was halved. If the HbA1c level was unchanged or lower at the following medical consultation, the glucose-lowering medication was discontinued. If HbA1c level exceeded 7.5%, the glucose-lowering medication was increased accordingly. 5 to 6 weekly aerobic sessions (duration 30-60 minutes), of which 2 to 3 sessions were combined with resistance training. For the first 4 months, all exercise ses sions were supervised, and supervision was progressively re duced during the 12 months. Participants were given an individual dietary plan with a macronutrient distribution of 45% to 60% carbohydrate, 15% to 20% protein, and 20% to 35% fat (<7% saturated fat). During the first 4 months the total energy intake was restricted. Additionally, participantswere encouraged to be physically active in their leisure time (≥10 000 steps per day). Steps and exercise sessions were objectively monitored with a smartwatch (Polar V800)."	
Control/Comparator	"All participants received standard care that included medical counseling, education in type 2 diabetes, and lifestyle advice by the study nurse at baseline and every 3months for 12months. The treatment target for glycemic control was 6.5% for HbA1c level, and if this target was reached, the glucose-lowering medication dose was halved. If the HbA1c level was unchanged or lower at the following medical consultation, the glucose-lowering medication was discontinued. If HbA1c level exceeded 7.5%, the glucose-lowering medication was increased accordingly."	
Treatment duration	12 months	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 98
Intervention group/s: Lifestyle Group (n=64)

Comparator group: Standard Care Group (n=34)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 53.6y (9.1); Control: 56.6y (8.1)</td></tr>
<tr><td>Sex</td><td>47.96% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline weight (kg)
Mean (SD)

Baseline BMI (kg/m2)
Mean (SD)

Baseline Fat mass, kg
Mean (SD)

Baseline Abdominal fat mass, kg
Mean (SD)</td><td>Lifestyle Group: 94.7 (14)

Lifestyle Group: 31.4 (3.9)

Lifestyle Group: 35.2 (9.2)

Lifestyle Group: 4 (1.2)</td><td>Standard Care Group: 98.1 (15)

Standard Care Group: 32.5 (4.5)

Standard Care Group: 36.4 (9.2)

Standard Care Group: 4.2 (1.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)

Change in BMI
Mean (95% CIs)

Change in Fat mass, kg
Mean (95% CIs)

Change in Abdominal fat mass, kg
Mean (95% CIs)</td><td>Lifestyle Group: -6.11 (-7.5--4.72)

Lifestyle Group: -2.01 (-2.46--1.56)

Lifestyle Group: -6.13 (-7.33--4.93)

Lifestyle Group: -0.81 (-0.98--0.65)</td><td>Standard Care Group: -1.97 (-4.02-0.1)

Standard Care Group: -0.69 (-1.35--0.02)

Standard Care Group: -1.16 (-2.94-0.66)

Standard Care Group: -0.1 (-0.34-0.14)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Johnston, 2010

Guideline record ID: 10360--1

Study characteristics		
Citation	Johnston, C. A., Tyler, C., McFarlin, B. K., Poston, W. S. C., Haddock, C. K., Reeves, R. S., & Foreyt, J. P. (2010). Effects of a school-based weight maintenance program for Mexican-American children: results at 2 years. Obesity, 18(3), 542-547. https://doi.org/https://dx.doi.org/10.1038/oby.2009.241	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of a school-based weight maintenance program for Mexican-American children: results at 2 years	
Location	US	
Trial name	Family Lifestyle Overweight Prevention Program (FLOW)	
Methods		
Inclusion criteria	"Children were between the ages of 10 and 14 (M = 12.3, s.d. = 0.7) and in the 6th or 7th grade. All children self-identified as Mexican American. All participants included in analyses were overweight or obese (i.e., BMI >85th or >95th percentile for age and gender, respectively) according to Centers for Disease Control and Prevention guidelines."	
Exclusion criteria	Not reported	
Setting	School	
Intervention	"Those randomized to the ILI condition participated in an instructor/trainer led intervention for 24 weeks of daily (Monday through Friday) sessions. Peanut butter and fruit were offered as afternoon snacks"	
Control/Comparator	"Children in the SH condition used a 12-week parent-guided manual intended to promote child weight loss and long-term maintenance of changes."	
Treatment duration	24 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 60 Intervention group/s: Instructor-led intervention (n=40) Comparator group: Self-help (n=20)	
Mean age ± SD	Intervention: 12.3y (0.7); Control: 12.5y (0.6)	
Sex	45.00% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	Baseline weight (kg) Mean (SD)	Instructor-led intervention: 59 (11.7)	Self-help: 62.5 (16.3)

	Baseline BMI (kg/m2) Mean (SD) Baseline zBMI Mean (SD)	Instructor-led intervention: 25.2 (4.4) Instructor-led intervention: 1.5 (0.6)	Self-help: 26.7 (5.5) Self-help: 1.7 (0.6)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight change Mean (SD) BMI change Mean (SD) zBMI change Mean (SD) BMI percentile change Mean (SD)	Instructor-led intervention: 3.6 (3.1) Instructor-led intervention: -0.1 (1.2) Instructor-led intervention: -0.2 (0.2) Instructor-led intervention: -5.5 (8)	Self-help: 7.4 (3.2) Self-help: 1.6 (1.1) Self-help: 0.1 (0.1) Self-help: -0.6 (2.9)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Weight change Mean (SD) BMI change Mean (SD) zBMI change Mean (SD) BMI percentile change Mean (SD)	Instructor-led intervention: 9.2 (10.1) Instructor-led intervention: -0.2 (0.5) Instructor-led intervention: 0.8 (3.4) Instructor-led intervention: -6.8 (10.9)	Self-help: 12.1 (4.9) Self-help: 0 (0.1) Self-help: 2.1 (1.3) Self-help: -0.8 (3.3)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data	Johnston, C. A., Moreno, J. P., Gallagher, M. R., Wang, J., Papaioannou, M. A., Tyler, C., & Foreyt, J. P. (2013). Achieving long-term weight maintenance in Mexican-American adolescents with a school-based intervention. Journal of Adolescent Health, 53(3), 335-341. https://doi.org/https://dx.doi.org/10.1016/j.jadohealth.2013.04.001		

N/A – Not applicable

Johnston, 2013

Guideline record ID: 10359--1

Study characteristics		
Citation	Johnston, C. A., Moreno, J. P., Gallagher, M. R., Wang, J., Papaioannou, M. A., Tyler, C., & Foreyt, J. P. (2013). Achieving long-term weight maintenance in Mexican-American adolescents with a school-based intervention. Journal of Adolescent Health, 53(3), 335-341. https://doi.org/https://dx.doi.org/10.1016/j.jadohealth.2013.04.001	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Achieving long-term weight maintenance in Mexican-American adolescents with a school-based intervention	
Location	USA	
Trial name	Family Lifestyle Overweight Prevention Program (FLOW)	
Methods		
Inclusion criteria	"Mexican-American adolescents, ages of 10 and 14 years, classified as overweight or obese (i.e., BMI 85th or 95th percentile for age and gender, respectively) based on Centers for Disease Control and Prevention guidelines."	
Exclusion criteria	Not reported	
Setting	School	
Intervention	"Adolescents in the ILI condition attended a nutrition class once a week and a physical activity training class 4 days a week, held during the final school period of the day, lasting 35e40 minutes. Parents were also involved in the intervention by attending monthly meetings. Participants who continued gaining weight for more than 2 weeks, missed class sessions, or had low grades in the biweekly quizzes that evaluated material acquisition were given individualized attention. participants in the ILI condition were provided with a 90-calorie cereal bar to promote satiety as a daily after noon snack and a small box of cereal to eat as a snack or break fast. Fruits or vegetables were also offered to enhance satiety and to provide an opportunity for fruit and vegetable consumption."	
Control/Comparator	"Study staff provided adolescents and their parents with a book, Trim Kids, which categorizes children and adolescents into groups based on their weight classification, normal weight to obese [26]. This manual provides a 12-week weight manage ment plan and instructions for long-term maintenance of changes [26]. During the intervention class, students assigned to the SH condition and all nonparticipating students attended a study hall in a room separate from adolescents in the intervention."	
Treatment duration	24 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 71 Intervention group/s: Instructor-led intervention (n=46) Comparator group: Self-help (n=25)	
Mean age ± SD	Intervention: 12.2y (0.8); Control: 12.2y (0 .7)	
Sex	54.93% female	

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Instructor-led intervention:
64.9
(16.9)</td><td>Self-help: 58.7
(9.1)</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Instructor-led intervention:
27.7
(5)</td><td>Self-help: 25.6
(3.4)</td></tr>
<tr><td>zBMI
Mean (SD)</td><td>Instructor-led intervention: 1.9
(0.5)</td><td>Self-help: 1.6
(0.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in weight
Mean (SD)</td><td>Instructor-led intervention: 4.5
(4.1)</td><td>Self-help: 5.3
(3.2)</td></tr>
<tr><td>Change in BMI
Mean (SD)</td><td>Instructor-led intervention: 0.2
(1.5)</td><td>Self-help: 0.9
(0.7)</td></tr>
<tr><td>Change in zBMI
Mean (SD)</td><td>Instructor-led intervention: -0.1
(0.2)</td><td>Self-help: 0
(0.1)</td></tr>
<tr><td>Change in BMI percentiles
Mean (SD)</td><td>Instructor-led intervention: -1.9
(4.2)</td><td>Self-help: 0.2
(1.1)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in weight
Mean (SD)</td><td>Instructor-led intervention: 9.3
(11.4)</td><td>Self-help: 12.1
(7.4)</td></tr>
<tr><td>Change in BMI
Mean (SD)</td><td>Instructor-led intervention: 0.5
(3.4)</td><td>Self-help: 2.4
(2)</td></tr>
<tr><td>Change in zBMI
Mean (SD)</td><td>Instructor-led intervention: -0.2
(0.4)</td><td>Self-help: 0.1
(0.2)</td></tr>
<tr><td>Change in BMI percentiles
Mean (SD)</td><td>Instructor-led intervention: -3.4
(8.6)</td><td>Self-help: 1.2
(2.8)</td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td>Johnston, C. A., Tyler, C., McFarlin, B. K., Poston, W. S. C., Haddock, C. K., Reeves, R. S., & Foreyt, J. P. (2010). Effects of a school-based weight maintenance program for Mexican-</td></tr>
</table>

contribute additional data	American children: results at 2 years. Obesity, 18(3), 542-547. https://doi.org/https://dx.doi.org/10.1038/oby.2009.241

N/A – Not applicable

Jolly, 2011

Guideline record ID: 10362A INTERVENTION ARMS 1-5

Study characteristics		
Citation	Jolly, K., Lewis, A., Beach, J., Denley, J., Adab, P., Deeks, J. J., Daley, A., & Aveyard, P. (2011). Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: Lighten Up randomised controlled trial. BMJ, 343, d6500. https://doi.org/https://dx.doi.org/10.1136/bmj.d6500	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: lighten Up randomised controlled trial	
Location	England	
Trial name	Lighten Up	
Methods		
Inclusion criteria	"Eligible participants were registered with general practices in South Birmingham Primary Care Trust, were aged at least 18 years, and had a raised body mass index recorded in their primary care notes within the previous 15 months. The body mass index threshold for invitation was that which makes them eligible for primary care obesity management services in the NHS and varied according to ethnic group and the presence or absence of comorbidities (box 1). The threshold for invitation for people with no obesity related comorbidity was a body mass index of 30 or above. For people of South Asian ethnicity, this threshold was lower. The general practitioner had to confirm that the patient had no medical contraindications for any of the intervention programmes before a letter of invitation was sent."	
Exclusion criteria	"We excluded patients if they were unable to understand English or were pregnant."	
Setting	GP clinic, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The participants allocated to the commercial operators Weight Watchers, Slimming World, and Rosemary Conley had a choice of locations and times for the programme.13-15 Participants were provided with vouchers that exempted them from paying for 12 consecutive weeks of the programmes. Each programme was provided in accordance with the respective organisation's guidance and ran continuously, with no set start date; the group leaders were trained by the respective organisations. The trial participants attended alongside people who paid to attend the programmes. The Size Down Programme is an NHS group based programme led by food advisers recruited from the local community and trained by the dietetics department; sessions took place in various community venues. All members of the group started together and followed a prescribed course of six sessions, with follow-up weighing sessions at nine and 12 weeks. Participants randomised to the general practice or pharmacy arms attended 12 one to one sessions in the general practice or pharmacy. Appointments were made at a time mutually convenient to the participant and the nurse/pharmacist. Staff delivering these programmes had attended a three day training course on weight management in adults delivered by dietitians experienced in the management of obesity. This included key messages on diet and physical activity, doing a behavioural assessment, goal setting, plans for change, dealing with resistance, enhancing motivation, and weight maintenance. It included both practical tasks and informational components."	
Control/Comparator	"Participants allocated to the comparator group were sent vouchers for 12 free sessions at a local authority run leisure centre (a council run facility open to all members of the public and usually consisting of a swimming pool, fitness suite, and other sports halls or courts).	

<table>
<tr><td></td><td>Participants were not given an appointment to attend and were given no individual advice or support on diet or physical activity. Box 2 gives further details of the interventions, and fuller details are online.”</td></tr>
<tr><td>Treatment duration</td><td>12 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 500
Intervention group/s: Weight Watchers (n=100); Slimming World (n=100); Rosemary Conley (n=100); Size Down (n=100); Group 5: General Practice n=(70); Group 6: Pharmacy n=(70)

Comparator group: Exercise/comparator (n=100)</td></tr>
<tr><td>Mean age ± SD</td><td>weight watchers: 50.71y 14.56; Slimming World: 48.84y (14.91); Rosemary Conley: 49.76y (14.51); Size down 48.75y (15.63); General Practice: 50.48y (13.79); Pharmacy: 48.94y (15.82); Exercise/Comparator: 49.67y (13.83)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Weight Watchers: 93.47 (14.15)
Slimming World: 94.35 (13.38)
Rosemary Conley: 93.72 (13.68)
Size Down: 95.47 (17.88)
General Practice: 92.04 (14.75)</td><td>Exercise/comparator: 93.14 (15.13)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Weight Watchers: 33.96 (3.9)
Slimming World: 33.83 (3.8)
Rosemary Conley: 33.38 (3.5)
Size Down: 33.77 (3.9)
General Practice: 33.06 (3.5)</td><td>Exercise/comparator: 33.88 (4.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)</td><td>Weight Watchers: 3.46 (2.1-4.8)
Slimming World: 1.89</td><td>Exercise/comparator: 1.08 (0.1-2.1)</td></tr>
</table>
</td></tr>
</table>

	Change in BMI (kg/m2) Mean (95% CIs)	(0.9-2.9) Rosemary Conley: 2.12 (0.9-3.4) Size Down: 2.45 (1.3-3.6) General Practice: 0.83 (-0.4-2) Weight Watchers: 1.17 (0.7-1.7) Slimming World: 0.71 (0.4-1) Rosemary Conley: 0.75 (0.3-1.1) Size Down: 0.67 (0.3-1) General Practice: 0.32 (-0.1-0.7)	Exercise/comparator: 0.45 (0.1-0.8)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Jolly, 2011

Guideline record ID: 10362B INTERVENTION ARM 6

Study characteristics		
Citation	Jolly, K., Lewis, A., Beach, J., Denley, J., Adab, P., Deeks, J. J., Daley, A., & Aveyard, P. (2011). Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: Lighten Up randomised controlled trial. BMJ, 343, d6500. https://doi.org/https://dx.doi.org/10.1136/bmj.d6500	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: lighten Up randomised controlled trial	
Location	England	
Trial name	Lighten Up	
Methods		
Inclusion criteria	"Eligible participants were registered with general practices in South Birmingham Primary Care Trust, were aged at least 18 years, and had a raised body mass index recorded in their primary care notes within the previous 15 months. The body mass index threshold for invitation was that which makes them eligible for primary care obesity management services in the NHS and varied according to ethnic group and the presence or absence of comorbidities (box 1). The threshold for invitation for people with no obesity related comorbidity was a body mass index of 30 or above. For people of South Asian ethnicity, this threshold was lower. The general practitioner had to confirm that the patient had no medical contraindications for any of the intervention programmes before a letter of invitation was sent."	
Exclusion criteria	"We excluded patients if they were unable to understand English or were pregnant."	
Setting	GP clinic, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The participants allocated to the commercial operators Weight Watchers, Slimming World, and Rosemary Conley had a choice of locations and times for the programme.13-15 Participants were provided with vouchers that exempted them from paying for 12 consecutive weeks of the programmes. Each programme was provided in accordance with the respective organisation's guidance and ran continuously, with no set start date; the group leaders were trained by the respective organisations. The trial participants attended alongside people who paid to attend the programmes. The Size Down Programme is an NHS group based programme led by food advisers recruited from the local community and trained by the dietetics department; sessions took place in various community venues. All members of the group started together and followed a prescribed course of six sessions, with follow-up weighing sessions at nine and 12 weeks. Participants randomised to the general practice or pharmacy arms attended 12 one to one sessions in the general practice or pharmacy. Appointments were made at a time mutually convenient to the participant and the nurse/pharmacist. Staff delivering these programmes had attended a three day training course on weight management in adults delivered by dietitians experienced in the management of obesity. This included key messages on diet and physical activity, doing a behavioural assessment, goal setting, plans for change, dealing with resistance, enhancing motivation, and weight maintenance. It included both practical tasks and informational components."	
Control/Comparator	"Participants allocated to the comparator group were sent vouchers for 12 free sessions at a local authority run leisure centre (a council run facility open to all members of the public and usually consisting of a swimming pool, fitness suite, and other sports halls or courts).	

<table>
<tr><td></td><td>Participants were not given an appointment to attend and were given no individual advice or support on diet or physical activity. Box 2 gives further details of the interventions, and fuller details are online.”</td></tr>
<tr><td>Treatment duration</td><td>12 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 500
Intervention group/s: Weight Watchers (n=100); Slimming World (n=100); Rosemary Conley (n=100); Size Down (n=100); Group 5: General Practice n=(70); Group 6: Pharmacy n=(70)

Comparator group: Exercise/comparator (n=100)</td></tr>
<tr><td>Mean age ± SD</td><td>weight watchers: 50.71y 14.56; Slimming World: 48.84y (14.91); Rosemary Conley: 49.76y (14.51); Size down 48.75y (15.63); General Practice: 50.48y (13.79); Pharmacy: 48.94y (15.82); Exercise/Comparator: 49.67y (13.83)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Pharmacy: 92.81
(13.71)

Pharmacy: 33.41
(3.4)</td><td>Exercise/comparator: 93.14
(15.13)

Exercise/comparator: 33.88
(4.4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)

BMI reduction (kg/m2)
Mean (95% CIs)</td><td>Pharmacy: -0.66
(-0.4-1.7)

Pharmacy: 0.31
(0-0.7)</td><td>Exercise/comparator: 1.08
(0.1-2.1)

Exercise/comparator: 0.45
(0.1-0.8)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Jospe, 2017

Guideline record ID: 10365--1

Study characteristics		
Citation	Jospe, M. R., Roy, M., Brown, R. C., Williams, S. M., Osborne, H. R., Meredith-Jones, K. A., McArthur, J. R., Fleming, E. A., & Taylor, R. W. (2017). The effect of different types of monitoring strategies on weight loss: a randomized controlled trial. Obesity, 25(9), 1490-1498. https://doi.org/https://dx.doi.org/10.1002/oby.21898	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Effect of Different Types of Monitoring Strategies on Weight Loss: A Randomized Controlled Trial	
Location	New Zealand	
Trial name	Support strategies for Whole-food diets, Intermittent Fasting, and Training (SWIFT)	
Methods		
Inclusion criteria	"Over 18 years of age, BMI 27 kg/m2, regular Internet access, living locally."	
Exclusion criteria	"Exclusion criteria were diabetes or fasting blood glucose 7 mmol/L (difficult to follow hunger training); medicated, moderate, or severe hypertension; pregnant or breastfeeding, or planning to conceive within the trial period; previously had a diagnosis or symptoms of cardiovascular disease or other serious medical conditions; taking medications that affect weight or body composition; or another household member already enrolled in the study."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs), University/research centre	
Intervention	"All participants (including those in the control group) were able to choose one of three possible dietary plans and one of two exercise programs they wished to follow (Supporting Information Figure S1). All five groups received the relevant diet and exercise advice in one face-to-face session (30-45 minutes) at baseline. These were delivered by trained researchers (nutritionist, dietitian, medical doctor) who advised participants on how to follow their chosen diet (three options available) and exercise (two options) plans. Extensive resources were provided for each diet and exercise plan, plus a comprehensive resource outlining several behavioral weight loss strategies (17). The three possible diets were chosen due to popularity (18), weight management effectiveness (19-21), and diversity in composition. The Mediterranean diet includes high amounts of fruits and vegetables, olive oil, legumes, nuts, seeds, and whole grains; moderate amounts of fish, dairy, and wine; and low amounts of red meat, refined grains, and foods with added sugar (20). The Paleo diet eschews grains, legumes, and dairy products, but does not limit meat intake (21). Intermittent fasting does not prescribe specific foods but rather limits energy intake on 2 days per week to 2 (females) or 2.5 (males) MJ, with ad libitum intake on the remaining 5 days (19). Those following the Mediterranean and Paleo diets were not provided with a kilojoule restriction unless they were randomized to the MyFitnessPal group. Instead, these participants were encouraged to use portion control and were provided with appropriate food-based recommendations. Similarly, participants selected whether they wanted to follow current exercise recommendations (30 minutes of moderate-intensity exercise at least 5 days a week (22)) or high-intensity interval training (vigorous exercise performed for brief intervals interposed with recovery periods (23), 5 to 15 minutes in total, 3 times per week). Participants were randomized to one of four monitoring groups or to the control group. . Participants in the brief support group (face-to-face monitoring) attended monthly individual meetings where they were weighed and could discuss ongoing successes and challenges. Sessions each lasted 10 to 15 minutes and were modeled on a successful earlier study (3). Participants in the daily self-weighing group (weight monitoring) were asked to weigh themselves at the same time every day (usually first thing in the morning). Participants texted their weight to the researchers each day or	

	entered it online in our secure database, which displayed a graph of their weight history. Monthly emails provided personalized feedback and encouragement. Participants in the MyFitnessPal group (diet monitoring) were asked to track their diet using the MyFitnessPal app or website. An account was made for each participant according to their characteristics (age, weight, activity level) and nutrient goals from their chosen diet. Participants were asked to track their dietary intake every day for the first month and for 1 week every month during months 2 to 12. Participants randomized to hunger training (hunger monitoring) were required to test their capillary blood glucose (finger prick) by portable glucometer (Freestyle Optium Glucose Meter, Abbott Diabetes Care, Inc., Alameda, California) every time they wanted to eat for the first 2 weeks. If their blood glucose was less than or equal to their individualized cutoff (average of fasting blood glucose from days 1 to 2), they could eat; otherwise, they were advised to retest in 1 hour if still hungry. Blood glucose monitoring was optional for the remainder of the trial. Participants were asked to complete a booklet all year in which perceived intensity of hunger was reported before and after every eating occasion on a 100-mm visual analogue scale (anchors: "not at all hungry," "extremely hungry"). Participants also recorded whether their hunger was stomach (physical need for food), mouth (eating for taste or pleasure), or heart (eating for nonphysical reasons) hunger (used with permission from Craving Change, www.cravingchange.ca) and recorded brief details of food consumed. After the first month of daily hunger training, participants were asked to complete their booklets for 1 week every month. Those in hunger training visited the clinic for two follow-up sessions in the first month to ensure understanding of and compliance to the monitoring strategy."
Control/Comparator	"All participants (including those in the control group) were able to choose one of three possible dietary plans and one of two exercise programs they wished to follow (Supporting Information Figure S1). All five groups received the relevant diet and exercise advice in one face-to-face session (30-45 minutes) at baseline. These were delivered by trained researchers (nutritionist, dietitian, medical doctor) who advised participants on how to follow their chosen diet (three options available) and exercise (two options) plans. Extensive resources were provided for each diet and exercise plan, plus a comprehensive resource outlining several behavioral weight loss strategies (17). The three possible diets were chosen due to popularity (18), weight management effectiveness (19-21), and diversity in composition. The Mediterranean diet includes high amounts of fruits and vegetables, olive oil, legumes, nuts, seeds, and whole grains; moderate amounts of fish, dairy, and wine; and low amounts of red meat, refined grains, and foods with added sugar (20). The Paleo diet eschews grains, legumes, and dairy products, but does not limit meat intake (21). Intermittent fasting does not prescribe specific foods but rather limits energy intake on 2 days per week to 2 (females) or 2.5 (males) MJ, with ad libitum intake on the remaining 5 days (19). Those following the Mediterranean and Paleo diets were not provided with a kilojoule restriction unless they were randomized to the MyFitnessPal group. Instead, these participants were encouraged to use portion control and were provided with appropriate food-based recommendations. Similarly, participants selected whether they wanted to follow current exercise recommendations (30 minutes of moderate-intensity exercise at least 5 days a week (22)) or high-intensity interval training (vigorous exercise performed for brief intervals interposed with recovery periods (23), 5 to 15 minutes in total, 3 times per week). Participants were randomized to one of four monitoring groups or to the control group. While all participants received the relevant diet and exercise advice at baseline, those randomized to the control group were not provided with any monitoring strategies."
Treatment duration	12 months
Follow-up from baseline	12 months
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	

<table>
<tr><td>Number of participants</td><td>n= 250
Intervention group/s: Daily weighing (n=51); MyFitnessPal (n=50); Brief support (n=51); Hunger training (n=50)

Comparator group: Control (n=48)</td></tr>
<tr><td>Mean age ± SD</td><td>Daily weighing: 46.1 (11.4); MyFitnessPal: 44.4 (10.2); Brief support: 40.6 (9.9); Hunger training: 40.7 (10.8); Control: 46.7 (11.4)</td></tr>
<tr><td>Sex</td><td>62.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg) (whole sample)
Mean (SD)</td><td>Daily weighing: 96.8
(16.6)
MyFitnessPal: 99.1
(17.3)
Brief support: 96.4
(14.4)
Hunger training: 95.9
(17)</td><td>Control: 91
(14.9)</td></tr>
<tr><td>BMI (kg/m2) (whole sample)
Mean (SD)</td><td>Daily weighing: 33.2
(4.8)
MyFitnessPal: 33.5
(4.5)
Brief support: 33
(4.1)
Hunger training: 33
(4.3)</td><td>Control: 32.3
(4.3)</td></tr>
<tr><td>Waist (cm) (whole sample)
Mean (SD)</td><td>Daily weighing: 102.7
(12.8)
MyFitnessPal: 103.2
(14.4)
Brief support: 101.3
(10.9)
Hunger training: 100.4
(13)</td><td>Control: 99.8
(11)</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Daily weighing: 97.5
(16.9)
MyFitnessPal: 99.9
(16.4)
Brief support: 95.6
(12.8)
Hunger training: 96
(17.5)</td><td>Control: 90.2
(14.4)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Daily weighing: 33.4
(4.9)
MyFitnessPal: 33.1
(4.4)
Brief support: 32.6
(3.6)
Hunger training: 32.6
(4.1)</td><td>Control: 32
(4.1)</td></tr>
<tr><td>Waist (cm)
Mean (SD)</td><td>Daily weighing: 103.5
(12.4)
MyFitnessPal: 103.2</td><td>Control: 99.7
(10.9)</td></tr>
</table>
</td></tr>
</table>

		(14.5) Brief support: 100.1 (9.7) Hunger training: 100.5 (14.2)	
	Fat Mass Index (kg) Mean (SD)	Daily weighing: 39.8 (9.9) MyFitnessPal: 39.7 (10.7) Brief support: 36.7 (8.4) Hunger training: 37.2 (8.6)	Control: 35.5 (9.9)
	Fat (%) Mean (SD)	Daily weighing: 40.4 (7) MyFitnessPal: 39.2 (7.4) Brief support: 38.4 (8.4) Hunger training: 39.2 (6.6)	Control: 38.8 (7.8)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight (kg) Mean (SD)	Daily weighing: 94.8 (18.7) MyFitnessPal: 97.9 (18.4) Brief support: 94.2 (12.1) Hunger training: 89.2 (15.7)	Control: 87.3 (15.2)
	BMI (kg/m2) Mean (SD)	Daily weighing: 32.1 (5.5) MyFitnessPal: 32.2 (4.8) Brief support: 31.9 (4.4) Hunger training: 30.8 (4.4)	Control: 30.9 (4.6)
	Waist (cm) Mean (SD)	Daily weighing: 100.3 (13.7) MyFitnessPal: 100.5 (14) Brief support: 98 (8.9) Hunger training: 95.6 (12.7)	Control: 96.8 (8.9)
	Fat mass index (kg) Mean (SD)	Daily weighing: 36.3 (11.1) MyFitnessPal: 37.1 (12.3) Brief support: 34.9 (10.5) Hunger training: 32.7 (9.5)	Control: 33 (10.3)
	Fat (%) Mean (SD)	Daily weighing: 38.7 (7.9) MyFitnessPal: 37.7 (8.5) Brief support: 37.1	Control: 37.4 (8.3)

		(10.1) Hunger training: 36.6 (8)	
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	As adherence to the strategies was skewed, medians and interquartile ranges (IQR) were reported. Participants weighed themselves on 186 of 365 scheduled days (IQR 228.5 days; 52.2% of the recommended days), attended 7 of 11 brief support meetings (IQR 7.5 days; 63.6% of the recommended days), entered food in MyFitness- Pal on 57 of 98 days (IQR 87.8 days; 58.2% of the recommended days), and filled in an entry in the hunger training booklets on 29 of 98 days (IQR 66.3 days; 29.6% of the recommended days). Adherence to all monitoring strategies decreased over time (Figure 2).		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Jung, 2020

Guideline record ID: 10366--1

Study characteristics		
Citation	Jung, M. E., Locke, S. R., Bourne, J. E., Beauchamp, M. R., Lee, T., Singer, J., MacPherson, M., Barry, J., Jones, C., & Little, J. P. (2020). Cardiorespiratory fitness and accelerometer-determined physical activity following one year of free-living high-intensity interval training and moderate-intensity continuous training: a randomized trial. International Journal of Behavioral Nutrition and Physical Activity, 17(1), 25. https://doi.org/10.1186/s12966-020-00933-8	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Cardiorespiratory fitness and accelerometer-determined physical activity following one year of free-living high-intensity interval training and moderate-intensity continuous training: a randomized trial	
Location	Canada	
Trial name	Small Steps for Big Changes	
Methods		
Inclusion criteria	"Eligible participants were between the ages of 30 and 65, were low-active (i.e., engaged in 2 or less bouts of moderate and/or vigorous aerobic exercise per week in the previous 6-months), had a body mass index (BMI) between 25 and 40 kg/m2, and were cleared to engage in vigorous exercise using the Physical Activity Readiness Questionnaire-Plus (PAR-Q+)."	
Exclusion criteria	"None reported."	
Setting	Home, University/research centre	
Intervention	"Participants in both conditions completed 10 exercise sessions over a two-week period, seven of which were one-on-one supervised sessions conducted in the laboratory (exercise training plus counselling), while three were conducted at home to foster independence. The exercise prescriptions for each condition were progressive and matched for estimated external work. HIIT involved sessions progressing from 4 to 10 × 1-min highintensity intervals at ~ 80-90% VO2peak interspersed with 1-min rest periods at ~ 40% VO2peak and with 5min of warm up and cool down. . All participants were exposed to a variety of exercise formats (e.g., stationary cycling, treadmill, elliptical, walking outside) and were able to self-select the exercise modality for four of the supervised sessions with the remaining three performed as stationary cycling to ensure accurate intensity based on the baseline VO2peak test. Participants wore a heart-rate monitor that provided them with feedback to understand the physiological exercise sensations (i.e., breathing, heart rate) associated with their prescribed exercise intensity zone. Following the two-week training program, participants were recommended to exercise three times a week performing either 10 × 1min high intensity intervals or 50 min of continuous moderate intensity exercise. Participants could vary the number of intervals or duration to achieve of the prescribed total volume (i.e., 30 high intensity intervals or 150 moderate minutes). Exercise counselling Participants in both conditions received the same brief exercise counselling intervention delivered throughout the two-week supervised training program. Counselling was delivered in a one-on-one format at each of the seven supervised sessions (~ 10 min per session, 70 min total) and via take-home worksheets for the three homebased sessions. A detailed description of the behaviour change techniques used to promote exercise selfmanagement are reported elsewhere [19]. Briefly, task self-efficacy to perform HIIT or MICT was primarily bolstered through: providing instruction on how to perform the behaviour, behavioural practice, and helping participants identify physiological cues associated with the assigned exercise intensity. Self-regulatory efficacy was bolstered through: providing participants with opportunities to practice, with feedback, on	

	selfmonitoring, planning, and solving exercise barriers for independent exercise. Finally, salience of the positive psychological and physiological outcomes associated with exercise engagement (i.e., outcome expectations) was fostered through education and by bringing awareness to participants' own subjective experiences of exercise and the experiences of similar individuals. Participants were provided with a self-monitoring mobile application [20] to track their exercise during the 12-month trial and were sent monthly booster messages through this app to reinforce the psychological mechanisms addressed in counselling sessions. Exercise trainers monitored their participants through the app and contacted them when they failed to login for three consecutive days [21]."
Control/Comparator	"Participants in both conditions completed 10 exercise sessions over a two-week period, seven of which were one-on-one supervised sessions conducted in the laboratory (exercise training plus counselling), while three were conducted at home to foster independence. The exercise prescriptions for each condition were progressive and matched for estimated external work. . MICT involved sessions progressing from 20 to 50min of continuous moderate-intensity exercise at ~ 45-55% VO2peak. All participants were exposed to a variety of exercise formats (e.g., stationary cycling, treadmill, elliptical, walking outside) and were able to self-select the exercise modality for four of the supervised sessions with the remaining three performed as stationary cycling to ensure accurate intensity based on the baseline VO2peak test. Participants wore a heart-rate monitor that provided them with feedback to understand the physiological exercise sensations (i.e., breathing, heart rate) associated with their prescribed exercise intensity zone. Following the two-week training program, participants were recommended to exercise three times a week performing either 10 × 1min high intensity intervals or 50 min of continuous moderate intensity exercise. Participants could vary the number of intervals or duration to achieve of the prescribed total volume (i.e., 30 high intensity intervals or 150 moderate minutes). Exercise counselling Participants in both conditions received the same brief exercise counselling intervention delivered throughout the two-week supervised training program. Counselling was delivered in a one-on-one format at each of the seven supervised sessions (~ 10 min per session, 70 min total) and via take-home worksheets for the three homebased sessions. A detailed description of the behaviour change techniques used to promote exercise selfmanagement are reported elsewhere [19]. Briefly, task self-efficacy to perform HIIT or MICT was primarily bolstered through: providing instruction on how to perform the behaviour, behavioural practice, and helping participants identify physiological cues associated with the assigned exercise intensity. Self-regulatory efficacy was bolstered through: providing participants with opportunities to practice, with feedback, on selfmonitoring, planning, and solving exercise barriers for independent exercise. Finally, salience of the positive psychological and physiological outcomes associated with exercise engagement (i.e., outcome expectations) was fostered through education and by bringing awareness to participants' own subjective experiences of exercise and the experiences of similar individuals. Participants were provided with a self-monitoring mobile application [20] to track their exercise during the 12-month trial and were sent monthly booster messages through this app to reinforce the psychological mechanisms addressed in counselling sessions. Exercise trainers monitored their participants through the app and contacted them when they failed to login for three consecutive days [21]."
Treatment duration	12 months
Follow-up from baseline	12 months
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 99 Intervention group/s: High-intensity interval training (HIIT) (n=47) Comparator group: Moderate-intensity continuous training (MICT) (n=52)

<table>
<tr><td>Mean age ± SD</td><td>50.9y (9.4)</td></tr>
<tr><td>Sex</td><td>69.70% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body Mass (kg)
Mean (SD)</td><td>High-intensity interval training (HIIT): 89.4
(21.7)</td><td>Moderate-intensity continuous training (MICT): 89.3
(19.3)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>High-intensity interval training (HIIT): 108.4
(15.7)</td><td>Moderate-intensity continuous training (MICT): 107.6
(14.7)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)</td><td>High-intensity interval training (HIIT): 0
(-1.32-1.31)</td><td>Moderate-intensity continuous training (MICT): -1.48
(-3.92-0.97)</td></tr>
<tr><td>Change in waist circumference (cm)
Mean (95% CIs)</td><td>High-intensity interval training (HIIT): -2.62
(-4.24--1.01)</td><td>Moderate-intensity continuous training (MICT): -4.95
(-7.41--2.49)</td></tr>
<tr><td>Change in body fat (%)
Mean (95% CIs)</td><td>High-intensity interval training (HIIT): -1.68
(-2.47--0.9)</td><td>Moderate-intensity continuous training (MICT): -1.9
(-2.88--0.92)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Those randomized to the MICT condition logged MICT an average of 3.8x/week (SD=1.2) in the first 6months following the intervention and 3.3x/week (SD = 1.3) in the second 6months. Those randomized to the HIIT condition logged HIIT an average of 1.9x/week (SD= 0.9) in the first 6months and 1.0x/week (SD = 0.9) in the second 6months. Interestingly, those in HIIT also reported engaging in MICT an average of 1.2x/week (SD = 1.0; 3.1x/week total exercise) in the first 6 months and 1.4x/week (SD= 1.2; 2.4x/week of total exercise) in the second 6 months.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Juul, 2016

Guideline record ID: 10369--1

Study characteristics		
Citation	Juul, L., Andersen, V. J., Arnoldsen, J., & Maindal, H. T. (2016). Effectiveness of a brief theory-based health promotion intervention among adults at high risk of type 2 diabetes: One-year results from a randomised trial in a community setting. Primary Care Diabetes, 10(2), 111-120. https://doi.org/10.1016/j.pcd.2015.07.002	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effectiveness of a brief theory-based health promotion intervention among adults at high risk of type 2 diabetes: One-year results from a randomised trial in a community setting	
Location	Denmark	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligibility criteria were: resident in the Municipality of Holstebro, aged <70 years, and a measurement of fasting plasma glucose: 6.1-6.9mmol/l (the thresholds for Impaired Fasting Glucose according to clin ical guidelines) and/or HbA1c: 6.0-<6.5% (42- <48mmol/mol) within the previous six months."	
Exclusion criteria	Not reported	
Setting	GP clinic	
Intervention	"Diet and general diabetes health promotion information delivered over four 2 h group sessions during five weeks, and two further sessions after one and six months"	
Control/Comparator	"usual care."	
Treatment duration	3 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 127 Intervention group/s: Intervention (n=63) Comparator group: Control (n=64)	
Mean age ± SD	Not reported	
Sex	68.50% female	
Pre-existing medical condition	Type 2 diabetes	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	Weight (kg) Median (IQR) Baseline BMI (kg/m2) Median (IQR)	Intervention: 89 (77-98) Intervention: 31 (27-35)	Control: 85 (74-95) Control: 30 (27-33)

	Waist circumference (cm) Mean (SD)	Intervention: 106 (14)	Control: 104 (11)

Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight (kg) Median (IQR) Waist circumference (cm) Mean (SD) Proportion of participants achieving >5% weight reduction Proportion (%)	Intervention: 85 (73-97) Intervention: 102.7 (14.5) Intervention: 33	Control: 81 (75-94) Control: 103.1 (11.5) Control: 16

Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in Weight Mean (95% CIs) Change in Waist circumference Mean (95% CIs)	Intervention: -2.4 (-3.4--1.3) Intervention: -2.8 (-4.4--1.1)	Control: -1.1 (-2.3-0.2) Control: -0.5 (-1.7-0.6)

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Kabisch, 2019

Guideline record ID: 10370--1

Study characteristics		
Citation	Kabisch, S., Meyer, N. M. T., Honsek, C., Gerbracht, C., Dambeck, U., Kemper, M., Osterhoff, M. A., Birkenfeld, A. L., Arafat, A. M., Weickert, M. O., & Pfeiffer, A. F. H. (2019). Obesity does not modulate the glycometabolic benefit of insoluble cereal fibre in subjects with prediabetes-a stratified post hoc analysis of the Optimal Fibre Trial (OptiFiT). Nutrients, 11(11), 2726. https://doi.org/https://dx.doi.org/10.3390/nu11112726	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Obesity Does Not Modulate the Glycometabolic Benefit of Insoluble Cereal Fibre in Subjects with Prediabetes-A Stratified Post Hoc Analysis of the Optimal Fibre Trial (OptiFiT)	
Location	Germany	
Trial name	Optimal Fibre Trial (OptiFiT)	
Methods		
Inclusion criteria	"Caucasian participants with impaired glucose tolerance."	
Exclusion criteria	Not reported	
Setting	Home	
Intervention	"All 180 participants underwent the 1 year structured "Treatment and Education Program for Prevention of Type 2 Diabetes" (PREDIAS) [26,27]. Based on the PREDIAS framework, we defined specific dietary goals that were in accordance with the recommendations of the German Nutrition Society (Deutsche Gesellschaft für Ernährung; DGE): fat intake below 30 kcal%, intake of saturated fat below 10 kcal% and intake of dietary fibre above 15 g/1000 kcal. We recommended frequent ingestion of whole-grain products, legumes, vegetables, fruits (in particular, berries), low-fat milk and meat products, soft margarines and vegetable oils rich in unsaturated fatty acids [15]. We encouraged physical activity (PA; 240 min/week) and used pedometers and the European Physical Activity Questionnaire (EPAQ-2) in order to monitor physical activity [15,28]. The participants were provided with drinking powder supplements. The fibre supplement contained a purified fibre extract derived from oat hulls (70 w (weight) % cellulose, 25 w% hemicellulose and 3-5 w% lignin (Vitacel OF 560-30; Rettenmaier & Söhne, Holzmuehle, Germany)). Our subjects were asked to consume the supplements twice a day after dissolving the recommended amount of drinking powder (two large 10 mL scoops provided with the supplement tins) in 300 mL of water. By doing so, subjects in the fibre group achieved an additional daily intake of 15 g of mainly insoluble fibre on top of their regular diet. Both supplements were similar in appearance, taste, odour and texture."	
Control/Comparator	"All 180 participants underwent the 1 year structured "Treatment and Education Program for Prevention of Type 2 Diabetes" (PREDIAS) [26,27]. Based on the PREDIAS framework, we defined specific dietary goals that were in accordance with the recommendations of the German Nutrition Society (Deutsche Gesellschaft für Ernährung; DGE): fat intake below 30 kcal%, intake of saturated fat below 10 kcal% and intake of dietary fibre above 15 g/1000 kcal. We recommended frequent ingestion of whole-grain products, legumes, vegetables, fruits (in particular, berries), low-fat milk and meat products, soft margarines and vegetable oils rich in unsaturated fatty acids [15]. We encouraged physical activity (PA; 240 min/week) and used pedometers and the European Physical Activity Questionnaire (EPAQ-2) in order to monitor physical activity [15,28]. The participants were provided with drinking powder supplements. Placebo consisted of waxy maize starch with a negligible content of insoluble fibre and guar gum and isomaltulose. Our subjects were asked to consume the supplements twice a day after dissolving the recommended amount of drinking powder (two large 10 mL scoops provided with the supplement tins) in 300 mL of water. By doing	

<table>
<tr><td></td><td>so, subjects in the fibre group achieved an additional daily intake of 15 g of mainly insoluble fibre on top of their regular diet. Both supplements were similar in appearance, taste, odour and texture.”</td></tr>
<tr><td>Treatment duration</td><td>2 years</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 136
Intervention group/s: NONOBESE Fibre (n=26); NONOBESE Placebo (n=23); OBESE Fibre (n=41)

Comparator group: Obese placebo (n=46)</td></tr>
<tr><td>Mean age ± SD</td><td>NONOBESE Fibre: 62.0y (9.7); NONOBESE Placebo: 62.4y (9.1); OBESE Fibre: 58.8y (8.9); OBESE Placebo: 58.7y (9.1)</td></tr>
<tr><td>Sex</td><td>61.76% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>NONOBESE Fibre: 26.9
(3.2)
NONOBESE Placebo: 27.3
(2.5)
OBESE Fibre: 34.8
(3.5)</td><td>Obese placebo: 36.5
(5.8)</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>NONOBESE Fibre: 77.5
(12)
NONOBESE Placebo: 75.9
(12.1)
OBESE Fibre: 94
(14)</td><td>Obese placebo: 103
(18.2)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>NONOBESE Fibre: 93.8
(9)
NONOBESE Placebo: 94
(9.2)
OBESE Fibre: 107.7
(11.7)</td><td>Obese placebo: 113.2
(13.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)</td><td>NONOBESE Fibre: -2.4
(3.2)
NONOBESE Placebo: -2
(3.2)
OBESE Fibre: -2.8</td><td>Obese placebo: -3.6
(6.6)</td></tr>
</table></td></tr>
</table>

	Change in waist circumference (cm) Mean (SD)	(5.3) NONOBESE Fibre: -2.6 (3.7) NONOBESE Placebo: -2.9 (5.6) OBESE Fibre: -3.1 (5.9)	Obese placebo: -3.5 (7.2)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Kahhan, 2021

Guideline record ID: 10371--1

Study characteristics		
Citation	Kahhan, N., Hossain, M. J., Lang, J., Harrison, C., Canas, J., Wysocki, T., Lochrie, A., & Balagopal, P. B. (2021). Durability of changes in biomarkers of cardiometabolic disease: 1-year family-based intervention in children with obesity. Metabolic Syndrome and Related Disorders, 19(5), 264-271. https://doi.org/https://dx.doi.org/10.1089/met.2020.0097	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Durability of Changes in Biomarkers of Cardiometabolic Disease: 1-Year Family-Based Intervention in Children with Obesity	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Children with overweight and obesity (age 8-11 years) and Tanner Stage £3."	
Exclusion criteria	"Exclusion criteria included current diagnosis of T2DM, impaired glucose tolerance, hypertension, and any other major chronic disease or cognitive impairment."	
Setting	GP clinic, Home	
Intervention	"Structured 60- to 90-min outpatient clinic meetings between the participants, a reg istered dietitian, and a psychologist to discuss and imple ment diet, physical activity, and behavior modifications for 6 months, followed by an additional 6 months follow-up without active intervention/monitoring. A total of 14 such group sessions were provided in a tapered regimen over a 6- month period"	
Control/Comparator	"one routine clinical consultation and education only, and they were not monitored closely by the research team during the entire 12-month study period."	
Treatment duration	6 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 87 Intervention group/s: Intervention (n=44) Comparator group: Education (n=43)	
Mean age ± SD	Control: 10y (1.0); Intervention: 9.9y (1.1)	
Sex	66.67% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	BMI percentile - baseline Mean (SD)	Intervention: 97.6 (2.8)	Education: 97.3 (2.2)

	BMI-z - Baseline Mean (SD) Waist circumference (cm) - Baseline only Mean (SD) BMI percentile modelled Mean (SE)	Intervention: 2.2 (0.4) Intervention: 85.1 (10.8) Intervention: 97.41 (0.32)	Education: 2.1 (0.4) Education: 84.1 (8.7) Education: 97.52 (0.33)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	BMI percentile modelled Mean (SE)	Intervention: 96.53 (0.4)	Education: 97.37 (0.34)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Kaikkonen, 2019

Guideline record ID: 10372--1

Study characteristics		
Citation	Kaikkonen, K. M., Saltevo, S. S., Korpelainen, J. T., Vanhala, M. L., Jokelainen, J. J., Korpelainen, R. I., & Keinänen-Kiukaanniemi, S. M. (2019). Effective weight loss and maintenance by intensive start with diet and exercise. Medicine & Science in Sports & Exercise, 51(5), 920-929. https://doi.org/10.1249/MSS.0000000000001855	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effective Weight Loss and Maintenance by Intensive Start with Diet and Exercise	
Location	Finland	
Trial name	N/A	
Methods		
Inclusion criteria	Not reported.	
Exclusion criteria	"Exclusion criteria included the following: body mass index (BMI) < 30, pregnancy, medication or health reasons that prevent from performing the exercise test or participating in the exercise intervention, previously diagnosed diabetes, and age under 18 or over 64 yr."	
Setting	Hospital, Home	
Intervention	"iBM: Behavioral modification using cognitive theory. 12-month intensified period followed by a 12-month follow-up period. Year1: 3 individual weight maintenance counseling times (nutritionist) + 11 times (personal therapist/qualified nurse). Year 2: personal therapist meetings 4 times/3 months. The counseling included themes of physical activity, healthy diet, and risk situations in weight management. All participants were instructed to reduce energy intake 500-1000 kcal/d based on measured RMR, 7-d food diary, physical activity diary, and interviews. The participants were instructed to gradually increase moderate aerobic physical activity for at least 150 minIwkj1 and muscle strengthening and balance training for 2 times a week. Short bouts, 10-15 min, of exercise sessions 2-3 times per day were encouraged. The participants advised to decrease their sedentary time. The goal was to achieve sustained 10% decrease in weight. Exercise intervention: The heart rate-controlled low-resistance CWT was performed with air-resistant fitness equipment. The CWT sessions were offered 3 times a week, 40 min at a time. The target heart rate of exercise was set to 70%-80% of the measured HRmax."	
Control/Comparator	"The subjects in the control group (CON) met the personal therapist face-to-face once at the beginning of the trial and again at the follow-up visit after 24 months. They received basic weight loss counseling, and they were also given a guidebook based on the current care guidelines of obesity treatment. Otherwise, the control subjects were told to continue their normal living."	
Treatment duration	24 months (WL: 12 months; WM: 12 months)	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 120 Intervention group/s: iBM (n=30); CWT1 (n=30); CWT2 (n=30) Comparator group: Control (CON) (n=30)	

Mean age ± SD	45.7y (10.4)
Sex	78.33% female
Pre-existing medical condition	No pre-existing medical condition
Results	

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Weight (kg) Mean (SD)	iBM: 96.9 (14.2) CWT1: 97.9 (11.9) CWT2: 97.6 (12.7)	Control (CON): 99.3 (15.8)
BMI, kg/m2 Mean (SD)	iBM: 35.7 (4.2) CWT1: 36.1 (4.6) CWT2: 36.5 (4.5)	Control (CON): 36.9 (4.5)
Waist Circumference, cm Mean (SD)	iBM: 108.6 (10) CWT1: 110.4 (9.3) CWT2: 106.8 (10)	Control (CON): 110.5 (10.8)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point

Variable	Intervention arm/s	Comparator
Change in weight (kg) Mean (95% CIs)	iBM: -8.7 (-11.7--5.7) CWT1: -10 (-13.5--6.5) CWT2: -6.9 (-9.9--4)	Control (CON): 0 (-1.8-1.9)
Change in waist circumference (cm) Mean (95% CIs)	iBM: -8.9 (-11.6--6.2) CWT1: -11.5 (-15.1--7.9) CWT2: -7.6 (-10.4--4.8)	Control (CON): -1.7 (-4-0.6)

Change in outcome measure from baseline to final follow-up/endpoint

Variable	Intervention arm/s	Comparator
Change in weight (kg) Mean (95% CIs)	iBM: -5.5 (-8.4--2.5) CWT1: -8.5 (-12.1--4.9) CWT2: -4.4 (-7.4--1.4)	Control (CON): 0.9 (-1.6-3.3)
Change in waist circumference (cm)	iBM: -5.3 (-3.5--2)	Control (CON): -0.4 (-2.6-1.9)

	Mean (95% CIs)	CWT1: -8.8 (-12.4--5.1) CWT2: -4.4 (-6.9--1.9)	
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Kaikkonen, 2023

Guideline record ID: 10948--1

Study characteristics		
Citation	Kaikkonen, K. M., Korpelainen, R., Vanhala, M. L., Keinänen-Kiukaanniemi, S. M., & Korpelainen, J. T. (2023). Long-term effects on weight loss and maintenance by intensive start with diet and exercise. Scandinavian Journal of Medicine & Science In Sports, 33(3), 246-256. https://doi.org/https://doi.org/10.1111/sms.14269	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-term effects on weight loss and maintenance by intensive start with diet and exercise	
Location	Finland	
Trial name	LILA	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	"The exclusion criteria included the follow ing: body mass index (BMI) <30, pregnancy, medication, or health issues that prevent from performing the exer cise test or participating in the exercise intervention, previously diagnosed diabetes, and age under 18 or over 64 years."	
Setting	Hospital	
Intervention	"Group 1: intensified behavioural modification (iBM), Group 2: iBM+ additional exercise from 0 to 3 months (CWT1), or Group 3: iBM+ additional exercise from 6 to 9 months (CWT2). iBM: year 1: 14 meetings of individual weight-maintenance counselling, year 2: four meetings, year 3: two meetings. Meetings focused on a healthy diet, physical activity, and risk situations in weight management. The participants were also given a guidebook based on current care guidelines of obesity treatment. All participants were instructed to reduce their daily energy intake 500-1000 kcal/d lower than their energy expenditure. The individual energy intake guidance was based on the measured RMR, 7-day food diary, physical activity diary, and interviews. The participants were also requested to gradually increase their moderate aerobic physical activity for at least 150min a week and to decrease their sedentary time. The participants were also advised to maintain these dietary and physical activity recommendations throughout the study period. The additional exercise intervention offered for the two other intervention groups consisted of 12 weeks of heartrate-controlled low-resistance circuit weight training (CWT) with air resistance fitness equipment. The CWT sessions were offered 3 times a week, 40min at a time."	
Control/Comparator	"The subjects in the CON group met the trained nurse at the beginning of the trial and at the 24-month and 36-month follow-up visits. They received basic weight loss counselling, and they were also given a guidebook based on the current care guidelines of obesity treatment. Otherwise, they were told to continue their normal living."	
Treatment duration	12 months	
Follow-up from baseline	36 months	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 120 Intervention group/s: iBM (n=30); CWT1 (n=30); CWT2 (n=30) Comparator group: CON (n=30)	

<table>
<tr><td>Mean age ± SD</td><td>44.5y (10.5)</td></tr>
<tr><td>Sex</td><td>78.33% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight, kg at Baseline
(Completers n=80)
Mean (SD)</td><td>iBM: 97.1
(14.6)
CWT1: 96.1
(10.7)
CWT2: 97.6
(13)</td><td>CON: 98.8
(14.8)</td></tr>
<tr><td>Baseline BMI (kg/m2)
(Completers n=80)
Mean (SD)</td><td>iBM: 35.6
(4.3)
CWT1: 35.7
(4.5)
CWT2: 36.4
(4.5)</td><td>CON: 36.4
(3.7)</td></tr>
<tr><td>Baseline Waist Circumference, cm (Completers n=80)
Mean (SD)</td><td>iBM: 109
(10)
CWT1: 109.1
(8.7)
CWT2: 106.5
(10.1)</td><td>CON: 110
(9.6)</td></tr>
<tr><td>Weight (kg)
Mean (95% CIs)</td><td>iBM: 98.9
(93.8-104)
CWT1: 99.1
(94-104.2)
CWT2: 102.4
(97.3-107.5)</td><td>CON: 98.9
(93.8-104)</td></tr>
<tr><td>Waist circumference (cm)
Mean (95% CIs)</td><td>iBM: 108.4
(104.3-112.5)
CWT1: 110.5
(106.4-114.6)
CWT2: 109.7
(105.6-113.8)</td><td>CON: 110.4
(106.3-114.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (95% CIs)</td><td>iBM: 92.2
(86.7-97.7)
CWT1: 93.3
(87.9-98.8)
CWT2: 99.6
(94.2-105.1)</td><td>CON: 98.9
(93.4-104.4)</td></tr>
<tr><td>Waist circumference (cm)
Mean (95% CIs)</td><td>iBM: 103.5
(99.2-107.8)
CWT1: 101.8
(97.6-106.1)
CWT2: 107.7
(103.5-112)</td><td>CON: 109.9
(105.6-114.3)</td></tr>
</table>
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</table>

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Mean reduction in body weight %
Mean (95% CIs)</td><td>iBM: -6
(-7.5--4.6)
CWT1: -6.6
(-8.1--2.5)
CWT2: -3.9
(-5.4--2.5)</td><td>CON: 0.2
(-1.3-1.6)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Kalarchian, 2011

Guideline record ID: 10373--1

Study characteristics		
Citation	Kalarchian, M. A., Levine, M. D., Klem, M. L., Burke, L. E., Soulakova, J. N., & Marcus, M. D. (2011). Impact of addressing reasons for weight loss on behavioral weight-control outcome. American Journal of Preventive Medicine, 40(1), 18-24. https://doi.org/https://dx.doi.org/10.1016/j.amepre.2010.09.019	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Impact of addressing reasons for weight loss on behavioral weight-control outcome	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	“Aged 18-55 years, (2) BMI ≥ 27 and ≤ 40, and (3) rating both "improve your physical appearance" and "improve your general health" as important reasons for weight loss (≥ 7) on a brief questionnaire evaluating reasons for weight loss based on a scale of 1 to 10, where 1 is not at all important and 10 is extremely important.”	
Exclusion criteria	“Presence of a serious condition that required medical supervision of diet or exercise, (2) physical problems that prevented regular exercise, (3) use of a weight-loss medication, (4) participation in a weight-loss program, currently or within the past 6 months, (5) pregnant or planning on becoming pregnant within 18 months, (6) self-reported substantial binge eating problem, and (7) current treatment for a psychological disorder.”	
Setting	University/research centre	
Intervention	“All treatment sessions were delivered in a group format. Group meetings provided information regarding diet and exercise as well as training in behavioral skills to modify eating and activity. Sessions were lead by a multidisciplinary team of clinical psychologists, nutritionists, and exercise physiologists. All four study arms were equivalent in intervention time and clinician attention. All participants were given a calorie goal based on current body weight with participants weighing < 90.9 kg receiving a goal of 1200 kcal/day, and those weighing ≥ 90.9 kg prescribed 1500 kcal/day, and a low-fat eating plan. Participants were asked to increase their participation in moderately vigorous physical activity to reach a minimum goal of 180 minutes per week, and to self-monitor food intake (calories and fat) and physical activity daily by recording these behaviors in a diary. They were also asked to complete simple homework assignments (e.g., reducing fat levels in a favorite recipe, removing a high-fat food from their kitchen). Participants were given the opportunity to earn four monetary incentives ($30 each) based on session attendance and completion of assessments. The HEALTH groups incorporated an intensified emphasis on health into the standard behavioral intervention. Health-focused activities included measuring waist circumference; body fat assessment; discussing results of blood work and blood pressure measurements; insession exercise; health expert lectures; and self-ratings of health. The APPEARANCE groups incorporated techniques to address concerns about physical appearance. These included additional activities geared to building body esteem; use of photographs taken "before" and "after" treatment; physical measurements; trying on clothing for fit; use of a computerized body size estimator; image consultant lectures; and self-ratings of physical appearance. To address both of the primary motivators for weight loss, the COMBINED groups received half of the content provided to the HEALTH and APPEARANCE groups.”	
Control/Comparator	“All treatment sessions were delivered in a group format. Group meetings provided information regarding diet and exercise as well as training in behavioral skills to modify eating and activity. Sessions were lead by a multidisciplinary team of clinical psychologists,	

<table>
<tr><td></td><td>nutritionists, and exercise physiologists. All four study arms were equivalent in intervention time and clinician attention. All participants were given a calorie goal based on current body weight with participants weighing < 90.9 kg receiving a goal of 1200 kcal/day, and those weighing ≥ 90.9 kg prescribed 1500 kcal/day, and a low-fat eating plan. Participants were asked to increase their participation in moderately vigorous physical activity to reach a minimum goal of 180 minutes per week, and to self-monitor food intake (calories and fat) and physical activity daily by recording these behaviors in a diary. They were also asked to complete simple homework assignments (e.g., reducing fat levels in a favorite recipe, removing a high-fat food from their kitchen). Participants were given the opportunity to earn four monetary incentives ($30 each) based on session attendance and completion of assessments. The STANDARD group did not include any additional focus on motivators for weight loss. Study manuals are available on request."</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 203
Intervention group/s: Appearance (n=45); Health (n=50); Combined (n=58)

Comparator group: Standard (n=50)</td></tr>
<tr><td>Mean age ± SD</td><td>41.8y (9.2)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Appearance: 96.7
(13.7)
Health: 95.6
(12.7)
Combined: 97.8
(11.5)</td><td>Standard: 98.1
(13.6)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Appearance: 34.1
(3.9)
Health: 33.9
(3.5)
Combined: 34.3
(3.7)</td><td>Standard: 34.3
(3.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SE)</td><td>Appearance: -8.16
(1.12)
Health: -7.34
(0.99)
Combined: -8.33</td><td>Standard: -5.13
(1.05)</td></tr>
</table>
</td></tr>
</table>

	Change in BMI (kg/m2) Mean (SE)	(0.99) Appearance: -3.13 (0.42) Health: -2.83 (0.38) Combined: -3.27 (0.38)	 Standard: -1.94 (0.4)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Kalarchian, 2012

Guideline record ID: 10375--1

Study characteristics		
Citation	Kalarchian, M. A., Marcus, M. D., Courcoulas, A. P., Cheng, Y., Levine, M. D., & Josbeno, D. (2012). Optimizing long-term weight control after bariatric surgery: a pilot study. Surgery for Obesity and Related Diseases, 8(6), 710-715. https://doi.org/https://dx.doi.org/10.1016/j.soard.2011.04.231	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Optimizing long-term weight control after bariatric surgery: a pilot study	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	“Patients over age 21 years were eligible to participate if they had undergone bariatric surgery at least 3 years prior to study enrollment and had lost less than 50% excess weight from presurgery to study enrollment.”	
Exclusion criteria	“Patients were excluded for: 1) BMI < 30; 2) Participation in a weight management program in the 6 months prior to study enrollment; 3) Psychiatric problems sufficiently severe to require immediate treatment (e.g., severe depression or suicidality) ; 4) Pregnant or lactating in the previous 6 months, or planning to become pregnant in the next year; 5) Taking a medication known to affect body weight in the previous 6 months (e.g., oral steroid or antipsychotic); 6) Mental retardation or psychosis; and 7) Participation in a conflicting research protocol in the past 6 months.”	
Setting	Hospital	
Intervention	“The objective was to decrease caloric intake through diet and increase energy expenditure through physical activity. Participants were given a calorie range of 1200-1400 calories per day and instructed to maintain a balanced diet based on the Food Guide Pyramid and postoperative dietary guidelines. Patients were prescribed an exercise program based on their choice of activity (e.g., walking or swimming). Strategies for increasing lifestyle activity (e.g., taking the stairs) and increasing involvement in activities of daily living also were emphasized. Participants were assisted in self-monitoring and setting small, incremental goals for lifestyle change. The skills required to make the recommended behavior changes were modeled, practiced, and reinforced throughout the program.Key adaptations for bariatric surgery patients with suboptimal outcome included 1) information about how surgery facilitates weight loss and the role of long-term self management; 2) addressing specific post-surgery eating behaviors associated with poor weight loss such as binge or "loss of control" eating, frequent eating episodes, and over consumption of high calorie liquids; and 3) utilizing the group to enhance social support for behavior change. A combination of face-to-face group meetings and telephone coaching were utilized to minimize participant burden while maximizing the intensity of counseling. The intervention occurred in 12 weekly group meetings followed by 5 bi-weekly telephone coaching sessions, extending over approximately 6 months. Group meetings lasted 1 hour, consisting of a weigh-in, review of self-monitoring records and homework, and a didactic presentation. Telephone coaching was shorter in duration (15 - 20 minutes).”	
Control/Comparator	“waitlisted for 12 months.”	
Treatment duration	6 months	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 36
Intervention group/s: Intervention (n=18)

Comparator group: Wait (n=18)</td></tr>
<tr><td>Mean age ± SD</td><td>52.5y (7.1)</td></tr>
<tr><td>Sex</td><td>75.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Bariatric surgery at least 3 years prior</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight at baseline (kg)
Mean (SD)

BMI at study entry (kg/m2)
Mean (SD)

Excess weight at study entry (kg)
Mean (SD)</td><td>Intervention: 124.3
(26.5)

Intervention: 44.9
(7)

Intervention: 62.5
(23.3)</td><td>Wait: 111
(16.6)

Wait: 41.4
(5)

Wait: 50.8
(14.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change at 12 months (kg)
Mean (SD)

Percent excess weight loss (%)
Mean (SD)</td><td>Intervention: -3.6
(9.6)

Intervention: 5.8
(3.5)</td><td>Wait: -0.6
(6.7)

Wait: 0.9
(3.2)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Kalarchian, 2016

Guideline record ID: 10374--1

Study characteristics		
Citation	Kalarchian, M. A., Marcus, M. D., Courcoulas, A. P., Cheng, Y., & Levine, M. D. (2016). Preoperative lifestyle intervention in bariatric surgery: a randomized clinical trial. Surgery for Obesity and Related Diseases, 12(1), 180-187. https://doi.org/https://dx.doi.org/10.1016/j.soard.2015.05.004	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Preoperative lifestyle intervention in bariatric surgery: a randomized clinical trial	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Participants were at least 18 years of age and seeking surgery through a Bariatric Center of Excellence at a large, urban medical center."	
Exclusion criteria	"Exclusion criteria included intellectual disability or psychosis; previously diagnosed genetic obesity syndrome; participation in a weight management program in the 6 months before study enrollment; uncontrolled psychiatric symptomatology sufficiently severe upon screening to require immediate treatment; pregnancy or lactation in the previous 6 months; taking a medication known to affect weight (e.g., second-generation antipsychotics) during the previous 6 months; previous weight loss surgery; medical condition requiring a specialized preoperative regimen (e.g., nonambu latory individuals, chronic obstructive pulmonary disease requiring oxygen, body mass index [BMI] over 70 kg/m2 requiring a low-energy liquid diet per the Center's practice algorithm); and participation in a conflicting research protocol."	
Setting	Hospital, Home, Bariatric centre	
Intervention	"Briefly, the intervention included state-of-the art information on diet, physical activity, and bariatric surgery, incorporating behavioral strategies such as self-monitoring and goal setting. The intervention consisted of weekly contacts. For the first 2 months, participants received 8 weekly face-to-face sessions. Over the next 4 months, participants completed 1 face-to-face session and 3 telephone phone sessions per month. In total, the program comprised 24 weekly contacts, including 12 face-to-face and 12 telephone sessions. After surgery, participants in the lifestyle intervention group received 3 monthly telephone contacts."	
Control/Comparator	"Briefly, the intervention included state-of-the art information on diet, physical activity, and bariatric surgery, incorporating behavioral strategies such as self-monitoring and goal setting. The intervention consisted of weekly contacts. For the first 2 months, participants received 8 weekly face-to-face sessions. Over the next 4 months, participants completed 1 face-to-face session and 3 telephone phone sessions per month. In total, the program comprised 24 weekly contacts, including 12 face-to-face and 12 telephone sessions. After surgery, the usual care group did not receive any additional contact."	
Treatment duration	6 months	
Follow-up from baseline	30 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 143
Intervention group/s: Lifestyle intervention (n=71)

Comparator group: Usual care (n=72)</td></tr>
<tr><td>Mean age ± SD</td><td>44.9y (11)</td></tr>
<tr><td>Sex</td><td>90.21% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>Lifestyle intervention: 47.4 (6.2)</td><td>Usual care: 47.6 (6.5)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (%)
Mean (SD)</td><td>Lifestyle intervention: 26.5</td><td>Usual care: 29.5</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Kalter-Leibovici, 2010

Guideline record ID: 10378--1

Study characteristics		
Citation	Kalter-Leibovici, O., Younis-Zeidan, N., Atamna, A., Lubin, F., Alpert, G., Chetrit, A., Novikov, I., Daoud, N., & Freedman, L. S. (2010). Lifestyle intervention in obese Arab women: a randomized controlled trial. Archives of Internal Medicine, 170(11), 970-976. https://doi.org/https://dx.doi.org/10.1001/archinternmed.2010.103	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Lifestyle intervention in obese Arab women: a randomized controlled trial	
Location	Israel	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligible women were 35 to 54 years old and living in 2 Mus lim Arab communities in the center of Israel, with a body mass index (BMI [calculated as weight in kilograms divided by height in meters squared]) of 30 to 40 and with 1 or more components of the metabolic syndrome. The syndrome components, defined by the National Cholesterol Education Program,13 include a waist circumference greater than 88 cm, blood pressure of at least 130/85 mm Hg, a fasting plasma glucose level of at least 110 mg/dL (to convert to millimoles per liter, multiply by 0.0555), triglycer ides of at least 150 mg/dL (to convert to millimoles per liter, mul tiply by 0.0113), and high-density lipoprotein cholesterol (HDL-C) levels less than 50 mg/dL (to convert to millimoles per liter, multiply by 0.0259)."	
Exclusion criteria	"Women with either prediagnosed diabetes or a plasma glucose level of at least 200 mg/dL 2 hours after a 75-g oral glucose load, current pregnancy, or a condition that might prevent physical activity were excluded."	
Setting	GP clinic	
Intervention	"Women in the intensive intervention had 11 individual and 11 group counseling sessions per year with a dieti tian and 22 physical activity group sessions per year"	
Control/Comparator	"Women in the moderate intervention had 3 individual and 2 group dietary counseling sessions per year and no guided physical activity."	
Treatment duration	6 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 201 Intervention group/s: Intensive (n=101) Comparator group: Moderate (n=100)	
Mean age ± SD	Intervention: 43.8y (5.6); Control: 44.0y (5.9)	
Sex	100.00% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline weight (kg)
Mean (SD)

Baseline BMI
Mean (SD)

Baseline Waist circumference, cm
Median (range)</td><td>Intensive: 87.9
(9.6)

Intensive: 34
(3.1)

Intensive: 98.9
(86.3-120.6)</td><td>Moderate: 87.7
(8.3)

Moderate: 33.8
(2.8)

Moderate: 98.8
(87.7-121.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight reduction >7%
Proportion (%)</td><td>Intensive: 21.0%</td><td>Moderate: 5.9%</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Waist circumference (cm) at 12 months
Median (range)

Change in Weight (kg) at 12 months
Mean (SD)

Change in weight (%)
Mean (SD)</td><td>Intensive: -5.4
(-26-9.7)

Intensive: -2.4
(5.9)

Intensive: -2.8
(6.5)</td><td>Moderate: -3.1
(-17.6-10)

Moderate: 0.4
(4.3)

Moderate: 0.4
(5)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Kashyap, 2013

Guideline record ID: 10380--1

Study characteristics		
Citation	Kashyap, S. R., Bhatt, D. L., Wolski, K., Watanabe, R. M., Abdul-Ghani, M., Abood, B., Pothier, C. E., Brethauer, S., Nissen, S., Gupta, M., Kirwan, J. P., & Schauer, P. R. (2013). Metabolic effects of bariatric surgery in patients with moderate obesity and type 2 diabetes: analysis of a randomized control trial comparing surgery with intensive medical treatment. Diabetes Care, 36(8), 2175-2182. https://doi.org/10.2337/dc12-1596	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Metabolic effects of bariatric surgery in patients with moderate obesity and type 2 diabetes: analysis of a randomized control trial comparing surgery with intensive medical treatment	
Location	USA	
Trial name	Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE)	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"Gastric sleeve or sleeve gastrectomy plus Intensive medical therapy included the use of the latest lifestyle guidelines by the American Diabetes Association, frequent home monitoring and titration strategies, and use of the latest U.S. Food and Drug Administration-approved drug therapy including incretin analogs or mimetics and insulin sensitizers for treatment of hyperglycemia. Patients were examined in the outpatient clinic every 3 months by a diabetes specialist at the Cleveland Clinic. The bariatric procedures were performed by a single primary surgeon. During the screening period, all patients received nutritional counseling by a certified diabetes educator. Subjects were encouraged to participate in Weight Watchers for additional nutritional counselling. Intensive medical therapy included the use of the latest lifestyle guidelines by the American Diabetes Association, frequent home monitoring and titration strategies, and use of the latest U.S. Food and Drug Administration-approved drug therapy including incretin analogs or mimetics and insulin sensitizers for treatment of hyperglycemia. Patients were examined in the outpatient clinic every 3 months by a diabetes specialist at the Cleveland Clinic. During the screening period, all patients received nutritional counseling by a certified diabetes educator. Subjects were encouraged to participate in Weight Watchers for additional nutritional counseling"	
Control/Comparator	"Intensive medical therapy included the use of the latest lifestyle guidelines by the American Diabetes Association, frequent home monitoring and titration strategies, and use of the latest U.S. Food and Drug Administration-approved drug therapy including incretin analogs or mimetics and insulin sensitizers for treatment of hyperglycemia. Patients were examined in the outpatient clinic every 3 months by a diabetes specialist at the Cleveland Clinic. During the screening period, all patients received nutritional counseling by a certified diabetes educator. Subjects were encouraged to participate in Weight Watchers for additional nutritional counseling."	
Treatment duration	24 months	
Follow-up from baseline	24 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 60
Intervention group/s: Gastric bypass (n=20); Sleeve Gastrectomy (n=20)

Comparator group: IMT (n=20)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Gastric bypass: 105.3 (13.6)
Sleeve Gastrectomy: 100 (16.5)</td><td>IMT: 107.9 (14.5)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Gastric bypass: 36.1 (2.6)
Sleeve Gastrectomy: 36.4 (3.2)</td><td>IMT: 35.8 (2.9)</td></tr>
<tr><td>Total body fat (%)
Mean (SD)</td><td>Gastric bypass: 41.1 (4.7)
Sleeve Gastrectomy: 46.1 (4.9)</td><td>IMT: 42.2 (4.5)</td></tr>
<tr><td>Truncal fat (%)
Mean (SD)</td><td>Gastric bypass: 50 (5.45)
Sleeve Gastrectomy: 51.8 (4.62)</td><td>IMT: 49.1 (4.23)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Gastric bypass: 77.6 (10)
Sleeve Gastrectomy: 75.8 (12.5)</td><td>IMT: 106.3 (14.7)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Gastric bypass: 26.7 (2.5)
Sleeve Gastrectomy: 27.6 (2.5)</td><td>IMT: 35.3 (3.3)</td></tr>
<tr><td>Total body fat (%)
Mean (SD)</td><td>Gastric bypass: 27 (8.5)
Sleeve Gastrectomy: 36 (6.3)</td><td>IMT: 42 (6.7)</td></tr>
<tr><td>Truncal fat (%)
Mean (SD)</td><td>Gastric bypass: 29.7 (10.02)
Sleeve Gastrectomy: 39.1 (6.49)</td><td>IMT: 47.9 (6.65)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)</td><td>Gastric bypass: 79.9</td><td>IMT: 107.4</td></tr>
</table>
</td></tr>
</table>

	Mean (SD) BMI (kg/m2) Mean (SD) Total body fat (%) Mean (SD) Truncal fat (%) Mean (SD)	(11.7) Sleeve Gastrectomy: 77.5 (14.3) Gastric bypass: 27.4 (2.9) Sleeve Gastrectomy: 28.2 (3.1) Gastric bypass: 30.5 (8.5) Sleeve Gastrectomy: 38.4 (6.1) Gastric bypass: 34.1 (9.66) Sleeve Gastrectomy: 41.7 (5.93)	(14.9) IMT: 43.3 (5.2) IMT: 42 (6.7) IMT: 50.0 (5.04)
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Body weight change from baseline (kg) Mean (SD) BMI change from baseline (kg/m2) Mean (SD) Total body fat (%) change from baseline Mean (SD) Truncal fat (%) change from baseline Mean (SD)	Gastric bypass: -25.4 (10.32) Sleeve Gastrectomy: -22.5 (8.79) Gastric bypass: -8.7 (3.13) Sleeve Gastrectomy: -8.2 (3.01) Gastric bypass: -10.6 (6.6) Sleeve Gastrectomy: -7.7 (3.5) Gastric bypass: -15.9 (10.7) Sleeve Gastrectomy: -10.1 (5.0)	IMT: -0.5 (4.09) IMT: -0.2 (1.41) IMT: 1.1 (1.7) IMT: 0.8 (2.3)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data	Maghrabi, A. H., Wolski, K., Abood, B., Licata, A., Pothier, C., Bhatt, D. L., Nissen, S., Brethauer, S. A., Kirwan, J. P., Schauer, P. R., & Kashyap, S. R. (2015). Two-year outcomes on bone density and fracture incidence in patients with T2DM randomized to bariatric surgery versus intensive medical therapy. Obesity, 23(12), 2344-2348. https://doi.org/https://dx.doi.org/10.1002/oby.21150; Schauer, P. R., Bhatt, D. L., Kirwan, J. P., Wolski, K., Aminian, A., Brethauer, S. A., Navaneethan, S. D., Singh, R. P., Pothier, C. E., Nissen, S. E., Kashyap, S. R., & for the STAMPEDE Investigators. (2017). Bariatric surgery versus intensive medical therapy for diabetes - 5-year outcomes. The New England Journal of Medicine, 376(7), 641-651. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1600869; Schauer, P. R., Bhatt, D. L., Kirwan, J. P., Wolski, K., Brethauer, S. A., Navaneethan, S. D., Aminian, A., Pothier, C. E., Kim, E. S. H., Nissen, S. E., Kashyap, S. R., & for the STAMPEDE		

	Investigators. (2014). Bariatric surgery versus intensive medical therapy for diabetes--3-year outcomes. The New England Journal of Medicine, 370(21), 2002-2013. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1401329; Schauer, P. R., Kashyap, S. R., Wolski, K., Brethauer, S. A., Kirwan, J. P., Pothier, C. E., Thomas, S., Abood, B., Nissen, S. E., & Bhatt, D. L. (2012). Bariatric surgery versus intensive medical therapy in obese patients with diabetes. The New England Journal of Medicine, 366(17), 1567-1576. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1200225

N/A – Not applicable

Katula, 2013

Guideline record ID: 10381--1

Study characteristics		
Citation	Katula, J. A., Vitolins, M. Z., Morgan, T. M., Lawlor, M. S., Blackwell, C. S., Isom, S. P., Pedley, C. F., & Goff, D. C., Jr. (2013). The Healthy Living Partnerships to Prevent Diabetes study: 2-year outcomes of a randomized controlled trial. American Journal of Preventive Medicine, 44(4 Suppl 4), S324-S332. https://doi.org/https://dx.doi.org/10.1016/j.amepre.2012.12.015	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Healthy Living Partnerships to Prevent Diabetes study: 2-year outcomes of a randomized controlled trial	
Location	US	
Trial name	Healthy Living Partnerships to Prevent Diabetes (HELP PD)	
Methods		
Inclusion criteria	"Eligibility criteria were selected to target a sample that was representative of the local community; had an elevated risk of developing type 2 diabetes (i.e., prediabetes) based on fasting blood glucose (95 mg/dL-125 mg/dL) and BMI (25 39); and possessed no contraindications to participation in a weight-loss program or independent physical activity."	
Exclusion criteria	"Main exclusion criteria included clinical history of diabetes, cardiovascular disease occurring within the past 6 months, uncontrolled hypertension, pregnancy, chronic use of medicine known to substantially affect glucose metabolism, other chronic disease likely to limit life span to 2-3 years, and any other factor likely to interfere with participation and willingness to accept randomization (e.g., major psychiatric or cognitive problems)."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Lifestyle Weight-Loss Intervention: The LWL was adapted from the DPPLI4 for use in groups and delivery by nonprofessional staff. The objective was to induce negative energy balance through reductions in daily caloric intake (1200 1800 kcal/day) and increases in moderate-intensity aerobic physical activity (180 minutes/week) in order to produce a weight loss of approximately 0.3 kg per week for the first 6 months of treatment (Phase 1) for a total weight loss of 5% 7%.17 During Phase 2 (Months 7 24), participants were encouraged to continue to meet their weight-loss goals as long as their BMI did not fall below 20, but the primary focus was on weight maintenance.17 Participants met weekly for group sessions during Phase 1 (Months 1 6), and all sessions were coordinated and facilitated by the CHW. In addition, all participants received three personalized consultations with an RD (during Months 1, 3, and 6). The group sessions consist of 8 12 participants and were conducted at community sites (e.g., parks and recreation centers) with arrangements facilitated by study staff. During Phase 2 (Months 7 24), participants received two scheduled contacts with the CHW each month, one group session and one phone contact."	
Control/Comparator	"Enhanced Usual Care Comparison Condition: The comparison intervention condition was designed to exceed the usual care provided to similar community members with prediabetes and to enhance retention. The UCC consisted of two individual sessions with an RD nutritionist during the first 3 months that involved discussions of basic aspects of healthy eating and activity to support healthy living and existing community resources that may fit the individual needs of comparison participants. UCC participants also received a monthly newsletter that focused on healthy lifestyle and community resources."	
Treatment duration	24 months	

Follow-up from baseline	24 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 301 Intervention group/s: LWL (n=151) Comparator group: UC (n=150)
Mean age ± SD	57.9y (9.5)
Sex	57.48% female
Pre-existing medical condition	No pre-existing medical condition
Results	

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Weight (kg) Mean (SE)	LWL: 94.38 (1.2)	UC: 93.02 (1.32)
BMI (kg/m2) Mean (SE)	LWL: 32.85 (0.32)	UC: 32.56 (0.34)
Waist circumference (cm) Mean (SE)	LWL: 104.93 (0.76)	UC: 104.93 (0.76)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator
Weight (kg) Mean (SE)	LWL: 87.44 (1.28)	UC: 90.93 (1.37)
BMI (kg/m2) Mean (SE)	LWL: 30.52 (0.36)	UC: 31.95 (0.36)
Waist circumference (cm) Mean (SE)	LWL: 99.22 (0.9)	UC: 103.45 (0.89)
>5% below baseline weight Proportion (%)	LWL: 58.5%	UC: 18.1%
>10% below baseline weight Proportion (%)	LWL: 30.4%	UC: 1.4%

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator
Weight (kg) Mean (SE)	LWL: 88.81 (1.33)	UC: 92.23 (1.43)
BMI (kg/m2) Mean (SE)	LWL: 30.94 (0.38)	UC: 32.16 (0.36)
Waist circumference (cm) Mean (SE)	LWL: 104.05 (0.91)	UC: 104.05 (0.91)
>5% below baseline weight Proportion (%)	LWL: 46.5%	UC: 15.00%
>10% below baseline weight Proportion (%)	LWL: 21.3%	UC: 5.30%

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss (%)
Mean (SE)</td><td>LWL: -7.21
(0.57)</td><td>UC: -1.33
(0.39)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss (%)
Mean (SE)</td><td>LWL: -5.39
(0.66)</td><td>UC: -0.57
(0.55)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>58.6%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Katzmarzyk, 2020

Guideline record ID: 10382

Study characteristics		
Citation	Katzmarzyk, P. T., Martin, C. K., Newton, R. L., Jr., Apolzan, J. W., Arnold, C. L., Davis, T. C., Price-Haywood, E. G., Denstel, K. D., Mire, E. F., Thethi, T. K., Brantley, P. J., Johnson, W. D., Fonseca, V., Gugel, J., Kennedy, K. B., Lavie, C. J., Sarpong, D. F., & Springgate, B. (2020). Weight loss in underserved patients - a cluster-randomized trial. The New England Journal of Medicine, 383(10), 909-918. https://doi.org/https://dx.doi.org/10.1056/NEJMoa2007448	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight Loss in Underserved Patients - A Cluster-Randomized Trial	
Location	US	
Trial name	Promoting Successful Weight Loss in Primary Care in Louisiana (PROPEL)	
Methods		
Inclusion criteria	"The primary inclusion criteria included an age of 20 to 75 years and a body-mass index (the weight in kilograms divided by the square of the height in meters) of 30 to 50."	
Exclusion criteria	"Exclusion criteria included current participation in a weight-loss program, use of weight-loss medications, and a history of bariatric surgery or recent weight loss."	
Setting	GP clinic	
Intervention	"The intervention consisted of weekly sessions (16 conducted in person and 6 conducted by telephone) in the first 6 months, followed by sessions (alternating in-person visits and telephone calls) held at least monthly for the remaining 18 months. Most sessions were conducted individually, although some sessions were conducted in small groups of two to four patients. The personal goal was a 10% loss in body weight; patients received coaching on how to set their own goals and develop action plans for eating and physical activity. Patients were encouraged to increase their physical activity to 175 minutes per week. The initial focus of the intervention was on portion-controlled foods (e.g., bananas, apples, soups, and frozen entrees) and the provision of prepackaged foods and meal-replacement shakes during the first month. After the first month, patients received instruction regarding how to purchase, prepare, and package foods to manage portion size and energy intake in collaboration with their health coaches. A weight loss calculator was used to calculate personalized energy-intake targets for each patient that would result in 10% weight loss at 6 months and was then used to create a weight graph that showed each patient's predicted weight loss over time. Patients were provided with an electronic scale (BodyTrace) and were encouraged to weigh themselves daily. The daily weights were automatically plotted onto the weight graph, which was available to patients and their health coaches and allowed the coaches to monitor weight loss and adapt the intensity of the intervention."	
Control/Comparator	"Patients in the usual-care group received routine care from their primary care team throughout the trial. In addition, they received six newsletters covering topics related to sitting and health, goal setting, staying safe in the heat, memory health, self-care, sleep hygiene, and smoking cessation."	
Treatment duration	24 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 803
Intervention group/s: Intensive-Lifestyle Group (n=452)

Comparator group: Usual-Care Group (n=351)</td></tr>
<tr><td>Mean age ± SD</td><td>49.4y (13.1)</td></tr>
<tr><td>Sex</td><td>84.43% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)

Baseline Body weight (kg)
Mean (SD)</td><td>Intensive-Lifestyle Group: 37.3 (4.6)

Intensive-Lifestyle Group: 101.6 (16.4)</td><td>Usual-Care Group: 37.2 (4.8)

Usual-Care Group: 102.7 (17)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Percent change in body weight
Mean (95% CIs)

Change in body weight - kg
Mean (95% CIs)

Change in waist circumference - cm
Mean (95% CIs)</td><td>Intensive-Lifestyle Group: -6.75 (-7.72--5.78)

Intensive-Lifestyle Group: -7.22 (-8.25--6.19)

Intensive-Lifestyle Group: -6.63 (-7.61--5.66)</td><td>Usual-Care Group: -0.59 (-1.61-0.43)

Usual-Care Group: -0.99 (-2.08-0.09)

Usual-Care Group: -0.68 (-1.7-0.33)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Percent change in body weight
Mean (95% CIs)

Change in body weight - kg
Mean (95% CIs)

Change in waist circumference - cm
Mean (95% CIs)</td><td>Intensive-Lifestyle Group: -4.99 (-6.02--3.96)

Intensive-Lifestyle Group: -5.43 (-6.52--4.34)

Intensive-Lifestyle Group: -4.42 (-5.44--3.41)</td><td>Usual-Care Group: -0.48 (-1.57-0.61)

Usual-Care Group: -0.91 (-2.07-0.24)

Usual-Care Group: 0.71 (-0.35-1.78)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Kegler, 2016

Guideline record ID: 10383--1

Study characteristics		
Citation	Kegler, M. C., Haardörfer, R., Alcantara, I. C., Gazmararian, J. A., Veluswamy, J. K., Hodge, T. L., Addison, A. R., & Hotz, J. A. (2016). Impact of improving home environments on energy intake and physical activity: a randomized controlled trial. American Journal of Public Health, 106(1), 143-152. https://doi.org/10.2105/AJPH.2015.302942	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Impact of Improving Home Environments on Energy Intake and Physical Activity: A Randomized Controlled Trial	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligible participants overweight and obese females aged 35 to 65 years at baseline, living with at least 1 other person, and lived no farther than 30 miles from the referring clinic."	
Exclusion criteria	"Participants were excluded if they had conditions that could have an impact on their ability to be physically active. Pregnant women were also excluded from the study."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The intervention was based on social-cognitive theory in that we attempted to leverage the reciprocal nature of social support, physical environments, and individual behavior. It consisted of 3 home visits and 4 coaching calls over 16 weeks. Core elements, informed by social-cognitive theory, include a tailored home environment profile, goal setting, and behavioral contracting for 6 healthy actions. Healthy actions were supported by correlational data and experience from our pilot study, and refined by Community Advisory Board members. Selected healthy actions included always having a low calorie beverage available instead of sugar sweetened soda or sweet tea, cutting back on how often your family eats restaurant food, and creating a place for exercise in your home or yard and committing to using it at least once a week. We used baseline data related to the healthy actions to generate a tailored home environment profile showing areas in need of improvement and positive aspects of the home environment. The profile had sections that matched the healthy actions, such as food and exercise equipment inventories. Coaches, hired and supervised by a community partner, used the home environment profile to guide participants in choosing healthy actions. The chosen healthy actions were recorded on a family contract that was signed by the participant and coach. On the basis of the healthy actions chosen, participants received supportive materials via mail (e.g., portion size plate)."	
Control/Comparator	"Control participants received 3 mailings of educational booklets at 6-week intervals. These mailings were government documents encouraging adoption of US dietary and PA guidelines."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 349
Intervention group/s: Intervention (n=172)

Comparator group: Control (n=177)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 50.5 (8.0); Control: 49.8 (8.2)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)

Weight, pounds</td><td>Intervention: 37.6
(8.5)

Intervention: 219.6
(51)</td><td>Control: 39
(8.4)

Control: 232.1
(49.7)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight
Mean (SD)</td><td>Intervention: -10.7
(17.4)</td><td>Control: -7.1
(14.6)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Only 12.2% of participants had fewer than 4 contacts with a coach</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Kelley, 2018

Guideline record ID: 10387--1

Study characteristics		
Citation	Kelley, J. C., Stettler-Davis, N., Leonard, M. B., Hill, D., Wrotniak, B. H., Shults, J., Stallings, V. A., Berkowitz, R., Xanthopoulos, M. S., Prout-Parks, E., Klieger, S. B., & Zemel, B. S. (2018). Effects of a randomized weight loss intervention trial in obese adolescents on tibia and radius bone geometry and volumetric density. Journal of Bone and Mineral Research, 33(1), 42-53. https://doi.org/https://dx.doi.org/10.1002/jbmr.3288	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of a Randomized Weight Loss Intervention Trial in Obese Adolescents on Tibia and Radius Bone Geometry and Volumetric Density	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	“Inclusion criteria were age 10 years and <15 years, the period in which peak bone mineral accretion velocity is greatest, and BMI above the 97th percentile for sex and age.”	
Exclusion criteria	“Exclusion criteria included reported developmental delay requiring special education, depression, psychosis, eating disorders, orthopedic problems interfering with moderate-tovigorous physical activity, diabetes, polycystic ovary syndrome, use of anticonvulsant medications, weight loss medications including diet supplements, cumulative lifetime systemic corticosteroid use exceeding 3 months, and any other medications or chronic conditions deemed likely to interfere with the intervention or bone health. Additional exclusion criteria included weight loss of at least 5% over the preceding 6 months, participation in another weight loss program, cigarette smoking, and, for females, sexual activity without contraception. Participants were also excluded for syndromic or obesity secondary to other medical diagnoses and BMI Z-score greater than þ3.00 SD to avoid comorbidities associated with severe obesity or for weight greater than 136 kg because of the weight limit of the DXA table.”	
Setting	Hospital	
Intervention	“Participants met weekly for the first 12 weeks, then every other week for the next 12 weeks and once a month thereafter through week 52. Adolescents and parents met in separate group sessions that reviewed causes of obesity; components of healthful nutrition; self-monitoring of caloric intake, physical activity, and inactivity; stimulus control procedures; coping with high-risk social or psychological situations that trigger excess eating; increasing physical activity; and minimizing inactivity. Self-monitoring diaries and completed homework were submitted at each session, and incentives were used as an integral part of the behavior modification program.”	
Control/Comparator	“Participants received individual nutrition education sessions with an experienced pediatric dietitian. The initial consultation lasted 60 minutes and follow-up sessions lasted 30 minutes. Sessions were held monthly for the first 6 months, followed by sessions in months 8, 10, and 12. During the initial session, the dietitian reviewed the adolescent's usual diet to identify treatment targets, such as decreased consumption of high-fat foods and sweetened beverages, portion control, and decreasing snacking. Recommended dietary changes were customized to subject's specific situation and provided to the child and family. Follow-up visits included review of challenges to implementing dietary changes, problem identification, suggestions for overcoming challenges, reinforcement of previous dietary recommendations, and introduction of additional dietary recommendations as appropriate. Lifestyle physical activity recommendations corresponding to the goals of Healthy People 2010 for adolescents included engagement in vigorous physical activity 3	

<table>
<tr><td></td><td>days per week for 20 or more minutes per occasion and decrease sedentary behaviors to 2 hours per day.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 91
Intervention group/s: Behavioral modification program (n=46)

Comparator group: Nutrition education program (n=45)</td></tr>
<tr><td>Mean age ± SD</td><td>12y</td></tr>
<tr><td>Sex</td><td>64.84% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>12-month change in BMI (kg/m2)
Mean (95% CIs)

12-month change in fat mass index (kg/m2)
Mean (95% CIs)</td><td>Behavioral modification program: -0.4
(-1.24-0.35)

Behavioral modification program: -0.77
(-1.36--0.19)</td><td>Nutrition education program: 1
(0.3-1.7)

Nutrition education program: 0.46
(-0.03-0.95)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Kelly, 2020

Guideline record ID: 11037

Study characteristics		
Citation	Kelly, A. S., Auerbach, P., Barrientos-Perez, M., Gies, I., Hale, P. M., Marcus, C., Mastrandrea, L. D., Prabhu, N., Arslanian, S., & for the NN8022-4180 Trial Investigators. (2020). A randomized, controlled trial of liraglutide for adolescents with obesity. The New England Journal of Medicine, 382(22), 2117-2128. https://doi.org/10.1056/NEJMoa1916038	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A Randomized, Controlled Trial of Liraglutide for Adolescents with Obesity	
Location	Belgium; Mexico; Russia; Sweden; USA	
Trial name	SCALE Teens trial	
Methods		
Inclusion criteria	"Pubertal adolescents (12 to <18 years of age) were eligible for inclusion in the trial if they met the following criteria: obesity, defined as a bodymass index (BMI; the weight in kilograms divided by the square of the height in meters) that corresponded to an adult value of 30 or more, in accordance with international cutoff points,20 and was in the 95th or higher percentile for age and sex5 ; stable body weight, defined as a self-reported weight change of less than 5 kg during the 90 days before screening; and a poor response to lifestyle therapy alone, based on the judgment of the site investigator and documented in the participant's medical records. Adolescents with type 2 diabetes were eligible."	
Exclusion criteria	"All exclusion criteria must be answered "no": 1. Pre-pubertal subjects (Tanner stage 1) at screening visit 2. 2. Body weight ≤60 kg. 3. Type 1 diabetes mellitus. 4. Calcitonin ≥50 ng/L. 5. Family or personal history of multiple endocrine neoplasia type 2 (MEN2). 6. Medullary thyroid carcinoma (MTC). 7. History of pancreatitis (acute or chronic). 8. Subjects with secondary causes of obesity (i.e., hypothalamic, genetic, or endocrine causes). 9. Treatment with medications within 90 days before screening visit 2 that, based on the site investigator's judgement, may cause significant weight change. This should also include treatment with any of the following medications: pramlintide, orlistat, zonisamide, topiramate, lorcaserin, phentermine, bupropion, naltrexone, glucagon-like peptide-1 (GLP-1) receptor agonists, or metformin (used as treatment for obesity). 10. Anti-diabetic treatment other than metformin. 11. Diet attempts using herbal supplements or over-the-counter medications within 90 days before screening visit 2. 12. Participation in an organized weight reduction program (e.g., Weight Watchers®) within 90 days before screening visit 2. 13. Previous surgical treatment for obesity (excluding liposuction if performed >1 year before screening visit 2). 14. History of major depressive disorder within 2 years before screening visit 2. 15. Any lifetime history of other severe psychiatric disorder (e.g., schizophrenia, bipolar disorder). 16. Patient Health Questionnaire-9 (PHQ-9) score of ≥15 at screening visit 2. 17. Any suicidal ideation of type 4 or 5 based on the baseline Columbia - Suicide Severity Rating Scale (C-SSRS) questionnaire at screening visit 2. 18. Any suicidal behavior within 30 days before screening visit 2. 19. Any lifetime history of suicidal attempt. 20. Uncontrolled treated or untreated hypertension >99th percentile for age and gender in children. If white-coat hypertension is suspected at screening visit 2, a repeated measurement at visit 3 prior to other trial-related activities is allowed (last measurement being conclusive). 10 21. Surgery scheduled for the trial duration period, except for minor surgical procedures, at the discretion of the investigator. 22. Subjects with confirmed bulimia nervosa disorder. 23. Diagnosis of malignant neoplasms within the last 5 years prior to screening visit 2 (except basal and squamous cell skin cancer). 24. Known or suspected abuse of alcohol or narcotics. 25. Language barrier, mental incapacity, unwillingness or inability to adequately understand or comply with study procedures. 26. Known or suspected hypersensitivity to trial product or related products. 27. Previous participation in this trial. Participation is defined as signed informed consent. 28. Subjects from the same household participating in the trial. 29. Participation in any clinical trial of an approved or	

	non-approved investigational medicinal product within 30 days before screening visit 2. 30. Female who is pregnant, breast-feeding, or intends to become pregnant or is of child-bearing potential and not using an adequate contraceptive method (adequate contraceptive measure as required by local regulation or practice). For Sweden only: Oral (except low-dose gestagen [lynestrenol and norethisterone]), injectable, or implanted hormonal contraceptives, intrauterine device, intrauterine system (e.g., progestinreleasing coil), vasectomized male (with appropriate post-vasectomy documentation of the absence of sperm in the ejaculate). Use of contraception is not required for female subjects who have not yet made their sexual debut and/or are not sexually active. For Belgium only: Highly effective methods of birth control are defined as those, alone or in combination, that result in a low failure rate (i.e., less than 1% per year) when used consistently and correctly; such as implants, injectables, combined oral contraceptives, some intrauterine devices, true sexual abstinence (i.e., refraining from heterosexual intercourse during the entire period of risk associated with the study treatments), or vasectomized partner. 31. Any condition which, in the opinion of the investigator, might jeopardize the subject's safety or compliance with the protocol."
Setting	University/research centre
Intervention	"Participants who fulfilled the randomization criteria were randomly assigned, in a 1:1 ratio, to receive liraglutide (3.0 mg) or volume-matched placebo administered subcutaneously once daily for 56 weeks, followed by 26 weeks of follow-up without treatment. Treatment was initiated at a dose of 0.6 mg daily for 1 week, and then the dose was increased weekly until the maximum tolerated dose or the 3.0-mg dose (highest dose allowed) was reached Participants received individualized counseling in healthy nutrition that was performed by a certified dietician and evaluated at every visit using a numerical rating scale. Participants received individualized counseling in physical activity at every visit that was performed by site staff trained in physical activity counseling. Participants were encouraged to engage in 60 minutes of moderate- to high-intensity physical activity daily."
Control/Comparator	"Participants received individualized counseling in healthy nutrition that was performed by a certified dietician and evaluated at every visit using a numerical rating scale. Participants received individualized counseling in physical activity at every visit that was performed by site staff trained in physical activity counseling. Participants were encouraged to engage in 60 minutes of moderate- to high-intensity physical activity daily."
Treatment duration	56 weeks
Follow-up from baseline	56 weeks
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 251 Intervention group/s: Liraglutide (n=125) Comparator group: Placebo (n=126)
Mean age ± SD	Liraglutide: 14.6y (1.6); Placebo: 14.5y (1.6)
Sex	59.36% female
Pre-existing medical condition	No pre-existing medical condition
Results	

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Body weight (kg) - Baseline
Mean (SD)

BMI (kg/m2) - Baseline
Mean (SD)

BMI-SDS - Baseline
Mean (SD)

Waist circumference (cm) - Baseline
Mean (SD)</td><td>Liraglutide: 99.3
(19.7)

Liraglutide: 35.3
(5.1)

Liraglutide: 3.14
(0.65)

Liraglutide: 104.87
(12.67)</td><td>Placebo: 102.2
(21.6)

Placebo: 35.8
(5.7)

Placebo: 3.2
(0.77)

Placebo: 106.99
(13.57)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in Absolute BMI SDS
Mean (SE)

Relative change in BMI-SDS (%)
Mean (SE)

Absolute change in BMI (kg/m2)
Mean (SE)

Absolute change in Body weight (kg)

Mean (SE)
Relative change in Body weight (%)

Mean (SE)
Change in waist circumference (cm)
Mean (SE)</td><td>Liraglutide: -0.23
(0.05)

Liraglutide: -8.32
(1.68)

Liraglutide: -1.39
(0.31)

Liraglutide: -2.26
(0.94)

Liraglutide: -2.65
(0.93)

Liraglutide: -4.35
(0.85)</td><td>Placebo: 0
(0.05)

Placebo: -0.68
(1.74)

Placebo: 0.19
(0.33)

Placebo: 2.25
(0.98)

Placebo: 2.37
(0.95)

Placebo: -1.42
(0.88)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>>80%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Kelly, 2022

Guideline record ID: 11038--1

Study characteristics		
Citation	Kelly, A. S., Bensignor, M. O., Hsia, D. S., Shoemaker, A. H., Shih, W., Peterson, C., Varghese, S. T., & for the Trial Investigators. (2022). Phentermine/topiramate for the treatment of adolescent obesity. NEJM Evidence, 1(6). https://doi.org/10.1056/EVIDoa2200014	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Phentermine/Topiramate for the Treatment of Adolescent Obesity	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligible participants were 12 to less than 17 years of age, with a BMI in the 95th percentile or greater for age and sex, a Tanner stage greater than 1, a stable body weight, and a documented history of insufficient weight loss with lifestyle modification."	
Exclusion criteria	"Major exclusion criteria included treatment with antiobesity medications, history of bariatric surgery or eating disorders, stimulant use, type 1 diabetes, congenital heart disease, obesity of a known genetic or endocrine origin, elevated blood pressure, history of bipolar disorder or psychosis, major depressive disorder, current depression of moderate or greater severity, or presence or history of suicidal behavior or ideation with intent to act."	
Setting	University/research centre	
Intervention	"Mid-dose PHEN/ TPM (7.5 mg/46 mg), or top-dose PHEN/TPM (15 mg/ 92 mg) taken orally once daily in the morning. Participants who were unable to tolerate the assigned dose were switched to a reduced dose level or could take a drug holiday, typically limited to less than 2 weeks. If intolerance persisted after down-titration and/or a drug holiday and reinstitution of treatment, participants were removed from study treatment and encouraged to remain in the trial for follow-up assessments according to the protocol. All participants, regardless of group assignment, were instructed to follow a mild hypocaloric diet modification program representing a 500-kilocalorie/day deficit and to implement a family-based lifestyle modification program for adolescents, as tolerated, throughout the study period. The lifestyle program included physical activity, behavior change, and family support. The same lifestyle modification program was implemented across all sites at routine study visits by a study coordinator or dietician and included training of both participants and their parents/ guardians. Typically, between 5 and 15 minutes of visit time was dedicated to lifestyle training, with early study visits (baseline through week 12) toward the high end of this range, and visits later in the study toward the low end."	
Control/Comparator	""Placebo, taken orally once daily in the morning.Participants who were unable to tolerate the assigned dose were switched to a reduced dose level or could take a drug holiday, typically limited to less than 2 weeks. If intolerance persisted after down-titration and/or a drug holiday and reinstitution of treatment, participants were removed from study treatment and encouraged to remain in the trial for follow-up assessments according to the protocol. All participants, regardless of group assignment, were instructed to follow a mild hypocaloric diet modification program representing a 500-kilocalorie/day deficit and to implement a family-based lifestyle modification program for adolescents, as tolerated, throughout the study period. The lifestyle program included physical activity, behavior change, and family support. The same lifestyle modification program was implemented across all sites at routine study visits by a study coordinator or dietician and included training of both participants and their parents/ guardians. Typically, between 5 and 15 minutes of visit time was dedicated to lifestyle training, with early study visits (baseline	

<table>
<tr><td></td><td>through week 12) toward the high end of this range, and visits later in the study toward the low end."."</td></tr>
<tr><td>Treatment duration</td><td>56 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>56 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 223
Intervention group/s: Mid-Dose PHEN/TPM (n=54); High-Dose PHEN/TPM (n=113)

Comparator group: Placebo (n=56)</td></tr>
<tr><td>Mean age ± SD</td><td>14y (1.35)</td></tr>
<tr><td>Sex</td><td>54.26% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Mid-Dose PHEN/TPM: 105.2 (22.4)
High-Dose PHEN/TPM: 108.5 (25)</td><td>Placebo: 102.2 (21.8)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Mid-Dose PHEN/TPM: 36.9 (6.8)
High-Dose PHEN/TPM: 39.6 (6.8)</td><td>Placebo: 36.4 (6.4)</td></tr>
<tr><td>Waist circumference
Mean (SD)</td><td>Mid-Dose PHEN/TPM: 111.9 (15.5)
High-Dose PHEN/TPM: 116.5 (16.8)</td><td>Placebo: 111.1 (14)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in BMI (%)
Mean (SE)</td><td>Mid-Dose PHEN/TPM: 4.78 (1.3)
High-Dose PHEN/TPM: -7.11 (1.01)</td><td>Placebo: 3.34 (1.44)</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (SE)</td><td>Mid-Dose PHEN/TPM: -2.53 (0.44)
High-Dose PHEN/TPM: -4.15 (0.31)</td><td>Placebo: 1.2 (0.46)</td></tr>
<tr><td>Change in weight (kg)
Mean (SE)</td><td>Mid-Dose PHEN/TPM: -5.49 (1.23)
High-Dose PHEN/TPM: -9.23 (0.86)</td><td>Placebo: 6.57 (1.28)</td></tr>
</table>
</td></tr>
</table>

	Change in waist circumference (cm) Mean (SE)	Mid-Dose PHEN/TPM: -7.42 (1.29) High-Dose PHEN/TPM: -9.23 (0.86)	Placebo: 0.31 (1.39)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Kempf, 2019

Guideline record ID: 10389--1

Study characteristics		
Citation	Kempf, K., Röhling, M., Martin, S., & Schneider, M. (2019). Telemedical coaching for weight loss in overweight employees: a three-armed randomised controlled trial. BMJ Open, 9(4), e022242. https://doi.org/https://dx.doi.org/10.1136/bmjopen-2018-022242	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Telemedical coaching for weight loss in overweight employees: a three-armed randomised controlled trial	
Location	Germany	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria for the present study were a (1) BMI ≥25kg/m2 and/or a (2) waist circumference >94cm in men or >80cm in women."	
Exclusion criteria	"Exclusion criteria comprised: (1) severe illness with inpatient treatment during the last 3 months, (2) weight reduction >2kg/week during the last month, (3) smoking cessation during the last 3 months, (4) medication for active weight reduction, (5) pregnancy and breastfeeding."	
Setting	Workplace, Over the phone	
Intervention	"Participants of the TMC-group were equipped with telemonitoring devices (scale and pedometer; Fitbit, Boston, Massachusetts, USA) at baseline, and were coached with weekly care calls in months 3-6 and after that with monthly calls from months 7 to 12. They were instructed to monitor their body weight and physical activity (step counter) during the whole 12months intervention phase. The TMC contained a 'medical mental motivation programme' and included information about healthy diet, physical activity, subjective possibilities for lifestyle change, data discussion and target agreements. Following the 12-month intervention phase, participants were offered further company health promotion offers like seminars for a healthy lifestyle (topics: smoking cessation, healthy eating or physical activity). The telemonitoring devices automatically transferred recorded data into a personalised online portal, which could be monitored from the participants and the coaches in the study centre."	
Control/Comparator	"The C2-group had only a short-term coaching phase in months 6-9 and was also equipped with pedometers and scales at the 6. month. C2-group participants were also instructed to monitor their body weight and physical activity. Following the 12-month intervention phase, participants were offered further company health promotion offers like seminars for a healthy lifestyle (topics: smoking cessation, healthy eating or physical activity). Volunteers of the C1-group were also equipped with scales and pedometers at baseline but received no further support during the study phase. They were instructed to monitor their body weight and physical activity (step counter) during the whole 12months intervention phase. Following the 12-month intervention phase, participants were offered further company health promotion offers like seminars for a healthy lifestyle (topics: smoking cessation, healthy eating or physical activity)."	
Treatment duration	12 months	
Follow-up from baseline	36 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 104
Intervention group/s: TMC-group (n=34)

Comparator group: C1-group (n=34); CONTROL GROUP: C2-group (n=36)</td></tr>
<tr><td>Mean age ± SD</td><td>TMC: 51y (6); C2: 48y (5); C1: 51y (5)</td></tr>
<tr><td>Sex</td><td>15.38% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>TMC-group: 100
(18)</td><td>C1-group: 98
(15)
CONTROL GROUP: C2-group: 97
(18)</td></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)</td><td>TMC-group: 32
(7)</td><td>C1-group: 30
(4)
CONTROL GROUP: C2-group: 31
(4)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>TMC-group: 107
(13)</td><td>C1-group: 103
(10)
CONTROL GROUP: C2-group: 105
(13)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss in kg
Mean (95% CIs)</td><td>TMC-group: -5.8
(-8.3--3.3)</td><td>C1-group: -4
(-6.7--1.3)
CONTROL GROUP: C2-group: -2.5
(-4.9--0.1)</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (95% CIs)</td><td>TMC-group: -1.9
(-2.8--1.1)</td><td>C1-group: -1
(-1.9--0.1)
CONTROL GROUP: C2-group: -0.8
(-1.6-0.4)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss in kg
Mean (95% CIs)</td><td>TMC-group: -5.7
(-8.6--2.9)</td><td>C1-group: -4.9
(-7.9--1.9)
CONTROL GROUP: C2-group: -4.2
(-7--1.5)</td></tr>
</table>
</td></tr>
</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Kennedy, 2015

Guideline record ID: 10390--1

Study characteristics		
Citation	Kennedy, B. M., Ryan, D. H., Johnson, W. D., Harsha, D. W., Newton, R. L., Jr., Champagne, C. M., Allen, H. R., & Katzmarzyk, P. T. (2015). Baton Rouge Healthy Eating and Lifestyle Program (BR-HELP): a pilot health promotion program. Journal of Prevention & Intervention in the Community, 43(2), 95-108. https://doi.org/10.1080/10852352.2014.973256	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Baton Rouge Healthy Eating and Lifestyle Program (BR-HELP)	
Location	USA	
Trial name	Baton Rouge Healthy Eating and Lifestyle Program (BR-HELP)	
Methods		
Inclusion criteria	“To be eligible for BRHELP, potential participants were: African-American men or women, age 18 years or older, body mass index (BMI)≥23 kg/m2, willing to participate, able to provide informed consent, and willing to make monthly visits to the program site for 12 months-the length of the program. Only one person per household was allowed to participate in the program.”	
Exclusion criteria	“Exclusion criteria included recent and serious medical conditions, medications such as diabetes drugs and lipid-lowering agents, on a medically supervised diet, diagnosed eating disorders, pregnancy, and participation in another lifestyle modification program.”	
Setting	University/research centre	
Intervention	“The lifestyle intervention group received 12 monthly classes taught by a research dietitian for 1 ½ hours each and included cooking demonstrations and techniques to increase physical activity. Lifestyle intervention materials currently available at PBRC were selected by the program investigators and were organized into 12 separate lesson plans. Participants monitored food intake and physical activity by keeping food and exercise diaries. Participants were asked to submit a 7-day food and exercise diary each month for 12 months. Each of the assigned 7-day blocks consisted of 5 weekdays and 2 weekend days. At each monthly visit to the program site, the research dietitian reviewed with participants the lesson plan, and provided feedback and guidance based on current recommendations to maintain and/or prevent weight gain. Examples of the lifestyle intervention lesson plans were: "Essentials for Better Health, Portion Control, and Move those Muscles."”	
Control/Comparator	“The financial counseling group received 12 monthly classes from "Small Steps to Health and Wealth"-- Rutgers Cooperative Extension program, including sessions on budgeting finances, balancing payload, how to avoid repossessions and bankruptcy, individual counseling sessions, and special guest lectures. Each class was 1 ½ hours in length and were taught by the Principal Investigator. Special guest lectures consisted of topics on entrepreneurship opportunities, banking, real estate, long-term disability, and living wills. Several participants in the financial counseling group took advantage of personal individual counseling sessions. These personal one-on-one counseling sessions highlighted steps participants could follow to take control of their finances.”	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 37
Intervention group/s: Lifestyle intervention (n=19)

Comparator group: Financial counselling (n=18)</td></tr>
<tr><td>Mean age ± SD</td><td>54y</td></tr>
<tr><td>Sex</td><td>83.78% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Lifestyle intervention: 101.1 (5.6)

Lifestyle intervention: 35.6 (1.6)</td><td>Financial counselling: 91.9 (4.3)

Financial counselling: 34.2 (1.4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)</td><td>Lifestyle intervention: -0.1 (0.8)

Lifestyle intervention: -0.04 (0.31)</td><td>Financial counselling: -0.3 (0.9)

Financial counselling: -0.11 (0.32)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Kennedy, 2018

Guideline record ID: 10778--1

Study characteristics		
Citation	Kennedy, S. G., Smith, J. J., Morgan, P. J., Peralta, L. R., Hilland, T. A., Eather, N., Lonsdale, C., Okely, A. D., Plotnikoff, R. C., Salmon, J., Dewar, D. L., Estabrooks, P. A., Pollock, E., Finn, T. L., & Lubans, D. R. (2018). Implementing resistance training in secondary schools: a cluster randomized controlled trial. Medicine & Science in Sports & Exercise, 50(1), 62-72. https://doi.org/https://doi.org/10.1249/MSS.0000000000001410	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Implementing Resistance Training in Secondary Schools: A Cluster Randomized Controlled Trial	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	“Government-funded secondary schools located within the Hunter, Central Coast, and Sydney regions of NSW, Australia, were considered eligible for inclusion, adolescents in year 9 who did not have an injury or illness that would preclude participation in a physical activity program.”	
Exclusion criteria	Not reported	
Setting	School	
Intervention	“The revised NEAT and ATLAS programs (known collectively as ''Resistance Training for Teens'') programs were designed to be delivered over one school term (10 wk), for approximately 90 min/wk-1 . The intervention was delivered through either: (i) compulsory PE, (ii) cocurricular school sport, or (iii) an elective course known as Physical Activity and Sports Studies. The intervention was guided by social cognitive theory (18) and self-determination theory (19) and included the following sex-targeted components: an interactive student seminar; a structured physical activity program, which focused on Resistance Training (RT); lunchtime fitness sessions; and a Web-based smartphone app. The NEAT and ATLAS interventions had the same structure and format. However, various sociocultural targeting strategies were applied to the interventions to increase their relevance and appeal to adolescent girls and boys. For example, the program resources, including the circuit cards, interactive seminars, and smartphone apps, included images of same-sex role models. In addition, separate interactive seminars, focusing on health behaviors common to each sex, were designed for girls and boys. Although teachers were advised to deliver the program separately to girls and boys, the flexible delivery mode allowed sessions to be conducted with mixed-sex groups. This was an important aspect of intervention scalability because it accounted for potential barriers such as staff availability and timetabling. The structured physical activity program followed a specified session format, including the following: (i) movement-based games and dynamic stretching warm-up; (ii) RT skill development; (iii) high-intensity RT (HIRT) workout; (iv) modified game involving fitness infusion, boxing, or core strength activity; (v) static stretching; and (vi) reinforcement of key behavioral. The level of intensity for each session component was guided by Borg's rating of perceived exertion scale. Choice and variety were included in each of the session components to fit with the individual school needs. The following implementation components were also used: school champions, professional learning workshop for teachers, teacher handbook, session resources, fitness equipment, and physical activity session observation and feedback (i.e., a member of the research team observing and providing feedback to the teacher). The professional learning workshop for teachers introduced the ''Supportive, Active, Autonomous, Fair, and Enjoyable'' (SAAFE) teaching principles (20), which served as the framework for the design and delivery of the	

<table>
<tr><td></td><td>physical activity sessions, as well as the session observations. Teachers were educated about the importance of, and provided with strategies for, integrating SAAFE principles within their lessons. The Resistance Training for Teens intervention was designed to be scalable. In particular, the following features reflect the scalability of the program: (i) partnership with the NSW DoE, including their commitment to support program delivery beyond the research study; (ii) flexibility of the program and adaptability for delivery within PE, school sport, or Physical Activity and Sports Studies; (iii) accredited teacher-training workshop and teacher-led delivery of the program; (iv) smartphone apps to support intervention delivery within and beyond schools; and (v) capability of the program to be delivered without elaborate equipment or access to a gym."</td></tr>
<tr><td>Control/Comparator</td><td>"The control group participated in usual practice (regularly scheduled PE and cocurricular school sport) for the duration of the intervention and received the intervention after the 12-month assessments."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 607
Intervention group/s: RT for Teens (n=353)

Comparator group: Control (n=254)</td></tr>
<tr><td>Mean age ± SD</td><td>14.1y (0.5)</td></tr>
<tr><td>Sex</td><td>50.08% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight status - overweight Proportion (%)</td><td>RT for Teens: 19.0%</td><td>Control: 19.8%</td></tr>
<tr><td>Weight status - obese Proportion (%)</td><td>RT for Teens: 5.7%</td><td>Control: 11.5%</td></tr>
<tr><td>BMI (kg/m2) (in overweight/obese sub population) Mean (95% CIs)</td><td>RT for Teens: 27.2 (26.28-28.12)</td><td>Control: 27.98 (27.01-28.95)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2) (in overweight/obese sub population) Mean (95% CIs)</td><td>RT for Teens: 27.24 (26.29-28.19)</td><td>Control: 28.57 (27.57-29.58)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<table>
<tr><td>12 months or closest time point</td><td></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Kirby, 2011

Guideline record ID: 10396--1

Study characteristics		
Citation	Kirby, M. L., Beatty, S., Stack, J., Harrison, M., Greene, I., McBrinn, S., Carroll, P., & Nolan, J. M. (2011). Changes in macular pigment optical density and serum concentrations of lutein and zeaxanthin in response to weight loss. British Journal of Nutrition, 105(7), 1036-1046. https://doi.org/10.1017/S0007114510004721	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Changes in macular pigment optical density and serum concentrations of lutein and zeaxanthin in response to weight loss	
Location	Ireland	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were as follows: BMI >= 28 kg/m2; age <=18 years;no known family history ofAMD; no ocular pathology."	
Exclusion criteria	"Exclusion criteria were as follows: pregnancy; planning pregnancy; currently participating in a weight loss programme; ocular pathology; positive family history of AMD (given the previously established compromised relationship between serum carotenoids and MPOD in this subgroup)."	
Setting	Hospital, Home, University/research centre	
Intervention	"A customised weight loss plan was provided to each subject randomised to the I group of the study as follows: dietary intervention; exercise intervention; motivational lectures; weekly weight checks. The weight-loss intervention programme was initiated for subjects randomised to the I group only by a one-to-one consultation with the study dietitian. This consultation was held immediately after the baseline study visit. Using the information obtained from the food diary, the study dietitian advised the I group subjects on customised dietary changes to achieve weight loss. Using the British Dietetic Association 'Weight Wise Plan' (www.bdaweightwise.com), which is a diet plan based on the classic food pyramid model, the study dietitian customised a low-fat and low-energy diet for each subject recruited into the I group. The 'Weight Wise Plan' assumes that women will lose weight by consuming 6300 kJ/d (1500 cal/d) and that men will lose weight by consuming 7560 kJ/d (1800 cal/d), while still maintaining adequate nutrition. For most subjects, it was estimated that a reduction of 2100-2520kJ/d (approximately 500-600 cal/d) was required in order to lose the recommended 0·5 kg (approximately 1 lb) per week. Exercise intervention. Moderate exercise for 1 h per day was recommended for all subjects recruited into the I group. Subjects recorded the type, duration and intensity of exercise performed per day on a customised exercise log form. Additionally, a series of exercise classes was provided to subjects in the I group (e.g. aerobics and walking classes). These weekly classes were held in 6-week blocks, evenly spread throughout the entire study period to ensure a standardised intervention for all subjects in the I group. Subject attendance to these classes was recorded and used to facilitate discussion in the motivational lectures Motivational lectures. A series of educational lectures were arranged each month for all subjects recruited into the I group. The lectures were designed to educate subjects on a range of topics, for example: weight loss and vision; health benefits of optimal nutrition and achieving and maintaining weight loss; exercise and weight loss; the psychology of weight loss motivation. These lectures also allowed for valuable interaction between subjects in the I group. Weekly weight checks. Subjects in the I group of the study were required to attend the Macular Pigment Research Group's health laboratory every week for a weight check over the 12-month study period. Weekly reminders were sent to all I group subjects using text messages encouraging them to attend their weekly weight check. Feedback with	

<table>
<tr><td></td><td>regard to weight loss progress was discussed at this weight check visit. The primary goals of these weekly weight checks were to monitor subject progress, maintain subject interest and set new weight loss targets for the week ahead based on their weight loss progress."</td></tr>
<tr><td>Control/Comparator</td><td>"During the 12-month study period, the C group subjects were permitted to take any steps necessary to achieve weight loss in a personal capacity; however, they were not actively encourage or discourage to loose weight."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 104
Intervention group/s: Intervention group (n=54)

Comparator group: Control group (n=50)</td></tr>
<tr><td>Mean age ± SD</td><td>46y (11)</td></tr>
<tr><td>Sex</td><td>75.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intervention group: 95.8
(18.7)</td><td>Control group: 90.9
(20.1)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intervention group: 34.9
(6.1)</td><td>Control group: 32.9
(4.6)</td></tr>
<tr><td>Body fat (%)
Mean (SD)</td><td>Intervention group: 41.7
(8.9)</td><td>Control group: 41.7
(7.8)</td></tr>
<tr><td>Body fat (kg)
Mean (SD)</td><td>Intervention group: 39.7
(11.5)</td><td>Control group: 39
(11.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intervention group: 92.9
(19.7)</td><td>Control group: 90.9
(22.1)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intervention group: 34.1
(6.3)</td><td>Control group: 32.8
(5.1)</td></tr>
<tr><td>Body fat (%)
Mean (SD)</td><td>Intervention group: 41.9
(8.1)</td><td>Control group: 42.9
(7.9)</td></tr>
<tr><td>Body fat (kg)
Mean (SD)</td><td>Intervention group: 38.8
(10.9)</td><td>Control group: 40.5
(13.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change (kg)
Mean</td><td>Intervention group: 2.9</td><td>Control group: 0</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>12 months or closest time point</td><td><table>
<tr><td>Change in Body fat (kg) Mean</td><td>Intervention group: 0.9</td><td>Control group: 1.5</td></tr>
<tr><td>Change in Body fat (%) Mean</td><td>Intervention group: 2.3</td><td>Control group: 3.7</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Knauper, 2018

Guideline record ID: 10397--1

Study characteristics		
Citation	Knäuper, B., Carrière, K., Frayn, M., Ivanova, E., Xu, Z., Ames-Bull, A., Islam, F., Lowensteyn, I., Sadikaj, G., Luszczynska, A., Grover, S., & the McGill Chip Healthy Weight Program Investigators. (2018). The effects of if-then plans on weight loss: results of the McGill CHIP Healthy Weight Program randomized controlled trial. Obesity, 26(8), 1285-1295. https://doi.org/https://dx.doi.org/10.1002/oby.22226	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Effects of If-Then Plans on Weight Loss: Results of the McGill CHIP Healthy Weight Program Randomized Controlled Trial	
Location	Canada	
Trial name	McGill CHIP Healthy Weight Program	
Methods		
Inclusion criteria	"Individuals with overweight or obesity (BMI of 28-45, waist circumference 88 cm for women, 102 cm for men, 18-75 years of age) were eligible if they engaged in fewer than 200 minutes of selfreported moderate or vigorous physical activity per week."	
Exclusion criteria	"Exclusion criteria included any limitation that would preclude full participation in the intervention or could have a confounding effect on the primary outcomes, including having been diagnosed with diabetes, taking metformin, and planning to become pregnant."	
Setting	University/research centre	
Intervention	"Groups comprised approximately 6 to 10 individuals, and the sessions lasted for approximately 1 hour. The active control group received the standard group-based DPP (13) delivered over 1 year (12 weekly core sessions, 4 transitional sessions over 3 months, and 6 monthly support sessions). The enhanced DPP group followed the same program as the standard DPP group, but instructions for if-then planning were integrated into it. Instructions for the delivery of if-then planning were based on previous studies (14-16). Specifically, the concepts of if-then planning were introduced to participants in Session 1 and subsequently practiced through the example of weighing oneself and tracking one's food intake. In subsequent sessions, participants made individualized if-then plans targeting eating and exercise behaviors. Coaches guided participants through the formation of if-then plans by using structured handout sheets that were revised throughout the program."	
Control/Comparator	"."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 208 Intervention group/s: Enhanced DPP (n=107) Comparator group: Standard DPP (n=101)	
Mean age ± SD	Not reported	
Sex	Not reported	

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline weight (lb)
Mean (SD)

Baseline waist circumference (cm)
Mean (SD)</td><td>Enhanced DPP: 199.36 (31.71)

Enhanced DPP: 108.43 (10.78)</td><td>Standard DPP: 208.81 (31.35)

Standard DPP: 109.16 (11.69)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
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<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change %
Mean

Weight change (lb)
Mean (SE)

Waist circumference change (cm)
Mean (SE)</td><td>Enhanced DPP: 10.63

Enhanced DPP: -21.19 (5.24)

Enhanced DPP: -10.07 (2.69)</td><td>Standard DPP: 9.42

Standard DPP: -19.66 (4.96)

Standard DPP: -5.75 (2.26)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Knäuper, B., Shireen, H., Carrière, K., Frayn, M., Ivanova, E., Xu, Z., Lowensteyn, I., Sadikaj, G., Luszczynska, A., Grover, S., & McGill CHIP Healthy Weight Program Investigators. (2020). The effects of if-then plans on weight loss: results of the 24-month follow-up of the McGill CHIP Healthy Weight Program randomized controlled trial. Trials, 21, 40. https://doi.org/https://dx.doi.org/10.1186/s13063-019-4014-z</td></tr>
</table>

N/A – Not applicable

Knauper, 2020

Guideline record ID: 10398--1

Study characteristics		
Citation	Knäuper, B., Shireen, H., Carrière, K., Frayn, M., Ivanova, E., Xu, Z., Lowensteyn, I., Sadikaj, G., Luszczynska, A., Grover, S., & McGill CHIP Healthy Weight Program Investigators. (2020). The effects of if-then plans on weight loss: results of the 24-month follow-up of the McGill CHIP Healthy Weight Program randomized controlled trial. Trials, 21, 40. https://doi.org/https://dx.doi.org/10.1186/s13063-019-4014-z	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The effects of if-then plans on weight loss: results of the 24-month follow-up of the McGill CHIP Healthy Weight Program randomized controlled trial	
Location	Canada	
Trial name	McGill CHIP Healthy Weight Program	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	University/research centre	
Intervention	"The GLB manual was adhered to in both groups and if-then plans were integrated into sessions of the enriched groups"	
Control/Comparator	"The GLB manual was adhered to in both groups."	
Treatment duration	12 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 208 Intervention group/s: Enriched GLB (n=107) Comparator group: Standard GLB (n=101)	
Mean age ± SD	Not reported	
Sex	Not reported	
Pre-existing medical condition	No pre-existing medical condition	
Results		

Outcome measure at baseline

Variable	Intervention arm/s	Comparator

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight change (lbs) from 12 (post-intervention) to 24 months
Mean (SE)

Waist circumference (cm) change from 12 (post-intervention) to 24 months
Mean (SE)</td><td>Enriched GLB: 10.78
(5.97)

Enriched GLB: 1.00
(2.84)</td><td>Standard GLB: 5.58
(5.26)

Standard GLB: -0.24
(2.46)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Knäuper, B., Carrière, K., Frayn, M., Ivanova, E., Xu, Z., Ames-Bull, A., Islam, F., Lowensteyn, I., Sadikaj, G., Luszczynska, A., Grover, S., & the McGill Chip Healthy Weight Program Investigators. (2018). The effects of if-then plans on weight loss: results of the McGill CHIP Healthy Weight Program randomized controlled trial. Obesity, 26(8), 1285-1295. https://doi.org/https://dx.doi.org/10.1002/oby.22226</td></tr>
</table>

N/A – Not applicable

Koehestanie, 2014

Guideline record ID: 10399--1

Study characteristics		
Citation	Koehestanie, P., de Jonge, C., Berends, F. J., Janssen, I. M., Bouvy, N. D., & Greve, J. W. M. (2014). The effect of the endoscopic duodenal-jejunal bypass liner on obesity and type 2 diabetes mellitus, a multicenter randomized controlled trial. Annals of Surgery, 260(6), 984-992. https://doi.org/https://dx.doi.org/10.1097/SLA.0000000000000794	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The effect of the endoscopic duodenal-jejunal bypass liner on obesity and type 2 diabetes mellitus, a multicenter randomized controlled trial	
Location	Netherlands	
Trial name	N/A	
Methods		
Inclusion criteria	"Patients were considered eligible if they were between 18 and 65 years of age; had a body mass index (BMI) between 30 and 50 kg/m2; and had T2DM for less than 10 years with a glycated hemoglobin A1c (HbA1c) level between 7.5% and 10.0%. Patients were allowed to take metformin, sulfonylurea (SU) derivates, and/or insulin with a maximum dose of 150 IU per day."	
Exclusion criteria	"Exclusion criteria were as follows: weight loss of more than 4.5 kg within 12 weeks before screening; pregnancy or intention to become pregnant; use of nonsteroidal anti-inflammatory drugs, anticoagulation therapy, corticosteroids, weight loss medication, or drugs known to affect gastrointestinal (GI) motility; substance abuse; active Helicobacter pylori infection; probable insulin production failure as indicated by a C-peptide level of less than 1.0 ng/mL; iron deficiency or iron deficiency anemia; GI tract abnormalities or previous surgery in the GI tract that could affect the ability to place the device; symptomatic gallstones or kidney stones; known infection; bleeding disorders; gastroesophageal reflux disorder; connective tissue disorders; and severe liver or kidney failure as indicated by a creatinine level of more than 180 mmol/L."	
Setting	Hospital, Home	
Intervention	"DJBL treatment in combination with dietary intervention. The DJBL is a single-use endoscopic device mimicking the intestinal bypass component of the Roux-en-Y gastric bypass. The device consist of a 60-cm long impermeable fluoropolymer liner and a nitinol anchor, which is used to reversibly affix the device to the duodenum. The anchor is located in the duodenal bulb, and the liner stretches out through the duodenum and the proximal part of the jejunum. To allow food passage, the DJBL is open at both the proximal and the distal end. As a result, chyme passes through the interior of the DJBL whereas pancreatic enzymes and bile pass on the outside of the liner. Digestion and absorption of nutrients therefore start at the end of the liner, creating a bypass of the proximal intestinal tract.Implantation of the DJBL was performed under general anesthesia with endotracheal intubation. Initial access to the stomach and the duodenum was achieved by standard gastroduodenoscopy. Next, a guide wire was advanced into the duodenum and the encapsulated device was tracked over the guide wire into the duodenum. The capsule at the distal end holds the liner and the anchor. The catheter has an atraumatic ball at the end, which is advanced through the intestine deploying the liner behind it. After full extension of the liner, the anchor was deployed in the duodenal bulb, approximately 0.5 cm distal to the pylorus. Endoscopic and fluoroscopic guidance was used to verify the correct position of the DJBL. During the study, all patients were prescribed a diet with a maximum of 1200 kcal for women and 1500 kcal for men, which was liquid for the first week. In addition, patients were advised to increase their physical activities."	

<table>
<tr><td>Control/Comparator</td><td>“Control participants received a dietary intervention only. All patients were prescribed a diet with a maximum of 1200 kcal for women and 1500 kcal for men, which was liquid for the first week. In addition, patients were advised to increase their physical activities.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 73
Intervention group/s: DJBL (n=34)

Comparator group: Diet (n=39)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>36.99% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>T2DM for less than 10 years with a glycated hemoglobin A1c (HbA1c) level between 7.5% and 10.0%.</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (IQR)

BMI (kg/m2)
Mean (IQR)</td><td>DJBL: 105.4
(98.2-116.1)

DJBL: 34.6
(32.4-38.1)</td><td>Diet: 110.8
(99.7-129)

Diet: 36.8
(32.6-42)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Mean (IQR)

Change in BMI (kg/m2)
Mean (IQR)

Excess weight loss (%)
Mean (IQR)

Total weight loss (%)
Mean (IQR)</td><td>DJBL: 6.8
(3.3-12)

DJBL: 2.2
(1.2-3.4)

DJBL: 19.8
(10.6-45)

DJBL: 5.8
(2.8-11.1)</td><td>Diet: 4
(0.8-8.6)

Diet: 1.3
(0.3-2.8)

Diet: 11.7
(1.4-25.4)

Diet: 3.5
(0.6-8.6)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Kokkvoll, 2015

Guideline record ID: 10401--1

Study characteristics		
Citation	Kokkvoll, A., Grimsgaard, S., Steinsbekk, S., Flægstad, T., & Njølstad, I. (2015). Health in overweight children: 2-year follow-up of Finnmark Activity School--a randomised trial. Archives of Disease in Childhood, 100(5), 441-448. https://doi.org/10.1136/archdischild-2014-307107	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Health in overweight children: 2-year follow-up of Finnmark Activity School--a randomised trial	
Location	Norway	
Trial name	Finnmark Activity School	
Methods		
Inclusion criteria	“Inclusion criteria were age 6-12 years and BMI corresponding to adult BMI ≥27.5 kg/m2 .”	
Exclusion criteria	“Exclusion criteria were diseases incompatible with ordinary physical activity and psy chosocial disorders incompatible with group interaction.”	
Setting	Hospital	
Intervention	“MUFI comprised a 3-day inpatient programme at the hospital with other families and a multidisciplinary team, individual and group-based follow-up visits in their hometown, weekly group-based physical activity and a 4-day family camp. Both intervention programmes focused on the families' own resources and aimed to reduce sedentary activity, increase physical activity and increase the intake of healthy food according to national guidelines. Principles from Solution-Focused Brief Therapy, Standardized Obesity Family Therapy and elements from motivational interviewing were applied in both interventions.”	
Control/Comparator	“SIFI comprised clinical examination and individual counselling by paediatric nurse, paediatric consultant, nutritionist at the hos pital and follow-up by a local public health nurse. Both intervention programmes focused on the families' own resources and aimed to reduce sedentary activity, increase physical activity and increase the intake of healthy food according to national guidelines. Principles from Solution-Focused Brief Therapy, Standardized Obesity Family Therapy and elements from motivational interviewing were applied in both interventions.”	
Treatment duration	24 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference	
Participant characteristics		
Number of participants	n= 91 Intervention group/s: Group Intervention (MUFI) (n=45) Comparator group: Individual Family Intervention (SIFI) (n=46)	
Mean age ± SD	Intervention: 10.1y (1.7); Control: 10.5y (1.7)	
Sex	53.85% female	

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI kg/m2
Mean (SD)</td><td>Group Intervention (MUFI):
26.9
(4.2)</td><td>Individual Family Intervention (SIFI): 27.6
(4.3)</td></tr>
<tr><td>BMI SD score * according to British reference
Mean (SD)</td><td>Group Intervention (MUFI):
2.76
(0.58)</td><td>Individual Family Intervention (SIFI): 2.81
(0.6)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Group Intervention (MUFI):
87.9
(12)</td><td>Individual Family Intervention (SIFI): 89.2
(11.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in BMI from baseline
Mean (95% CIs)</td><td>Group Intervention (MUFI):
0.37
(-0.18-0.91)</td><td>Individual Family Intervention (SIFI): 0.78
(0.21-1.35)</td></tr>
<tr><td>Change in BMI SDS from baseline
Mean (95% CIs)</td><td>Group Intervention (MUFI): -0.15
(-0.23--0.07)</td><td>Individual Family Intervention (SIFI): -0.07
(-0.16-0.01)</td></tr>
<tr><td>Change in Waist circumference from baseline (cm)
Mean (95% CIs)</td><td>Group Intervention (MUFI): -0.96
(-2.45-0.52)</td><td>Individual Family Intervention (SIFI): 0.96
(-0.56-2.48)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in BMI
Mean (95% CIs)</td><td>Group Intervention (MUFI):
1.29
(0.74-1.84)</td><td>Individual Family Intervention (SIFI): 2.02
(1.44-2.6)</td></tr>
<tr><td>Change in BMI SDS from baseline
Mean (95% CIs)</td><td>Group Intervention (MUFI): -0.2
(-0.29--0.12)</td><td>Individual Family Intervention (SIFI): -0.08
(-0.17-0.01)</td></tr>
<tr><td>Change in Waist circumference from baseline (cm)
Mean (95% CIs)</td><td>Group Intervention (MUFI):
0.21
(-1.32-1.74)</td><td>Individual Family Intervention (SIFI): 2.6
(0.95-4.26)</td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Kokkvoll, A. S., Grimsgaard, S., Flægstad, T., Andersen, L. B., Ball, G. D. C., Wilsgaard, T., & Njølstad, I. (2020). No additional long-term effect of group vs individual family intervention in the treatment of childhood obesity-a randomised trial. Acta Paediatrica, 109(1), 183-192. https://doi.org/https://dx.doi.org/10.1111/apa.14916</td></tr>
</table>

N/A – Not applicable

Kokkvoll, 2020

Guideline record ID: 10402--1

Study characteristics		
Citation	Kokkvoll, A. S., Grimsgaard, S., Flægstad, T., Andersen, L. B., Ball, G. D. C., Wilsgaard, T., & Njølstad, I. (2020). No additional long-term effect of group vs individual family intervention in the treatment of childhood obesity-a randomised trial. Acta Paediatrica, 109(1), 183-192. https://doi.org/https://dx.doi.org/10.1111/apa.14916	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	No additional long-term effect of group vs individual family intervention in the treatment of childhood obesity-A randomised trial	
Location	Norway	
Trial name	Finnmark Activity School	
Methods		
Inclusion criteria	“Inclusion criteria were age 6-12 years and BMI corresponding to adult BMI ≥27.5 kg/m2 . The latter was calculated as the middle between the two international cut-off points defining overweight and obesity in children,13 by age and gender.”	
Exclusion criteria	“Exclusion criteria were diseases incompatible with ordinary physical activity and psy chosocial disorders incompatible with group interaction.”	
Setting	Hospital	
Intervention	“The group intervention included an initial 3-day inpatient stay at the hospital with other families and a multidisciplinary team, indi- vidual and group-based follow-up visits by local public health nurses, weekly physical activity (PA) sessions in their local community and a 4-day family camp. Local coaches with experience in children's sports led the PA sessions. During the 24-month intervention period, health-care provider contact in the group intervention was 119 hours of contact, which included 76 hours of PA sessions. Both intervention programmes focused on the families' own resources and aimed to reduce sedentary activity, increase physical activity and increase the intake of healthy food according to national guidelines. Principles from Solution-Focused Brief Therapy, Standardized Obesity Family Therapy and elements from motivational interviewing were applied in both interventions.”	
Control/Comparator	“The individual family intervention included counselling by a nurse, consultant physician and nutritionist at the paediatric outpatient clinic and follow-up by a public health nurse in the local community. During the 24-month intervention pe- riod, children in individual family intervention were offered 11 hours of health-care provider contact while their peers in the group in- tervention were offered 119 hours of contact, which included 76 hours of PA sessions.8 Families who requested more support after 24 months were recommended to contact their primary care provider for follow-up care, no additional intervention sessions were offered through the study. Both intervention programmes focused on the families' own resources and aimed to reduce sedentary activity, increase physical activity and increase the intake of healthy food according to national guidelines. Principles from Solution-Focused Brief Therapy, Standardized Obesity Family Therapy and elements from motivational interviewing were applied in both interventions.”	
Treatment duration	24 months	
Follow-up from baseline	36 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 91
Intervention group/s: Group Intervention (n=46)

Comparator group: Individual Family Intervention (n=45)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 10.1y (1.7); Control: 10.5y (1.7)</td></tr>
<tr><td>Sex</td><td>53.85% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)

BMI (kg/m2)
Mean (SD)

BMI SD score * according to British reference
Mean (SD)</td><td>Group Intervention: 87.9
(12)

Group Intervention: 26.9
(4.2)

Group Intervention: 2.76
(0.58)</td><td>Individual Family Intervention:
89.2
(11.9)

Individual Family Intervention:
27.6
(4.3)

Individual Family Intervention:
2.81
(0.6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Waist Circumference (cm)
Mean (95% CIs)</td><td>Group Intervention: -0.99
(-2.78-0.81)</td><td>Individual Family Intervention:
0.95
(-0.89-2.79)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Waist Circumference (cm)
Mean (95% CIs)

Change in BMI
Mean (SD)

Change in BMI SDS
Mean (SD)</td><td>Group Intervention: 1.99
(-0.05-4.02)

Group Intervention: 2.1

Group Intervention: -0.24</td><td>Individual Family Intervention:
4.24
(2.2-6.29)

Individual Family Intervention:
3

Individual Family Intervention:
-0.13</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td>Kokkvoll, A., Grimsgaard, S., Steinsbekk, S., Flægstad, T., & Njølstad, I. (2015). Health in overweight children: 2-year follow-up of Finnmark Activity School--a randomised trial. Archives of Disease in Childhood, 100(5), 441-448. https://doi.org/10.1136/archdischild-2014-307107</td></tr>
</table>

contribute additional data	

N/A – Not applicable

Kolt, 2012

Guideline record ID: 10779--1

Study characteristics		
Citation	Kolt, G. S., Schofield, G. M., Kerse, N., Garrett, N., Ashton, T., & Patel, A. (2012). Healthy Steps trial: pedometer-based advice and physical activity for low-active older adults. The Annals of Family Medicine, 10(3), 206-212. https://doi.org/https://dx.doi.org/10.1370/afm.1345	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Healthy Steps trial: pedometer-based advice and physical activity for low-active older adults	
Location	New Zealand	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria included an age of 65 years or older, ability to communicate in English, ability to give informed consent, residing in the community, ability to walk, and freedom from health conditions that contraindicate participation in physical activity."	
Exclusion criteria	"Exclusion criteria included visual impairment that would make it impossible to read a pedometer screen."	
Setting	GP clinic, Home	
Intervention	"Participants in the pedometer based Green Prescription group received initial face-to-face advice on engaging in physical activity from their physician that was then followed up by 3 telephone counseling sessions by trained physical activity counselors over 3 to 4 months. Telephone counseling call 1 focused on information provision and goal setting (15-30 minutes), call 2 focused on assessing progress and further goal setting (10-15 minutes), and call 3 provided further encouragement and discussions around relapse prevention (10-15 minutes). All participants took part in all sessions. Goal setting based on steps was used as a main component of this intervention, and participants were encouraged to use their pedometer to monitor steps taken throughout the day. Goals were set by participants as part of their interaction with the physical activity counselor, in which they received guidance on how to set relevant goals based on identified barriers and on factors that enable increasing activity. Individual goals were predominantly based on pursuing activities that increase step counts in an incremental manner over time, and were dependent on identified lifestyle factors, accessibility to facilities, level of mobility, and current level of activity. Some goals were specifically based on engaging in an activity and receiving feedback via the pedometer on step-based gains, whereas other goals were based on increasing the number of steps per day (eg, by 1,000 steps). Examples of goals included walking rather than driving to the shopping center to accumulate 1,500 steps, walking to a friend's house rather than using the telephone, and participating in an older adult dance activity at the local community center. We did not specifically use the 10,000 steps target used in some other studies."	
Control/Comparator	"Participants in the standard Green Prescription group received the same intervention as the pedometer based Green Prescription group, with the exception that counseling focused on accumulating physical activity around time-related goals rather than step-related goals."	
Treatment duration	3 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 330
Intervention group/s: Pedometer Green Pescription (n=165)

Comparator group: Standard Green Pescription (n=165)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 74.3y (6.2); Control: 73.9y (5.9)</td></tr>
<tr><td>Sex</td><td>53.94% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (95% CIs)</td><td>Pedometer Green Pescription:
27.2
(26.4-28)</td><td>Standard Green Pescription:
27.2
(26.4-28)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (95% CIs)</td><td>Pedometer Green Pescription:
27
(26.2-27.8)</td><td>Standard Green Pescription:
27
(26.2-27.8)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Koschker, 2023

Guideline record ID: 12016--1

Study characteristics		
Citation	Koschker, A.-C., Warrings, B., Morbach, C., Seyfried, F., Jung, P., Dischinger, U., Edelmann, F., Herrmann, M. J., Stier, C., Frantz, S., Malzahn, U., Störk, S., Fassnacht, M., & WAS study group. (2023). Effect of bariatric surgery on cardio-psycho-metabolic outcomes in severe obesity: a randomized controlled trial. Metabolism, 147, 155655. https://doi.org/https://doi.org/10.1016/j.metabol.2023.155655	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of bariatric surgery on cardio-psycho-metabolic outcomes in severe obesity: A randomized controlled trial	
Location	Germany	
Trial name	The WAS trial	
Methods		
Inclusion criteria	"Age ≥18 years, BMI >40 kg/m2 or BMI >35 kg/m2 with severe comorbidities, Indication for Roux-en-Y gastric bypass surgery (RYGB), Ability to perform cardiopulmonary exercise testing (CPET), written informed consent."	
Exclusion criteria	"Pregnancy or breast feeding, Unstable angina pectoris, Life expectancy <12 months, Endocrine or psychiatric disorder as cause of obesity, Systemic glucocorticoid treatment (with exception of glucocorticoid replacement therapy), Abuse of drugs or alcohol within the last 5 years, Inability to attend regular study visits for logistic reasons,Participation of competing trials."	
Setting	Hospital	
Intervention	"Roux-en-Y gastric bypass (RYGB) surgery"	
Control/Comparator	"12- month psychotherapy-enhanced lifestyle intervention (PELI)."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Weight for height growth chart	
Participant characteristics		
Number of participants	n= 60 Intervention group/s: RYGB (n=25) Comparator group: PELI (n=35)	
Mean age ± SD	Intervention: 42.6y (10.3y); Control: 38.7y (9.9y)	
Sex	88.33% female	
Pre-existing medical condition		
Results		
Outcome measure at baseline	Variable / Intervention arm/s / Comparator	

Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Body weight (kg) Mean (95% CIs) BMI (kg/m2) Mean (95% CIs) Waist circumference (cm) Mean (95% CIs)	RYGB: -47.1 (-53.2--41.1) RYGB: -17.1 (-19.5--14.7) RYGB: -30.8 (-36.9--24.8)	PELI: -2 (-4.5-0.6) PELI: -0.7 (-1.5-0.2) PELI: -2.4 (-6.5-1.7)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Kosiborod, 2023

Guideline record ID: 12017--1

Study characteristics		
Citation	Kosiborod, M. N., Abildstrøm, S. Z., Borlaug, B. A., Butler, J., Rasmussen, S., Davies, M., Hovingh, G. K., Kitzman, D. W., Lindegaard, M. L., Møller, D. V., Shah, S. J., Treppendahl, M. B., Verma, S., Abhayaratna, W., Ahmed, F. Z., Chopra, V., Ezekowitz, J., Fu, M., Ito, H., . . . for the STEP-HFpEF Trial Committees and Investigators. (2023). Semaglutide in patients with heart failure with preserved ejection fraction and obesity. The New England Journal of Medicine, 389(12), 1069-1084. https://doi.org/10.1056/NEJMoa2306963	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Semaglutide in Patients with Heart Failure with Preserved Ejection Fraction and Obesity	
Location	USA, Argentina, Australia; Canada; Czechia; Denmark; Germany; Hungary; Israel; Netherlands; Poland; Spain; UK	
Trial name	STEP-HFpEF	
Methods		
Inclusion criteria	"Male or female, age above or equal to 18 years at the time of signing informed consent. Body mass index (BMI) greater than or equal to 30.0 kg/m^2 New York Heart Association (NYHA) Class II-IV Left ventricular ejection fraction (LVEF) greater than or equal to 45 percentage at screening."	
Exclusion criteria	"A self-reported change in body weight greater than 5 kg (11 lbs) within 90 days before screening irrespective of medical records Haemoglobin A1c (HbA1c) greater than or equal to 6.5 percentage (48 mmol/mol) based on latest available value from medical records, no older than 3 months or if unavailable a local measurement at screening."	
Setting	Hospital, University/research centre	
Intervention	"Once weekly subcutaneous semaglutide at a dose of 2.4 mg for 52 weeks, followed by a 5-week follow-up period."	
Control/Comparator	"Once weekly subcutaneous placebo for 52 weeks, followed by a 5-week follow-up period."	
Treatment duration	52 weeks	
Follow-up from baseline	52 weeks	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 529 Intervention group/s: Semaglutide (n=263) Comparator group: Placebo (n=266)	
Mean age ± SD	69y (62y-75y)	
Sex	56.14% female	
Pre-existing medical condition	Left ventricular ejection fraction of at least 45%	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Baseline BMI (kg/m2)
Median (IQR)

Baseline body weight
Median (IQR)

Baseline waist circumference
Median (IQR)</td><td>Semaglutide: 37.2
(33.9-41.1)

Semaglutide: 104.7
(92.4-120.1)

Semaglutide: 119
(110.5-127.1)</td><td>Placebo: 36.9
(33.3-41.6)

Placebo: 105.3
(92.4-122)

Placebo: 120
(110.5-129)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Greater than or equal to 10% percentage reduction in body weight
Proportion (%)

Greater than or equal to 15% percentage reduction in body weight
Proportion (%)

Greater than or equal to 20% percentage reduction in body weight
Proportion (%)</td><td>Semaglutide: 65.9

Semaglutide: 43.9

Semaglutide: 23.6</td><td>Placebo: 9.5

Placebo: 2.1

Placebo: 0.4</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Percentage change in body weight from baseline to week 52
Mean (SD)

Change from baseline to week 52 in waist circumference - cm
Mean (SD)

Greater than or equal to 15% percentage reduction in body weight at week 52 - % of participants</td><td>Semaglutide: -13.3

Semaglutide: -11.7

Semaglutide: 43.9</td><td>Placebo: -2.6

Placebo: -2.7

Placebo: 2.1</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Kouwenhoven-Pasmooij, 2018

Guideline record ID: 10780--1

Study characteristics		
Citation	Kouwenhoven-Pasmooij, T. A., Robroek, S. J. W., Kraaijenhagen, R. A., Helmhout, P. H., Nieboer, D., Burdorf, A., & Hunink, M. G. M. (2018). Effectiveness of the blended-care lifestyle intervention 'PerfectFit': a cluster randomised trial in employees at risk for cardiovascular diseases. BMC Public Health, 18, 766. https://doi.org/10.1186/s12889-018-5633-0	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effectiveness of the blended-care lifestyle intervention 'PerfectFit': a cluster randomised trial in employees at risk for cardiovascular diseases	
Location	Netherlands	
Trial name	PerfectFit	
Methods		
Inclusion criteria	"Inclusion criteria were: 1) having angina or myocardial infarction in first degree relatives; 2) not meeting the Dutch physical activity norm of exercising five times a week at moderate intensity for at least half an hour; 3) smoking; 4) self-reported diabetes mellitus or random glucose ≥ 11.1 mmol/l; 5) obesity (BMI ≥ 30 kg/m2 and / or waist circumference ≥ 102 cm for men or BMI ≥ 30 kg/m2 and/or ≥ 88 cm for women); 6) hypertension (diastolic value > 90 mmHg or a systolic value > 140 mmHg) or the use of antihypertensive drugs); and 7) dyslipidaemia (total cholesterol ≥ 5 mmol/l or LDL cholesterol ≥ 2.5 mmol/l or triglycerides: ≥ 1.7, mmol/l or HDL cholesterol: ≤ 1.0 mmol/l)."	
Exclusion criteria	Not reported	
Setting	Workplace	
Intervention	"The extensive intervention group, the intervention was extended, with: c) Seven individual coaching sessions (3 face-to-face and 4 by telephone) with an occupational health physicians (OP), together with more personalized suggestions for health promotion activities based on motivational elements in the Health Risk Assessment (HRA), and an additional motivational paragraph in the newsletters. During the coaching sessions, the OP applied a client-centered counselling style with MI techniques such as asking open questions, reflecting, supporting, and raising ambivalence. Starting point of the counselling was problem feedback by discussing the person's CVD risk profile and motivation to change health behaviour, which was integrated with important life goals and values. All OPs in the extensive intervention group received a basic training in MI of 3 full days and 3 follow-up coaching sessions of 4 h."	
Control/Comparator	"The limited (control) intervention programme consisted of the following elements: a) A web-based Health Risk Assessment (HRA), including tailored and personalized feedback based on the participant's risk profile, Health behaviours addressed were physical activity (PA), fruit and vegetables, smoking, alcohol, and perceived stress. Compliance with the Dutch guideline on physical activity (PA) was measured by asking 'are you at least 5 days a week, for at least 30 minutes per day, physically active at a moderate intensity (i.e. with a slightly increased heart rate and breathing rate, such as in vigorous walking or cycling), with suggestions for particular health promotion activities, available within each organisation. b) An electronic newsletter, providing information on the intervention (PerfectFit) and general information on a healthy lifestyle, which was sent to email-addresses using newsletter-software, every 2 to 3 months during the study period."	
Treatment duration	12 months	

<table>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 491
Intervention group/s: Extensive intervention (n=274)

Comparator group: Limited intervention (n=217)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 50.19y (5.6); Control: 51.62y (6.0)</td></tr>
<tr><td>Sex</td><td>18.74% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>Extensive intervention: 27.5 (3.6)</td><td>Limited intervention: 26.9 (3.4)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m),
Mean (95% CIs)

Change in Bodyweight (kg)
Mean (95% CIs)</td><td>Extensive intervention: -0.69 (-1--0.39)

Extensive intervention: -3.12 (-4.26--1.99)</td><td>Limited intervention: 0.24 (-0.2-0.67)

Limited intervention: 0.17 (-1.44-1.77)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Intervention-group only: MI-adherence (%, SD) 83.7 (9.7)</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Kuller, 2012

Guideline record ID: 10407--1

Study characteristics		
Citation	Kuller, L. H., Pettee Gabriel, K. K., Kinzel, L. S., Underwood, D. A., Conroy, M. B., Chang, Y., Mackey, R. H., Edmundowicz, D., Tyrrell, K. S., Buhari, A. M., & Kriska, A. M. (2012). The Women on the Move Through Activity and Nutrition (WOMAN) study: final 48-month results. Obesity, 20(3), 636-643. https://doi.org/https://dx.doi.org/10.1038/oby.2011.80	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Women on the Move Through Activity and Nutrition (WOMAN) study: final 48-month results	
Location	US	
Trial name	Women on the Move through Activity and Nutrition (WOMAN)	
Methods		
Inclusion criteria	"Eligible women were between the ages of 52 and 62 years, had a BMI of 25-39.9kg/m2, waist circumference >80cm diameter, BP <140/90mmHg, with or without antihypertensive therapy, not on lipid-lowering drug therapy, LDL cholesterol (LDL-C) between 100 and 160 mg% and no history of CVD."	
Exclusion criteria	Not reported	
Setting	University/research centre	
Intervention	"The intervention was primarily group-based and was facilitated by a multidisciplinary team of nutritionists, exercise physiologists, and psychologists. Contact was frequent throughout the program with 40 visits during the first year and a minimum of 12 monthly visits in year 2 and beyond. Dietary goals for the intervention (Lifestyle Change) group were to reduce the saturated fat to <7% of total energy or <10g/day, reduction in total energy intake to 1,300 cal or 1,500 cal when baseline body weight was >175 lbs to support a 10% loss of weight and a decrease in waist circumference. They were also encouraged to increase the use of foods high in soluble fiber and nutrient-dense, high-volume, low-caloric foods such as fruits, vegetables, and whole grains. Also, during the first year of the intervention consumption of functional foods such as stanol esther containing margarines, soy products and n-3 fatty acids from fish were encouraged. The physical activity component of the lifestyle intervention began after the first 6 months of group initiation. It was a stepped care approach to reach 150min/week of moderate intensity physical activity as the standard minimum goal for all women. Women who reached the minimum goal were then encouraged to increase to 180min and then to 240min/week. Resistance training of large skeletal muscle groups was also encouraged to facilitate beneficial body composition changes and bone health."	
Control/Comparator	"The Health Education group had a series of six seminars during the first year of participation and then several times per year through 36 months. Most of these sessions focused on women's health and not specifically on CV risk factors."	
Treatment duration	30 months	
Follow-up from baseline	48 months	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 508
Intervention group/s: Lifestyle Change (n=253)

Comparator group: Health Education (n=255)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 56.9y (2.94); Control: 57.1y (2.94</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg) Mean (SD)

Waist circumference change (cm)</td><td>Lifestyle Change: -7.8 (7.1)

Lifestyle Change: -9.8 (7.7)</td><td>Health Education: -1.6 (5.5)

Health Education: -3.6 (6.3)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg) Mean (SD)

Waist circumference change (cm)</td><td>Lifestyle Change: -3.4 (7.2)

Lifestyle Change: -7.7 (8.5)</td><td>Health Education: -0.2 (5.6)

Health Education: -4.3 (6.8)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Gabriel, K. K. P., Conroy, M. B., Schmid, K. K., Storti, K. L., High, R. R., Underwood, D. A., Kriska, A. M., & Kuller, L. H. (2011). The impact of weight and fat mass loss and increased physical activity on physical function in overweight, postmenopausal women: results from the Women on the Move Through Activity and Nutrition study. Menopause, 18(7), 759-765. https://doi.org/https://dx.doi.org/10.1097/gme.0b013e31820acdcc</td></tr>
</table>

N/A – Not applicable

Kumanyika, 2012

Guideline record ID: 10408--1

Study characteristics		
Citation	Kumanyika, S. K., Fassbender, J. E., Sarwer, D. B., Phipps, E., Allison, K. C., Localio, R., Morales, K. H., Wesby, L., Harralson, T., Kessler, K., Tan-Torres, S., Han, X., Tsai, A. G., & Wadden, T. A. (2012). One-year results of the Think Health! study of weight management in primary care practices. Obesity, 20(6), 1249-1257. https://doi.org/10.1038/oby.2011.329	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	One-year results of the think health! Study of weight management in primary care practices	
Location	USA	
Trial name	Think Health!	
Methods		
Inclusion criteria	"Eligible participants were men and women ages 18-70 years, with a BMI ≥27kg/m2 and ≤55kg/ m2 and weighing less than 182kg (400lb), who had been patients at the practice for at least 1 year or seen at the practice at least twice."	
Exclusion criteria	"Exclusions were: being pregnant or lactating; being nonambulatory; taking systemic steroids, second generation anti-psychotics, or mood stabilizing agents (for which weight gain is often a side effect); undergoing active cancer treatment; and having unstable cardiovascular disease or significant mental health conditions."	
Setting	GP clinic	
Intervention	"The moderate-intensity Think Health! condition ("Basic Plus") offered about 2-4h total contact over an entire year (10-15min sessions every 4 months with the PCP and similarly brief contacts with a LC monthly. Think Health! advised a dietary pattern consistent with the US Dietary Guidelines (18) while reducing dietary fat and other sources of calories. Recommended calorie levels were 1,200-1,499 for individuals weighing less than 100kg (220lb) and usually 1,500-1,800kcal/d for those weighing more than 100kg. The weight loss goal was 5-10% of initial weight; the physical activity goal was to achieve at least 150min of moderate activity per week. The 16 core DPP sessions were modified based on a prior DPP adaptation (19) (see Supplementary Appendix online). Some DPP core content was put in supplemental handouts, and some was shifted to the maintenance period in the second year of treatment. The amount of content conveyed per session was reduced to a set of key points that could be summarized in a two-page handout (19). These handouts were packaged in participant manuals (see Figure 1), which also included a CD with audio narration of the first 12 sessions, supplemental handouts, and food and activity record forms (Keeping Track logs), along with a calorie counter and resistance band to assist with adherence. Handouts and the audio narration were in both English and Spanish. For Think Health! the initial intervention period was extended to 1 year rather than the 24 week core in DPP. The DPP initially offered highintensity contact (30-60min sessions, weekly, for about 6 months, or 8-16 contact hours over 6 months). Contact was then tapered to every-othermonth at a minimum for the remainder of the first year."	
Control/Comparator	"The comparison condition ("Basic") offered only the brief PCP counseling every 4 months. Think Health! advised a dietary pattern consistent with the US Dietary Guidelines (18) while reducing dietary fat and other sources of calories. Recommended calorie levels were 1,200-1,499 for individuals weighing less than 100kg (220lb) and usually 1,500-1,800kcal/d for those weighing more than 100kg. The weight loss goal was 5-10% of initial weight; the physical activity goal was to achieve at least 150min of moderate activity per week. The 16 core DPP sessions were modified based on a prior DPP adaptation (19) (see Supplementary Appendix online). Some DPP core content was put in supplemental handouts, and some	

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<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 261
Intervention group/s: Basic Plus (n=124)

Comparator group: Basic (n=137)</td></tr>
<tr><td>Mean age ± SD</td><td>47.2y (11.7)</td></tr>
<tr><td>Sex</td><td>84.29% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline Mean (SD)

BMI (kg/m2) - Baseline Mean (SD)</td><td>Basic Plus: 100.7 (18.7)

Basic Plus: 37.2 (6.5)</td><td>Basic: 101.6 (20.9)

Basic: 37.3 (6.4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of participants who lost >5% of baseline weight Proportion (%)</td><td>Basic Plus: 22.5</td><td>Basic: 10.2</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg) Mean (SD)</td><td>Basic Plus: -1.61 (5.1)</td><td>Basic: -0.62 (4.1)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>A total of 116 (85%) of 137 randomized participants in Basic and 118 (95%) of the 124 participants in Basic Plus initiated treatment by attending at least one visit with a PCP or LC within their first 12 months in the study. more than half (58 and 66%, respectively) of Basic</td></tr>
</table>

	and Basic Plus participants attended at least two of the four possible year 1 PCP visits, and about 40% in each treatment group attended at least three of four visits. In Basic Plus, 44% of participants attended at least five of the possible 13 LC visits.
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Larsen, 2016

Guideline record ID: 10414--1

Study characteristics		
Citation	Larsen, K. T., Huang, T., Ried-Larsen, M., Andersen, L. B., Heidemann, M., & Møller, N. C. (2016). A multi-component day-camp weight-loss program is effective in reducing BMI in children after one year: a randomized controlled trial. PLOS ONE, 11(6), e0157182. https://doi.org/https://dx.doi.org/10.1371/journal.pone.0157182	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A Multi-Component Day-Camp Weight-Loss Program Is Effective in Reducing BMI in Children after One Year: A Randomized Controlled Trial	
Location	Denmark	
Trial name	Odense Overweight Intervention Study (OOIS)	
Methods		
Inclusion criteria	"Fifth grade primary school children in the Municipality of Odense. Children with a BMI above the limit for overweight according to the International Obesity Task Force (IOTF)."	
Exclusion criteria	"Exclusion criteria included: 1. Children participated in other intervention research involving cardiovascular risk management. 2. Children that did not attend a regular school due to personal problems of psycho-social nature. 3. Children taking any medications, during three months prior to entering the study, which are known to affect weight status. 4. Children with a known endogenous cause of overweight. 5. Children with a motor-control handicap that prohibited normal participation in physical activity."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs), Day camp	
Intervention	"The day camp was located in the city of Odense, Denmark, and took place from mid-May to the end of June in 2012 and 2013, respectively. The camp lasted for six consecutive weeks, seven days a week. The children arrived every morning at 7 a.m. and left at 8.30 p.m. Except for commuting between home and the day-camp, children typically stayed at home with their families outside this time period. Each day the children were engaged in minimum three hours of exercise with a focus on physical activity enjoyment and motivation (e.g. dancing, team building, and alternative ball-games), one hour of health classes (focused on theory and behavior change), and one hour of homework assignment (as the intervention took place during school weeks). Trained instructors planned and conducted the intervention components and supported the children during the day-camp. Meals were prepared, supervised and guided by the camp instructors according to the national Danish dietary recommendations, but no caloric restriction was enforced. During the intervention period, parents received written information about the intervention, healthy cooking in the household, and advice on how best to support the child's health behavior. Furthermore, parents participated in a dietary course, with the children at the camp, led by a certified dietician. Subsequent family-based intervention. After the six week intervention, a family-based intervention including four joint meetings during the subsequent 46 weeks was conducted. The meetings were led by trained school nurses and instructors from the day-camp intervention. At all meetings, the families discussed and shared experiences related to a chosen topic. After the second meeting, an "activity day" was arranged for the children by the camp instructors in order to support and motivate the children for the remaining intervention period."	
Control/Comparator	"For comparison with the day-camp program, a short term and low intensive weight-loss program was constructed. The standard intervention consisted of one weekly exercise session (two hours duration) for six weeks, as well as a single health and lifestyle educational session for the parents, delivered by a dietician and a physical activity	

<table>
<tr><td></td><td>specialist. The standard intervention program was taking place simultaneously with the day-camp program and ended after six weeks.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 106
Intervention group/s: Day Camp Intervention (n=55)

Comparator group: Standard Intervention (n=51)</td></tr>
<tr><td>Mean age ± SD</td><td>12.0y (0.4)</td></tr>
<tr><td>Sex</td><td>55.66% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Day Camp Intervention: 25.2 (2.8)</td><td>Standard Intervention: 24.5 (2.9)</td></tr>
<tr><td>BMI z-score
Mean (SD)</td><td>Day Camp Intervention: 1.99 (0.46)</td><td>Standard Intervention: 1.87 (0.51)</td></tr>
<tr><td>Total body fat (%)
Mean (SD)</td><td>Day Camp Intervention: 39.5 (6.2)</td><td>Standard Intervention: 39.2 (6.2)</td></tr>
<tr><td>Abdominal fat (%)
Mean (SD)</td><td>Day Camp Intervention: 48 (7.1)</td><td>Standard Intervention: 47.5 (7.3)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Day Camp Intervention: 85.5 (7.8)</td><td>Standard Intervention: 82.4 (8.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Day Camp Intervention: 23.8 (3.1)</td><td>Standard Intervention: 24.8 (3.7)</td></tr>
<tr><td>BMI z-score
Mean (SD)</td><td>Day Camp Intervention: 1.53 (0.63)</td><td>Standard Intervention: 1.73 (0.66)</td></tr>
<tr><td>Total body fat (%)
Mean (SD)</td><td>Day Camp Intervention: 34.4 (7.3)</td><td>Standard Intervention: 37.3 (8.1)</td></tr>
<tr><td>Abdominal fat (%)
Mean (SD)</td><td>Day Camp Intervention: 41.5 (9.6)</td><td>Standard Intervention: 44.2 (9.9)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Day Camp Intervention: 79.8 (8.3)</td><td>Standard Intervention: 79.8 (9)</td></tr>
</table>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to</td><td>
<table>
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<table>
<tr><td>12 months or closest time point</td><td></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>During the six-week camp period, 50 out of 52 children who initiated the camp program completed the six weeks according to the predetermined acceptable attendance rate (85% of the total time). Twenty-five children (48.1%) lived up to the predefined attendance rate during the subsequent family-based intervention period (4 of 6 meetings).</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Latner, 2013

Guideline record ID: 10415--1

Study characteristics		
Citation	Latner, J. D., Ciao, A. C., Wendicke, A. U., Murakami, J. M., & Durso, L. E. (2013). Community-based behavioral weight-loss treatment: long-term maintenance of weight loss, physiological, and psychological outcomes. Behaviour Research and Therapy, 51(8), 451-459. https://doi.org/https://dx.doi.org/10.1016/j.brat.2013.04.009	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Community-based behavioral weight-loss treatment: long-term maintenance of weight loss, physiological, and psychological outcomes	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Participants included overweight or obese men and women between the ages of 20e72, with a Body Mass Index (BMI; kg/m2) $\geq$26."	
Exclusion criteria	"Participants were excluded from the study if they were currently in another weight control program, had a current or past weight-related medical disorder (e.g., diabetes), were taking medications affecting weight and had not been on a stable dose for at least 2 months, had a current or past severe psychiatric disorder, were planning to move in the following two years, or were pregnant or breastfeeding in the past year or were planning to become pregnant in the following 2 years."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Participants in both standard care and continuing care received 20 sessions of behavioral weight loss treatment over a six-month period. Participants in continuing care were taught continuing care self-support strategies and instructed to continue meeting weekly on their own throughout the 18 months following treatment. Treatment was administered in group format with 10-15 participants per group. Each session lasted approximately 2 h, and groups met at participants' own local community organizations. The content of group meetings was based on the Diabetes Prevention Program (DPP) treatment manual (http://www.bsc.gwu. edu/dpp/lifestyle/dpp_acor.html), which has demonstrated efficacy in the treatment of obesity and prevention of diabetes (Diabetes Prevention Program Research Group, 2002). Treatment principles focused on behavior modification and developing and maintaining healthy eating behaviors and physical activity (with a goal of 150 min of moderate activity per week). Thus, meetings focused on teaching behavior change strategies (e.g., selfmonitoring food intake, slowing down eating), reviewing participants' progress, helping participants set specific eating and physical activity goals for the week, and providing positive reinforcement and group support. The DPP treatment manual was adapted for group format and expanded by culturally tailoring the program to the unique population while retaining all key elements of the original treatment. After receiving the treatment, all participants were provided with a maintenance manual of additional behavioral strategies and skills. participants assigned to continuing care were additionally trained to guide mutually supportive groups of their peers in their joint efforts to maintain lost weight. During treatment, each group recruited two volunteer co-facilitators from within the group who committed to continue guiding the group in weekly meetings following treatment. These co-facilitators were assigned the responsibility of leading their group. Those participants willing to continue facilitating groups for an 18-month period were chosen as co-facilitators. However, it was anticipated that the length of time that each volunteer would be willing to remain in the leadership role might vary. Thus, co-facilitators were encouraged to commit to the position for at least six months, though preferably for 18 months, but groups were informed that if their co-facilitator(s) decided to	

	step down from their volunteer position and resume normal group membership at any point, at this time another volunteer would be selected from the remaining group members. All group members were asked to make a commitment to continue to meet for the 18-months following treatment. Continuing care groups were instructed to choose topics from the maintenance manual to review during weekly maintenance meetings. These groups were given a structure to follow in each meeting, mirroring the format of sessions 1-20. The structure included a review of the past week, discussion of new material selected by group leaders from the maintenance manual, a discussion of challenges faced by group members, goal setting, and ending with a positive statement made by each group member. The two initial treatment groups were co-facilitated by a doctorate-level psychologist and a masters-level psychology graduate student (ACC), and subsequent groups were co-led by two masters-level psychology graduate student volunteers (ACC, LED, and three additional therapists) supervised by the doctorate-level psychologist (JDL)."
Control/Comparator	"Participants in both standard care and continuing care received 20 sessions of behavioral weight loss treatment over a six-month period. Treatment was administered in group format with 10-15 participants per group. Each session lasted approximately 2 h, and groups met at participants' own local community organizations. The content of group meetings was based on the Diabetes Prevention Program (DPP) treatment manual (http://www.bsc.gwu. edu/dpp/lifestyle/dpp_acor.html), which has demonstrated efficacy in the treatment of obesity and prevention of diabetes (Diabetes Prevention Program Research Group, 2002). Treatment principles focused on behavior modification and developing and maintaining healthy eating behaviors and physical activity (with a goal of 150 min of moderate activity per week). Thus, meetings focused on teaching behavior change strategies (e.g., selfmonitoring food intake, slowing down eating), reviewing participants' progress, helping participants set specific eating and physical activity goals for the week, and providing positive reinforcement and group support. The DPP treatment manual was adapted for group format and expanded by culturally tailoring the program to the unique population while retaining all key elements of the original treatment. After receiving the treatment, all participants were provided with a maintenance manual of additional behavioral strategies and skills. The two initial treatment groups were co-facilitated by a doctorate-level psychologist and a masters-level psychology graduate student (ACC), and subsequent groups were co-led by two masters-level psychology graduate student volunteers (ACC, LED, and three additional therapists) supervised by the doctorate-level psychologist (JDL)."
Treatment duration	6 months
Follow-up from baseline	18 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 90 Intervention group/s: Continuing care (n=52) Comparator group: Standard care (n=38)
Mean age ± SD	49.65y (12.33)
Sex	64.44% female
Pre-existing medical condition	No pre-existing medical condition
Results	

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Continuing care: 96.39
(27.8)

Continuing care: 35.58
(8.13)

Continuing care: 108.82
(18.83)</td><td>Standard care: 99.34
(27.21)

Standard care: 36.08
(7.76)

Standard care: 113.66
(16.27)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Proportion who lost >5% (% sample)
Proportion (%)

Waist circumference (cm)
Mean (SD)</td><td>Continuing care: 93.96
(28.46)

Continuing care: 34.55
(8.45)

Continuing care: 30.8%

Continuing care: 105.97
(19.68)</td><td>Standard care: 96.07
(27.04)

Standard care: 34.89
(7.75)

Standard care: 21.10%

Standard care: 109.46
(16.96)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Percent weight loss (% initial weight)
Mean (SD)</td><td>Continuing care: 2.71
(4.75)</td><td>Standard care: 3.2
(5.96)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>In both conditions, participants attended a mean of 14 (70%) of 20 sessions. Ninety percent of participants attended at least five sessions.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Leahey, 2015

Guideline record ID: 10418--1

Study characteristics		
Citation	Leahey, T. M., Subak, L. L., Fava, J., Schembri, M., Thomas, G., Xu, X., Krupel, K., Kent, K., Boguszewski, K., Kumar, R., Weinberg, B., & Wing, R. (2015). Benefits of adding small financial incentives or optional group meetings to a web-based statewide obesity initiative. Obesity, 23(1), 70-76. https://doi.org/10.1002/oby.20937	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Benefits of adding small financial incentives or optional group meetings to a web-based statewide obesity initiative	
Location	USA	
Trial name	Shape Up Rhode Island 2012 (SURI)	
Methods		
Inclusion criteria	“Enrolled in SURI and were interested in weight loss were invited to participate.”	
Exclusion criteria	“Exclusion criteria included age <18 or >70; BMI < 25 kg/m2 ; current or planned pregnancy; uncontrolled medical condition (e.g., heart problem); previous study participation; unreliable Internet access; planned relocation; and non-English speaking.”	
Setting	Home, University/research centre	
Intervention	“AII participants received all components described in SI. In addition, they received incentives for adherence and weight loss. Given that website engagement is associated with greater weight loss (15), small financial rewards were provided for website use. Consistent with principles from behavioral economics, we rewarded/incentivized participants frequently, varied the size of the incentive, and did not inform participants of the reinforcement schedule (16-19). Specifically, participants were told that each week they submit at least 5 days of weight, calorie, and activity information into the study website, they would earn anywhere from $1 to $10. To reinforce and engage participants at intervention outset, larger incentives were delivered at the beginning of the program (Week 1: $8, Week 2: $10) and incentive size varied thereafter ($1, $2, $7, etc.). If participants completed all reporting, they earned a maximum of $45 during the entire program. The SII website included a "bank" which displayed the participant's previous week's earnings and total earnings. Weekly reminders to submit information into the study website were framed using regret aversion language ("Don't miss out on your money, be sure to submit your information by Sunday at midnight") (20). In addition, we incentivized achieving a clinically significant weight loss. Those who lost 5-10% of initial body weight were entered into a $50 raffle. Those who lost 10% were entered into a $100 raffle. Ten winners were chosen from each raffle. Participants received all payouts after their 3-month assessment. SIG participants received everything described in SI plus the option to attend weekly group sessions at the research center. Given that SURI is an Internet-based low intensity campaign, we wanted SIG to appeal to the SURI audience and, therefore, made group attendance optional. The 12 weekly sessions were led by dietitians or exercise physiologists, included a private weigh-in, and covered topics that supplemented the Internet program (e.g., recipe modification, exercise motivation).”	
Control/Comparator	“SURI+Internet behavioral weight loss (SI). Participants in SI received the standard 3-month team-based SURI program plus an Internet behavioral weight loss program. As part of the SURI program, participants received access to a website where they submitted weekly weight and activity data, a pedometer, a paper log for recording weight and activity, newsletters and community resources on healthy eating and exercise, and recognition for meeting weight and exercise goals. Given our prior findings that adding an Internet behavioral intervention improved weight losses in SURI (1,3), all participants in SI also	

<table>
<tr><td></td><td>received an Internet behavioral intervention. Before SURI began, participants attended a one time, in-person group session where they received a weight loss goal (lose 1-2 lb/week), calorie and fat gram goals (gradually increase to 250 min/week) and were taught how to selfmonitor and how to use the behavioral weight loss website. The Internet behavioral program included weekly multimedia videos based on the Diabetes Prevention Program (14). It also had a selfmonitoring platform where participants submitted their daily weight, calorie, and activity information and received weekly, automated feedback on their progress. Participants received automated weekly reminders to report their self-monitoring information into the platform. Supporting information on meal plans, prepackaged meals, and meal replacements was also on the website.”</td></tr>
<tr><td>Treatment duration</td><td>3 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 268
Intervention group/s: SII (n=89); SIG (n=88)

Comparator group: SI (n=91)</td></tr>
<tr><td>Mean age ± SD</td><td>46.3y (10.5)</td></tr>
<tr><td>Sex</td><td>82.46% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)</td><td>SII: 92.8
(21.8)
SIG: 92.7
(20)</td><td>SI: 90.1
(17.1)</td></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)</td><td>SII: 33.5
(6.5)
SIG: 34.3
(6.8)</td><td>SI: 32.9
(5.5)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (%)
Mean (95% CIs)</td><td>SII: 3.1
(1.8-4.4)
SIG: 4.5
(3.2-5.8)</td><td>SI: 1.2
(-0.1-2.6)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>LOGIN WEEKS (out of 12): SI: 9.0 (8.3 to 9.7); SII: 10.6 (10.0 to 11.2); SIG: 9.1 (8.3 to 10.0)
LESSONS VIEWED (out of 12): SI: 5.5 (5.0 to 6.4); SII: 7.1 (6.3 to 8.0); SIG: 6.3 (5.4 to 7.1)</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Leehey, 2016

Guideline record ID: 10424--1

Study characteristics		
Citation	Leehey, D. J., Collins, E., Kramer, H. J., Cooper, C., Butler, J., McBurney, C., Jelinek, C., Reda, D., Edwards, L., Garabedian, A., & O''Connell, S. (2016). Structured exercise in obese diabetic patients with chronic kidney disease: a randomized controlled trial. American Journal of Nephrology, 44(1), 54-62. https://doi.org/https://dx.doi.org/10.1159/000447703	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Structured Exercise in Obese Diabetic Patients with Chronic Kidney Disease: A Randomized Controlled Trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	“Eligibility criteria were type 2 DM, obesity (body mass index, BMI >30 kg/m 2), and CKD stages 2-4 (eGFR 15-90 ml/min/ 1.73 m 2) with persistent proteinuria, that is, urine protein/creatinine >200 mg/g for at least 3 months.”	
Exclusion criteria	“Patients were excluded if they had cardiovascular disease precluding participation in an exercise program, moderate to severe congestive heart failure (NYHA class III-IV), moderate to severe chronic obstructive pulmonary disease, history of cerebrovascular accident with cognitive impairment, presence of a renal transplant, or inability to walk on a treadmill.”	
Setting	GP clinic, Hospital, Home	
Intervention	“All participants underwent medical care by their usual physicians, with medications adjusted according to standards of medical practice at the medical center. This included referral to the hospital's MOVE program, a lifestyle modification program including instruction on weight loss and increasing physical activity. The Exercise Plus Diet Group, in addition to nutritional counseling, patients randomized to exercise underwent a supervised exercise program. The principal aerobic training method employed was interval training on a treadmill, supplemented with training on an elliptical trainer and cycle ergometer. Metabolic and hemodynamic measures recorded during the baseline symptom-limited treadmill were used to develop an individualized exercise prescription (table 1). Every training session also included progressive resistance lower body exercise using elastic bands, hand-held weights or weight machine [19] . Supervised exercise was carried out thrice weekly, with approximately 60 min of aerobic and approximately 20-30 min of resistance training each session. The home exercise phase consisted of exercise done either as 60 min thrice weekly or 30 min 6-times a week. During this phase, patients received weekly phone calls and were also encouraged to meet with their trainer on a monthly basis.”	
Control/Comparator	“All participants underwent medical care by their usual physicians, with medications adjusted according to standards of medical practice at the medical center. This included referral to the hospital's MOVE program, a lifestyle modification program including instruction on weight loss and increasing physical activity. The Diet-Alone Group received a nutritional counseling session at baseline with 9 follow-up telephone calls during the study.”	
Treatment duration	52 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 36
Intervention group/s: Exercise + diet (n=18)

Comparator group: Diet alone (n=18)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 65.4y (8.7); Control: 66.6y (7.5)</td></tr>
<tr><td>Sex</td><td>100.00% male</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes, chronic kidney disease (CKD) stages 2-4 (eGFR 15-90 ml/min/ 1.73 m 2) with persistent proteinuria, that is, urine protein/creatinine >200 mg/g for at least 3 months.</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI
Mean (SD)</td><td>Exercise + diet: 36.2
(4.8)</td><td>Diet alone: 37.4
(4.2)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI
Mean (SD)</td><td>Exercise + diet: 36
(6)</td><td>Diet alone: 36.4
(6.2)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>The dietalone group attended slightly more lifestyle modification classes (42%) than did the exercise + diet group (34%).</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Levy, 2010

Guideline record ID: 10427--1

Study characteristics		
Citation	Levy, R. L., Jeffery, R. W., Langer, S. L., Graham, D. J., Welsh, E. M., Flood, A. P., Jaeb, M. A., Laqua, P. S., Finch, E. A., Hotop, A. M., & Yatsuya, H. (2010). Maintenance-tailored therapy vs. standard behavior therapy for 30-month maintenance of weight loss. Preventive Medicine, 51(6), 457-459. https://doi.org/10.1016/j.ypmed.2010.09.010	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Maintenance-tailored therapy vs. standard behavior therapy for 30-month maintenance of weight loss	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"≥ 18 years of age, body mass index (BMI) between 30 and 39 kg/m2, freedom from serious medical conditions, and consent to be randomized to either of the two treatment groups."	
Exclusion criteria	Not reported	
Setting	University/research centre, University of Minnesota	
Intervention	"Standard Behavioral Treatment (SBT) with recommendations for behavior (self-monitoring, calorie counting and goal setting)"	
Control/Comparator	"MTT employed varied behavioral prescriptions with treatment breaks."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 213 Intervention group/s: Standard Behavior Therapy (SBT) (n=106) Comparator group: Maintenance-Tailored Therapy for obesity (MTT) (n=107)	
Mean age ± SD	Intervention: 49.1y (10.6); Control: 48.5y (10.5)	
Sex	53.05% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
BMI (kg/m2) - baseline Mean (SD)	SBT: 35.2 (2.8)	MTT: 34.6

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight change between 18 and 30 months post baseline Mean (SD)</td><td>SBT: 4.1
(4.4)</td><td>MTT: 2.8
(4.5)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Li, 2010

Guideline record ID: 10784--1

Study characteristics		
Citation	Li, Y.-P., Hu, X.-Q., Schouten, E. G., Liu, A.-L., Du, S.-M., Li, L.-Z., Cui, Z.-H., Wang, D., Kok, F. J., Hu, F. B., & Ma, G.-S. (2010). Report on childhood obesity in China (8): effects and sustainability of physical activity intervention on body composition of Chinese youth. Biomedical and Environmental Sciences, 23(3), 180-187. https://doi.org/https://dx.doi.org/10.1016/S0895-3988(10)60050-5	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Report on childhood obesity in China (8): effects and sustainability of physical activity intervention on body composition of Chinese youth	
Location	China	
Trial name	N/A	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	School	
Intervention	"Based on the principle of TAKE10!® (http://www.take10.net), the Happy 10 program was initiated jointly by the National Institute for Nutrition and Food Safety, Chinese Center for Disease Control and Prevention (CDC), and the International Life Science Institute Focal Point in China. It consisted of two daily 10-min physical activity sessions conducted in the break between classes. The program provided a variety of safe, moderate, age-, and space-appropriate exercises. Teaching materials included activity cards, video demonstrations, tracking posters, and stickers. Each activity card introduced one exercise and explained how to perform it. The videos showed students from the pilot study performing the activities. Teachers could either demonstrate the activity or show it on a video. The tracking poster and stickers were used to illustrate the progress of each class. There were several activity models directly from TAKE 10! Program, such as "invisible jump rope"; "copy cat"; "all about you"; "stories on the move!"; "stories in space". Clear introduction were colourfully printed in the activity card. Students, teachers and parents were encouraged to develop new activity models, so did the program staffs. Many new programs, much more than that directly from TAKE 10!, were developed, such as "Story in zoo"; "story in farm"; "who is wearing yellow today"; "time like a colt"; "happy and health"; "little frog". The 10-minute sessions consisted of four parts: 1) the teacher or student selected the cards to determine the activities; 2) several children were chosen to model the exercises in the front of the classroom and the other students followed along (one to three activities were performed at each session); 3) a cool-down period took place after the activities; and 4) the students were taught a health message. If they chose the "invisible jump rope", each student pretended to have an invisible jump rope and began to jump. Teacher called out numbers from 1-10 starting with one. Everyone jumped as they counted up to that number. Starting at 20 and counting backwards, while students did the invisible jump rope backwards. The students jumped more and more quickly as the teacher was increasing the counting speed. Some teachers also combined math calculating into the activities. The average caloric expenditure for both 10-minute sessions ranged from 60 to 70 kcal/ school day, which translated to 43-50 kcal/day, as measured by physical activity sensors[10] . The average metabolic equivalent task (MET) rate/session ranged from 4.8 to 7.3 kcal kg-1 h -1[10]. All activities were of moderate to vigorous intensity."	
Control/Comparator	"No intervention took place in the control schools."	

<table>
<tr><td>Treatment duration</td><td>1 school year</td></tr>
<tr><td>Follow-up from baseline</td><td>2 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 4700
Intervention group/s: Intervention (n=2329)

Comparator group: Control (n=2371)</td></tr>
<tr><td>Mean age ± SD</td><td>9.3y (0.7)</td></tr>
<tr><td>Sex</td><td>47.70% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Overweight children - Weight (kg)
Mean (SD)</td><td>Intervention: 40.5 (4.7)</td><td>Control: 40.4 (4.9)</td></tr>
<tr><td>Overweight children - BMI (kg/m2)
Mean (SD)</td><td>Intervention: 19.98 (1.08)</td><td>Control: 20.03 (1.08)</td></tr>
<tr><td>Overweight children - BMI Z score
Mean (SD)</td><td>Intervention: 1.46 (0.28)</td><td>Control: 1.47 (0.28)</td></tr>
<tr><td>Obese children - Weight (kg)
Mean (SD)</td><td>Intervention: 51.5 (9)</td><td>Control: 52.1 (8.6)</td></tr>
<tr><td>Obese children - BMI (kg/m2)
Mean (SD)</td><td>Intervention: 24.36 (2.7)</td><td>Control: 24.4 (2.61)</td></tr>
<tr><td>Obese children - BMI Z score
Mean (SD)</td><td>Intervention: 2.67 (0.57)</td><td>Control: 2.62 (0.51)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Overweight children - Weight change (kg)
Mean (SD)</td><td>Intervention: 5.2 (3.1)</td><td>Control: 5.4 (2.8)</td></tr>
<tr><td>Overweight children - BMI change (kg/m2)
Mean (SD)</td><td>Intervention: 0.74 (1.39)</td><td>Control: 0.8 (1.26)</td></tr>
<tr><td>Overweight children - BMI Z score change
Mean (SD)</td><td>Intervention: -0.06 (0.41)</td><td>Control: -0.04 (0.41)</td></tr>
</table>
</td></tr>
</table>

	Obese children - Weight change (kg) Mean (SD) Obese children - BMI change (kg/m2) Mean (SD) Obese children - BMI Z score change Mean (SD)	Intervention: 5.7 (3.9) Intervention: 0.56 (1.73) Intervention: -0.2 (0.4)	Control: 6.7 (4) Control: 0.93 (1.65) Control: -0.12 (0.34)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Li, 2019

Guideline record ID: 10428--1

Study characteristics		
Citation	Li, B., Pallan, M., Liu, W. J., Hemming, K., Frew, E., Lin, R., Liu, W., Martin, J., Zanganeh, M., Hurley, K., Cheng, K. K., & Adab, P. (2019). The CHIRPY DRAGON intervention in preventing obesity in Chinese primary-school--aged children: a cluster-randomised controlled trial. PLOS Medicine, 16(11), e1002971. https://doi.org/10.1371/journal.pmed.1002971	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The CHIRPY DRAGON intervention in preventing obesity in Chinese primary-school--aged children: A cluster-randomised controlled trial	
Location	China	
Trial name	Chinese Primary School Children Physical Activity and Dietary Behaviour Changes Intervention (CHIRPY DRAGON)	
Methods		
Inclusion criteria	"All nonboarding, state-funded primary schools (clusters) in traditional urban districts of Guangzhou were eligible. All children from Year-One classes (6-7 years) within the consented schools were eligible."	
Exclusion criteria	Not reported	
Setting	Home, School	
Intervention	"The developed intervention programme included 4 school- and family-based components targeting children, main carers (parents or guardians and grandparents) as well as school physical activity and food provision to encourage physical activity and healthy eating behaviours in children both within and outside of school. A range of stakeholders (parents, grandparents, school teachers, managers and workers of school catering providers, and managers of food stores located near schools) contributed to the prioritisation of intervention components that had previously been identified as promising from published international and Chinese systematic reviews and our own formative research [6,7]. We incorporated a range of behaviour-change techniques and social marketing principles in designing the intervention and tested and refined the programme through a feasibility study. COMPONENT 1: To improve childhood obesity related knowledge, skills and behaviours among children and their main carers. Main Carers: (A) Interactive education workshops for carers with summarising leaflet to take home (focused on correcting common misperceptions identified through our formative research in relation to child healthy weight and healthy behaviours, and introducing practical parenting tips for encouraging healthy behavioural change in children), 2 school based sessions. Children: (B) Interactive educational activities for children (focused on key messages related to healthy eating and an active lifestyle), 4 school based sessions. Children and their main carers: (C) Child setting challenging but achievable healthy behaviour goals & child self-monitoring, with parent and CHIRPY DRAGON teacher feedback and prize for highest achievers (see next page for examples and explanation of child self-monitoring fun cards), Home based. Predetermined daily themes (eating at least five portions of fruit and vegetables daily; engaging in no more than 2 hours of sedentary screen-based activities a day; and consuming fewer snacks and drinks that are high in sugar and/or fats) were rotated every 2 weeks, plus one continuous weekend challenge (see Component 3, part B), (D) Health knowledge quiz, 1 school based session. COMPONENT 2: School lunch providers and catering staff: (A) Introduce school lunch improvement goals that were agreed jointly by researchers and school lunch providers and then tested by school lunch providers (including both commercial suppliers and school funded catering units), 1 introduction meeting held in the Guangzhou CDC, (B)Supportive evaluation of school lunch provision against agreed goals and feedback, Continued throughout the intervention year, school-	

<table>
<tr><td></td><td>based. COMPONENT 3: Children and their parents: (A)Taster session to teach fun & active family games that could be undertaken with minimal equipment and space at home, 2 school based sessions. (B)Assign homework (a family-wide healthy behaviour challenge) - practicing taught family games or other non-sedentary activities involving the child and parents for at least 30 minutes every weekend, home based, continuous weekend challenge. COMPONENT 4. Children and school staff: (A) Situation analysis in relation to current implementation of the Chinese national standard of having one-hour physical activity on campus every school day, (B) Setting monthly goals (measurable and achievable) and action plans to meet, maintain or exceed the national standard, with continuous evaluation and feedback, monthly school-based. meetings held throughout the intervention year”</td></tr>
<tr><td>Control/Comparator</td><td>“Schools assigned to the control arm continued with their usual provision during the full trial period with no access to any of the CHIRPY DRAGON intervention activities and resources.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 1641
Intervention group/s: Intervention (n=832)

Comparator group: Control (n=809)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 6.15y (0.36); Control: 6.14y (0.35)</td></tr>
<tr><td>Sex</td><td>45.52% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Prevalence of overweight/obesity Proportion (%)</td><td>Intervention: 18.0%</td><td>Control: 17.9%</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Prevalence of overweight/obesity Proportion (%)</td><td>Intervention: 15.5%</td><td>Control: 18.8%</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Lier, 2012

Guideline record ID: 10433--1

Study characteristics		
Citation	Lier, H. Ø., Biringer, E., Stubhaug, B., & Tangen, T. (2012). The impact of preoperative counseling on postoperative treatment adherence in bariatric surgery patients: a randomized controlled trial. Patient Education and Counseling, 87(3), 336-342. https://doi.org/https://dx.doi.org/10.1016/j.pec.2011.09.014	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The impact of preoperative counseling on postoperative treatment adherence in bariatric surgery patients: a randomized controlled trial	
Location	Norway	
Trial name	N/A	
Methods		
Inclusion criteria	"Patients with obesity referred for bariatric surgery from general practitioners (GPs) to the Department of Surgery at Haugesund Hospital on the West coast of Norway."	
Exclusion criteria	"Pregnancy, bariatric surgery at private hospitals, did not want bariatric surgery, lack of consent, or severe mood or eating disorder."	
Setting	Hospital	
Intervention	"The intervention group received a cognitive-behavioral treatment program prior to gastric bypass surgery. The program included: one preoperative group session weekly for six weeks and three postoperative group sessions (about six months, one year and two years after surgery). The intervention was given by a team of three professionals (psychiatrist, psychologist, and physiotherapist) who applied a semi-structured therapy manual based on principles from cognitive therapy and mindfulness training. Each session lasted for about three hours including mindfulness training (one hour). The main components of the intervention were: Information about bariatric surgery and appropriate eating and physical exercise behavior change. Problem solving skills and cognitive restructuring techniques. Mindfulness training focused on stress reduction techniques such as breathing and yoga exercises and mindfulness-based practices regarding food consumption. Introduction of diary keeping for eating, physical activity, and mindfulness training. Real-time self monitoring of eating behavior was initiated from the beginning of counseling and was continued throughout treatment. Homework: diary for food intake, diary for planned and executed exercise, and mindfulness training (instruction on a CD for 20- 30 min, six days a week). We encouraged the participants to eat three to four balanced meals and two snacks daily and to engage in physical activities for at least 30 min daily (physical activity that they were able to perform with their physical limitations). A person who had undergone bariatric surgery and agreed to participate in one of the sessions shared with them his/her personal history of the challenges that follow surgery. The patients were encouraged to register daily food intake and physical exercise, which was then discussed in the group sessions. All patients were encouraged to engage in physical activity for at least 30 min each day. Obstacles to do so, including cognitions about exercise, were discussed. At the last group session, the patients were asked their opinion about the usefulness of the treatment program in regards to preparing them for bariatric surgery and giving them a better understanding of the consequences of bariatric surgery and the recommendations concerning eating habits and physical exercise."	
Control/Comparator	"Patients in the Control group received ''treatment as usual'' prior to gastric bypass surgery, which included two four hours educational seminars: one preoperative and one postoperative. These seminars included information about the surgical procedure from the surgeon and information about dietary strategies and behaviors associated with beneficial	

<table>
<tr><td></td><td>nutritional outcomes from a dietician. In addition, a former patient who had undergone bariatric surgery told them about the experiences and the challenges after the operation. The preoperative, but not the postoperative, seminar was mandatory. About 25% of the patients who had undergone bariatric surgery at our centre participated in the postoperative seminar.”</td></tr>
<tr><td>Treatment duration</td><td>6 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>58 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 97
Intervention group/s: Treatment group (n=49)

Comparator group: Control group (n=48)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 43.5y (11.1); Control: 42.4y (9.1)</td></tr>
<tr><td>Sex</td><td>70.10% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2) - Baseline
Mean (SD)</td><td>Treatment group: 45.5
(4.3)</td><td>Control group: 45.1
(5.9)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight lost one year after surgery
Mean (SD)

50% Excess Weight Lost Proportion (%)</td><td>Treatment group: 46.1
(9.9)

Treatment group: 91.0%</td><td>Control group: 42.9
(12.7)

Control group: 85.00%</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Of the patients in the Treatment group, 35 patients (83%) attended at least five of the preoperative sessions, and 23 patients (55%) attended at least two of the post-surgery sessions. Thirty-four patients (81%) registered their food intake more than 50% of the days in the preoperative counseling program, 2 patients (5%) for less than 50% of the days in the preoperative counseling program, 6 patients (14%) did not answer the question about registration of food intake. During the preoperative counseling program, 17 patients (40%) practiced mindfulness training as recommended for more than 50% of the days, 14 patients (33%) did some mindfulness training, 4 patients (10%) reported no mindfulness training at</td></tr>
</table>

	all and 7 patients (17%) did not answer the question about registration of mindfulness training.
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Lillis, 2016

Guideline record ID: 10435--1

Study characteristics		
Citation	Lillis, J., Niemeier, H. M., Thomas, J. G., Unick, J., Ross, K. M., Leahey, T. M., Kendra, K. E., Dorfman, L., & Wing, R. R. (2016). A randomized trial of an acceptance-based behavioral intervention for weight loss in people with high internal disinhibition. Obesity, 24(12), 2509-2514. https://doi.org/10.1002/oby.21680	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A randomized trial of an acceptance-based behavioral intervention for weight loss in people with high internal disinhibition	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Included participants were 18 to 70 years of age, had a body mass index (BMI) between 30 and 50 kg/m2, and a score of 5 or higher (women) or 4 or higher (men) on the ID subscale of the Eating Inventory (a detailed description of the screening process and establishment of the ID cutoff can be found in the study protocol)."	
Exclusion criteria	"Participants were excluded for current participation in another weight loss program; current pregnancy or plans to become pregnant during the study period; reported heart condition, chest pain or inability to exercise; reported conditions that would render them unlikely to follow the protocol, including terminal illness, plans to relocate, a history of substance abuse, or a recent psychiatric hospitalization."	
Setting	University/research centre	
Intervention	"Shared components Core behavioral strategies Calorie goal (1,200-1,800 kcal/d; 25% from fat) Gradually increase physical activity to 250 min/wk Self-monitoring of weight and food intake Stimulus control, problem solving, and goal setting Acceptance-based behavioral (ABBI) only Acceptance and mindfulness strategies Mindful awareness of/detachment from problematic thoughts Acceptance of unwanted emotions and food cravings Values clarification techniques Commitment to values-consistent behavior in the presence of difficult thoughts, feelings, and cravings"	
Control/Comparator	"Shared components Core behavioral strategies Calorie goal (1,200-1,800 kcal/d; 25% from fat) Gradually increase physical activity to 250 min/wk Self-monitoring of weight and food intake Stimulus control, problem solving, and goal setting Standard behavioral (SBT) only Cognitive and emotional control strategies Stopping/replacing negative thoughts Distraction techniques Relaxation skills Environmental control methods."	
Treatment duration	12 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 162 Intervention group/s: ABBI (n=81) Comparator group: SBT (n=81)	
Mean age ± SD	50.2y (10.9)	

<table>
<tr><td>Sex</td><td>85.19% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)</td><td>ABBI: 102.5
(17.3)</td><td>SBT: 102.2
(17.7)</td></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)</td><td>ABBI: 37.5
(5.4)</td><td>SBT: 37.7
(5.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Percent weight change
Estimated marginal mean (SE)</td><td>ABBI: -8.52
(0.97)</td><td>SBT: -9.31
(0.96)</td></tr>
<tr><td>Weight change in kilograms
Estimated marginal mean (SE)</td><td>ABBI: -8.92
(1.05)</td><td>SBT: -9.7
(1.03)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Percent weight change
Estimated marginal mean (SE)</td><td>ABBI: -4.16
(0.88)</td><td>SBT: -2.47
(0.87)</td></tr>
<tr><td>Weight change in kilograms
Estimated marginal mean (SE)</td><td>ABBI: -4.29
(0.89)</td><td>SBT: -2.65
(0.88)</td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Mean number of sessions attended was 28.5 of 32 (89%) for ABBI and 28.7 of 32 (89%) for SBT. Treatment completion for both groups was 74% (at least 70% of sessions attended and continued attendance throughout the 12 months). Average weekly food and exercise diary completion was 60% for ABBI and 61% for SBT.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Lillis, 2021

Guideline record ID: 10434--1

Study characteristics		
Citation	Lillis, J., Dunsiger, S., Thomas, J. G., Ross, K. M., & Wing, R. R. (2021). Novel behavioral interventions to improve long-term weight loss: A randomized trial of acceptance and commitment therapy or self-regulation for weight loss maintenance. Journal of Behavioral Medicine, 44(4), 527-540. https://doi.org/10.1007/s10865-021-00215-z	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Novel behavioral interventions to improve long-term weight loss: A randomized trial of acceptance and commitment therapy or self-regulation for weight loss maintenance	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Individuals were eligible to participate if they were 18-70 years of age and had a body mass index (BMI) between 27.5-45 kg/m2 . The lower BMI level was set at 27.5 in order to recruit individuals for whom it made sense to recommend an initial 10% weight loss goal. Individuals who lost 5% or more of their initial weight during, Phase 1, the online intervention were eligible to participate in Phase 2."	
Exclusion criteria	"Individuals were excluded for current participation in another weight loss program; current pregnancy or plans to become pregnant during the study period; reported heart condition, chest pain or inability to engage in walking exercise; report of conditions that would render them unlikely to follow the protocol, including terminal illness, plans to relocate, a history of substance abuse, or a recent psychiatric hospitalization. Individuals who had not lost 5% or more of their initial weight during Phase 1, the online intervention, were ineligible to participate in Phase 2."	
Setting	University/research centre	
Intervention	"Months 1-3: internet based weight loss program including target calorie goals ranging from 1200-1500 kcal/ day and 33-42 g of fat/day. Months 4-6: weight loss maintenance intervention phase: The ACT and SR workshop interventions (described below) included a single, 5-h, in-person group meeting with 10-15 participants per group. Two Ph.D. level behavioral psychologists delivered the interventions. Each was an expert in the specifc approach they delivered (SR or ACT) and conducted all of the workshops for their specifc condition. Participants were informed of what condition they were assigned to at the beginning of the workshop (for both ACT and SR). In addition, ACT and SR received 3 monthly phone calls, which were 10-15 min in length, delivered by the workshop interventionists, semi-structured, and focused on problem-solving the use of skills taught in the workshop. For example, on ACT calls participants were asked to identify specifc situations (e.g. at a social event) in which using ACT skills might be helpful and select specifc ACT skills to use in those situations. On SR calls, participants were most often directed to identify barriers to daily tracking and were assisted in developing plans (e.g. using an app, recording before eating, weighing frst thing in the morning) to address adherence drift. Finally, participants in all three groups (ACT, SR, and Control) received weekly emails during the maintenance intervention (months 3-6). The weekly emails contained a brief survey for participants to: (a) report their current weight, and, (b) report their average daily calorie intake. After the last email and phone call (end of month 6), there was no further clinical contact, only the scheduling and attending of assessments."	
Control/Comparator	"Months 1-3: internet based weight loss program including target calorie goals ranging from 1200-1500 kcal/ day and 33-42 g of fat/day. The control condition did not receive a workshop-based intervention nor any other kind of intervention in its place during the WM	

<table>
<tr><td></td><td>phase. Control participants did receive weekly emails during the maintenance intervention (months 3-6) to control for general weekly monitoring. The weekly emails contained a brief survey for participants to: (a) report their current weight, and, (b) report their average daily calorie intake. After the last email and phone call (end of month 6), there was no further clinical contact, only the scheduling and attending of assessments.”</td></tr>
<tr><td>Treatment duration</td><td>3 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 102
Intervention group/s: ACT (n=34); SR (n=34)

Comparator group: Control (n=34)</td></tr>
<tr><td>Mean age ± SD</td><td>57.8y (8.9)</td></tr>
<tr><td>Sex</td><td>69.61% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline Mean (SD)</td><td>ACT: 97 (18.2)
SR: 95.4 (14.9)</td><td>Control: 93.6 (17.7)</td></tr>
<tr><td>BMI (kg/m2) - Baseline Mean (SD)</td><td>ACT: 34.5 (4.6)
SR: 34.2 (4.1)</td><td>Control: 34.4 (4.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Percent weight change (%) Estimated marginal mean (SE)</td><td>ACT: -9.14 (0.78)
SR: -7.78 (0.78)</td><td>Control: -4.81 (0.84)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Percent weight change (%) Estimated marginal mean (SE)</td><td>ACT: -7.18 (1.33)
SR: -4.18 (1.32)</td><td>Control: -1.15 (1.5)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Treatment engagement was measured by the number of weekly email surveys completed by participants during months 4-6 (Phase 2) of the study. ACT participants completed an average of 10.88 email surveys compared to 9.62 for SR and 8.12 for Control. Results of the one-way ANOVA (overall F=4.33, p=0.016) show that ACT participants completed signifcantly more emails on average as compared to Control participants (p = 0.004) and that there were no signifcant diferences between ACT and SR participants (p=0.182). In</td></tr>
</table>

	addition, 65% of ACT participants completed all 12 surveys as compared to 38% for SR and 38% for Control, a signifcant diference ($\chi 2=6.38$, $p=0.041$).
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Lin, 2023

Guideline record ID: 12018--1

Study characteristics		
Citation	Lin, S., Cienfuegos, S., Ezpeleta, M., Pavlou, V., Chakos, K., McStay, M., Runchey, M.-C., Alexandria, S. J., & Varady, K. A. (2023). Effect of time-restricted eating versus daily calorie restriction on mood and quality of life in adults with obesity. Nutrients, 15(20), 4313. https://doi.org/https://doi.org/10.3390/nu15204313	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Time-Restricted Eating versus Daily Calorie Restriction on Mood and Quality of Life in Adults with Obesity	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were female, male, age between 18 and 65 years, and BMI between 30 and 50 kg/m2."	
Exclusion criteria	"Exclusion criteria were history of diabetes mellitus, use of weight loss medications, weight unstable for 3 months before the beginning of the study (>4 kg weight loss or gain), eating within less than a 10-hour window, perimenopausal or otherwise irregular menstrual cycle, nightshift workers, pregnant or trying to become pregnant, and current smokers."	
Setting	Home, University/research centre	
Intervention	"Participants in all 3 groups were instructed not to change their physical activity habits throughout the trial to avoid potential confounding. The TRE and CR interventions consisted of a weight loss phase (6 months) and a weight maintenance phase (6 months) (Supplement Figure 1, available at Annals.org). Trained registered dietitians delivered dietary counselling to TRE and CR intervention participants (by telephone or Zoom [Zoom Video Communications]) every week during the first 3 months of the study, then biweekly from months 4 to 6. During these sessions, participants were taught how to make general healthy food choices to conform with American Diabetes Association nutrition guidelines (13). During the weight maintenance phase between months 6 and 12, participants in the TRE and CR (but not control) groups met individually with the dietitian every month to learn cognitive behavioural strategies to prevent weight regain (14). TRE Dietary Strategy - During the 6-month weight loss phase, participants in the TRE group were instructed to eat ad libitum from noon to 8:00 p.m. daily and fast from 8:00 p.m. to noon. During the 8-hour eating window, participants were not required to monitor caloric intake, and there were no restrictions on types of or quantities of food consumed. During the 16-hour fasting window, participants were encouraged to drink plenty of water and were permitted to consume energy-free drinks, such as black tea, coffee, and diet sodas (limit 2 diet sodas per day). During the 6-month weight maintenance phase, participants were instructed to maintain their body weight and to widen their eating window to 10:00 a.m. to 8:00 p.m. and fast from 8:00 p.m. to 10:00 a.m. This maintenance eating window was chosen because our previous TRE trials (4, 5) showed that eating within a 10-hour window resulted in no change in body weight in this population group. Thus, we hypothesized that this would be an ideal eating window for sustained weight loss. As in the weight loss phase, participants were not required to monitor caloric intake and could eat food as desired. During the 14-hour fasting window, participants were encouraged to drink plenty of water and were permitted to consume energy-free drinks. Calorie Counting Dietary Strategy - During the 6-month weight loss phase, participants in the CR group were instructed to reduce their energy intake by 25% every day. Total energy expenditure was calculated by the Mifflin-St. Jeor equation (15) and multiplied by the appropriate activity factor for each participant. Participants in the CR group met with the study dietitian at the beginning of the trial to	

<table>
<tr><td></td><td>develop individualized weight loss meal plans. The plans included menus, portion sizes, and food lists that were consistent with the participant's food preferences and prescribed calorie levels for weight loss. The food lists contained examples of healthy foods that should be purchased to make the meals-for example, lean proteins (chicken, turkey, fish, and tofu), fruits, vegetables, nuts, and low-fat dairy products. Participants were asked to fill half their plates with fruits or vegetables at every meal and to consume roughly 50% of energy as carbohydrates, 30% of energy as fat, and 20% of energy as protein. During the weight maintenance phase, CR participants were instructed to consume 100% of their energy needs every day. Total daily energy expenditure was recalculated at the beginning of this period for all participants. The net caloric reduction from baseline was approximately 15%."</td></tr>
<tr><td>Control/Comparator</td><td>"Participants in all 3 groups were instructed not to change their physical activity habits throughout the trial to avoid potential confounding. Control - Control participants were instructed to maintain their weight, physical activity habits, and baseline eating window of 10 or more hours per day throughout the trial. This eating window was chosen because our previous TRE studies (4, 5) indicated that persons in the Chicago area typically eat within 10 or more hours each day. Control participants received no food or dietary counseling but visited the research center at the same frequency as the intervention participants to provide outcome measurements. Control participants who completed the 12-month trial received free weight loss counseling at the end of the study."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 90
Intervention group/s: TRE (n=30); CR (n=30)

Comparator group: Control (n=30)</td></tr>
<tr><td>Mean age ± SD</td><td>TRE: 44y (12); Daily CR: 44y (9); Control: 44y (13)</td></tr>
<tr><td>Sex</td><td>82.22% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>N/A</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in body weight, kg
Mean (95% CIs)</td><td>TRE: -3.49
(-5.65--1.32)
CR: -4.3
(-7.63--0.96)</td><td>Control: 1.12
(-0.69-2.94)</td></tr><tr><td>Change in body weight, %
Mean (95% CIs)</td><td>TRE: -3.76
(-5.89--1.64)</td><td>Control: 1.11
(-0.72-2.94)</td></tr></table></td></tr>
</table>

		CR: -4.2 (-7.59--0.8)	
	Change in fat mass, kg Mean (95% CIs)	TRE: -2.2 (-3.88--0.52) CR: -2.61 (-5.97-0.74)	Control: 0.57 (-1.14-2.27)
	Change in visceral fat mass, kg Mean (95% CIs)	TRE: -0.14 (-0.23--0.04) CR: -0.12 (-0.29-0.06)	Control: -0.03 (-0.16-0.1)
	Change in Waist circumference, cm Mean (95% CIs)	TRE: -6.44 (-8.65--4.24) CR: -3.77 (-7.46--0.08)	Control: -1.46 (-3.77-0.84)
	Change in BMI, kg/m2 Mean (95% CIs)	TRE: -1.29 (-2.09--0.5) CR: -1.62 (-2.98--0.26)	Control: 0.4 (-0.29-1.08)

Change in outcome measure from baseline to final follow-up/endpoint	

Variable	Intervention arm/s	Comparator

Compliance with treatment	Participants in the TRE group reported being adherent with their eating window on average 6.1 days per week (SD, 0.8) (87% of days) over the course of the 12-month study. As for CR, 61% of participants reported being adherent with their prescribed calorie goal during the 12- month trial.
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Linde, 2012

Guideline record ID: 10785--1

Study characteristics		
Citation	Linde, J. A., Nygaard, K. E., MacLehose, R. F., Mitchell, N. R., Harnack, L. J., Cousins, J. M., Graham, D. J., & Jeffery, R. W. (2012). HealthWorks: results of a multi-component group-randomized worksite environmental intervention trial for weight gain prevention. International Journal of Behavioral Nutrition and Physical Activity, 9, 14. https://doi.org/https://dx.doi.org/10.1186/1479-5868-9-14	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	HealthWorks: Results of a multi-component group-randomized worksite environmental intervention trial for weight gain prevention	
Location	USA	
Trial name	HealthWorks	
Methods		
Inclusion criteria	"Employees were considered eligible if they were employed at least 50% time on-site during a daytime shift."	
Exclusion criteria	Not reported	
Setting	Workplace	
Intervention	"Intervention components were primarily targeted at making changes at the worksite level and are described as follows: Food environment. The primary aims of the food environment intervention were: 1) to increase the availability of calorie smart foods (as defined earlier) to at least 50% of all cafeteria and vending machine offerings, as defined by previous work by colleagues in this area [13,26,27], 2) to reduce the price of calorie smart foods by 15% while increasing the price of non-calorie smart foods by 15%, 3) to offer smaller portion sizes as substitutes (e.g., 12 oz. soda cans to replace 20 oz. bottles in vending machines or cafeteria lines), and 4) to label calorie smart items at the point of purchase and promote these items through table tents in the cafeteria and posters near vending machines. Benchmarks for calorie smart food presence (i.e., 50% or greater) were determined from prior research [26,27] and were communicated to worksites by intervention staff, primarily the lead interventionist who had extensive food service experience, who worked directly with site food managers and vending delivery drivers to facilitate changes. Physical activity environment. The primary aims of the activity environment intervention were to promote walking at work (via organized group walks, competition between co-workers, and activity monitoring) and to encourage stair use. Participants were provided with pedometers and access to a free online step tracking site http://www.americaonthemove.org for use throughout the intervention. Up to seven 6- to 8-week walking challenges were implemented, with input from study staff, at each intervention site. Walking challenges involved assisting worksite employees in organizing competitions designed to encourage walking as an activity to promote health. Employees were grouped into competitive teams (self-selected or based on worksite units) and tracked step counts collected during challenge periods; other walks were staged around charitable giving events or fun activities at work (e.g., games played outdoors while walking). In addition, regular walking was encouraged as a means of meeting activity goals during the workday (e.g., by promotion of walking meetings, taking time from lunch to walk, or walking before or after shifts). Motivational signs, decorative posters, and music were placed in select stairwells to enhance the stair environment and promote use. Body weight tracking environment. Balance beam scales were placed at four accessible yet private locations (e.g., restroom or break room) at each intervention site. BMI charts were posted near scales to promote knowledge of parameters for healthy weight, and weight tracking forms were placed nearby to encourage participants to monitor their weight regularly. Up	

<table>
<tr><td></td><td>to three weight tracking competitions, framed around maintaining current weight (e.g., during the winter holidays) were held at each intervention site to encourage social support for weight tracking during the study. Health media environment. In addition to placement of signs and posters related to food, activity, or body weight intervention targets, a two-page monthly newsletter was created by intervention staff and distributed for 24 months, via worksite email channels, at all intervention sites. The first page of the newsletter addressed general information related to healthy eating, activity, or other relevant behaviors; the sidebar on page one also presented site-specific information regarding upcoming events. The second page reported recent site-specific activities (e.g., competition results, co-worker testimonials). Advisory panels. At each intervention site, advisory panels of 8-11 worksite employees were instituted to provide guidance and ongoing feedback to study staff. At each site, the worksite liaison identified during recruitment served on the panel and assisted with recommending additional site employees for the panel; efforts were made to ensure that the advisory panel represented a cross-section of employee classifications and organizational units. Panels met every other month during intervention to advise study staff on planning, implementation, and acceptability of all intervention activities."</td></tr>
<tr><td>Control/Comparator</td><td>"Control sites had no contact with study staff, except to engage in evaluation procedures at baseline, one, and two years; following the last round of data collection, control sites were offered a DVD containing intervention materials (e.g., poster templates, newsletter content, descriptions of intervention activity procedures) and an opportunity to ask questions of intervention staff as needed. Two of three control sites requested and received materials following study completion."</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 1672
Intervention group/s: Intervention (n=723)

Comparator group: Control (n=949)</td></tr>
<tr><td>Mean age ± SD</td><td>42.9y</td></tr>
<tr><td>Sex</td><td>60.47% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intervention: 82.2
(21)</td><td>Control: 81.1
(19.4)</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Intervention: 28.7
(6.6)</td><td>Control: 28.3
(6.1)</td></tr>
<tr><td>Percent Overweight
Proportion (%)</td><td>Intervention: 33.8%</td><td>Control: 37.3%</td></tr>
<tr><td>Percent Obese
Proportion (%)</td><td>Intervention: 34.5%</td><td>Control: 31.9%</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight kg/m2 Mean</td><td>Intervention: 0.3</td><td>Control: 0.19</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Lindstrom, 2013

Guideline record ID: 10440

Study characteristics		
Citation	Lindström, J., Peltonen, M., Eriksson, J. G., Ilanne-Parikka, P., Aunola, S., Keinänen-Kiukaanniemi, S., Uusitupa, M., Tuomilehto, J., & the Finnish Diabetes Prevention Study (DPS). (2013). Improved lifestyle and decreased diabetes risk over 13 years: long-term follow-up of the randomised Finnish Diabetes Prevention Study (DPS). Diabetologia, 56(2), 284-293. https://doi.org/https://dx.doi.org/10.1007/s00125-012-2752-5	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Improved lifestyle and decreased diabetes risk over 13 years: long-term follow-up of the randomised Finnish Diabetes Prevention Study (DPS)	
Location	Finland	
Trial name	Finnish Diabetes Prevention Study (DPS)	
Methods		
Inclusion criteria	"Overweight and had impaired glucose tolerance (IGT) based on the mean of two 75 g OGTTs."	
Exclusion criteria	Not reported	
Setting	Home, Face to face counselling sessions with study nutritionist	
Intervention	"Individualised lifestyle intervention included seven face-toface counselling sessions with the study nutritionist during the first year and every 3 months thereafter, as well as voluntary free-of-charge supervised exercise sessions in the gym. The specific intervention goals were weight reduction (5% or more from baseline weight), dietary modification (energy proportion of total fat less than 30% and saturated fat less than 10% of total energy, dietary fibre intake 3.6 g/MJ (15 g/1,000 kcal)) or more and increased physical activity (4 h per week or more"	
Control/Comparator	"control group that received standard advice at baseline."	
Treatment duration	Median 4 years (range 1-6y)	
Follow-up from baseline	Median 11 years (rang 1-10 years)	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 522 Intervention group/s: Intervention (n=265) Comparator group: Control (n=257)	
Mean age ± SD	55y(7)	
Sex	67.05% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		
Outcome measure at baseline	Variable / Intervention arm/s / Comparator	

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% Body weight change
Mean</td><td>Intervention: -5</td><td>Control: 1</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Ruusunen, A., Voutilainen, S., Karhunen, L., Lehto, S. M., Tolmunen, T., Keinänen-Kiukaanniemi, S., Eriksson, J., Tuomilehto, J., Uusitupa, M., & Lindström, J. (2012). How does lifestyle intervention affect depressive symptoms? results from the Finnish Diabetes Prevention Study. Diabetic Medicine, 29(7), e126-e132. https://doi.org/10.1111/j.1464-5491.2012.03602.x</td></tr>
</table>

N/A – Not applicable

Lisevick, 2021

Guideline record ID: 10441--1

Study characteristics		
Citation	Lisevick, A., Cartmel, B., Harrigan, M., Li, F., Sanft, T., Fogarasi, M., Irwin, M. L., & Ferrucci, L. M. (2021). Effect of the Lifestyle, Exercise, and Nutrition (LEAN) study on long-term weight loss maintenance in women with breast cancer. Nutrients, 13(9), 3265. https://doi.org/https://dx.doi.org/10.3390/nu13093265	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of the Lifestyle, Exercise, and Nutrition (LEAN) Study on Long-Term Weight Loss Maintenance in Women with Breast Cancer	
Location	USA	
Trial name	Lifestyle, Exercise, and Nutrition (LEAN)	
Methods		
Inclusion criteria	"Women with BMI ≥ 25.0 kg/m2 diagnosed with Stage 0 to III breast cancer within five years prior to study enrollment were eligible for the LEAN Study. . Eligible participants had completed chemotherapy and/or radiation therapy, were physically able to exercise, accessible by telephone, and able to read and communicate in English."	
Exclusion criteria	"Women were excluded if they were pregnant, intending to become pregnant within a year, had a history of stroke or myocardial infarction within six months, or had a severe uncontrolled mental illness."	
Setting	Hospital, Home	
Intervention	"The intervention groups received 11 sessions of 30 min counseling led by a registered dietitian who was also a certified specialist in oncology nutrition, over the span of 6 months, either in person or via telephone, a breast cancer-specific healthy eating and exercise LEAN educational book, and a journal to guide counseling sessions. The in-person and telephone groups received the same lifestyle intervention. Participants received counseling sessions once per week throughout the first month, followed by every two weeks in the following two months, and then once per month in the final three months. The LEAN journal was used by participants to record all food and beverage intake, minutes of physical activity, and daily pedometer step counts, as well as their weight measured once a week on a scale provided by the study. Participants were provided with personalized energy intake goals based on baseline weight, such that they incurred an energy intake deficit of 500 kcal/day. The dietary fat goal was <25% total energy intake. Participants were encouraged to consume a plant-based diet and incorporate mindful eating practices alongside a homebased physical activity program with a goal of 150 moderate-intensity activity minutes per week and 10,000 steps per day"	
Control/Comparator	"The usual care group received one 30 min counselling session at the end of the six month study period, in addition to the LEAN book and journal, American Institute for Cancer Research pamphlets on healthy eating and exercise, and referral to the Yale Cancer Center Survivorship Clinic, which offers a two-session weight management program [25]. Participant weights were measured by study staff in duplicate at baseline and the end of the six-month study period. Additional follow-up weight data assessed objectively via scales during patient visits at affiliated clinical sites through July 2019 was obtained retrospectively via patient electronic health records at Yale-New Haven."	
Treatment duration	6 months	
Follow-up from baseline	8 years	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 92
Intervention group/s: LEAN Intervention (n=60)

Comparator group: Usual care (n=32)</td></tr>
<tr><td>Mean age ± SD</td><td>58.8y (7.3)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Diagnosed with Stage 0 to III breast cancer</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>LEAN Intervention: 86.1
(16.8)</td><td>Usual care: 90.4
(20.3)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Yearly Mean Rate of Weight Change (kg)
Mean (SE)</td><td>LEAN Intervention: -0.2
(0.07)</td><td>Usual care: -0.32
(0.1)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Little, 2017

Guideline record ID: 10786

Study characteristics		
Citation	Little, P., Stuart, B., Hobbs, R. R., Kelly, J., Smith, E. R., Bradbury, K. J., Hughes, S., Smith, P. W., Moore, M. V., Lean, M. E., Margetts, B. M., Byrne, C. D., Griffin, S., Davoudianfar, M., Hooper, J., Yao, G., Zhu, S., Raftery, J., & Yardley, L. (2017). Randomised controlled trial and economic analysis of an internet-based weight management programme: POWeR+ (Positive Online Weight Reduction). Health Technology Assessment, 21(4). https://doi.org/https://dx.doi.org/10.3310/hta21040	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Randomised controlled trial and economic analysis of an internet-based weight management programme: POWeR+ (Positive Online Weight Reduction)	
Location	UK	
Trial name	POWeR+ (Positive Online Weight Reduction)	
Methods		
Inclusion criteria	"Patients with a BMI of ≥ 30 kg/m2 (or ≥ 28 kg/m2 with additional risk factors of hypertension, diabetes mellitus or hypercholesterolaemia) documented in GP case records4 were eligible."	
Exclusion criteria	"Patients were excluded if they had current major mental problems, such as psychosis, or were very ill (e.g. severe left ventricular failure), that is, they had difficulty completing outcomes, were unable to change diet, were pregnant or breastfeeding, or had a perceived inability to walk 100 m (physical activity difficult)."	
Setting	GP clinic, Home, Web intervention	
Intervention	"POWeR+ is a theory- and evidence-based intervention that is designed to teach patients self-regulation and cognitive-behavioural techniques and that aims to help them to form sustainable eating and physical activity habits for long-term weight management. POWeR+ was developed, as with POWeR, using the person-based approach to maximise acceptability, feasibility and engagement. 24 web-based sessions lasting up to 6 months with novel content, links to external content and e-mail reminders to encourage patients to continue to use the website weekly to track their weight, set and review eating and physical activity goals, and receive personalised advice. After entering their weight and whether or not they had achieved the goals they had set themselves the previous week, patients receive tailored feedback giving encouragement if maintaining weight loss (e.g. reminders of health benefits accrued) and meeting goals. Weight gain and failing to meet goals triggers automated personalised advice, such as appropriate goal-setting and planning, boosting motivation, overcoming difficulties and recovering from lapses. POWeR+F: web intervention with face-to-face appointments for nurse support. The rationale for this intervention was to provide automated behavioural counselling with just three scheduled (and four optional) face-to-face nurse support sessions, thus requiring substantially less health professional skill and time than the evidence-based lifestyle interventions documented in the NICE review, and, hence, much easier to implement in the NHS. In addition to 6-monthly weighing, as in the control group, participants had three scheduled face-to-face appointments in the first 3 months and then up to four more during the next 3 months, if needed. Weight gain on two consecutive logins triggered an automated e-mail to the nurse advising that the patient required further support. Patients could also request additional support. POWeR+R: web intervention with remote support. The rationale here was to test whether or not even briefer professional support for the web intervention could be effective. Patients could access the same web-based intervention as in the face-to-face group. In addition to 6-monthly weighing, as in the control group, participants had three scheduled telephone or e-mail contacts and up to two optional	

<table>
<tr><td></td><td>telephone/e-mail contacts during the first 6 months (triggered by weight gain or patient request as in the face-to-face group). This level of support was confirmed as acceptable and helpful during the development and piloting stages."</td></tr>
<tr><td>Control/Comparator</td><td>"Those randomised to the control group were taken to pages of the POWeR+ website containing two brief, structured, printable pages of advice about a healthy diet (healthy food swaps and NHS 5-a-day leaflet27). These materials had previously been developed by the Institute of Food Research, and had been trialled by us in primary care, resulting in modest weight loss (around 2%) compared with a generic advice booklet.12 To enhance retention in the control group, participants were informed that this intervention had been shown to support weight loss. For follow-up, nurses arranged brief 5- to 10-minute appointments with sufficient time to measure weight at 6 months and 12 months, but not to provide extensive counselling."</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 818
Intervention group/s: POWeR+F (n=269); POWeR+R (n=270)

Comparator group: Control (n=279)</td></tr>
<tr><td>Mean age ± SD</td><td>POWeR+F: 53.70y (13.21); POWeR+R: 54.74y (12.95); Control: 52.69y (13.25)</td></tr>
<tr><td>Sex</td><td>63.57% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg),
Mean (SD)</td><td>POWeR+F: 102.4
(16.87)
POWeR+R: 102.93
(18.26)</td><td>Control: 104.38
(21.11)</td></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)</td><td>POWeR+F: 36.66
(5.36)
POWeR+R: 36.28
(5.65)</td><td>Control: 37.1
(5.97)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg),
Mean (SD)</td><td>POWeR+F: 98.56
(15.95)
POWeR+R: 99.72
(18.88)</td><td>Control: 101.73
(19.57)</td></tr>
<tr><td>Proportion losing ≥ 5% of baseline weight
Proportion (%)</td><td>POWeR+F: 28.1
POWeR+R: 31.7</td><td>Control: 18.5</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
</table></td></tr>
</table>

12 months or closest time point	
Change in outcome measure from baseline to final follow-up/endpoint	
Compliance with treatment	Of the 539 participants randomised to the POWeR+ intervention groups, 524 started the first session and 404 completed all three core sessions (196 of the POWeR+R group and 208 of the POWeR+F group). Participants completed an average of 10.97 (SD 12.65; range 0-52) weight and goal reviews; the average was 10.16 (SD 11.92) in the POWeR+F group and 11.85 (SD 13.38) in the POWeR+R group. The median number of nurse contacts was four (range 0-7) in both intervention groups, with a median of two face-to-face, one telephone and one e-mail contacts in the POWeR+F group, and a median of one telephone call and three e-mails in the POWeR+R group.
Notes	
Additional included publications arising from this study that did not contribute additional data	

Variable	Intervention arm/s	Comparator

N/A – Not applicable

Liu, 2022

Guideline record ID: 10170

Study characteristics		
Citation	Liu, D., Huang, Y., Huang, C., Yang, S., Wei, X., Zhang, P., Guo, D., Lin, J., Xu, B., Li, C., He, H., He, J., Liu, S., Shi, L., Xue, Y., & Zhang, H. (2022). Calorie Restriction with or without time-restricted eating in weight loss. The New England Journal of Medicine, 386(16), 1495-1504. https://doi.org/10.1056/NEJMoa2114833	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Calorie Restriction with or without Time-Restricted Eating in Weight Loss	
Location	China	
Trial name	N/A	
Methods		
Inclusion criteria	"Participants were eligible if they were 18 to 75 years of age and had a body-mass index (BMI, the weight in kilograms divided by the square of the height in meters) that was between 28 and 45."	
Exclusion criteria	"Among the criteria for exclu sion were acute or chronic viral hepatitis, malig nant tumors, diabetes, serious liver dysfunction or chronic kidney disease, current smoking, seri ous cardiovascular or cerebrovascular disease within 6 months before randomization, severe gastrointestinal diseases or gastrointestinal sur gery in the 12 months before randomization, active participation in a weight-loss program, use of medications that affect weight or energy balance, and current or planned pregnancy."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs), University/research centre, Nanfang Hospital of Southern Medical University	
Intervention	"Time-restricted eating (eating only between 8:00 a.m. and 4:00 p.m.) with calorie restriction. For 12 months, all the participants were instructed to follow a calorie-restricted diet that consisted of 1500 to 1800 kcal per day for men and 1200 to 1500 kcal per day for women"	
Control/Comparator	"daily calorie re striction alone. For 12 months, all the participants were instructed to follow a calorie-restricted diet that consisted of 1500 to 1800 kcal per day for men and 1200 to 1500 kcal per day for women."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 139 Intervention group/s: Time restricted eating (n=69) Comparator group: Daily Calorie Restriction (n=70)	
Mean age ± SD	Intervention: 31.6y (9.3); Control: 32.2y (8.8)	
Sex	49.64% female	

Pre-existing medical condition	No pre-existing medical condition
Results	

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Baseline Body weight - kg Mean (SD)	Time restricted eating: 88.4 (10.2)	Daily Calorie Restriction: 87.9 (12.8)
Baseline Body-mass index Mean (SD)	Time restricted eating: 31.8 (2.9)	Daily Calorie Restriction: 31.3 (2.6)
Baseline Body fat mass - kg Mean (SD)	Time restricted eating: 33 (7.3)	Daily Calorie Restriction: 33.2 (6.3)
Baseline Body lean mass - kg Mean (SD)	Time restricted eating: 51.2 (7.8)	Daily Calorie Restriction: 50.9 (9.1)
Baseline Body fat - % Mean (SD)	Time restricted eating: 38.3 (5.5)	Daily Calorie Restriction: 38.4 (5.3)
Baseline Waist circumference - cm Mean (SD)	Time restricted eating: 99.4 (7.8)	Daily Calorie Restriction: 99.2 (9.1)
Baseline abdominal fat area (visceral) - cm2 Median (IQR)	Time restricted eating: 122.3 (97.2-159.7)	Daily Calorie Restriction: 124.9 (91.4-160)
Baseline abdominal fat area (subcutaneous) - cm2 Mean (95% CIs)	Time restricted eating: 312.8 (264.5-386.3)	Daily Calorie Restriction: 302.9 (248-360.4)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point

Variable	Intervention arm/s	Comparator
Change in Body weight - kg Mean (95% CIs)	Time restricted eating: -8 (-9.6--6.4)	Daily Calorie Restriction: -6.3 (-7.8--4.7)
Change in Body-mass index Mean (95% CIs)	Time restricted eating: -2.9 (-3.5--2.3)	Daily Calorie Restriction: -2.3 (-2.8--1.7)
Change in Waist circumference - cm Mean (95% CIs)	Time restricted eating: -8.8 (-10.4--7.1)	Daily Calorie Restriction: -7 (-8.5--5.4)
Change in Body fat mass - kg Mean (95% CIs)	Time restricted eating: -5.9 (-7.1--4.7)	Daily Calorie Restriction: -4.5 (-5.6--3.3)
Change in Body lean mass - kg Mean (95% CIs)	Time restricted eating: -1.7 (-2.3--1.1)	Daily Calorie Restriction: -1.4 (-2--0.9)
Change in Body fat percent - % Mean (95% CIs)	Time restricted eating: -4.3 (-5.3--3.3)	Daily Calorie Restriction: -3 (-3.9--2)
Change in Area of abdominal visceral fat - cm2 Mean (95% CIs)	Time restricted eating: -26 (-35--17.1)	Daily Calorie Restriction: -21.1 (-29.5--12.8)

	Change in Area of abdominal subcutaneous fat - cm2 Mean (95% CIs)	Time restricted eating: -53.2 (-71.9--34.6)	Daily Calorie Restriction: -37 (-52.1--21.9)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Llaneza, 2012

Guideline record ID: 10787--1

Study characteristics		
Citation	Llaneza, P., González, C., Fernández-Iñarrea, J., Alonso, A., Díaz, F., & Pérez-López, F. R. (2012). Soy isoflavones improve insulin sensitivity without changing serum leptin among postmenopausal women. Climacteric, 15(6), 611-620. https://doi.org/10.3109/13697137.2011.631062	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Soy isoflavones improve insulin sensitivity without changing serum leptin among postmenopausal women	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	Hospital, University/research centre	
Intervention	"Soy isoflavone group: SIG- Physical exercise and Mediterranean diet plus a daily oral intake of a soy isoflavone extract. The soy isoflavone extract contained 200 mg of Glycine max, corresponding to 80 mg of isoflavones (60.8 mg genistein, 16 mg daidzein and 3.2 mg glicitein). Diet and physical activity were monitored during the study through compliance interviews and motivational and support counseling sessions. Educational sessions were carried out once women were included in the study, in which they received verbal and written instructions regarding the health benefits of increasing their physical activity to at least 30 min of moderate walking or aerobic exercising (biking, jogging, dancing, swimming, etc.) five times a week, and shifting to a Mediterranean diet in which meat and pastries, cakes, and sweets are decreased while intake of virgin olive oil, nuts, vegetables, legumes, oily fish and fruits is increased"	
Control/Comparator	"Control group: CG- Physical exercise and Mediterranean diet. Diet and physical activity were monitored during the study through compliance interviews and motivational and support counseling sessions. Educational sessions were carried out once women were included in the study, in which they received verbal and written instructions regarding the health benefits of increasing their physical activity to at least 30 min of moderate walking or aerobic exercising (biking, jogging, dancing, swimming, etc.) five times a week, and shifting to a Mediterranean diet in which meat and pastries, cakes, and sweets are decreased while intake of virgin olive oil, nuts, vegetables, legumes, oily fish and fruits is increased."	
Treatment duration	24 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 75 Intervention group/s: SIG (n=40) Comparator group: CG (n=35)	

<table>
<tr><td>Mean age ± SD</td><td>56.7y (3.5)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>SIG: 30.5
(4.2)</td><td>CG: 30.6
(4.7)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>SIG: 29.6
(4.6)</td><td>CG: 30.6
(4.3)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>SIG: 27.9
(2.8)</td><td>CG: 30.6
(4.8)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Llargues, 2011

Guideline record ID: 10788--1

Study characteristics		
Citation	Llargues, E., Franco, R., Recasens, A., Nadal, A., Vila, M., Pérez, M. J., Manresa, J. M., Recasens, I., Salvador, G., Serra, J., Roure, E., & Castells, C. (2011). Assessment of a school-based intervention in eating habits and physical activity in school children: the AVall study. Journal of Epidemiology and Community Health, 65(10), 896-901. https://doi.org/10.1136/jech.2009.102319	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Assessment of a school-based intervention in eating habits and physical activity in school children: the AVall study	
Location	Spain	
Trial name	Avall	
Methods		
Inclusion criteria	"All the children born in 2000 who attended any of the schools in Granollers were eligible to participate."	
Exclusion criteria	"The exclusion criteria were school children who need a special diet for a metabolic or digestive disorder, physical activity incapacity, no family acceptance or attendance to school."	
Setting	School	
Intervention	"At the beginning of the project, an information session with the parents of the school children in the intervention group was organised. The educational methodology IVAC,17 based on the principle that the school children are actors able to operate over their environment, was used. The children investigate and reflect on how the environment determines their health and lifestyle, while the teacher assists them in developing skills to change these conditions. This educational method allows the inclusion of activities related to healthy food habits and physical activity in any subject of the curriculum. At the beginning of the study, a group of educators specialised in community projects (PAU Education) carried out training sessions on this methodology for the teachers of the intervention group. Over the 2-year period, six meetings with the research team, the teachers and the educators took place in order to monitor the activities accomplished and to plan subsequent actions. Every classroom used 3 h a week to develop activities related to health food habits and/or physical activity. This time was part of regular classes - math, science, language, knowledge of the environment - developing posters, food tables, games, crafts, cooking workshops and promotion of games in the playground. Every month healthy recipes were distributed to the families for children to carry out at home. All these activities were reported at the meetings with the research team. The intervention group of each school was given educational material on healthy food, as well as educational material on games to promote physical activity during break time. Each school was also offered the necessary equipment for these games. During the study period, each family in the intervention group received monthly recipes for a balanced diet taking into account traditional food habits. The families also received a guide of the local areas and paths to exercise during weekends and books about balanced eating were recommended."	
Control/Comparator	"No intervention."	
Treatment duration	2 years	
Follow-up from baseline	2 years	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 509
Intervention group/s: Intervention (n=237)

Comparator group: Control (n=272)</td></tr>
<tr><td>Mean age ± SD</td><td>6.03y (0.3)</td></tr>
<tr><td>Sex</td><td>45.97% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of participants overweight (%)
Proportion (%)

Proportion of participants obese (%)
Proportion (%)</td><td>Intervention: 20.3

Intervention: 9.6</td><td>Control: 16.7

Control: 8.1</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of participants overweight (%)
Proportion (%)

Proportion of participants obese (%)
Proportion (%)</td><td>Intervention: 25.1

Intervention: 8.9</td><td>Control: 24.9

Control: 10.7</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Llauradó, 2018

Guideline record ID: 10442--1

Study characteristics		
Citation	Llauradó, E., Tarro, L., Moriña, D., Aceves-Martins, M., Giralt, M., & Solà, R. (2018). Follow-up of a healthy lifestyle education program (the EdAl study): four years after cessation of randomized controlled trial intervention. BMC Public Health, 18, 104. https://doi.org/10.1186/s12889-017-5006-0	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Follow-up of a healthy lifestyle education program (the EdAl study): four years after cessation of randomized controlled trial intervention	
Location	Spain	
Trial name	Educació en Alimentació (EDAl)	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	School	
Intervention	"Briefly, the EdAl program consisted of 12 educational intervention activities [16, 18] that focused on 8 lifestyle topics selected based on the scientific evidence to improve nutritional food selection, healthy habits such as teeth brushing and hand washing, the overall adoption of behaviors that encourage PA (i.e., walking to school and playground games) and the avoidance of sedentary behavior. These intervention activities were based on 12 activities (1 h/activity/session) conducted 4 per year every 15 days in the third trimester of a Spanish academic course (April to June) over 15 weeks per academic year [21]. The design, standardization and implementation were made by university students who acted as health promoting agents (HPAs) to 7- and 8-year-old children at primary schools over 28 months during 3 academic years that ended in 2010. All activities were described in a lesson planning format, a tool that is usually used by primary school teachers. All the activities had the same following format: 5-10 min of funny theory about nutritional characteristics or health benefits; 15 min of play based on the theory of this activity (for example, memory cards); 30 min of experimental activity (children played and tasted the food that related to the activity); and 5- 10 min of discussion and to answer questions. The university students used the service-learning method to develop activities and practices that were geared toward children, and the HPAs' reflections related their service to their academic work [21-23]. Moreover, each intervention activity had an educational message that related to one of the following eight lifestyle topics: (First year) (1) to improve toward a healthy lifestyle; (2) to encourage the intake of healthy drinks (and the avoidance of unhealthy carbonated/sweetened beverages); (3) to increase the consumption of vegetables and legumes; (4) to decrease the consumption of candies and pastries while increasing the intake of fresh fruits and nuts; (Second year) (5) to improve healthy habits within a set timetable (i.e., homecooked meals, teeth brushing, and hand washing) and PA participation; (6) to increase fruit intake; (7) to improve dairy product consumption; and (8) to increase fish consumption. In the Third year, these eight lifestyle topics were reinforced. Furthermore, the parents were involved in these activities with their children. For each activity, the children took home some recommendations on healthy lifestyles and shared with their parents the information of the activity that was developed at school. Optionally, depending on the schools and parents, the same educational activities that the children participated in were offered to their parents. In this way, the parents and children interacted with the same healthy nutrition and lifestyle activities"	
Control/Comparator	"No intervention."	

<table>
<tr><td>Treatment duration</td><td>28 months</td></tr>
<tr><td>Follow-up from baseline</td><td>68 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 2350
Intervention group/s: Intervention (n=1550)

Comparator group: Control (n=800)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of participants overweight based on WHO BMI criteria (%)
Proportion (%)</td><td>Intervention: 22.1</td><td>Control: 16.9</td></tr>
<tr><td>Proportion of participants obese based on WHO BMI criteria (%)
Proportion (%)</td><td>Intervention: 10</td><td>Control: 7.1</td></tr>
<tr><td>Proportion of participants overweight based on IOTF BMI criteria (%)
Proportion (%)</td><td>Intervention: 19.8</td><td>Control: 15.6</td></tr>
<tr><td>Proportion of participants obese based on IOTF BMI criteria (%)</td><td>Intervention: 3.4</td><td>Control: 2.6</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of participants overweight based on WHO BMI criteria (%)
Proportion (%)</td><td>Intervention: 12.3</td><td>Control: 11.7</td></tr>
<tr><td>Proportion of participants obese based on WHO BMI criteria (%)
Proportion (%)</td><td>Intervention: 2.0</td><td>Control: 3.2</td></tr>
<tr><td>Proportion of participants overweight based on IOTF BMI criteria (%)
Proportion (%)</td><td>Intervention: 11.7</td><td>Control: 3.2</td></tr>
<tr><td>Proportion of participants obese based on IOTF BMI criteria (%)</td><td>Intervention: 1.4</td><td>Control: 3.2</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Tarro, L., Llauradó, E., Albaladejo, R., Moriña, D., Arija, V., Solà, R., & Giralt, M. (2014). A primary-school-based study to reduce the prevalence of childhood obesity - the EdAl (Educació en Alimentació) study: a randomized controlled trial. Trials, 15, 58. https://doi.org/https://doi.org/10.1186/1745-6215-15-58</td></tr>
</table>

N/A – Not applicable

Lloyd-Richardson, 2012

Guideline record ID: 10443--1

Study characteristics		
Citation	Lloyd-Richardson, E. E., Jelalian, E., Sato, A. F., Hart, C. N., Mehlenbeck, R., & Wing, R. R. (2012). Two-year follow-up of an adolescent behavioral weight control intervention. Pediatrics, 130(2), e281-e288. https://doi.org/https://dx.doi.org/10.1542/peds.2011-3283	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Two-year follow-up of an adolescent behavioral weight control intervention	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Participants aged 13 to 16 years, who were between 30% and 90% overBMI (as defined with reference to median BMI for age and gender), had at least 1 parent available to participate, and were English speaking."	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"Participants received 16 weeks of either a group based BWC+PEAT or a group-based BWC+EXER. Groups met twice a week for 16 weeks, once a week for BWC intervention content and once a week for on-site physical activity. Weekly BWC intervention consisted of nutrition intervention, physical activity prescription, and topics on behavior modification. Treatment groups were conducted by doctoral-level psychologists with experience in adolescent weight management. The nutrition intervention consisted of a prescribed balanced-deficit diet of 1400 to 1600 calories, with a focus on obtaining a balance of nutrients and calories across the day (ie, breakfast, lunch, dinner, and snacks). Participants were asked to complete weekly detailed nutrition journals, with feedback provided by the study dietician. Nutrition topics included presentation of the dietary exchange system, portion control, dining out, dietary fat, and healthy snack choices, presented by a registered dietitian. The physical activity prescription included gradual increase to a minimum of 30 minutes a day of aerobic activity for 5 days per week. Behavioral topics included self-monitoring of diet and physical activity, portion control, problem solving, goal setting, use of stimulus control strategies, motivation for weight loss, social influences on diet and exercise, and relapse prevention. Each adolescent participated in the BWC intervention with a parent, attending concurrent but separate group meetings. Parent group sessions focused on similar content, as well as guidance regarding family-level support and implementation of behavioral changes. Following the 16 weekly sessions, adolescents were asked to attend 4 biweekly maintenance group sessions. After completion of these 20 group sessions, periodic (quarterly) activities were scheduled to encourage and maintain study contact. These largely consisted of seasonal activities (eg, apple picking, miniature golf) and contained no BWC content. Treatment groups differed inthe weekly on-site activity program that accompanied the standard BWC program. Adolescents randomized to BWC+PEAT participated in weekly peer-based physical activity based on the principles of Outward Bound and designed to increaseteamwork, social skills, and self efficacy"	
Control/Comparator	"Groups met twice a week for 16 weeks, once a week for BWC intervention content and once a week for on-site physical activity. Weekly BWC intervention consisted of nutrition intervention, physical activity prescription, and topics on behavior modification. Treatment groups were conducted by doctoral-level psychologists with experience in adolescent weight management. The nutrition intervention consisted of a prescribed balanced-deficit diet of 1400 to 1600 calories, with a focus on obtaining a balance of nutrients and calories	

<table>
<tr><td></td><td>across the day (ie, breakfast, lunch, dinner, and snacks). Participants were asked to complete weekly detailed nutrition journals, with feedback provided by the study dietician. Nutrition topics included presentation of the dietary exchange system, portion control, dining out, dietary fat, and healthy snack choices, presented by a registered dietitian. The physical activity prescription included gradual increase to a minimum of 30 minutes a day of aerobic activity for 5 days per week. Behavioral topics included self-monitoring of diet and physical activity, portion control, problem solving, goal setting, use of stimulus control strategies, motivation for weight loss, social influences on diet and exercise, and relapse prevention. Each adolescent participated in the BWC intervention with a parent, attending concurrent but separate group meetings. Parent group sessions focused on similar content, as well as guidance regarding family-level support and implementation of behavioral changes. Following the 16 weekly sessions, adolescents were asked to attend 4 biweekly maintenance group sessions. After completion of these 20 group sessions, periodic (quarterly) activities were scheduled to encourage and maintain study contact. These largely consisted of seasonal activities (eg, apple picking, miniature golf) and contained no BWC content. Adolescents randomized to BWC+EXER participated in weekly supervised aerobic exercise sessions. Theseactivity sessionswere supervised by either an exercise physiologist or physical therapist.”</td></tr>
<tr><td>Treatment duration</td><td>16 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 118
Intervention group/s: BWC+PEAT (n=62)

Comparator group: BWC+EXER (n=56)</td></tr>
<tr><td>Mean age ± SD</td><td>14.33y (1.02)</td></tr>
<tr><td>Sex</td><td>67.80% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (lbs)
Mean (SD)</td><td>BWC+PEAT: 187.04
(30.91)</td><td>BWC+EXER: 187.78
(31.17)</td></tr>
<tr><td>BMI
Mean (SD)</td><td>BWC+PEAT: 31.49
(3.55)</td><td>BWC+EXER: 31.33
(3.1)</td></tr>
<tr><td>Percent over BMI
Mean (SD)</td><td>BWC+PEAT: 161
(17.99)</td><td>BWC+EXER: 161.74
(15.44)</td></tr>
<tr><td>BMI z-score
Mean (SD)</td><td>BWC+PEAT: 2.02
(0.34)</td><td>BWC+EXER: 2.05
(0.27)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (lbs)
Mean (SD)</td><td>BWC+PEAT: 183.28
(31.06)</td><td>BWC+EXER: 187.12
(35.56)</td></tr>
<tr><td>BMI
Mean (SD)</td><td>BWC+PEAT: 30.08
(4.08)</td><td>BWC+EXER: 30.32
(4.01)</td></tr>
</table>
</td></tr>
</table>

	Percent over BMI Mean (SD) BMI z-score Mean (SD)	BWC+PEAT: 151.37 (19.69) BWC+PEAT: 1.78 (0.49)	BWC+EXER: 153.43 (18.7) BWC+EXER: 1.85 (0.43)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Weight (lbs) Mean (SD) BMI Mean (SD) Percent over BMI Mean (SD) BMI z-score Mean (SD)	BWC+PEAT: 189.24 (31.26) BWC+PEAT: 30.86 (4.66) BWC+PEAT: 151.44 (20.75) BWC+PEAT: 1.77 (0.52)	BWC+EXER: 197.36 (37.54) BWC+EXER: 31.39 (4.32) BWC+EXER: 154.56 (19.54) BWC+EXER: 1.88 (0.45)
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data	Jelalian, E., Lloyd-Richardson, E. E., Mehlenbeck, R. S., Hart, C. N., Flynn-O'Brien, K., Kaplan, J., Neill, M., & Wing, R. R. (2010). Behavioral weight control treatment with supervised exercise or peer-enhanced adventure for overweight adolescents. The Journal of Pediatrics, 157(6), 923-928.e921. https://doi.org/https://dx.doi.org/10.1016/j.jpeds.2010.05.047		

N/A – Not applicable

Lombard, 2016

Guideline record ID: 10789--1

Study characteristics		
Citation	Lombard, C., Harrison, C., Kozica, S., Zoungas, S., Ranasinha, S., & Teede, H. (2016). Preventing weight gain in women in rural communities: a cluster randomised controlled trial. PLOS Medicine, 13(1), e1001941. https://doi.org/10.1371/journal.pmed.1001941	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Preventing Weight Gain in Women in Rural Communities: A Cluster Randomised Controlled Trial	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligibility criteria included female, age of 18-50 yr, and residing in or near participating towns."	
Exclusion criteria	"Exclusion criteria were minimal and included pregnancy or serious medical conditions that would inhibit full participation in the program."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs), Phone	
Intervention	"The intervention (HeLP-her) was based on the self-determination and cognitive behavioural theory, with motivational interviewing the primary method of interaction with participants. Behavioural strategies were informed by established practices. Participants attended one facilitator-led interactive small group session held in each town. The trained facilitator presented lifestyle information related to weight gain in the form of five simple health messages (e.g., try to eat two servings of fruit and five servings of vegetables per day; take a brisk walk for at least 30 min on most days of the week). Using the topics and activities in the program manual as a guide, participants identified personal health priorities and practiced skills in goal setting, problem solving, relapse prevention, and self-monitoring. Participants were assisted by the facilitator to generate goals and action plans based on their personal priorities. Each participant therefore developed a personalised weight gain prevention strategy. Participants were instructed to work through the manual over the next four weeks in their own time. Intervention participants received an SMS text message every 4 wk to reinforce program messages. At 12 wk, they participated in one 20-min phone coaching session, delivered by staff trained in motivational interviewing, which utilised client-orientated counselling to explore and resolve ambivalence and review progress."	
Control/Comparator	"The control group received one 45-min group education session on general women's health topics including the readily available Australian Dietary Guidelines and the Australian Physical Activity Guidelines. The session was not interactive, and women were not given any individual advice. No further contact with the control group occurred until the follow up visit at 1 yr. Trained facilitators delivered the intervention and control group sessions. To ensure high program fidelity, we centralised training and used standardised delivery methods and resources. In addition, working in pairs, a facilitator delivered the intervention and a field researcher observed each session and completed a program checklist. Participants were provided with the study contact details to enable spontaneous reporting of any adverse events."	
Treatment duration	12 weeks	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 649
Intervention group/s: Intervention (n=348)

Comparator group: Control (n=301)</td></tr>
<tr><td>Mean age ± SD</td><td>39.6y (6.7)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)

Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 28.8
(6.5)

Intervention: 77.99
(18.01)

Intervention: 95.07
(15.26)</td><td>Control: 28.7
(6.7)

Control: 76.16
(18.73)

Control: 93.03
(15.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 77.51
(18.06)

Intervention: 94.64
(15.86)</td><td>Control: 76.6
(18.85)

Control: 93.66
(15.43)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Weight
Mean (95% CIs)

Change in Waist circumference
Mean (95% CIs)</td><td>Intervention: -0.48
(-0.99-0.03)

Intervention: -0.43
(-1.13-0.27)</td><td>Control: 0.44
(-0.09-0.97)

Control: 0.63
(-0.2-1.5)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Looijmans, 2017

Guideline record ID: 10790--1

Study characteristics		
Citation	Looijmans, A., Stiekema, A. P. M., Bruggeman, R., van der Meer, L., Stolk, R. P., Schoevers, R. A., Jörg, F., & Corpeleijn, E. (2017). Changing the obesogenic environment to improve cardiometabolic health in residential patients with a severe mental illness: cluster randomised controlled trial. The British Journal of Psychiatry, 211(5), 296-303. https://doi.org/https://dx.doi.org/10.1192/bjp.bp.117.199315	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Changing the obesogenic environment to improve cardiometabolic health in residential patients with a severe mental illness: cluster randomised controlled trial	
Location	The Netherlands	
Trial name	Effectiveness of Lifestyle Interventions in PSychiatry (ELIPS)	
Methods		
Inclusion criteria	"Patients with SMI from all sheltered and long-term clinical care teams of two mental health organisations in The Netherlands were included in the study."	
Exclusion criteria	"Exclusion criteria were age below 18, pregnancy, Korsakoff syndrome or inability to participate in tests."	
Setting	Mental health residential facilities	
Intervention	"The Effectiveness of Lifestyle Interventions in PSychiatry (ELIPS) intervention was directed at nursing teams and addressed the obesogenic environment of patients with severe mental illness (SMI) living in residential facilities. The intervention consisted of a preparation, implementation and monitoring phase. In the 1-month preparation phase, lifestyle coaches introduced themselves to staff and patients, screened the environment and teams' daily routines, and listed patients' and teams' preferences and sites' logistic possibilities. Lifestyle coaches created a team-tailored lifestyle plan based on listed preferences and possibilities and four pre-established ELIPS lifestyle goals: (a) to stimulate physical activity; (b) to increase supply/availability of healthy food products; (c) to organise at least one activity per week focused on a healthy diet; and (d) to improve the obesogenic environment at an organisational level. In the 3-months implementation phase, lifestyle coaches implemented the planned ELIPS lifestyle activities as described in the team-tailored lifestyle plan. Lifestyle coaches first demonstrated activities to staff, then carried out the activities together with staff and finally supervised staff while they carried out the activities. Lifestyle coaches trained teams to create a healthy environment and stimulate healthy behaviours in patients. At the end of the implementation phase, teams set goals to achieve in the 9-month monitoring phase. In the monitoring phase, a lifestyle coach visited all intervention teams twice and discussed with the team and team leader whether goals were achieved, which barriers in achieving the goals were encountered and discussed options to tackle these barriers. Also, the researchers organised one benchmark meeting for all intervention team leaders where difficulties in achieving team goals were discussed and tips, tricks and successful examples were shared Lifestyle coaches were trained for 2 days about the ELIPS lifestyle programme, motivational interviewing techniques and the patient population. Lifestyle coaches were fulfilling the final of 4 years of education to become professional lifestyle coaches. Because lifestyle coaches were still in training, each team had two lifestyle coaches at its disposal, who were appointed by the research team. Per week, lifestyle coaches spent on average 8h on activities with patients (6 contact hours and about 2h preparation time) and 8 h on training of staff and organisational aspects, such as developing information materials, meetings with staff and project management."	
Control/Comparator	"Patients in the control condition received care as usual."	

<table>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 814
Intervention group/s: Intervention (n=400)

Comparator group: Control (n=414)</td></tr>
<tr><td>Mean age ± SD</td><td>48.3y (12.6)</td></tr>
<tr><td>Sex</td><td>33.29% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Severe mental illness (SMI)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intervention: 27.8 (6.3)</td><td>Control: 28.3 (6.2)</td></tr>
<tr><td>Proportion of overweight (BMI 25-29)
Proportion (%)</td><td>Intervention: 33.9%</td><td>Control: 34.3%</td></tr>
<tr><td>Proportion Obese I (BMI 30-34)
Proportion (%)</td><td>Intervention: 16.3%</td><td>Control: 21.5%</td></tr>
<tr><td>Proportion Obese II (BMI 35-39)
Proportion (%)</td><td>Intervention: 9.2%</td><td>Control: 7.2%</td></tr>
<tr><td>Proportion Obese III (BMI >=40)
Proportion (%)</td><td>Intervention: 4.1%</td><td>Control: 5.3%</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Intervention effect on Waist circumference
Beta coefficient (95% CIs)</td><td>Intervention: -1.28 (-2.79-0.23)</td><td></td></tr>
<tr><td>Intervention effect on body mass index
Beta coefficient (95% CIs)</td><td>Intervention: 0.34 (-0.12-0.79)</td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Lopez-Padros, 2020

Guideline record ID: 10445--1

Study characteristics		
Citation	López-Padrós, C., Salord, N., Alves, C., Vilarrasa, N., Gasa, M., Planas, R., Montsserrat, M., Virgili, M. N., Rodríguez, C., Pérez-Ramos, S., López-Cadena, E., Ramos, M. I., Dorca, J., & Monasterio, C. (2020). Effectiveness of an intensive weight-loss program for severe OSA in patients undergoing CPAP treatment: a randomized controlled trial. Journal of Clinical Sleep Medicine, 16(4), 503-514. https://doi.org/https://dx.doi.org/10.5664/jcsm.8252	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effectiveness of an intensive weight-loss program for severe OSA in patients undergoing CPAP treatment: a randomized controlled trial	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	"Age 25-60 years, class I and II obesity (BMI 30-40 kg/m2), severe OSA (AHI > 30 events/h), and treatment with CPAP for a minimum of 6 months previous to inclusion."	
Exclusion criteria	"Contraindications for physical activity or diet, cognitive impairment, or psychiatric disorders that impeded patients' understanding of the program; severe diseases; major cardiovascular disease; clinical instability within the previous month; prior bariatric surgery; refusal to participate in the study; and participation in another clinical trial."	
Setting	Hospital	
Intervention	"Patients randomized to the intervention group followed an IWLP under the supervision of an expert nutritionist who conducted behavioral counseling during all the visits. The program consisted of a very low calorie diet (600-800 kcal) with low-calorie liquid meal replacements during 15 days and a 1,200 kcal diet during the rest of the initial intensive diet phase lasting 12 weeks, followed by a hypocaloric (1,200-1,800 kcal) Mediterranean diet32 for the remaining 36 weeks. Unsupervised physical activity was introduced after 15 days. The full protocol is described in the supplemental material."	
Control/Comparator	"The participants in the control group were given general oral and written information about diet and exercise at baseline. To estimate nutrient intake, patients completed a 24-hour food record at baseline, and again at 3 and 12 months."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 42 Intervention group/s: Intensive weight-loss program (n=20) Comparator group: Control group (n=22)	
Mean age ± SD	49y (6.7)	
Sex	9.52% female	

Pre-existing medical condition	Severe Obstructive Sleep Apnoea (AHI > 30 events/hour)
Results	
Outcome measure at baseline	

Variable	Intervention arm/s	Comparator
Weight Mean (SD)	Intensive weight-loss program: 99.5 (10.7)	Control group: 106 (8.8)
BMI Mean (SD)	Intensive weight-loss program: 34.5 (2.6)	Control group: 35.4 (2.9)
Waist Circumference Baseline Mean (SD)	Intensive weight-loss program: 109 (7.4)	Control group: 118 (8.6)
Fat mass kg Mean (SD)	Intensive weight-loss program: 36.7 (8.8)	Control group: 42.9 (6.47)
Body fat % Median (O1-Q3)	Intensive weight-loss program: 33 (32-44)	Control group: 40 (35.8-44)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point

Variable	Intervention arm/s	Comparator
Change in weight Mean (SD)	Intensive weight-loss program: -8.2 (5.9)	Control group: -0.1 (4.8)
Change in BMI Mean (SD)	Intensive weight-loss program: -2.8 (1.9)	Control group: -0.07 (1.5)
Change in fat mass, kg Mean (SD)	Intensive weight-loss program: -9.96 (10.1)	Control group: -1.1 (7.5)
Change in body fat (%) Median (Q1-Q3)	Intensive weight-loss program: -8 (-12--6)	Control group: 0 (-2-1)

Change in outcome measure from baseline to final follow-up/endpoint

Variable	Intervention arm/s	Comparator

Compliance with treatment	81.8%
Notes	
Additional included publications arising from this study that did not	

contribute additional data	

N/A – Not applicable

Lovell, 2014

Guideline record ID: 10446

Study characteristics		
Citation	Lovell, K., Wearden, A., Bradshaw, T., Tomenson, B., Pedley, R., Davies, L. M., Husain, N., Woodham, A., Escott, D., Swarbrick, C. M., Femi-Ajao, O., Warburton, J., & Marshall, M. (2014). An exploratory randomized controlled study of a healthy living intervention in early intervention services for psychosis: the INTERvention to encourage ACTivity, improve diet, and reduce weight gain (INTERACT) study. The Journal of Clinical Psychiatry, 75(5), 498-505. https://doi.org/https://dx.doi.org/10.4088/JCP.13m08503	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	An exploratory randomized controlled study of a healthy living intervention in early intervention services for psychosis: the INTERvention to encourage ACTivity, improve diet, and reduce weight gain (INTERACT) study	
Location	UK	
Trial name	INTERvention to Encourage ACTivity, Improve Diet, and Reduce Weight Gain (INTERACT)	
Methods		
Inclusion criteria	“Inclusion criteria were the following: 16 to 35 years old; diagnosis of schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, brief reactive psychosis, or psychosis not otherwise specified; first episode of psychosis occurring within the 3 years preceding the trial; current user of an early intervention service; stable accommodation; ability to give informed consent; and BMI of ≥25 or of ≥24 for service users from the South Asian community.”	
Exclusion criteria	“Diagnosis of substance dependence or abuse at a level that would interfere with participation, a significant history of organic factors implicated in the etiology of psychotic symptoms, and pregnancy.”	
Setting	Early intervention services for psychosis	
Intervention	“The healthy living intervention drew on Leventhal's Common Sense Model,24,25 which suggests that a person's behavioral responses to a threat to their health (in this case, the threat posed by weight gain and associated cardiometabolic consequences) are generated by and congruent with that person's perceptions of the health threat. The intervention contained both motivational and behavioral components, starting with exploration of existing beliefs and psychoeducation to provide the motivation for embarking on a weight control program, followed by the facilitation of participatory exercise and dietary change through the development of patient-centered goals and implementation and review of patient-led action plans. Participants received 7 individual face-to-face sessions over 6 months, with a "booster" session at 9-10 months. The intervention was delivered by support, time, and recovery workers, who attended a 3-day training program prior to delivering the intervention. The support, time, and recovery workers received supervision from the study team. In addition to the face-to-face sessions, access to a range of optional group activities (eg, football, walking, cycling, cooking groups) was offered by the support, time, and recovery workers. A booklet26 and a Web site27 were developed to provide educational advice, action plans, goals, and healthy-eating recipes”	
Control/Comparator	“The early intervention services works individually with service users and their families to address problems/needs that are identified through detailed assessments; all service users have enhancedcare coordination and all have a specific care plan. When appropriate as part of the care plan, service users in the TAU group received some level of support from their case managers to undertake physical health activities, although there was no systematic approach to weight control.”	

<table>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Weight for height growth chart</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 105
Intervention group/s: Healthy Living Intervention (n=54)

Comparator group: Treatment as Usual (n=51)</td></tr>
<tr><td>Mean age ± SD</td><td>25.7y (5.7)</td></tr>
<tr><td>Sex</td><td>40.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Diagnosis of schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, brief reactive psychosis, or psychosis not otherwise specified.</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Healthy Living Intervention: 97.5
(22.5)</td><td>Treatment as Usual: 93
(14.9)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Healthy Living Intervention: 32.7
(5.9)</td><td>Treatment as Usual: 32.1
(4.3)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Healthy Living Intervention: 108.1
(16.3)</td><td>Treatment as Usual: 107.9
(11.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)</td><td>Healthy Living Intervention: -0.9
(7)</td><td>Treatment as Usual: 0
(10.1)</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (SD)</td><td>Healthy Living Intervention: -0.3
(2.3)</td><td>Treatment as Usual: 0
(3.4)</td></tr>
<tr><td>Change in waist circumference (cm)
Mean (SD)</td><td>Healthy Living Intervention: -1.4
(8.6)</td><td>Treatment as Usual: -0.7
(8.7)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>52 (96.3%) had at least 1 session and 42 (77.7%) completed 6-8 sessions.</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Lowe, 2018

Guideline record ID: 10447--1

Study characteristics		
Citation	Lowe, M. R., Butryn, M. L., & Zhang, F. (2018). Evaluation of meal replacements and a home food environment intervention for long-term weight loss: a randomized controlled trial. The American Journal of Clinical Nutrition, 107(1), 12-19. https://doi.org/10.1093/ajcn/nqx005	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Evaluation of meal replacements and a home food environment intervention for long-term weight loss: a randomized controlled trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria for the study were as follows: men and women between the ages of 18 and 65 y, with a BMI (kg/m2) between 27 and 45, able to travel regularly to the study location, and interested in participating in a weight-loss program."	
Exclusion criteria	"Exclusion criteria for the study were as follows: currently enrolled in another organized weight-loss program, lactose intolerance, taking medications that affect appetite (unless dosage had been stable for at least the previous 6 mo), history of gastric bypass or other surgical weight-loss procedures, medical conditions (e.g., cancer, substance abuse, psychotic disorders) that could limit participants' ability to comply with the behavioral recommendations or pose a risk to the participant during weight loss, pregnancy or planning to become pregnant during the next 2 y, breastfeeding, and consuming an amount of alcohol that could interfere with study completion."	
Setting	Home, University/research centre	
Intervention	"Group 1: behavioural therapy plus 2 meal replacements per day, Group 2: modification of the home food environment"	
Control/Comparator	"behavioural therapy including nutrition and physical activity elements."	
Treatment duration	12 months	
Follow-up from baseline	36 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 262 Intervention group/s: Behavioural therapy + meal replacements (BT+MR) (n=91); Home Food Environment (HFE) (n=81) Comparator group: Behavioural therapy (BT) (n=90)	
Mean age ± SD	BT: 47.7y (12.57); BT+MR: 50.38y (9.39); HFE: 51.46y (9.42)	
Sex	80.53% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (lbs)
Mean (SD)</td><td>Behavioural therapy + meal replacements (BT+MR): 209.89
(35.73)
Home Food Environment (HFE): 211.8
(39.56)</td><td>Behavioural therapy (BT): 222.96
(39.39)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Percentage weight loss
Mean (SD)</td><td>Behavioural therapy + meal replacements (BT+MR): 10.37
(7.77)
Home Food Environment (HFE): 10.97
(7.79)</td><td>Behavioural therapy (BT): 9.41
(7.92)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Percentage weight loss
Mean (SD)</td><td>Behavioural therapy + meal replacements (BT+MR): 3.06
(6.93)
Home Food Environment (HFE): 4.49
(7.83)</td><td>Behavioural therapy (BT): 4.21
(8.64)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Lubans, 2016

Guideline record ID: 10448--1

Study characteristics		
Citation	Lubans, D. R., Smith, J. J., Plotnikoff, R. C., Dally, K. A., Okely, A. D., Salmon, J., & Morgan, P. J. (2016). Assessing the sustained impact of a school-based obesity prevention program for adolescent boys: the ATLAS cluster randomized controlled trial. International Journal of Behavioral Nutrition and Physical Activity, 13, 92. https://doi.org/10.1186/s12966-016-0420-8	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Assessing the sustained impact of a school-based obesity prevention program for adolescent boys: the ATLAS cluster randomized controlled trial	
Location	Australia	
Trial name	Active Teen Leaders Avoiding Screen-time (ATLAS)	
Methods		
Inclusion criteria	"Schools located in the Newcastle, Hunter and Central Coast regions of NSW classified within an IRSD decile ≤ 5 (lowest 50 %) were considered eligible. All male students in their first year at the study schools completed a short screening questionnaire to assess their eligibility for inclusion. Students failing to meet either international physical activity (<60 mins MVPA each day) or screen-time (≥2 h per day) guidelines [15] were considered eligible and invited to participate."	
Exclusion criteria	Not reported	
Setting	Home, School	
Intervention	"ATLAS was a 20-week school-based intervention [19] and included the following key components: teacher professional learning (2 × 5 h workshops); provision of fitness equipment to schools (1 × pack/school valued at ~ $1500); researcher-led seminars for students (3 × 20 min); face-toface physical activity sessions delivered by teachers during the school sport period (20 × ~90 min, in addition to regular PE lessons); lunch-time physical activity leadership sessions run by students (6 × 20 min); pedometers for physical activity self-monitoring (17 weeks); parental strategies for reducing recreational screen-time (4 × newsletters); and a purpose-built web-based smartphone application (15 weeks). The intervention was based on Self-determination theory [20] and Social cognitive theory [21] and aimed to support students' psychological needs for autonomy, competence and relatedness to improve their autonomous motivation for school sport and leisure-time physical activity. As national and international physical activity guidelines recommend young people engage in activity to strengthen muscles (e.g., resistance training) at least twice a week [14, 15], the intervention aimed to improve boys' self-efficacy for resistance-based exercise, by explicitly targeting resistance training movement skill competency. Teachers were provided with professional development and equipment to deliver resistancebased exercise. These intervention components were important as muscular fitness levels of school-age youth are decreasing [22, 23] and schools and teachers often lack the necessary facilities and expertise to deliver nontraditional activities, such as resistance training [24]. The ATLAS intervention targeted adolescent boys considered to be 'at risk' of obesity. Although weight status was not an inclusion criteria (such an approach may lead to stigmatization and bullying), we designed the program to be appropriate for overweight youth. Resistance training is an ideal activity for overweight adolescents because they find it easier than aerobic exercise [25-27] and it can improve muscular fitness and body composition [28, 29]. In addition, resistance training has the potential to improve adolescents' self-esteem via the mechanisms of task mastery (self-efficacy) and physical self-concept (i.e., perceived strength and appearance) [26, 30]. This is especially true among adolescent boys. because power and strength appear to be aligned with male	

<table>
<tr><td></td><td>ideals of masculinity [31-33]. The ATLAS recruitment strategies were socio-culturally [34] adapted to focus on valued outcomes for young western males (e.g., "Would you like to get fitter and stronger?"). However, the intervention was carefully designed to minimize adolescents' expectations of hypertrophy (i.e., increase in skeletal muscle size) and emphasized technical skill and competency, as recommended in pediatric resistance training guidelines [27, 35]. Teachers were trained to deliver the enhanced sport sessions using the SAAFE (Supportive, Active, Autonomous, fair and Enjoyable) teaching principles [36], designed to enhance students' autonomous motivation for physical activity. Each session included the following structure: (i) warm up: movement-based games and dynamic stretches; (ii) resistance training skill development: resistance band and body weight exercise circuit; (iii) fitness challenge: short duration, high intensity Crossfit™-style workout [37] performed individually with the aim of completing the workout as quickly as possible; (iv) modified games: minor strength and aerobicbased games (e.g., sock wrestling, tag-style games) and small-sided ball games that maximize participation and active learning time (e.g., touch football); and (v) cool down: static stretching and discussion of ATLAS messages. Professional learning workshops and session observations were conducted to ensure that the intervention was delivered as intended and to maximize intervention impact [34]. Following the primary study endpoint (8-months), schools and participants received no further contact from the research team (except to organize data collection). However, boys continued to have access to the smartphone app."</td></tr>
<tr><td>Control/Comparator</td><td>"Waitlist control received regular curriculum."</td></tr>
<tr><td>Treatment duration</td><td>8 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 361
Intervention group/s: ATLAS Intervention (n=181)

Comparator group: Control (n=180)</td></tr>
<tr><td>Mean age ± SD</td><td>12.7y (0.5)</td></tr>
<tr><td>Sex</td><td>100.00% male</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2) in overweight/obese children Mean (SE)</td><td>ATLAS Intervention: 24.9 (0.8)</td><td>Control: 25.4 (0.7)</td></tr>
<tr><td>BMI z-score in overweight/obese children Mean (SE)</td><td>ATLAS Intervention: 1.93 (0.17)</td><td>Control: 1.96 (0.14)</td></tr>
<tr><td>Waist circumference (cm) in overweight/obese children Mean (SE)</td><td>ATLAS Intervention: 89.7 (2.9)</td><td>Control: 91 (2.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2) in overweight/obese children</td><td>ATLAS Intervention: 26.1 (0.8)</td><td>Control: 29.6 (0.7)</td></tr>
</table>
</td></tr>
</table>

	Mean (SE) BMI z-score in overweight/obese children Mean (SE) Waist circumference (cm) in overweight/obese children Mean (SE)	 ATLAS Intervention: 1.8 (0.17) ATLAS Intervention: 89.1 (2.9)	 Control: 1.91 (0.14) Control: 91.7 (2.4)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Lugones-Sanchez, 2022

Guideline record ID: 10793--1

Study characteristics		
Citation	Lugones-Sanchez, C., Recio-Rodriguez, J. I., Agudo-Conde, C., Repiso-Gento, I., G Adalia, E., Ramirez-Manent, J. I., Sanchez-Calavera, M. A., Rodriguez-Sanchez, E., Gomez-Marcos, M. A., Garcia-Ortiz, L., & EVIDENT 3 Investigators. (2022). Long-term effectiveness of a smartphone app combined with a smart band on weight loss, physical activity, and caloric intake in a population with overweight and obesity (Evident 3 Study): randomized controlled trial. Journal of Medical Internet Research, 24(2), e30416. https://doi.org/https://dx.doi.org/10.2196/30416	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-term Effectiveness of a Smartphone App Combined With a Smart Band on Weight Loss, Physical Activity, and Caloric Intake in a Population With Overweight and Obesity (Evident 3 Study): Randomized Controlled Trial	
Location	Spain	
Trial name	Evident 3 study	
Methods		
Inclusion criteria	"The inclusion criteria were age between 20 and 65 years, a BMI between 27.5 kg/m2 and 40 kg/m2, classified as sedentary (20 minutes of vigorous-intensity activity ≤3 times per week; 30 minutes of moderate-intensity activity ≤5 times per week; or any combination of moderate and vigorous activity ≤5 times per week [33]), agreement to participate in the study, and signing the informed consent document."	
Exclusion criteria	Not reported	
Setting	GP clinic	
Intervention	"A trained nurse at each primary health centre, who was not involved in other aspects of the study, gave 5 minutes of lifestyle counselling to both groups (CG and IG) before randomization, focusing on physical activity and diet in compliance with the international recommendations for the general population. The health benefits of physical activity were explained as well as the recommendation to complete at least 30 minutes of moderate activity 5 days a week, or 20 minutes of vigorous activity 3 days a week. Counselling on food was in compliance with the plate method, in which a plate is divided into 4 parts: half the plate for salad or vegetables, one-quarter for proteins (white meat preferred over red meat), and the final quarter for carbohydrates. In addition, a medium-sized piece of fruit and a skimmed dairy product should be consumed for dessert. This advice enhanced the intake of healthy food, according to the Mediterranean diet pattern, and daily caloric intake goals were not included. The IG received a low-intensity intervention consisting of a smartphone with the EVIDENT 3 app (Samsung Galaxy J3) and a smart band (Xiaomi Mi Band 2) for 3 months, corresponding to the length of the intervention, without any additional reinforcement or counselling by the investigators throughout the study. Participants were trained at another 15-minute visit scheduled 7 days after the baseline visit in the use of the app (EVIDENT 3 app) specifically designed for the study by CGB Computer Company and APISAL, as well as the use of the smart band, instructing them to use both tools daily. It was designed to allow full daily self-monitoring of food intake (Figure 2) and automatically record physical activity through the smart band, which was configured to synchronize with the app. Participants entered their food intake daily by selecting dishes and foods from the app menu and indicating the portion size. The app integrates the data to create personalized healthy food recommendations based on the Mediterranean diet pattern and specific targets for daily calorie intake that would lead to weight loss. It was configured to achieve a hypocaloric diet. The smart band was set to congratulate the user when reaching 10,000 steps/day, and the app displayed this step recommendation in the	

<table>
<tr><td></td><td>goals section. Behavioural strategies were included in the mHealth intervention to enhance self-efficacy using self-monitoring, goal-setting, and positive reinforcement. At the 3-month visit, participants returned the intervention tools to the researchers. Thereafter, participants did not have access to the intervention devices and were advised not to use other digital tools for weight loss until the end of the study. In addition, once the tools were returned, monthly mean daily steps and activity minutes were collected for the last 2 of the 3 months of the intervention from the Mi Fit app (Xiaomi) to assess whether the smart band was worn."</td></tr>
<tr><td>Control/Comparator</td><td>"Standard Counseling (CG and IG) A trained nurse at each primary health center, who was not involved in other aspects of the study, gave 5 minutes of lifestyle counseling to both groups (CG and IG) before randomization, focusing on physical activity and diet in compliance with the international recommendations for the general population. The health benefits of physical activity were explained as well as the recommendation to complete at least 30 minutes of moderate activity 5 days a week, or 20 minutes of vigorous activity 3 days a week. Counseling on food was in compliance with the plate method [46], in which a plate is divided into 4 parts: half the plate for salad or vegetables, one-quarter for proteins (white meat preferred over red meat), and the final quarter for carbohydrates. In addition, a medium-sized piece of fruit and a skimmed dairy product should be consumed for dessert. This advice enhanced the intake of healthy food, according to the Mediterranean diet pattern, and daily caloric intake goals were not included. No reinforcement of counseling was offered at any other study visit or between the 3- and 12-month visits."</td></tr>
<tr><td>Treatment duration</td><td>3 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 650
Intervention group/s: Intervention (n=318)

Comparator group: Control (n=332)</td></tr>
<tr><td>Mean age ± SD</td><td>48.31y (9.67)</td></tr>
<tr><td>Sex</td><td>68.46% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)

Waist circumference (cm) - Baseline
Mean (SD)

BMI (kg/m2) - Baseline
Mean (SD)</td><td>Intervention: 91.4
(14.8)

Intervention: 107.4
(12.9)

Intervention: 33.1
(3.4)</td><td>Control: 91.1
(14.8)

Control: 107.4
(10.7)

Control: 32.9
(3.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss of ≥5%
Proportion (%)</td><td>Intervention: 19.4</td><td>Control: 18.5</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in Weight (kg)
Mean (95% CIs)

Change in Waist circumference (cm)
Mean (95% CIs)

Change in BMI (kg/m2)
Mean (95% CIs)</td><td>Intervention: -1.46
(-2.15--0.77)

Intervention: -2.28
(-3.14--1.43)

Intervention: -0.49
(-0.74--0.24)</td><td>Control: -1.2
(-1.87--0.54)

Control: -1.8
(-2.57--1.04)

Control: -0.43
(-0.66--0.19)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>The median app use was 64.5 days out of the 90 days of the intervention (71.67%). Of the 318 participants assigned to the IG, 150 (47.2%) adhered sufficiently by recording data in the app between 61 and 90 days.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Lundgren, 2021

Guideline record ID: 10449

Study characteristics		
Citation	Lundgren, J. R., Janus, C., Jensen, S. B. K., Juhl, C. R., Olsen, L. M., Christensen, R. M., Svane, M. S., Bandholm, T., Bojsen-Møller, K. N., Blond, M. B., Jensen, J.-E. B., Stallknecht, B. M., Holst, J. J., Madsbad, S., & Torekov, S. S. (2021). Healthy weight loss maintenance with exercise, liraglutide, or both combined. The New England Journal of Medicine, 384(18), 1719-1730. https://doi.org/10.1056/NEJMoa2028198	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Healthy Weight Loss Maintenance with Exercise, Liraglutide, or Both Combined	
Location	Denmark	
Trial name	Synergy effect of the appetite hormone GLP-1 (Liraglutide) and Exercise (S-LiTE)	
Methods		
Inclusion criteria	"Eligible participants were adults (18 to 65 years of age) with obesity, which was defined as a body-mass index (BMI; the weight in kilograms divided by the square of the height in meters) of 32 to 43."	
Exclusion criteria	"Diabetes (type 1 or 2) was a major exclusion criterion. Angina pectoris, coronary heart disease, or congestive heart failure (NYHA III-IV). Severe renal impairment (creatinine clearance (eGFR) <30 mL/min). Severe hepatic impairment. Inflammatory bowel disease. Gastroparesis. Cancer. Chronic obstructive lung disease. Psychiatric disease, a history of major depressive, or other severe psychiatric disorders. The use of medications that cause clinically significant weight gain or loss. Previous bariatric surgery. A history of idiopathic acute pancreatitis. A family or personal history of multiple endocrine neoplasia type 2 or familial medullary thyroid carcinoma. Osteoarthritis, which is judged to be too severe to manage the exercise program. Pregnancy, expecting pregnancy, or breastfeeding. Allergy to any of the ingredients of the study medication: liraglutide, disodium phosphate dihydrate, propylene glycol, phenol, hydrochloric acid, and sodium hydroxide. Regular exercise training at high intensity (e.g. spinning) >2 hours per week."	
Setting	Home, University/research centre	
Intervention	"The exercise program was designed to meet the World Health Organization (WHO) recommendations on physical activity for health of a minimum of 150 minutes per week of moderate-intensity aerobic physical activity, or 75 minutes per week of vigorous-intensity aerobic physical activity, or an equivalent combination of both.27 Each participant was assigned to an instructor (who had a bachelor's or master's degree in exercise physiology) who planned and monitored the individualized programs. After an initial 6-week rampup phase, participants were encouraged to attend supervised group exercise sessions (which involved 30 minutes of vigorous-intensity, interval-based indoor cycling and 15 minutes of circuit training) two times per week and to perform moderate-tovigorous-intensity exercise individually (which mostly involved outdoor or indoor cycling, running, or brisk walking) two times per week. Heart-rate monitors were worn at all exercise sessions to determine whether the requirement regarding weekly time spent at moderate or vigorous intensity was met. The exercise program was structured but flexible, which meant that participants could substitute group exercise with individual exercise or vice versa; participants could also reduce exercise frequency if the duration was prolonged or the intensity was increased. Modifications were made in agreement between the participant and instructor if deemed necessary in order to reach the sufficient exercise volume (duration×intensity). Adherence was based on the weekly exercise volume; Liraglutide (at a concentration of 6 mg per milliliter) or volume-matched placebo was injected subcutaneously, starting at a dose of 0.6 mg per day, with supervised weekly increments of 0.6 mg per day; the dose was intended to eventually reach 3.0 mg per day. Participants who had unacceptable adverse	

<table>
<tr><td></td><td>effects at a given dose received the maximum dose at which they did not have such effects.”</td></tr>
<tr><td>Control/Comparator</td><td>“Placebo and were instructed to maintain usual physical activity.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 195
Intervention group/s: Exercise (n=48); Liraglutide (n=49); Exercise + Liraglutide (n=49)

Comparator group: Placebo (n=49)</td></tr>
<tr><td>Mean age ± SD</td><td>43y (12)</td></tr>
<tr><td>Sex</td><td>63.59% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)</td><td>Exercise: 96.8
(13.2)
Liraglutide: 95.1
(12.8)
Exercise + Liraglutide: 98.3
(11.5)</td><td>Placebo: 96.7
(12.7)</td></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)</td><td>Exercise: 32.7
(3)
Liraglutide: 32.7
(3.1)
Exercise + Liraglutide: 32.8
(2.4)</td><td>Placebo: 32.3
(3)</td></tr>
<tr><td>% Body fat - Baseline
Mean (SD)</td><td>Exercise: 37.8
(7)
Liraglutide: 39.3
(6.7)
Exercise + Liraglutide: 39.5
(6.7)</td><td>Placebo: 37.9
(7.1)</td></tr>
<tr><td>Fat mass (kg)
Mean (SD)</td><td>Exercise: 37.1
(8.8)
Liraglutide: 37.7
(6.9)
Exercise + Liraglutide: 39
(6.2)</td><td>Placebo: 37
(6.8)</td></tr>
<tr><td>Waist circumference (cm) - Baseline
Mean (SD)</td><td>Exercise: 99
(9)
Liraglutide: 100.7
(11.8)
Exercise + Liraglutide: 102
(8.3)</td><td>Placebo: 99.6
(10.4)</td></tr>
</table>
</td></tr>
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<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Proportion with ≥5% loss of initial body weight, %
Proportion (%)</td><td>Exercise: 80
Liraglutide: 88
Exercise + Liraglutide: 87</td><td>Placebo: 70</td></tr>
<tr><td>Proportion with ≥10% loss of initial body weight,%
Proportion (%)</td><td>Exercise: 45
Liraglutide: 59
Exercise + Liraglutide: 69</td><td>Placebo: 28</td></tr>
<tr><td>Proportion with ≥15% loss of initial body weight, %
Proportion (%)</td><td>Exercise: 30
Liraglutide: 29
Exercise + Liraglutide: 49</td><td>Placebo: 10</td></tr>
<tr><td>Proportion with ≥20% loss of initial body weight, %
Proportion (%)</td><td>Exercise: 18
Liraglutide: 22
Exercise + Liraglutide: 33</td><td>Placebo: 2</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in Body weight (kg) from baseline
Mean (95% CIs)</td><td>Exercise: 2
(-0.7-4.6)
Liraglutide: -0.7
(-3.2-1.8)
Exercise + Liraglutide: -3.4
(-5.9--0.9)</td><td>Placebo: 6.1
(3.5-8.7)</td></tr>
<tr><td>Change in % Body fat
Mean (95% CIs)</td><td>Exercise: -1.8
(-2.9)
Liraglutide: -1.6
(-2.6--0.6)
Liraglutide: -3.5
(-4.5--2.5)</td><td>Placebo: 0.4
(-0.6-1.5)</td></tr>
<tr><td>Change in Fat mass (kg)
Mean (95% CIs)</td><td>Exercise: -1.4
(-3.4-0.6)
Liraglutide: -2
(-3.9--0.2)
Exercise + Liraglutide: -4.7
(-6.5--2.9)</td><td>Placebo: 2.6
(0.7-4.5)</td></tr>
<tr><td>Change in waist circumference (cm)
Mean (95% CIs)</td><td>Exercise: 0.5
(-1.8-2.8)
Liraglutide: -1.1
(-3.2-1.1)
Exercise + Liraglutide: -3.9
(-6--1.8)</td><td>Placebo: 4.4
(2.2-6.7)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Exercise and Exercise +Liraglutide groups: compliance to WHO guidelines 119% (70) and 113% (71) respectively.; Mean dose of liraglutide was 2.8±0.4 mg per day in the liraglutide group and 2.8±0.7 mg per day in the combination group</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Lutes, 2017

Guideline record ID: 10450--1

Study characteristics		
Citation	Lutes, L. D., Cummings, D. M., Littlewood, K., Dinatale, E., & Hambidge, B. (2017). A community health worker-delivered intervention in African American women with type 2 diabetes: a 12-month randomized trial. Obesity, 25(8), 1329-1335. https://doi.org/https://dx.doi.org/10.1002/oby.21883	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A Community Health Worker-Delivered Intervention in African American Women with Type 2 Diabetes: A 12-Month Randomized Trial	
Location	USA	
Trial name	Empowering Rural African American Women and Communities to Improve Diabetes Outcomes (EMPOWER)	
Methods		
Inclusion criteria	"The study recruited rural, adult (19-75 years old), African American women, either self-referred or provider-referred, with an established diagnosis of T2D and HbA1c ≥7.0% at the time of enrollment. Other inclusion criteria included competency to provide consent and ability to communicate in English."	
Exclusion criteria	"Exclusion criteria were limited to a diagnosis of advanced disease (e.g., end-stage renal disease, advanced heart failure, blindness, metastatic cancer), the presence of alcoholism or major psychiatric disease that would preclude active participation, or participation in another weight loss or diabetes program."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Each patient in the Small Changes group was provided with a 16- week EMPOWER treatment manual, recording forms, a weight scale, a glucose monitor, and a pedometer (to monitor physical activity) during the first treatment session. Each additional session started with a patient check-in led by the CHW, reviewing monitored behaviors, successes, challenges, and barriers to treatment. CHWs next covered the session material on one of the following topics: self-monitoring, goal setting, nutrition, physical activity, skill power versus willpower, diabetes 101, planning and time management, communication, mindfulness and awareness, breaking negative thought chains, dealing with slips/challenges, coping with stress, utilizing the community, and problem solving. Finally, CHWs ended each session with specific Small Changes-consistent goal setting for the upcoming weeks."	
Control/Comparator	"All patients in the mail-based comparison group received educational materials from the Academy of Nutrition and Dietetics regarding diet selection, healthy snacking, managing medications, monitoring blood glucose, and engaging in physical activity. The number of mailings was consistent with the 16 contacts received in the CHW intervention group."	
Treatment duration	16 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 200 Intervention group/s: Intervention (n=100)	

<table>
<tr><td></td><td>Comparator group: Control (n=100)</td></tr>
<tr><td>Mean age ± SD</td><td>53.45y (10.24)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>T2D and HbA1c ≥7.0%</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 98.09
(21.21)

Intervention: 36.59
(7.48)</td><td>Control: 104.2
(25.36)

Control: 38.8
(8.43)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>Intervention: 96.74
(22.13)</td><td>Control: 103.81
(25.74)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Mean (SD)</td><td>Intervention: -1.35
(6.22)</td><td>Control: -0.39
(4.57)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Lutes, 2017

Guideline record ID: 10795--1

Study characteristics		
Citation	Lutes, L. D., Cummings, D. M., Littlewood, K., Dinatale, E., & Hambidge, B. (2017). A community health worker-delivered intervention in African American women with type 2 diabetes: a 12-month randomized trial. Obesity, 25(8), 1329-1335. https://doi.org/https://dx.doi.org/10.1002/oby.21883	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Behavioral Treatment for Veterans with Obesity: 24-Month Weight Outcomes from the ASPIRE-VA Small Changes Randomized Trial	
Location	USA	
Trial name	Aspiring to Lifelong Health in VA (ASPIRE-VA)	
Methods		
Inclusion criteria	"Participants were provider- or self-referred for weight management services and were eligible for the MOVE! program (BMI > 30 kg/m2, or BMI of 25-30 kg/m2 and at least one obesity-related health condition). Other inclusion criteria were capacity to consent, reliable access to a telephone, and ability to communicate in English."	
Exclusion criteria	"Exclusion criteria included current enrollment in another weight loss or physical activity trial, inability to complete a 6-min walking test, and pregnancy."	
Setting	GP clinic, Home	
Intervention	"The two ASPIRE programs (phone and group) used a small-changes approach. In the first year of this study, goals were designed to achieve a modest daily caloric deficit (100-200 fewer calories) through increased physical activity and modifications to eating patterns that were attainable and self-reinforcing. Logbooks were provided to track food intake and pedometers were provided to track daily step count. ASPIRE-Group sessions were weekly for 90 min in the active treatment phase of the first 3 months. The maintenance phase in months 4 to 12 comprised biweekly 60-min sessions for 6 months, and then monthly 60-min sessions for the next 3 months. The total treatment dose was 33 h. ASPIRE-Phone sessions were up to 30 min in the first 3 months and 20 min in the maintenance phase, for a total treatment dose of 11 h. ASPIRE was a manualized intervention in which the coach sought to elicit active engagement and discussion with participants regarding key self-regulatory topics and skills based on social cognitive theory (5), problem-solving therapy (30), and motivational interviewing. The current study focuses on the second year, in which participants were offered the opportunity to continue with their same coach in the same program as during the first year (i.e., phone for ASPIRE-Phone, in-person groups for ASPIRE Group). However, coaching sessions were less frequent; rather than monthly, they were scheduled every other month (n = 6 sessions). Both SC arms had the same number of sessions, but total contact time was different: phone sessions lasted 20 min and group sessions lasted 60 min. As in the last 3 months of the first year, sessions consisted in 1) checking in on progress toward patient-selected goals, 2) problem-solving any issues related to barriers and challenges to making dietary and physical activity changes, and 3) setting goals for the following 2 months."	
Control/Comparator	"In the first year, individuals who were randomized to the MOVE! program had 11-12 weekly sessions delivered by a team of leaders in each of the two study sites. Sessions were led by an interdisciplinary group of providers, including dietitians, health psychologists, and physical therapists who rotated from session to session. After completion of the weekly sessions, the sites offered a range of options: quarterly 90-min or biweekly 60-min group sessions, repeating the initial series of 11 or 12 weekly sessions, or engaging in other programs (e.g., TeleMOVE, an in-home technology-based program). These offerings	

<table>
<tr><td></td><td>continued, unchanged, into the second year, which this study is focused on. Study staff contacted MOVE! participants only to obtain consent for participation in the study's second year and to schedule and conduct their 18- and 24-month assessments.”</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 332
Intervention group/s: Aspire-Phone (n=105); Aspire-Group (n=115)

Comparator group: MOVE!-Usual Care (n=112)</td></tr>
<tr><td>Mean age ± SD</td><td>55.0y (10.0)</td></tr>
<tr><td>Sex</td><td>85.54% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>Aspire-Phone: 35.5
(5.6)
Aspire-Group: 36.4
(6)</td><td>MOVE!-Usual Care: 36.5
(6.4)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight change from baseline
Mean (95% CIs)</td><td>Aspire-Phone: -1.93
(-3.13--0.74)
Aspire-Group: -3
(-4.14--1.86)</td><td>MOVE!-Usual Care: -1.32
(-2.48--0.16)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight change from baseline
Mean (95% CIs)</td><td>Aspire-Phone: -2.13
(-3.43--0.83)
Aspire-Group: -1.4
(-2.61--0.18)</td><td>MOVE!-Usual Care: -1.78
(-3.07--0.49)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Vimalananda, V., Damschroder, L., Janney, C. A., Goodrich, D., Kim, H. M., Holleman, R., Gillon, L., & Lutes, L. (2016). Weight loss among women and men in the ASPIRE-VA behavioral weight loss intervention trial. Obesity, 24(9), 1884-1891. https://doi.org/https://doi.org/10.1002/oby.21574</td></tr>
</table>

N/A – Not applicable

Ma, 2013

Guideline record ID: 10796--1

Study characteristics		
Citation	Ma, J., Yank, V., Xiao, L., Lavori, P. W., Wilson, S. R., Rosas, L. G., & Stafford, R. S. (2013). Translating the Diabetes Prevention Program lifestyle intervention for weight loss into primary care: a randomized trial. JAMA Internal Medicine, 173(2), 113-121. https://doi.org/10.1001/2013.jamainternmed.987	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Translating the Diabetes Prevention Program lifestyle intervention for weight loss into primary care: a randomized trial	
Location	US	
Trial name	Evaluation of Lifestyle Interventions to Treat Elevated Cardiometabolic Risk in Primary Care (E-LITE)	
Methods		
Inclusion criteria	"Inclusion criteria included age≥18 years, BMI≥25 kg/m2, and the presence of pre-diabetes (defined by impaired fasting plasma glucose of 5.6 to 6.9 mmol/L) or metabolic syndrome (defined by 2005 joint criteria of the American Heart Association [AHA] and National Heart, Lung, and Blood Institute)."	
Exclusion criteria	"Exclusion criteria included serious medical or psychiatric conditions (e.g., stroke, psychotic disorder) or special life circumstances (e.g., pregnancy, planned move)."	
Setting	Home, Primary care clinic	
Intervention	"All participants continued to receive standard medical care. Participants' primary care providers were not involved in the conduct of the study. Participants in both intervention groups completed a 3-month intensive intervention phase and a 12-month maintenance phase. During the intensive intervention phase, participants received an adapted, 12-session DPP lifestyle intervention curriculum, Group Lifestyle Balance (GLB)™, that was developed by DPP investigators at the University of Pittsburgh after conclusion of the DPP trial.21-23 The curriculum was delivered face-to-face in 12-weekly classes to coach-led intervention participants or via a home-based DVD to self-directed intervention participants. In addition to receiving GLB intervention materials, coach-led intervention participants had food tastings at check-in and 30-45 minutes of guided physical activity at the end of each weekly class. The E-LITE Lifestyle Coach, a registered dietitian certified to deliver the GLB program, and a contracted fitness instructor jointly taught all the classes at the participating clinic. We made no modifications to the GLB DVD, although self-directed intervention participants attended a single orientation class. During this class (class 1 in the coach-led intervention), participants were trained to use the AHA free Heart360 Web portal (www.heart360.org) for weight and physical activity goal setting and self-monitoring and were given a weight scale and pedometer. Via secure email embedded in the EHR and available to all intervention participants, the Lifestyle Coach sent standardized biweekly reminder messages about self-monitoring to self-directed intervention participants throughout the intensive and maintenance phases and standardized monthly motivational messages to participants in both interventions during the maintenance phase. Participants in both interventions could submit questions or concerns and received responses within 1-2 business days. Only coach-led intervention participants received personalized messages on at least a monthly basis that provided progress feedback and lifestyle coaching based on their Heart360 self-monitoring records during the maintenance phase. Table 1 shows key features of the coach-led intervention."	

<table>
<tr><td>Control/Comparator</td><td>“All participants continued to receive standard medical care. Participants' primary care providers were not involved in the conduct of the study. The study provided no information about weight loss or weight loss goals to participants in the usual care group.”</td></tr>
<tr><td>Treatment duration</td><td>15 months</td></tr>
<tr><td>Follow-up from baseline</td><td>15 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 241
Intervention group/s: Coach-Led (n=79); Self-Directed (n=81)

Comparator group: Usual Care (n=81)</td></tr>
<tr><td>Mean age ± SD</td><td>52.9y (10.6)</td></tr>
<tr><td>Sex</td><td>46.47% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight, kg - Baseline
Mean (SD)</td><td>Coach-Led: 95.3
(18)
Self-Directed: 93.6
(17.1)</td><td>Usual Care: 92.6
(18.1)</td></tr>
<tr><td>Body mass index, kg/m2 - Baseline
Mean (SD)</td><td>Coach-Led: 31.8
(5.1)
Self-Directed: 31.7
(4.7)</td><td>Usual Care: 32.4
(6.3)</td></tr>
<tr><td>Waist circumference, cm
Mean (SD)</td><td>Coach-Led: 106.2
(11.6)
Self-Directed: 105.9
(11.5)</td><td>Usual Care: 106.8
(12.7)</td></tr>
<tr><td>Body Mass Index (intention-to-treat population)
Mean (SE)</td><td>Coach-Led: 32.4
(6.3)
Self-Directed: 31.8
(5.1)</td><td>Usual Care: 32
(5.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body Mass Index (intention-to-treat population)
Mean (SE)</td><td>Coach-Led: 29.6
(0.3)
Self-Directed: 30.2
(0.3)</td><td>Usual Care: 30.9
(0.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (SE)</td><td>Coach-Led: -2.2
(0.3)
Self-Directed: -1.6
(0.3)</td><td>Usual Care: -0.9
(0.3)</td></tr>
</table>
</td></tr>
</table>

	Weight Change (kg) Mean (SE) Percent Weight Change Mean (SE) Change in Waist circumference, cm Mean (SE)	Coach-Led: -6.3 (0.9) Self-Directed: -4.5 (0.9) Coach-Led: -6.6 (0.9) Self-Directed: -5 (0.9) Coach-Led: -5.8 (1) Self-Directed: -4.9 (1)	Usual Care: -2.4 (0.9) Usual Care: -2.6 (0.9) Usual Care: -2.2 (1.1)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Participants in the coach-led intervention attended 75.1±25.6% (74.6±26.3% among men, 75.7±25.2% among women) of the 12 weekly group sessions (median number of sessions attended, 10; interquartile range [IQR], 9 to 11). Only 4 participants (1 man, 3 women) in the self-directed intervention did not attend the single group orientation session. Selfdirected intervention participants had a median number of 31 secure email messages (IQR, 30 to 32) during the 15-month period, and coach-led intervention participants had 19 (IQR, 18 to 22) during the 12-month period after weekly classes were over.		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Ma, 2015

Guideline record ID: 10452--1

Study characteristics		
Citation	Ma, J., Strub, P., Xiao, L., Lavori, P. W., Camargo, C. A., Jr., Wilson, S. R., Gardner, C. D., Buist, A. S., Haskell, W. L., & Lv, N. (2015). Behavioral weight loss and physical activity intervention in obese adults with asthma. A randomized trial. Annals of the American Thoracic Society, 12(1), 1-11. https://doi.org/https://dx.doi.org/10.1513/AnnalsATS.201406-271OC	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Behavioral weight loss and physical activity intervention in obese adults with asthma. A randomized trial	
Location	USA	
Trial name	Breathe Easier through Weight Loss Lifestyle (BE WELL)	
Methods		
Inclusion criteria	"Inclusion criteria included age 18 to 70 years, BMI greater than or equal to 30 kg/m2, and confirmation of uncontrolled persistent asthma through a multistage screening process (i.e., electronic asthma registry queries; completion of the Asthma Control Test (ACT); pre- and post-bronchodilator spirometry; and, if necessary, medical chart reviews by an asthma specialist)."	
Exclusion criteria	"Exclusion criteria included serious medical or psychiatric conditions (e.g., chronic obstructive pulmonary disease, stroke, and psychosis) or special life circumstances (e.g., pregnancy and planned relocation)."	
Setting	Home, University/research centre	
Intervention	"The intervention dually targeted modest weight loss and increased physical activity and had three successive stages: Intensive (13 weekly in-person group sessions over 4 months using a published curriculum, Transitional (two monthly in-person individual sessions), and Extended (three bimonthly or more frequent phone consultations depending on participant needs, preferences, and availability). It was grounded in Social Cognitive Theory (18) and used proven behavior change strategies (e.g., selfmonitoring, action planning, and problem solving) to help participants achieve and maintain realistic, clinically meaningful weight loss (7-10% of baseline) and physical activity (at least 150 min/wk of moderate-intensity physical activity) goals. Following a structured, comprehensive protocol similar to that recommended in the latest obesity treatment guideline, the BE WELL intervention staff monitored and responded to participants' individual weight-loss needs, preferences, and personal circumstances by counseling them on healthy eating with moderate calorie reductions (by 500-1,000 kcal/d, but daily total calories no less than 1,200 kcal), moderate-intensity physical activity (e.g., brisk walking), and behavioral selfmanagement skills suited to what each participant was eating and doing, and the changes (s)he was willing and able to make."	
Control/Comparator	"All participants continued to receive standard medical care from their providers, who were not informed by the study of participants' treatment assignment. Each participant received a pedometer, a body weight scale, a list of routinely offered KPNC weight management services, and a KPNC standard asthma self management educational DVD. The research team made no other attempts to intervene with control participants."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 330
Intervention group/s: Intervention (n=165)

Comparator group: Enhanced Usual Care (n=165)</td></tr>
<tr><td>Mean age ± SD</td><td>47.6y (12.4)</td></tr>
<tr><td>Sex</td><td>70.61% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Uncontrolled persistent asthma</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 104.2 (19.1)

Intervention: 37.4 (6)

Intervention: 118 (13.9)</td><td>Enhanced Usual Care: 104.2 (20.1)

Enhanced Usual Care: 37.6 (5.7)

Enhanced Usual Care: 117.7 (14.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion (%) of participants weight loss ≥5% of baseline
Proportion (%)

Proportion (%) of participants with weight loss ≥7% of baseline
Proportion (%)

Proportion (%) of participants with weight loss ≥10% of baseline
Proportion (%)</td><td>Intervention: 38.7

Intervention: 33.3

Intervention: 25.3</td><td>Enhanced Usual Care: 27.7

Enhanced Usual Care: 18.8

Enhanced Usual Care: 15.5</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SE)

Change in weight (%)
Mean (SE)

Change in BMI (kg/m2)
Mean (SE)

Change in waist circumference (cm)
Mean (SE)</td><td>Intervention: -4 (0.8)

Intervention: -4.1 (0.7)

Intervention: -1.4 (0.3)

Intervention: -4.3 (1.2)</td><td>Enhanced Usual Care: -2.1 (0.8)

Enhanced Usual Care: -2.1 (0.7)

Enhanced Usual Care: -0.7 (0.3)

Enhanced Usual Care: -2.7 (1.2)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Maddison, 2023

Guideline record ID: 12019--1

Study characteristics		
Citation	Maddison, R., Hargreaves, E. A., Jiang, Y., Calder, A. J., Wyke, S., Gray, C. M., Hunt, K., Lubans, D. R., Eyles, H., Draper, N., Heke, I., Kara, S., Sundborn, G., Arandjus, C., Gao, L., Lee, P., Lim, M., & Marsh, S. (2023). Rugby Fans in Training New Zealand (RUFIT NZ): a randomized controlled trial to assess the effectiveness of a healthy lifestyle program for overweight men delivered through professional rugby clubs. International Journal of Behavioral Nutrition and Physical Activity, 20(1), 37. https://doi.org/https://doi.org/10.1186/s12966-022-01395-w	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Rugby Fans in Training New Zealand (RUFIT NZ): a randomized controlled trial to assess the effectiveness of a healthy lifestyle program for overweight men delivered through professional rugby clubs	
Location	New Zealand	
Trial name	RUFIT NZ	
Methods		
Inclusion criteria	"Eligible participants were overweight men (defned as a BMI≥28 kg/m2) aged 30-65 years, who were able to safely undertake physical activity, understand and read English, and provide written informed consent."	
Exclusion criteria	"Exclusion criteria included participation in any other healthy lifestyle program, or if participants knew in advance they could not complete the 52-week follow-up."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs), University/research centre	
Intervention	"The overall aim of the intervention was to support men to engage in healthy lifestyle behaviours to reduce weight and develop the necessary skills to maintain these behaviours in the long-term. RUFIT-NZ involved a 12-week healthy lifestyle program, consisting of 12×weekly 2-h sessions. Each intervention session included a 1-h workshop-based education component (See Appendix) and 1-h group-based, but individually tailored, exercise training session. During the education component, participants were introduced to a range of topics relating to physical activity, nutrition, sleep, and alcohol consumption, as well as to key theory-based behaviour change techniques. Education sessions were delivered predominantly by RUFIT-NZ-trained trainers, however nutrition-based components were delivered by the clubs' nutritionists or qualified dieticians, supported by the study nutritionist (HE). This approach differed from the original FFIT program but was consistent with the RUFIT-NZ pilot, which indicated a preference for expert advice on diet and nutrition. All RUFIT-NZ trainers were qualified strength and conditioning trainers involved with the respective rugby clubs. Registered dietitians involved in delivering RUFIT-NZ had a previous connection to the club. For the purpose of this trial, the trainers and nutritionists were employed by the respective clubs and agreed to deliver RUFIT-NZ. Classroom content was standardized, so that all participants received the same education information, but the individual trainers could tailor the format of delivery and level of detail as required. RUFIT-NZ did not engage professional team players in the delivery of the intervention. That decision was based on previous experience with FFIT [7] and our previous pilot trial [9]. the education sessions and the overall delivery of the program was interactive, with RUFIT-NZ trainers and dieticians enabling interactive learning and encouraging camaraderie and a sense of team to facilitate discussion of key topics. Group-based in-stadia physical activity sessions were delivered by the trainers who were given basic guidance to deliver sessions (e.g., start low and build slow), but were also given freedom to structure each session as they chose. This approach allowed trainers to best	

	meet the needs of individuals attending their RUFIT-NZ sessions. Activity sessions were tailored to individual fitness levels and ability. They included aerobic (e.g., stationary rowing and cycling, walking and jogging), muscle strengthening (e.g., weight/circuit training) and flexibility (e.g., warm-up/cool-down activities) exercises [18]. Participants were instructed to use the rating of perceived exertion (RPE) scale to ensure their activity was appropriate for their own fitness level. The difficulty (intensity) of each physical activity session increased over the 12 weeks, accounting for each participant's level of fitness. Throughout the intervention men were encouraged to consider what types of activity they could continue to engage with in community settings. Sessions were varied and utilized the supportive group involvement to foster the sense of being in a 'team'. Group size ranged from approximately 15-20 men per trainer. Roll calls were taken at the beginning of each session to record attendance. To inspire habitual physical activity, men were encouraged to follow a daily step-based walking program over the course of the 12-week intervention period and beyond [19-21] and to use a step counter (pedometer or smartphone app) to track their daily and weekly progress. Trainers encouraged men to engage in other forms of physical activity and with a focus on integrating walking and other forms of incidental activity into daily life (e.g., walking up stairs). RUFIT-NZ trainers also provided physical activity 'homework' that participants could undertake outside of the structured sessions (e.g., researching places in their community to be physically active). Participants' lifestyle behaviours in terms of alcohol, sleep, sedentary behaviour, and nutrition were guided by individual goals, which men set for themselves during the group education sessions and recorded in a workbook. Nutrition content for RUFIT-NZ was developed by our investigator nutritionist (HE), and was consistent with the NZ guidelines approach for weight management using a Family, Activity, Behaviour (FAB) approach [22]. Our aim was to ensure all nutrition sessions were positively framed (e.g., 'what are some good examples of healthy snacks?' and 'where can I find quick easy recipes?'), and involved the delivery of simple messages focused on practical elements of improving diet. Messages aligned with the NZ Eating and Activity Guidelines for Adults [23]. To facilitate an understanding of what men were eating and to help them record their diet, we provided men with a food diary to use as they wished. RUFIT-NZ nutrition sessions targeted the following biggest healthy eating 'wins': • Eating as many fruit and vegetables as possible. • Cooking and preparing food and snacks at home as much as possible. • Eating mostly whole foods (as opposed to packaged/ processed foods and takeaways). • Drinking sugar-free beverages. • Conscious eating (screen-free, mindful eating, ideally in the company of others). A key focus of RUFIT-NZ was to provide men with a range of skills and strategies they could use to develop and maintain a healthy lifestyle, which included managing their weight. To that end, a range of evidence-based behaviour change techniques shown to be effective in improving diet and physical activity were used throughout the education and exercise sessions [24]. Key techniques included: i) identifying autonomous reasons for lifestyle change, ii) goal setting for, and self-monitoring of, weight, physical activity, and healthy diet; iii) intention formation with action plans; iv) experiencing exercise sessions with increased challenges as well as positive feedback on exercise achievements and change reinforcement from trainers to build self-efficacy; and v) identification of barriers and coping planning to help avoid relapse during, and on completion of, the program (see Appendix, for details)."
Control/Comparator	"We used a wait-list control approach- those randomized to the control group were asked to continue with their usual lifestyle for 52 weeks during the trial period but were ofered the RUFIT-NZ intervention at the end of the 12-month follow-up period."
Treatment duration	52 weeks
Follow-up from baseline	52 weeks
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	

<table>
<tr><td>Number of participants</td><td>n= 200
Intervention group/s: Intervention (n=103)

Comparator group: Control (n=97)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 45.1y (8.7); Control: 46.3y (8.7)</td></tr>
<tr><td>Sex</td><td>100.00% male</td></tr>
<tr><td>Pre-existing medical condition</td><td></td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 112.13
(19.35)

Intervention: 35.55
(5.65)

Intervention: 118.14
(13.6)</td><td>Control: 111.46
(17.25)

Control: 35.3
(4.87)

Control: 116.93
(11.39)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 108.47
(19.86)

Intervention: 34.5
(5.52)

Intervention: 113
(13.65)</td><td>Control: 111.34
(19.76)

Control: 35.47
(5.48)

Control: 116.29
(12.79)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in body weight at 52 weeks
Mean (SD)</td><td>Intervention: -2.59
(6.95)</td><td>Control: 0.1
(5.73)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Madrona Marcos, 2019

Guideline record ID: 10799--1

Study characteristics		
Citation	Madrona Marcos, F., Panisello Royo, J. M., Tarraga Marcos, M. L., Rosich, N., Carbayo Herencia, J. A., Alins, J., Castell, E., & Tárraga López, P. J. (2019). Effect of a motivational physical activity program on lipid parameters in patients with obesity and overweight. Clínica e Investigación en Arteriosclerosis (English Edition), 31(6), 245-250. https://doi.org/https://doi.org/10.1016/j.artere.2019.11.002	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a motivational physical activity program on lipid parameters in patients with obesity and overweight	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	"Patients, women and men, should have been referred from their company doctors with the diagnosis of overweight or obesity and an age between 25 and 70 years. They came from the health areas of Anoia and Barcelona."	
Exclusion criteria	"The exclusion criteria that were considered were: (1) severe diseases (bedridden, affected by neoplasms, cognitive disor ders, etc.); (2) secondary obesity (hypothyroidism, Cushing's disease, etc.); (3) severe sensory diseases that interfere with motivational intervention, such as uncorrected visual or auditory impairments, etc.; (4) severe psychiatric diseases; (5) diagnosis of type 1 or type 2 diabetes mellitus with phar macological tmnt; (6) diagnosis of arterial hypertension with pharmacologicaltmnt, and (7) diagnosis of dyslipidemia with pharmacological tmnt."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Group 2 (G2): was added to the intervention of G1 and includes the use of a digital platform that monitors and promoted physical activity (iwopi). This platform allows for registering physical activity and donating it for any of the social causes that exist on the platform. In fact, iwopi is a digital health platform with a methodology based on the science of behavior and behavioral activation, whose objective is to generate the necessary motivation in people to boost physical activity and, subsequently, healthy lifestyle habits. The ability to motivate and activate users is realized through elements of social gamification based on the improvement of physical, mental and social wellbeing. Among these elements of social gamification, iwopi promotes programs and emotional, collective and collaborative challenges, to stimulate physical activity and social relations with a solidary purpose. The user can monitor his or her physical activity through specific physical activity Apps, Devices (wearables, smartwatches, GPS watches), or through a Smartphone and systems such as Apple Health or Google Fit, and convert his or her movement into a real social impact."	
Control/Comparator	"Group 1 (G1): motivated obesity intervention (IMOAP), with trained nurse and small periodic work groups. An hour-long motivational group intervention every two weeks from weeks 1 to 12, following the Lifestyle, Exercise, Attitudes, Relationships, Nutrition (LEARN)19---21 program guidelines, and then monthly from weeks 13 to 32, following the instructions of the Weight Maintenance Survival Guide program, conducted by a nurse who had previously been trained by psychological experts."	
Treatment duration	12 months	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 121
Intervention group/s: G2 (n=60)

Comparator group: G1 (n=61)</td></tr>
<tr><td>Mean age ± SD</td><td>45.55y (12.83)</td></tr>
<tr><td>Sex</td><td>57.02% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>G2: 86.8
(13.2)

G2: 30.8
(3.4)

G2: 90
(9.3)</td><td>G1: 88.8
(14.3)

G1: 31
(3.5)

G1: 87.2
(10.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>G2: 80.473

G2: 28.545</td><td>G1: 83.946

G1: 29.317</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)</td><td>G2: -6.294

G2: -2.475</td><td>G1: -4.898

G1: -1.703</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Maghrabi, 2015

Guideline record ID: 10453--1

Study characteristics		
Citation	Maghrabi, A. H., Wolski, K., Abood, B., Licata, A., Pothier, C., Bhatt, D. L., Nissen, S., Brethauer, S. A., Kirwan, J. P., Schauer, P. R., & Kashyap, S. R. (2015). Two-year outcomes on bone density and fracture incidence in patients with T2DM randomized to bariatric surgery versus intensive medical therapy. Obesity, 23(12), 2344-2348. https://doi.org/https://dx.doi.org/10.1002/oby.21150	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Two-year outcomes on bone density and fracture incidence in patients with T2DM randomized to bariatric surgery versus intensive medical therapy	
Location	USA	
Trial name	Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE)	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	“Gastric bypass + IMT, or sleeve gastrectomy + IMT.”	
Control/Comparator	“Intensive medical therapy alone.”	
Treatment duration	24 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 60 Intervention group/s: Gastric bypass (n=20); Sleeve Gastrectomy (n=20) Comparator group: IMT (n=20)	
Mean age ± SD	Not reported	
Sex	Not reported	
Pre-existing medical condition	Type 2 diabetes	
Results		

Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	Baseline body weight (kg) Median (IQR)	Gastric bypass: 107.6 (92.8-112.5) Sleeve Gastrectomy: 98.5 (87.9-107.4)	IMT: 109.4 (91-122.6)

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% Body weight change
Median (IQR)</td><td>Gastric bypass: -26.3
(-30.9--18.9)
Sleeve Gastrectomy: -24.7
(-29.7--21.2)</td><td>IMT: -0.6
(-5.4-3.6)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% Body weight change
Median (IQR)</td><td>Gastric bypass: -25.3
(-32--18.3)
Sleeve Gastrectomy: -23.4
(-27.1--17.1)</td><td>IMT: -0.3
(-3.6-1.2)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Kashyap, S. R., Bhatt, D. L., Wolski, K., Watanabe, R. M., Abdul-Ghani, M., Abood, B., Pothier, C. E., Brethauer, S., Nissen, S., Gupta, M., Kirwan, J. P., & Schauer, P. R. (2013). Metabolic effects of bariatric surgery in patients with moderate obesity and type 2 diabetes: analysis of a randomized control trial comparing surgery with intensive medical treatment. Diabetes Care, 36(8), 2175-2182. https://doi.org/10.2337/dc12-1596; Schauer, P. R., Bhatt, D. L., Kirwan, J. P., Wolski, K., Aminian, A., Brethauer, S. A., Navaneethan, S. D., Singh, R. P., Pothier, C. E., Nissen, S. E., Kashyap, S. R., & for the STAMPEDE Investigators. (2017). Bariatric surgery versus intensive medical therapy for diabetes - 5-year outcomes. The New England Journal of Medicine, 376(7), 641-651. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1600869; Schauer, P. R., Bhatt, D. L., Kirwan, J. P., Wolski, K., Brethauer, S. A., Navaneethan, S. D., Aminian, A., Pothier, C. E., Kim, E. S. H., Nissen, S. E., Kashyap, S. R., & for the STAMPEDE Investigators. (2014). Bariatric surgery versus intensive medical therapy for diabetes--3-year outcomes. The New England Journal of Medicine, 370(21), 2002-2013. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1401329; Schauer, P. R., Kashyap, S. R., Wolski, K., Brethauer, S. A., Kirwan, J. P., Pothier, C. E., Thomas, S., Abood, B., Nissen, S. E., & Bhatt, D. L. (2012). Bariatric surgery versus intensive medical therapy in obese patients with diabetes. The New England Journal of Medicine, 366(17), 1567-1576. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1200225</td></tr>
</table>

N/A – Not applicable

Mai, 2018

Guideline record ID: 10801--1

Study characteristics		
Citation	Mai, K., Brachs, M., Leupelt, V., Jumpertz-von Schwartzenberg, R., Maurer, L., Grüters-Kieslich, A., Ernert, A., Bobbert, T., Krude, H., & Spranger, J. (2018). Effects of a combined dietary, exercise and behavioral intervention and sympathetic system on body weight maintenance after intended weight loss: results of a randomized controlled trial. Metabolism, 83, 60-67. https://doi.org/https://dx.doi.org/10.1016/j.metabol.2018.01.003	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of a combined dietary, exercise and behavioral intervention and sympathetic system on body weight maintenance after intended weight loss: Results of a randomized controlled trial	
Location	Germany	
Trial name	N/A	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	"Subjects with abnormal thyroid function, hypercortisolism (excluded by 1 mg dexamethasone suppression test), severe chronic diseases, with changes of smoking habits or diet behavior during the last three months, and recent weight changes of N5 kg during the last two months, were excluded."	
Setting	Hospital, University/research centre, University hospital	
Intervention	"All subjects participated in a standardized weight reduction program for 12 weeks to achieve a weight loss of at least 8%. Subjects who lost at least 8% of their body weight during the weight loss phase were considered to be eligible for randomization. Intervention: Subjects in the intervention group received continuous counseling for the next twelve months in gradually diminishing frequency. Weekly group sessions were performed for the first 16 weeks of the 12 months' study period. These were comparable to sessions of the weight loss period including dietary advices for healthy living, workshops with practical cooking exercises, specific recipes, cooking advices, instructions for behavior modifications as well as psychological support. Within the intervention group, the dietary advices were focused on a balanced diet including 35-45% carbohydrates, 25-35% fat, and 25-30% protein. Counseling focused on dietary recommendations advocating the preferential intake of specific foods (like high intake of vegetables, cereals, fat reduced foods, lean meat consumption (lean fish and chicken)). An individual caloric intake was calculated and further adapted in accordance to the information of the eating protocols to achieve body weight maintenance.In case of body weight gain within this intervention period, a lower energy intake (500 kcal below the calculated energy demand) was recommended. The supervised physical activity regime was maintained for the first 12 weeks of weight maintenance period. Thereafter participants were encouraged to exercise at least twice a week but without direct supervision."	
Control/Comparator	"All subjects participated in a standardized weight reduction program for 12 weeks to achieve a weight loss of at least 8%. Subjects who lost at least 8% of their body weight during the weight loss phase were considered to be eligible for randomization. Control: Subjects in the control group were no longer involved in any form of counseling. They received an advice leaflet and were asked to return for examination after 12 and 18 months."	
Treatment duration	12 months	

<table>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 143
Intervention group/s: Intervention (n=72)

Comparator group: Control (n=71)</td></tr>
<tr><td>Mean age ± SD</td><td>50.5y (12.6)</td></tr>
<tr><td>Sex</td><td>78.32% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (95% CIs)</td><td>Intervention: 32.26
(31.88-32.63)</td><td>Control: 32.64
(32.32-32.96)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (95% CIs)</td><td>Intervention: 33.49
(32.64-34.33)</td><td>Control: 34.18
(33.61-34.75)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in BMI (kg/m2)
Mean (SE)</td><td>Intervention: 1.17
(1.34)</td><td>Control: 0.57
(0.93)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Mangieri, 2019

Guideline record ID: 10803

Study characteristics		
Citation	Mangieri, C. W., Johnson, R. J., Sweeney, L. B., Choi, Y. U., & Wood, J. C. (2019). Mobile health applications enhance weight loss efficacy following bariatric surgery. Obesity Research & Clinical Practice, 13(2), 176-179. https://doi.org/10.1016/j.orcp.2019.01.004	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Mobile health applications enhance weight loss efficacy following bariatric surgery	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were patients between the ages of 18-89 who had undergone a laparoscopic sleeve gastrectomy (LSG) within 1 year of enrollment."	
Exclusion criteria	"Exclusion criteria were pregnant females, subjects with immediate post-operative complications, and patients who were not fluent in English."	
Setting	University/research centre, Online	
Intervention	"For the mHealth cohort patients an individual one hour training session on how to use the iPad© and MyFitnessPal© application was performed by the research coordinator to ensure proficiency. Furthermore, the research coordinator ensured the patients in the mHealth group were regularly using the application and assisted with any technical issues using the application. The research coordinator had access to each MyFitnessPal© application profile and would contact patients who did not record any data in the application for greater than 48 h. When the research coordinator contacted patients in the mHealth group it was simply to either remind them to use the application or provide technical support for the application and they did not instruct, educate, or in any other way alter the patients' behavioral patterns. The coordinator was not allowed in any way encourage or ensure mHealth patients were being compliant with the post-operative nutritional and caloric guidelines. For all the study patients they received the exact same standard post-operative care which involved structured outpatient follow-up with the Bariatric Surgery team at 2 weeks, 1 month, 3 months, 6 months, and annually following their index surgery. The research protocol was written to exclude any patients that developed technical failures during the study observation that would lead to suboptimal outcomes following (e.g. dilated sleeve requiring re-sleeve or conversion to Roux-en-Y gastric bypass); however no study participants developed technical failures."	
Control/Comparator	"For patients in the control group they were specifically instructed to not use any mobile health applications as to prevent confounding results. The control patients were informed and encouraged to use self-monitoring journals if they would like however it was not required. For all the study patients they received the exact same standard post-operative care which involved structured outpatient follow-up with the Bariatric Surgery team at 2 weeks, 1 month, 3 months, 6 months, and annually following their index surgery. The research protocol was written to exclude any patients that developed technical failures during the study observation that would lead to suboptimal outcomes following (e.g. dilated sleeve requiring re-sleeve or conversion to Roux-en-Y gastric bypass); however no study participants developed technical failures."	
Treatment duration	Not reported	
Follow-up from baseline	24 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 56
Intervention group/s: mHealth group (n=28)

Comparator group: Control group (n=28)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 52.5y (9.0); Control: 53y (10.6)</td></tr>
<tr><td>Sex</td><td>87.50% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI
Mean (SD)</td><td>mHealth group: 35.34
(8.27)</td><td>Control group: 36.97
(6.91)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Excess body weight loss percentage (%EWL)
Mean (SD)

Percent of excess BMI loss (%EBL)
Mean (SD)</td><td>mHealth group: 81.41
(6.9)

mHealth group: 32.15
(2.26)</td><td>Control group: 74.4
(8)

Control group: 28.02
(2.26)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Excess body weight loss percentage (%EWL)
Mean (SD)

Percent of excess BMI loss (%EBL)
Mean (SD)</td><td>mHealth group: 71.4
(6.8)

mHealth group: 27.87
(2.2)</td><td>Control group: 59.1
(9.9)

Control group: 25.39
(2.2)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Manini, 2010

Guideline record ID: 10804--1

Study characteristics		
Citation	Manini, T. M., Newman, A. B., Fielding, R., Blair, S. N., Perri, M. G., Anton, S. D., Goodpaster, B. C., Katula, J. A., Rejeski, W. J., Kritchevsky, S. B., Hsu, F.-C., Pahor, M., & the LIFE Research Group. (2010). Effects of exercise on mobility in obese and nonobese older adults. Obesity, 18(6), 1168-1175. https://doi.org/https://dx.doi.org/10.1038/oby.2009.317	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of exercise on mobility in obese and nonobese older adults	
Location	US	
Trial name	Lifestyle Interventions and Independence for Elders Pilot (LIFE-P)	
Methods		
Inclusion criteria	"Subjects were eligible for the study if they were between the ages of 70 and 89 years, sedentary (as defined as spending <20 min per week in regular structured PA), Short Physical Performance Battery (SPPB) score ≤9 (9), and were able to walk 400m within 15min."	
Exclusion criteria	Not reported	
Setting	University/research centre	
Intervention	"Participants randomized to the PA intervention performed walking, strength, flexibility, and balance training. The goal for all participants was to walk for 150 minutes at a moderate intensity on 5 or more days of the week, which was approached in three phases. In the adoption phase (weeks 1-8), three supervised center-based PA sessions per week were conducted. These sessions were 40-60 min in length and used to initiate the walking program and to introduce participants to the strength, stretching, and balance portions of the program in a safe and effective manner. The strength exercises included standing chair squats, toe stands, leg curl, knee extensions, and side hip raises with ankle weights. The balance exercises involved a series of dual and signal leg standing movements. Participants were instructed to walk at a ratings of perceived exertion (RPE) intensity of 13 ("SOMEWHAT HARD", range 12-14) and perform strength training at an intensity of 15-16 (10). In the transition phase (weeks 9-24), the number of center-based sessions was reduced to two times per week and home-based walking/strengthening/flexibility activities were increased. In the maintenance phase (week 25 to the end), participants were encouraged to perform homebased PA a minimum of 5 days per week and one weekly center-based session was offered. The maintenance phase was continued until the final closeout assessment visits."	
Control/Comparator	"The SA health education control was designed to provide attention and health education. Study participants attended weekly group presentations for the first 26 weeks and then monthly until the end of the trial. Presentations were given on health topics that were relevant to older adults such as nutrition, medication use, foot care, and preventive medicine. All SA participants received basic information about PA participation and each class was concluded with upper extremity stretching. Regular telephone contact was made to encourage participation."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 179
Intervention group/s: PA (n=102)

Comparator group: SA (n=77)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 75.7y (4.01); Control: 75.5y (3.7)</td></tr>
<tr><td>Sex</td><td>68.16% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)

Body weight (kg)
Mean (SE)

Waist circumference (cm)
Mean (SE)</td><td>PA: 35.7
(5)

PA: 96.3
(1.6)

PA: 113.5
(1.2)</td><td>SA: 35.7
(4.7)

SA: 97.3
(1.8)

SA: 112.9
(1.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SE)

Waist circumference (cm)
Mean (SE)</td><td>PA: 94.4
(1.9)

PA: 111.6
(1.4)</td><td>SA: 96.3
(1.9)

SA: 111.5
(1.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>In total, there were no differences in the number of sessions attended for nonobese and obese individuals who reported to 71.4% and 67.0% of the total sessions, respectively. For the entire 12 month intervention, nonobese individuals had 21% more total walking activity recorded at the clinic-based sessions than obese individuals (median: 1,910 vs. 1,506 walking min)</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Manzoni, 2016

Guideline record ID: 10805--1

Study characteristics		
Citation	Manzoni, G. M., Cesa, G. L., Bacchetta, M., Castelnuovo, G., Conti, S., Gaggioli, A., Mantovani, F., Molinari, E., Cárdenas-López, G., & Riva, G. (2016). Virtual reality-enhanced cognitive-behavioral therapy for morbid obesity: a randomized controlled study with 1 year follow-up. Cyberpsychology, Behavior, and Social Networking, 19(2), 134-140. https://doi.org/https://dx.doi.org/10.1089/cyber.2015.0208	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Virtual Reality-Enhanced Cognitive-Behavioral Therapy for Morbid Obesity: A Randomized Controlled Study with 1 Year Follow-Up	
Location	Italy	
Trial name	Virtual reality in eating disorders (VEPSY)	
Methods		
Inclusion criteria	"Criteria for participation in the study included: (a) a BMI ≥40; (b) 18-50 years of age; (c) no other concurrent severe eating (bulimia, binge eating, or eating disorder not otherwise specified) or psychiatric disturbances (psychosis, depression with suicidal risk, or alcohol or drug abuse); (d) no concurrent involvement in other treatment, including medication; (e) no concurrent medical condition not related to the disorder; and (f) written and informed consent to participate."	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"CBT: Therapists followed a detailed manual that outlined the content of each session. This manual was based on the CBT approach described by Cooper et al.32,33 It was developed during a year of intensive pilot work and adapted to the inpatient setting. Patients were taught to self-monitor their food intake and eating patterns thoughts, as well as the circumstances and environment surrounding eating (e.g., whether eating alone or with others, speed of eating, and place of eating). Patients were also taught to identify problems in eating, mood, and thinking patterns and to develop alternative patterns gradually. In particular, after the first week, the patients entered five weekly group sessions aimed at addressing weight and primary goals, and 10 biweekly individual sessions aimed at establishing and maintaining weight loss, addressing barriers to weight loss, increasing activity, addressing body image concerns, and supporting weight maintenance.; VR: Like the CBT condition, participants allocated to this treatment received 15 additional sessions over 5 weeks.34 After the first inpatients week, participants entered five weekly group sessions similar to the CBT ones (focused on concerns about body weight and shape and problematic eating) and 10 biweekly VR sessions. The treatment was based on a detailed protocol describing the contents of each of the 15 sessions.31,34 For the VR sessions, the NeuroVR open source software (www .neurovr.org) was used.35-37 NeuroVR includes 14 virtual environments used by the therapist during a 60 minute session with the patient. The environments present critical situations related to the maintaining/relapse mechanisms (home, supermarket, pub, restaurant, swimming pool, beach, gymnasium) and two body-image comparison areas. Through the VR experience, patients practice both eating/emotional/ relational management and general decision-making and problem-solving skills. By directly practicing these skills within the VR environment, patients are helped in developing specific strategies for avoiding and/or coping with triggering situations."	
Control/Comparator	"This was the common treatment condition for all the participants. It consists of hospital-based living for 6 weeks. Inpatients receive medical, nutritional, physical, and psychological	

<table>
<tr><td></td><td>care the goal of which is to provide practical guidelines (e.g., stressing gradual weight loss with the caloric restriction achieved largely by reductions in fat intake), plus a low-calorie diet (1,200 kcal/day) and physical training (30 minutes of walking twice a week as a minimum).”</td></tr>
<tr><td>Treatment duration</td><td>6 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 158
Intervention group/s: VR (n=56); CBT (n=52)

Comparator group: SBP (n=50)</td></tr>
<tr><td>Mean age ± SD</td><td>35.63y (8.04)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>VR: 112.1
(15.6)
CBT: 108
(12.1)</td><td>SBP: 110
(15.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>VR: 105.4
(16.2)
CBT: 105.8
(17.1)</td><td>SBP: 114.7
(19.3)</td></tr>
<tr><td>Proportion with weight maintenance/loss after treatment (%)
Proportion (%)</td><td>VR: 48
CBT: 29</td><td>SBP: 11.5</td></tr>
<tr><td>Proportion with weight equal or higher than initial weight
Proportion (%)</td><td>VR: 17.39
CBT: 34.2%</td><td>SBP: 72.4%</td></tr>
<tr><td>Odds of maintaining or further improving weight loss at 1 year - VR vs SBP
Odds Ratio (OR) and 95% CIs</td><td>VR: 7.03
(1.85-26.7)</td><td></td></tr>
<tr><td>Odds of maintaining or further improving weight loss at 1 year - VR vs CBT
Odds Ratio (OR) and 95% CIs</td><td>VR: 2.25
(0.91-5.58)</td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</table>

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Marild, 2013

Guideline record ID: 10806--1

Study characteristics		
Citation	Mårild, S., Gronowitz, E., Forsell, C., Dahlgren, J., & Friberg, P. (2013). A controlled study of lifestyle treatment in primary care for children with obesity. Pediatric Obesity, 8(3), 207-217. https://doi.org/https://dx.doi.org/10.1111/j.2047-6310.2012.00105.x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A controlled study of lifestyle treatment in primary care for children with obesity	
Location	Sweden	
Trial name	N/A	
Methods		
Inclusion criteria	"Children with obesity were eligible if they had obesity in accordance with the IOTF criteria and no ongoing or previous treatment for obesity at registration for the study."	
Exclusion criteria	Not reported	
Setting	Hospital, Outpatient paediatric clinic	
Intervention	"Nurse-dietician-physiotherapist managed treatment (NDPT): Both treatment arms had a total of 12 appointments throughout 1 year. The duration of each treatment session was approximately 60 min. To obtain a common platform for intervention activities, all centres shared a four-page brochure, 'Lätta tips'. A non-stigmatizing communication was used, inspired by educational cognitive treatment models, motivational interviewing and some distinct tools from cognitive behavioural treatment programmes, such as goal setting, monitoring of goals and reinforcement. This programme was designed to put a special emphasis on physical activity. A physiotherapist was engaged to highlight this component, substituting for the nurse in the NDT programme at 4 of the 12 monthly appointments, i.e. each professional had 4 visits or one-third of the 12 sessions. The following elements were discussed and introduced by the physiotherapist using a stepwise approach: • Stimulate the child to reach the recommended duration of 60 min of daily moderated and vigorous intensity physical activity. • Use pedometers for motivation. • Make use of a special diary to register the daily number of pedometer steps, sport activities, inactivity and screen time. Registrations were used to set individual goals and stepwise improve the level of physical activity. • Change transportation to and from school from passive to active (i.e. walking or cycling). • Stimulate the child to participate in physical exercise lessons at school and to have three occasions each week with some kind of special training. • Reduce inactivity; a maximum of 3 h in front of the television or computer was recommended. The physiotherapist provided telephone reminders between her scheduled meetings. Incentives such as movie tickets to the child were used. The exposure to the dietician for participants in this programme did not differ from the NDT programme. The nurse had the same key messages regarding diet and family routines as in the NDT programme but fewer follow-up sessions of goals and messages and to monitor weight development."	
Control/Comparator	"Nurse-dietician managed treatment NDT: Both treatment arms had a total of 12 appointments throughout 1 year. The duration of each treatment session was approximately 60 min. To obtain a common platform for intervention activities, all centres shared a four-page brochure, 'Lätta tips'. A non-stigmatizing communication was used, inspired by educational cognitive treatment models, motivational interviewing and some distinct tools from cognitive behavioural treatment programmes, such as goal setting, monitoring of goals and reinforcement. A paediatric nurse and a dietician were responsible for this treatment option, the nurse offering 8 visits and the dietician offering 4 visits during 12 months (12 visits in total). Ten sessions were in an individual setting, and two were arranged as group meetings with cooking and advice about buying food. Key messages	

<table>
<tr><td></td><td>were: to eat breakfast; to eat at regular times; to eat meals together with the family; and to reduce processed sugar of any kind, especially in soft drinks. Use of the 'plate-model' (a template for how to serve cooked food on the plate to obtain a healthy meal) was another common feature: vegetables comprising one-third of the plate; potatoes, rice or pasta comprising one-third, and meat or fish comprising the final one-third. The nurse monitored the weight development and reinforced the diet-related messages. She also tried to reduce inactivity, discuss the possibility of parents and children spending more time together, limit TV viewing, and highlight the importance of adequate sleep and sound bedtime routines.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 55
Intervention group/s: NDPT (n=28)

Comparator group: NDT (n=27)</td></tr>
<tr><td>Mean age ± SD</td><td>NDPT: 10.6 (1.4); NDT: 10.8 (1.0)</td></tr>
<tr><td>Sex</td><td>54.55% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>NDPT: 66.1
(12.4)

NDPT: 28.7
(2.6)

NDPT: 94.6
(9.37)</td><td>NDT: 71.8
(15.5)

NDT: 29.7
(3.9)

NDT: 96.4
(12.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>NDPT: 72
(12.7)

NDPT: 28.2
(2.7)

NDPT: 95.1
(8.33)</td><td>NDT: 78.1
(16.4)

NDT: 29.4
(4.2)

NDT: 98.8
(11.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)</td><td>NDPT: 5.83
(6.12)

NDPT: -0.46
(2.1)</td><td>NDT: 6.27
(6.65)

NDT: -0.39
(1.9)</td></tr>
</table>
</td></tr>
</table>

	Change in waist circumference (cm) Mean (SD)	NDPT: 0.5 (6.8)	NDT: 1.9 (7.6)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Marin-Alejandre, 2021

Guideline record ID: 10807--1

Study characteristics		
Citation	Marin-Alejandre, B. A., Cantero, I., Perez-Diaz-Del-Campo, N., Monreal, J. I., Elorz, M., Herrero, J. I., Benito-Boillos, A., Quiroga, J., Martinez-Echeverria, A., Uriz-Otano, J. I., Huarte-Muniesa, M. P., Tur, J. A., Martinez, J. A., Abete, I., & Zulet, M. A. (2021). Effects of two personalized dietary strategies during a 2-year intervention in subjects with nonalcoholic fatty liver disease: a randomized trial. Liver International, 41(7), 1532-1544. https://doi.org/https://dx.doi.org/10.1111/liv.14818	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of two personalized dietary strategies during a 2-year intervention in subjects with nonalcoholic fatty liver disease: A randomized trial	
Location	Spain	
Trial name	Fatty Liver in Obesity (FLiO)	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	"Exclusion criteria included the presence of known hepatic disease other than NAFLD, excessive alcohol consumption (>21 units of alcohol per week for men and >14 per women12), weight loss ≥3 kg in the last 3 months, endocrine disorders (hyperthyroidism or uncontrolled hypothyroidism), pharmacological treatment with immunosuppressants, cytotoxic agents, corticosteroids or other drugs that could potentially cause liver steatosis or alteration in hepatic tests,13 severe psychiatric disorders, active autoimmune disease or requiring pharmacological treatment, the use of weight modifiers, and the lack of autonomy or inability to follow the diet, as well as the difficulties in following the scheduled visits."	
Setting	Home, University/research centre	
Intervention	"The Fatty Liver in Obesity (FLiO) diet was designed with a higher meal frequency (7 meals/d). The macronutrient distribution according to the total energy value was: 40%-45% carbohydrates (preferring those with low glycemic index), 25% proteins (predominantly from vegetable sources), and 30%-35% from lipids (favouring extra virgin olive oil and omega-3 polyunsaturated fatty acids to the detriment of saturated and trans fats). The FLiO diet proposed a high adherence to the MedDiet, involving an increased quantity of natural antioxidants based on previous studies of this research group"	
Control/Comparator	"The AHA diet was based on the guidelines of the AHA 15 which propose 3-5 meals/day with a conventionally balanced distribution of macronutrients in relation to the total caloric value: 55% from carbohydrates, 15% from proteins and 30% from lipids with a healthy fatty acid profile."	
Treatment duration	2 years	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 98 Intervention group/s: FLiO diet (n=50) Comparator group: AHA diet (n=48)	

Mean age ± SD	FLiO: 49.2y (8.9); AHA: 51.1y (9.8)
Sex	43.88% female
Pre-existing medical condition	Ultrasonography confirmed NAFLD
Results	

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Weight (kg) Mean (SD)	FLiO diet: 95.1 (14)	AHA diet: 94.4 (14)
BMI (kg/m2) Mean (SD)	FLiO diet: 33.3 (4)	AHA diet: 33.7 (4)
Waist circumference (cm) Mean (SD)	FLiO diet: 108 (9)	AHA diet: 110 (10)
Total fat mass (%) Mean (SD)	FLiO diet: 42.3 (6)	AHA diet: 42.7 (6)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator
Weight (kg) Mean (SD)	FLiO diet: 86.3 (13)	AHA diet: 87.3 (15)
BMI (kg/m2) Mean (SD)	FLiO diet: 30.1 (4)	AHA diet: 31.2 (5)
Waist circumference (cm) Mean (SD)	FLiO diet: 98 (10)	AHA diet: 102 (11)
Total fat mass (%) Mean (SD)	FLiO diet: 37.9 (8)	AHA diet: 38.6 (8)
Proportion (%) with weight loss <3% Proportion (%)	FLiO diet: 20.6	AHA diet: 31.6
Proportion (%) with weight loss 3-5% Proportion (%)	FLiO diet: 5.9	AHA diet: 10.5
Proportion (%) with weight loss >5% Proportion (%)	FLiO diet: 73.5	AHA diet: 57.9

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator
Weight (kg) Mean (SD)	FLiO diet: 89.1 (13)	AHA diet: 89.8 (16)
BMI (kg/m2) Mean (SD)	FLiO diet: 30.8 (4)	AHA diet: 32.1 (5)
Waist circumference (cm) Mean (SD)	FLiO diet: 102 (11)	AHA diet: 108 (13)
Total fat mass (%) Mean (SD)	FLiO diet: 39.2 (8)	AHA diet: 40.1 (7)
Proportion (%) with weight loss <3% Proportion (%)	FLiO diet: 19.2	AHA diet: 46.9

	Proportion (%) with weight loss 3-5% Proportion (%) Proportion (%) with weight loss >5% Proportion (%)	FLiO diet: 11.5 FLiO diet: 69.2	AHA diet: 6.3 AHA diet: 46.9
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in weight (%) Mean (SD)	FLiO diet: -9.6	AHA diet: -6.7
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in weight (%) Mean (SD)	FLiO diet: -7.6	AHA diet: -4.8
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Markert, 2014

Guideline record ID: 10808

Study characteristics		
Citation	Markert, J., Herget, S., Petroff, D., Gausche, R., Grimm, A., Kiess, W., & Blüher, S. (2014). Telephone-based adiposity prevention for families with overweight children (T.A.F.F.-Study): one year outcome of a randomized, controlled trial. International Journal of Environmental Research and Public Health, 11(10), 10327-10344. https://doi.org/https://dx.doi.org/10.3390/ijerph111010327	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Telephone-based adiposity prevention for families with overweight children (T.A.F.F.-Study): one year outcome of a randomized, controlled trial	
Location	Germany	
Trial name	Telephone based Adiposity prevention For Families (T.A.F.F.)	
Methods		
Inclusion criteria	"4-17 years of age and BMI > 90th percentile (last measurement within the past six months)."	
Exclusion criteria	Not reported	
Setting	Home, Telephone based	
Intervention	"The core of the intervention was computer-aided telephone counseling (interviews 20-30 min each) over one year by trained prevention managers according to a standardized manual, based on family therapy approaches and solution-focused systemic therapy. Each counseling interview was preceded by the release of a newsletter (14 issues) via mail or email that addresses the specific topic of the interview (medical background of obesity and associated co-morbidities (one issue), dietary habits (three issues), eating behavior (two issues) physical activity and leisure time habits (three issues), psychological support (two issues), stress management (two issues), and a summary of the intervention including additional information (one issue). The telephone-counselling, as well as the newsletters were tailored to the age of the participating child (4-9 years, 10-13 years, 14-18 years). The telephone counseling addressed the parents or caregivers of the child and primarily targeted self-regulatory capacities by solution focused counseling. The intervention consisted of 14 obligatory telephone calls every three to four weeks and two optional coaching telephone sessions at the end of the intervention as well as a final evaluation of the intervention design itself."	
Control/Comparator	Not reported	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 289 Intervention group/s: Intervention (n=145) Comparator group: Control (n=144)	
Mean age ± SD	Intervention: 9.7y (3.0); Control: 9.8y (3.1)	

<table>
<tr><td>Sex</td><td>50.52% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

BMI-SDS
Mean (SD)</td><td>Intervention: 51.6
(19.9)

Intervention: 24.1
(4.2)

Intervention: 2
(0.52)</td><td>Control: 51.9
(19)

Control: 24.2
(3.5)

Control: 2.04
(0.47)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>% successful in losing weight
Proportion (%)</td><td>Intervention: 21.0%</td><td>Control: 16.0%</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in BMI-SDS
Mean (95% CIs)</td><td>Intervention: -0.015
(-0.09-0.06)</td><td>Control: 0.018
(-0.03-0.07)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Marrero, 2016

Guideline record ID: 10809--1

Study characteristics		
Citation	Marrero, D. G., Palmer, K. N. B., Phillips, E. O., Miller-Kovach, K., Foster, G. D., & Saha, C. K. (2016). Comparison of commercial and self-initiated weight loss programs in people with prediabetes: a randomized control trial. American Journal of Public Health, 106(5), 949-956. https://doi.org/https://dx.doi.org/10.2105/AJPH.2015.303035	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Comparison of Commercial and Self-Initiated Weight Loss Programs in People With Prediabetes: A Randomized Control Trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"To be eligible, a person had to be aged 18 years or older, have a body mass index (BMI; defined as weight in kilograms divided by the square of height in meters) of 24 or higher (persons of Asian descent BMI ǂ 23), and to complete the 7-item American Diabetes Association (ADA) Diabetes Risk Assessment with a score of 5 or greater. In addition, they had to have prediabetes, which was determined by a hemoglobin A1c value between 5.7% and 6.5%. Women with a self-reported history of gestational diabetes with a hemoglobin A1c value less than 6.5% or causal capillary blood glucose (CCBG) less than 199 milligrams per deciliter were also included."	
Exclusion criteria	"Persons were noneligible if they had no evidence of prediabetes; were currently pregnant or planning to become pregnant during the study; had any condition or used any medication that could alter glucose metabolism; suffered heart attack, stroke, or transient ischemic attack in the past 6 months; had uncontrolled hypertension (systolic blood pressure > 180 mm Hg or diastolic blood pressure > 105 mm Hg); received treatment of cancer (excluding surgery alone) within the past 2 years (excluding skin cancer); reported chest pain, shortness of breath with minimal activity or at rest, or unexplained dizziness or fainting with physical activity; had chronic lung disease (chronic obstructive pulmonary disease or asthma requiring home oxygen therapy); current use of antidiabetes medications for the treatment of diagnosed diabetes; were unable to communicate with research staff; were unable to read written English; and were unable or unwilling to provide consent."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The intervention was the lifestyle modification program offered by Weight Watchers International. The Weight Watchers core curriculum is evidence-based and covers the same behavioural topics used in the Diabetes Prevention Program (DPP): 1. self-monitoring of weight, intake, and activity; 2. dietary modification; 3. physical activity; 4. stimulus control; and 5. relapse prevention. The curriculum is delivered in a supportive, weekly group environment by appropriately trained group leaders."	
Control/Comparator	"Participants assigned to the control condition were provided a review of how they could initiate a weight loss and activity program with Your Game Plan to Prevent Type 2 Diabetes educational materials developed by the National Diabetes Education Program. These materials review the meaning and implications of prediabetes, the results of the DPP study, an overview of how to initiate a risk-reducing lifestyle program, a reproducible tracker to help monitor their food intake, and a booklet with fat gram and calorie content for common foods. Emphasis was placed on strategies for tracking food intake and calculating fat grams by using the food tracker and calorie fat gram guide provided in the materials."	

<table>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 225
Intervention group/s: WW (n=112)

Comparator group: Control (n=113)</td></tr>
<tr><td>Mean age ± SD</td><td>52y (11) - WW: 51.5y (11.5); Control: 51.7y (11.0)</td></tr>
<tr><td>Sex</td><td>84.89% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Pre-diabetes: 7-item American Diabetes Association (ADA) Diabetes Risk Assessment with a score of 5 or greater; hemoglobin A1c value between 5.7% and 6.5%.</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>WW: 100.9
(21.7)

WW: 36.9
(7.3)</td><td>Control: 100
(19.9)

Control: 36.7
(7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Percentage weight change (%)
Mean (SE)

Weight change (kg)
Mean (SE)

Change in BMI (kg/m2)
Mean (SE)</td><td>WW: -5.55
(0.62)

WW: -5.51
(0.63)

WW: -2.06
(0.23)</td><td>Control: -0.21
(0.68)

Control: -0.22
(0.69)

Control: -0.07
(0.25)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Mason, 2014

Guideline record ID: 10459--1

Study characteristics		
Citation	Mason, C., Xiao, L., Imayama, I., Duggan, C., Wang, C.-Y., Korde, L., & McTiernan, A. (2014). Vitamin D3 supplementation during weight loss: a double-blind randomized controlled trial. The American Journal of Clinical Nutrition, 99(5), 1015-1025. https://doi.org/https://dx.doi.org/10.3945/ajcn.113.073734	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Vitamin D3 supplementation during weight loss: a double-blind randomized controlled trial	
Location	USA	
Trial name	Vitamin D, Diet and Activity (ViDA)	
Methods		
Inclusion criteria	"Postmenopausal women from the greater Seattle, WA, area aged 50- 75 y who were overweight or obese [BMI (in kg/m2) $25, or $23 for Asian-American women) and had serum 25(OH)D concentrations $10 ng/mL but,32 ng/mL."	
Exclusion criteria	"Specific exclusion criteria included the following: current use of .400 IU vitamin D from supplemental sources; diagnosis of osteoporosis or diabetes; renal disease or history of kidney stones; severe congestive heart failure; history of breast cancer or other invasive cancer, except for nonmelanomatous skin cancer; use of hormone replacement therapy within the past 6 mo; alcohol intake .2 drinks/d; current smoking; contraindication to taking 2000 IU vitamin D/d; current participation in a diet or exercise intervention; history of bariatric surgery; use of weight-loss medications; and additional factors that might interfere with measurement of outcomes or with the success of the intervention (eg, inability to attend facility-based sessions)."	
Setting	University/research centre	
Intervention	"The vitamin D preparation consisted of 2000 IU cholecalciferol (vitamin D3) + WEIGHT LOSS INTERVENTION: The ViDA lifestyle program included a diet and an exercise component, adapted from a successful intervention that we used in a similar population of overweight and obese postmenopausal women (22), and was based on the Diabetes Prevention Program and Look Ahead lifestyle change weight-loss programs (24, 25). The goals of the diet program were as follows: total daily energy intake of 1200 to 2000 kcal/d based on baseline weight, 30% daily energy intake from fat, and a 10% reduction in body weight by 6 mo with maintenance thereafter to 12 mo. The diets were not supplemented with calcium, but the women were advised on how to obtain sufficient calcium in their diets. The diet intervention was led by registered dietitians with extensive training in behavior modification. Participants met individually with a study dietitian for personalized goal setting at the start of the program, followed by weekly meetings in groups of w5 to 25 women for 6 mo. Thereafter (months 7-12), women attended monthly support groups facilitated by a study dietitian. This combination of individual and group-based sessions was used to maximize the benefits of targeted personalized recommendations along with the social support and greater cost-effectiveness of a group setting. The diet counseling sessions instructed participants on how to achieve the target calorie reduction, including setting calorie and fat goals, food intake and calorie counts of foods, reducing fat and improving fiber intake, selfmonitoring, and coping with challenges to eating behavior changes. In addition, the women were asked to record all food eaten daily for $6 mo or until they reached their individual weight loss goal (10%). Thereafter, the women were encouraged to keep a food journal for $1 wk/mo. Food journals were collected weekly. Journaling, weekly weigh-ins, and session attendance were tracked to promote adherence to the diet intervention. The goal of the exercise program was $45 min of moderateto-vigorous intensity exercise 5 d/wk week (225 min/wk) for 12 mo. The women attended 2	

<table>
<tr><td></td><td>sessions/wk at our study facility, where they were supervised by an exercise physiologist, and performed their remaining sessions at home. Facility-based exercise consisted of treadmill walking or jogging, stationary bicycling, and use of other aerobic machines; a variety of home exercises were encouraged, including walking/hiking, aerobics, and bicycling. The exercise training program began with 15-min sessions at 60-70% of the age-predicted maximal heart rate and progressed to the target 70-85% maximal heart rate for 45 min by the seventh week after enrollment, when it was maintained for the remainder of the study. The women wore heart rate monitors (Polar Electro) during the exercise sessions at the facility to assist with attaining their target heart rate. They recorded the mode and duration of all exercise sessions and the peak heart rate achieved for each facility sessions and their relative perceived exertion by using a Borg CR10 scale (26) for home sessions. The women were also offered the use of a pedometer throughout the exercise intervention and were encouraged to track their steps daily. Activities of $4 metabolic equivalents according to the Compendium of Physical Activities (27) were counted toward the prescribed exercise target."</td></tr>
<tr><td>Control/Comparator</td><td>"Sunflower oil placebo + Weight loss intervention: The ViDA lifestyle WL intervention program included a diet and an exercise component, adapted from a successful intervention that we used in a similar population of overweight and obese postmenopausal women (22), and was based on the Diabetes Prevention Program and Look Ahead lifestyle change weight-loss programs (24, 25). The goals of the diet program were as follows: total daily energy intake of 1200 to 2000 kcal/d based on baseline weight, 30% daily energy intake from fat, and a 10% reduction in body weight by 6 mo with maintenance thereafter to 12 mo. The diets were not supplemented with calcium, but the women were advised on how to obtain sufficient calcium in their diets. The diet intervention was led by registered dietitians with extensive training in behaviour modification. Participants met individually with a study dietitian for personalized goal setting at the start of the program, followed by weekly meetings in groups of w5 to 25 women for 6 mo. Thereafter (months 7-12), women attended monthly support groups facilitated by a study dietitian. This combination of individual and group-based sessions was used to maximize the benefits of targeted personalized recommendations along with the social support and greater cost-effectiveness of a group setting. The diet counselling sessions instructed."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 218
Intervention group/s: Vitamin D (n=109)

Comparator group: Placebo (n=109)</td></tr>
<tr><td>Mean age ± SD</td><td>59.6y (5.1)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Vitamin D: 87.4
(15.5)

Vitamin D: 32.3
(5.5)</td><td>Placebo: 88.1
(17.1)

Placebo: 32.5
(6.1)</td></tr>
</table>
</td></tr>
</table>

	Waist circumference (cm) Mean (SD) Body fat percentage (%) Mean (SD)	Vitamin D: 100 (11) Vitamin D: 47.3 (5.2)	Placebo: 100.3 (13.5) Placebo: 47.5 (4.5)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight (kg) Mean (SD) BMI (kg/m2) Mean (SD) Waist circumference (cm) Mean (SD) Body fat percentage (%) Mean (SD)	Vitamin D: 80.2 (15.6) Vitamin D: 29.5 (5.6) Vitamin D: 95.1 (12.7) Vitamin D: 43.1 (7.5)	Placebo: 80.7 (17.6) Placebo: 29.7 (6.1) Placebo: 95.8 (13.8) Placebo: 44 (7)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in weight (kg) Mean (SD) Change in BMI (kg/m2) Mean (SD) Change in waist circumference Mean (SD) Change in body fat percentage (%) Mean (SD)	Vitamin D: -7.1 Vitamin D: -2.8 Vitamin D: -4.9 Vitamin D: -4.1	Placebo: -7.4 Placebo: -2.8 Placebo: -4.5 Placebo: -3.5
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	INTERVENTION: 56.1% attended all diet counselling sessions, 97.9% medication adherence CONTROL: 59.5% attended all diet counselling sessions, 95.8% placebo adherence		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Mason, 2016

Guideline record ID: 10813--1

Study characteristics		
Citation	Mason, A. E., Epel, E. S., Aschbacher, K., Lustig, R. H., Acree, M., Kristeller, J., Cohn, M., Dallman, M., Moran, P. J., Bacchetti, P., Laraia, B., Hecht, F. M., & Daubenmier, J. (2016). Reduced reward-driven eating accounts for the impact of a mindfulness-based diet and exercise intervention on weight loss: data from the SHINE randomized controlled trial. Appetite, 100, 86-93. https://doi.org/10.1016/j.appet.2016.02.009	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Reduced reward-driven eating accounts for the impact of a mindfulness-based diet and exercise intervention on weight loss: Data from the SHINE randomized controlled trial	
Location	US	
Trial name	Supporting Health by Integrating Nutrition and Exercise (SHINE)	
Methods		
Inclusion criteria	"Additional inclusion criteria included abdominal obesity (waist circumference > 102 cm for men and >88 cm for women) and age 18 years or older."	
Exclusion criteria	"Exclusion criteria included type 1 or type 2 diabetes mellitus (fasting glucose >126 or hemoglobin A1C (HbA1c) between 6.0 and 6.5% with an abnormal oral glucose tolerance test); pregnancy; breastfeeding or fewer than 6 months post-partum; corticosteroid and/or immune-suppressing or immune-modulating medications; prescription weight-loss medi cations; untreated hypothyroidism; history of or active bulimia; current meditation or yoga practice; engagement in any other structured weight management or weight-loss program; or participation in MBSR."	
Setting	University/research centre	
Intervention	"Both intervention arms included 12 weekly group evening sessions (2x2.5 h), 3 biweekly sessions, 1 follow-up session four weeks later, and an all-day weekend session near the eighth week (5.0 h for the active control group, 6.5 h for the mindfulness intervention group) across a 5.5-month period. Diet and exercise components were the same in each intervention arm. Participants set a goal of reducing daily food intake of their choice by 500 calories. Moreover, participants were encouraged to focus on decreasing calorically dense, nutrient-poor foods such as refined carbohydrates, and increasing fresh fruits and vegetables, healthy oils, and proteins. The exercise component focused on increasing activity throughout the day as well as structured aerobic and anaerobic exercise, such as bicycling, swimming, strength training, and walking. The mindfulness intervention included mindfulness training for eating awareness, stress management, emotion regulation, and exercise. Mindful eating practices, modeled on the Mindfulness-Based Eating Awareness Training program (MB-EAT), were designed to promote awareness and self-regulation of emotions, physical hunger, stomach fullness, taste satisfaction, food cravings, and other eating triggers in the context of reduced caloric intake. We did not instruct participants to avoid particular foods, but encouraged them to eat favorite foods in smaller portions that fit within their calorie goals. We also encouraged participants to practice awareness and savoring of food tastes and textures, with a particular focus on drawing hedonic value from smaller amounts of highly preferred foods, such as sweets. Mindfulness training for stress management and emotion regulation incorporated components of mindfulness-based programs including sitting meditation, mindful yoga, loving kindness meditations towards self and others, and mindful walking. We also taught participants a brief extended exhalation breathing technique to promote initial physiological relaxation. Home practice guidelines included meditation practice for up to 30 min a day and 6 days a week, eating meals mindfully, use of mini-meditations, and mindful walking."	

<table>
<tr><td>Control/Comparator</td><td>“Both intervention arms included 12 weekly group evening sessions (2x2.5 h), 3 biweekly sessions, 1 follow-up session four weeks later, and an all-day weekend session near the eighth week (5.0 h for the active control group, 6.5 h for the mindfulness intervention group) across a 5.5-month period. Diet and exercise components were the same in each intervention arm. Participants set a goal of reducing daily food intake of their choice by 500 calories. Moreover, participants were encouraged to focus on decreasing calorically dense, nutrient-poor foods such as refined carbohydrates, and increasing fresh fruits and vegetables, healthy oils, and proteins. The exercise component focused on increasing activity throughout the day as well as structured aerobic and anaerobic exercise, such as bicycling, swimming, strength training, and walking. The control intervention included additional content to ensure equivalence across intervention arms on a number of dimensions. To account for the additional time, attention, social support, and expectations of benefit that the mindfulness participants may have experienced during the mindfulness training, control participants received additional information about nutrition and physical activity. This included in-depth presentations on nutrition concepts, discussion of socio-political issues that impact food choice, how to make well-informed decisions about diet products, and tutorials on strength training with exercise bands. To account for the active ingredients of a mindfulness-based approach to stress management training, control participants received instruction in progressive muscle relaxation and cognitive-behavioral skills, although at a lower dose than in the mindfulness intervention. To reduce participant burden while ensuring perceptions of benefit, the control group sessions were reduced from 2.5 to 2.0 h after session 9. Participants completed weekly assignments at home that reinforced diet and exercise lessons.”</td></tr>
<tr><td>Treatment duration</td><td>5.5 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 194
Intervention group/s: Mindfulness (n=100)

Comparator group: Control (n=94)</td></tr>
<tr><td>Mean age ± SD</td><td>47.0y (12.7)</td></tr>
<tr><td>Sex</td><td>81.96% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Mindfulness: 35.4
(3.5)</td><td>Control: 35.6
(3.8)</td></tr>
<tr><td>Weight (kg) model 1:12 months
Mean (SD)</td><td>Mindfulness: 98.1
(13.98)</td><td>Control: 95.09
(13.25)</td></tr>
<tr><td>Weight (kg) Model 2:18 months
Mean (SD)</td><td>Mindfulness: 98.35
(14.08)</td><td>Control: 94.86
(13.3)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg) model 1:12 months
Mean (SD)

Weight (kg) Model 2:18 months
Mean (SD)

Total effects of Reward-based Eating Drive (RED) scale and Perceived Stress Scale (PSS) on weight
Beta coefficient</td><td>Mindfulness: 92.64 (13.47)

Mindfulness: 92.64 (13.47)

Mindfulness: -0.13 (-0.28-0.01)</td><td>Control: 90.93 (14.29)

Control: 90.87 (14.18)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Mason, A. E., Hecht, F. M., Daubenmier, J. J., Sbarra, D. A., Lin, J., Moran, P. J., Schleicher, S. G., Acree, M., Prather, A. A., & Epel, E. S. (2018). Weight loss maintenance and cellular aging in the supporting health through nutrition and exercise study. Psychosomatic Medicine, 80(7), 609-619. https://doi.org/10.1097/PSY.0000000000000616</td></tr>
</table>

N/A – Not applicable

Mason, 2018

Guideline record ID: 10814--1

Study characteristics		
Citation	Mason, A. E., Hecht, F. M., Daubenmier, J. J., Sbarra, D. A., Lin, J., Moran, P. J., Schleicher, S. G., Acree, M., Prather, A. A., & Epel, E. S. (2018). Weight loss maintenance and cellular aging in the supporting health through nutrition and exercise study. Psychosomatic Medicine, 80(7), 609-619. https://doi.org/10.1097/PSY.0000000000000616	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight Loss Maintenance and Cellular Aging in the Supporting Health Through Nutrition and Exercise Study	
Location	US	
Trial name	Supporting Health by Integrating Nutrition and Exercise (SHINE)	
Methods		
Inclusion criteria	"Inclusion Criteria: Age 18+ years old BMI > 30-45 Waist circumference > 102 cm (men) or > 88 cm (women) Live in San Francisco Bay Area and able to attend more than 16 classes and up to 12 assessment visits in San Francisco over an 18 month period."	
Exclusion criteria	"Exclusion criteria: Inability to provide informed consent, Age < 18 A substance abuse, mental health, or medical condition that, in the opinion of investigators, will make it difficult for the potential participant to participate in the group intervention, Type I or II Diabetes or fasting glucose ≥ 126 mg/dl or hemoglobin A1c ≥ 6.5; those with HbA1c between 6-6.5% may complete an OGTT to rule out diabetes (glucose <200 mg/dl), Use of systemic (oral or IV) corticosteroids in the 6 months prior to enrollment or severe autoimmune disorders or other conditions (e.g. rheumatoid arthritis, lupus), that are likely to require these medications, Use of immunosuppressive or immunomodulating drugs or chronic or acute conditions that would require the use of such medications, A history of known coronary artery disease (CAD), or typical or atypical anginal chest pain requires a letter from the participant's physician that he or she has been adequately evaluated and that a moderate exercise program is appropriate, Non English speaker, Pregnant or planning to get pregnant in the next 12 months, breastfeeding or less than 6 months post-partum, Initiation of new class of psychiatric medications in past 2 months, Currently on a specific weight loss diet, For influenza vaccine administration: a prior allergic reaction to the influenza vaccine or eggs. These participants can be included in the trial but will be excluded from participation in influenza vaccination. Active bulimia or strong history of bulimia, Current use of weight loss medications or supplements such as amphetamine-based drugs that are believed to have some effect on weight, History of or planned weight loss surgery, Untreated hypothyroidism: TSH > 4mU/mL (or the upper limit of normal reference defined by the lab doing the assay)."	
Setting	University/research centre	
Intervention	"Each intervention arm included 12 weekly group evening sessions (2-2.5 h), followed by 3 biweekly sessions, followed by 1 follow-up session 4 weeks later (5.5 months total). Participants completed an all-day weekend session near the eighth week (5.0 hours for the active control arm, 6.5 hours for the mindfulness intervention arm). Intervention content included mindfulness training for eating behavior, stress management, emotion regulation, and exercise. Mindful eating practices targeted awareness of physical hunger, stomach fullness, taste satisfaction, food cravings, and other eating triggers. Instructors did not teach participants to avoid particular foods but rather encouraged them to eat favorite foods in smaller portions that fit with their calorie goals. Instructors encouraged participants to become aware of and to savor food tastes and textures, with the intention of deriving satisfaction from smaller amounts of favorite foods that tended to be of higher caloric density (e.g., sweets and desserts). Mindfulness training targeting stress	

<table>
<tr><td></td><td>management and emotion regulation incorporated components of mindfulness-based programs including seated meditation, mindful yoga and walking, and loving-kindness meditations. Instructors also led extended exhalation breathing practices to promote initial physiological relaxation. Home-based activities included sitting meditation for up to 30 minutes a day/6 days a week, eating meals mindfully, minimeditations before meals, and mindful (chi) walking."</td></tr>
<tr><td>Control/Comparator</td><td>"Each intervention arm included 12 weekly group evening sessions (2-2.5 h), followed by 3 biweekly sessions, followed by 1 follow-up session 4 weeks later (5.5 months total). Participants completed an all-day weekend session near the eighth week (5.0 hours for the active control arm, 6.5 hours for the mindfulness intervention arm). Intervention content accounted for the additional time, attention, social support, and expectations of benefit that the mindfulness participants may have experienced by providing additional group curricula about nutrition and physical activity. This included presentations about nutritional choices, discussion of sociopolitical issues that affect food choice, how to make well-informed decisions about diet products, and tutorials on strength training with exercise bands. To address participant expectations of receiving stress management tools, intervention content included instruction in progressive muscle relaxation and cognitive-behavioral skills, although at a lower dose than in the mindfulness intervention. To reduce participant burden while ensuring perceptions of benefit, sessions were reduced from 2.5 to 2.0 hours after session 9. Home-based activities reinforced diet and exercise lessons."</td></tr>
<tr><td>Treatment duration</td><td>5.5 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 194
Intervention group/s: Mindfulness (n=100)

Comparator group: Active Control (n=94)</td></tr>
<tr><td>Mean age ± SD</td><td>48.2y (12.5)</td></tr>
<tr><td>Sex</td><td>83.51% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>Mindfulness: 35.3
(3.5)</td><td>Active Control: 35.1
(3.8)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight change at 12 months (kg)
Mean (SD)</td><td>Mindfulness: -5.1
(7.1)</td><td>Active Control: -3
(6.5)</td></tr></table></td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Session attendance was similar for the mindfulness and control arms (74.7% versus 71.2%, respectively)</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Mason, A. E., Epel, E. S., Aschbacher, K., Lustig, R. H., Acree, M., Kristeller, J., Cohn, M., Dallman, M., Moran, P. J., Bacchetti, P., Laraia, B., Hecht, F. M., & Daubenmier, J. (2016). Reduced reward-driven eating accounts for the impact of a mindfulness-based diet and exercise intervention on weight loss: data from the SHINE randomized controlled trial. Appetite, 100, 86-93. https://doi.org/10.1016/j.appet.2016.02.009</td></tr>
</table>

N/A – Not applicable

McElfish, 2023

Guideline record ID: 10949--1

Study characteristics		
Citation	McElfish, P. A., Felix, H. C., Bursac, Z., Rowland, B., Yeary, K. H. K., Long, C. R., Selig, J. P., Keaweʻaimoku Kaholokula, J., & Riklon, S. (2023). A cluster randomized controlled trial comparing diabetes prevention program interventions for overweight/obese Marshallese adults. INQUIRY: The Journal of Health Care Organization, Provision, and Financing, 60. https://doi.org/https://doi.org/10.1177/00469580231152051	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A Cluster Randomized Controlled Trial Comparing Diabetes Prevention Program Interventions for Overweight/Obese Marshallese Adults	
Location	USA	
Trial name	Diabetes Prevention Program Lifestyle Intervention in the Marshallese Population	
Methods		
Inclusion criteria	"Marshallese adults (aged 18 and older) who had a body mass index (BMI) of ≥25kg/m2 (ie, those classified as overweight or obese) were eligible to participate in the study."	
Exclusion criteria	"Exclusion criteria included: (1) a medical condition likely to impact weight (eg, cancer, HIV/AIDS); (2) currently pregnant or breastfeeding an infant 6months old or younger; or (3) conditions that make it unlikely that the participant will be able to follow the proto col, such as terminal illness, plans to move out of the area, or an inability to finish the intervention."	
Setting	N/A	
Intervention	"PILI DPP: 8 weekly lessons in phase 1 and 6 biweekly lessons in phase 2. The program (culturally adapted to be relevant to Pacific Islanders) focused on self-monitoring, behavioural strategies for weight loss, decreasing caloric intake for weight loss, and increasing physical activity. The two-phase PILI DPP curriculum integrated family and community support. Phase 1 of PILI DPP included all original core DPP lessons, plus topics on the economics of healthy eating (i.e., eating healthy within your budget) and talking with your doctor (i.e., how to communicate effectively with your healthcare provider). Phase 2 integrated participants' families and friends in the study, allowing participants specific support from their families and friends for their long-term behaviour changes."	
Control/Comparator	"WORD DPP focused on self-monitoring, behavioural strategies for weight loss, decreasing caloric intake for weight loss, and increasing physical activity. Program was based on a community-engaged approach for rural African American communities of faith with revisions to ensure relevance to Marshallese faith communities; however, the curriculum was not adapted for other aspects of Marshallese culture. The WORD DPP curriculum included 16 lessons delivered in 90-min lessons over 24 weeks. The WORD DPP intervention encouraged participants to make healthy lifestyle changes by connecting their health to their faith. This included discussing bible verses and prayers selected by the community that focused on living a healthy lifestyle."	
Treatment duration	24 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 378
Intervention group/s: PILI DPP (n=166)

Comparator group: WORD DPP (n=212)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 41.4y (12.8); Control: 42.9y (10.6)</td></tr>
<tr><td>Sex</td><td>56.61% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline weight (kg) - unadjusted
Mean (SD)

Weight (kg) - Unadjusted
Mean (95% CIs)

Weight (kg) - Adjusted
Mean (95% CIs)</td><td>PILI DPP: 83.4
(14.3)

PILI DPP: 83.83
(80.75-86.91)

PILI DPP: 84.32
(80.7-87.93)</td><td>WORD DPP: 85.4
(15.6)

WORD DPP: 86.67
(83.8-89.54)

WORD DPP: 86.44
(83.14-89.76)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Unadjusted
Mean (95% CIs)

Weight (kg) - Adjusted
Mean (95% CIs)</td><td>PILI DPP: 83.41
(80.23-86.6)

PILI DPP: 83.8
(79.59-88.01)</td><td>WORD DPP: 85.8
(82.95-88.65)

WORD DPP: 86.18
(82.49-89.86)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

McRobbie, 2019

Guideline record ID: 10465--1

Study characteristics		
Citation	McRobbie, H., Hajek, P., Peerbux, S., Kahan, B. C., Eldridge, S., Trépel, D., Parrott, S., Griffiths, C., Snuggs, S., & Smith, K. M. (2019). Randomised controlled trial and economic evaluation of a task-based weight management group programme. BMC Public Health, 19, 365. https://doi.org/10.1186/s12889-019-6679-3	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Randomised controlled trial and economic evaluation of a task-based weight management group programme	
Location	UK	
Trial name	Weight Action Programme (WAP)	
Methods		
Inclusion criteria	"We recruited adults (aged ≥18 years) living in the study areas who had BMI ≥ 30 kg/m2 or a BMI of ≥28 kg/m2 with co-morbidities (criteria for referring patients for weight loss interventions in the UK)."	
Exclusion criteria	"Exclusion criteria included not speaking English, BMI > 45, losing > 5% of their body weight in the previous 6 months, pregnancy, and currently taking a psychiatric medication (because of medication effects on weight). No other co-morbidities were excluded to ensure that the study addressed the needs of the National Health Service (NHS) and the results are generalisable to target populations."	
Setting	GP clinic	
Intervention	"WAP aims to provide clear and simple advice on diet, physical activity and self-monitoring via a range of concrete and verifiable tasks agreed individually with each participant, as opposed to providing written and verbal advice as is typically done (see Practice Nurse Intervention). Where printed information is provided, it is mostly in pictorial and a simple English format making it more accessible to clients whose first language is not English or who have lower levels of education. The main innovative feature of the programme is that participants aim to complete a number of tasks that are monitored via 'task cards' marked every day for at least one week. Participants can choose not to continue with the task if they found it unhelpful, but they commit to trying it first for one full week. The tasks include increasing pedometer targets gradually up to 10,000 steps per day (participants were provided with an Oregon pedometer PE980), using a food diary, removing triggers to eating from the environment, implementing 'easy switches' (food swaps), monitoring hunger levels before and during eating, exercising three times a week, recording instances of saying "No" to unnecessary food and monitoring weight. Participants also receive information about using orlistat (see below). Sessions also include imparting and testing the knowledge of caloric content of food. The other key feature of WAP is the use of a group format focusing on social support. The programme comprises 8 weekly group sessions lasting one hour each, followed by optional monthly group meetings. Two advisors trained in WAP delivery conducted the sessions in groups of 10 to 21 participants"	
Control/Comparator	"The PNI incorporated all of the suggested practices to mimic a more intense model of "best practice". The nurses were trained to give the intervention which took place over eight weeks (4 sessions in total), with the intervention incorporating national and NHS guidelines. The nurse provided advice on (1) Diet, e.g. basic introduction to different food groups, how to read food labels and identify calories in food; limiting the size of the portions of food eaten; and choosing healthier options; (2) Activity, e.g. finding exercise options they will enjoy and can do each day; minimise sitting, watching TV (sedentary activities); encouraged to go to local exercise classes/activities; and (3) Self-monitoring, i.e.	

<table>
<tr><td></td><td>keeping track of eating habits with a food diary, using a pedometer (this was not provided), and taking weight at home. Participants also received a recommendation to use orlistat (see below). The advice was accompanied by the standard set of NHS 'Change4Life' leaflets. Each session lasted up to 30 min.”</td></tr>
<tr><td>Treatment duration</td><td>8 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 330
Intervention group/s: Weight action Programme (WAP) (n=221)

Comparator group: Practice nurse intervention (PNI) (n=109)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 46.6y (15.0); Control: 45.1y (14.2)</td></tr>
<tr><td>Sex</td><td>71.52% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

waist circumference (cm)
Mean (SD)</td><td>Weight action Programme (WAP): 95.5
(15.8)

Weight action Programme (WAP): 35
(4.2)

Weight action Programme (WAP): 113.4
(10.8)</td><td>Practice nurse intervention (PNI): 98.3
(16.6)

Practice nurse intervention (PNI): 35.7
(4.3)

Practice nurse intervention (PNI): 114.2
(10.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss (ITT)
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)

Change in waist circumference (cm)
Mean (SD)</td><td>Weight action Programme (WAP): -4.2
(7.3)

Weight action Programme (WAP): -1.5
(2.6)

Weight action Programme (WAP): -4.1
(7.9)</td><td>Practice nurse intervention (PNI): -2.3
(6.6)

Practice nurse intervention (PNI): -2
(7.3)

Practice nurse intervention (PNI): -2
(7.3)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Mellberg, 2014

Guideline record ID: 10467--1

Study characteristics		
Citation	Mellberg, C., Sandberg, S., Ryberg, M., Eriksson, M., Brage, S., Larsson, C., Olsson, T., & Lindahl, B. (2014). Long-term effects of a Palaeolithic-type diet in obese postmenopausal women: a 2-year randomized trial. European Journal of Clinical Nutrition, 68(3), 350-357. https://doi.org/10.1038/ejcn.2013.290	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-term effects of a Palaeolithic-type diet in obese postmenopausal women: a 2-year randomized trial	
Location	Sweden	
Trial name	N/A	
Methods		
Inclusion criteria	"Postmenopausal non-smoking women with a BMI>=27 kg/m2."	
Exclusion criteria	"Exclusion criteria included consumption of a restricted or vegetarian diet, allergy to key components in the intervention diets, history of heart disease, kidney disease, hyperthyreosis or hypothyreosis, osteoporosis or diabetes. Other exclusion criteria were abnormal fasting plasma glucose levels (X7 mmol/l), blood pressure exceeding 150/90 mm Hg, hormone replacement therapy, statins, beta-blockers or any medication for psychiatric disorders."	
Setting	Hospital, Home	
Intervention	"Palaeolithic-type diet (PD) Both diets were consumed ad libitum. The PD provided 30% of energy intake (E%) from protein, 40 E% fat and 30 E% carbohydrates and included a recommendation for a high intake of MUFA and polyunsaturated fatty acids (PUFA). The diet was based on lean meat, fish, eggs, vegetables, fruits, berries and nuts. Additional fat sources were avocado and oils (rapeseed and olive oil) used in food preparation and dressing. Dairy products, cereals, added salt and refined fats and sugar were excluded. Each group took part in a total of 12 group sessions held by a trained study dietician (one dietician per diet) throughout the 24-month study period. The group sessions consisted of information on and cooking of the intervention diets, dietary effects on health, behavioral changes and group discussions. The subjects were given recipes and written instructions to facilitate the preparation of meals at home. Eight group sessions (four cooking classes and four follow-up sessions) were held during the first 6 months of the intervention. Additional group meetings were held at 9, 12, 18 and 24 months."	
Control/Comparator	"Nordic Nutrition Recommendations (NNR)The NNR diet12 was aiming at a daily intake of 15 E% protein, 25-30 E% fat and 55-60 E% carbohydrates, with emphasis on lowfat dairy products and high-fibre products. Each group took part in a total of 12 group sessions held by a trained study dietician (one dietician per diet) throughout the 24-month study period. The group sessions consisted of information on and cooking of the intervention diets, dietary effects on health, behavioral changes and group discussions. The subjects were given recipes and written instructions to facilitate the preparation of meals at home. Eight group sessions (four cooking classes and four follow-up sessions) were held during the first 6 months of the intervention. Additional group meetings were held at 9, 12, 18 and 24 months."	
Treatment duration	24 months	
Follow-up from baseline	24 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 70
Intervention group/s: PD group (n=35)

Comparator group: NNR diet group (n=35)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 59.5y (5.5); Control: 60.3y (5.9)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>PD group: 87
(10.6)</td><td>NNR diet group: 86.8
(10)</td></tr>
<tr><td>Body mass index (kg/m2)
Mean (SD)</td><td>PD group: 32.7
(3.6)</td><td>NNR diet group: 32.6
(3.3)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>PD group: 105.4
(10)</td><td>NNR diet group: 104.7
(10.4)</td></tr>
<tr><td>Total fat mass (kg)
Mean (SD)</td><td>PD group: 39.8
(7.2)</td><td>NNR diet group: 40.9
(8.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss
Mean (SE)</td><td>PD group: -8.7</td><td>NNR diet group: -4.4</td></tr>
<tr><td>Change in BMI
Mean (SE)</td><td>PD group: 3.3
(0.36)</td><td>NNR diet group: 1.7
(0.38)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in total fat mass
Mean (SE)</td><td>PD group: -4.6</td><td>NNR diet group: -2.9</td></tr>
<tr><td>Change in BMI
Mean (SE)</td><td>PD group: 2.4
(0.41)</td><td>NNR diet group: 1.4
(0.34)</td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>A total of 406 urine collections from 65 subjects (34 PD, 31 NNR) at baseline, 51 subjects (30 PD, 21 NNR) at 6 months and 39 subjects (21 PD, 18 NNR) at 24 months were available for comparison of reported protein intake and NU. Mean NU were 13 g/day in both the groups at baseline (Table 2). There was no difference in NU within or between groups at 6 or 24 months follow-up, indicating poor adherence to the target protein intake (30 E%) in the PD group.</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	Franklin, K. A., Lindberg, E., Svensson, J., Larsson, C., Lindahl, B., Mellberg, C., Sahlin, C., Olsson, T., & Ryberg, M. (2022). Effects of a palaeolithic diet on obstructive sleep apnoea occurring in females who are overweight after menopause-a randomised controlled trial. International Journal of Obesity, 46(10), 1833-1839. https://doi.org/https://dx.doi.org/10.1038/s41366-022-01182-4

N/A – Not applicable

Melnyk, 2015

Guideline record ID: 10819--1

Study characteristics		
Citation	Melnyk, B. M., Jacobson, D., Kelly, S. A., Belyea, M. J., Shaibi, G. Q., Small, L., O'Haver, J. A., & Marsiglia, F. F. (2015). Twelve-month effects of the COPE Healthy Lifestyles TEEN program on overweight and depressive symptoms in high school adolescents. Journal of School Health, 85(12), 861-870. https://doi.org/https://doi.org/10.1111/josh.12342	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Twelve-Month Effects of the COPE Healthy Lifestyles TEEN Program on Overweight and Depressive Symptoms in High School Adolescents	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Youth 14-16 years old (mainly freshmen and sophomores) enrolled in required health education courses were recruited to participate, teens who could read and speak English and of any sex, ethnicity/race, or socioeconomic status were eligible for participation."	
Exclusion criteria	Not reported	
Setting	School	
Intervention	"The COPE/Healthy Lifestyles TEEN (Thinking, Emotions, Exercise and Nutrition) program is a manualized 15-session educational and cognitive-behavioral skills building program. Table 2 shows the major content in each COPE session. COPE is guided by Cognitive Theory (CT) with 20 minutes of physical activity (eg, dancing, walking, and kick boxing movements) as a component of each session. COPE teaches the adolescents that how they think is directly related to how they feel, and how to turn negative beliefs triggered by activating events into positive beliefs so that they feel emotionally better and engage in healthy behaviors. The COPE intervention was developed originally by the first author and pilot tested 3 times with white, Hispanic and African-American adolescents as a group intervention in high school settings. COPE also uses pedometers as cue recognition for increasing physical activity throughout the program and instructs students to increase their step counts by 10% each week regardless of baseline steps. The teens are instructed to keep track of their steps on a daily tracking sheet so that weekly averages can be monitored to determine if the teens met their weekly physical activity goal. Teachers were provided with a full-day training workshop on COPE, which introduced Cognitive Theory, the framework used to create and develop the COPE content and program. During the training workshop, the teachers engaged in cognitive-behavioral skills building practice exercises with the facilitators. Teachers then integrated the manualized COPE sessions into their health course, once a week for 15 weeks. Teens received a COPE manual that contained the content of the program along with the homework/cognitive-behavioral skills building activities to help them put into practice the content that they were learning in class. Parent newsletters describing the content of the COPE program or the Healthy Teens program were sent home to the parents with the teens 4 times during each 15-week program. The teens were asked to review each newsletter with their parents as part of their health course homework assignments."	
Control/Comparator	"The Healthy Teens program is a 15-week attention control program to control for the time the health teachers in the COPE group spent delivering the experimental program to their students. Healthy Teens teachers also received a full-day training workshop on the Healthy Teens program content. The content was manualized and concentrated on common health issues for adolescents, including dental care, skin care, infectious diseases, and immunizations. The complete list of all session titles has been published.16 The control	

<table>
<tr><td></td><td>teens also received a manual with homework assignments each week that focused on the topics being covered in class. The control program was formatted similar to the COPE intervention and included the same number of sessions with no overlap of content. Parent newsletters describing the content of the COPE program or the Healthy Teens program were sent home to the parents with the teens 4 times during each 15-week program. The teens were asked to review each newsletter with their parents as part of their health course homework assignments.”</td></tr>
<tr><td>Treatment duration</td><td>15 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 779
Intervention group/s: COPE (n=358)

Comparator group: Healthy Teens (n=421)</td></tr>
<tr><td>Mean age ± SD</td><td>14.74y (.73)</td></tr>
<tr><td>Sex</td><td>51.60% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Proportion of Overweight Adolescents Proportion (%)</td><td>COPE: 44.08</td><td>Healthy Teens: 41.01</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Proportion of Overweight Adolescents Proportion (%)</td><td>COPE: 40.43</td><td>Healthy Teens: 43.18</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Mensinger, 2016

Guideline record ID: 10468--1

Study characteristics		
Citation	Mensinger, J. L., Calogero, R. M., Stranges, S., & Tylka, T. L. (2016). A weight-neutral versus weight-loss approach for health promotion in women with high BMI: a randomized-controlled trial. Appetite, 105, 364-374. https://doi.org/10.1016/j.appet.2016.06.006	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A weight-neutral versus weight-loss approach for health promotion in women with high BMI: A randomized-controlled trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"30-45 years old, female, BMI 30-45, physically inactive (i.e., scoring in one of the bottom two categories on the Stanford Brief Activity Survey) (Taylor-Piliae et al., 2006), and practicing birth control if heterosexual and pre-menopausal."	
Exclusion criteria	"Current smokers; did not speak fluent English; were taking medications known to effect weight; were presently participating in a weight-loss program or diet; were pregnant or intending to become pregnant; had or were planning to have bariatric surgery; had type 1 or insulin-dependent type 2 diabetes; had an active neoplasm; or had a history of myocardial infarction, congestive heart failure, cerebrovascular disease, renal disease, or cirrhosis. Specific psychological contraindications included bulimia nervosa, anorexia nervosa, alcohol or substance abuse, and psychiatric disturbances that significantly disrupt daily functioning (e.g., suicide ideation, current manic episode, schizophrenia)."	
Setting	Hospital	
Intervention	"The weight-loss program employed was the LEARN Program for Weight Management (Brownell, 2000); LEARN is a behaviour modification approach to weight loss that stands for Lifestyle, Exercise, Attitudes, Relationships, and Nutrition. While the program emphasizes weight loss as an ultimate goal, the focus is on changing diet and lifestyle and gaining skills to overcome weight-loss barriers. It is an evidence-based curriculum and has been referred to as the gold standard in weight-management approaches (Gardner et al., 2007). Participants in the LEARN program received the LEARN Program for Weight Management manual (Brownell, 2000), the LEARN Weight Stabilization and Maintenance Guide (Brownell, 2008), and the LEARN Program CD set. As with the weight-neutral program, at the end of the weight-loss program, participants were encouraged to maintain their lifestyle changes by utilizing their new social support network. Participant email and phone number lists were distributed and conference call lines were created to help facilitate this network. This program was delivered by a registered dietician with over 15 years of experience working with bariatric populations and patients with type 2 diabetes. The two programs shared many common principles, and both emphasized the importance of healthy lifestyle choices and gradual sustainable change. However, in the weight-loss program, food intake recommendations were based on external prescriptions and caloric restriction, and weight loss was an explicit goal. In contrast, the weight-neutral program taught strategies to recognize and respond to internal physiological signs of hunger and satiety to determine food intake, and, size acceptance was promoted in lieu of weight-loss goals. We ensured fidelity of the programs by using checklists derived from the leaders' manuals and randomly selecting sessions for audit by trained research technicians."	
Control/Comparator	"The weight-neutral program employed was the HUGS Program for Better Health (Omichinski, 2007); HUGS stands for Health-focused, Understanding lifestyle, Group supported, and Self-esteem building. This integrated approach is based on an evidence-	

<table>
<tr><td></td><td>based (Omichinski & Harrison, 1995) manualized curriculum that incorporates the key components of popular weight-neutral approaches (Bacon and Aphramor, 2011, O'Hara and Gregg, 2014, Robison et al., 2007, Tylka et al., 2014). The HUGS Program emphasized the principles of eating for well-being and pleasure, size acceptance, and the importance of engaging in physical activity for personal enjoyment and fulfillment. Participants received the books, Staying Off of the Diet Roller Coaster (Omichinski, 2000) and Tailoring Your Tastes (Omichinski & Hildebrand, 1995), in addition to a booklet of psycho-educational worksheets and a set of affirmation CDs produced by HUGS Inc. At the end of the program, participants were encouraged to maintain their non-dieting lifestyles and self-affirming attitudes about their bodies by utilizing the social support network developed during the program. Participant email and phone number lists were distributed and conference call lines were created to help facilitate this network. The weight-neutral program was led by a psychotherapist and fitness professional with 15 years of experience working with high BMI clients from a Health At Every Size framework.”</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 80
Intervention group/s: Weight-loss program (n=40)

Comparator group: Weight-neutral program (control group) (n=40)</td></tr>
<tr><td>Mean age ± SD</td><td>Weight-loss program: 39.35y (3.91); Weight-neutral program: 39.83y (4.34)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Estimated marginal means (SE)</td><td>Weight-loss program: 38.6 (0.61)</td><td>Weight-neutral program (control group): 37.4 (0.61)</td></tr>
<tr><td>Weight kg
Estimated marginal means (SE)</td><td>Weight-loss program: 105.3 (2.1)</td><td>Weight-neutral program (control group): 102.1 (2.1)</td></tr>
<tr><td>Waist circumference (inches)
Estimated marginal means (SE)</td><td>Weight-loss program: 46.2 (0.8)</td><td>Weight-neutral program (control group): 45.4 (0.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Estimated marginal means (SE)</td><td>Weight-loss program: 37.2 (0.66)</td><td>Weight-neutral program (control group): 37.2 (0.67)</td></tr>
<tr><td>Weight kg
Estimated marginal means (SE)</td><td>Weight-loss program: 101.6 (2.2)</td><td>Weight-neutral program (control group): 101.3 (2.2)</td></tr>
</table>
</td></tr>
</table>

	Waist circumference (inches) Estimated marginal means (SE)	Weight-loss program: 44.3 (1)	Weight-neutral program (control group): 44.4 (1)
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in BMI (kg/m2) Mean (SD)	Weight-loss program: -1.3	Weight-neutral program (control group): -0.26
	Change in weight (kg) Mean (SD)	Weight-loss program: -3.7	Weight-neutral program (control group): -0.83
	Change in waist circumference (inches) Mean (SD)	Weight-loss program: -1.9	Weight-neutral program (control group): -0.97
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Metzgar, 2016

Guideline record ID: 10820--1

Study characteristics		
Citation	Metzgar, C. J., & Nickols-Richardson, S. M. (2016). Effects of nutrition education on weight gain prevention: a randomized controlled trial. Nutrition Journal, 15, 31. https://doi.org/10.1186/s12937-016-0150-4	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of nutrition education on weight gain prevention: a randomized controlled trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Women were eligible to participate if they met age and BMI criteria and desired to prevent weight gain."	
Exclusion criteria	"Women were excluded if they were amenorrheic; presented with depressive symptomology as suggested by a score of >50 on the Zung Self-Rating Depression Scale/Status Inventory [41]; self-reported cardiovascular, metabolic or musculoskeletal abnormalities or used medications to manage such conditions; used supplements and/or medications that may influence BW regulation; had undergone weight loss surgery; or were currently pregnant, lactating or planning to become pregnant."	
Setting	Home	
Intervention	"Two intervention arms involved participants being assigned to either a weight gain prevention intervention delivered by a registered dietitian (RDG) or counselor (CSG). Women in the RDG and CSG attended a total of 24 nutrition education sessions over the course of the 1-year intervention period. All sessions were 1-h in length and emphasized portion control, planning ahead and vegetable consumption [42, 43]. For the first 16 weeks of the intervention (months 1-4), participants attended weekly sessions; for the remaining 8 months of the study (months 5-12), participants attended monthly sessions [44]. Weekly sessions focused on general nutrition education topics, including basic nutrition and food groups, food selection and preparation, recipe modification, nutritious snack choices and snacking and nutrient density, among others, while monthly sessions addressed other areas of lifestyle behavior such as stress management, problem solving and motivation [40, 42-47]. Six session times were offered each week/month per group. Participants were permitted to attend the session day and time that worked best for them during the respective week/month. Dates, times and building location were matched between RDG and CSG to ensure all participants had the same opportunities to attend sessions. Education sessions were randomly selected for process evaluation using investigator-established criteria to assess fidelity; all selected sessions were evaluated by the same process observer. The number of participants attending each session was recorded, as was the start and end time. The fidelity checklist included educator-oriented items along with content-related items. The process observer rated the educator using a 'yes/no' rating system on items such as preparedness, familiarity, accuracy and ability to respond appropriately to questions. A comment box was also used to note general feedback on these items as deemed relevant by the process observer. Content-related items addressed whether underlying key concepts (portion control, vegetable consumption, planning ahead) and problem-solving were covered. The process observer also recorded comments regarding challenges or difficulties of the education sessions (i.e., technological problems, outside distractions). These evaluations assessed whether content for each session was presented and delivered appropriately and that all session activities were completed."	
Control/Comparator	"Women randomized to the CON received no intervention."	

<table>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 81
Intervention group/s: RDG (n=26); CSG (n=29)

Comparator group: CON (n=26)</td></tr>
<tr><td>Mean age ± SD</td><td>31.4y (8.1)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SE)</td><td>RDG: 73.9
(1.6)
CSG: 74.2
(1.1)</td><td>CON: 77.9
(1.9)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SE)</td><td>RDG: 26.1
(0.5)
CSG: 27.4
(0.4)</td><td>CON: 29.3
(0.7)</td></tr>
<tr><td>Waist circumference
Mean (SE)</td><td>RDG: 80.2
(1.3)
CSG: 82.5
(0.9)</td><td>CON: 85.9
(1.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SE)</td><td>RDG: 75.2
(1.9)
CSG: 75.1
(1.3)</td><td>CON: 77.2
(2.2)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SE)</td><td>RDG: 26.6
(0.6)
CSG: 27.8
(0.5)</td><td>CON: 29.1
(0.8)</td></tr>
<tr><td>Waist circumference
Mean (SE)</td><td>RDG: 81.5
(1.3)
CSG: 82.8
(0.9)</td><td>CON: 83.7
(1.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
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</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	81.5%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Miguel Soca, 2012

Guideline record ID: 10469--1

Study characteristics		
Citation	Miguel Soca, P. E., Peña Pérez, I., Niño Escofet, S., Cruz Torres, W., Niño Peña, A., & Ponce De León, D. (2012). [Randomised controlled trial: the role of diet and exercise in women with metabolic syndrome]. Atención Primaria, 44(7), 387-393. https://doi.org/https://dx.doi.org/10.1016/j.aprim.2011.07.010	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	[Randomised controlled trial: the role of diet and exercise in women with metabolic syndrome]	
Location	Cuba	
Trial name	N/A	
Methods		
Inclusion criteria	"Women with metabolic syndrome (without glycemic alterations) and obese (BMI 30kg/m2)."	
Exclusion criteria	"Pregnancy, diabetes, fasting glucose >5.5mmol/L & physical or mental limitations that prevent adherence to treatment."	
Setting	GP clinic	
Intervention	"In the women of the experimental group, a program based on a hypocaloric diet and aerobic exercises was applied. . The ATP-III diet was individualized in the experimental group with a deficit of 300 Kcal/day, divided into 55% carbohydrates, less than 30% fat, 15% protein and less than 150 mg/day of cholesterol. The consumption of vegetables and fruits was recommended. The exercise program was structured for 48 weeks, with 3 frequencies/week according to the principles10: training specificity, overload, progressive load increase, individuality, reversibility, systematicity and of the adequate work-rest relationship."	
Control/Comparator	"The control group continued with the usual diet and physical activity."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 122 Intervention group/s: Experimental group (n=60) Comparator group: Control group (n=62)	
Mean age ± SD	Experimental: 50.0y (1.6); Control: 59.2y (1.5)	
Sex	100.00% female	
Pre-existing medical condition	Metabolic syndrome	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight kg
Mean (SE)

BMI
Mean (SE)

Abdominal circumference cm
Mean (SE)</td><td>Experimental group: 84.19
(1.55)

Experimental group: 33.55
(0.41)

Experimental group: 99.48
(1.25)</td><td>Control group: 80.16
(1.46)

Control group: 32.42
(0.37)

Control group: 107.9
(1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight kg
Mean (SE)

BMI
Mean (SE)

Abdominal circumference cm
Mean (SE)</td><td>Experimental group: 82.2
(1.67)

Experimental group: 32.41
(0.37)

Experimental group: 97.91
(1.5)</td><td>Control group: 80.87
(1.43)

Control group: 32.83
(0.39)

Control group: 109.16
(0.98)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Miller, 2017

Guideline record ID: 10474

Study characteristics		
Citation	Miller, K., Turró, R., Greve, J. W., Bakker, C. M., Buchwald, J. N., & Espinos, J. C. (2017). MILEPOST multicenter randomized controlled trial: 12-month weight loss and satiety outcomes after pose SM vs. medical therapy. Obesity Surgery, 27(2), 310-322. https://doi.org/https://dx.doi.org/10.1007/s11695-016-2295-9	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	MILEPOST Multicenter Randomized Controlled Trial: 12-Month Weight Loss and Satiety Outcomes After pose SM vs. Medical Therapy	
Location	Austria; Spain; Netherlands	
Trial name	Multicenter Study of an Incisionless Operating Platform for Primary Obesity vs. Diet and Exercise (MILEPOST)	
Methods		
Inclusion criteria	"Men and women with classes I and II obesity (body mass index (BMI), 30-<40 kg/m2) between the ages of 20 and 60 were required to undergo eligibility screening via history and examination. Initial screening included the requirement that a patient must have failed conservative weight reduction alternatives (e.g., supervised diet, exercise or behavior modification programs) within the last year, had no significant weight change (±5.0 % TBWL) in the last 6 months, had an American Society of Anesthesiologists score of ≤2, not taken any weight-loss medications for ≥6 months, agreed not to have additional weight-loss interventions or liposuction for ≥30 months after study enrollment, and been willing to cooperate with postoperative dietary recommendations and assessments."	
Exclusion criteria	"Subjects were excluded if they had a history of bariatric, gastric, or esophageal surgery, stricture, or other anatomy or condition that could preclude passage of endolumenal instruments, gastroesophageal reflux disease (L.A. classification of grade B, C, or D), known hiatal hernia >3 cm, pancreatic insufficiency/disease; active peptic ulcer; pregnancy or plans OBES SURG (2017) 27:310-322 311 of pregnancy within 12 months; present corticosteroid use; inflammatory gastrointestinal disease; coagulation disorders; hepatic insufficiency or cirrhosis; >2 years type 2 diabetes mellitus (HbA1C >6.5) or uncontrolled type 2 diabetes (HbA1C >7 %); diabetes treatment with insulin; quit smoking in last 6 months; immunosuppression; portal hypertension or varices; or active gastric ulcer disease, outlet obstruction, or stenosis. Subjects were also excluded with: a Beck Depression Inventory (Short Form) score of ≥12, drug or alcohol abuse, severe eating disturbances, the presence of a significant depression, psychosis, or other mood or eating disorder (except for stable treated depression for >1 year and normal Beck and psychological examinations); significant mobility impairment; known hormonal or genetic cause for obesity with the exception of treated hypothyroidism; history of recent participation in another clinical study; or who were first-degree relatives of anyone involved in the study, or were unable to provide written informed consent."	
Setting	Hospital, Home	
Intervention	"Pose subjects received gastric fundus and distal body sutureanchor plications with diet/exercise counseling. The pose procedure was performed with a set of minimally invasive gastroendoscopic instruments developed by USGI Medical (San Clemente, CA). Procedure instrumentation and technique, including operation of the Incisionless Operating Platform™ (IOP) with the TransPort® Endoscopic Access Device and g-Cath EZ™ Suture Anchors have been described previously in detail [22, 24]. Approximately 8-11 sutureanchor plications were placed in the gastric fundus with the IOP, forming two rows, or Bridges,^ in order to invaginate the fundus to reduce its overall size, thereby preventing it from expanding to accommodate a meal portion. After completing the fundal ridges,	

<table>
<tr><td></td><td>three to four additional suture anchors were placed in the distal gastric body to create a ridge with the intent of disrupting the gastric antral mill, yet not creating a complete mechanical restriction. Within 23 h of receiving the pose procedure, treatment-group subjects were discharged, as medically indicated. With the exception of the pose procedure and follow-up observation, both the treatment and the control groups underwent the same plan of care. Both the treatment- and control-group subjects were advised to follow a custom diet for the first four study weeks. The calorie-restricted diet transitioned from liquids to soft and mashed solids to full solids over the course of 5 weeks; a target amount of protein, carbohydrates, and fat was specified, in addition to a recommended quantity of liquids. Exercise in the form of walking for 10-15 min 2-3 times/day was strongly encouraged from the first week through week 4, at which time, based on investigator authorization, subjects were encouraged to undertake a more rigorous aerobic regimen that included 30-45 min of approved exercise 5 times/week.”</td></tr>
<tr><td>Control/Comparator</td><td>“Control-group subjects received diet/exercise guidance only. They were advised to follow a custom diet for the first four study weeks. The calorie-restricted diet transitioned from liquids to soft and mashed solids to full solids over the course of 5 weeks; a target amount of protein, carbohydrates, and fat was specified, in addition to a recommended quantity of liquids. Exercise in the form of walking for 10-15 min 2-3 times/day was strongly encouraged from the first week through week 4, at which time, based on investigator authorization, subjects were encouraged to undertake a more rigorous aerobic regimen that included 30-45 min of approved exercise 5 times/week.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 44
Intervention group/s: Treatment (n=34)

Comparator group: Control (n=10)</td></tr>
<tr><td>Mean age ± SD</td><td>38.3y (10.7)</td></tr>
<tr><td>Sex</td><td>77.27% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Weight (kg)
Mean (95% CIs)</td><td>Treatment: 36.2
(3.3)

Treatment: 100.3
(96.0-104.6)</td><td>Control: 37.2
(3.7)

Control: 97.8
(88.3-107.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (95% CIs)</td><td>Treatment: 87.7
(82.8-92.6)</td><td>Control: 89.6
(77.2-102)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
</table></td></tr>
</table>

12 months or closest time point	TBWL (%) Mean (95% CIs) EWL (%) Mean (95% CIs) Change in weight (kg) Mean (95% CIs)	Treatment: 13 (10.3-15.8) Treatment: 45 (4.8-55.2) Treatment: 12.6 (9.9-15.3)	Control: 5.3 (0.3-10.3) Control: 18.1 (1.9-38.1) Control: 8.2 (-0.9-17.3)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Miller, 2017

Guideline record ID: 10472--1

Study characteristics		
Citation	Miller, G. D., Beavers, D. P., Hamm, D., Mihalko, S. L., & Messier, S. P. (2017). Nutrient intake during diet-induced weight loss and exercise interventions in a randomized trial in older overweight and obese adults. The Journal of Nutrition, Health & Aging, 21(10), 1216-1224. https://doi.org/https://dx.doi.org/10.1007/s12603-017-0892-5	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Nutrient Intake During Diet-Induced Weight Loss and Exercise Interventions in a Randomized Trial in Older Overweight and Obese Adults	
Location	USA	
Trial name	Intensive Diet and Exercise for Arthritis (IDEA)	
Methods		
Inclusion criteria	“Body mass index (BMI) = 27 - 41 kg/m2 ; ≥ 55 years of age; radiographic evidence of mild to moderate tibiofemoral OA or tibiofemoral + patellofemoral OA in at least one knee, defined as a KellgrenLawrence grade of II or III; and pain on most days due to knee OA.”	
Exclusion criteria	Not reported	
Setting	Home, University/research centre	
Intervention	“Individuals in the dietary interventions (D and D+E groups) were placed on an energy restricted diet. Initial diet plans included an energy-intake deficit of 800 to 1000 kcal/day depending on the individual's anticipated energy expenditure with a minimum of 1100 kcal/day for women and 1200 kcal/ day for men. A calorie distribution goal was set as follows: 45-60% from carbohydrates; 15-20% from protein; and <30% from fat. Participants in D and D+E consumed up to two meal replacements per day with a third meal consisting of approximately 500-750 kcal. Participants were provided for 6-months with the 'Lean Shake' meal replacements from GNC consisting of 180 calories/serving. The nutritional breakdown of the meal replacement can be found in Table 1. For the third meal of the day, dietary interventionists gave participants a weekly menu guide with recipes that consisted of meals that were high in fruits and vegetables, low in fat, and contained 2100-3100 kjoules (500-750 kcals) per meal. Participants could also consume snacks such as fruits, vegetables, and meal replacement bars all equaling approximately 420-500 kjoules (100-120 kcals) per serving. Interventionists monitored weight weekly and adjusted daily caloric intake based on each individual's rate of weight change. Participants attended three group sessions and 1 individual session each month for the first six months of the study. For months 7 to 18 they attended biweekly group sessions and 1 individual session every two months. Participants were asked to monitor their own diet by completing daily logs of their food and beverage intake. Further details of the dietary intervention has been described elsewhere (19). Individuals in D+E group also undertook The exercise training consisted of 60 minutes of exercise 3 days a week. The program consisted of aerobic walking (15 minutes), strength training (20 minutes), another aerobic phase (15 minutes), and cool-down (10 minutes). During the first 6-months, participants reported to the exercise facility. Following a 2-week transition phase, an option was provided to either remain in the facility program, change to a home-based program, or combine the facility and home-based programs”	
Control/Comparator	“The exercise training consisted of 60 minutes of exercise 3 days a week. The program consisted of aerobic walking (15 minutes), strength training (20 minutes), another aerobic phase (15 minutes), and cool-down (10 minutes). During the first 6-months, participants reported to the exercise facility. Following a 2-week transition phase, an option was	

<table>
<tr><td></td><td>provided to either remain in the facility program, change to a home-based program, or combine the facility and home-based programs.”</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 388
Intervention group/s: Diet (n=132); Diet+Exercise (n=130)

Comparator group: Exercise (n=126)</td></tr>
<tr><td>Mean age ± SD</td><td>65.8y (6.1)</td></tr>
<tr><td>Sex</td><td>70.36% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Osteoarthritis</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline Body weight (kg)
Mean (SD)

Baseline BMI (kg/m2)
Mean (SD)</td><td>Diet: 93.6
(15.5)
Diet+Exercise: 93.6
(14.7)

Diet: 33.7
(3.8)
Diet+Exercise: 33.8
(3.8)</td><td>Exercise: 92.5
(14.7)

Exercise: 33.5
(3.7)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss (%)
Mean (SD)</td><td>Diet: 11.3
(8.3)
Diet+Exercise: 10.3
(9.3)</td><td>Exercise: 1.1
(4.3)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td>Beavers, K. M., Beavers, D. P., Newman, J. J., Anderson, A. M., Loeser, R. F., Jr., Nicklas, B. J., Lyles, M. F., Miller, G. D., Mihalko, S. L., & Messier, S. P. (2015). Effects of total and regional fat loss on plasma CRP and IL-6 in overweight and obese, older adults with knee</td></tr>
</table>

contribute additional data	osteoarthritis. Osteoarthritis and Cartilage, 23(2), 249-256. https://doi.org/10.1016/j.joca.2014.11.005

N/A – Not applicable

Miller, 2020

Guideline record ID: 10471--1

Study characteristics		
Citation	Miller, C. T., Fraser, S. F., Selig, S. E., Rice, T., Grima, M., van den Hoek, D. J., Ika Sari, C., Lambert, G. W., & Dixon, J. B. (2020). Fitness, strength and body composition during weight loss in women with clinically severe obesity: a randomised clinical trial. Obesity Facts, 13(4), 307-321. https://doi.org/https://dx.doi.org/10.1159/000506643	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Fitness, Strength and Body Composition during Weight Loss in Women with Clinically Severe Obesity: A Randomised Clinical Trial	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	"Premenopausal women aged 18-50 years, with a BMI ≥40 or a BMI ≥30 with at least 1 obesity-related comorbidity."	
Exclusion criteria	"Unstable cardiovascular conditions, type 1 diabetes, active musculoskeletal conditions preventing exercise participation, pregnancy or planning pregnancy, weight loss greater than 5 kg in the past 3 months, using weight loss medications, previous bariatric surgery, medications which significantly influence weight and more than 150 min of moderate intensity exercise per week."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Participants received identical energy-restricted diet and dietary consultations (Fig. 2) which were designed to resemble that of standard clinical care for free-living adults by dietitians with experience with severe obesity. The consultations and intervention consisted of a very low energy diet protocol (Optifast®, Nestle, Australia) with an energy intake ranging from 450-680 kcal (1,900-2,800 kJ) per day during the intensive phase to 1,200 kcal (5,000 kJ) per day during the stabilisation phase. Participants met every 2 weeks for the first 12 weeks with an accredited practicing dietitian and continued as clinically relevant for the remaining 9 months. All participants started with an intensive phase for at least 12 weeks if tolerated, moving into a transition phase for 6-12 weeks, maintenance phase for the next 6-12 weeks, and then a stabilisation phase for the remaining 6 months. The diet transitioned gradually from full meal replacements to whole food as clinically indicated. There was no attempt to directly control for energy intake beyond the advice and support provided by the study dietitian. The average daily macronutrient content during the intensive phase (3 meal replacement products) for the Optifast® diet was: protein 54 g, carbohydrate 59 g, fat 14 g; plus 2 cups of low starch vegetables and 1 teaspoon of oil of the participant's choice. Participants randomised to EXER completed a supervised exercise training programme delivered by accredited exercise physiologists and postgraduate clinical exercise physiology students. Participants underwent a stepped-down approach to supervised exercise training designed to accommodate free-living adults. There was no attempt to control for the degree of energy deficit, energy expenditure or net energy balance between the two interventions. Each supervised exercise training session consisted of 20-30 min aerobic (60-80% heart rate reserve) and 30 min of resistance training (1-3 sets of 8-10 repetitions for 8 different upper and lower body exercises) for a total of 60 min. Exercise training consisted of 3 supervised training sessions per week for the first 6 weeks, 2 sessions per week for weeks 7-12, 1 session per week for the next 3 months and 1 session per fortnight for the final 6 months. The supervised training sessions were supplemented with self-administered sessions for a total of 300 min per week of moderate intensity exercise. The modes of exercise for the self-administered training sessions were developed in consultation with each participant based on their access to facilities and preferences."	

<table>
<tr><td>Control/Comparator</td><td>“Participants received identical energy-restricted diet and dietary consultations (Fig. 2) which were designed to resemble that of standard clinical care for free-living adults by dietitians with experience with severe obesity. The consultations and intervention consisted of a very low energy diet protocol (Optifast®, Nestle, Australia) with an energy intake ranging from 450-680 kcal (1,900-2,800 kJ) per day during the intensive phase to 1,200 kcal (5,000 kJ) per day during the stabilisation phase. Participants met every 2 weeks for the first 12 weeks with an accredited practicing dietitian and continued as clinically relevant for the remaining 9 months. All participants started with an intensive phase for at least 12 weeks if tolerated, moving into a transition phase for 6-12 weeks, maintenance phase for the next 6-12 weeks, and then a stabilisation phase for the remaining 6 months. The diet transitioned gradually from full meal replacements to whole food as clinically indicated. There was no attempt to directly control for energy intake beyond the advice and support provided by the study dietitian. The average daily macronutrient content during the intensive phase (3 meal replacement products) for the Optifast® diet was: protein 54 g, carbohydrate 59 g, fat 14 g; plus 2 cups of low starch vegetables and 1 teaspoon of oil of the participant's choice. Control participants were encouraged to be active but were not provided with specific advice on exercise.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 60
Intervention group/s: Energy restriction plus exercise training (n=30)

Comparator group: Energy restriction (n=30)</td></tr>
<tr><td>Mean age ± SD</td><td>37y (9)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Unclear ("at least 1 obesity-related comorbidity" in inclusion criteria)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight, kg (baseline)
Mean (SD)</td><td>Energy restriction plus exercise training: 111.9 (17.8)</td><td>Energy restriction: 114.4 (23.7)</td></tr>
<tr><td>Waist circumference, cm (Baseline)
Mean (SD)</td><td>Energy restriction plus exercise training: 112.5 (11.6)</td><td>Energy restriction: 114.3 (13)</td></tr>
<tr><td>Body mass index (baseline)
Mean (SD)</td><td>Energy restriction plus exercise training: 40.2 (6.8)</td><td>Energy restriction: 40.6 (6.7)</td></tr>
<tr><td>Fat mass (Baseline)
Mean (SD)</td><td>Energy restriction plus exercise training: 56.9 (12.9)</td><td>Energy restriction: 59.4 (15.4)</td></tr>
<tr><td>Weight, kg
Mean (SD)</td><td>Energy restriction plus exercise training: 111.4 (17.5)</td><td>Energy restriction: 114.1 (23.6)</td></tr>
</table>
</td></tr>
</table>

	Body mass index Mean (SD) Fat mass, kg Mean (SD) Waist circumference, cm Mean (SD)	Energy restriction plus exercise training: 40.2 (6.8) Energy restriction plus exercise training: 56.9 (12.9) Energy restriction plus exercise training: 112.7 (11.6)	Energy restriction: 40.6 (6.7) Energy restriction: 59.4 (15.4) Energy restriction: 114.3 (13)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight change Mean (SE) Change in body mass index Mean (SE) Change in Fat mass, kg Mean (SE) Change in waist circumference Mean (SE)	Energy restriction plus exercise training: -12.3 (2.7) Energy restriction plus exercise training: -4.45 (1) Energy restriction plus exercise training: -11.2 (2.7) Energy restriction plus exercise training: -12.6 (2.1)	Energy restriction: -8.9 (2.7) Energy restriction: -3.3 (1) Energy restriction: -8.1 (2.8) Energy restriction: -9.1 (2.2)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Attendance to dietary consultations were similar between groups. 12 ± 5 (M ± SD) dietary consultations in ER, and 14 ± 4 (M ± SD) in EXER, (Mean diff ± SEM; 1.9±1.2; p=0.139). Attendance to the supervised exercise training decreased over time with attendance highest in the first three months (Mean± SD, 73± 26%), reducing to 64± 36% (Mean± SD) between three and six months, and to 42± 39% (Mean± SD) between six and twelve months. Overall attendance to supervised training sessions was 63± 27% (Mean± SD).		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Mingrone, 2015

Guideline record ID: 10475--1

Study characteristics		
Citation	Mingrone, G., Panunzi, S., De Gaetano, A., Guidone, C., Iaconelli, A., Nanni, G., Castagneto, M., Bornstein, S., & Rubino, F. (2015). Bariatric-metabolic surgery versus conventional medical treatment in obese patients with type 2 diabetes: 5 year follow-up of an open-label, single-centre, randomised controlled trial. The Lancet, 386(9997), 964-973. https://doi.org/https://dx.doi.org/10.1016/S0140-6736(15)00075-6	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Bariatric-metabolic surgery versus conventional medical treatment in obese patients with type 2 diabetes: 5 year follow-up of an open-label, single-centre, randomised controlled trial	
Location	Italy	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were an age of 30-60 years, a BMI of 35 kg/m² or more, a history of type 2 diabetes lasting at least 5 years, glycated haemoglobin A1c (HbA1c) concentration of ≥7·0% or more (≥53 mmol/mol), and ability to understand and comply with the study protocol."	
Exclusion criteria	"Exclusion criteria were a history of type 1 diabetes, diabetes secondary to a specifi c disease or glucocorticoid treatment, previous bariatric surgery, pregnancy, other medical disorders requiring short-term hospital admission, severe diabetes complications, other severe medical disorders, and geographical inaccessibility."	
Setting	Hospital	
Intervention	"Roux-en-Y gastric bypass and biliopancreatic diversion were done in accordance with standard surgical techniques as previously described. Study participants had visits at baseline and at months 1, 3, 6, 9, and 12, and then every 6 months until month 60, or more often, as clinically necessary for diabetes control. All patients complied with follow-up visits and self-reported compliance with the drug regimen."	
Control/Comparator	"For conventional medical treatment and lifestyle intervention, patients were assessed and managed by a multidisciplinary team as they were in the surgery/intervention arms."	
Treatment duration	2 years	
Follow-up from baseline	5 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 60 Intervention group/s: Roux-en-Y gastric bypass group (n=20); Biliopancreatic diversion group (n=20) Comparator group: Medical treatment group (n=20)	
Mean age ± SD	Not reported	
Sex	Not reported	

<table>
<tr><td></td><td></td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Roux-en-Y gastric bypass group: 127.2
(20.6)
Biliopancreatic diversion group: 137.5
(31.2)</td><td>Medical treatment group: 137.1
(23.5)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Roux-en-Y gastric bypass group: 123.9
(15.4)
Biliopancreatic diversion group: 131.2
(19.9)</td><td>Medical treatment group: 127.7
(16.2)</td></tr>
<tr><td>BMI (kg/m²)
Mean (SD)</td><td>Roux-en-Y gastric bypass group: 44
(4.6)
Biliopancreatic diversion group: 44.7
(7.7)</td><td>Medical treatment group: 45.4
(6.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Roux-en-Y gastric bypass group: 90.3
(12.7)
Biliopancreatic diversion group: 92.8
(14)</td><td>Medical treatment group: 127.1
(20.5)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Roux-en-Y gastric bypass group: 101.5
(12.8)
Biliopancreatic diversion group: 102.4
(12.6)</td><td>Medical treatment group: 113.9
(14.2)</td></tr>
<tr><td>BMI (kg/m²)
Mean (SD)</td><td>Roux-en-Y gastric bypass group: 31.3
(2.5)
Biliopancreatic diversion group: 30.3
(4)</td><td>Medical treatment group: 42.1
(5.8)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Absolute change in Weight (kg)
Mean (SD)</td><td>Roux-en-Y gastric bypass group: -37
(13.8)</td><td>Medical treatment group: -10
(12.2)</td></tr>
</table>
</td></tr>
</table>

		Biliopancreatic diversion group: -44.7 (22.4)	
	Percent change (%) in Weight Mean (SD)	Roux-en-Y gastric bypass group: -28.4 (7.4) Biliopancreatic diversion group: -31.1 (9.3)	Medical treatment group: -6.9 (8.4)
	Absolute change in Waist circumference (cm) Mean (SD)	Roux-en-Y gastric bypass group: -22.4 (12.5) Biliopancreatic diversion group: -28.8 (14.1)	Medical treatment group: -13.8 (12.3)
	Percent change (%) Waist circumference (cm) Mean (SD)	Roux-en-Y gastric bypass group: -17.6 (8.5) Biliopancreatic diversion group: -21.2 (8.2)	Medical treatment group: -10.3 (9.1)
	Absolute change in BMI (kg/m^2) Mean (SD)	Roux-en-Y gastric bypass group: -12.7 (4.4) Biliopancreatic diversion group: -14.3 (6.3)	Medical treatment group: -3.3 (4.1)
	Percent change (%) in BMI Mean (SD)	Roux-en-Y gastric bypass group: -28.4 (7.4) Biliopancreatic diversion group: -31.1 (9.3)	Medical treatment group: -6.9 (8.4)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Mobasseri, 2015

Guideline record ID: 10476--1

Study characteristics		
Citation	Mobasseri, M., Yavari, A., Najafipoor, F., Aliasgarzadeh, A., & Niafar, M. (2015). Effect of a long-term regular physical activity on hypertension and body mass index in type 2 diabetes patients. The Journal of Sports Medicine and Physical Fitness, 55(1-2), 84-90. https://ezproxy.deakin.edu.au/login?url=https://search.ebscohost.com/login.aspx?direct=true&AuthType=ip,sso&db=ccm&AN=109796089&site=ehost-live&scope=site	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a long-term regular physical activity on hypertension and body mass index in type 2 diabetes patients	
Location	Iran	
Trial name	N/A	
Methods		
Inclusion criteria	"Established T2DM for more than one year duration, treatment only with oral hypoglycemic agents (no taking insulin), an inactive previous lifestyle, A1c level <11%. For BP eligibility, participants were required to have SBP between 139-159 or diastolic BP between 80-99mmHg during two consecutive weekly visits and average in this range over four visits, or use of antihypertensive medications."	
Exclusion criteria	"Serious cardiovascular diseases or diabetic complications such as neuropathy and retinopathy, cancer, smoking, age >70 years, insulin taking, BMI >43, A1c value >11 and regular exercise >90min/week."	
Setting	unclear (the program consisted of 3 supervised weekly sessions for three years. Exercise program was supervised by training professionals))	
Intervention	"The program consisted of 3 supervised weekly session for three-years. Since the endurance is most effective exercise for management of hypertension, we chose and aerobic exercise as mode of intervention. The exercise program was progressed gradually in duration (from 50% to 75% of max HR). Each session was began with a warm-up, included 10-15 minutes stretching movements, followed by aerobic exercises 50-60 minutes based on the participants choice of a treadmill, stationary cycle or elliptical and then 10 minutes of relaxation was done to cool down. The target HR was range set at 50-80% of the max HR during baseline treadmill testing and was monitored with heart rate monitors (Polar FT60, china). As fitness improved, the aerobic workload was increased to maintenance the HR within the heart rate at target levels. Exercise program was supervised by training professionals. all of the participants were recommended to continue their previous drugs and diet to minimize the related variability."	
Control/Comparator	"Participants were recommended to maintain their previous activity level and all of the participants were recommended to continue their previous drugs and diet to minimize the related variability."	
Treatment duration	3 years	
Follow-up from baseline	3 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		

Number of participants	n= 60 Intervention group/s: Exercise group (n=30) Comparator group: Control group (n=30)		
Mean age ± SD	Intervention: 51.04y (8.87); Control: 50.41y (7.97)		
Sex	Not reported		
Pre-existing medical condition	Type 2 diabetes mellitus		
Results			
Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	BMI Mean (SD)	Exercise group: 28 (5.26)	Control group: 30.02 (4.79)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	BMI Mean (SD)	Exercise group: 26.42 (4.36)	Control group: 31.05 (4.84)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Mokhtari, 2019

Guideline record ID: 10480--1

Study characteristics		
Citation	Mokhtari, Z., Karbaschian, Z., Pazouki, A., Kabir, A., Hedayati, M., Mirmiran, P., & Hekmatdoost, A. (2019). The effects of probiotic supplements on blood markers of endotoxin and lipid peroxidation in patients undergoing gastric bypass surgery; a randomized, double-blind, placebo-controlled, clinical trial with 13 months follow-up. Obesity Surgery, 29(4), 1248-1258. https://doi.org/https://dx.doi.org/10.1007/s11695-018-03667-6	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Effects of Probiotic Supplements on Blood Markers of Endotoxin and Lipid Peroxidation in Patients Undergoing Gastric Bypass Surgery; a Randomized, Double-Blind, Placebo-Controlled, Clinical Trial with 13 Months Follow-Up	
Location	Iran	
Trial name	N/A	
Methods		
Inclusion criteria	"Subjects who were 18-60 years old, candidates for the laparoscopic OAGB surgery in the next month, morbid obese (BMI ≥ 40 kg/m2 or 40 > BMI > 35 kg/ m2 with comorbidities), and no evidence of chronic gastrointestinal, liver, and kidney disorders, were recruited."	
Exclusion criteria	"Participants who took antibiotics, probiotic supplements, foods fortified with probiotics and/or immunosuppressive treatment, and insulin within 4 weeks before the start of the study and during the study were excluded from the study. Furthermore, subjects were excluded if they were pregnant."	
Setting	Hospital, Home	
Intervention	"After stratifying (1:1) into two groups based on their type 2 diabetes (T2D) status (with or without T2D), they were randomly allocated to receive the probiotic supplement (n = 23) for 4 months (from a month before surgery to 3 months after the surgery). Randomization sequence was computer-generated by a statistician in blocks of four patients and stratified based on their T2D status (with or without T2D). Patients were allocated to randomization code letters (A or B) in chronological order. Information about the treatment each participant was placed in a sealed envelope, which was not opened until the investigation was completed. Patients were instructed to take one supplement capsule each day and to refrigerate the unused capsules. The patients were requested not to consume the probiotic supplements on the day of surgery until hospital discharge (about 2 days). Each probiotic capsule (ZistTakhmir, Co., Tehran, Iran) contained seven species of probiotic bacteria (Lactobacillus casei (3.5 × 109 CFU/g), Lactobacillus rhamnosus (7.5 × 108 CFU/g), Streptococcus thermophiles (1 × 108 CFU/g), Bifidobacterium breve (1 × 1010 CFU/g), Lactobacillus acidophilus (1 × 109 CFU/g), Bifidobacteriumlongum (3.5 × 109 CFU/g), and Lactobacillus bulgaricus (1 × 108 CFU/g)) and 38.5-mg fructo-oligosaccharide. Placebo capsules contained the same amount of maltodextrin. The surgeon, medical staff related to the care of the patient, the research staff, and patients were all blinded to the treatment assignment. Gastric-bypass surgery by OAGB included the creation of a long sleeved gastric tube along the lesser curvature side with a Billroth type II loop gastro-jejunostomy with a 180-200 cm or longer afferent limb [8]."	
Control/Comparator	"After stratifying (1:1) into two groups based on their type 2 diabetes (T2D) status (with or without T2D), they were randomly allocated to receive the placebo supplement (n = 23) for 4 months (from a month before surgery to 3 months after the surgery). Randomization sequence was computer-generated by a statistician in blocks of four patients and stratified based on their T2D status (with or without T2D). Patients were allocated to randomization	

<table>
<tr><td></td><td>code letters (A or B) in chronological order. Information about the treatment each participant was placed in a sealed envelope, which was not opened until the investigation was completed. Patients were instructed to take one supplement capsule each day and to refrigerate the unused capsules. The patients were requested not to consume the probiotic supplements on the day of surgery until hospital discharge (about 2 days). Each probiotic capsule (ZistTakhmir, Co., Tehran, Iran) contained seven species of probiotic bacteria (Lactobacillus casei (3.5 × 109 CFU/g), Lactobacillus rhamnosus (7.5 × 108 CFU/g), Streptococcus thermophiles (1 × 108 CFU/g), Bifidobacterium breve (1 × 1010 CFU/g), Lactobacillus acidophilus (1 × 109 CFU/g), Bifidobacteriumlongum (3.5 × 109 CFU/g), and Lactobacillus bulgaricus (1 × 108 CFU/g)) and 38.5-mg fructo-oligosaccharide. Placebo capsules contained the same amount of maltodextrin. The surgeon, medical staff related to the care of the patient, the research staff, and patients were all blinded to the treatment assignment. Gastric-bypass surgery by OAGB included the creation of a long sleeved gastric tube along the lesser curvature side with a Billroth type II loop gastro-jejunostomy with a 180-200 cm or longer afferent limb [8].”</td></tr>
<tr><td>Treatment duration</td><td>4 months</td></tr>
<tr><td>Follow-up from baseline</td><td>13 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 46
Intervention group/s: Probiotic group (n=23)

Comparator group: Placebo group (n=23)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 32.35y (6.88); Control: 36.95y (11.00)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI
Mean (SD)</td><td>Probiotic group: 44.59
(4.3)</td><td>Placebo group: 44.95
(4.52)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Data could not be extracted</td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Molenaar, 2010

Guideline record ID: 10481

Study characteristics		
Citation	Molenaar, E. A., van Ameijden, E. J. C., Vergouwe, Y., Grobbee, D. E., & Numans, M. E. (2010). Effect of nutritional counselling and nutritional plus exercise counselling in overweight adults: a randomized trial in multidisciplinary primary care practice. Family Practice, 27(2), 143-150. https://doi.org/https://dx.doi.org/10.1093/fampra/cmp104	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of nutritional counselling and nutritional plus exercise counselling in overweight adults: a randomized trial in multidisciplinary primary care practice	
Location	Netherlands	
Trial name	Utrecht Health Project (UHP)	
Methods		
Inclusion criteria	"All men and non-pregnant women aged 18-65 years with a body mass index (BMI) 28-35 kg/m2 (n = 877)."	
Exclusion criteria	"The GPs were asked to exclude potential participants from the list selected, who were unable to speak Dutch, who were already treated for their overweight by a dietician and/or physiotherapist or who had diagnosed mental health problems or known plans to move out of the residential area shortly."	
Setting	Multidisciplinary primary care setting	
Intervention	"All randomized participants were provided with a referral letter from their GP to attend seven individual face-to-face counselling sessions with a dietician during 6 months (with Sessions 4 and 7 fixed at, respectively, 3 and 6 months after the first session) and one follow-up session at 12 months. At the first session, the dietician went through a 3-day food record (2 weekdays and 1 weekend day), which the participants were asked to complete beforehand and bring to the counselling appointment. Participants were informed about the significant health gains that can be achieved with relatively small long-lasting weight loss of 5 to 10%, and in order to establish realistic expectations, it was emphasized that successful weight loss and maintenance require gradual changes in lifestyle that can be continued over time. In cooperation with the participants, individualized attainable goals for a healthy diet (based on the guidelines from the Health Council of The Netherlands) and effective caloric intake reduction were set and a strategy was developed to gradually achieve a moderate sustainable weight reduction, taking dietary history and habitual diet routines into account. At subsequent sessions, the dietician provided support, dietary advice and encouraged the participants to achieve or maintain their goals. The weight and waist circumference of the participants were measured at each counselling session and additionally at the 6- and 12-month session, a 3-day food record was completed. The duration of the initial session was assumed to be 40 minutes and later sessions 20 minutes. Participants randomized to the D + E group were additionally provided with a referral letter from their GP to attend six individual face-to-face counselling sessions with a physiotherapist during 6 months (with Sessions 4 and 6 fixed at, respectively, 3 and 6 months after the first session) and one follow-up session at 12 months. At the first session, the physiotherapist went through a physical activity questionnaire known as the SQUASH (Short Questionnaire to ASses Health enhancing physical activity).13 Under the supervision of the physiotherapist, the participants performed the Astrand submaximal cycle test to determine their maximal oxygen uptake as a measure of cardiorespiratory fitness.14 In cooperation with the participants individualized, attainable goals for an increase in daily physical activity were set and a strategy was developed to gradually achieve a moderate sustainable weight reduction and improve cardiorespiratory fitness, taking habitual physical activity, fitness and personal preferences into account. The physiotherapist provided advice	

<table>
<tr><td></td><td>on exercise and building physical activity into daily life and informed the participants about possibilities for voluntary exercise (swimming, fitness/aerobics and running) at reduced costs as part of the intervention. At subsequent sessions, the physiotherapist provided support, physical activity advice and encouraged the participants to achieve or maintain their goals. At the 6- and 12-month counselling session, the participants were asked to perform another Astrand submaximal cycle test. The duration of the initial counselling session was assumed to be 45 to 60 minutes and later sessions 30 minutes."</td></tr>
<tr><td>Control/Comparator</td><td>"All randomized participants were provided with a referral letter from their GP to attend seven individual face-to-face counselling sessions with a dietician during 6 months (with Sessions 4 and 7 fixed at, respectively, 3 and 6 months after the first session) and one follow-up session at 12 months. At the first session, the dietician went through a 3-day food record (2 weekdays and 1 weekend day), which the participants were asked to complete beforehand and bring to the counselling appointment. Participants were informed about the significant health gains that can be achieved with relatively small long-lasting weight loss of 5 to 10%, and in order to establish realistic expectations, it was emphasized that successful weight loss and maintenance require gradual changes in lifestyle that can be continued over time. In cooperation with the participants, individualized attainable goals for a healthy diet (based on the guidelines from the Health Council of The Netherlands) and effective caloric intake reduction were set and a strategy was developed to gradually achieve a moderate sustainable weight reduction, taking dietary history and habitual diet routines into account. At subsequent sessions, the dietician provided support, dietary advice and encouraged the participants to achieve or maintain their goals. The weight and waist circumference of the participants were measured at each counselling session and additionally at the 6- and 12-month session, a 3-day food record was completed. The duration of the initial session was assumed to be 40 minutes and later sessions 20 minutes."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 134
Intervention group/s: D+E (n=67)

Comparator group: D (n=67)</td></tr>
<tr><td>Mean age ± SD</td><td>43y (9)</td></tr>
<tr><td>Sex</td><td>41.79% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>D+E: 94
(10.7)

D+E: 104.1
(7.1)</td><td>D: 96.9
(13)

D: 103.7
(8.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Mean (95% CIs)

Change in waist circumference (cm)
Mean (95% CIs)</td><td>D+E: -3.2
(-4.5--1.8)

D+E: -4.3
(-6.1--2.7)</td><td>D: -2.3
(-3.7--1)

D: -2.3
(-4--0.7)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>DIETITIAN VISIT - D: 88%; D+E: 89%; PHYSIOTHERAPIST VISIT - D+E: 87%</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Moncrieft, 2016

Guideline record ID: 10482--1

Study characteristics		
Citation	Moncrieft, A. E., Llabre, M. M., McCalla, J. R., Gutt, M., Mendez, A. J., Gellman, M. D., Goldberg, R. B., & Schneiderman, N. (2016). Effects of a multicomponent life-style intervention on weight, glycemic control, depressive symptoms, and renal function in low-income, minority patients with type 2 diabetes: results of the Community Approach to Lifestyle Modification for Diabetes randomized controlled trial. Psychosomatic Medicine, 78(7), 851-860. https://doi.org/10.1097/PSY.0000000000000348	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of a Multicomponent Life-Style Intervention on Weight, Glycemic Control, Depressive Symptoms, and Renal Function in Low-Income, Minority Patients With Type 2 Diabetes: Results of the Community Approach to Lifestyle Modification for Diabetes Random	
Location	USA	
Trial name	Community Approach to Lifestyle Modification for Diabetes (CALM-D)	
Methods		
Inclusion criteria	"Eligible participants were overweight or obese (body mass index ≥ 27 kg/m2), between the ages of 18 and 70 years, with self-report of Type 2 diabetes confirmed by medical records, current treatment, or verification by study physician (fasting plasma glucose ≥ 7 mM or 2-hour plasma glucose value after a 75-g glucose load ≥ 11 mM), and significant depressive symptoms (Beck Depression Inventory II [BDI-II] total score ≥ 11). Participants with preexisting cardiovascular disease were eligible if they met the functional criteria for inclusion (as determined during a submaximal exercise stress test) and diagnosis of the condition occurred at least 6 months before screening."	
Exclusion criteria	"Exclusionary criteria included any factors that could limit participant life span, affect the safety of the intervention, limit adherence to intervention, or affect conduct of the trial including advanced renal disease (dialysis, urine dipstick protein +4, serum creatinine ≥132 μM for men and ≥124 μM for women), blood pressure ≥ 160/100 mm Hg, fasting triglycerides ≥ 7 mM, and glycosylated hemoglobin (HbA1c) ≥ 97 mmol/mol (11%), inability to walk, and severe mental illness. Participants with BDI-II scores at least 35 were excluded if the magnitude of depression was deemed likely to prevent effective participation in the program."	
Setting	GP clinic, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Intervention components consisted of diet and physical activity largely consistent with the Diabetes Prevention Program protocol combined with cognitive behavioral and social learning approaches to address depressive symptoms. Each participant received a weight loss goal (7% of initial body weight) at the beginning of the intervention. To achieve the weight loss goal, participants also received goals for physical activity (150-minute aerobic activity/wk) and caloric intake (based on initial body) stress management, coping skills training, and modification of behavioral, environmental, and cognitive factors to promote healthy levels of social support. During the first 6 months, participants learned and implemented strategies to achieve physical activity and dietary goals; the second half of the intervention focused on problem solving and maintenance of behaviors. Intervention participants were also compensated ($10) for attendance at individual sessions. Weekly 1 Getting Started Being Active, Losing Weight and Managing Stress CALM-D goals; Deep breathing 2 Where's the Fat?/Three Ways to Eat Less Fat Using fat counter; Identify ways to eat less fat; Food logging 3 Move those Muscles/Being Active: A Way of Life Life-style activity; Preventing injury; Physical activity goal 4 Negative Thoughts and Emotions Types of	

<table>
<tr><td></td><td>negative thinking; Emotional eating Biweekly 5 Taking Your Medications/Stress and You Doctor patient communication; Stress effects on the body; Pleasurable activities 6 Healthy Eating Calorie goals; Food pyramid; Rate your plate 7 Tip the Calorie Balance/Communication Calories and weight loss; Body language; Listening techniques 8 Take Charge of What's Around You/Social Support Identifying and changing food and activity cues; Social support Monthly 9 Problem Solving 5 steps of problem solving; Action plans 10 Four Keys to Healthy Eating Out Practice four keys to eating out 11 The Slippery Slope of Lifestyle Change Identify potential slips 12 Challenging and Changing Negative Thoughts Identify negative thoughts; Challenge negative thoughts 13 Jump Start Your Activity Plan FITT principles; Heart rate monitoring; Target heart rates 14 You Can Manage Stress 3As of stress management; Unavoidable stressors 15 Assertiveness/Make Social Cues Work for You Assertiveness; Social cues 16 Life Goals Set personal goals 17 Ways to Stay Motivated/Review Develop action plan to maintain motivation”</td></tr>
<tr><td>Control/Comparator</td><td>“Participants assigned to usual care received a short educational booklet that covered topics related to diabetes management, but were not formally instructed to make any life-style changes. Participants in both arms were also expected to be treated in accordance with ADA Clinical Practice Guidelines (2005) by their primary care providers whenever possible. Of note, 53 (48%) participants, including 27 (50%) usual care and 26 (46%) intervention participants, were not recruited at community clinics but via word of mouth. Because having a primary care provider was not necessary for study participation, quality of usual care may vary significantly by recruitment site. All participants received compensation for completing assessments at baseline ($225) and 6 and 12 months ($100 each), as well as free transportation to and from the study site.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 111
Intervention group/s: Intervention (n=54)

Comparator group: Usual care (n=57)</td></tr>
<tr><td>Mean age ± SD</td><td>54.81y (7.36)</td></tr>
<tr><td>Sex</td><td>71.17% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes mellitus</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Weight (kg)
Mean (SD)</td><td>Intervention: 32.3
(3.7)

Intervention: 85.04
(12.22)</td><td>Usual care: 32.9
(5.5)

Usual care: 85.57
(16.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intervention: 82.03
(12.58)</td><td>Usual care: 84.19
(15.48)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Montemayor, 2022

Guideline record ID: 10483--1

Study characteristics		
Citation	Montemayor, S., Bouzas, C., Mascaró, C. M., Casares, M., Llompart, I., Abete, I., Angullo-Martinez, E., Zulet, M. Á., Martínez, J. A., & Tur, J. A. (2022). Effect of dietary and lifestyle interventions on the amelioration of NAFLD in patients with metabolic syndrome: the FLIPAN study. Nutrients, 14(11), 2223. https://doi.org/10.3390/nu14112223	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Dietary and Lifestyle Interventions on the Amelioration of NAFLD in Patients with Metabolic Syndrome: The FLIPAN Study	
Location	Spain	
Trial name	Prevention and Reversion of Non-Alcoholic Fatty Liver Disease in Obese Patients With Metabolic Syndrome by Mediterranean Diet and Physical Activity (FLIPAN)	
Methods		
Inclusion criteria	"Inclusion criteria were aged 40-60 years, Body Mass Index (BMI) between 27 and 40 kg/m2, NAFLD diagnosed by magnetic resonance imaging (MRI; Signa Explorer 1.5T, General Electric Healthcare, Chicago, IL, USA), and with MetS traits as described by the International Diabetes Federation (IDF) consensus [9]."	
Exclusion criteria	"Exclusion criteria were previous cardiovascular disease, congestive heart failure, liver diseases (other than NAFLD), cancer or a history of malignancy in the previous 5 years, previous bariatric surgery, acute febrile illnesses, urinary tract infections, post-renal hematuria, hemochromatosis, protein overload, non-medicated depression or anxiety, alcohol and drug abuse, pregnancy, primary endocrinological diseases (other than hypothyroidism and type 2 diabetes mellitus), concomitant therapy with steroids, intense physical exercise, or being unable to provide informed consent."	
Setting	Home, University/research centre	
Intervention	"The Mediterranean Diet-high meal frequency (MD-HMF) group adhered to a MedDiet based on a distribution of macronutrients of 30-35% fat (mainly mono- and polyunsaturated fatty acids from extra virgin olive oil, nuts, and omega-3 containing foods), 25% protein (mainly from vegetable sources), and 40-45% carbohydrates (50-70% of the total carbohydrate intake should be low glycemic index and rich in fiber). Patients allocated this treatment were advised to consume 7 meals a day, gradually reducing the caloric content at each main meal, with the highest calorie meals to be consumed early during the day (breakfast, lunch, dinner and two snacks in the morning and two snacks in the afternoon). Moreover, this diet was previously observed to reduce fat mass and overall weight and improve general oxidative stress in patients with metabolic syndrome [15], providing high Total Antioxidant Capacity (TAC), and focused on the chronological distribution of meals, as factors such as meal frequency and distribution could aid in reducing the feeling of hunger, thus improving compliance to an energy-restricted dietary regime [16]. Additionally, with the previous group, subjects were instructed to accumulate a minimum of 10,000 steps a day also recorded by a personal pedometer [17]. The Mediterranean Diet-physical activity (MD-PA) group also followed an energyrestricted MedDiet. However, meal frequency was of 4-5 meals a day including snacks. This group consumed 35-40% of total calories from fat (8-10% of saturated fatty acids, >20% of monounsaturated fatty acids, >10% of polyunsaturated fatty acids and <300 mg/day of cholesterol), approximately 20% of total calories from proteins and 40-45% or more of total calories from carbohydrates (low glycemic index). Sodium chloride should not exceed 6 g a day (2.4 g of sodium), and dietary fiber should be no less than 30-35 g/day [17]. Participants in this group, on the other hand, were instructed to undergo a 35 min interval training session three times a week, with a combination of two instructor-led on-site	

<table>
<tr><td></td><td>training sessions and one remote prescribed training session a week for the whole duration of the trial. Physical activity sessions of 35 min consisted of 5 min warm-up, 20 min interval training, and 10 min breathing and stretching. It has been pointed out that an association between physical activity and risk of nonalcoholic fatty liver disease, and people with NAFLD showed low levels of PA [18]. Three to five sessions per week of moderate or vigorous physical activity, an equivalent of 150-200 min per week, have been shown to decrease the development of NAFLD”</td></tr>
<tr><td>Control/Comparator</td><td>“The Conventional Diet (CD) group followed the American Association for the Study of Liver Disease (AASLD) recommendations [12] that recommends an energy restriction enough to lose 3-5% of body weight to improve steatosis, and 7-10% to improve most of the histopathological features of NAFLD/NASH, including fibrosis, following the general guidelines of the U.S. Department of Health and Human Services and the U.S. Department of Agriculture (20-35% fat, 10-35% protein, 45-65% carbohydrate) [13], and maintain an adequate fiber (25 g/day) and cholesterol (<250 mg/day) intake. Moreover, this group was instructed to accumulate a minimum of 10,000 steps a day (recorded by a personal pedometer).”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 128
Intervention group/s: MD-HMF (n=43); MD-PA (n=42)

Comparator group: CD (n=43)</td></tr>
<tr><td>Mean age ± SD</td><td>CD: 54.1y (8.9); MD-HMF:52.3y (7.1); MD-PA: 52.2y (5.8)</td></tr>
<tr><td>Sex</td><td>36.72% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>NAFLD</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>MD-HMF: 34.3
(4)
MD-PA: 33.4
(3.1)</td><td>CD: 33.6
(3.7)</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>MD-HMF: 96.3
(13.8)
MD-PA: 95.3
(12.3)</td><td>CD: 92.7
(14.4)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>MD-HMF: 112.1
(9.1)
MD-PA: 112.7
(8.5)</td><td>CD: 110.7
(9,4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>MD-HMF: 31.7
(4.3)
MD-PA: 31.8
(3.5)</td><td>CD: 31.9
(4.1)</td></tr>
</table>
</td></tr>
</table>

	Weight (kg) Mean (SD) Waist circumference (cm) Mean (SD)	MD-HMF: 89.5 (14.4) MD-PA: 91.6 (13) MD-HMF: 104.8 (12) MD-PA: 107.3 (9.9)	CD: 88.4 (14.4) CD: 105 (10.25)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in BMI (kg/m2) Mean (SD) Change in weight (kg) Mean (SD) Change in waist circumference (cm) Mean (SD)	MD-HMF: -2.6 (2.2) MD-PA: -1.6 (1.8) MD-HMF: -6.8 (6.4) MD-PA: -3.7 (5) MD-HMF: -7.3 (6.1) MD-PA: -4.1 (6)	CD: -1.7 (1.8) CD: -4.3 (5.5) CD: -5.2 (6.3)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Increase in adherence between the control group (+3.6 ± 3.0 p < 0.001) and the MD-HMF group (+6.2 ± 3.5 p < 0.001)		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Moore, 2019

Guideline record ID: 10484

Study characteristics		
Citation	Moore, S. M., Borawski, E. A., Love, T. E., Jones, S., Casey, T., McAleer, S., Thomas, C., Adegbite-Adeniyi, C., Uli, N. K., Hardin, H. K., Trapl, E. S., Plow, M., Stevens, J., Truesdale, K. P., Pratt, C. A., Long, M., & Nevar, A. (2019). Two family interventions to reduce BMI in low-income urban youth: a randomized trial. Pediatrics, 143(6), e20182185. https://doi.org/https://dx.doi.org/10.1542/peds.2018-2185	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Two Family Interventions to Reduce BMI in Low-Income Urban Youth: A Randomized Trial	
Location	United States of America	
Trial name	Ideas Moving Parents and Adolescents to Change Together (IMPACT)	
Methods		
Inclusion criteria	"BMI >85th percentile and entering the sixth grade."	
Exclusion criteria	"Children were excluded if they were taking medications that alter appetite or weight, had stage 2 hypertension or stage 1 hypertension with end organ damage,24 had type 1 or 2 diabetes, had sickle cell disease (conditions that are primarily treated with medication rather than lifestyle interventions), or had a known medical condition that itself causes obesity (eg, Prader-Willi syndrome)."	
Setting	Home, School	
Intervention	"The effects of 2 theoretically different family-based interventions, Healthy Change and System Change, were assessed against a control group. The Healthy Change intervention consisted of behavior change strategies commonly used in cognitive behavioral and motivational interviewing interventions, such as problem-solving, goal setting, selfmonitoring, and relapse-prevention skills. The System Change intervention was based on process improvement techniques and emphasized restructuring family daily routines (systems) to establish new healthy living habits. Participants were taught to use a series of small, family self-designed experiments to design new routines. Families also charted their daily routines associated with home, school, and work and used a storyboard to track their family change processes. Descriptions of and distinctions between the 2 experimental interventions are described in detail elsewhere.22,27 In the 3-year interventions, both experimental interventions focused on the same healthy living behaviors (diet, physical activity, sedentary activity, sleep, and stress management). The intervention modes of delivery were the same across the 2 interventions, consisting of small group sessions of 12 to 15 families who met in 25 face-to-face sessions in Year 1, alternating monthly face-to-face group and individualized telephone sessions in Year 2, and 4 face-to-face and 8 telephone sessions in Year 3. Each intervention session was delivered by 2 trained interventionists (1 man and 1 woman), at least 1 of whom was of minority race and/or ethnicity. The interventionists were generally school teachers or recreation center personnel who were independently contracted for this role and were trained by using a structured protocol. All intervention materials and curricula for both parent and child were developed at the fifthgrade reading level. All didactic sessions (group and telephone coaching) were audiotaped, and 10% were randomly selected for review of fidelity of content delivery. Interventions were tailored for adolescent participants in both intervention arms by using a responsive intervention design28,29 in which a set of tailoring variables and decision rules for their application were specified a priori. In this responsive intervention protocol, adolescents received up to 60 minutes of personal coaching each month of the study in addition to the usual standard intervention if they met any of the following 4 criteria: identified as a binge eater, morbidly obese at baseline (.99.5 BMI percentile), low parent and/or family involvement (adolescent attending .50% of sessions	

<table>
<tr><td></td><td>alone without a parent), or excessive weight gain during the study (.2 lb per month in a 3-month period resulting in an increase in BMI).”</td></tr>
<tr><td>Control/Comparator</td><td>“A control group of brief education and social interaction only comprised the third study arm. Parent and child participants in this arm received 1 hour of private coaching from a registered dietitian on healthy eating and physical activity in Year 1 as well as a social telephone call and social event in all study years to enhance study retention.”</td></tr>
<tr><td>Treatment duration</td><td>3 years</td></tr>
<tr><td>Follow-up from baseline</td><td>3 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 360
Intervention group/s: Healthy Change (n=118); System Change (n=123)

Comparator group: Education Only Control (n=119)</td></tr>
<tr><td>Mean age ± SD</td><td>11.6y (0.6)</td></tr>
<tr><td>Sex</td><td>57.78% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Healthy Change: 27.3 (4.8)
System Change: 27.4 (5.1)</td><td>Education Only Control: 26.8 (4.7)</td></tr>
<tr><td>BMI percentile
Mean (SD)</td><td>Healthy Change: 95.8 (3.6)
System Change: 95.8 (3.6)</td><td>Education Only Control: 95.5 (4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Unadjusted annualised change in BMI (kg/m2) (over 3 years)
Mean (SD)</td><td>Healthy Change: 0.821 (1.363)
System Change: 1.083 (1.129)</td><td>Education Only Control: 0.952 (1.318)</td></tr>
<tr><td>Unadjusted annualised change in BMI percentile
Mean (SD)</td><td>Healthy Change: -1.363 (3.836)
System Change: -0.26 (1.555)</td><td>Education Only Control: -1.101 (3.206)</td></tr>
</table></td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	99%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Morales-Palomo, 2018

Guideline record ID: 10485--1

Study characteristics		
Citation	Morales-Palomo, F., Ramirez-Jimenez, M., Ortega, J. F., & Mora-Rodriguez, R. (2018). Exercise periodization over the year improves metabolic syndrome and medication use. Medicine & Science in Sports & Exercise, 50(10), 1983-1991. https://doi.org/https://dx.doi.org/10.1249/MSS.0000000000001659	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Exercise Periodization over the Year Improves Metabolic Syndrome and Medication Use	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	"Untreated cardiovascular or renal disease, or any condition associated with exercise intolerance."	
Setting	GP clinic, training location unclear (One group underwent supervised high-intensity interval training)	
Intervention	"Supervised high-intensity interval training (HIIT) with a frequency of three times per week for 16 wk. Training consisted on pedaling for 10-min as warm-up at 70% of their individual peak heart rate (HRPEAK; Seego; Realtrack Systems, Almeria, Spain) followed by 4 4-min intervals at 90% HRPEAK interspersed with 3-min active recovery at 70% HRPEAK and a 5-min cool-down period for a total of 43 min per workout. Exercise intensity was increased as training adaptations developed to maintain target heart rate (HR) (22). Participants were required to attend at least 90% of all the exercise sessions. All subjects were advised to maintain their normal dietary and physical activity habits during the whole study. Monthly, during the intervention period, (4 months per year) subjects filled out a 3-day nutritional diary that was analyzed for caloric intake and macronutrient composition with a software that included common Spanish foodstuff (CESNICD v1.0; Barcelona, Spain). Likewise, every month, subjects wore a wrist band activity monitor (Polar Loop Electro, Kempele, Finland) for 48 h to monitor steps per day, standing time and supine resting time. During the intervention, feedback to prevent fluctuations in caloric intake or physical activity was delivered to the subject monthly."	
Control/Comparator	"The control group (CONT; n = 22), from an intervention waiting list, remained sedentary for the duration of the study. All subjects were advised to maintain their normal dietary and physical activity habits during the whole study. Monthly, during the intervention period, (4 months per year) subjects filled out a 3-day nutritional diary that was analyzed for caloric intake and macronutrient composition with a software that included common Spanish foodstuff (CESNICD v1.0; Barcelona, Spain). Likewise, every month, subjects wore a wrist band activity monitor (Polar Loop Electro, Kempele, Finland) for 48 h to monitor steps per day, standing time and supine resting time. During the intervention, feedback to prevent fluctuations in caloric intake or physical activity was delivered to the subject monthly."	
Treatment duration	2 years	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 44
Intervention group/s: Train group (n=22)

Comparator group: Control group (n=22)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>31.82% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SE)

Body weight
Mean (SE)

Waist circumference
Mean (SE)</td><td>Train group: 32.2
(0.9)

Train group: 92.5
(3.2)

Train group: 105.7
(2)</td><td>Control group: 33.2
(0.8)

Control group: 89.2
(3.1)

Control group: 106.7
(2.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SE)

Body weight
Mean (SE)

Waist circumference
Mean (SE)</td><td>Train group: 31.7
(0.8)

Train group: 91
(2.8)

Train group: 104.9
(1.8)</td><td>Control group: 33.3
(0.8)

Control group: 89.7
(3.2)

Control group: 109.6
(2.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SE)

Body weight
Mean (SE)

Waist circumference
Mean (SE)</td><td>Train group: 31.5
(0.7)

Train group: 90.6
(3.3)

Train group: 105.6
(1.8)</td><td>Control group: 33.7
(0.9)

Control group: 90.5
(3.3)

Control group: 110.5
(2.6)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in waist circumference
Mean (SE)</td><td>Not reported</td><td>Control group: 2.86
(0.32)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in waist circumference
Mean (SE

Change in BMI
Mean (SE)

Change in weight
Mean (SE)</td><td>Not reported

Train group: -0.72
(0.36)

Train group: -1.9
(1.1)</td><td>Control group: 3.83
(1.07)

Control group: 0.43
(0.36)

Control group: 0.43
(0.36)</td></tr>
</table>
</td></tr>
</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Moreno, 2014

Guideline record ID: 10486--1

Study characteristics		
Citation	Moreno, B., Bellido, D., Sajoux, I., Goday, A., Saavedra, D., Crujeiras, A. B., & Casanueva, F. F. (2014). Comparison of a very low-calorie-ketogenic diet with a standard low-calorie diet in the treatment of obesity. Endocrine, 47(3), 793-805. https://doi.org/https://dx.doi.org/10.1007/s12020-014-0192-3	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Comparison of a very low-calorie-ketogenic diet with a standard low-calorie diet in the treatment of obesity	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	“Age 18-65 years, body mass index (BMI) C 30, stable body weight in the previous 3 months, desire to lose weight, and history of failed dietary efforts.”	
Exclusion criteria	“Type 1 diabetes mellitus or insulin therapy, obesity induced by other endocrine disorders or by drugs, and use of any weight loss diet or pills in the previous 6 months. Secondary exclusion criteria were, severe depression or any other psychiatric disease, abuse of narcotics or alcohol, severe hepatic insufficiency, any type of renal insufficiency or gout episodes, neoplasia (except basal cell skin cancer), previous events of cardiovascular or cerebrovascular disease, kidney ltiasis, uncontrolled hypertension, and hydroelectrolytic alterations. Females with child-bearing potential, who were pregnant, breast-feeding, intending to become pregnant, or not using adequate contraceptive methods were excluded.”	
Setting	Hospital	
Intervention	“Very low-calorie-ketogenic diet The VLCK diet group, followed a very low-calorie-ketogenic diet according to a commercial weight loss program (PronoKal method) based on a high-biological-value protein preparations diet and natural foods. Each protein preparation contained 15 g protein, 4 g carbohydrates, and 3 g fat, and provided 90-100 kcla [27] ''Fig 1''. This method has three stages: active, re-education, and maintenance. The active stage consists of a very low-calorie diet (600-800 kcal/day), low in carbohydrates (\50 g daily from vegetables) and lipids (only 10 g of olive oil per day). The amount of high-biological-value proteins ranged between 0.8 and 1.2 g per each Kg of ideal body weight, to ensure meeting the minimal body requirements and to prevent the loss of lean mass. This method produces three ketogenic phases. In phase 1, the patients eat high-biological-value protein preparations five times a day, and vegetables with low glycemic index. In phase 2, one of the protein servings is substituted by a natural protein (e.g., meat and fish) either at lunch or at dinner. In the phase 3, a second serve of the natural protein low in fat substituted the second serve of biological protein preparation. Throughout these ketogenic phases, supplements of vitamins and minerals, such as K, Na, Mg, Ca, and omega-3 fatty acids, were provided in accordance to international recommendations [28]. This active stage is maintained until the patient loses most of weight loss target, ideally 80 %. Hence, the ketogenic phases were variable in time depending on the individual and the weight loss target, but they lasted between 30 and 45 days in total. In the re-education stage, the ketogenic phases were ended by the physician in charge of the patient based on the amount of weight lost, and started a low-calorie diet. At this point, the patients underwent a progressive incorporation of different food groups and participated in a program of alimentary re-education to guarantee the long-term maintenance of the weight lost (see ''Fig. 1''). The maintenance stage, consist of an eating plan balanced in carbohydrates, protein, and fat, that lasted one year. Depending on the individual the calories consumed	

<table>
<tr><td></td><td>ranged between 1,500 and 2,000 kcal/day and the target was to maintain the lost weight and promote healthy life styles.”</td></tr>
<tr><td>Control/Comparator</td><td>“Low-calorie diet The standard LC diet of the Obesity Unit was provided to this group. This equilibrated diet had a caloric value 10 % below the total metabolic expenditure of each individual. The total metabolic expenditure was calculated from the basal metabolic expenditure (based on the formula FAO/ WHO/UN) [25] multiplied by the coefficient of activity, which was calculated according to the physical activity of each participant. The calories provided to this group ranged between 1,400 and 1,800 kcal/day. The ration of macronutrients provided was 45-55 % carbohydrates, 15-25 % proteins, and 25-35 % fat [26], in addition to a recommended intake of 20-40 g/day of fiber in the form of vegetables and fruits. A ratio exchange model was followed.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 53
Intervention group/s: VLCK (n=26)

Comparator group: LC (n=27)</td></tr>
<tr><td>Mean age ± SD</td><td>45.3 (8.9)</td></tr>
<tr><td>Sex</td><td>88.68% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight kg
Mean (SD)

BMI
Mean (SD)

Waist circumference cm
Mean (SD)</td><td>VLCK: 97.9
(18.9)

VLCK: 35.1
(4.5)

VLCK: 111.3
(13.4)</td><td>LC: 92.1
(17.7)

LC: 35.1
(5.3)

LC: 108.2
(11.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference cm
Mean (SD)</td><td>VLCK: 92.8
(8)</td><td>LC: 101.2
(13.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)

Change in BMI
Mean (SD)</td><td>VLCK: -19.9
(12.3)

VLCK: 7
(3.9)</td><td>LC: 7
(5.6)

LC: 2.6
(2.2)</td></tr>
</table>
</td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment			
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Morey, 2012

Guideline record ID: 10487--1

Study characteristics		
Citation	Morey, M. C., Pieper, C. F., Edelman, D. E., Yancy, W. S., Jr., Green, J. B., Lum, H., Peterson, M. J., Sloane, R., Cowper, P. A., Bosworth, H. B., Huffman, K. M., Cavanaugh, J. T., Hall, K. S., Pearson, M. P., & Taylor, G. A. (2012). Enhanced fitness: a randomized controlled trial of the effects of home-based physical activity counseling on glycemic control in older adults with prediabetes mellitus. Journal of the American Geriatrics Society, 60(9), 1655-1662. https://doi.org/10.1111/j.1532-5415.2012.04119.x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Enhanced fitness: A randomized controlled trial of the effects of home-based physical activity counseling on glycemic control in older adults with prediabetes mellitus	
Location	USA	
Trial name	Enhanced Fitness	
Methods		
Inclusion criteria	"Individuals from the Durham and Raleigh VA clinics (n = 10,221). Eligible individuals were required to be followed by a primary care provider (PCP) in VA primary care, geriatrics, or women's health clinics and have had at least one visit in the previous 12 months. They had to have impaired glucose tolerance (fasting glucose 100-125 mg/dL), be free from a diagnosis of diabetes mellitus, have a glycosylated hemoglobin (HbA1c) of less than 7%, and not be taking diabetes mellitus medications. A body mass index between 25 and 45 kg/m2 was required."	
Exclusion criteria	"Other exclusion criteria, described previously,7 assessed overall health for safe participation in this study. Individuals who exceeded current physical activity recommendations were excluded.8."	
Setting	GP clinic, Home	
Intervention	"The Enhanced Fitness intervention was designed to enhance self-efficacy for physical activity by integrating self-monitoring, goal-setting, reinforcement, modeling, and cognitive reframing into an ongoing individualized counseling program of physical activity for endurance and strengthening activities.9 Consistent with recommendations from the American Diabetes Association,10 the American College of Sports Medicine, the American Heart Association,8 and the U.S. Physical Activity Guidelines,11 each individual was given the long-term goal of engaging in 30 or more minutes of lower extremity aerobic exercise, preferably walking, on five or more days of the week and 15 minutes of exercises to increase lower extremity strength on three nonconsecutive days each week. The intervention has been described previously.7,12 Individuals assigned to the PAC arm received an in-person baseline counseling consultation with a trained health counselor. Using a structured protocol, the counselor assessed current activity status and established a realistic 2-week physical activity prescription. Individuals were given a notebook containing handouts on the health benefits of exercise, tips for exercising safely, a poster with specific exercises, elastic bands of different resistances, and a pedometer. The baseline counseling was supplemented with regular telephone counseling every 2 weeks for 6 weeks followed by monthly calls over the entire 1-year intervention period. Individuals assigned to fewer telephone calls received telephone calls every other month during the final 6 months. To enhance partnership with primary care, the PCP endorsed physical activity and involvement in the study at the next clinic visit. This was followed by regular PCP encouragement using an automated telephone system. The final component of the intervention was a quarterly individualized feedback report that summarized progress toward each long-term goal of endurance and strengthening exercise."	

<table>
<tr><td>Control/Comparator</td><td>“Participants randomized to the usual care group received the standard of care as provided in their usual VA primary, women's health, or geriatrics clinic. PAC within the context of a clinic visit varies considerably according to provider, with some providers endorsing physical activity routinely at each visit and others not. In addition to provider discretionary approaches to care, the VA also has a nationally mandated weight management program for veterans called MOVE!, a voluntary program that offers various levels of support for veterans desiring to lose weight and includes interactive self-management programs, classroom sessions, and individualized counseling. MOVE! provides guidance on nutrition and physical activity using a step-level approach coupled with individualized goal setting. Therefore, participants were informed at randomization that they would be referred to the MOVE! program. Once a consultation was submitted, MOVE! personnel would send each participant a lifestyle questionnaire, and it was up to the individuals to decide whether they would participate in the various MOVE! activities offered at the VA. The current study tracked participation in MOVE!.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 302
Intervention group/s: Intervention (n=180)

Comparator group: Usual Care (n=122)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 67.1y (6.3); Usual Care: 67.7y (6.2)</td></tr>
<tr><td>Sex</td><td>3.31% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Weight (kg)
Mean (SD)

waist circumference (cm)
Mean (SD)</td><td>Intervention: 31.35
(3.75)

Intervention: 94.98
(13.03)

Intervention: 104.22
(9.04)</td><td>Usual Care: 30.97
(3.45)

Usual Care: 94.51
(12.81)

Usual Care: 103.98
(8.51)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 30.74
(3.88)

Intervention: 92.6
(13.62)

Intervention: 103.92
(10.02)</td><td>Usual Care: 30.64
(3.62)

Usual Care: 93.67
(13.13)

Usual Care: 104.43
(11.73)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>86.8%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Morgan, 2011

Guideline record ID: 10488--1

Study characteristics		
Citation	Morgan, P. J., Lubans, D. R., Collins, C. E., Warren, J. M., & Callister, R. (2011). 12-month outcomes and process evaluation of the SHED-IT RCT: an internet-based weight loss program targeting men. Obesity, 19(1), 142-151. https://doi.org/https://dx.doi.org/10.1038/oby.2010.119	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	12-month outcomes and process evaluation of the SHED-IT RCT: an internet-based weight loss program targeting men	
Location	Australia	
Trial name	Self-Help, Exercise, and Diet using Information Technology (SHED-IT)	
Methods		
Inclusion criteria	"Overweight or obese (BMI between 25 and 37kg/m2) male staff (academic and nonacademic) and students aged 18-60 years were recruited from the University of Newcastle."	
Exclusion criteria	"Ineligibility criteria included a history of major medical problems that would be a barrier to physical activity, recent weight loss of ≥4.5kg, or taking medications that might affect body weight."	
Setting	unclear (program involved one face-to-face information session on weight loss)	
Intervention	Not reported.	
Control/Comparator	"The control group attended one face-to-face information session (60min), which was identical to that of the Internet group (but without a 15-min online component description), and received a weight loss program booklet, but had no website access. Separate information sessions were conducted for Internet and control participants to avoid contamination."	
Treatment duration	3 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 65 Intervention group/s: Internet (n=34) Comparator group: Control (n=31)	
Mean age ± SD	35.9y (11.1)	
Sex	100.00% male	
Pre-existing medical condition	No pre-existing medical condition	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference
Mean (SD)</td><td>Internet: 99.1
(12.2)

Internet: 30.6
(2.7)

Internet: 102.8
(6.8)</td><td>Control: 99.2
(13.7)

Control: 30.5
(3)

Control: 103.4
(8.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)

Change in waist circumference (cm)
Mean (95% CIs)

Change in BMI (kg/m2)
Mean (95% CIs)</td><td>Internet: -5.3
(-7.5--3)

Internet: -5.8
(-7.9--3.6)

Internet: -1.7
(-2.4--1)</td><td>Control: -5.1
(-5.4--0.7)

Control: -3.8
(-6.1--1.6)

Control: -0.9
(-1.7--0.2)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td><50%</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Mundbjerg, 2018

Guideline record ID: 10490--1

Study characteristics		
Citation	Mundbjerg, L. H., Stolberg, C. R., Cecere, S., Bladbjerg, E.-M., Funch-Jensen, P., Gram, B., & Juhl, C. B. (2018). Supervised physical training improves weight loss after Roux-en-Y gastric bypass surgery: a randomized controlled trial. Obesity, 26(5), 828-837. https://doi.org/https://dx.doi.org/10.1002/oby.22143	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Supervised Physical Training Improves Weight Loss After Roux-en-Y Gastric Bypass Surgery: A Randomized Controlled Trial	
Location	Denmark	
Trial name	N/A	
Methods		
Inclusion criteria	"Participants eligible for RYGB according to the guidelines issued by Danish Regions (BMI > 35 with obesity-related disease or BMI > 50 with obesity-related social or physical complications) were recruited among patients referred to bariatric surgery at the Hospital of Southwest Jutland, Denmark."	
Exclusion criteria	"Participants were excluded if they were using hormones or anticoagulant therapy or became pregnant during the study period. Furthermore, the patients had to be physically capable of completing the intervention, and therefore patients with severe musculoskeletal disabilities were excluded."	
Setting	Fitness centre	
Intervention	"All patients underwent RYGB surgery at the Department of Surgery at the Hospital of Southwest Jutland, and surgery was performed by three surgeons. Laparoscopic RYGB was performed with a 20- to 30-mL gastric pouch, a 60-cm biliopancreatic limb, and a Roux limb of 150 cm. There were no surgical complications that influenced the participants' ability to complete the physical training intervention. Six months after RYGB surgery, the participants were randomly assigned to either INT or CON. The intervention lasted for 26 consecutive weeks and consisted of two weekly supervised physical training sessions, each of 40 minutes' duration. The exercise program was strictly described as including 15 minutes of bicycle training followed by 10 minutes of resistance training for the upper extremities. Finally, the session was completed with 15 minutes of training in which the subjects could choose either stair climbing, the treadmill, or rowing. The duration of the physical training session of 40 minutes was chosen to accommodate the participants' decreased physical capacity at the start of the intervention. The intervention was divided into three phases: the initial phase (weeks 1-8), middle phase (weeks 9-18), and end phase (weeks 19- 26). To ensure progression in muscle strength, three tests of repetition maximum were conducted at the beginning of each intervention phase. The supervising physiotherapists used the Borg Scale (6-20) at each endurance training to estimate training intensity (31). During the 26- week intervention program, training intensity gradually increased from a Borg Scale score of 15 (50% of maximal oxygen consumption) in the initial phase to Borg Scale 17 (70% of maximal oxygen consumption) in the end phase of the intervention period. Subjects in INT were provided with free access to the training facility for a 7-month period in addition to the supervised sessions. They were continuously encouraged to do 3.5 h/wk of physical activity at minimum. Participants in INT were registered at each training session. Both cancellations and absence from scheduled physical training were registered, and the participants were subsequently contacted and encouraged to participate in extra training sessions to counterbalance the missing sessions. The compliance limit was set to attendance of 50% or more of the supervised training sessions. Standard dietary	

<table>
<tr><td></td><td>recommendations with focus on sufficient protein and vitamin intake were given equally to INT and CON. No dietary registration was performed."</td></tr>
<tr><td>Control/Comparator</td><td>"All patients underwent RYGB surgery at the Department of Surgery at the Hospital of Southwest Jutland, and surgery was performed by three surgeons. Laparoscopic RYGB was performed with a 20- to 30-mL gastric pouch, a 60-cm biliopancreatic limb, and a Roux limb of 150 cm. There were no surgical complications that influenced the participants' ability to complete the physical training intervention. Six months after RYGB surgery, the participants were randomly assigned to either INT or CON. Standard dietary recommendations with focus on sufficient protein and vitamin intake were given equally to INT and CON. No dietary registration was performed. Subjects in CON received standard information about the importance of physical activity after RYGB. There were no restrictions on the amount of physical activity in CON."</td></tr>
<tr><td>Treatment duration</td><td>26 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 60
Intervention group/s: INT (n=32)

Comparator group: CON (n=28)</td></tr>
<tr><td>Mean age ± SD</td><td>42.3y (9.1)</td></tr>
<tr><td>Sex</td><td>70.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>INT: 99.7
(18)

INT: 33.3
(6.2)</td><td>CON: 98.4
(19.3)

CON: 34.1
(5.4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>INT: 91.5
(19.2)

INT: 30.1
(5.8)</td><td>CON: 94
(19.7)

CON: 32.6
(5.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</table>

<table>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Compliance was defined as attendance of 50% or more of the supervised physical training sessions. Per this definition, 19 (59.4%) of the participants in the INT group were compliant; 8 participants (25% of the INT group) attended less than 10% of the sessions.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Muollo, 2021

Guideline record ID: 10492--1

Study characteristics		
Citation	Muollo, V., Rossi, A. P., Milanese, C., Zamboni, M., Rosa, R., Schena, F., & Pellegrini, B. (2021). Prolonged unsupervised Nordic walking and walking exercise following six months of supervision in adults with overweight and obesity: a randomised clinical trial. Nutrition, Metabolism & Cardiovascular Diseases, 31(4), 1247-1256. https://doi.org/https://dx.doi.org/10.1016/j.numecd.2020.12.012	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Prolonged unsupervised Nordic walking and walking exercise following six months of supervision in adults with overweight and obesity: A randomised clinical trial	
Location	Italy	
Trial name	N/A	
Methods		
Inclusion criteria	"Men and women living in Verona (Italy), aged 50-80 years affected by overweight (body mass index (BMI) > 27 kg/m2)) or obesity (BMI> 30 kg/m2). Other inclusion criteria were: i) stable weight in the previous three months; ii) not being involved in other physical exercise program."	
Exclusion criteria	"i) Cardiovascular diseases (e.g., unstable angina, recent myocardial infarction, cardiac arrhythmias, heart failure, valvular heart disease, aortic aneurism, recent intracerebral/ subdural haemorrhage and not controlled hypertension); musculoskeletal diseases (e.g., symptomatic discal hernia, symptomatic arthrosis, acute articular, tendon or ligament lesions, hip prothesis)."	
Setting	Not specified	
Intervention	"During the first 6 months (from T0-T6) the subjects performed a supervised Nordic Walking (NW) training program, (i.e. walking with poles), 3 times per week, from 60 to 90 min per session, and a controlled diet with measurements assessed after 3 and 6 months of the intervention. At post-intervention (T6) the subjects trained on their own (unsupervised) for a further 6 months. Participants were recommended to maintain during unsupervised intervention a training frequency of three times per week, with no advice given on intensity or duration. During the training sessions performed on their own, the participants were equipped with a pedometer (Geonaute Onwalk 900, Decathlon Group, Villeneuve d'Ascq, France) and a heart ratemonitor (Polar FT1, Polar, Kempele, Finland). At the end of each training session, the subjects recorded in a diary the number of steps with the correspondent heart rate mean (HRmean)."	
Control/Comparator	"During the first 6 months (from T0-T6) the subjects performed a supervised Walking (W) training program, 3 times per week, from 60 to 90 min per session, and a controlled diet with measurements assessed after 3 and 6 months of the intervention. At post-intervention (T6) the subjects trained on their own (unsupervised) for a further 6 months. Participants were recommended to maintain during unsupervised intervention a training frequency of three times per week, with no advice given on intensity or duration. During the training sessions performed on their own, the participants were equipped with a pedometer (Geonaute Onwalk 900, Decathlon Group, Villeneuve d'Ascq, France) and a heart ratemonitor (Polar FT1, Polar, Kempele, Finland). At the end of each training session, the subjects recorded in a diary the number of steps with the correspondent heart rate mean (HRmean)."	
Treatment duration	supervised: 6 months; unsupervised: 6 months	

<table>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 38
Intervention group/s: Nordic Walking (NW) (n=19)

Comparator group: Walking (W) (n=19)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 66y (7); Control: 66y (8)</td></tr>
<tr><td>Sex</td><td>Not reported.</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)

Total fat mass (kg)
Mean (SD)

Total lean mass (kg)
Mean (SD)</td><td>Nordic Walking (NW): 33.7
(4.6)

Nordic Walking (NW): 34.3
(7.1)

Nordic Walking (NW): 46.5
(8)</td><td>Walking (W): 32
(5.3)

Walking (W): 32.8
(7.6)

Walking (W): 45.7
(9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)

Total fat mass (kg)
Mean (SD)

Total lean mass (kg)
Mean (SD)</td><td>Nordic Walking (NW): 31.9
(5.1)

Nordic Walking (NW): 31.3
(8.1)

Nordic Walking (NW): 45.7
(7.7)</td><td>Walking (W): 30.4
(5.3)

Walking (W): 29.8
(7.3)

Walking (W): 45.2
(9.7)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Supervised period: 81.4% (6.3); Unsupervised 6-9 month: 76.6% (25.7), 9-12 month: 62.2% (25.7)</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Murphy, 2012

Guideline record ID: 10821--1

Study characteristics		
Citation	Murphy, J. C., McDaniel, J. L., Mora, K., Villareal, D. T., Fontana, L., & Weiss, E. P. (2012). Preferential reductions in intermuscular and visceral adipose tissue with exercise-induced weight loss compared with calorie restriction. Journal of Applied Physiology, 112(1), 79-85. https://doi.org/https://dx.doi.org/10.1152/japplphysiol.00355.2011	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Preferential reductions in intermuscular and visceral adipose tissue with exercise-induced weight loss compared with calorie restriction	
Location	USA	
Trial name	Comprehensive Assessment of Long-Term Effects of Reducing Intake of Energy (CALERIE) - Phase I	
Methods		
Inclusion criteria	"Men and postmenopausal women aged 50 - 60 yr with a body mass index of 23.5-29.9 kg/m2. Subjects had to be nonsmokers and sedentary (defined as exercising 20 min/day, twice per week during the 6 mo before baseline testing)."	
Exclusion criteria	"Potential subjects were excluded if they had a history of diabetes or fasting blood glucose value of 126 mg/dl or a resting blood pressure of 170 mmHg systolic or 100 mmHg diastolic. Other exclusion criteria included a history or clinical evidence of coronary artery disease, stroke, or lung disease as well as a recent history or evidence of malignancy."	
Setting	University/research centre	
Intervention	"CR intervention: The objective of the CR intervention was for participants to decrease calorie intake by 16% during the first 3 mo and by 20% during the remaining 9 mo. Prescriptions were based on total daily energy intake, which was assumed to equal total daily energy expenditure. Participants met with study dietitians once a week for body weight checks and for education on reducing portion sizes and replacing high-energy density foods with lower energy density foods. EX intervention: The EX intervention was designed to induce the same energy deficit as was induced by the CR intervention. Thus participants increased their energy expenditure from baseline by 16% during the first 3 mo and by 20% during the remaining 9 mo. Prescriptions were based on total daily energy expenditure. Participants met with an exercise trainer on a weekly basis, and exercise energy expenditure goals were established at this time. Subjects were encouraged to use cardiovascular exercise as the most time-efficient approach to meeting the energy expenditure prescriptions. Participants were able to exercise at the site's facility or on their own with no specifications for frequency, duration, or intensity."	
Control/Comparator	"Participants in the CON group had minimal contact with the research team and were not provided with a diet or exercise prescription. General information on a healthy diet was provided if requested by the participants, and free access to yoga classes was provided in the form of class passes/vouchers. Although requests for dietary advice and yoga class passes were not documented and/or quantified, requests for these benefits were minimal."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 48
Intervention group/s: Calorie Restriction (n=19); Exercise (n=19)

Comparator group: Control (n=10)</td></tr>
<tr><td>Mean age ± SD</td><td>Calorie Restriction: 55.0y (0.7); Exercise: 59.0y (0.7); Control: 55.7y (1.2)</td></tr>
<tr><td>Sex</td><td>52.08% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SE)

Weight (kg)
Mean (SE)</td><td>Calorie Restriction: 26.7
(0.5)
Exercise: 26.8
(0.5)

Calorie Restriction: 78.1
(2.5)
Exercise: 76.8
(2.6)</td><td>Control: 27.2
(0.8)

Control: 81.2
(4.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (%)
Mean (SE)</td><td>Calorie Restriction: -10.8
(1.4)
Exercise: -8.3
(1.5)</td><td>Control: -2
(2.4)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Fontana, L., Villareal, D. T., Das, S. K., Smith, S. R., Meydani, S. N., Pittas, A. G., Klein, S., Bhapkar, M., Rochon, J., Ravussin, E., Holloszy, J. O., & the Calerie Study Group. (2016). Effects of 2-year calorie restriction on circulating levels of IGF-1, IGF-binding proteins and cortisol in nonobese men and women: a randomized clinical trial. Aging Cell, 15(1), 22-27. https://doi.org/https://dx.doi.org/10.1111/acel.12400</td></tr>
</table>

N/A – Not applicable

Nackers, 2013

Guideline record ID: 10498--1

Study characteristics		
Citation	Nackers, L. M., Middleton, K. R., Dubyak, P. J., Daniels, M. J., Anton, S. D., & Perri, M. G. (2013). Effects of prescribing 1,000 versus 1,500 kilocalories per day in the behavioral treatment of obesity: a randomized trial. Obesity, 21(12), 2481-2487. https://doi.org/10.1002/oby.20439	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of prescribing 1,000 versus 1,500 kilocalories per day in the behavioral treatment of obesity: a randomized trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	“Obese women between the ages of 25 and 75 years who weighed between 91 and 136 kg and had BMIs between 30 and 45 kg/m2.”	
Exclusion criteria	“Participants were excluded for the following reasons: the presence of a major psychiatric disorder, excessive alcohol intake, unable to read English at a sixth grade level, or unavailable or unwilling to attend weekly group meetings, self-monitor daily intake, adhere to the prescribed caloric goal, or provide informed consent. Potential participants were also excluded if they lost 4.5 kg or more during the preceding 6 months, were participating in another randomized trial, or previously participated in a behavioral weight-loss program.”	
Setting	Home	
Intervention	“Participants were assigned to intake goals of 1,000 kcal/day. The dietary prescriptions was implemented within a standard behavioral lifestyle intervention for weight management that included two phases: Months 0-6 involved an initial treatment period of 24 weekly group sessions; During months 0-6, participants were instructed to follow their prescribed condition-specific energy intake goal and adhere to a balanced diet according to recommendations from the U.S. Department of Agriculture and the National Institutes of Health's Dietary Approaches to Stop Hypertension (16). Participants in both conditions were provided pedometers to monitor daily step counts. Based on the American College of Sports Medicine recommendations (17), participants were encouraged to increase walking to 10,000 steps per day (or by 3,000 steps above baseline levels). To assist in accomplishing these behavioral goals, participants were instructed to maintain detailed daily written records of dietary intake and physical activity. Treatment included training in cognitive and behavioral skills for weight management including stimulus control, self-reinforcement, cognitive restructuring, and problem solving. Each group session involved a private weigh-in, review of participants' progress toward goals, feedback, and encouragement from group leaders and other group members, and a brief presentation related to nutrition, physical activity, stress management, or behavioral management of eating and physical activity.Months 7-12 entailed an extended-care phase with six monthly group sessions. Intervention groups were led by master's level graduate students with experience in conducting behavioral weight-management groups. The interventionists (assigned to treatment conditions in a counter-balanced fashion) were supervised by a licensed psychologist with extensive experience in obesity management. During months 7-12, participants were asked to attend monthly inperson group sessions and maintain caloric intake goals and exercise behaviors prescribed during the initial treatment phase. If a participant obtained a BMI of <25 kg/m2, she was instructed to gradually increase caloric intake to achieve weight maintenance. Participants were also instructed to continue monitoring dietary intake and physical activity through written logs”	

<table>
<tr><td>Control/Comparator</td><td>“Participants were assigned to intake goals of 1,500 kcal/day. The dietary prescriptions was implemented within a standard behavioral lifestyle intervention for weight management that included two phases: Months 0-6 involved an initial treatment period of 24 weekly group sessions; During months 0-6, participants were instructed to follow their prescribed condition-specific energy intake goal and adhere to a balanced diet according to recommendations from the U.S. Department of Agriculture and the National Institutes of Health's Dietary Approaches to Stop Hypertension (16). Participants in both conditions were provided pedometers to monitor daily step counts. Based on the American College of Sports Medicine recommendations (17), participants were encouraged to increase walking to 10,000 steps per day (or by 3,000 steps above baseline levels). To assist in accomplishing these behavioral goals, participants were instructed to maintain detailed daily written records of dietary intake and physical activity. Treatment included training in cognitive and behavioral skills for weight management including stimulus control, self-reinforcement, cognitive restructuring, and problem solving. Each group session involved a private weigh-in, review of participants' progress toward goals, feedback, and encouragement from group leaders and other group members, and a brief presentation related to nutrition, physical activity, stress management, or behavioral management of eating and physical activity.Months 7-12 entailed an extended-care phase with six monthly group sessions. Intervention groups were led by master's level graduate students with experience in conducting behavioral weight-management groups. The interventionists (assigned to treatment conditions in a counter-balanced fashion) were supervised by a licensed psychologist with extensive experience in obesity management. During months 7-12, participants were asked to attend monthly inperson group sessions and maintain caloric intake goals and exercise behaviors prescribed during the initial treatment phase. If a participant obtained a BMI of <25 kg/m2, she was instructed to gradually increase caloric intake to achieve weight maintenance. Participants were also instructed to continue monitoring dietary intake and physical activity through written logs.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 125
Intervention group/s: 1,000 kcal (n=65)

Comparator group: 1,500 kcal (n=60)</td></tr>
<tr><td>Mean age ± SD</td><td>51.98y (10.85)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>1,000 kcal: 104.99
(10.63)

1,000 kcal: 38.09
(4.02)</td><td>1,500 kcal: 104.7
(10.72)

1,500 kcal: 37.59
(3.84)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight change
Mean (SE)</td><td>1,000 kcal: -8.52
(1.17)</td><td>1,500 kcal: -5.84
(1.11)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>During months 0-6, the 1,000 and 1,500 kcal/day conditions did not differ in rates of attendance (sessions attended = 19.1 6 4.5 vs. 17.1 6 6.3, respectively, P = 0.377) or number of weeks with completed self-monitoring logs (14.6 6 7.2 vs. 14.7 6 8.3, respectively, P = 0.973). During months 7-12, the 1,000 and 1,500 kcal/day conditions did not differ in number of monthly sessions attended (3.7 6 1.8 vs. 3.3 6 2.3, respectively, P = 0.670) or number of weeks with completed self-monitoring logs (4.8 6 7.2 vs. 6.8 6 9.7, respectively, P = 0.182).</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Nakade, 2012

Guideline record ID: 10499--1

Study characteristics		
Citation	Nakade, M., Aiba, N., Suda, N., Morita, A., Miyachi, M., Sasaki, S., & Watanabe, S. (2012). Behavioral change during weight loss program and one-year follow-up: Saku Control Obesity Program (SCOP) in Japan. Asia Pacific Journal of Clinical Nutrition, 21(1), 22-34. https://doi.org/https://search.informit.org/doi/10.3316/ielapa.004014331025523	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Behavioral change during weight loss program and one-year follow-up: Saku Control Obesity Program (SCOP) in Japan	
Location	Japan	
Trial name	Saku Control Obesity Program (SCOP)	
Methods		
Inclusion criteria	“Aged 40 to 64 who visited the Dock Center from 2000 and were in the top 5% (≥28.4 kg/m2) in terms of the result of the latest BMI screening.”	
Exclusion criteria	“Exclusion criteria were psychiatric conditions or physical conditions that would preclude full participation in the study (i.e., significant hepatic or renal dysfunction and cardiovascular diseases), current treatment for obesity and current treatments known to affect eating or weight (e.g., medications).”	
Setting	Hospital	
Intervention	“This program was a one-year lifestyle intervention for weight loss based on a behavioral approach (Figure 1). The program was conducted at the Saku Health Dock Center from July, 2006. The participants in the intervention group received individual counseling (30 minutes) and group sessions about effective exercise (20 minutes) provided by registered dietitians and exercise instructors at baseline and at 1, 3, 6 and 9 months. In the exercise group session, an exercise instructor taught participants effective exercises for weight loss, such as how to stretch and walk, by providing examples, and participants mimicked the motions. In the individual counseling sessions, the participants discussed lifestyle habits (diet, dietary habit and physical activities) that needed improvement and set monthly plans to modify them with the support of dietitians and exercise instructors. At least one objective for each energy intake (diet/eating behavior) and energy expenditure (exercise) parameter was set for each month. In addition, they were instructed to self-monitor daily weight, daily step counts, diet and implementation of the plans using a self-monitoring sheet (Appendix). Participants wrote down in the remarks column of the sheet if they attended an event such as a drinking party. The months between these five face-to-face counseling sessions (that is, at 2, 4, 5, 7, 8, 10 and 11 months), participants reported their progress for the previous month and their new plans for the following month by mailing the records to the dietitians. The dietitians checked these and sent back comments to each participant. Fifteen dietitians, who usually worked as registered dietitians in their own places of employment participated on every counseling day in this program. To standardize the intervention, they received training in advance (for example, we advised them to respect participants' thoughts when setting objectives and to set easier objectives in the beginning of the program, etc). In the program, dietitians explained adequate % fat and carbohydrate intake compared with each participant's actual intake as assessed by the diet history questionnaire. However, dietary instruction, such as to lower the fat or carbohydrate intake were not forced on the participants. When setting objectives, the dietitians considered the stage of change for each participant and judged whether or not the objective was appropriate. The dietitians encouraged the participants throughout the program and each dietitian continuously supported the same participants as much as possible.”	

<table>
<tr><td>Control/Comparator</td><td>“Participants in the control group did not receive any support for one year.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 235
Intervention group/s: SCOP Intervention (n=119)

Comparator group: Control (n=116)</td></tr>
<tr><td>Mean age ± SD</td><td>N/A</td></tr>
<tr><td>Sex</td><td>50.64% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>MALE Weight (kg)
Mean (SD)</td><td>SCOP Intervention: 84.1 (8.4)</td><td>Control: 87 (11.7)</td></tr>
<tr><td>MALE: BMI (kg/m2)
Mean (SD)</td><td>SCOP Intervention: 29.8 (2.3)</td><td>Control: 30.5 (3.7)</td></tr>
<tr><td>MALE: Waist circumference (cm)
Mean (SD)</td><td>SCOP Intervention: 100 (6.4)</td><td>Control: 102 (8.8)</td></tr>
<tr><td>FEMALE: Weight (kg)
Mean (SD)</td><td>SCOP Intervention: 74.4 (8.5)</td><td>Control: 75 (10.2)</td></tr>
<tr><td>FEMALE: BMI (kg/m2)
Mean (SD)</td><td>SCOP Intervention: 30.9 (3)</td><td>Control: 31.1 (3.1)</td></tr>
<tr><td>FEMALE: Waist circumference (cm)
Mean (SD)</td><td>SCOP Intervention: 103 (7.9)</td><td>Control: 104 (8.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>MALE Weight (kg)
Mean (SD)</td><td>SCOP Intervention: 79.1 (8.7)</td><td>Control: 87.2 (12.6)</td></tr>
<tr><td>MALE: BMI (kg/m2)
Mean (SD)</td><td>SCOP Intervention: 28.1 (2.5)</td><td>Control: 30.5 (4.1)</td></tr>
<tr><td>MALE: Waist circumference (cm)
Mean (SD)</td><td>SCOP Intervention: 95.9 (7.5)</td><td>Control: 103 (9)</td></tr>
<tr><td>FEMALE: Weight (kg)
Mean (SD)</td><td>SCOP Intervention: 70.4 (9.2)</td><td>Control: 74.9 (10.8)</td></tr>
<tr><td>FEMALE: BMI (kg/m2)
Mean (SD)</td><td>SCOP Intervention: 29.2 (3.4)</td><td>Control: 30.9 (3.2)</td></tr>
</table>
</td></tr>
</table>

	FEMALE: Waist circumference (cm) Mean (SD)	SCOP Intervention: 99.2 (9.4)	Control: 104 (8.9)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	The participation rate at each face-to-face intervention (that is, at 1, 3, 6, and 9 months) was 98.3%, 98.3%, 97.4% and 95.8%, respectively. The percentage of participants who mailed records to the dietitians at 2, 4, 5, 7, 8, 10 and 11 months were 88.2%, 83.2%, 76.5%, 79.0%, 69.7%, 74.8%, and 65.5%, respectively.		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Nakata, 2014

Guideline record ID: 10500--1

Study characteristics		
Citation	Nakata, Y., Okada, M., Hashimoto, K., Harada, Y., Sone, H., & Tanaka, K. (2014). Weight loss maintenance for 2 years after a 6-month randomised controlled trial comparing education-only and group-based support in Japanese adults. Obesity Facts, 7(6), 376-387. https://doi.org/https://dx.doi.org/10.1159/000369913	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight loss maintenance for 2 years after a 6-month randomised controlled trial comparing education-only and group-based support in Japanese adults	
Location	Japan	
Trial name	N/A	
Methods		
Inclusion criteria	"Age of 40-65 years, a BMI of 25-40 kg/m 2 and the presence of at least one of the following components involved in the diagnosis of metabolic syndrome, according to the Japanese criteria [17]: i) waist circumference ≥ 85 cm in men or ≥ 90 cm in women, ii) systolic blood pressure ≥ 130 mm Hg, iii) diastolic blood pressure ≥ 85 mm Hg, iv) triglyceride level ≥ 150 mg/dl (1.70 mmol/l), v) high-density lipoprotein cholesterol level < 40 mg/dl (1.04 mmol/l) and vi) fasting plasma glucose level ≥ 110 mg/dl (6.11 mmol/l)."	
Exclusion criteria	"Current or planned pregnancy, past history of coronary disease or stroke, and drug treatment for diabetes to avoid a potential influence on weight change; participants whose cohabiting family member(s) participated in this study."	
Setting	Hospital	
Intervention	"After taking the baseline measurements in which the participants were assessed for eligibility, all participants attended a 2-hour, group-based, single motivational lecture. The lecture consisted of the introduction of the Japanese national health screening and intervention programme conducted since April 2008 that specifically target at metabolic syndrome, combined cardiovascular risk factors and the outcome, and the target value for improving metabolic syndrome. The participants also received typical weight control instructions on diet, exercise and behavioural changes. The recommendations included a calorie-restricted diet of 1,200 and 1,600 kcal/day for women and men, respectively and a minimum of 1,000 kcal/week of increased physical activity. All participants were encouraged to self-monitor their body weight every day. After the motivational lecture, the participants were randomly assigned to one of the groups. At week 1, the participants in the education-only and the group-based support groups attended a group-based, 2-hour session in which they were provided with educational materials such as textbooks and notebooks containing information on daily diet and other lifestyle-related issues. The content of the textbooks and notebooks was based on the prior work of the investigators. The dietary programme was based on the Four-Food-Group Point Method. Participants in the education-only and the group-based support groups were encouraged to modify their diet according to the information in the provided textbooks and were instructed to record their body weight, the content of meals and the daily step counts in the provided notebook. A pedometer (FB-720; Tanita, Tokyo, Japan) was also provided to motivate the participants to increase their physical activity. The participants in the group-based support group attended a group-based, 2-hour session at weeks 2, 4, 6, 10, 14, 18 and 22. In the present study, in the initial part of the intervention period, we reduced the frequency of the support meetings from every 2 weeks to every 4 weeks in order to provide the participants information on the basics of changing behaviours. Each group-based support meeting was conducted by 3 staff members who were trained by the investigators (YN and KT). One staff member conducted lectures to explain the content of the textbooks, and 2	

<table>
<tr><td></td><td>other staff members reviewed the participants' notebooks and advised them on their diet and other lifestyle factors at each session. After the intervention phase had ended, the participants in the education-only and the group-based support groups underwent annual follow-up measurements during a 2-year follow-up period.”</td></tr>
<tr><td>Control/Comparator</td><td>“After taking the baseline measurements in which the participants were assessed for eligibility, all participants attended a 2-hour, group-based, single motivational lecture. The lecture consisted of the introduction of the Japanese national health screening and intervention programme conducted since April 2008 that specifically target at metabolic syndrome, combined cardiovascular risk factors and the outcome, and the target value for improving metabolic syndrome. The participants also received typical weight control instructions on diet, exercise and behavioural changes. The recommendations included a calorie-restricted diet of 1,200 and 1,600 kcal/day for women and men, respectively and a minimum of 1,000 kcal/week of increased physical activity. All participants were encouraged to self-monitor their body weight every day. After the motivational lecture, the participants were randomly assigned to one of the groups. At week 1, the participants in the education-only and the group-based support groups attended a group-based, 2-hour session in which they were provided with educational materials such as textbooks and notebooks containing information on daily diet and other lifestyle-related issues. The content of the textbooks and notebooks was based on the prior work of the investigators. The dietary programme was based on the Four-Food-Group Point Method. Participants in the education-only and the group-based support groups were encouraged to modify their diet according to the information in the provided textbooks and were instructed to record their body weight, the content of meals and the daily step counts in the provided notebook. A pedometer (FB-720; Tanita, Tokyo, Japan) was also provided to motivate the participants to increase their physical activity. After the intervention phase had ended, the participants in the education-only and the group-based support groups underwent annual follow-up measurements during a 2-year follow-up period.”</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>30 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 125
Intervention group/s: Group-based support (n=63)

Comparator group: Education-only (n=62)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 50.7 (6.7); Control: 51.7 (6.8)</td></tr>
<tr><td>Sex</td><td>73.60% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist Circumference (cm)
Mean (SD)</td><td>Group-based support: 73.5
(9.9)

Group-based support: 29
(3)

Group-based support: 99.2
(7.3)</td><td>Education-only: 74.9
(12.1)

Education-only: 29.2
(3.8)

Education-only: 100.7
(7.9)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist Circumference (cm)
Mean (SD)</td><td>Group-based support: 65.7
(9.5)

Group-based support: 25.9
(3)

Group-based support: 91.1
(8.4)</td><td>Education-only: 70.2
(12.6)

Education-only: 27.4
(4)

Education-only: 96
(9.1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist Circumference (cm)
Mean (SD)</td><td>Group-based support: 70.2
(10.6)

Group-based support: 27.7
(3.5)

Group-based support: 94.3
(8.5)</td><td>Education-only: 71.6
(12.5)

Education-only: 28
(4)

Education-only: 96.1
(9.1)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)</td><td>Group-based support: -7.7
(-8.8--6.7)</td><td>Education-only: -4.7
(-5.7--3.7)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)

Change in BMI (baseline to 30 months)
Mean (95% CIs)

Change in Waist circumference (baseline to 30 months)
Mean (95% CIs)</td><td>Group-based support: -3.3
(-4.4--2.2)

Group-based support: -1.3
(-1.7--0.9)

Group-based support: -4.9
(-6.3--3.4)</td><td>Education-only: -3.3
(-4.7--1.9)

Education-only: -1.3
(-1.8--0.7)

Education-only: -4.6
(-6.1--3)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Napolitano, 2021

Guideline record ID: 10501--1

Study characteristics		
Citation	Napolitano, M. A., Whiteley, J. A., Mavredes, M., Tjaden, A. H., Simmens, S., Hayman, L. L., Faro, J., Winston, G., Malin, S., & DiPietro, L. (2021). Effect of tailoring on weight loss among young adults receiving digital interventions: an 18 month randomized controlled trial. Translational Behavioral Medicine, 11(4), 970-980. https://doi.org/https://dx.doi.org/10.1093/tbm/ibab017	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of tailoring on weight loss among young adults receiving digital interventions: an 18 month randomized controlled trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	“Eligible participants had a measured BMI between 25 and 45 kg/m 2, were between 18 and 35 years of age and a university student (undergraduate or graduate) in the Washington, DC, or Boston areas, and had no known contraindications for participating in weight loss and physical activity. Furthermore, they were active on Facebook (indicated by a log-in within the prior month) with regular text message access and were fluent in English.”	
Exclusion criteria	Not reported	
Setting	Home	
Intervention	“Tailored: The Facebook component was the same as that in the TARGETED intervention group. Similar to the TARGETED group, text messaging was centered on self-monitoring and high-risk eating behaviors. The TAILORED group received text messaging with specific prompts to report weight, calorie, and minutes of physical activity. This information was used to generate a personalized feedback report that included individual weight and physical activity progress. Tips on high-risk behaviors for the TAILORED group were delivered based on participant's own selection of behaviors they anticipated to be most challenging. The TAILORED intervention provided personalized, specific feedback that was delivered via a weekly personal report. At the completion of each content week, participants received a report that included a summary of the weekly topic, as well as their personalized, specific feedback on their progress.; Targeted: Each week, content was posted to Facebook on 5 days. Postings included: (a) a didactic video (range: 1:30-7:42 min) summarizing the adapted DPP-lesson topic for the week with handouts to accompany the didactic video; (b) a peer-led video (range: 0:29-13:09 min), which depicted a prescripted situation of young adults modeling a key behavioral skill or problemsolving message; (c) a poll or discussion; (d) wrap-up and live moderated session; and (e) a reminder to review the weekly report. Sample didactic lesson topics included: Tip the Calorie Balance; Jumpstarting Your Activity Plan; and Ways to Stay Motivated. The private Facebook groups were monitored by study staff to validate participation (e.g., "liking" a participant's post) and for inappropriate postings. Additionally, participants received text messaging each day. The purpose of the text messaging was to reinforce the self-monitoring and provide tips about monitoring (e.g., "Set up an announcement on ur computer asking if u self-monitored today, that way u can't miss it") and high-risk weight related behaviors, such as prolonged sitting, late night snacking, portion size (e.g., "U might feel the urge to late night eat bc ur bored! Call a friend to chat to keep u occupied". For the Targeted group, self-monitoring questions were generic (i.e., What did you monitor [weight, calories, and physical activity minutes]?), and high-risk behavior tips were randomly selected from a	

<table>
<tr><td></td><td>pregenerated list. At the end of each contentweek, participants received a report summarizing the topic for the week.”</td></tr>
<tr><td>Control/Comparator</td><td>“Participants in the CONTROL group received general healthy body content on three branded topic areas, mind, body, and energy. Sample weekly topics included Technology and Your Sleep, Building Body Attitude, and Signs of Stress. The content was educational rather than focused on specific behavior change. The Facebook delivery and content structure were the same as that for the TARGETED intervention group and, similar to the TARGETED group, text messaging was centered on generic selfmonitoring and tips. At the end of each content week, participants received a report summarizing the topic for the week.”</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 459
Intervention group/s: Tailored (n=150); Targeted (n=152)

Comparator group: Control (n=157)</td></tr>
<tr><td>Mean age ± SD</td><td>23.3y (4.4)</td></tr>
<tr><td>Sex</td><td>78.65% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>Tailored: 31.6
(4.6)
Targeted: 31.1
(4.4)</td><td>Control: 31
(4.3)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)</td><td>Tailored: -0.7
(6.1)
Targeted: 0.3
(5.5)</td><td>Control: -0.2
(5.8)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)</td><td>Tailored: -0.3
(7.6)
Targeted: 0.9
(6.5)</td><td>Control: 0.2
(6.2)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Neale, 2017

Guideline record ID: 10502--1

Study characteristics		
Citation	Neale, E. P., Tapsell, L. C., Martin, A., Batterham, M. J., Wibisono, C., & Probst, Y. C. (2017). Impact of providing walnut samples in a lifestyle intervention for weight loss: a secondary analysis of the HealthTrack trial. Food & Nutrition Research, 61(1). https://doi.org/10.1080/16546628.2017.1344522	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Impact of providing walnut samples in a lifestyle intervention for weight loss: a secondary analysis of the HealthTrack trial	
Location	Australia	
Trial name	HealthTrack	
Methods		
Inclusion criteria	"Inclusion criteria were: permanent residents of the Illawarra region, adults aged 25- 54 years, and with a BMI in the range 25-40 kg/m2 ."	
Exclusion criteria	"Exclusion criteria were: unable to communicate in English; have severe medical con ditions, an impaired ability to participate in study; or have other medical conditions thought to limit survival to 1 year; suffer from immunodeficiency; have reported illegal drug use or regular alcohol intake associated with alcoholism (N50 g/day); or have difficulties or major impediments to participating in the components of the study."	
Setting	GP clinic	
Intervention	"An intensive phase was conducted for three months (monthly clinic visits), followed by quarterly follow up visits to 12 months. All groups received dietary advice based on the food groups forming the Australian Guide to Healthy Eating (AGHE), namely vegetables, fruit, cereals/grains, lean meat and alternatives (including fish and seafood), and low-fat dairy foods. The diet plans for participants in the I and IW groups were individualized with a prescribed number of serves of each food group to meet energy intake targets, and the dietary advice was delivered by Accredited Practising Dietitians (APDs). For the IW group, the diet plan included the free sample of 30g walnuts/day provided for the duration of the study. The energy value of the walnuts was modelled into the overall diet plan. The advice was accompanied by menu-style suggestions. Consultations with APDs (I and IW groups) also included categorical exercise advice, again following the National Physical Activity Guidelines and supported by an exercise physiologist if requested. Participants in both intervention groups also received quarterly phone calls from a trained health coach, who counselled participants on Acceptance and Commitment therapy via a printed workbook."	
Control/Comparator	"Control group received the same dietary advice based on the food groups forming the Australian Guide to Healthy Eating (AGHE), namely vegetables, fruit, cereals/grains, lean meat and alternatives (including fish and seafood), and low-fat dairy foods. The group was given general advice from a practice nurse with reference to standard servings from AGHE related pamphlets, as well as receiving National Physical Activity Guidelines."	
Treatment duration	3 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 377
Intervention group/s: Intervention (n=124); Intervention + Walnuts (n=127)

Comparator group: Control (n=126)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 43.79y (7.97); Intervention+Walnuts: 42.10y (8.69); Control: 43.80y (7.46)</td></tr>
<tr><td>Sex</td><td>73.74% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>Intervention: 91.86
(15.22)
Intervention + Walnuts: 91.38
(15.51)</td><td>Control: 91.84
(14.69)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight change at 12 months (kg)
Median (IQR)</td><td>Intervention: -2.4
(-7.7-0.9)
Intervention + Walnuts: -4.6
(-10.7--1.2)</td><td>Control: -1.1
(-4.18-0.5)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Tapsell, L. C., Lonergan, M., Batterham, M. J., Neale, E. P., Martin, A., Thorne, R., Deane, F., & Peoples, G. (2017). Effect of interdisciplinary care on weight loss: a randomised controlled trial. BMJ Open, 7(7), e014533. https://doi.org/https://dx.doi.org/10.1136/bmjopen-2016-014533</td></tr>
</table>

N/A – Not applicable

Nguyen, 2013

Guideline record ID: 10507--1

Study characteristics		
Citation	Nguyen, B., Shrewsbury, V. A., O'Connor, J., Steinbeck, K. S., Hill, A. J., Shah, S., Kohn, M. R., Torvaldsen, S., & Baur, L. A. (2013). Two-year outcomes of an adjunctive telephone coaching and electronic contact intervention for adolescent weight-loss maintenance: the Loozit randomized controlled trial. International Journal of Obesity, 37(3), 468-472. https://doi.org/10.1038/ijo.2012.74	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Two-year outcomes of an adjunctive telephone coaching and electronic contact intervention for adolescent weight-loss maintenance: the Loozit randomized controlled trial	
Location	Australia	
Trial name	Loozit	
Methods		
Inclusion criteria	"Eligible participants were overweight and obese (BMI z-score: 1.0-2.5), but otherwise healthy, 13-16-year-olds, who could attend group sessions with a parent/carer, and had landline telephone and mobile phone and/or email access."	
Exclusion criteria	"Severely obese adolescents (BMI z score > 3.5), adolescents with secondary causes for overweight/obesity, intellectual disability, significant medical illness, psychiatric disturbance, lack of facility with spoken English, extreme dietary restriction, inability to take part in physical activity sessions, on medications that affect weight."	
Setting	Hospital, Home	
Intervention	"The Loozit group behavioral lifestyle intervention was conducted at a community health center and CHW, Sydney, Australia, commencing with 7 75-min weekly group sessions (Phase 1), held separately for adolescents and parents/carers in both study arms. From 2-24 months (Phase 2), the maintenance program involved 5 60-min quarterly adolescent booster group sessions plus 12- and 24-month outcome assessment sessions. Facilitated by trained dietitians, group sessions were based upon a cognitive behavioral approach, and recommendations were consistent with clinical practice guidelines.7 In Phase 2, 'G þ ATC' adolescents were scheduled to receive ATC fortnightly (overall 14 telephone coaching sessions and 32 SMS and/or email messages)."	
Control/Comparator	"The Loozit group behavioral lifestyle intervention was conducted at a community health center and CHW, Sydney, Australia, commencing with 7 75-min weekly group sessions (Phase 1), held separately for adolescents and parents/carers in both study arms. From 2-24 months (Phase 2), the maintenance program involved 5 60-min quarterly adolescent booster group sessions plus 12- and 24-month outcome assessment sessions. Facilitated by trained dietitians, group sessions were based upon a cognitive behavioral approach,6 and recommendations were consistent with clinical practice guidelines."	
Treatment duration	24 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 151 Intervention group/s: G + ATC (n=73)	

<table>
<tr><td></td><td>Comparator group: G-Only (n=78)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported in this article</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>G + ATC: 84.2
(16.3)</td><td>G-Only: 82.4
(12.4)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>G + ATC: 30.8
(4.2)</td><td>G-Only: 30.8
(3.5)</td></tr>
<tr><td>BMI z-score
Mean (SD)</td><td>G + ATC: 2.03
(0.37)</td><td>G-Only: 2.02
(0.29)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>G + ATC: 97.4
(12)</td><td>G-Only: 95.6
(9.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>G + ATC: 88.1
(17.7)</td><td>G-Only: 85.9
(13.4)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>G + ATC: 31.4
(4.8)</td><td>G-Only: 30.8
(3.8)</td></tr>
<tr><td>BMI z-score
Mean (SD)</td><td>G + ATC: 1.97
(0.42)</td><td>G-Only: 1.94
(0.32)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>G + ATC: 96.3
(12)</td><td>G-Only: 95.1
(9.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
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<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
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<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Booster session attendance declined from 69% to 31% between the first and final session</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Tejera, C., Porca, C., Rodriguez-Carnero, G., Andújar, P., Casanueva, F. F., Bellido, D., & Crujeiras, A. B. (2022). Reducing metabolic syndrome through a group educational intervention program in adults with obesity: IGOBE program. Nutrients, 14(5), 1066. https://doi.org/https://dx.doi.org/10.3390/nu14051066</td></tr>
</table>

N/A – Not applicable

Nordklint, 2021

Guideline record ID: 11047

Study characteristics		
Citation	Nordklint, A. K., Almdal, T. P., Vestergaard, P., Lundby-Christensen, L., Boesgaard, T. W., Breum, L., Gade-Rasmussen, B., Sneppen, S. B., Gluud, C., Hemmingsen, B., Perrild, H., Madsbad, S., Mathiesen, E. R., Tarnow, L., Thorsteinsson, B., Vestergaard, H., Lund, S. S., & Eiken, P. (2021). Effect of metformin and insulin vs. placebo and insulin on whole body composition in overweight patients with type 2 diabetes: a randomized placebo-controlled trial. Osteoporosis International, 32(9), 1837-1848. https://doi.org/https://doi.org/10.1007/s00198-021-05870-1	
Design & type	Randomised controlled trial (RCT)	Factorial design
Title	Effect of metformin and insulin vs. placebo and insulin on whole body composition in overweight patients with type 2 diabetes: a randomized placebo-controlled trial	
Location	Denmark	
Trial name	Copenhagen Insulin and Metformin Therapy (CIMT) trial	
Methods		
Inclusion criteria	"Included participants with T2DM, aged 30 years and over, with a BMI between 25 and 40 kg/m2, HbA1c ≥ 7.5% (≥ 58 mmol/mol), treated with oral antihyperglycemic drugs for ≥ 1 year and/or insulin treatment for ≥ 3 months."	
Exclusion criteria	"Patients with recent cardiovascular disease (previous myocardial infarcts, stroke, coronary or vascular surgery), cancer, and renal or liver disease; pregnant or breastfeeding women; fertile women not using oral contraceptives; and patients with other chronic diseases as defined in the study protocol [19] were excluded."	
Setting	Hospital	
Intervention	"Patients received 18 months of treatment with Metformin. Participants who received metformin prior to the trial initiated metformin 1 g twice daily, whereas metformin-naive participants were titrated up from an initial dose of 500 mg metformin once daily to 1 g twice daily, during 4 weeks. In addition, all participants were randomized to one of three different insulin regimens aiming at a HbA1c ≤ 7% (≤ 53 mmol/mol)"	
Control/Comparator	"Patients received 18 months of treatment with placebo. Participants who received metformin prior to the trial initiated placebo 1 g twice daily, whereas metformin-naive participants were titrated up from an initial dose of 500 mg placebo once daily to 1 g twice daily, during 4 weeks.In addition, all participants were randomized to one of three different insulin regimens aiming at a HbA1c ≤ 7% (≤ 53 mmol/mol)."	
Treatment duration	18 months	
Follow-up from baseline	18 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA)	
Participant characteristics		
Number of participants	n= 407 Intervention group/s: Metformin + Insulin (n=202) Comparator group: Placecbo + Insulin (n=205)	
Mean age ± SD	Metformin + insulin: 60.4y (8.7); Placebo + insulin: 59.8y (9.2)	

<table>
<tr><td>Sex</td><td>31.94% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2) - Baseline only
Mean (SD)

Total fat mass (kg)
Mean (95% CIs)

Total fat mass (%)
Mean (95% CIs)</td><td>Metformin + Insulin: 32.2
(4.2)

Metformin + Insulin: 29.4
(28.2-30.6)

Metformin + Insulin: 32
(31-33.1)</td><td>Placecbo + Insulin: 32
(4.2)

Placecbo + Insulin: 29.3
(28.1-30.5)

Placecbo + Insulin: 32
(31-33)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Total fat mass (kg)
Mean (95% CIs)

Total fat mass (%)
Mean (95% CIs)</td><td>Metformin + Insulin: 30.6
(29.2-32)

Metformin + Insulin: 32.5
(31.5-33.6)</td><td>Placecbo + Insulin: 32
(30.6-33.4)

Placecbo + Insulin: 33.2
(32.1-34.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Total fat mass (kg)
Mean (95% CIs)

Change in total fat mass (%)
Mean (95% CIs)</td><td>Metformin + Insulin: 1.2
(0.7-1.6)

Metformin + Insulin: 0.5
(0.2-0.8)</td><td>Placecbo + Insulin: 2.7
(2.1-3.3)

Placecbo + Insulin: 1.2
(0.8-1.6)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Norman, 2016

Guideline record ID: 10515A--GIRLS

Study characteristics		
Citation	Norman, G., Huang, J., Davila, E. P., Kolodziejczyk, J. K., Carlson, J., Covin, J. R., Gootschalk, M., & Patrick, K. (2016). Outcomes of a 1-year randomized controlled trial to evaluate a behavioral 'stepped-down' weight loss intervention for adolescent patients with obesity. Pediatric Obesity, 11(1), 18-25. https://doi.org/https://dx.doi.org/10.1111/ijpo.12013	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Outcomes of a 1-year randomized controlled trial to evaluate a behavioral 'stepped-down' weight loss intervention for adolescent patients with obesity	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Adolescents with obesity (BMI > 95 percentile for age and gender) aged 11-13 years. planned to be a San Diego County resident for the next year, had a parent or guardian willing to participate, were willing to return to the physician office for counselling sessions and could attend measurement visits. Parents were eligible if they were literate in English or Spanish."	
Exclusion criteria	"Without reliable transportation, taking weight-altering medications within 6 months prior to study initiation, unable to do moderate-to-vigorous PA, more than 300 lb, in foster care, receiving special needs education, a previous participant in our weight loss studies, currently enrolled in a weight loss programme, or diagnosed with obesity-related disorders requiring immediate weight loss management or diseases affecting absorption or processing of nutrients."	
Setting	GP clinic	
Intervention	"The intervention followed modified recommendations from the American Academy of Pediatrics for treatment of childhood obesity and consisted of three 4-month steps (Fig. 1). The goal was for adolescents to lose at least 4 lb every 4 months. If the participant did not meet the goal, then the step was repeated. If a 4-lb weight loss was achieved, the participant was 'stepped-down' to the next level of reduced intensity. The number and frequency of treatment elements varied for each intervention step. At the start of the programme, the physician provided brief counselling on healthy dietary and PA behaviours. If progress is not made, then follow-up physician visit occurred at month 8 and focused on weight management strategies. Face-to-face health educator visits occurred monthly in step 1 and bi-monthly in step 2, and included discussing weight management concepts, identifying barriers to healthy eating and PA, and brainstorming problem-solving strategies to overcome barriers. These meeting were available to the child and parent, but the parent was not required to attend. Phone calls, which were biweekly in steps 1 and 2, and monthly in step 3, were used to review progress as the last clinical interaction, help adolescents set new goals and discuss barriers and solutions, and speak to parent to reinforce parental involvement and emphasize importance of healthy changes in the home environment to encourage goal attainment. Diet and PA education materials were distributed to adolescents and their parents at health education visits at the paediatric clinics. The adolescent and parent were asked to keep self-monitoring logs for steps and weight that could be e-mailed or mailed to their health counsellor for feedback. Pedometers (New Lifestyle NL-800) were distributed at the initial health educator visit to monitor PA and help participants set appropriate PA goals."	
Control/Comparator	"The EUC participants received an initial counselling visit by the physician, one visit with a health educator, materials on how to improve weight-related behaviours, and monthly	

<table>
<tr><td></td><td>follow-up mailings on weight-related issues. This condition was labelled 'enhanced' because participants received more than the current standard of practice in the Children's Primary Care Medical Group for adolescents with obesity with no medical comorbidities. These adolescents also received the NL-800 pedometer at the initial health educator visit.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 106
Intervention group/s: Stepped-down care (SDC) (n=53)

Comparator group: Enhanced usual care (EUC) (n=53)</td></tr>
<tr><td>Mean age ± SD</td><td>Overall: 11.9 (0.9); Intervention (SDC): Girls 12.0 (0.9); Boys 12.0 (0.8), Control (EUC): Girls 11.8 (1.0); Boys 11.7 (0.9)</td></tr>
<tr><td>Sex</td><td>50.94% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (Girls)
Mean (95% CIs)</td><td>Stepped-down care (SDC):
29.8
(28.4-31.3)</td><td>Enhanced usual care (EUC):
28.9
(27.4-30.4)</td></tr>
<tr><td>BMI z-score (Girls)
Mean (95% CIs)</td><td>Stepped-down care (SDC): 2.1
(1.9-2.1)</td><td>Enhanced usual care (EUC): 2
(1.9-2.2)</td></tr>
<tr><td>DXA % body fat (Girls)
Mean (95% CIs)</td><td>Stepped-down care (SDC):
43.7
(41.6-45.7)</td><td>Enhanced usual care (EUC):
46.3
(44.2-48.3)</td></tr>
<tr><td>Waist circumference (Girls)
Mean (95% CIs)</td><td>Stepped-down care (SDC):
99.3
(95.3-103.4)</td><td>Enhanced usual care (EUC):
98.7
(94.4-103.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (Girls)
Mean (95% CIs)</td><td>Stepped-down care (SDC):
30.7
(29.1-32.4)</td><td>Enhanced usual care (EUC):
29.1
(27.4-30.9)</td></tr>
<tr><td>BMI z-score (Girls)
Mean (95% CIs)</td><td>Stepped-down care (SDC): 2
(1.8-2.1)</td><td>Enhanced usual care (EUC):
1.9
(1.7-2.1)</td></tr>
<tr><td>DXA % body fat (Girls)
Mean (95% CIs)</td><td>Stepped-down care (SDC):
42.8
(40.3-45.3)</td><td>Enhanced usual care (EUC):
43.9
(41.4-46.3)</td></tr>
<tr><td>Waist circumference (Girls)
Mean (95% CIs)</td><td>Stepped-down care (SDC):
99.6
(95-104.2)</td><td>Enhanced usual care (EUC):
97.6
(92.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Norman, 2016

Guideline record ID: 10515A--BOYS

Study characteristics		
Citation	Norman, G., Huang, J., Davila, E. P., Kolodziejczyk, J. K., Carlson, J., Covin, J. R., Gootschalk, M., & Patrick, K. (2016). Outcomes of a 1-year randomized controlled trial to evaluate a behavioral 'stepped-down' weight loss intervention for adolescent patients with obesity. Pediatric Obesity, 11(1), 18-25. https://doi.org/https://dx.doi.org/10.1111/ijpo.12013	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Outcomes of a 1-year randomized controlled trial to evaluate a behavioral 'stepped-down' weight loss intervention for adolescent patients with obesity	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Adolescents with obesity (BMI > 95 percentile for age and gender) aged 11-13 years. planned to be a San Diego County resident for the next year, had a parent or guardian willing to participate, were willing to return to the physician office for counselling sessions and could attend measurement visits. Parents were eligible if they were literate in English or Spanish."	
Exclusion criteria	"Without reliable transportation, taking weight-altering medications within 6 months prior to study initiation, unable to do moderate-to-vigorous PA, more than 300 lb, in foster care, receiving special needs education, a previous participant in our weight loss studies, currently enrolled in a weight loss programme, or diagnosed with obesity-related disorders requiring immediate weight loss management or diseases affecting absorption or processing of nutrients."	
Setting	GP clinic	
Intervention	"The intervention followed modified recommendations from the American Academy of Pediatrics for treatment of childhood obesity and consisted of three 4-month steps (Fig. 1). The goal was for adolescents to lose at least 4 lb every 4 months. If the participant did not meet the goal, then the step was repeated. If a 4-lb weight loss was achieved, the participant was 'stepped-down' to the next level of reduced intensity. The number and frequency of treatment elements varied for each intervention step. At the start of the programme, the physician provided brief counselling on healthy dietary and PA behaviours. If progress is not made, then follow-up physician visit occurred at month 8 and focused on weight management strategies. Face-to-face health educator visits occurred monthly in step 1 and bi-monthly in step 2, and included discussing weight management concepts, identifying barriers to healthy eating and PA, and brainstorming problem-solving strategies to overcome barriers. These meeting were available to the child and parent, but the parent was not required to attend. Phone calls, which were biweekly in steps 1 and 2, and monthly in step 3, were used to review progress as the last clinical interaction, help adolescents set new goals and discuss barriers and solutions, and speak to parent to reinforce parental involvement and emphasize importance of healthy changes in the home environment to encourage goal attainment. Diet and PA education materials were distributed to adolescents and their parents at health education visits at the paediatric clinics. The adolescent and parent were asked to keep self-monitoring logs for steps and weight that could be e-mailed or mailed to their health counsellor for feedback. Pedometers (New Lifestyle NL-800) were distributed at the initial health educator visit to monitor PA and help participants set appropriate PA goals."	
Control/Comparator	"The EUC participants received an initial counselling visit by the physician, one visit with a health educator, materials on how to improve weight-related behaviours, and monthly	

<table>
<tr><td></td><td>follow-up mailings on weight-related issues. This condition was labelled 'enhanced' because participants received more than the current standard of practice in the Children's Primary Care Medical Group for adolescents with obesity with no medical comorbidities. These adolescents also received the NL-800 pedometer at the initial health educator visit.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 106
Intervention group/s: Stepped-down care (SDC) (n=53)

Comparator group: Enhanced usual care (EUC) (n=53)</td></tr>
<tr><td>Mean age ± SD</td><td>Overall: 11.9 (0.9); Intervention (SDC): Girls 12.0 (0.9); Boys 12.0 (0.8), Control (EUC): Girls 11.8 (1.0); Boys 11.7 (0.9)</td></tr>
<tr><td>Sex</td><td>50.94% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (Boys)
Mean (95% CIs)</td><td>Stepped-down care (SDC):
29.4
(27.8-31)</td><td>Enhanced usual care (EUC):
28.9
(27.4-30.4)</td></tr>
<tr><td>BMI z-score (Boys)
Mean (95% CIs)</td><td>Stepped-down care (SDC): 2.1
(2-2.3)</td><td>Enhanced usual care (EUC):
2.1
(2-2.2)</td></tr>
<tr><td>DXA % body fat (Boys)
Mean (95% CIs)</td><td>Stepped-down care (SDC):
45.1
(42.4-47.8)</td><td>Enhanced usual care (EUC):
45.3
(42.8-47.8)</td></tr>
<tr><td>Waist circumference (Boys)
Mean (95% CIs)</td><td>Stepped-down care (SDC):
98.1
(94-102.1)</td><td>Enhanced usual care (EUC):
97.1
(93.4-100.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (Boys)
Mean (95% CIs)</td><td>Stepped-down care (SDC):
28.8
(27.1-30.4)</td><td>Enhanced usual care (EUC):
29.5
(27.9-31)</td></tr>
<tr><td>BMI z-score (Boys)
Mean (95% CIs)</td><td>Stepped-down care (SDC): 2
(1.8-2.1)</td><td>Enhanced usual care (EUC):
2.1
(1.9-2.2)</td></tr>
<tr><td>DXA % body fat (Boys)
Mean (95% CIs)</td><td>Stepped-down care (SDC):
39.2
(35.5-42.9)</td><td>Enhanced usual care (EUC):
41.1
(37.6-44.5)</td></tr>
<tr><td>Waist circumference (Boys)
Mean (95% CIs)</td><td>Stepped-down care (SDC):
97.7
(93-102.4)</td><td>Enhanced usual care (EUC): 98
(93.6-102.4)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Nybacka, 2011

Guideline record ID: 10516--1

Study characteristics		
Citation	Nybacka, Å., Carlström, K., Ståhle, A., Nyrén, S., Hellström, P. M., & Hirschberg, A. L. (2011). Randomized comparison of the influence of dietary management and/or physical exercise on ovarian function and metabolic parameters in overweight women with polycystic ovary syndrome. Fertility and Sterility, 96(6), 1508-1513. https://doi.org/https://dx.doi.org/10.1016/j.fertnstert.2011.09.006	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Randomized comparison of the influence of dietary management and/or physical exercise on ovarian function and metabolic parameters in overweight women with polycystic ovary syndrome	
Location	Sweden	
Trial name	N/A	
Methods		
Inclusion criteria	"A diagnosis of PCOS including all three criteria according to the Rotterdam Consensus (i.e., oligo- or anovulation, hyperandrogenism, and polycystic ovaries (PCO) on ultrasound) (28); an age of 18-40 years; body mass index (BMI) >27 kg/m2; absence of hormonal treatment for the past 3 months; and no pregnancy, lactation, or change in weight during the past year."	
Exclusion criteria	"The presence of other disease or a different endocrine disorder; an eating disorder; smoking; or continuous medication including insulin-sensitizing drugs."	
Setting	Hospital	
Intervention	"The diets were designed individually under the close supervision of a dietician. It was recommended that total daily caloric intake be reduced by ≥600 kcal/d compared with before the intervention, while maintaining a well-balanced diet containing 55%-60% carbohydrates, 25%-30% fat (10% saturated), and 10%-15% proteins, according to Swedish nutritional recommendations (SNO) in 2005. A strict schedule of three main meals and two or three snacks was also introduced. Food intake was assessed by self-reporting once every 24 hours during the 4 days both immediately before and at the end of intervention. The exercise program, which was individually adjusted and overseen by a physical therapist, was designed to enhance both the type (endurance, aerobic, and/or weight training depending on each subjects' preferences) and the level of physical activity to a level conforming to each individual patient's capacity, goals, and interest at the beginning of this intervention. Physical activity was assessed with the use of pedometers (Yamax SW-200) during the 4 days immediately before and at the end of the program. During both types of intervention, monthly follow-ups with the dietician and/or physical therapist were scheduled for discussion of the goals achieved as well as setting up new goals for the next month."	
Control/Comparator	"The exercise program, which was individually adjusted and overseen by a physical therapist, was designed to enhance both the type (endurance, aerobic, and/or weight training depending on each subjects' preferences) and the level of physical activity to a level conforming to each individual patient's capacity, goals, and interest at the beginning of this intervention. Physical activity was assessed with the use of pedometers (Yamax SW-200) during the 4 days immediately before and at the end of the program. Monthly follow-ups with the physical therapist were scheduled for discussion of the goals achieved as well as setting up new goals for the next month."	
Treatment duration	4 months	

<table>
<tr><td>Follow-up from baseline</td><td>mean 33 months (range 19-56 months)</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 43
Intervention group/s: Diet alone (n=14); Diet + Exercise (n=17)

Comparator group: Exercise (n=12)</td></tr>
<tr><td>Mean age ± SD</td><td>Diet alone: 29.3y (5.9); Diet + exercise: 31.1y (4.7); Exercise (control): 31.8y (4.9)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Polycystic ovary syndrome (PCOS)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2) - Baseline Mean (SD)</td><td>Diet alone: 34.7 (5)
Diet + Exercise: 38.8 (7.9)</td><td>Exercise: 34.9 (5.3)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in BMI (kg/m2) Mean (95% CIs)</td><td>Diet alone: -1.74 (-2.66--0.81)
Diet + Exercise: -1.9 (-2.9--0.9)</td><td>Exercise: -0.85 (-1.69--0.02)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

O'Brien, 2010

Guideline record ID: 10518--1

Study characteristics		
Citation	O'Brien, P. E., Sawyer, S. M., Laurie, C., Brown, W. A., Skinner, S., Veit, F., Paul, E., Burton, P. R., McGrice, M., Anderson, M., & Dixon, J. B. (2010). Laparoscopic adjustable gastric banding in severely obese adolescents: a randomized trial. JAMA, 303(6), 519-526. https://doi.org/https://dx.doi.org/10.1001/jama.2010.81	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Laparoscopic adjustable gastric banding in severely obese adolescents: a randomized trial	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligibility criteria included age between 14 and 18 years; body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) greater than 35; identifiable medical complications such as hypertension, metabolic syndrome, asthma, back pain; physical limitations such as an inability to play a sport, difficulties with activities of daily living; or psychosocial difficulties such as isolation or low selfesteem, subject to bullying that stems from obesity and evidence of attempts to lose weight by lifestyle means for more than 3 years."	
Exclusion criteria	"Three applicants excluded with intellectual disability and 1 with Prader Willi syndrome."	
Setting	Hospital, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"This program centered on reduced energy intake (individualized diet plans ranging between 800 and 2000 kcal/d, depending on age and weight status), increased activity (target of 10 000 steps per day on pedometer) with a structured exercise schedule of at least 30 minutes a day and behavioral modification. Compliance was monitored intermittently with food diaries and step counts. Consultation occurred approximately every 6 weeks throughout the 24-month study period by an adolescent physician and a dietitian or exercise consultant, the study nurse coordinator, and a sports medicine physician. The participant's family was included in activities and education where appropriate. Exercise and activity recommendations included decrease of sedentary activities with a limit of 2-hour computer or television screen time, increase of formal exercise including bicycle riding, walking, and swimming plus informal individual and group activities. Group outings to fun parks, bike rides, hiking trips, walking, jogging, kickboxing, indoor bowling, and outdoor reunions were scheduled. A personal trainer was provided to each participant for a 6-week period. Parents were invited to participate in a specific educational program that included sports motivational talks, nutritional education, and discussions of the psychological aspects of adolescence."	
Control/Comparator	"Participants in the gastric banding group had the procedure performed within a month of randomization. The LAP-BAND Adjustable Gastric Banding system (Allergan, Irvine, California) was used in all cases. Detailed instructions on the requirements for correct eating and exercise after gastric banding were provided by discussion as well as in written form before the procedure. Eating rules centered on having 3 or fewer small (approximately 125 mL), protein-containing meals per day, eaten slowly (1 min/ bite) and chewed well. Each participant was encouraged to undertake at least 30 minutes of formal exercise per day and to maintain a high level of activity through the day. Clinical reviews were conducted approximately every 6 weeks for 2 years by experienced medical staff. Adjustments to the volume of fluid in the band were conducted in the office, without use of x-ray imaging, based on weight loss, sense of satiety, and eating pattern and symptoms."	

<table>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 50
Intervention group/s: Laparoscopic Adjustable Gastric Banding Group (n=25)

Comparator group: Lifestyle Group (n=25)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 16.5y (1.4); Control: 16.6y (1.2)</td></tr>
<tr><td>Sex</td><td>68.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Laparoscopic Adjustable Gastric Banding Group: 42.3 (6.1)</td><td>Lifestyle Group: 40.4 (3.1)</td></tr>
<tr><td>BMI percentile
Mean (SD)</td><td>Laparoscopic Adjustable Gastric Banding Group: 99.25 (0.51)</td><td>Lifestyle Group: 99.2 (0.43)</td></tr>
<tr><td>z Score
Mean (SD)</td><td>Laparoscopic Adjustable Gastric Banding Group: 2.54 (0.31)</td><td>Lifestyle Group: 2.46 (0.22)</td></tr>
<tr><td>Weight, kg
Mean (SD)</td><td>Laparoscopic Adjustable Gastric Banding Group: 120.7 (25.3)</td><td>Lifestyle Group: 115.4 (14)</td></tr>
<tr><td>Waist circumference, cm
Mean (SD)</td><td>Laparoscopic Adjustable Gastric Banding Group: 120.8 (14.2)</td><td>Lifestyle Group: 118.1 (10.6)</td></tr>
<tr><td>Change in BMI z score</td><td>Laparoscopic Adjustable Gastric Banding Group: 2.39</td><td>Lifestyle Group: 2.41</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Greater than 50% of excess weight loss
Proportion (%)</td><td>Laparoscopic Adjustable Gastric Banding Group: 84.0%</td><td>Lifestyle Group: 12.0%</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Changes in Waist circumference, cm
Mean (SD)</td><td>Laparoscopic Adjustable Gastric Banding Group: -28.2 (12.4)</td><td>Lifestyle Group: -3.5 (14.6)</td></tr>
<tr><td>Between-Group Difference in Change in Waist circumference
Mean (95% CIs)</td><td>Laparoscopic Adjustable Gastric Banding Group: -24.7 (-33.1)</td><td>Lifestyle Group: 3 (2.1-8.1)</td></tr>
</table>
</td></tr>
</table>

	Weight lost in kg at 2 years Mean (95% CIs)	Laparoscopic Adjustable Gastric Banding Group: -34.6 (30.2-39)	Lifestyle Group: 3.1 (0.7-6.8)
	% total body weight lost Mean (95% CIs)	Laparoscopic Adjustable Gastric Banding Group: 28.3 (24.9-31.7)	Lifestyle Group: 13.2 (2.6-21)
	% excess weight lost Mean (95% CIs)	Laparoscopic Adjustable Gastric Banding Group: 78.8 (66.6-91)	Lifestyle Group: 1.3 (0.4-2.9)
	Change in BMI units Mean (95% CIs)	Laparoscopic Adjustable Gastric Banding Group: 12.7 (11.3-14.2)	Lifestyle Group: 2.26
	Change in BMI z score Mean (95% CIs)	Laparoscopic Adjustable Gastric Banding Group: 1.32	Lifestyle Group: 0.23 (0.05-0.39)
	Difference in BMI z score Mean (95% CIs)	Laparoscopic Adjustable Gastric Banding Group: 1.08 (0.86-1.31)	
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	The gastric banding group had a mean of 20.4 visits (range, 10-31) during the 2-year follow-up and had 9.5 adjustments made to the volume of saline in the band (range, 5-18).		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

O'Brien, 2017

Guideline record ID: 11048--1

Study characteristics		
Citation	O'Brien, M. J., Perez, A., Scanlan, A. B., Alos, V. A., Whitaker, R. C., Foster, G. D., Ackermann, R. T., Ciolino, J. D., & Homko, C. (2017). PREVENT-DM comparative effectiveness trial of lifestyle intervention and metformin. American Journal of Preventive Medicine, 52(6), 788-797. https://doi.org/https://doi.org/10.1016/j.amepre.2017.01.008	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	PREVENT-DM Comparative Effectiveness Trial of Lifestyle Intervention and Metformin	
Location	USA	
Trial name	PREVENT-DM	
Methods		
Inclusion criteria	"The inclusion criteria for study participants were Latinas aged ≥20 years with prediabetes, defined by impaired fasting glucose (fasting plasma glucose of 100-125 mg/dL), elevated hemoglobin A1c (HbA1c) of 5.7%-6.4% (39-46 mmol/mol), or both."	
Exclusion criteria	"Potential participants were excluded if they had diabetes at baseline, were currently pregnant or planned to become pregnant, or were participating in a supervised weight loss program. In addition, those with any of the following clinical criteria were excluded: blood pressure ≥160/100 mmHg, contraindication to metformin, chronic conditions that could affect a participant's ability to participate (e.g., severe osteoarthritis), medical comorbidities that could influence body weight (e.g., uncontrolled thyroid disease), or medications that could affect weight or glucose metabolism (e.g., oral corticosteroids)."	
Setting	University/research centre, Health centre	
Intervention	"The promotora-led ILI is based on the Group Lifestyle Balance program (copyright 2008, 2010, 2011; University of Pittsburgh), which is an evidence-supported adaptation of the original NIH/National Institute of Diabetes and Digestive and Kidney Diseases-funded DPP.18,19 Findings from formative research informed minimal modifications to the Spanish-language Group Lifestyle Balance program participant handouts to increase their cultural salience for the target population.15,20,21 The 24-session intervention was delivered in Spanish by one promotora to four groups of between five and nine participants, with each session lasting approximately 90 minutes. A second promotora provided logistic support during ILI sessions such as weighing participants and distributing printed materials. There were three part-time promotoras on the intervention team, one of whom led two groups and the other two promotoras each led one group. The first 14 sessions occurred weekly, and the final ten sessions took place biweekly and then monthly. ILI sessions were delivered in a large conference room at the Puentes de Salud health center. The intervention used behavioral strategies such as goal setting, self-monitoring, stimulus control, and problem solving to achieve modest weight loss (5%-7% of initial body weight) by improving dietary patterns (decreasing fat and calorie consumption) and promoting moderate physical activity (≥150 minutes per week). Participants were provided with a digital scale, pedometer, measuring cups, and logs for tracking dietary intake and physical activity;Metformin: Participants randomized to receive metformin began taking 850 mg daily for the first month and 850 mg twice daily thereafter. This dose was reduced if participants experienced side effects, and then titrated to the highest tolerated dose up to 850 mg twice daily"	
Control/Comparator	"Those randomized to standard care continued their regular medical care. In addition, the research coordinator gave them educational materials on diabetes prevention from the National Diabetes Education Program and described these materials briefly during quarterly study visits.23."	

<table>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 92
Intervention group/s: Intensive lifestyle intervention (ILI) (n=33); Metformin (n=29)

Comparator group: Standard care (n=30)</td></tr>
<tr><td>Mean age ± SD</td><td>45.1y (12.5)</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Body weight (kg) - Baseline
Mean (SD)</td><td>Intensive lifestyle intervention (ILI): 85.4
(23)
Metformin: 79.7
(13)</td><td>Standard care: 78.2
(15)</td></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)</td><td>Intensive lifestyle intervention (ILI): 34.4
(7.9)
Metformin: 33.2
(5.5)</td><td>Standard care: 32.2
(5.7)</td></tr>
<tr><td>Waist circumference (cm) - Baseline
Mean (SD)</td><td>Intensive lifestyle intervention (ILI): 101.4
(13)
Metformin: 95.6
(9.1)</td><td>Standard care: 94.9
(9.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)</td><td>Intensive lifestyle intervention (ILI): -4
(-5.5--2.6)
Metformin: -0.9
(-2.4-0.6)</td><td>Standard care: 0.8
(-0.8-2.3)</td></tr>
<tr><td>Change in weight (%)
Mean (95% CIs)</td><td>Intensive lifestyle intervention (ILI): -5
(-6.8--3.2)
Metformin: -1.1
(-3-0.7)</td><td>Standard care: 0.9
(-0.9-2.8)</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (95% CIs)</td><td>Intensive lifestyle intervention (ILI): -1.6</td><td>Standard care: 0.3
(-0.3-1)</td></tr>
</table>
</td></tr>
</table>

	Change in waist circumference (cm) Mean (95% CIs)	(-2.3--1) Metformin: -0.4 (-1-0.3) Intensive lifestyle intervention (ILI): -4 (-5.5) Metformin: -1.8 (-3.3--0.3)	Standard care: -0.2 (-1.7-1.3)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	66.4%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Ockene, 2012

Guideline record ID: 10520--1

Study characteristics		
Citation	Ockene, I. S., Tellez, T. L., Rosal, M. C., Reed, G. W., Mordes, J., Merriam, P. A., Olendzki, B. C., Handelman, G., Nicolosi, R., & Ma, Y. (2012). Outcomes of a Latino community-based intervention for the prevention of diabetes: the Lawrence Latino Diabetes Prevention Project. American Journal of Public Health, 102(2), 336-342. https://doi.org/10.2105/AJPH.2011.300357	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Outcomes of a Latino Community-Based Intervention for the Prevention of Diabetes: The Lawrence Latino Diabetes Prevention Project	
Location	USA	
Trial name	Lawrence Latino Diabetes Prevention Project (LLDPP)	
Methods		
Inclusion criteria	"25 years or older, body mass index (BMI; defined as weight in kilograms divided by the square of height in meters) greater than 24, and a 30% or greater likelihood of being diagnosed with diabetes over the succeeding 7.5 years (risk was calculated by using a validated predictive algorithm based on age, gender, ethnicity, fasting blood glucose, systolic blood pressure, high-density lipoprotein (HDL) cholesterol, BMI, and family history of diabetes)."	
Exclusion criteria	"Exclusion criteria included the inability to walk 5 city blocks (one quarter mile), life-limiting medical conditions, and taking a medication or having a medical condition that interfered with the assessment of diabetes risk."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The LLDPP intervention included participation in 3 individual and 13 group sessions over a 12-month period. The duration of the first group session was 1.5 hours and the remaining group sessions were 1 hour. The first individual visit was 1 hour and the last 2 were 30 minutes each. Additional individual sessions were scheduled when the patients missed group sessions and were willing to schedule a makeup session. The number of sessions varied slightly depending on the start date of the group sessions in relation to the enrollment date. On 40 occasions (2.3% of the total), home visits replaced participation in a group session. The intervention goals included increasing intake of whole grains and nonstarchy vegetables and reducing sodium, total and saturated fat, portion sizes, and the intake of refined carbohydrates and starches. The physical activity goal was to increase walking by 4000 steps per day over baseline. Participants received a pedometer and instructions on its use and information on safe places for walking and exercise in the community. We developed the intervention by using principles of social cognitive theory and patient-centered counseling,11,12 with emphasis on providing basic information on diabetes prevention, promoting positive attitudes toward dietary and physical activity change (i.e., confidence in ability to make changes or self-efficacy), and building skills for making dietary and physical activity changes (i.e., goal-setting, self-monitoring, problem-solving challenges, healthy cooking skills, and grocery shopping skills). The adaptation of the DPP intervention to this new population of Latinos at risk for diabetes involved the use of focus groups to identify knowledge gaps, attitudes toward diabetes prevention, and challenges to lifestyle change for weight loss. We then adapted the intervention to address the identified knowledge gaps (diabetes can be prevented or its onset delayed; weight loss requires a change in energy balance), attitudes toward diabetes prevention ("I can prevent developing diabetes"), and anticipated challenges to participation. Individual sessions were conducted in the participants' homes, and group-based sessions were conducted at a community site to which the participants had easy access (the Lawrence Senior Center).	

	The intervention built on earlier research conducted by members of the research team. This work identified constructs to address to facilitate lifestyle change among Latinos with type 2 diabetes13 and served as the basis for intervention development.14,15 The intervention was tailored to the population by being culturally and literacy-sensitive. Cultural tailoring included dietary advice based on Latino foods, including the customization of Latino recipes; targeting cultural beliefs and attitudes toward diabetes prevention through a videotape novella (watching soap operas is a popular activity in this population); and delivery of the intervention in Spanish by bicultural and bilingual individuals from the community. Low literacy, which is prevalent in the population (even in Spanish), was addressed through visual adaptations of materials that simplified complex information and utilized hands-on experiences. A picture-based food guide that classified foods into 3 colors, green, yellow, and red, was used to assist participants in identifying the dietary quality of foods with regard to glycemic index, sodium, and saturated fat content. Participants used this food guide during a supermarket tour. Goal-setting and self-monitoring worksheets were designed to be simple and the information easy to record by individuals with little formal education. Other hands-on activities included demonstrations of healthy cooking methods, demonstration of portion sizes with real foods, and practice walking with pedometers during the sessions. sessions. We modified the previously developed DPP intervention to be appropriate for Latino individuals at risk for type 2 diabetes. Focus groups16 were conducted to assess unique knowledge gaps regarding diabetes prevention, attitudes toward prevention, and challenges to weight loss in this population. Additional focus groups were used to pretest the acceptability of the intervention materials (e.g., soap opera, goal sheets). The intervention was modified to be less intensive (13 sessions instead of 20) and to include a flexible format to match the needs of this population (i.e., delivered in a group format with some of the sessions delivered in an individual format in the participant's home, as needed). Participants were encouraged to set realistic goals and to self-monitor their dietary intake and physical activity between sessions. At each session, participants weighed in, discussed their goal attainment, and discussed challenges and solutions to achieve their goals. A healthy meal was served at all sessions and preparation methods were discussed. Significant others were invited to attend each group session. Patients received session reminder calls and transportation."
Control/Comparator	"Usual care."
Treatment duration	12 months
Follow-up from baseline	12 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 312 Intervention group/s: Intervention (n=150) Comparator group: Control (n=162)
Mean age ± SD	Intervention: 51.37y (10.9); Control: 52.37y (11.6)
Sex	74.36% female
Pre-existing medical condition	No pre-existing medical condition
Results	

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)

Weight (lb)
Mean (SD)</td><td>Intervention: 33.57
(5.1)

Intervention: 190.19
(31.9)</td><td>Control: 34.18
(5.9)

Control: 191.16
(36.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in weight (lbs)
Median (95% CIs)

Change in BMI (kg/m2)
Median (95% CIs)</td><td>Intervention: -2.5
(-4--1.5)

Intervention: -0.4
(-0.76--0.25)</td><td>Control: 0.63
(-1.05-2)

Control: 0.11
(-0.22-0.38)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>94%</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Ogden, 2015

Guideline record ID: 10521--1

Study characteristics		
Citation	Ogden, J., Hollywood, A., & Pring, C. (2015). The impact of psychological support on weight loss post weight loss surgery: a randomised control trial. Obesity Surgery, 25(3), 500-505. https://doi.org/https://dx.doi.org/10.1007/s11695-014-1428-2	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The impact of psychological support on weight loss post weight loss surgery: a randomised control trial	
Location	UK	
Trial name	N/A	
Methods		
Inclusion criteria	"Bariatric service for patients with extreme obesity with a BMI over 40 (or 35 with serious co morbidities). Consecutive adult patients were recruited, if they consented, once they had been assessed by the multidisciplinary bariatric team (physician, anaesthetist, dietician, psychologist and surgeon) and approved for surgery."	
Exclusion criteria	"Those who could not effectively read or speak English were excluded as this would pose a difficulty in implementing the intervention."	
Setting	Hospital	
Intervention	"Patients allocated to the BRS (intervention) group received usual care as described above plus three one-to-one 50-min sessions with a health psychologist 2 weeks preoperatively, postoperatively (before they were discharged from hospital) and at 3 months follow-up. The design of the BRS was based on the preparation procedures for surgery and cardiac rehabilitation services used for patients post MI [22, 23]. The programme was also developed in line with the needs of bariatric patients following previous qualitative and quantitative research [9-11] and ongoing input from users of two active support groups who had highlighted the need for increased psychological input. The health psychologist used both didactic and non didactic methods and addressed five key factors: (i) knowledge (i.e. information about dietary change), (ii) beliefs (concerning the causes and solutions to obesity), (iii) behaviours (with a focus on diet and physical activity), (iv) coping strategies (i.e. managing emotions without using food, identifying alternative and healthy methods of coping, managing other addictions) and (v) adjustment (i.e. exploring ways to work with the restriction imposed by the operation)."	
Control/Comparator	"Patients allocated to the usual care (control) group received preoperative tests and a standard diet sheet postoperatively informing them about their desired diet and the stages of food progression from only consuming liquids to soft food then back to all foods. Patients returned for surgery approximately 2 weeks later, and after a median post surgical stay of two nights, they were discharged home. They then returned to the clinic at 6 weeks, 3, 6 and 12 months to see the dietician and/ or specialist nurse."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 162
Intervention group/s: BRS intervention (n=82)

Comparator group: Usual care control (n=80)</td></tr>
<tr><td>Mean age ± SD</td><td>45.2y (10.84)</td></tr>
<tr><td>Sex</td><td>75.31% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

BMI (kg/m2)
Mean (95% CIs)</td><td>BRS intervention: 50.42 (7.31)

BRS intervention: 50.42 (38.7-69.5)</td><td>Usual care control: 50.89 (8.33)

Usual care control: 50.89 (36.1-74.8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

BMI (kg/m2)
Mean (95% CIs)</td><td>BRS intervention: 33.8 (5.86)

BRS intervention: 33.8 (32.48-35.14)</td><td>Usual care control: 34.53 (6.4)

Usual care control: 34.53 (33.17-35.88)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in BMI (kg/m2) (mean SD)
Mean (SD)

Change in BMI (kg/m2) (95% CI)
Mean (95% CIs)</td><td>BRS intervention: -16.6 (5.4)

BRS intervention: -16.6 (15.42-17.81)</td><td>Usual care control: -16.37 (5.6)

Usual care control: -16.37 (15.15-17.57)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Okely, 2010

Guideline record ID: 10523--1

Study characteristics		
Citation	Okely, A. D., Collins, C. E., Morgan, P. J., Jones, R. A., Warren, J. M., Cliff, D. P., Burrows, T. L., Colyvas, K., Steele, J. R., & Baur, L. A. (2010). Multi-site randomized controlled trial of a child-centered physical activity program, a parent-centered dietary-modification program, or both in overweight children: the HIKCUPS study. The Journal of Pediatrics, 157(3), 388-394.e381. https://doi.org/10.1016/j.jpeds.2010.03.028	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Multi-site randomized controlled trial of a child-centered physical activity program, a parent-centered dietary-modification program, or both in overweight children: the HIKCUPS study	
Location	Australia	
Trial name	Hunter Illawarra Kids Challenge Using Parent Support (HIKCUPS)	
Methods		
Inclusion criteria	"Child being overweight or obese (referred to hereafter as ''overweight'') according to International Obesity Task Force cut points,8 aged 5.5 to 9.9 years, prepubertal (Tanner Stage I) and generally healthy."	
Exclusion criteria	"Exclusion criteria included extreme obesity (body mass index [BMI] z-score >4), known syndromal obesity, a chronic illness, following a therapeutic diet, and taking medications associated with weight gain or long-term steroids."	
Setting	Home, University/research centre	
Intervention	"Diet: The DM program was designed specifically for parents, as parents of young children play a pivotal role in facilitating changes in a child's food choice, intake and behaviors and are the major role models for healthy lifestyle behaviors [9]. The DM program is based on the Health Belief Model and assumes that parents will make the recommended actions to modify the food behaviors relevant to their family members if they feel that doing so will help to control their child's weight problems and avoid obesity-associated complications [10]. It emphasizes making small changes daily, building on success and developing supporting factors to achieve a sustainable healthy family-eating pattern. Goal setting, problem-solving, role-modeling and positive reinforcement are used to manage changes in food behaviours and strategies incorporated to help parents increase their confidence in making changes related to their goals. The structure and content of the program uses a cognitive behavioral, solution-focused approach from the emerging field of health coaching; 3) The DM/PASD programDiet + Activity: The third intervention involves a combination of the DM and PASD programs whereby the children participate in the PASD program at the same time as their parent(s) participate in the DM program."	
Control/Comparator	"The child-centered Physical Activity Skill-Development program (PASD) The physical activity skill-development program (PASD) is based on Competence Motivation Theory [16] modified for the physical domain [17]. Competence Motivation Theory posits that children's motivation to participate in physical activity is influenced by their actual and perceived physical competence, social support, and enjoyment of physical activity [16]. The PASD program focuses on increasing the children's actual competence in performing fundamental movement skills, perceived competence, and encouraging and improving the level of social support provided to children in their physical activity endeavours. Like the DM program, the PASD program has three components: (i) Child-focused group sessions Children attend ten 2-hour face-to-face weekly sessions. Each week children participate in a variety of activities aimed at improving their mastery of 12 fundamental movement skills (run, jump, leap, hop, slide, gallop, strike, roll, kick, throw, catch, bounce). Each session	

	covers three fundamental movement skills, such that over the course of the 10-weeks each skill is re-visited, although the focus is on more complex components of the skill, in subsequent sessions. Skill mastery is aided by adherence to lesson plans for each skill incorporating several learning stages: a) contextual stage (questions children as to what games, sports and activities require mastery of the specific skill and how the skill is performed proficiently); b) exploration stage (allows children to explore the different movement patterns related to the skill using movement concepts such as force, speed, levels and relationships); c) guided discovery stage (isolates specific components of a skill and using a problem solving approach, guides children to discover the correct way to perform the skill); and d) skill application stage (applies the skills in small drill activities and modified game contexts). The various activities included in the program have been purposefully selected and adapted to enable children to experience success in their skill practice in a non-threatening and supportive learning environment. Facilitators utilise key pedagogical strategies to ensure students have fun, improve their skill performance and are motivated to practice. The activities conducted in the PASD program have accessed from a variety of resources [18,19] and are also based on the experience of several of the authors and facilitators who have a number of years of primary school teaching experience. (ii) Homework In order to maximise the children's competence and confidence, they are strongly encouraged to practice the fundamental movement skills at home with their parents and/or siblings, between each group session. Each participant is given a 'Home-challenge folder', which includes fun, relevant and developmentally appropriate activities enabling practice of skills at home. The home challenges take approximately 30 mins and children are encouraged to complete three sessions each week. The importance of the home challenges and the parent/sibling involvement in the program is explained to the parents during a 1 hour workshop held by the facilitators in the first group session. A sticker chart and certificates are used as incentives to maximise adherence to the home challenges. (iii) Follow-up In the final session of the program, parents attend another 1 hour workshop where they are encouraged to set realistic short- to medium-term SMART goals for increasing physical activity and reducing sedentary behaviours. They are asked to identify barriers in their family lives that may prevent their child from participating in sufficient physical activity or that leads to their child spending excessive amounts of time in small screen recreation (e.g. watching television, videos or DVDs, playing computer games or using the computer for fun). As described in the DM program, parents then write down several short- to mediumterm SMART goals on goal setting charts and postcards. Families are telephoned monthly for three months to discuss and re-evaluate these goals with discussion based on the REGROW model of coaching. Additionally children attend a 2 hour 'refresher' session two months after the final session where all the fundamental movement skills are revised. In this session the key components of each skill are again reinforced through modified and minor games and the importance of practising each skill is reiterated, along with the importance of staying active and having fun whilst being active.”
Treatment duration	6 months
Follow-up from baseline	12 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 206 Intervention group/s: Diet (n=63); Diet + Activity (n=70) Comparator group: Activity (n=73)
Mean age ± SD	Diet: 8.2 (1.2); Activity: 8.3 (1.0); Diet + Activity: 8.1 (1.2)
Sex	Not reported

Pre-existing medical condition	No pre-existing medical condition

Results

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Weight (kg) Mean (SD)	Diet: 46.3 (8.6) Diet + Activity: 45.5 (12.2)	Activity: 48 (10.8)
BMI (kg/m2) Mean (SD)	Diet: 24.6 (3) Diet + Activity: 24.4 (3.7)	Activity: 25.2 (4.1)
BMI z-score Mean (SD)	Diet: 2.8 (0.6) Diet + Activity: 2.8 (0.7)	Activity: 2.8 (0.7)
Waist circumference (cm) Mean (SD)	Diet: 76.4 (6.3) Diet + Activity: 75.8 (10.6)	Activity: 77.6 (9.9)
Waist circumference z-score Mean (SD)	Diet: 3.1 (0.7) Diet + Activity: 3.1 (1)	Activity: 3.2 (1)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point

Variable	Intervention arm/s	Comparator
Weight change (kg) Mean (95% CIs)	Diet: 3.3 (1.9-4.7) Diet + Activity: 3.9 (2.7-5)	Activity: 5.1 (3.9-6.4)
BMI change Mean (95% CIs)	Diet: -0.5 (-1.1) Diet + Activity: -0.2 (-0.7-0.3)	Activity: 0.4 (-0.1-1)
BMI z-score change Mean (95% CIs)	Diet: -0.39 (-0.51--0.27) Diet + Activity: -0.32 (-0.42--0.22)	Activity: -0.17 (-0.28--0.06)
Waist circumference change (cm) Mean (95% CIs)	Diet: -1.1 (-2.9-0.7) Diet + Activity: 1 (-0.5-2.5)	Activity: 2.3 (0.6-4)
Waist circumference z-score change (cm) Mean (95% CIs)	Diet: -0.4 (-0.57--0.23) Diet + Activity: -0.19 (-0.34--0.05)	Activity: -0.14 (-0.29-0.02)

<table>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Collins, C. E., Okely, A. D., Morgan, P. J., Jones, R. A., Burrows, T. L., Cliff, D. P., Colyvas, K., Warren, J. M., Steele, J. R., & Baur, L. A. (2011). Parent diet modification, child activity, or both in obese children: an RCT. Pediatrics, 127(4), 619-627. https://doi.org/10.1542/peds.2010-1518</td></tr>
</table>

N/A – Not applicable

O'Neil, 2018

Guideline record ID: 10519--1

Study characteristics		
Citation	O'Neil, P. M., Birkenfeld, A. L., McGowan, B., Mosenzon, O., Pedersen, S. D., Wharton, S., Carson, C. G., Jepsen, C. H., Kabisch, M., & Wilding, J. P. H. (2018). Efficacy and safety of semaglutide compared with liraglutide and placebo for weight loss in patients with obesity: a randomised, double-blind, placebo and active controlled, dose-ranging, phase 2 trial. The Lancet, 392(10148), 637-649. https://doi.org/10.1016/S0140-6736(18)31773-2	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Efficacy and safety of semaglutide compared with liraglutide and placebo for weight loss in patients with obesity: a randomised, double-blind, placebo and active controlled, dose-ranging, phase 2 trial	
Location	Australia; Belgium; Canada; Germany; Israel; Russia; United Kingdom; United States of America	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligible participants were adults who were 18 years or older without diabetes, and with a body-mass index (BMI) of 30 kg/m² or more that was not of endocrine aetiology (eg, Cushing's syndrome). Self-reported bodyweight must not have fluctuated by more than 5 kg in the 90 days before screening. Eligible individuals must have undergone at least one previous unsuccessful nonsurgical weight-loss attempt and been free from major depressive symptoms (defined as a screening Patient Health Questionnaire-9 [PHQ-9] score <15). To ensure sufficient enrolment of men, recruitment of women was capped at 70%."	
Exclusion criteria	Not reported	
Setting	Not reported	
Intervention	"Participants received semaglutide at one of five doses (0·05 mg, 0·1 mg, 0·2 mg, 0·3 mg, or 0·4 mg) or liraglutide (3·0 mg) as once-daily subcutaneous injections. For each active treatment group (semaglutide or liraglutide), there was a matching placebo group of equal injection volume as well as escalation and dosing schedule. Study medication, including placebo, was provided as prefilled FlexPen devices (Novo Nordisk A/S, Søborg, Denmark) by the study sponsor. Training in their handling and use was given at the baseline visit. Semaglutide was initiated at 0·05 mg per day and incrementally escalated to the next dosing level every 4 weeks until reaching the final dose. Two additional fast-escalation groups of semaglutide (0·3 mg and 0·4 mg) were escalated every 2 weeks, which was exploratory. Liraglutide was initiated at 0·6 mg per day and escalated by 0·6 mg per week to 3·0 mg. The dose escalation schedules are shown in the appendix (p 10). The study consisted of a 1-week screening period, 52 weeks of treatment, and a post-treatment follow-up of 7 weeks. Study visits occurred at screening, baseline (randomisation visit; day 1), every 2 weeks through week 20, and every 4 weeks thereafter through week 52 (end of treatment), plus a follow-up visit at week 59. Bodyweight, vital signs, and adverse events were monitored at every visit, whereas waist and hip circumferences were measured at screening, at baseline, every 4 weeks, and at the follow-up visit. Laboratory parameters were monitored at baseline and weeks 4, 16, 28, 40, and 52. These were fasting visits in which participants were required to abstain from food or drink (except water) for at least 8 h before attendance. Changes from baseline in the use of antihypertensive or lipid-lowering medications (decrease, increase, or no change) were assessed at weeks 16, 28, 40, and 52. For English-speaking participants in the USA only, patient-reported outcomes were assessed with the 36-Item Short Form Health Survey (SF-36) questionnaire administered at baseline and at weeks 28 and 52. Certain preselected adverse events of interest required additional data collection, of which assessment by an event adjudication committee was	

	required for fatal events, coronary or cerebrovascular events (myocardial ischaemia, coronary revascularisation, stroke, transient ischaemic attack, admission to hospital for heart failure, or unstable angina), pancreatitis, neoplasms, and thyroidectomy. Other thyroid events, injection-site reactions, and acute gallbladder disease were adverse events of interest not requiring adjudication. Participants were instructed in hypoglycaemic symptom recognition and management at baseline visit. Hypoglycaemic episodes were identified by self-report or a free plasma glucose concentration of 3·9 mmol/L or less at a site visit, and graded according to the American Diabetes Association criteria. Nutritional compliance was assessed and nutritional and physical activity counselling was provided by qualified research staff every 4 weeks. Participants were advised to follow a daily energy intake limit of approximately 500 kcal below their total energy expenditure, estimated from their basal metabolic rate using a method described elsewhere20 with a physical activity level of 1·3. A maintenance diet without an energy deficit was recommended to participants if their BMI declined to 22 kg/m² or less. Compliance was assessed on a 10-point numeric rating scale from 0 (not at all compliant) to 10 (fully compliant) monthly from week 4. Physical activity counselling was based on participant capability, emphasising a recommended minimum activity time of 150 min per week without specifying exercise intensity. Individuals discontinuing the study treatment before week 52 were requested to undergo the same end-of-treatment procedures as those who received the full course, and to attend a follow-up visit 7 weeks after discontinuation. These individuals were also encouraged to attend a week 52 visit as retrieved participants for determination of bodyweight, blood pressure, and adverse events but not intermediate visits."
Control/Comparator	"For each active treatment group (semaglutide or liraglutide), there was a matching placebo group of equal injection volume as well as escalation and dosing schedule. Study medication, including placebo, was provided as prefilled FlexPen devices (Novo Nordisk A/S, Søborg, Denmark) by the study sponsor. Training in their handling and use was given at the baseline visit. The study consisted of a 1-week screening period, 52 weeks of treatment, and a post-treatment follow-up of 7 weeks. Study visits occurred at screening, baseline (randomisation visit; day 1), every 2 weeks through week 20, and every 4 weeks thereafter through week 52 (end of treatment), plus a follow-up visit at week 59. Bodyweight, vital signs, and adverse events were monitored at every visit, whereas waist and hip circumferences were measured at screening, at baseline, every 4 weeks, and at the follow-up visit. Laboratory parameters were monitored at baseline and weeks 4, 16, 28, 40, and 52. These were fasting visits in which participants were required to abstain from food or drink (except water) for at least 8 h before attendance. Changes from baseline in the use of antihypertensive or lipid-lowering medications (decrease, increase, or no change) were assessed at weeks 16, 28, 40, and 52. For English-speaking participants in the USA only, patient-reported outcomes were assessed with the 36-Item Short Form Health Survey (SF-36) questionnaire administered at baseline and at weeks 28 and 52. Certain preselected adverse events of interest required additional data collection, of which assessment by an event adjudication committee was required for fatal events, coronary or cerebrovascular events (myocardial ischaemia, coronary revascularisation, stroke, transient ischaemic attack, admission to hospital for heart failure, or unstable angina), pancreatitis, neoplasms, and thyroidectomy. Other thyroid events, injection-site reactions, and acute gallbladder disease were adverse events of interest not requiring adjudication. Participants were instructed in hypoglycaemic symptom recognition and management at baseline visit. Hypoglycaemic episodes were identified by self-report or a free plasma glucose concentration of 3·9 mmol/L or less at a site visit, and graded according to the American Diabetes Association criteria. Nutritional compliance was assessed and nutritional and physical activity counselling was provided by qualified research staff every 4 weeks. Participants were advised to follow a daily energy intake limit of approximately 500 kcal below their total energy expenditure, estimated from their basal metabolic rate using a method described elsewhere20 with a physical activity level of 1·3. A maintenance diet without an energy deficit was recommended to participants if their BMI declined to 22 kg/m² or less. Compliance was assessed on a 10-point numeric rating scale from 0 (not at all compliant) to 10 (fully compliant) monthly from week 4. Physical activity counselling was based on participant capability, emphasising a recommended minimum activity time of 150 min per week without specifying exercise intensity. Individuals discontinuing the study

<table>
<tr><td></td><td>treatment before week 52 were requested to undergo the same end-of-treatment procedures as those who received the full course, and to attend a follow-up visit 7 weeks after discontinuation. These individuals were also encouraged to attend a week 52 visit as retrieved participants for determination of bodyweight, blood pressure, and adverse events but not intermediate visits.”</td></tr>
<tr><td>Treatment duration</td><td>52 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 547
Intervention group/s: Semaglutide 0·05 mg (n=103); Semaglutide 0·1 mg (n=102); Semaglutide 0·2 mg (n=103); Semaglutide 0·3 mg (n=103); Semaglutide 0·4 mg n=(102); Semaglutide 0·3 mg FE n=(102); Semaglutide 0·4 mg FE n=(103); Liraglutide 3·0 mg n=(103)

Comparator group: Placebo (n=136)</td></tr>
<tr><td>Mean age ± SD</td><td>47y (12)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Bodyweight (kg) - Baseline
Mean (SD)</td><td>Semaglutide 0.05 mg: 111.3 (23.2)
Semaglutide 0.1 mg: 111.3 (21.5)
Semaglutide 0.2 mg: 114.5 (24.5)
Semaglutide 0.3 mg: 111.5 (23)
Liraglutide 3.0 mg: 108.7 (21.9)</td><td>Placebo: 114.2 (25.4)</td></tr>
<tr><td>BMI (kg/m²) - Baseline
Mean (SD)</td><td>Semaglutide 0.05 mg: 39.1 (6.5)
Semaglutide 0.1 mg: 39.6 (7.4)
Semaglutide 0.2 mg: 40.1 (6.9)
Semaglutide 0.3 mg: 39.6 (7.1)
Liraglutide 3.0 mg: 38.6 (6.6)</td><td>Placebo: 40.1 (7.2)</td></tr>
<tr><td>Waist circumference (cm) - Baseline
Mean (SD)</td><td>Semaglutide 0.05 mg: 117 (14.6)
Semaglutide 0.1 mg: 117.1 (13.7)
Semaglutide 0.2 mg: 119.1 (15.2)
Semaglutide 0.3 mg: 118.1 (15.1)
Liraglutide 3.0 mg: 116.2 (13.8)</td><td>Placebo: 119.5 (15.9)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in Bodyweight (kg)
Mean (SE)</td><td>Semaglutide 0.05 mg: -6.66 (0.94)
Semaglutide 0.1 mg: -9.34 (0.93)
Semaglutide 0.2 mg: -12.3 (0.93)
Semaglutide 0.3 mg: -12.45 (0.93)
Liraglutide 3.0 mg: -8.47 (0.93)</td><td>Placebo: -2.48 (0.82)</td></tr><tr><td>Change in BMI (kg/m²)
Mean (SE)</td><td>Semaglutide 0.05 mg: -2.37 (0.33)
Semaglutide 0.1 mg: -3.36 (0.33)
Semaglutide 0.2 mg: -4.38 (0.33)
Semaglutide 0.3 mg: -4.4 (0.33)
Liraglutide 3.0 mg: -3.03 (0.33)</td><td>Placebo: -0.88 (0.29)</td></tr><tr><td>Change in Waist circumference (cm)
Mean (SE)</td><td>Semaglutide 0.05 mg: -6.11 (0.93)
Semaglutide 0.1 mg: -8.75 (0.9)
Semaglutide 0.2 mg: -11.02 (0.89)
Semaglutide 0.3 mg: -10.91 (0.89)
Liraglutide 3.0 mg: -8.35 (0.89)</td><td>Placebo: -3.47 (0.81)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Mean compliance scores across all semaglutide dosing groups at week 52 ranged from 6·85 (SD 2·47; 0·3 mg 4-weekly escalation) to 7·36 (SD 2·22 [0·4 mg 4-weekly escalation] and SD 1·85 [0·3 mg 2-weekly escalation]), versus 6·87 (SD 2·07) for liraglutide 3·0 mg and 6·09 (SD 2·39) for the pooled placebo group.</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Orazio, 2011

Guideline record ID: 10826--1

Study characteristics		
Citation	Orazio, L. K., Isbel, N. M., Armstrong, K. A., Tarnarskyj, J., Johnson, D. W., Hale, R. E., Kaisar, M., Banks, M. D., & Hickman, I. J. (2011). Evaluation of dietetic advice for modification of cardiovascular disease risk factors in renal transplant recipients. Journal of Renal Nutrition, 21(6), 462-471. https://doi.org/https://dx.doi.org/10.1053/j.jrn.2010.12.002	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Evaluation of dietetic advice for modification of cardiovascular disease risk factors in renal transplant recipients	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	"Renal transplant recipients (RTR) with abnormal glucose tolerance (AGT)."	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"Regular consultations with nephrologist (bimonthly), dietitian (4 weeks initial program, reviews bimonthly, 6 monthly group meetings), nurse (bimonthly) and endocrinologist (bimonthly). Nephrologist monitoring and treatment of renal clinical and biochemical factors and overall patients health; dietitian delivery of initial diet and PA program, then individualised dietetic reviews including weight, WC and hip circumference measurements; nurse overall co-ordination of study, patient education and support, measurement of blood pressure; endocrinologist monitoring of blood glucose levels, HbA1C, prescribing and adjusting diabetes medications. Advice regarding diabetes management. Individualized dietary advice was provided to participants for the duration of the trial. Achievement and/or maintenance of a healthy weight (BMI [body mass index], 20 to 25 kg/m2) was the primary goal of nutrition therapy using a Mediterranean-style (,30% total energy from fat), low glycemic index diet. A moderate energy deficit of 500 kcal/day (2,000 kJ/day) to promote 0.5 kg of weight loss per week was used. Study materials used to teach participants included a study manual with dietary and lifestyle information, food models, and pictures. PA advice was to achieve 150 minutes of accumulated PA per week, in accordance with current National Physical Activity Recommendations.23 To help achieve this, goals were individualized for each patient according to mobility, fitness, personal preference, and self-efficacy for activities. Moderate PA, such as walking, was encouraged, both as structured activity and activity of daily living. The Transtheoretical Model of Health Behavior Change or Stage of Change Model was a vital component underpinning the lifestyle intervention because it helped provide a framework for goal-setting throughout the trial"	
Control/Comparator	"Routine post-transplant follow-up at discretion of treating Nephrologist. Patients were referred for dietetic care in the general outpatients setting, for either an individual appointment or group education. Frequency of follow-up was not set and was determined by the dietitian as per usual care within our centre. Routine diabetes management."	
Treatment duration	2 years	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 102
Intervention group/s: Intervention (n=56)

Comparator group: Control (n=46)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 54.9y (9.9); Control: 54.7y1(1.8)</td></tr>
<tr><td>Sex</td><td>39.22% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Renal transplant recipients >6 months post transplant</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>No data extracted due to concerns with data fidelity.</td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Ortner Hadziabdic, 2016

Guideline record ID: 10524--1

Study characteristics		
Citation	Ortner Hadžiabdić, M., Vitali Čepo, D., Rahelić, D., & Božikov, V. (2016). The effect of the Mediterranean diet on serum total antioxidant capacity in obese patients: a randomized controlled trial. Journal of the American College of Nutrition, 35(3), 224-235. https://doi.org/https://dx.doi.org/10.1080/07315724.2014.982770	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Effect of the Mediterranean Diet on Serum Total Antioxidant Capacity in Obese Patients: A Randomized Controlled Trial	
Location	Croatia	
Trial name	N/A	
Methods		
Inclusion criteria	"18-69 years old, with a body mass index (BMI) of 30 kg/m2 or higher."	
Exclusion criteria	"Newly diagnosed diabetes, hypertension or cardiovascular disease, or change in antihypertensive and oral antidiabetic therapy in the 3 months prior to commencement of the study; Patients on insulin therapy; Reported history of alcohol abuse (alcohol consumption > 500 g of alcohol/ week in the last year), pregnancy or breastfeeding, and use of drugs affecting weight control (e.g., weight loss medicines or systemic glucocorticoids)."	
Setting	Hospital	
Intervention	"Each diet group participated in the intensive 5-day weight reduction program in the outpatient clinic of Dubrava University Hospital, followed by 5 visits throughout the one-year period (week 1 and 1, 3, 6, and 12 months). Equal intensity and quality of dietetic supervision during education and follow-up was provided for the MD and SHD groups. The weight reduction program consisted of educational activities and practical application exercises in the areas of nutrition and eating behavior, physical activity and exercise, and behavior modification. Breakfast and lunch were consumed each day in the outpatient clinic, which served as an educational measure because patients could see the amount and type of food they were to eat at home. Patients were provided the full menu for the 2 weeks period and were instructed on how to design their own diet-specific menus for the following period. Patients were instructed to increase their level of physical activity mostly by walking for a minimum of 30 minutes per day. Each patient underwent a 30-minute session with a physiotherapist, where a set of techniques and exercises was demonstrated to help them achieve maximum mobility. On each visit, participants had biochemical, anthropometric, and clinical measurements taken; completed the International Quality of Life Assessment (IQOLA SF-36v2), a food frequency questionnaire, and the International Physical Activity Questionnaire (IPAQ); and conducted an interview with the dietitian. Patients were also asked to keep a 7-day diet diary on 4 occasions during the study, just before the follow-up visit (at 1, 3, 6, and 12 months). The MD was rich in vegetables, fruits, whole grains (e.g., non-refined cereals, whole-grain bread, pasta, etc.) and low in red meat, with poultry and fish replacing pork, beef, and lamb. Energy intake was restricted to an average of 1573kcal/day, with the goal to fulfill about 35% of calories from fat; the main sources of added fat were >>33 g of olive oil per day and 56 g of nuts (5-7 nuts per day) per week. Patients consuming the MD were provided with extra virgin olive oil at study entry and were advised that they needed to consume 3-4 portions of fish per week, a handful of nuts per day, and 2 tablespoons (corresponding to 30 ml) of extra virgin olive oil per day."	
Control/Comparator	"Each diet group participated in the intensive 5-day weight reduction program in the outpatient clinic of Dubrava University Hospital, followed by 5 visits throughout the one-	

<table>
<tr><td></td><td>year period (week 1 and 1, 3, 6, and 12 months). Equal intensity and quality of dietetic supervision during education and follow-up was provided for the MD and SHD groups. The weight reduction program consisted of educational activities and practical application exercises in the areas of nutrition and eating behavior, physical activity and exercise, and behavior modification. Breakfast and lunch were consumed each day in the outpatient clinic, which served as an educational measure because patients could see the amount and type of food they were to eat at home. Patients were provided the full menu for the 2 weeks period and were instructed on how to design their own diet-specific menus for the following period. Patients were instructed to increase their level of physical activity mostly by walking for a minimum of 30 minutes per day. Each patient underwent a 30-minute session with a physiotherapist, where a set of techniques and exercises was demonstrated to help them achieve maximum mobility. On each visit, participants had biochemical, anthropometric, and clinical measurements taken; completed the International Quality of Life Assessment (IQOLA SF-36v2), a food frequency questionnaire, and the International Physical Activity Questionnaire (IPAQ); and conducted an interview with the dietitian. Patients were also asked to keep a 7-day diet diary on 4 occasions during the study, just before the follow-up visit (at 1, 3, 6, and 12 months). The standard hypolipemic diet was based on a type of reduction diet designed for patients with hyperlipidemia. According to the generally accepted principles in the treatment of hyperlipidemia, the recommended diet contained 25%-30% of the total consumed energy from fat, less than 7% of total energy from saturated fatty acids, and less than 200 mg daily cholesterol; it was rich in whole grains, fruits, and vegetables and restricted additional fats, sweets, and high-fat snacks (Table 1). Energy intake was limited to 1287kcal/day. Subjects allocated to SHD were advised to consume white meat instead of red meat and were not advised to consume fish but could continue with once weekly consumption if fish was previously part of their menu."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 124
Intervention group/s: Mediterranean diet (MD) combined with physical activity (n=63)

Comparator group: Standard hypolypemic diet (SHD) with physical activity (n=61)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 46.2 (12.7); Control: 49.0 (12.1)</td></tr>
<tr><td>Sex</td><td>74.19% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kgs)
Mean (SD)</td><td>Mediterranean diet (MD) combined with physical activity: 112.72
(19.47)</td><td>Standard hypolypemic diet (SHD) with physical activity: 111.51
(21.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kgs)
Mean (SD)</td><td>Mediterranean diet (MD) combined with physical activity: 103.79
(17.81)</td><td>Standard hypolypemic diet (SHD) with physical activity: 106.19
(21.93)</td></tr>
</table></td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Ospanov, 2021

Guideline record ID: 10526--1

Study characteristics		
Citation	Ospanov, O., Akilzhanova, A., Buchwald, J. N., Fursov, A., Bekmurzinova, F., Rakhimova, S., Yeleuov, G., Kozhamkulov, U., Abdina, Z., Fursov, R., & Jumayeva, L. (2021). Stapleless vs stapled gastric bypass vs yypocaloric diet: a three-arm randomized controlled trial of body mass evolution with secondary outcomes for telomere length and metabolic syndrome changes. Obesity Surgery, 31(7), 3165-3176. https://doi.org/https://dx.doi.org/10.1007/s11695-021-05454-2	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Stapleless vs Stapled Gastric Bypass vs Hypocaloric Diet: a Three-Arm Randomized Controlled Trial of Body Mass Evolution with Secondary Outcomes for Telomere Length and Metabolic Syndrome Changes	
Location	Kazakhstan	
Trial name	Life Expectancy of Patients with Metabolic Syndrome After Weight Loss (LIFEXPE-RT)	
Methods		
Inclusion criteria	"Patients were included in the study if they were 18 to 65 years old, had a BMI of 35-50 kg/m2, and MetS with adiposity and at least two of the following four MetS components: elevated fasting plasma glucose levels detected before T2DM or prediabetes (HbA1C = 5.7-6.4% or a threefold increase in fasting plasma glucose >5.6 mmol/L), previously diagnosed T2DM (HbA1C > 6.5% or glucose > 6.1 mmol/L), arterial hypertension (AD 130/85 mmHg or receiving antihypertensive therapy), elevated triglyceride levels (>1.7 mmol/L or receiving specific treatment for this disorder), and low levels of highdensity lipoprotein cholesterol (HDL-C < 1.03 mmol/L in men and <1.29 mmol/L in women or receiving treatment for this disorder). Patients were included in the study if their MetS was inadequately controlled despite optimal pharmacological treatment for their T2DM, hypertension, or dyslipidemias. Patients were required to be available to receive treatment for 12 months with the possibility of follow-up, and if they provided written informed consent for randomization and treatment."	
Exclusion criteria	"Patients were excluded from the study if they were <18 or >65 years of age, or if they had a BMI <30 or >50 kg/m2 . Patients were excluded if they had a drug or alcohol addiction, were immobilized (paralysis), a history of bariatric surgery, insulin-dependent T2DM, serious mental disorders, were socially vulnerable (according to ethical principles), could not understand the purpose of t."	
Setting	Hospital, Home	
Intervention	"Group 1 included patients who underwent the laparoscopic one anastomosis gastric bypass with an obstructive stapleless pouch and anastomosis (LOAGB-OSPAN). The previously described technique [17, 18] is shown in a schematic drawing (Fig. 1a) and demonstrated in a surgical video (see online video supplement; Fig. 1b). A gastroplication is used to obstruct any connection between the gastric pouch and the bypassed greater part of the stomach. Gastrojejunostomy is performed using a hand-sewn suture 150-200-cm distal from the ligament of Treitz. Group 2 included patients who underwent stapled laparoscopic mini-gastric bypass-one anastomosis gastric bypass (LMGB-OAGB) according to standard surgical technique [19]."	
Control/Comparator	"Group 3 comprised patients who undertook a nonsurgical hypocaloric diet therapy with energy restriction (HDER) regimen. The standard diet for men and women without major physical activity was of 1500-2000 kcal/day minus 500- 1000 kcal/day (hypocaloric diet therapy) = 1000-1500 kcal/ day (nutrition). An energy deficit that was of 500-1000 kcal/ day	

<table>
<tr><td></td><td>[3] was established. The medical nutrition therapy provided was 20-25 kcal/kg/day for ideal body weight.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 60
Intervention group/s: LMGB-OAGB Group 2 (n=20)

Comparator group: HDER Group 3 (n=20)</td></tr>
<tr><td>Mean age ± SD</td><td>44.18y (10.9)</td></tr>
<tr><td>Sex</td><td>76.67% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI
Mean (SD)</td><td>LMGB-OAGB Group 2: 45.91 (5.5)</td><td>HDER Group 3: 36.51 (8.1)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI
Mean (SD)</td><td>LMGB-OAGB Group 2: 29.85 (7.8)</td><td>HDER Group 3: 33.74 (12.13)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in BMI
Mean (95% Cis)</td><td>LMGB-OAGB Group 2: -16.04 (-11.7-20.37)</td><td>HDER Group 3: -2.76 (-9.36--3.84)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Ostbye, 2015

Guideline record ID: 10829--1

Study characteristics		
Citation	Østbye, T., Stroo, M., Brouwer, R. J. N., Peterson, B. L., Eisenstein, E. L., Fuemmeler, B. F., Joyner, J., Gulley, L., & Dement, J. M. (2015). Steps to Health employee weight management randomized control trial: short-term follow-up results. Journal of Occupational and Environmental Medicine, 57(2), 188-195. https://doi.org/https://dx.doi.org/10.1097/JOM.0000000000000335	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Steps to Health employee weight management randomized control trial: short-term follow-up results	
Location	USA	
Trial name	Steps to Health (STH)	
Methods		
Inclusion criteria	"Having a measured BMI of 30 kg/m2 or more, and having completed an annual health risk appraisal. Interested employees were approached by study staff, screened for eligibility, and consented. To be eligible for the study, employees must have been benefit-eligible, enrolled in one of the health insurance programs offered through Duke, and not planning to leave Duke during the next 12 months."	
Exclusion criteria	"Current pregnancy precluded inclusion, as did enrollment in the weight management program as a means to qualify for bariatric surgery."	
Setting	Workplace, University/research centre	
Intervention	"WM+ is focused on behavior modification and is informed by social cognitive theory and the transtheoretical model. It involves once-a-month contacts with a health coach who provides relevant materials, helps with goal setting, encourages self-monitoring to boost self-efficacy, and assists in problem solving and reduction of barriers. The intervention is stage-based, and counselors work with the participant at his/her level of readiness to change using, motivational interviewing. The WM+ program was originally based on the employee health and wellness program offered at Johnson & Johnson. This program has been offered at Duke for the past 15 years and is well established and supported within the institution. Participants in the WM+ program have (1) monthly meetings with a health coach (in person at months 1, 4, 8, and 12, and the rest via telephone), (2) optional meetings at months 2 and 5 with an exercise physiologist, (3) quarterly biometric feedback, (4) targeted health education materials, and (5) information and active linking with various Duke programs and wellness resources. Both programs last 12 months, and to accommodate the additional time needed for the program to assign a health coach after randomization and conduct an initial in-person visit, the immediate postintervention was scheduled 14 months after the date of randomization."	
Control/Comparator	"The WM program was developed at Duke 10 years ago and incorporates portions of the WM+ program, but without the behavioral modification coaching aspect. This program relies mostly on educating participants about weight management strategies and is informed by constructs of the information processing paradigm. WM leverages the concept of frequent exposure to health to weight management tips, delivered via e-mail or print, in attractive packaging. WM also offers three contacts with a health coach (one in-person meeting in month 1, and one contact via the telephone in months 6 and 12), and optional meetings at months 2 and 5 with an exercise physiologist and with a nutritionist (a total of four optional meetings over the course of the study). The coaching contacts focus discussions on self-reported weight, as well as educational materials. In both programs, the health coaches are required to be registered dieticians. All coaching contacts are made	

<table>
<tr><td></td><td>during work hours, with the coaches traveling to the participant's work location for inperson meetings. Individual work areas set policies for time related to participation in these programs; some employees are allowed to have "release time" to complete coaching sessions, whereas others have to complete the sessions during their break times. Both programs last 12 months, and to accommodate the additional time needed for the program to assign a health coach after randomization and conduct an initial in-person visit, the immediate postintervention was scheduled 14 months after the date of randomization.”</td></tr>
<tr><td>Treatment duration</td><td>14 months</td></tr>
<tr><td>Follow-up from baseline</td><td>14 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 550
Intervention group/s: WM+ (n=275)

Comparator group: WM (n=275)</td></tr>
<tr><td>Mean age ± SD</td><td>45y</td></tr>
<tr><td>Sex</td><td>83.09% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline BMI for all particpants
Mean (SD)

Baseline BMI (Lost-to-follow-up excluded)
Mean (SE)</td><td>WM+: 37.37
(6.61)

WM+: 36.94
(0.4)</td><td>WM: 37.02
(6.14)

WM: 37.09
(0.41)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in BMI
Mean (95% CIs)</td><td>WM+: -0.36
(-0.66--0.05)</td><td>WM: -0.25
(-0.53-0.02)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Mean participation in the intervention, defined as the number of completed coaching contacts, was 2.74 visits (out of a possible 7 total) or 39.2% in the WM arm and 6.76 visits (out of a possible 12 total) or 56.3% in the WM± arm.</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Pakpour, 2015

Guideline record ID: 10530--1

Study characteristics		
Citation	Pakpour, A. H., Gellert, P., Dombrowski, S. U., & Fridlund, B. (2015). Motivational interviewing with parents for obesity: an RCT. Pediatrics, 135(3), e644-e652. https://doi.org/10.1542/peds.2014-1987	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Motivational Interviewing With Parents for Obesity: An RCT	
Location	Iran	
Trial name	N/A	
Methods		
Inclusion criteria	"Obese adolescents (i.e., BMI 95th percentile for age and gender) between 13 and 18 years of age. Eligible adolescents lived with a parent or adult caregiver who was prepared to be involved in treatment."	
Exclusion criteria	"Taking weight-related medication, having a diagnosis of an eating disorder, being pregnant, and having clinical mental health conditions or psychosis."	
Setting	Hospital	
Intervention	"Participants in both intervention groups received 6 individual counselling sessions on diet and exercise with an extra session for parents in the MI + PI group. All sessions were delivered weekly, and each session lasted ∼40 minutes. All adolescents were encouraged to express their personal motivation to change their physical activity and dietary behaviour. The adolescents were encouraged to eat a variety of foods from each of the 4 major food groups and low-fat alternatives. They were also encouraged to achieve at least 60 minutes of moderate to vigorous intensity physical activity daily. The goal of the MI session was to assist the adolescents with reducing resistance and overcoming ambivalence about behaviour change. For the MI+PI, an identical MI style was used for parents, focusing on the adolescents' weight, parents' attitudes and behaviours regarding children's physical activity and dietary habits, parent monitoring, and supervision; the goal was to promote progress toward the child's intervention goals and attitudes by the parents."	
Control/Comparator	"Assessments only."	
Treatment duration	6 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference	
Participant characteristics		
Number of participants	n= 357 Intervention group/s: Motivational interviewing (MI) (n=119); MI intervention with parental involvement (MI + PI) (n=119) Comparator group: Passive Control (n=119)	
Mean age ± SD	MI intervention: 15.59 (1.31); MI+PI intervention: 15.57 (1.38); Control: 15.78 (1.19)	
Sex	51.54% female	

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI
Mean (SD)</td><td>MI: 33.07
(8.87)
MI + PI: 33.09
(5.86)</td><td>Passive Control: 32.92
(7.79)</td></tr>
<tr><td>BMI z score
Mean (SD)</td><td>MI: 2.83
(0.79)
MI + PI: 2.82
(0.62)</td><td>Passive Control: 2.75
(0.67)</td></tr>
<tr><td>DXA, % fat
Mean (SD)</td><td>MI: 47.73
(7.42)
MI + PI: 47.7
(6.35)</td><td>Passive Control: 45.37
(8.31)</td></tr>
<tr><td>Waist circumference, cm
Mean (SD)</td><td>MI: 102.59
(9.27)
MI + PI: 103.48
(8.19)</td><td>Passive Control: 95.51
(8.75)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI
Mean (SD)</td><td>MI: 32.44
(7.45)
MI + PI: 31.04
(6.46)</td><td>Passive Control: 32.95
(8.78)</td></tr>
<tr><td>BMI z score
Mean (SD)</td><td>MI: 2.81
(0.76)
MI + PI: 2.58
(0.61)</td><td>Passive Control: 2.76
(0.7)</td></tr>
<tr><td>DXA, % fat
Mean (SD)</td><td>MI: 46.61
(7.91)
MI + PI: 45.96
(6.34)</td><td>Passive Control: 45.4
(7.45)</td></tr>
<tr><td>Waist circumference, cm
Mean (SD)</td><td>MI: 101.97
(9.11)
MI + PI: 101.7
(9.21)</td><td>Passive Control: 99.9
(8.26)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Percent MI-adherent: 91.51 (16.12)</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Pannen, 2021

Guideline record ID: 10534--1

Study characteristics		
Citation	Pannen, S. T., Maldonado, S. G., Nonnenmacher, T., Sowah, S. A., Gruner, L. F., Watzinger, C., Nischwitz, K., Ulrich, C. M., Kaaks, R., Schübel, R., Grafetstätter, M., Kühn, T., & Ingram, D. K. (2021). Adherence and dietary composition during intermittent vs. continuous calorie restriction: follow-up data from a randomized controlled trial in adults with overweight or obesity. Nutrients, 13(4), 1195. https://doi.org/10.3390/nu13041195	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Adherence and Dietary Composition during Intermittent vs. Continuous Calorie Restriction: Follow-Up Data from a Randomized Controlled Trial in Adults with Overweight or Obesity	
Location	Germany	
Trial name	Healthy nutrition and energy restriction as cancer prevention strategies (HELENA)	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	Home	
Intervention	“Participants in the ICR group were advised to follow a "5:2 diet" with an energy intake of 25% of the isoenergetic energy requirement on two self-selected, non-consecutive R days and an isoenergetic "healthy balanced diet" (100% energy intake) on the remaining five NR days (net weekly energy intake of approximately 80%). For R days, a meal plan list with pre-selected food items was provided on the basis of which participants were free to choose their meals (four vegetable items, two low-fat dairy products, one item out of each of the meat/fish, carbohydrate, and fruits group).”	
Control/Comparator	“CCR participants were encouraged to reduce energy intake to ~80% of the individual energy requirement daily. Based on the 7-day food records filled out at baseline, personalized diet plans incorporating individual eating habits were provided by the dietitians.”	
Treatment duration	12 weeks	
Follow-up from baseline	102 weeks	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 98 Intervention group/s: ICR (n=49) Comparator group: CCR (n=49)	
Mean age ± SD	Intervention: 49.4y (9.0); Control:50.5y (8.0)	
Sex	48.98% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight
Mean (SD)</td><td>ICR: 96.4
(15.8)</td><td>CCR: 92.5
(15.7)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight
Mean (SD)</td><td>ICR: 92
(17.1)</td><td>CCR: 87.9
(14.4)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (%)
Mean (SD)</td><td>ICR: -5.2
(1.2)</td><td>CCR: -4.9
(1.1)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Papalazarou, 2010

Guideline record ID: 10536

Study characteristics		
Citation	Papalazarou, A., Yannakoulia, M., Kavouras, S. A., Komesidou, V., Dimitriadis, G., Papakonstantinou, A., & Sidossis, L. S. (2010). Lifestyle intervention favorably affects weight loss and maintenance following obesity surgery. Obesity, 18(7), 1348-1353. https://doi.org/10.1038/oby.2009.346	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Lifestyle intervention favorably affects weight loss and maintenance following obesity surgery	
Location	Greece	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were female sex and being candidates for bariatric surgery: BMI >40kg/m2, history of multiple, failed, previous attempts for weight loss and absence of psychiatric illness, as determined by psychiatric profiles conducted by a hospital psychiatrist (26)."	
Exclusion criteria	Not reported	
Setting	Hospital, Home	
Intervention	"Volunteers were randomly assigned to one of two intervention groups: Usual care (UC) or lifestyle intervention (LS). Both groups were seen by an appropriately trained dietitian and they were instructed to follow a liquid diet of very low calorie content (665kcal, 66g protein/day, 100% of the recommended dietary allowance for vitamins and minerals) for 4weeks postoperatively. Following this period, soft and solid foods were gradually introduced to the diet of both groups. By the end of the sixth month, most patients had adopted conventional dietary habits. Patients visited the Dietetics Department of the hospital for their regular assessment on a weekly basis for the first 3 months postoperatively, every other week for the next 3 months, monthly for the following 6 months, every 3 months for the second postoperative year and every 6 months for the third postoperative year (total number of sessions in the 3 years = 30). During these assessment sessions general information was provided on adopting healthier eating and physical habits; furthermore the LS group attended additional 40-min individualized sessions with the dietitian during these assessment visits. Lifestyle intervention Aim of the intervention was to help patients to overcome barriers and regulate their body weight by adopting healthier eating habits and a less sedentary lifestyle. A patient-centered collaborative approach was used, along with behavior modification techniques, such as self-monitoring, self-evaluation, goal setting, reinforcement, stimulus control, and relapse prevention (Table 1). Patients had the opportunity to discuss their own thoughts on food intake and physical activity. Every session consisted of three parts: nutrition education, dietary intake, and physical activity. Information was provided with regards to fat and fiber sources, nutritional value of foods and health benefits related to the adoption of a balanced dietary pattern and increased physical activity. The dietary guidelines for Greeks (27) as well as the American College of Sports Medicine guidelines for physical activity (28) were the optimal goal. In specific, fruits, vegetables, whole grain cereals, and legumes consumption was emphasized, along with moderately high intake of fish, moderate intake of dairy products (mainly low fat versions), low intake of meat and poultry, regular but moderate intake of ethanol, primarily in the form of wine and during meals, and prudent use of olive oil, as the main dietary fat. Patients were also encouraged to eat breakfast, to reduce intake of high energy density foods, including fast foods, sweets and sauces, to adopt a more physically active lifestyle (around 150min of moderate intensity exercise per	

<table>
<tr><td></td><td>week), to identify external and internal stimuli related to eating, to provide effective solutions and to set manageable, individualized, short-term goals. The importance of weight loss maintenance was also emphasized for the purposes of both health benefits and satisfactory body image. The content of the sessions was individualized following patients' needs.”</td></tr>
<tr><td>Control/Comparator</td><td>“Volunteers were randomly assigned to one of two intervention groups: Usual care (UC) or lifestyle intervention (LS). Both groups were seen by an appropriately trained dietitian and they were instructed to follow a liquid diet of very low calorie content (665kcal, 66g protein/day, 100% of the recommended dietary allowance for vitamins and minerals) for 4weeks postoperatively. Following this period, soft and solid foods were gradually introduced to the diet of both groups. By the end of the sixth month, most patients had adopted conventional dietary habits. Patients visited the Dietetics Department of the hospital for their regular assessment on a weekly basis for the first 3 months postoperatively, every other week for the next 3 months, monthly for the following 6 months, every 3 months for the second postoperative year and every 6 months for the third postoperative year (total number of sessions in the 3 years = 30). During these assessment sessions general information was provided on adopting healthier eating and physical habits; furthermore the LS group attended additional 40-min individualized sessions with the dietitian during these assessment visits.”</td></tr>
<tr><td>Treatment duration</td><td>3 years</td></tr>
<tr><td>Follow-up from baseline</td><td>36 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= Not reported
Intervention group/s: LS (n=Not reported)

Comparator group: UC (n=Not reported)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 32.7y (1.6) Control: 33.4y (2.0)</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI
Mean (SD)</td><td>LS: 48.5
(2.1)</td><td>UC: 49.8
(1.6)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight
Mean (SD)

Percent excess weight loss
Mean (SD)</td><td>LS: 84.2
(3.3)

LS: 74.8
(3.8)</td><td>UC: 102.5
(3.5)

UC: 49.1
(3.8)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
</table>

<table>
<tr><td>12 months or closest time point</td><td></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Parker, 2022

Guideline record ID: 10537--1

Study characteristics		
Citation	Parker, S. M., Barr, M., Stocks, N., Denney-Wilson, E., Zwar, N., Karnon, J., Kabir, A., Nutbeam, D., Roseleur, J., Liaw, S.-T., McNamara, C., Frank, O., Tran, A., Osborne, R., Lau, A. Y. S., & Harris, M. (2022). Preventing chronic disease in overweight and obese patients with low health literacy using eHealth and teamwork in primary healthcare (HeLP-GP): a cluster randomised controlled trial. BMJ Open, 12(11), e060393. https://doi.org/https://dx.doi.org/10.1136/bmjopen-2021-060393	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Preventing chronic disease in overweight and obese patients with low health literacy using eHealth and teamwork in primary healthcare (HeLP-GP): a cluster randomised controlled trial	
Location	Australia	
Trial name	HeLP-GP	
Methods		
Inclusion criteria	"The trial was conducted in general practices located in metropolitan and urban fringe areas of south-western and western Sydney in New South Wales and Adelaide in South Australia. Practice eligibility included: Geographical location in Local Government Areas with a Socio-Economic Index for Area Index of Relative Socio-economic Disadvantage28 equal to or below the eighth decile. Using clinical software compatible with the trial data extraction and recruitment tool, Doctors Control Panel (DCP),29 and an active internet connection. Participation by at least one practice nurse (PN) and one GP from the practice. Participation of reception staff to distribute trial materials to eligible trial participants as they present for appointments. Patient eligibility included: Aged 40-74 years. BMI ≥28 recorded within the previous 12 months (the cut-off point for BMI was chosen to target people at higher risk and to capture people from Asian backgrounds who have a lower equivalent BMI). BP and total serum cholesterol recorded within the previous 12 months. Speaking English and/or Arabic, Vietnamese or Chinese (languages representing common migrant groups in the catchment areas-there were very few patients who spoke other languages but not English). Access to a smartphone or tablet device and internet connection."	
Exclusion criteria	"Had a diagnosis of diabetes requiring insulin or a current prescription for insulin, a diagnosis of cardiovascular disease (angina, myocardial infarction, heart failure, heart valve disease (rheumatic or nonrheumatic)), stroke (cerebrovascular accident). Had experienced weight loss of >5% in the past 3 months, were taking medication for weight loss (orlistat or phentermine) or had undergone weight loss surgery. Had cognitive impairment (including serious mental illness). Had a physical impairment which would prohibit engaging in moderate-level physical activity."	
Setting	GP clinic, Home	
Intervention	"Aimed to increase the knowledge of patients relating to diet and physical activity and their individual skills to address weight management behaviours. It comprised: 1. A PN-led health check designed to support Australian Guidelines for the management of overweight and obesity5 33 and based on the 5As (Assess, Advise, Agree, Assist and Arrange).34 35 Review was conducted by the PN at 6 weeks and the GP at 12 weeks. 2. A lifestyle app (mysnapp) modified from healthy.me, a personally controlled health management platform designed to help patients and consumers to manage their health.36 The components of mysnapp were informed by research into behaviour change through mobile and electronic platforms that suggest that goal setting and self-monitoring, and additional methods to interact with patients, particularly text messaging, can be more effective than advice	

<table>
<tr><td></td><td>alone.37-40 Mysnapp allowed patients to set and revise physical activity and diet-based goals and to view graphs of their progress over the previous 6 weeks. A free-text diary allowed patients to document individualised content. A range of video and written resources related to diet and physical activity, linked to the app, were available for the patient to view. Text messages reminded patients to attend the follow-up with the PN and GP and once registered, each patient received one nutrition and one physical activity message each week for 6 weeks.32 3. Health coaching via the 'Get Healthy' telephone coaching programme (https://www.gethealthynsw. com.au/) provided free, confidential telephone-based health coaching to support patients to reach personalised lifestyle goals relating to healthy eating, increasing physical activity, alcohol reduction and achieving and maintaining a healthy weight. Coaching was available in multiple languages with the assistance of an interpreter service. At the health check, patients could choose to take up mysnapp, Get Healthy or both”</td></tr>
<tr><td>Control/Comparator</td><td>“Control practices provided 'usual care' (the clinical practice routinely offered to patients by the GP and PN of the practice).”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 215
Intervention group/s: HeLP-GP Intervention (n=120)

Comparator group: Control (n=95)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 58.9y (8.8); Control: 56.2y (9.6)</td></tr>
<tr><td>Sex</td><td>42.79% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)

Waist circumference
Mean (SD)</td><td>HeLP-GP Intervention: 34.7
(5.3)

HeLP-GP Intervention: 109.4
(13.6)</td><td>Control: 34.9
(6.9)

Control: 112.9
(15.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)

waist circumference
Mean (SD)</td><td>HeLP-GP Intervention: 34.3
(6)

HeLP-GP Intervention: 112.4
(15.6)</td><td>Control: 32.9
(5.7)

Control: 107
(9.6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
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<table>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Paskett, 2018

Guideline record ID: 10540--1

Study characteristics		
Citation	Paskett, E. D., Baltic, R. D., Young, G. S., Katz, M. L., Lesko, S. M., Webber, K. H., Roberto, K. A., Lengerich, E. J., Schoenberg, N. E., Kennedy, S. K., Mama, S., Midkiff, C. C., & Dignan, M. B. (2018). A group randomized trial to reduce obesity among Appalachian church members: the Walk by Faith study. Cancer Epidemiology, Biomarkers & Prevention, 27(11), 1289-1297. https://doi.org/https://dx.doi.org/10.1158/1055-9965.EPI-17-1085	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A Group Randomized Trial to Reduce Obesity among Appalachian Church Members: The Walk by Faith Study	
Location	USA	
Trial name	Walk by Faith	
Methods		
Inclusion criteria	"At least 18 years of age, attending services at the church at least 4 times in the past two months, able to understand and read English, cognitively able to provide informed consent, resident of an Appalachian county, not residing in a nursing facility or residential home, not planning to move away from the study area, willing to use a computer, no dietary restrictions prescribed for weight loss or part of a formal weight-loss program, weight less than 400 pounds, having a BMI of at least 25 kg/m2, and, if female, not pregnant, breastfeeding, or less than 9 months postpartum, or planning to become pregnant during study period."	
Exclusion criteria	Not reported	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The intervention program, WbF, focused on environmental and individual-level behavioral changes to reduce overweight/obesity by focusing on components of a healthy diet and increasing physical activity. Educational and motivational materials were delivered to participants at monthly sessions held at each church and with the aid of a dedicated website, Faithfully Living Well (FLW). Each session was approximately one hour in length. Print handouts of any presentations were provided to attendees and made available in the church for participants who were unable to attend. A touchscreen computer, printer and highspeed internet were installed in each church to encourage participants to visit FLW and print healthy recipes or health-related articles. At least one member of each church volunteered to be a church navigator who facilitated program events and assisted participants, as needed. The diet intervention focused on increasing fruit and vegetable and water intake, reducing sugary drink consumption, and reducing dietary fat. Short-term and long-term goals were set for each participant with the personal assistance of trained regional staff using the output of the baseline web surveys as a starting point. Participants were encouraged to meet with regional staff quarterly to discuss previous goals, adjust if necessary, and set new shortterm and long-term goals. Examples of goals included trying a new fruit and/or vegetable each month, increasing number of servings of fruits or vegetables per day, increasing average steps per day over a period of time, and losing a certain amount of weight over a period of time. The navigators, community advisors, and regional project staff worked together to identify strategies to support environmental approaches to increase physical activity, such as setting up walking courses, group walks, and walking challenges. They also identified safe walking paths within the communities and secured promotional offers and donations from local businesses and organizations to be used as incentives to encourage participants to increase their physical activity levels and utilize program components, such as completing dietary inventories, attending events, and using the FLW website. Healthy potluck meals were held in the churches. Omron HJ-720ITC	

<table>
<tr><td></td><td>pedometers, nutrition guides, and diet and exercise journals were provided to each enrolled participant. The FLW website also allowed participants to upload steps from their pedometers, track progress toward their individual walking and weight-loss goals, read health-related articles, submit and access recipes, participate in discussion forums, view photo albums, and have access to a rewards page-all tailored to each county. A celebration event was held in each church after the active program was completed 12 months after the first event. During these events, participants were invited to talk about their experiences and progress and were given rewards and certificates of completion."</td></tr>
<tr><td>Control/Comparator</td><td>"RoF focused on environmental and individual level behavior changes to increase cancer screening knowledge and promote cancer screening as recommended by the American Cancer Society. Each church was provided a touchscreen computer, printer, and high-speed internet to allow participants to access and print cancer screening information online. At least one volunteer navigator in each church was appointed to facilitate program events. Components of the RoF program included an information session, a health fair, cancer education inserts in church bulletins, and monthly education sessions with brochures and other handouts. Monthly education sessions were approximately one hour in length and spanned a variety of cancer-related topics, such as the importance of understanding their family health history and encouraging loved ones to get cancer screening, and site-specific cancer education sessions on colon, skin, lung, breast, cervical, prostate and testicular cancers. Church members were encouraged to complete age- and sex-appropriate screening tests for cervical, breast, colorectal, prostate, testicular, and skin cancers. A celebration event was held after the 12-month active phase."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 663
Intervention group/s: Walk by Faith (n=426)

Comparator group: Ribbons of Faith (n=237)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>70.74% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>Walk by Faith: 92.6
(19.9)</td><td>Ribbons of Faith: 91.6
(18.9)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>change in weight
Mean (95% CIs)</td><td>Walk by Faith: -1.2
(-2.5-0)</td><td>Ribbons of Faith: 0.1
(1.2-1.5)</td></tr></table></td></tr>
</table>

<table>
<tr><td>12 months or closest time point</td><td></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Patel, 2021

Guideline record ID: 10541--1

Study characteristics		
Citation	Patel, M. S., Small, D. S., Harrison, J. D., Hilbert, V., Fortunato, M. P., Oon, A. L., Rareshide, C. A. L., & Volpp, K. G. (2021). Effect of behaviorally designed gamification with social incentives on lifestyle modification among adults with uncontrolled diabetes: a randomized clinical trial. JAMA Network Open, 4(5), e2110255. https://doi.org/10.1001/jamanetworkopen.2021.10255	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Behaviorally Designed Gamification With Social Incentives on Lifestyle Modification Among Adults With Uncontrolled Diabetes: A Randomized Clinical Trial	
Location	USA	
Trial name	iDiabetes	
Methods		
Inclusion criteria	"Participants were eligible for the program if they were between ages 18 and 70 years; able to read and provide informed consent; had a diagnosis of type 2 diabetes with the most recent HbA1c level greater than or equal to 8.0%; and, within the past 90 days, had a self-reported BMI greater than or equal to 25; and owned a smartphone or tablet compatible with the wearable device and a smart weight scale."	
Exclusion criteria	"Individuals were excluded if there was a condition that made their participation infeasible (eg, inability to provide informed consent or inability to speak, read, or write in the English language); if there was a condition that made participation unsafe (eg, pregnancy, previous diagnosis of an eating disorder, or history of unsafe weight loss practices); if they were already enrolled in another study targeting physical activity, weight loss, or glycemic control; or if any other medical conditions or reasons prohibited the individual from participating in the 1-year trial."	
Setting	Home	
Intervention	"During the in-person visit, all participants received education on the importance of diet and physical activity for weight loss and glycemic control using recommendations from the Centers for Disease Control and Prevention. Participants randomly assigned to 1 of the 3 gamification interventions conducted goal setting during the in-person visit including selecting an HbA1c reduction goal (1.5%, 2%, or 2.5%), a weight loss goal (6%, 7%, or 8%), and a step count increase (33%, 40%, 50%, or any goal 1500 steps above baseline). These options were based on prior work18-20; participants were told to strive for these goals during the first 6 months and maintain them through 12 months. Participants were given a weekly weight target (about 1 lb or less) that gradually declined to the goal by 6 months. If a weekly goal was not achieved, the target remained the same for the following week. Similar to earlier work,19 step targets increased gradually over 4 weeks. Participants in the intervention arms were entered into a game with points and levels that ran automatically (participants did not have to actively play the game-just strive for their goals) and provided a daily notification on their progress. The design was based on previous work that incorporated principles from behavioral economics.18-20 First, participants in the gamification arms signed a precommitment pledge to strive to achieve their goals during the 1-year trial.31,32 In earlier work,18 step goal targets began immediately, which was challenging for some participants. Therefore, in this trial, participants had a ramp-up period during the first 4 weeks in which daily step goal targets increased by 25% per week from baseline to the goal. Participants were asked to strive for this step goal for the rest of the trial but could change the goal at any point as long as it was within the options provided. Second, every Monday, the participant received 70 points (10 for each day of the week). If the participant did not weigh in on the prior day, they lost 10 points from their balance.	

	This practice leverages prospect theory,33 which has demonstrated that loss framing is more effective at motivating behavior change than gain framing.25,33 Third, at the end of each week, participants could move up or down levels (from lowest to highest: blue, bronze, silver, gold, and platinum). This design creates achievable goal gradients, a sense of social status, and progression through the game. If at the end of each week the participant had at least 40 points, achieved their weekly weight target, and averaged at or above their daily step goal, they would move up a level. Fourth, we leveraged the "fresh start effect," which is the tendency for aspirational behavior around temporal landmarks, such as the beginning of the year, month, or week.34 Similar to prior work,18-20 participants started each week with a fresh set of 70 points. To help re-engage participants who were struggling to meet their goals at months 3, 6, and 9 (defined as being in the blue or bronze levels of the game), the study team called them to inquire about their progress in the study, reset them to the silver level, and offered them the opportunity to readjust their goals based on their initial options. Fifth, similar to an earlier study,20 the participants' primary care physician was mailed a monthly report with data on their change in step counts, weight, HbA1c level, and LDL-C level as a way of increasing social accountability.35 A copy of this letter was also sent to the participant by email each month. Sixth, the game varied based on the social incentive arm as follows. In the support arm, participants were asked to identify a family member or friend who would be a support sponsor and be emailed a weekly report on the participant's performance in the game over the past week (goal attainment, points, and level) and their targets for the upcoming week (step counts, weight, and points). This sponsor was sent a message at the start of the trial to do their best to support the participant in their progress during the interventions. In the collaboration arm, participants were placed into a team of 3 total participants. These individuals typically did not know each other before the study but were introduced to each other by email. Each day one of the members of the group was randomly selected to represent their team for that day, and that information was shared with the entire group. If the selected participant weighed in on the previous day, the team kept their points. If he or she did not, then the entire team lost 10 points. In this design, each person is accountable to the others on the team, and this strategy was intended to induce a collaborative effort to meet their daily goals. The entire team moved up a level only if the team had at least 40 points by the end of the week. In the competition arm, participants were placed into a group of 3 total participants. These individuals typically did not know each other before the study but were introduced to each other by email. At the end of each week, the participants received an email with a leaderboard that ranked them on their cumulative points in the study thus far and displayed their level. This feedback was intended to encourage participants to compete for the top spot among the group”
Control/Comparator	“During the in-person visit, all participants received education on the importance of diet and physical activity for weight loss and glycemic control using recommendations from the Centers for Disease Control and Prevention.30 Participants in the control arm received regular feedback and goal setting from the devices and smartphone application but received no other interventions.”
Treatment duration	12 months
Follow-up from baseline	12 months
Eligible outcome(s) reported	Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 361 Intervention group/s: Gamification with support (n=92); Gamification with collaboration (n=95); Gamification with competition (n=87) Comparator group: Control (n=87)
Mean age ± SD	52.5y (10.1)

<table>
<tr><td>Sex</td><td>55.96% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Uncontrolled type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Gamification with support: 103.4
(18.2)
Gamification with collaboration: 110.8
(21.4)
Gamification with competition: 108.3
(20.7)</td><td>Control: 106.8
(22.5)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)</td><td>Gamification with support: -3.6
(-5--2.2)
Gamification with collaboration: -3.4
(-4.7--2)
Gamification with competition: -2.9
(-4.8)</td><td>Control: -2
(-3.5--0.05)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Patrick, 2011

Guideline record ID: 10542--1

Study characteristics		
Citation	Patrick, K., Calfas, K. J., Norman, G. J., Rosenberg, D., Zabinski, M. F., Sallis, J. F., Rock, C. L., & Dillon, L. W. (2011). Outcomes of a 12-month web-based intervention for overweight and obese men. Annals of Behavioral Medicine, 42(3), 391-401. https://doi.org/https://dx.doi.org/10.1007/s12160-011-9296-7	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Outcomes of a 12-month web-based intervention for overweight and obese men	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Adult men with BMI of at least 25 kg/m2 (overweight or obese)."	
Exclusion criteria	"None specified."	
Setting	Web-based	
Intervention	"Intervention was designed to improve diet and physical activity behaviours in five areas: (a) increased fruit and vegetable intake to five to nine or more servings per day; (b) increased consumption of whole grain products to more than or equal to three servings per day; (c) decreased saturated fat intake to ≤20 g per day through the use of strategies such as substitution, reducing portion size, decreasing frequency, or changing cooking methods; (d) increasing steps per day to at least 10,000 on at least 5 days/week; and (e) strength training at least two times per week targeting at least two body areas (upper body, core, lower body). The intervention consisted of three components, an initial computerized assessment to tailor recommendations for behavioural targets, weekly Web-based learning activities, and individualized feedback on their progress. Intervention participants met at the study office with a "case manager" to orient them to the web site. Participants completed a computerized assessment of five dietary and physical activity behaviours and set goals for each. Based on these results, participants set an initial goal in each area representing a small improvement over the baseline assessment. The intervention focused on making small, incremental improvements over time. Participants were allowed to choose what behaviours to work on each week. Participants were encouraged, but not required, to take a printed copy of their goals to their health care provider and to discuss their goals and importance of weight loss. Over the next 12 months, participants completed weekly Web-based activities, including learning about and applying theoretically derived behaviour change skills and reading about diet and physical activity topics. The web site included skill-building tools and physical activity and nutrition information and tips; a goal setting and reporting page where goals could be set on the target behaviours; progress graphs for each of the five behaviours; and relevant news stories that rotated every few weeks. Personalized graphical feedback was provided weekly and displayed improvements and instances where behaviours fell below previously attained levels. Finally, participants had an opportunity to e-mail a question to our study experts (dietitian, physical activity expert, clinical psychologist), and selected questions and answers would be posted on the web site for all to see. Intervention men were given pedometers (Yamax Digiwalker) to assist in self-monitoring daily steps and were encouraged to input the data on the web site to assist with goal setting. Men also reported minutes spent in physical activities not measurable by a pedometer (e.g., swimming, cycling, and activities in settings such as gyms) enabling manual entry of activities unlinked to actual step counts. The web site converted activity reports to an equivalent number of steps using an energy expenditure algorithm developed for this intervention, based upon standard energy expenditure values [41]. Finally, the case manager had occasional e-mail, and, if necessary, telephone contact	

<table>
<tr><td></td><td>with participants to facilitate interaction with the web site and troubleshoot technical difficulties. These calls did not involve weight-related counselling as the intent was to keep costs low and test an eHealth intervention."</td></tr>
<tr><td>Control/Comparator</td><td>"The wait-list control condition were given access to an alternate website containing general health information of interest to men but not likely to lead to changes in diet or physical activity behaviours (e.g., information on stress, hair loss, worksite injury prevention)."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 441
Intervention group/s: Weight loss intervention (n=224)

Comparator group: Wait-list control (n=217)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 44.9 (7.8); Control: 42.8 (8.0)</td></tr>
<tr><td>Sex</td><td>100.00% male</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)

Body weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Weight loss intervention: 34.2
(4.2)

Weight loss intervention:
104.7
(15.3)

Weight loss intervention:
113.7
(11)</td><td>Wait-list control: 34.3
(4)

Wait-list control: 104.6
(15.3)

Wait-list control: 112.9
(11.1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)

Body weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Weight loss intervention: 33.8
(4.5)

Weight loss intervention:
103.8
(16.1)

Weight loss intervention:
112.1
(11.8)</td><td>Wait-list control: 34.2
(4.2)

Wait-list control: 104.4
(15.4)

Wait-list control: 111.6
(11.6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<table>
<tr><td>12 months or closest time point</td><td></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Patrick, 2013

Guideline record ID: 10543--1

Study characteristics		
Citation	Patrick, K., Norman, G. J., Davila, E. P., Calfas, K. J., Raab, F., Gottschalk, M., Sallis, J. F., Godbole, S., & Covin, J. R. (2013). Outcomes of a 12-month technology-based intervention to promote weight loss in adolescents at risk for type 2 diabetes. Journal of Diabetes Science and Technology, 7(3), 759-770. http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med10&NEWS=N&AN=23759410	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Outcomes of a 12-month technology-based intervention to promote weight loss in adolescents at risk for type 2 diabetes	
Location	USA	
Trial name	Pace-Internet for Diabetes Prevention Intervention (PACEi-DP)	
Methods		
Inclusion criteria	"Eligible adolescents were between the ages of 12 and 16 years and at "high risk" for diabetes, as defined by the American Diabetes Association expert consensus panel,16 i.e., overweight [body mass index (BMI) > 85th percentile for age and sex, weight and height >85th percentile, or weight >120% of ideal for height] plus any two of the following risk factors: family history of T2DM in a first- or second-degree relative, race/ethnicity (American Indian, African-American, Hispanic, Asian/Pacific Islander), or signs of insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, polycystic ovary syndrome). Other inclusion criteria for both teens and parents included access to the Internet at home, work, or school for both parent and teen; having a functioning telephone; ability to speak and read English (for adolescent) or English or Spanish (for the parent); and willingness to participate in online activities and attend monthly group sessions."	
Exclusion criteria	"Had a diagnosis of diabetes, were pregnant, were not planning to be in the San Diego area over the entire study period, or had any medical condition that would prevent them from participating in the intervention."	
Setting	Hospital, Home	
Intervention	"The W arm included individual case management that included weekly "check-in" emails, monthly mailed tip sheets, and access to the program website and its web tutorials. The purpose of the weekly emails was to remind the participants to complete the web tutorials. If participants did not log on to the web program, they received repeated reminders via email and, if necessary, a phone call from a health counselor. The WG arm consisted of access to the program website and its web tutorials, monthly mailed tip sheets, and monthly 90 min group sessions of 5-10 adolescents and their parents where they discussed the behavioral skills from the web tutorials. Participants in this condition also received brief (~20 min) bimonthly phone calls from the health counselor reviewing concepts presented in the web tutorial and reinforcing behavioral strategies such as goal setting and problem solving of barriers/solutions. Attendance and participation in the group sessions were rewarded with mileage incentives and a lottery for prizes such as cookbooks or other materials to assist with healthy behavior change. Nutrition demonstrations and physical activities were also integrated in each group session. The WSMS arm included the program website and its web tutorials, monthly mailed tip sheets, and a minimum of three text messages per week that related to weekly challenges and intervention goals. Reminder text messages were sent if the participant did not log on to the website by the fourth day of the intervention. Participants could also communicate via text messages with a health counselor if they had questions. Participants were provided with cell phones and prepaid text message plans that allowed research staff to monitor SMS use."	

<table>
<tr><td>Control/Comparator</td><td>“Participants in the UC arm were given printed materials produced by the American Diabetes Association and the American Heart Association. Participants were encouraged to attend three 1 h group nutrition sessions at Rady Children's Hospital of San Diego during the first 6 weeks at no charge. They also received monthly tip sheets by mail. This combination of intervention elements reflected the prevailing community standard of care for adolescents judged to be at risk for T2DM.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 101
Intervention group/s: W (n=26); WSMS (n=24); WG (n=26)

Comparator group: UC (n=25)</td></tr>
<tr><td>Mean age ± SD</td><td>14.3y (1.5)</td></tr>
<tr><td>Sex</td><td>63.37% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI z-score
Mean (SE)</td><td>W: 2.2
(0.07)
WSMS: 2.2
(0.07)
WG: 2.2
(0.07)</td><td>UC: 2.2
(0.07)</td></tr>
<tr><td>BMI percentile
Mean (SE)</td><td>W: 98.1
(0.01)
WSMS: 97.9
(0.01)
WG: 97.8
(0.01)</td><td>UC: 98.1
(0.01)</td></tr>
<tr><td>Percentage body fat
Mean (SE)</td><td>W: 46.2
(1.21)
WSMS: 44.6
(1.25)
WG: 46
(1.21)</td><td>UC: 46.1
(1.23)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI z-score
Mean (SE)</td><td>W: 2.1
(0.09)
WSMS: 2.1
(0.09)
WG: 2
(0.09)</td><td>UC: 2.2
(0.09)</td></tr>
<tr><td>BMI percentile
Mean (SE)</td><td>W: 97.2
(0.01)</td><td>UC: 97.2
(0.01)</td></tr>
</table>
</td></tr>
</table>

	Percentage body fat Mean (SE)	WSMS: 97.1 (0.01) WG: 97.5 (0.01) W: 43.5 (1.61) WG: 42.6 (1.66) WG: 45.3 (1.67)	UC: 45.6 (1.43)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	63%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Paul, 2022

Guideline record ID: 10544

Study characteristics		
Citation	Paul, L., van der Heiden, C., van Hoeken, D., Deen, M., Vlijm, A., Klaassen, R., Biter, L. U., & Hoek, H. W. (2022). Three- and five-year follow-up results of a randomized controlled trial on the effects of cognitive behavioral therapy before bariatric surgery. International Journal of Eating Disorders, 55(12), 1824-1837. https://doi.org/https://dx.doi.org/10.1002/eat.23825	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Three- and five-year follow-up results of a randomized controlled trial on the effects of cognitive behavioral therapy before bariatric surgery	
Location	Netherlands	
Trial name	N/A	
Methods		
Inclusion criteria	"Patients who had passed preoperative screening for bariatric surgery in one of the hospitals were informed about the study and invited to participate. The following inclusion criteria were used: (1) having successfully passed preoperative screening and on the waiting list for bariatric surgery in one of the hospitals and (2) aged between 21 and 65 years."	
Exclusion criteria	"Exclusion criteria were: (1) current treatment by a psychologist, psychiatrist, or dietitian; (2) current bipolar or psychotic disorder, suicidality, or substance abuse; (3) insufficient fluency in Dutch; or (4) taking part in another study on bariatric surgery and weight outcomes."	
Setting	Hospital	
Intervention	"Patients in the CBT intervention group additionally received 10 individual, weekly, face-to-face sessions of CBT of 45 min duration at PsyQ. In those incidental cases where bariatric surgery was planned less than 10 weeks after the start of the CBT intervention, two CBT sessions a week were planned in order to complete the intervention before the surgery. During the intervention phase of the study, between T0 and T1, psychiatric medication was not changed in either group. There were no costs involved for individual patients. Therapy costs were covered by patients' health insurance and travel expenses were fully reimbursed. The CBT intervention focused on reducing problematic eating behaviors, improving lifestyle regarding physical activity and eating, and psychological functioning, as well as preparing for the postsurgery period"	
Control/Comparator	"In the TAU control group patients only received the regular preparation procedure for bariatric surgery in the hospitals, consisting of a mandatory informative group meeting and a detailed information booklet on the bariatric surgery procedure."	
Treatment duration	10 weeks	
Follow-up from baseline	5 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 130 Intervention group/s: CBT (n=65) Comparator group: Control (n=65)	

<table>
<tr><td>Mean age ± SD</td><td>41.4y (9.8)</td></tr>
<tr><td>Sex</td><td>74.62% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>CBT: 42.7
(5)</td><td>Control: 43.4
(5.4)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>CBT: 29.2
(4.6)</td><td>Control: 30.1
(4.7)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>CBT: 30.6
(5.2)</td><td>Control: 31.5
(5.4)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% Total weight loss
Mean (SD)</td><td>CBT: -31.4
(7.7)</td><td>Control: 30.7
(7.3)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% Total weight loss
Mean (SD)</td><td>CBT: 27.3
(9.9)</td><td>Control: 26.5
(10)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>CBT group (83%) completed 8-10 sessions, with a mean number of 8.5 completed sessions for the whole group.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Pavic, 2019

Guideline record ID: 10546--1

Study characteristics		
Citation	Pavić, E., Hadžiabdić, M. O., Mucalo, I., Martinis, I., Romić, Ž., Božikov, V., & Rahelić, D. (2019). Effect of the Mediterranean diet in combination with exercise on metabolic syndrome parameters: 1-year randomized controlled trial. International Journal for Vitamin and Nutrition Research, 89(3-4), 132-143. https://doi.org/https://dx.doi.org/10.1024/0300-9831/a000462	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of the Mediterranean diet in combination with exercise on metabolic syndrome parameters: 1-year randomized controlled trial	
Location	Croatia	
Trial name	N/A	
Methods		
Inclusion criteria	"Obese individuals (BMI > 30 kg/m2) recruited from the outpatient clinic of a University hospital; aged 18-69 years old."	
Exclusion criteria	"Newly diagnosed diabetes, hypertension or cardiovascular disease, or change in antihypertensive and oral antidiabetic therapy in the period of 3 months prior to the commencement of the study, insulin use, abuse of alcohol or drugs, pregnancy or lactation and use of drugs affecting weight control."	
Setting	Hospital	
Intervention	"The overall goal of the weight loss intervention program was to attain a weight loss of ≥5 % of baseline patient weight, as well as to reduce the remaining CVD risk factors (blood pressure, lipid profile, glucose level) by introducing two healthy eating patterns. The intervention aimed to encourage patients to increase their physical activity and to reduce their calorie intake by normalizing their eating habits. The 12-month structured interdisciplinary weight loss program involved group and individual therapies including nutritional education, physical activity and exercise, and standard behaviour modification techniques. Physical activity topics included information about the energy expenditure associated with various activities and choosing the right type of exercise depending on their capabilities. The physical exercise consisted of minimum 30 min walking in a group during the 5-day Daily hospital period and patients were advised to continue with that activity throughout the 12-month weight loss program. Participants were prescribed an individualized exercise program based on their history of physical activity and their physical condition. Since many patients had musculoskeletal problems, physiotherapists who designed safe and appropriate activities were included in the team. Each patient underwent a 30 minute session with a physiotherapist where they were demonstrated a set of techniques and exercises to help them achieve maximum mobility. The nutritional education was provided by clinical dieticians during an intensive five-day educational program in group sessions and at each follow-up session individually. It included lectures and practical application exercises in the areas of diet eating behaviour, breakfast and lunch consummation, and precise cooking instructions. Emotional feelings towards obesity and their lifestyle were also tackled within group sessions. Following group sessions, participants had the possibility of individual consultations with any of the members of the multidisciplinary team comprising endocrinologists, clinical pharmacists, clinical dieticians, physiotherapists, and nurses. The MD consisted of vegetables (2-3 servings/day), fresh fruits (3 servings/day), whole grains (e.g., non-refined cereals, whole-grain bread, pasta etc.), non-fat or low-fat dairy products (1-2 servings/day). It was low in red meat, with poultry and fish (3-4 servings/week) replacing pork, beef and lamb. Energy intake was restricted to an average of 1573 kcal/day (Table 1). Patients consuming the MD were	

	provided with extra virgin olive oil at the study entry and were explained they needed to consume 3-4 portions of fish per week, a handful of nuts per day (56 g/week) and 2 tablespoons (corresponding to 30 ml) of extra virgin olive oil per day."
Control/Comparator	"The overall goal of the weight loss intervention program was to attain a weight loss of ≥5 % of baseline patient weight, as well as to reduce the remaining CVD risk factors (blood pressure, lipid profile, glucose level) by introducing two healthy eating patterns. The intervention aimed to encourage patients to increase their physical activity and to reduce their calorie intake by normalizing their eating habits. The 12-month structured interdisciplinary weight loss program involved group and individual therapies including nutritional education, physical activity and exercise, and standard behaviour modification techniques. Physical activity topics included information about the energy expenditure associated with various activities and choosing the right type of exercise depending on their capabilities. The physical exercise consisted of minimum 30 min walking in a group during the 5-day Daily hospital period and patients were advised to continue with that activity throughout the 12-month weight loss program. Participants were prescribed an individualized exercise program based on their history of physical activity and their physical condition. Since many patients had musculoskeletal problems, physiotherapists who designed safe and appropriate activities were included in the team. Each patient underwent a 30 minute session with a physiotherapist where they were demonstrated a set of techniques and exercises to help them achieve maximum mobility. The nutritional education was provided by clinical dieticians during an intensive five-day educational program in group sessions and at each follow-up session individually. It included lectures and practical application exercises in the areas of diet eating behaviour, breakfast and lunch consummation, and precise cooking instructions. Emotional feelings towards obesity and their lifestyle were also tackled within group sessions. Following group sessions, participants had the possibility of individual consultations with any of the members of the multidisciplinary team comprising endocrinologists, clinical pharmacists, clinical dieticians, physiotherapists, and nurses. The SHD diabetic diet based on Dubrava University Hospital guidelines, SHD, was rich in whole grains, fruit (3 servings/day), vegetables (2-3 servings/day) and restricted additional fats, sweets and high-fat snacks with energy intake limited to 1287 kcal/day. Recommended intake of non-fat or low-fat dairy products (1-2 servings/day) and legumes (4 servings/week) was equivalent for both diets. Participants assigned to the SHD were not specifically advised to consume fish, but if fish was a part of their regular diet they were encouraged to continue with this eating pattern, albeit not more than once weekly."
Treatment duration	12 months
Follow-up from baseline	12 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 124 Intervention group/s: Mediterranean diet (MD) (n=63) Comparator group: Standard hypolipemic diet (SHD) (n=61)
Mean age ± SD	Intervention: 46.2 (12.7); Control: 49.0 (12.1)
Sex	74.19% female
Pre-existing medical condition	No pre-existing medical condition
Results	

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)

Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Mediterranean diet (MD): 40.6
(6.74)

Mediterranean diet (MD):
112.7
(19.47)

Mediterranean diet (MD): 121
(12.63)</td><td>Standard hypolipemic diet
(SHD): 40.41
(6.41)

Standard hypolipemic diet
(SHD): 111.5
(21.3)

Standard hypolipemic diet
(SHD): 118.9
(15.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)

Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Mediterranean diet (MD): 37.5
(6.74)

Mediterranean diet (MD):
103.7
(17.81)

Mediterranean diet (MD):
113.2
(13.27)</td><td>Standard hypolipemic diet
(SHD): 38.4
(6.18)

Standard hypolipemic diet
(SHD): 106.1
(21.93)

Standard hypolipemic diet
(SHD): 113.4
(15.58)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in BMI
Mean (SD)

Change in body weight (kg)
Mean (SD)

Change in Waist
Circumference (cm)
Mean (SD)</td><td>Mediterranean diet (MD): -3
(3.2)

Mediterranean diet (MD): 8.7
(9.6)

Mediterranean diet (MD): 7.7
(7.3)</td><td>Standard hypolipemic diet
(SHD): 1.8
(2.9)

Standard hypolipemic diet
(SHD): 4.9
(8.1)

Standard hypolipemic diet
(SHD): 5.1
(6.6)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Data reported for each dietary component. See tables.</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Pearl, 2020

Guideline record ID: 10547

Study characteristics		
Citation	Pearl, R. L., Wadden, T. A., Bach, C., Tronieri, J. S., & Berkowitz, R. I. (2020). Six-month follow-up from a randomized controlled trial of the Weight BIAS program. Obesity, 28(10), 1878-1888. https://doi.org/https://dx.doi.org/10.1002/oby.22931	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Six-Month Follow-up from a Randomized Controlled Trial of the Weight BIAS Program	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Participants were men and women, ages 18-65 years old, who were seeking weight loss and had obesity (body mass index [BMI] ≥ 30kg/m2). Participants were eligible if they reported a history of experiencing weight bias (e.g., teasing/bullying, discrimination, or other unfair treatment due to weight) and showed elevated levels of WBI, as indicated by a score of 4.0 or greater on the Weight Bias Internalization Scale. Applicants had to confirm in an in-person interview, conducted by a psychologist, that their weight negatively affected how they felt about themselves. Participants taking anti-depressant medication that did not affect weight were eligible if the dose had been stable for at least 3 months."	
Exclusion criteria	"Type 1 or 2 diabetes; uncontrolled hypertension (blood pressure ≥160/100 mm Hg); a cardiovascular event (e.g., stroke, myocardial infarction) in the past year; any major active kidney, liver, cardiovascular, or cerebrovascular disease; loss of ≥5% of initial weight in the past 6 months; use of medications that significantly affect weight; history of bariatric surgery; women who were nursing, pregnant, or planning to become pregnant; severe symptoms of mood (Beck Depression Inventory-II score ≥29, with clinician discretion), anxiety, or binge eating disorder (eight or more binge episodes per week), or any severity of bulimia nervosa or thought or substance use disorder; and current, active suicidal ideation and/or a suicide attempt within the past year. Participants were not eligible if they had participated in individual or group psychotherapy in the past 3 months (due to the potentially confounding effects of receiving a simultaneous cognitive-behavioral intervention), with the exception of participants receiving counseling for concerns unrelated to mood, self-esteem, or weight (e.g. career counseling or caregiver support)."	
Setting	N/A	
Intervention	"All participants attended 90-minute group meetings, which consisted of 11-13 participants and were led by a psychologist or registered dietitian at an academic weight management center. Participants received 12 weekly group sessions, followed by 2 every-other-week sessions and 2 monthly sessions (16 sessions over 26 weeks). Participants in both groups were provided with 60 minutes of BWL treatment, based on the Diabetes Prevention Program and LEARN Program. A goal of 1200-1499 kcal per day was prescribed for participants <250 lb and 1500-1800 kcal for those ≥250 lb. Participants were instructed to eat a balanced diet and to record their daily food and caloric intake. Weight was measured at every group session. Session topics during the first 12 weeks included self-monitoring, stimulus control, social support, portion sizes, and goal-setting. Group sessions during weeks 13-26 focused on skills required for weight loss maintenance and relapse prevention. Physical activity prescriptions began at week 2 and gradually progressed to a goal of 150 minutes per week by week 12 and 200-250 minutes per week by week 26. Moderate intensity was prescribed, with an emphasis on walking. At the end of treatment, participants were provided with referrals to other weight management programs for continued support with weight loss maintenance if desired. In the BWL+BIAS group, an additional 30 minutes each session (8 hours total) was devoted to stigma content. Content	

	was adapted from cognitive-behavioral therapy and "third-wave" therapies, such as dialectical behavior therapy and acceptance and commitment therapy. Session topics included: psychoeducation about weight and weight bias; challenging myths/stereotypes and cognitive distortions related to weight; the relationship between thoughts, feelings, and behaviors (with an emphasis on weight management behaviors); restructuring negative thoughts and reappraising stigmatizing situations; interpersonal effectiveness skills; increasing self-efficacy; reducing self-criticism; and increasing empowerment, self-compassion, and body and self-acceptance."
Control/Comparator	"All participants attended 90-minute group meetings, which consisted of 11-13 participants and were led by a psychologist or registered dietitian at an academic weight management center. Participants received 12 weekly group sessions, followed by 2 every-other-week sessions and 2 monthly sessions (16 sessions over 26 weeks). Participants in both groups were provided with 60 minutes of BWL treatment, based on the Diabetes Prevention Program and LEARN Program. A goal of 1200-1499 kcal per day was prescribed for participants <250 lb and 1500-1800 kcal for those ≥250 lb. Participants were instructed to eat a balanced diet and to record their daily food and caloric intake. Weight was measured at every group session. Session topics during the first 12 weeks included self-monitoring, stimulus control, social support, portion sizes, and goal-setting. Group sessions during weeks 13-26 focused on skills required for weight loss maintenance and relapse prevention. Physical activity prescriptions began at week 2 and gradually progressed to a goal of 150 minutes per week by week 12 and 200-250 minutes per week by week 26. Moderate intensity was prescribed, with an emphasis on walking. At the end of treatment, participants were provided with referrals to other weight management programs for continued support with weight loss maintenance if desired. In the standard BWL group, an additional 30 minutes was devoted each session to discussing recipes and food preparation, allowing for equal time spent in group sessions across conditions, without giving additional weight loss counseling to the standard BWL group."
Treatment duration	26 weeks
Follow-up from baseline	12 months
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 72 Intervention group/s: behavioral weight loss + Weight BIAS Program (BWL+BIAS) (n=36) Comparator group: Standard behavioral weight loss (BWL) (n=36)
Mean age ± SD	Overall: 47.1±11.5; Intervention: 47.7±11.4; Control: 46.6±11.8
Sex	84.72% female
Pre-existing medical condition	No pre-existing medical condition
Results	
Outcome measure at baseline	Variable | Intervention arm/s | Comparator
Outcome measure at 12 months or closest time point	Variable | Intervention arm/s | Comparator
Outcome measure at final follow-up/endpoint	Variable | Intervention arm/s | Comparator

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Percent Weight Change
Mean (SE)</td><td>Behavioral weight loss + Weight BIAS Program (BWL+BIAS): -3.1
(1)</td><td>Standard behavioral weight loss (BWL): -4
(1)</td></tr>
<tr><td>Change in Waist Circumference (cm)
Mean (SE)</td><td>Behavioral weight loss + Weight BIAS Program (BWL+BIAS): -4.4
(1)</td><td>Standard behavioral weight loss (BWL): -4.4
(1)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Pearl, 2023

Guideline record ID: 12023--1

Study characteristics		
Citation	Pearl, R. L., Wadden, T. A., Bach, C., LaFata, E. M., Gautam, S., Leonard, S., Berkowitz, R. I., Latner, J. D., & Jakicic, J. M. (2023). Long-term effects of an internalized weight stigma intervention: a randomized controlled trial. Journal of Consulting and Clinical Psychology, 91(7), 398-410. https://doi.org/https://doi.org/10.1037/ccp0000819	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-term effects of an internalized weight stigma intervention: A randomized controlled trial	
Location	USA	
Trial name		
Methods		
Inclusion criteria	"Participants were 105 treatment-seeking men and women, ages ≥18 years old, who had obesity, defined as a body mass index (BMI) ≥30 kg/m2, or with a BMI ≥ 27 kg/m2 with a health condition that confers CVD risk (National Institutes of Health, 2000). Eligible participants reported a history of experiencing weight bias (i.e., teasing/bullying, discrimination, or unfair treatment due to weight) and a high level of IWS, as defined by a score of 4.0 on the Weight Bias Internalization Scale (WBIS; Durso & Latner, 2008; described below) and confirmed by interview. Eligible participants were under the care of a primary care physician and, if taking medications, were on a stable dose for the prior 3 months. Participants were eligible to participate if they exhibited mild to moderate severity of depression, anxiety, or binge eating disorder, because elevated WBIS scores are associated with these conditions."	
Exclusion criteria	"Exclusion criteria included: Type 1 or 2 diabetes; uncontrolled hypertension (blood pressure ≥160/100 mm Hg); a cardiovascular event (e.g., stroke, myocardial infarction) in the past year; loss of ≥5% of initial weight in the past 3 months or ≥10% in the past 2 years; participation in psychotherapy related to weight in the last 3 months; severe symptoms of depression, anxiety, or binge eating disorder, or any severity of bulimia nervosa or thought or substance use disorder; or current, active suicidal ideation and/or a suicide attempt in the past year. Participants were excluded if they were taking medications known to significantly affect weight, reported a history of bariatric surgery, or reported obtaining ≥150 min of structured physical activity per week. Women who were nursing, pregnant, or planning to become pregnant in the next 16 months were not eligible to participate due to contraindications for weight loss."	
Setting	Not reported	
Intervention	"All participants attended 90-min group meetings, led by a clinical psychologist, postdoctoral psychology fellow, or registered dietitian. Each group included 8-12 participants. Participants received 20 weekly group sessions, followed by six monthly sessions and three every-other-month sessions (total of 29 sessions over 72 weeks). This length of treatment is consistent with recommendations for long-term weight loss treatment (Perri et al., 2014). Participants who missed group meeting were offered a brief make-up session with the group leader or study staff member, held in person or by phone. For the first 20 weeks of the intervention, participants were given the opportunity to meet with their group leader for up to three brief individual sessions if they did not lose at least 1% of their body weight in the first 4 weeks, reported difficulty controlling their eating, or described other challenges that prevented them from adhering to the program which could not be fully addressed during group sessions. Interventionists were certified by the principal investigator, and treatment fidelity was confirmed at Weeks 3, 6, and 11 through observation and completion of structured evaluations (i.e., the percentage of key points in	

	the session covered satisfactorily by the interventionist was computed and averaged across sessions). All participants were provided with behavioral weight loss (BWL treatment), based on the Diabetes Prevention Program and LEARN manuals (Brownell, 2004; Diabetes Prevention Program Research Group, 2002). Participants were recommended to consume 1,200-1,500 calories per day if their weight was 250 min per week by week 72, based on recommendations for long-term weight loss maintenance (Jakicic et al., 2008). Participants were encouraged to engage in structured physical activity for a minimum of 10 min bouts across at least 5 days per week, with an emphasis on moderate intensity exercises (e.g., brisk walking). Lifestyle activity was also encouraged in order to reduce sedentary time and increase daily step counts. For the first 4 weeks, the full 90 min of group meetings were devoted to BWL content. This first month of treatment was used to introduce participants to core BWL skills (e.g., self-monitoring) and allow time for initial changes to lifestyle habits before introducing new content. Beginning at Week 5, 60 min of the group sessions were dedicated to BWL content, and the remaining 30 min were devoted to the Weight BIAS Program (BWL + BIAS group. Weight BIAS Program Session topics were based on those tested in previous pilot research (Pearl et al., 2018; Pearl, Wadden, Bach, Gruber, et al., 2020) including psychoeducation about weight and weight stigma; challenging myths and cognitive distortions related to weight; identifying links between stigma-related thoughts, feelings, and behaviors; coping with instances of stigma; interpersonal effectiveness skills to ask others to stop stigmatizing; boosting self-efficacy; reducing self-criticism; and increasing empowerment, self-compassion, body esteem, and self-acceptance (see Pearl et al., 2022, for a detailed description of session content). Participants learned how weight stigma may impact health behaviors relevant to weight management, with a focus on overcoming stigma-related barriers to physical activity."
Control/Comparator	"All participants attended 90-min group meetings, led by a clinical psychologist, postdoctoral psychology fellow, or registered dietitian. Each group included 8-12 participants. Participants received 20 weekly group sessions, followed by six monthly sessions and three every-other-month sessions (total of 29 sessions over 72 weeks). This length of treatment is consistent with recommendations for long-term weight loss treatment (Perri et al., 2014). Participants who missed group meeting were offered a brief make-up session with the group leader or study staff member, held in person or by phone. For the first 20 weeks of the intervention, participants were given the opportunity to meet with their group leader for up to three brief individual sessions if they did not lose at least 1% of their body weight in the first 4 weeks, reported difficulty controlling their eating, or described other challenges that prevented them from adhering to the program which could not be fully addressed during group sessions. Interventionists were certified by the principal investigator, and treatment fidelity was confirmed at Weeks 3, 6, and 11 through observation and completion of structured evaluations (i.e., the percentage of key points in the session covered satisfactorily by the interventionist was computed and averaged across sessions). All participants were provided with behavioral weight loss (BWL treatment), based on the Diabetes Prevention Program and LEARN manuals (Brownell, 2004; Diabetes Prevention Program Research Group, 2002). Participants were recommended to consume 1,200-1,500 calories per day if their weight was 250 min per week by week 72, based on recommendations for long-term weight loss maintenance (Jakicic et al., 2008). Participants were encouraged to engage in structured physical activity for a minimum of 10 min bouts across at least 5 days per week, with an emphasis on moderate intensity exercises (e.g., brisk walking). Lifestyle activity was also encouraged in order to reduce sedentary time and increase daily step counts. For the first 4 weeks, the full 90 min of group meetings were devoted to BWL content. This first month of treatment was used to introduce participants to core BWL skills (e.g., self-monitoring) and allow time for initial changes to lifestyle habits before introducing new content. Beginning at Week 5, 60 min of the group sessions were dedicated to BWL content, and the remaining 30 min were devoted to engaging in a recipe exchange that included discussion of healthy recipes and food preparation tips (BWL group). This recipe exchange (an inactive treatment component) served to time match the groups without providing additional weight loss counseling to the BWL group."
Treatment duration	20 weeks

<table>
<tr><td>Follow-up from baseline</td><td>72 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 105
Intervention group/s: BWL+BIAS (n=52)

Comparator group: BWL (n=53)</td></tr>
<tr><td>Mean age ± SD</td><td>49.06y (12.40)</td></tr>
<tr><td>Sex</td><td>90.48% female</td></tr>
<tr><td>Pre-existing medical condition</td><td></td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Percentage of participants with weight loss of 5% or more
Proportion (%)

Percentage of participants with weight loss of 10% or more
Proportion (%)</td><td>BWL+BIAS: 38.5%

BWL+BIAS: 26.9%</td><td>BWL: 39.60%

BWL: 13.20%</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% weight change
Mean (SE)

Waist circumference (cm)
Mean (SE)</td><td>BWL+BIAS: -7.2

BWL+BIAS: -6.05
(1.29)</td><td>BWL: -5.2

BWL: -3.93
(1.32)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Total average session attendance was 73.8%, which included attendance of an average of 18.1 of 29 group sessions, plus an average of 3.3 makeup sessions (total attendance of 21.4 sessions). Attendance did not significantly differ by treatment condition (BWL + BIAS = 74.1%, BWL = 73.5%, p = .92). Interventionists had an average treatment fidelity rating of 99.4%.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Pedersen, 2014

Guideline record ID: 10550--1

Study characteristics		
Citation	Pedersen, E., Jesudason, D. R., & Clifton, P. M. (2014). High protein weight loss diets in obese subjects with type 2 diabetes mellitus. Nutrition, Metabolism & Cardiovascular Diseases, 24(5), 554-562. https://doi.org/10.1016/j.numecd.2013.11.003	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	High protein weight loss diets in obese subjects with type 2 diabetes mellitus	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	"Overweight or obese (BMI 27 kg/m2), participants with type 2 diabetes aged 18e75 years, with albuminuria (30e600 mg/24 h or an albumin to creatinine ratio of 3.0e60.0 mg/mmol, with an estimated glomerular filtration rate (eGFR) of >40 ml/min/1.73 m2) were included."	
Exclusion criteria	"Participants were excluded if they had impaired kidney function not due to diabetes."	
Setting	University/research centre	
Intervention	"A high protein diet (HPD) The planned protein:fat:carbohydrate ratio was 30:30:40% total energy (TE) for the HPD. The planned range of protein intake was 90e120 g/day in the HPD. Saturated fat intake was around 10%TE. All other nutrients were similar. Both diet regimes aimed at reducing body weight with energy content reduced to 6000 kJ. Alcohol was limited to 2 standard drinks per week (4g or 2%TE). Fibre intake was high in both diet plans (31g/day in HPD and 36g/day in SPD)."	
Control/Comparator	"Standard protein diet (SPD) The planned protein:fat:carbohydrate ratio was 20:30:50 %TE for the SPD. The planned range of protein intake was 55e70 g/day in the SPD. Saturated fat intake was around 10%TE. All other nutrients were similar. Both diet regimes aimed at reducing body weight with energy content reduced to 6000 kJ. Alcohol was limited to 2 standard drinks per week (4g or 2%TE). Fibre intake was high in both diet plans (31g/day in HPD and 36g/day in SPD)."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 64 Intervention group/s: HPD (n=31) Comparator group: SPD (n=33)	
Mean age ± SD	Intervention: 59.4y (2.2); Control: 62.4y (1.7)	
Sex	31.25% female	
Pre-existing medical condition	Type 2 diabetes	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SE)

BMI
Mean (SE)</td><td>HPD: 104.3
(3.9)

HPD: 36
(1.1)</td><td>SPD: 104.5
(3.2)

SPD: 35
(0.8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SE)

BMI
Mean (SE)</td><td>HPD: 96.5
(3.5)

HPD: 34
(1.1)</td><td>SPD: 98.8
(3.2)

SPD: 34
(0.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Total weight lost, kg
Mean (SE)

% body weight lost
Mean % (range)</td><td>HPD: -9.7
(2.9)

HPD: 8.7
(-34.7-5.5)</td><td>SPD: 6.6
(1.4)

SPD: 6.3
(-17.3-4)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Dietary compliance - At baseline urea excretion did not differ significantly between groups (496 31 and 521 32 mmol/24 h in HPD and SPD respectively; p Z 0.41). At 12 months the UUE was not significantly different compared to baseline (p Z 0.13), however the adjusted urea excretion at 12 months was significantly different between groups (519 39, for the HPD and 456 25 for the SPD group; p Z 0.04) indicating compliance to the protein prescription</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Pedersen, 2019

Guideline record ID: 10551--1

Study characteristics		
Citation	Pedersen, L. R., Olsen, R. H., Anholm, C., Astrup, A., Eugen-Olsen, J., Fenger, M., Simonsen, L., Walzem, R. L., Haugaard, S. B., & Prescott, E. (2019). Effects of 1 year of exercise training versus combined exercise training and weight loss on body composition, low-grade inflammation and lipids in overweight patients with coronary artery disease: a randomized trial. Cardiovascular Diabetology, 18, 127. https://doi.org/https://dx.doi.org/10.1186/s12933-019-0934-x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of 1 year of exercise training versus combined exercise training and weight loss on body composition, low-grade inflammation and lipids in overweight patients with coronary artery disease: a randomized trial	
Location	Denmark	
Trial name	N/A	
Methods		
Inclusion criteria	“Inclusion criteria were stable CAD diagnosed > 6 months prior to inclusion, age 45-75 years and BMI 28-40 kg/m2 .”	
Exclusion criteria	“Exclusion criteria were known diabetes or diabetes diagnosed at the screening visit, other severe heart disease (i.e. heart failure EF < 35%, severe or moderate valve disease, main stem stenosis and arrhythmias or ischaemia revealed by the cardiopulmonary exercise test and 2. or 3. degree AV block not protected by a pacemaker) or severe comorbidity (i.e. chronic pulmonary disease, active cancer or severe kidney failure). Furthermore, candidates who participated in organised sports more than twice weekly or had experienced a signifcant weight loss or gain (> 5%) more than 3 months prior to the screening visit were excluded.”	
Setting	Not reported	
Intervention	“LED+AIT: 8-10 weeks' LED (800-1000 kcal/day, the Cambridge Weight Plan, Northants, UK) followed by 2-4 weeks' transition to a maintenance diet to avoid examining the participants in a catabolic state. The last 40 weeks included the maintenance diet and AIT twice weekly. The maintenance diet was a low glycaemic load diet achieved by slightly higher protein content and focus on low glycaemic index carbohydrates as described in the DIOGenes study [34]. The LED and the maintenance diet were supervised by experienced dieticians. Each AIT exercise session was preceded by a 10-minute warm-up on stairs or an exercise bike followed by high intensity interval training on an exercise bike. The high intensity intervals (85-90% of VO2peak, Borg scale 17-18) lasted between 1 and 4 min, to achieve a total of 16 min, separated by active pauses (65-70% of VO2peak) of 1- and 3-min duration. The total duration of each training session was 48 min including the warm-up. Physiotherapists with experience in cardiac rehabilitation instructed the participants and supervised all training session. Training intensity was monitored with heart rate monitors and perceived exertion using the Borg Scale.”	
Control/Comparator	“AIT: 12 weeks' supervised AIT three times weekly followed by 40 weeks' AIT twice weekly. Each exercise session was preceded by a 10-minute warm-up on stairs or an exercise bike followed by high intensity interval training on an exercise bike. Te high intensity intervals (85-90% of VO2peak, Borg scale 17-18) lasted between 1 and 4 min, to achieve a total of 16 min, separated by active pauses (65-70% of VO2peak) of 1- and 3-min duration. Te total duration of each training session was 48 min including the warm-up. Physiotherapists with experience in cardiac rehabilitation instructed the participants and supervised all training	

<table>
<tr><td></td><td>session. Training intensity was monitored with heart rate monitors and perceived exertion using the Borg Scale.”</td></tr>
<tr><td>Treatment duration</td><td>52 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 55
Intervention group/s: LED+AIT (n=29)

Comparator group: AIT (n=26)</td></tr>
<tr><td>Mean age ± SD</td><td>63y (6.2)</td></tr>
<tr><td>Sex</td><td>29.09% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Coronary artery disease</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>LED+AIT: 95.6
(10.7)</td><td>AIT: 96.2
(13.8)</td></tr>
<tr><td>Body mass index (kg/m2)
Mean (SD)</td><td>LED+AIT: 32.2
(3.1)</td><td>AIT: 32.1
(3.2)</td></tr>
<tr><td>Body fat mass (kg)
Mean (SD)</td><td>LED+AIT: 34.6
(8)</td><td>AIT: 32.6
(7.6)</td></tr>
<tr><td>Body fat %
Mean (SD)</td><td>LED+AIT: 36.7
(6.8)</td><td>AIT: 34.6
(6.5)</td></tr>
<tr><td>Waist (cm)
Mean (SD)</td><td>LED+AIT: 107.7
(7.1)</td><td>AIT: 109.9
(9.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight
Mean (95% CIs)</td><td>LED+AIT: -7.2
(-8.4--6.1)</td><td>AIT: -1.7
(-2.6--0.7)</td></tr>
<tr><td>Change in BMI
Mean (95% CIs)</td><td>LED+AIT: -2.5
(-2.9--2.1)</td><td>AIT: -0.6
(-0.9--0.2)</td></tr>
<tr><td>Change in Body fat mass (kg)
Mean (95% CIs)</td><td>LED+AIT: -6.6
(-7.7--5.5)</td><td>AIT: -1.9
(-2.8--1)</td></tr>
<tr><td>Change in body fat (%)
Mean (95% CIs)</td><td>LED+AIT: -4.7
(-5.8--3.7)</td><td>AIT: -1.5
(-2.4--0.7)</td></tr>
<tr><td>Change in waist (cm)
Mean (95% CIs)</td><td>LED+AIT: -6.6
(-8.6--4.6)</td><td>AIT: -3.3
(-5.1--1.5)</td></tr>
</table>
</td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Pedrosa, 2011

Guideline record ID: 10553--1

Study characteristics		
Citation	Pedrosa, C., Oliveira, B. M. P. M., Albuquerque, I., Simões-Pereira, C., Vaz-de-Almeida, M. D., & Correia, F. (2011). Markers of metabolic syndrome in obese children before and after 1-year lifestyle intervention program. European Journal of Nutrition, 50(6), 391-400. https://doi.org/https://dx.doi.org/10.1007/s00394-010-0148-1	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Markers of metabolic syndrome in obese children before and after 1-year lifestyle intervention program	
Location	Portugal	
Trial name	N/A	
Methods		
Inclusion criteria	"Children classified as obese (C95th BMI percentile) according to the US Centers for Disease Control and Prevention (CDC)."	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"The children were randomly assigned to one of the two treatments: an individual conventional treatment (IT) or a group-based treatment (GT). Since GT implies more visits, and due to staff and space limitations, GT was assigned with probability 1/3 and IT with probability 2/3. The main objective of both interventions was to promote lifestyle changes in children and their families, and consequently to stop weight gain and promote weight loss. At baseline, anthropometric and biochemical measurements were carried out to all children.In GT, children and their parents participated in a group-based nutrition education program (4 children per group), which consisted of 4 consecutive sessions each of 60 min duration, conducted by a nutritionist. These sessions covered several topics regarding childhood obesity and comorbidities, healthy eating habits, healthy cooking methods, portion size control, food labeling and physical activity promotion. The acquired knowledge was reinforced at each session and whenever necessary at follow-up visits that were held at 3- and 6 months and 1 year after the first visit. Forty-two children at the IT and 19 at the GT completed the 1-year follow-up visit."	
Control/Comparator	"The children were randomly assigned to one of the two treatments: an individual conventional treatment (IT) or a group-based treatment (GT). Since GT implies more visits, and due to staff and space limitations, GT was assigned with probability 1/3 and IT with probability 2/3. The main objective of both interventions was to promote lifestyle changes in children and their families, and consequently to stop weight gain and promote weight loss. At baseline, anthropometric and biochemical measurements were carried out to all children. In IT, a healthy eating plan meeting nutrient needs according to the recommended daily allowance (&1,800 kcal) was prescribed and explained to children and their parents. The diet recommended the reduced intake of refined carbohydrates and saturated fats, with an increased consumption of vegetables and fruits. Additionally, physical activity was encouraged and sedentary behaviors, such as TV watching and computer/video game playing, were discouraged. Follow-up visits were held at 3- and 6 months and 1 year after the first visit."	
Treatment duration	1 month	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 61
Intervention group/s: GT (n=19)

Comparator group: IT (n=42)</td></tr>
<tr><td>Mean age ± SD</td><td>8.6y (0.7)</td></tr>
<tr><td>Sex</td><td>44.26% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

zBMI
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>GT: 40.7
(6.2)

GT: 22.3
(1.57)

GT: 1.86
(0.25)

GT: 70.9
(6)</td><td>IT: 42.6
(6.8)

IT: 23.23
(2.52)

IT: 1.96
(0.29)

IT: 73.6
(6.5)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

zBMI
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>GT: 43.9
(6.4)

GT: 22.14
(1.81)

GT: 1.61
(0.34)

GT: 71.6
(5.6)</td><td>IT: 46.5
(8)

IT: 23.39
(2.77)

IT: 1.78
(0.33)

IT: 74.9
(7.5)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Pekkarinen, 2015

Guideline record ID: 10555--1

Study characteristics		
Citation	Pekkarinen, T., Kaukua, J., & Mustajoki, P. (2015). Long-term weight maintenance after a 17-week weight loss intervention with or without a one-year maintenance program: a randomized controlled trial. Journal of Obesity, 2015, 651460. https://doi.org/https://dx.doi.org/10.1155/2015/651460	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-term weight maintenance after a 17-week weight loss intervention with or without a one-year maintenance program: a randomized controlled trial	
Location	Finland	
Trial name	N/A	
Methods		
Inclusion criteria	"The inclusion (BMI over 35 kg/m2, age 18- 65 years, and stable weight three months)."	
Exclusion criteria	"Exclusion criteria (contraindications to use VLCD, participating in the same treatment within five years, pregnancy, malignant disease, acute coronary event, current severe alcohol/narcotic abuse, or psychic problem/bulimia nervosa) were equal to the referral to our usual care. Contrary to usual care, visit to the endocrinologist was free (normal cost 30 EUR), group treatment was free (normal cost 120 EUR), and the patients received some VLCD for free (daily cost about 10 EUR)."	
Setting	Hospital, Home	
Intervention	"Group 2 A 17-week behavior modification program including a 10-week very-low-calorie diet (VLCD)followed by a one-year maintenance therapy with monthly meetings (Group 2). A 17-week behavior modification program including a 10-week very-low-calorie diet (VLCD) (Group 1) Seventeen-Week Weight Loss Program. This program was similar in both treatments. The interventionists used a Finnish manual based on the LEARN Programme for weight control. Of the 17 sessions, group coaches guided 15 (1,5 hour each for groups of 13-15 patients), one was guided by a physiotherapist at gym or with Nordic walking and one by a physician discussing medical issues. VLCD. The patients used VLCD (Nutrilett, Nutrifast, or Dietta Mini) as only diet during study weeks 2-11. These commercially available diets provide 52-58 g of protein, 52- 64 g of carbohydrates, 8-13 g of fat and daily requirements of vitamins, trace elements, and minerals, and daily energy intake of 2200-2340 kJ. A moderate amount of vegetables was allowed. During the first week the patients ate normal food and kept diary for self-monitoring. From the second week the VLCD started for ten weeks, followed by a two-week refeeding phase. The need to change previous energy intake and exercise habits after VLCD in order to maintain weight loss was emphasized. Each patient rather than therapist planned behavior modifications. Each session had one or two themes of behavior control, nutrition, or exercise with related homework. Themes included recording of eating and physical activity for self-monitoring, goal setting, regular weighing and regular meals, slowing down with eating, portion size, coping with overeating and eating impulses, importance of social support, lapses and relapse prevention, coping with risk situations, challenging negative thinking, problem solving, fat, fibre, sugar, and alcohol in diet, energy density of food, and energy expenditure. Increase in physical activity (like walking) and in lifestyle activity (using stairs and increasing number of steps) was repeatedly discussed, and participants were advised to buy and use a pedometer to monitor the amount of steps. Towards the end, focus was set on the importance of continuous self-monitoring. Maintenance Program. The maintenance program was designed for this study. Each monthly session (1,5 hour) had one or two themes and related homework. The themes were monitoring eating, eating at regular times, control of eating impulses, fat and energy density in food, lifestyle activity	

<table>
<tr><td></td><td>and related energy expenditure, monitoring exercise and obstacles to increase exercise, importance of regular weighing, social support, body image changes, cooking/shopping together, lapses and relapses, problem solving, goal setting, and self-confidence. Two sessions were led by physiotherapist with Nordic walking or at gym.”</td></tr>
<tr><td>Control/Comparator</td><td>“Group 1 A 17-week behavior modification program including a 10-week very-low-calorie diet (VLCD) (Group 1) Seventeen-Week Weight Loss Program. This program was similar in both treatments. The interventionists used a Finnish manual based on the LEARN Programme for weight control. Of the 17 sessions, group coaches guided 15 (1,5 hour each for groups of 13-15 patients), one was guided by a physiotherapist at gym or with Nordic walking and one by a physician discussing medical issues. VLCD. The patients used VLCD (Nutrilett, Nutrifast, or Dietta Mini) as only diet during study weeks 2-11. These commercially available diets provide 52-58 g of protein, 52- 64 g of carbohydrates, 8-13 g of fat and daily requirements of vitamins, trace elements, and minerals, and daily energy intake of 2200-2340 kJ. A moderate amount of vegetables was allowed. During the first week the patients ate normal food and kept diary for self-monitoring. From the second week the VLCD started for ten weeks, followed by a two-week refeeding phase. The need to change previous energy intake and exercise habits after VLCD in order to maintain weight loss was emphasized. Each patient rather than therapist planned behavior modifications. Each session had one or two themes of behavior control, nutrition, or exercise with related homework. Themes included recording of eating and physical activity for self-monitoring, goal setting, regular weighing and regular meals, slowing down with eating, portion size, coping with overeating and eating impulses, importance of social support, lapses and relapse prevention, coping with risk situations, challenging negative thinking, problem solving, fat, fibre, sugar, and alcohol in diet, energy density of food, and energy expenditure. Increase in physical activity (like walking) and in lifestyle activity (using stairs and increasing number of steps) was repeatedly discussed, and participants were advised to buy and use a pedometer to monitor the amount of steps. Towards the end, focus was set on the importance of continuous self-monitoring.”</td></tr>
<tr><td>Treatment duration</td><td>69 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>121 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 199
Intervention group/s: Group 2 (n=100)
Comparator group: Group 1 (n=99)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 47.4y (10.1); Control: 47.3y (10.5)</td></tr>
<tr><td>Sex</td><td>71.36% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Group 2: 117.8
(22)

Group 2: 41.4
(6.4)</td><td>Group 1: 120.6
(23.5)

Group 1: 42.1
(5.7)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight
Mean (SD)

BMI (kg/m2)
Mean (SD)

Weight loss ≥5%
Proportion (%)</td><td>Group 2: 111.3
(23)

Group 2: 39
(6.9)

Group 2: 52</td><td>Group 1: 113.8
(25.9)

Group 1: 39.7
(6.9)

Group 1: 44</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight
Mean (SD)

BMI (kg/m2)
Mean (SD)

Weight loss ≥5%
Proportion (%)</td><td>Group 2: 114.4
(23.1)

Group 2: 40.1
(6.9)

Group 2: 33</td><td>Group 1: 116.6
(27.2)

Group 1: 40.7
(7.4)

Group 1: 34</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change % (95% CI)
Mean (95% CIs)</td><td>Group 2: -5.7
(-7.1--4.1)</td><td>Group 1: -5.8
(-7.4--4.4)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change % (95% CI)
Mean (95% CIs)</td><td>Group 2: -2.9
(-4.6--1.3)</td><td>Group 1: -3.5
(-5.2--1.8)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Together 148 patients completed the 17-week phase: 69 (70%) in Group 1 and 79 (79%) in Group 2.</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Perri, 2014

Guideline record ID: 10559

Study characteristics		
Citation	Perri, M. G., Limacher, M. C., von Castel-Roberts, K., Daniels, M. J., Durning, P. E., Janicke, D. M., Bobroff, L. B., Radcliff, T. A., Milsom, V. A., Kim, C., & Martin, A. D. (2014). Comparative effectiveness of three doses of weight-loss counseling: two-year findings from the rural LITE trial. Obesity, 22(11), 2293-2300. https://doi.org/10.1002/oby.20832	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Comparative effectiveness of three doses of weight-loss counseling: two-year findings from the rural LITE trial	
Location	USA	
Trial name	Rural LITE	
Methods		
Inclusion criteria	"21-75 years of age, with a body-mass index (BMI, kg/m2) 30 and 45. Eligible participants were free of uncontrolled hypertension and diabetes and had no active (within 12 months) manifestations of cardiovascular, cerebrovascular, renal, or hepatic disease."	
Exclusion criteria	"Use of medications known to affect body weight, a weight change 4.5 kg in the preceding six months, and musculoskeletal conditions that precluded walking for 30 min. Psychosocial contraindications included substance abuse and clinically significant depression."	
Setting	Home, Workplace	
Intervention	"Content of lifestyle treatment The contents of the lifestyle program employed in the LOW, MOD, and HIGH conditions were modeled after the Diabetes Prevention Program (DPP) (18,19) and included the following components: (a) a low-calorie eating pattern (1,200 kcal/day for participants weighing <114 kg, 1,500 kcal/day for those weighing 114-136 kg, and 1,800 kcal/day for those weighing >136 kg); (b) increased physical activity in the form of 30 min/day of walking above baseline levels; and (c) training in behavior modification strategies including goal setting, self-monitoring, stimulus control, cognitive restructuring, and problem solving. Modifications to the DPP approach included group rather than individual counseling (20) and home-based rather than center-based exercise (21). Also included were topics that pilot testing suggested were issues of special concern to residents of the rural community in Florida, such as cooking demonstrations to illustrate low-calorie preparation of Southern dishes and strategies for coping with a lack of family support for weight loss (12). Doses of lifestyle treatment The intervention content and the accompanying written materials provided to participants was the same for the LOW, MOD, and HIGH conditions, but the time available for discussion varied according to the dose of treatment. In each of the three lifestyle conditions, the program was delivered in two phases: Phase 1, initial weight-loss induction, and Phase 2, extended care. Phase 1 consisted of weekly sessions (8 for LOW, 16 for MOD, and 24 for HIGH). Phase 2 targeted maintenance of behavior change (22,23) and was conducted on a faded schedule, using a combination of scheduled telephone sessions and office-based "campaign sessions." Telephone sessions were used to reduce the travel burden for participants. Periodic campaigns (clusters of five weekly sessions) were employed to enhance motivation by setting specific weight-loss targets (e.g., 1.82 kg in one month) and providing motivational incentives (e.g., water bottles, caps, tee shirts, etc.) for the achievement of campaign objectives. Both the number of sessions allocated for extended care and the number of scheduled campaigns was carried out in proportion to the dosing schedules for the LOW, MOD, and HIGH conditions (i.e., 8, 16, and 24 extended care sessions, and 1, 2 and 3 campaigns, respectively)."	

<table>
<tr><td>Control/Comparator</td><td>“The nutrition education (CONTROL) condition served as a control for staff attention and for the delivery of appropriate information regarding proper diet and exercise for weight management. Each session included a lecture on a topic relevant to nutrition, physical activity, or weight control, followed by a group discussion of how the information was relevant to health and weight management. The information presented in the lectures was derived from resources available from US government agencies, including the National Institutes of Health (24) and the USDA (25). The schedule of sessions provided to participants in the CONTROL condition was identical to that of the LOW dose lifestyle condition.”</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 612
Intervention group/s: Low Dose (n=148); Moderate Dose (n=134); High Dose (n=161)

Comparator group: Control (n=169)</td></tr>
<tr><td>Mean age ± SD</td><td>52.3y (11.5)</td></tr>
<tr><td>Sex</td><td>78.27% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>Low Dose: 102
(16.6)
Moderate Dose: 98.6
(15.6)
High Dose: 101.6
(14.8)</td><td>Control: 100.1
(14.4)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Mean (95% CIs)</td><td>Low Dose: -3.5
(2-4.8)
Moderate Dose: -6.7
(5.3-7.9)
High Dose: 6.8
(5.5)</td><td>Control: 2.9
(1.7-4.3)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Phase 1: 83.8%; Phase 2: 53.1%</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Perry, 2016

Guideline record ID: 10560--1

Study characteristics		
Citation	Perry, C. D., Degeneffe, D., Davey, C., Kollannoor-Samuel, G., & Reicks, M. (2016). Weight gain prevention among midlife women: a randomized controlled trial to address needs related to the physical and social environment. International Journal of Environmental Research and Public Health, 13(6), 530. https://doi.org/https://dx.doi.org/10.3390/ijerph13060530	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight Gain Prevention among Midlife Women: A Randomized Controlled Trial to Address Needs Related to the Physical and Social Environment	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Women, aged 40-60 years; no history of chronic disease; no physician-prescribed diet and not pregnant or breastfeeding."	
Exclusion criteria	Not reported	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Women in the intervention group received ten hours of individualized counseling from a registered dietitian in 1-h sessions every two weeks over a 6-month period. Counseling was tailored to provide advice about healthful eating based on eating occasion needs based on the physical and social environment. All women attended a data collection session every six months over two years to have height, weight and waist circumference measurements recorded and to provide completed food record forms and other questionnaires. For these data collection sessions, women were asked to attend an individual session during a specific time in the morning before they ate breakfast (8:00-10:30 a.m.). Lesson Development and Implementation A previous segmentation study based on 5556 eating occasions from a national sample of 1663 midlife women (40-60 years) identified and described six distinct categories of needs for eating occasions. Descriptive names were assigned: healthy express, comforting interludes, indulgent escapes, nurturing family meals, sensible meals, and fast fueling. Health-oriented eating occasions (healthy express, comforting interludes, and sensible meals) were characterized by lower fat and higher fruit and whole grain intakes, whereas occasions with less-healthy needs (indulgent escapes, fast fueling, and nurturing family meals) were highest in fat intake, and higher in energy, refined grain, and sucrose intakes. The number of less-healthy eating occasions experienced was positively associated with BMI. The research team including five registered dietitians developed learning objectives and instructional activities for three lessons for each eating occasion need category by applying Social Cognitive Theory constructs. For example, food intake during "nurturing family meals" occasions may be influenced by social environmental needs to make dinner a family time with minimal complaints, and suppression of personal nutrition needs to meet food preferences of family members. In response, a lesson topic addressed the improvement of meal planning skills to include healthy foods the whole family liked, thus improving availability and accessibility of healthy foods for the participant. The lessons were interactive in nature, requiring participants to personalize content according to their physical and social environments and to complete goal-setting and progress-monitoring homework between lessons. Small, incremental, positive dietary changes were introduced and reinforced consistent with the small change approach recommended by others. The lessons were focused solely on improving eating behaviors and not on weight loss, weight maintenance or promotion of physical activity. The goal was to determine if addressing common needs related to	

<table>
<tr><td></td><td>environmental factors within eating occasions that contribute to less healthful dietary intakes could prevent weight gain over time. Registered dietitians conducted individualized counseling for women in the intervention group in homes, coffee shops or community locations in approximately 1-h sessions every two weeks for six months. The lessons were also personalized to each participant based on the most common needs they had within eating occasions, as determined by a classification tool designed for this study. The tool included a set of 20 statements to classify needs based on a previous study. Women selected strongly agree/strongly disagree responses to the 20 statements regarding usual eating occasions (meals and snacks) over the previous week. The items were based on (1) needs within the eating occasion: "I wanted to . . . " (e.g., "treat myself" or "connect with others/family") and (2) benefits sought in the food/beverages consumed: "I wanted something that . . . " (e.g., "is healthy to eat" or "is portable"). Values assigned to agree/disagree responses were entered into an algorithm to indicate the frequency with which women experienced the various needs within eating occasions."</td></tr>
<tr><td>Control/Comparator</td><td>"Women in the control group did not participate in counseling sessions. All women attended a data collection session every six months over two years to have height, weight and waist circumference measurements recorded and to provide completed food record forms and other questionnaires. For these data collection sessions, women were asked to attend an individual session during a specific time in the morning before they ate breakfast (8:00-10:30 a.m.)."</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 354
Intervention group/s: Intervention Group (n=185)

Comparator group: Control Group (n=169)</td></tr>
<tr><td>Mean age ± SD</td><td>50.1y (5.1)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI Category - BMI 25.0-29.9
Proportion (%)</td><td>Intervention Group: 29.9</td><td>Control Group: 35</td></tr>
<tr><td>BMI Category - BMI 30 and above
Proportion (%)</td><td>Intervention Group: 30.5</td><td>Control Group: 23.4</td></tr>
<tr><td>BMI (kg/m2)
Mean (SE)</td><td>Intervention Group: 28
(0.5)</td><td>Control Group: 27.5
(0.5)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SE)</td><td>Intervention Group: 85.4
(1)</td><td>Control Group: 83.7
(1)</td></tr>
<tr><td>Weight (kg)
Mean (SE)</td><td>Intervention Group: 76.6
(1.3)</td><td>Control Group: 74.2
(1.4)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI (kg/m2)
Mean (SE)

Waist circumference (cm)
Mean (SE)

Weight (kg)
Mean (SE)</td><td>Intervention Group: 27.9
(0.5)

Intervention Group: 85.2
(1)

Intervention Group: 76.5
(1.3)</td><td>Control Group: 27.6
(0.5)

Control Group: 83.6
(1)

Control Group: 74.4
(1.4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI (kg/m2)
Mean (SE)

Waist circumference (cm)
Mean (SE)

Weight (kg)
Mean (SE)</td><td>Intervention Group: 28.1
(0.5)

Intervention Group: 85.1
(1)

Intervention Group: 76.8
(1.3)</td><td>Control Group: 28.1
(0.5)

Control Group: 83.6
(1)

Control Group: 74.6
(1.4)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Phillips, 2017

Guideline record ID: 10573--1

Study characteristics		
Citation	Phillips, E. G., Wells, M. T., Winston, G., Ramos, R., Devine, C. M., Wethington, E., Peterson, J. C., Wansink, B., & Charlson, M. (2017). Innovative approaches to weight loss in a high-risk population: the small changes and lasting effects (SCALE) trial. Obesity, 25(5), 833-841. https://doi.org/10.1002/oby.21780	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Innovative approaches to weight loss in a high-risk population: The small changes and lasting effects (SCALE) trial	
Location	USA	
Trial name	Small Changes and Lasting Effects (SCALE)	
Methods		
Inclusion criteria	"Eligibility criteria included age 21 years, body mass index (BMI) 25 to 50 kg/m2, Black and/or Hispanic race/ethnicity, and fluency in English or Spanish."	
Exclusion criteria	"Exclusion criteria were pregnancy within the year, participating in another weight loss program, weight loss surgery within the year, untreated mental illness or thyroid disease, active cancer, active eating disorder, advanced chronic obstructive pulmonary disease, renal disease on dialysis, or the inability to control meal contents."	
Setting	University/research centre	
Intervention	"Control treatment + After goal setting, participants randomized to the PA/SA group were taught the PA/SA script. They were instructed to identify small things that made them feel good and asked to think about those things when they first woke up in the morning and throughout their day. For the self-affirmation component, participants were asked to think of a proud moment in their lives and to remember that moment when faced with barriers to their new behavior goals (17)."	
Control/Comparator	"At enrollment, participants identified their specific eating challenges. CHWs then guided participants in the selection of one of ten small change eating strategies to address these challenges. The 10 small change eating strategies were as follows: prepare the main meal at home, take time for meals, drink water instead of sweetened beverages, eat a fruit or vegetable before snacking, eat breakfast daily, make half the main meal vegetables, turn off the television during meals, stop buying snack foods, hide snacks in an inconvenient place, and eat main meals on a 10-inch plate (19). Participants also set self-selected physical activity goals (e.g., walk 20 min daily) and made a behavior contract to adhere to their goals at least 6 days per week. Followed for 1 year by trained community health workers (CHWs) at routine intervals (weekly for months 1-3; biweekly for months 4- 9; once monthly for months 10-12). Closeout interviews were conducted in person at 12 months."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 405 Intervention group/s: Intervention (n=284) Comparator group: Control (n=121)	

<table>
<tr><td>Mean age ± SD</td><td>Intervention: 49.1y (14.1); Control: 46.3y (14.4)</td></tr>
<tr><td>Sex</td><td>89.14% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intervention: 34.2
(6.2)</td><td>Control: 33.4
(5.7)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (%)
Mean (SD)</td><td>Intervention: -1.2
(4.3)</td><td>Control: -1.1
(4.6)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Pimentel, 2010

Guideline record ID: 10577

Study characteristics		
Citation	Pimentel, G. D., Portero-McLellan, K. C., Oliveira, É. P., Spada, A. P. M., Oshiiwa, M., Zemdegs, J. C. S., & Barbalho, S. M. (2010). Long-term nutrition education reduces several risk factors for type 2 diabetes mellitus in Brazilians with impaired glucose tolerance. Nutrition Research, 30(3), 186-190. https://doi.org/https://dx.doi.org/10.1016/j.nutres.2010.03.003	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-term nutrition education reduces several risk factors for type 2 diabetes mellitus in Brazilians with impaired glucose tolerance	
Location	Brazil	
Trial name	N/A	
Methods		
Inclusion criteria	"Impaired glucose tolerance and at least 1 other risk factor for DM2, that is, overweight or obesity (body mass index [BMI] N25 kg/m2), visceral adiposity (waist circumference ≥88 cm for women and ≥102 cm for men), family history of DM2, low serum high density lipoprotein cholesterol (HDL-c b50 mg/dL for women and b40 mg/dL for men), high serum triglycerides (TG; ≥150mg/dL), or a sedentary lifestyle (self-reported)."	
Exclusion criteria	"Participants who had DM2."	
Setting	Not reported	
Intervention	"The intervention group, which underwent the NEP, Participants in the intervention group received individual and group counseling with a team of nutritionists. The dietary intervention consisted of discussion-format group sessions that took place twice per month and individual sessions that took place once per month. The intervention included written and oral didactic instructions to improve diet quality, for example, consumption of more vegetables, fruits, whole grains, and less saturated fatty acids."	
Control/Comparator	"The control group did not receive nutritional education."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 67 Intervention group/s: Intervention group (n=24) Comparator group: Control group (n=43)	
Mean age ± SD	Intervention: 51.7y (14.5); Control: 59.8y (9.2)	
Sex	62.69% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight
Mean (SD)

BMI
Mean (SD)</td><td>Intervention group: 70.65
(17)

Intervention group: 26.5
(5.3)</td><td>Control group: 76
(15)

Control group: 28
(5.1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight
Mean (SD)

BMI
Mean (SD)</td><td>Intervention group: 68.2
(17.6)

Intervention group: 25
(4.5)</td><td>Control group: 76.2
(16.2)

Control group: 28
(5.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Pi-Sunyer, 2015

Guideline record ID: 10574--1

Study characteristics		
Citation	Pi-Sunyer, X., Astrup, A., Fujioka, K., Greenway, F., Halpern, A., Krempf, M., Lau, D. C. W., le Roux, C. W., Violante Ortiz, R., Jensen, C. B., Wilding, J. P. H., & for the SCALE Obesity and Prediabetes NN8022-1839 Study Group. (2015). A randomized, controlled trial of 3.0 mg of liraglutide in weight management. The New England Journal of Medicine, 373(1), 11-22. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1411892	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A Randomized, Controlled Trial of 3.0 mg of Liraglutide in Weight Management	
Location	Europe; North America; South America; Asia; Africa; Australia	
Trial name	Satiety and Clinical Adiposity - Liraglutide Evidence in Nondiabetic and Diabetic Individuals (SCALE)	
Methods		
Inclusion criteria	“Patients 18 years of age or older who had stable body weight and a bodymass index (BMI; the weight in kilograms divided by the square of the height in meters) of 30 or higher, or 27 or higher if the patient had treated or untreated dyslipidemia or hypertension (.”	
Exclusion criteria	“Key exclusion criteria were type 1 or 2 diabetes, the use of medications that cause clinically significant weight gain or loss, previous bariatric surgery, a history of pancreatitis, a history of major depressive or other severe psychiatric disorders, and a family or personal history of multiple endocrine neoplasia type 2 or familial medullary thyroid carcinoma.”	
Setting	University/research centre	
Intervention	“Eligible patients were randomly assigned, in a 2:1 ratio, to receive once-daily subcutaneous injections of liraglutide, starting at a dose of 0.6 mg with weekly 0.6-mg increments to 3.0 mg both groups received counseling on lifestyle modification”	
Control/Comparator	“receive once-daily subcutaneous injections of placebo. both groups received counseling on lifestyle modification.”	
Treatment duration	56 weeks	
Follow-up from baseline	56 weeks	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 3731 Intervention group/s: Liraglutide (n=2487) Comparator group: Placebo (n=1244)	
Mean age ± SD	Intervention: 45.2y (12.1); Control: 45.0y (12.0)	
Sex	78.48% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline Body weight (kg)
Mean (SD)

Baseline BMI (kg/m2)
Mean (SD)

Baseline Waist circumference (cm)
Mean (SD)</td><td>Liraglutide: 106.2
(21.2)

Liraglutide: 38.3
(6.4)

Liraglutide: 115
(14.4)</td><td>Placebo: 106.2
(21.7)

Placebo: 38.3
(6.3)

Placebo: 114.5
(14.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Loss of ≥5% body weight
Proportion (%)

Loss of >10% body weight
Proportion (%)</td><td>Liraglutide: 63.2

Liraglutide: 33.1</td><td>Placebo: 27.1

Placebo: 10.6</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>% change in body weight
Mean (SD)

Change in body weight (kgs)
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)

Change in waist circumference (cm)</td><td>Liraglutide: -8
(6.7)

Liraglutide: -8.4
(7.3)

Liraglutide: -3
(2.6)

Liraglutide: -8.2
(7.3)</td><td>Placebo: -2.6
(5.7)

Placebo: -2.8
(6.5)

Placebo: -1
(2.3)

Placebo: -3.9
(6.6)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>97%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Poddar, 2013

Guideline record ID: 10578--1

Study characteristics		
Citation	Poddar, K. H., Ames, M., Hsin-Jen, C., Feeney, M. J., Wang, Y., & Cheskin, L. J. (2013). Positive effect of mushrooms substituted for meat on body weight, body composition, and health parameters. A 1-year randomized clinical trial. Appetite, 71, 379-387. https://doi.org/10.1016/j.appet.2013.09.008	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Positive effect of mushrooms substituted for meat on body weight, body composition, and health parameters. A 1-year randomized clinical trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Adult men and women aged 18+ years, BMI 25-40, who were interested in losing weight and reported a willingness to substitute mushrooms for beef in their daily meals. The participants had no known history of HIV, carcinoma, rheumatoid arthritis, or other uncontrolled chronic health conditions. Participants enrolled in the study were not known to be allergic to mushrooms."	
Exclusion criteria	"Participants were excluded if they reported regular use of medications and/or supplements that could affect their weight, or if they were pregnant or nursing."	
Setting	Home	
Intervention	"These participants were also prescribed a 500 kcal/d energy deficit diet for the first 6 months. In addition, they were instructed and monitored in the preparation and use of mushroom substitutes for meat and other high ED foods and provided with mushroom recipes. Participants were asked to incorporate mushrooms in sautéed vegetables, ''burgers'' and other normally meat-containing dishes; they could include them in mixed dishes, have them raw, or in any other form that they wished. Participants received a $6.00 per week voucher for local grocery stores, and were asked to substitute mushrooms (8 oz) for meat at three meals each week. Purchases were confirmed by receipt collection at the next visit for both groups. Weight loss phase (biweekly visits-first 6 months) Visits 1 through 15 comprised the weight-loss phase. At these biweekly visits, participants received diet counseling. Since the study was single blinded, the study counselor was not made aware of the group to which the participant had been randomized, and the participants were instructed not to disclose their diet assignment to the counselor. Weight maintenance phase (monthly visits-second 6 months) Visit 16 through endpoint (Visit 22) comprised the weight maintenance phase. At these monthly visits, data were collected without providing diet counseling. If participants had specific diet questions, however, they were answered."	
Control/Comparator	"Meat diet (Control group): Participants were prescribed a 500 kcal/d energy-deficit diet designed to achieve 20 lbs weight loss (resulting in a BMI no less than 22) over the first 6 months of intervention, based upon estimation of their resting metabolic rate, adjusted for physical activity level. Instruction regarding various methods to improve the diet (without the recommendation of mushroom substitution) was offered. Participants received a $6.00 per week voucher for local grocery stores for the entire study period (1 year), and were asked to eat 90+% lean ground beef at three meals each week. Weight loss phase (biweekly visits-first 6 months) Visits 1 through 15 comprised the weight-loss phase. At these biweekly visits, participants received diet counseling. Since the study was single blinded, the study counselor was not made aware of the group to which the participant had been randomized, and the participants were instructed not to disclose their diet assignment to the counselor. Weight maintenance phase (monthly visits-second 6 months) Visit 16	

<table>
<tr><td></td><td>through endpoint (Visit 22) comprised the weight maintenance phase. At these monthly visits, data were collected without providing diet counseling. If participants had specific diet questions, however, they were answered."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 73
Intervention group/s: Mushroom diet group (n=36)

Comparator group: Standard diet group (n=37)</td></tr>
<tr><td>Mean age ± SD</td><td>48.4y (1.4)</td></tr>
<tr><td>Sex</td><td>87.67% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (lbs)
Estimated marginal mean ± standard error (SE)
BMI (kg/m2)

Estimated marginal mean ± standard error (SE)

Waist circumference (in.)
Estimated marginal mean ± standard error (SE)</td><td>Mushroom diet group: 196.88 (4.91)

Mushroom diet group: 33.89 (0.63)

Mushroom diet group: 42.6 (0.63)</td><td>Standard diet group: 200.43 (5.83)

Standard diet group: 33.98 (0.62)

Standard diet group: 43.49 (0.63)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight
Estimated marginal mean ± standard error (SE)

Change in BMI
Estimated marginal mean ± standard error (SE)

Change in waist circumference
Estimated marginal mean ± standard error (SE)</td><td>Mushroom diet group: -7.03 (3.34)

Mushroom diet group: -1.53 (0.36)

Mushroom diet group: -2.58 (3.47)</td><td>Standard diet group: -2.2 (3.29)

Standard diet group: -1 (0.36)

Standard diet group: 3.32 (3.42)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

Compliance with treatment	In the first 6 months, overall mean (±SE) mushroom intake was 38.0 ± 3.5 oz (total 4.75 servings/2 wks) every 2 wks for participants randomized to the mushroom diet. In the second 6 months, overall mean (±SE) mushroom intake was 37.9 ± 3.5 oz (4.73 servings/2 wks) every 2 wks on the mushroom diet.
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Poulsen, 2015

Guideline record ID: 10581--1

Study characteristics		
Citation	Poulsen, S. K., Crone, C., Astrup, A., & Larsen, T. M. (2015). Long-term adherence to the New Nordic Diet and the effects on body weight, anthropometry and blood pressure: a 12-month follow-up study. European Journal of Nutrition, 54(1), 67-76. https://doi.org/https://dx.doi.org/10.1007/s00394-014-0686-z	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-term adherence to the New Nordic Diet and the effects on body weight, anthropometry and blood pressure: a 12-month follow-up study	
Location	Denmark	
Trial name	Optimal well-being, development and health for Danish children through a healthy New Nordic Diet (OPUS)	
Methods		
Inclusion criteria	"Men and women between 18 and 65 years with waist circumference C80 cm for women and C94 cm for men."	
Exclusion criteria	Not reported	
Setting	Home	
Intervention	"The NND was developed as a part of the multidisciplinary 5 years research project OPUS, described in detail elsewhere [13, 16] and presented in Online Resource 2. A cookery book with 180 recipes (including starters, main courses, desserts) organised into menu plans according to the seasonal variation (three menu plans for each season) was developed, in order to guide and inspire the participants in creating NND meals. Twenty-six weeks of controlled dietary intervention with either NND or Average Danish Diet (ADD) were followed by 52 weeks of followup. In the intervention period, food and beverages were provided ad libitum and free of charge from a study shop, as described previously, whereas no food or beverages were provided during the follow-up. Irrespective of the randomisation to either the NND or ADD in the intervention period, all participants were encouraged to follow NND during follow-up, and apart from scheduling of visits, no contact was established between study staff and the participants."	
Control/Comparator	"Twenty-six weeks of controlled dietary intervention with either NND or Average Danish Diet (ADD) were followed by 52 weeks of followup. In the intervention period, food and beverages were provided ad libitum and free of charge from a study shop, as described previously, whereas no food or beverages were provided during the follow-up. Irrespective of the randomisation to either the NND or ADD in the intervention period, all participants were encouraged to follow NND during follow-up, and apart from scheduling of visits, no contact was established between study staff and the participants. The ADD group was introduced to NND just after completing the intervention period by participating in a half-day cooking course on NND, receiving NND cookery books and being provided a few central NND ingredients."	
Treatment duration	26 weeks	
Follow-up from baseline	78 weeks	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 147
Intervention group/s: NND (n=91)

Comparator group: ADD (n=56)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>68.71% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>NND: 4.1 (0.1); ADD: 4.1 (0.1)</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Psota, 2020

Guideline record ID: 10585

Study characteristics		
Citation	Psota, T. L., Tindall, A. M., Lohse, B., Miller, P. E., Petersen, K. S., & Kris-Etherton, P. M. (2020). The Weight Optimization Revamping Lifestyle using the Dietary Guidelines (WORLD) study: sustained weight loss over 12 months. Obesity, 28(7), 1235-1244. https://doi.org/https://dx.doi.org/10.1002/oby.22824	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Weight Optimization Revamping Lifestyle using the Dietary Guidelines (WORLD) Study: Sustained Weight Loss Over 12 Months	
Location	USA	
Trial name	Weight Optimization: Revamping Lifestyles using the Dietary Guidelines (WORLD)	
Methods		
Inclusion criteria	"Briefly, pre-menopausal women with overweight or obesity and elevated low density lipoprotein (LDL) cholesterol were recruited."	
Exclusion criteria	"Individuals were ineligible if they had elevated tri glycerides, used lipid-lowering medications, experienced recent weight loss, or had a history/diagnosis of comorbid conditions."	
Setting	University/research centre	
Intervention	"Low Fat diet (20% kilocalories from fat). The two phases of the study were a weight-loss phase (phase 1) and a weight-maintenance phase (phase 2). During phase 1 (months 1-4), participants consumed a hypocaloric diet. During phase 2 (months 5-12), participants transitioned to weight main tenance and they were instructed to consume a eucaloric diet. During the first 4 months, participants were instructed to reduce intake to achieve a 500- to 1,000-calorie deficit per day with an overall weight loss goal of 10% of initial body weight. Nutrition educators led 28 1-hour sessions throughout the 12-month intervention. Sessions were held weekly for the first 4 months, bimonthly for the next 4 months, and monthly for the last 4 months of the study. The exercise component of the intervention, which was the same for both arms of the trial, consisted of daily stretching and five aerobic sessions, two supervised and three on their own, and two unsupervised strength-training sessions per week."	
Control/Comparator	"Moderate Fat diet (35% kilocalories from fat). The two phases of the study were a weight-loss phase (phase 1) and a weight-maintenance phase (phase 2). During phase 1 (months 1-4), participants consumed a hypocaloric diet. During phase 2 (months 5-12), participants transitioned to weight main tenance and they were instructed to consume a eucaloric diet. During the first 4 months, participants were instructed to reduce intake to achieve a 500- to 1,000-calorie deficit per day with an overall weight loss goal of 10% of initial body weight. Nutrition educators led 28 1-hour sessions throughout the 12-month intervention. Sessions were held weekly for the first 4 months, bimonthly for the next 4 months, and monthly for the last 4 months of the study. The exercise component of the intervention, which was the same for both arms of the trial, consisted of daily stretching and five aerobic sessions, two supervised and three on their own, and two unsupervised strength-training sessions per week."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 101
Intervention group/s: Low Fat Group (n=50)

Comparator group: Moderate Fat Group (n=51)</td></tr>
<tr><td>Mean age ± SD</td><td>38.9y (0.6)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SE)

BMI (kg/m2)
Mean (SE)

Waist circumference (cm)
Mean (SE)

Percent body fat
Mean (SE)</td><td>Low Fat Group: 84.2
(1.9)

Low Fat Group: 31
(0.6)

Low Fat Group: 99.4
(1.8)

Low Fat Group: 37.7
(0.7)</td><td>Moderate Fat Group: 81.6
(1.9)

Moderate Fat Group: 30.6
(0.6)

Moderate Fat Group: 99.7
(1.8)

Moderate Fat Group: 38.1
(0.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SE)

BMI (kg/m2)
Mean (SE)

Waist circumference (cm)
Mean (SE)

Percent body fat
Mean (SE)</td><td>Low Fat Group: 79.2
(1.9)

Low Fat Group: 29.1
(0.6)

Low Fat Group: 97.6
(1.8)

Low Fat Group: 35.7
(0.7)</td><td>Moderate Fat Group: 77.5
(1.9)

Moderate Fat Group: 29.1
(0.6)

Moderate Fat Group: 97.1
(1.8)

Moderate Fat Group: 36.5
(0.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss after 1 year vs baseline (kg)
mean</td><td>Low Fat Group: -5</td><td>Moderate Fat Group: -4.3</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Ptomey, 2018

Guideline record ID: 10587--1

Study characteristics		
Citation	Ptomey, L. T., Saunders, R. R., Saunders, M., Washburn, R. A., Mayo, M. S., Sullivan, D. K., Gibson, C. A., Goetz, J. R., Honas, J. J., Willis, E. A., Danon, J. C., Krebill, R., & Donnelly, J. E. (2018). Weight management in adults with intellectual and developmental disabilities: a randomized controlled trial of two dietary approaches. Journal of Applied Research in Intellectual Disabilities, 31(S1), 82-96. https://doi.org/10.1111/jar.12348	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight management in adults with intellectual and developmental disabilities: A randomized controlled trial of two dietary approaches	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Overweight or obese (BMI ≥ 25 kg/m2), adult men and women (age ≥ 18 years) with mild-to-moderate intellectual and developmental disabilities living with parents or in a supported environment with a caregiver and with up to five other adults with intellectual and developmental disabilities were eligible to participate. Intellectual and developmental disability diagnoses were verified by the Community Service Provider operating in Kansas under the auspices of a Community Developmental Disability Organization. Additionally, participants were required to be able to walk and to communicate preferences (e.g., foods liked/disliked), wants (e.g., more to eat/drink) and needs (e.g., assistance with food preparation) through spoken or sign language, or via alterative communication systems such as voice output communication aides."	
Exclusion criteria	"Potential participants with significant medical conditions (e.g., uncontrolled hypertension, severe heart disease, cancer, HIV, insulin-dependent diabetes), currently being treated for eating disorders, who were pregnant or who had participated in a weight management or physical activity programme in the past 6 months were ineligible."	
Setting	Home	
Intervention	"Enhanced stop light diet (eSLD)-Components • 2 portion-controlled entrées/day • 2 portion-controlled shakes/day • 5 one-cup servings of fruits and vegetables/day • Ad libitum non-caloric beverages • Additional meals and snacks selected using the stop light diet guide. The original SLD (Epstein & Squires, 1988) which categorized foods by energy content, green (low energy, consume freely), yellow (moderate energy, consume in moderation) and red (high energy, consume sparingly), is easy to understand and implement compared with a conventional reduced energy meal plan diet and has received a grade 1 ranking for effectiveness (strong, consistent supporting evidence) from the Academy of Nutrition and Dietetics Evidence Analysis Library (Academy of Nutrition and Dietetics, 2005). A chart which included lists and pictures of common food items, colour-coded to the SLD system, was provided to assist with meal planning, food shopping and selection of appropriate snacks. As in our pilot trial (Saunders et al., 2011), the SLD was enhanced (eSLD) by encouraging consumption of high-volume, low-energy, portion-controlled meals (PCMs; entrées/ shakes) and fruits and vegetables (Academy of Nutrition and Dietetics, 2011). PCMs are effective in controlling portion size and reducing both energy and fat intake and simplify meal planning, food shopping and meal preparation for individuals with intellectual and developmental disabilities and their study partners. PCMs include nutritional information on the label (calories, fat, protein, etc.) making it easier to adhere to specific energy and nutrient recommendations. The simplicity of using PCMs may be especially relevant as caregivers (study partners) frequently have limited formal education specific to nutrition, and the turnover rate among paid caregivers is high	

	(Humphries, Traci, & Seekins, 2008). Participants were asked to consume a minimum daily total of 4 PCMs, two entrées (~200-300 kcal each with saturated fat ≤3 g and sodium <600 mg), two shakes (~100 kcal each), five one-cup servings of fruits and vegetables and ad libitum non-caloric beverages. Participants and study partners were provided with a list of entrées available from several manufacturers (e.g., Healthy Choice™, Smart Ones ™, Michelina's ™, etc.) which met our caloric, fat and sodium requirements. They were asked to purchase entrées of their choice which are available at most grocery stores at a cost of $2.00 to $4.00 each. Two low-energy, high-volume shakes/day (HMR Weight Management Services Corp) were provided at no cost to participants in the eSLD group during the 6-month weight loss phase. These shakes could be consumed as a snack or as a drink with a portion-controlled entrée. Participants desiring foods in addition to these recommendations were encouraged to select additional low-energy (green) foods from the SLD chart. During weight maintenance (7-18 months), participants in the eSLD group were counselled to continue consumption of PCMs (two entrées/shakes/day) and increase consumption of foods in the yellow category of the stop light diet. Participants were encouraged to accumulate a minimum of 30 min/day of moderate intensity physical activity 5 days/week (150 min/week). The present authors are aware that this level of physical activity is less than recommended by current guidelines for weight management (Donnelly et al., 2009; Jensen et al., 2014). However, based on experience from our pilot trial in adults with intellectual and developmental disabilities, and other reports in the literature demonstrating the low levels of physical activity in this group (Barnes, Howie, McDermott,& Mann, 2013), accumulating 150 min/week of moderate intensity physical activity represents a reasonable recommendation. Brisk walking was recommended as it is inexpensive, safe, fits easily into the daily routine and can be performed alone or with others. Pedometers (Omron HJ-320, Lake Forest, IL) were provided to all participants as both a motivational tool and to self-monitor physical activity. All education/behavioural sessions were conducted during home visits with both participants and their study partner. The frequency and duration of these sessions was equal for both the eSLD and CD groups across the intervention. All sessions were led by health educators trained to deliver the intervention by shadowing a co-investigator experienced with weight management for adults with intellectual and developmental disabilities and classroom instruction specific to the diet and physical activity components of the intervention. This coinvestigator also supervised health educators during their initial session with participants and study partners and attended a minimum of 4-monthly sessions, at random, to insure the intervention was delivered as intended using a checklist. The co-investigator and health educators met twice per month to discuss and solve any issues regarding the delivery of the intervention that may have occurred. Health educators were assigned to participant/study partners at baseline and delivered both the weight loss (0-6 months) and maintenance interventions (7-18 months) to those individuals. Health educators were assigned to deliver the intervention to participants randomized to the eSLD or CD groups over the same time frame to reduce the potential for health educator effects."
Control/Comparator	"Conventional diet (CD) components • 500-700 kcal/day energy deficit • Provided recommended servings of fruits, vegetables, grains, dairy and protein to meet energy intake goals. • Instructions regarding appropriate serving sizes of food items, and measuring foods to ensure compliance with serving size recommendations Participants randomized to the CD group were taught to consume a nutritionally balanced, low-calorie, high-volume, lower fat (20%-30% energy intake) diet following the MyPlate approach as recommended by the US Department of Agriculture (Agriculture, 2013). Participants and study partners were taught to select, purchase and prepare appropriate foods, as well as to serve a portion of appropriate size to achieve the desired reduction in energy intake. During weight loss energy intake was reduced to ~500-700 kcal below daily estimated resting energy expenditure as estimated using the equation of Mifflin-St Jeor (Mifflin et al., 1990) multiplied by 1.4-1.6 to account for energy expenditure associated with physical activity. The present authors were aware that this equation, which estimates resting energy expenditure based on age, sex, height and weight, or any other equation for estimating resting energy expenditure, was not developed for use in individuals with intellectual and developmental disabilities and that body composition and energy metabolism among individuals with intellectual and developmental disabilities may differ from the general

	population. Therefore, the estimated energy intake was used as a starting point, which was adjusted in response to weight loss or gain as assessed during monthly home visits. Participants and study partners were provided with examples of meal plans, which suggested the number of servings of grains, proteins, fruits and vegetables, dairy and fats to achieve the desire energy intake for weight loss, and were counselled on appropriate portion sizes using three-dimensional food models and taught to measure foods to facilitate compliance with serving size recommendations. Participants in the CD group received the monetary equivalent of the cost of the shakes provided to the eSLD group ($30.00/ month) for the purchase of foods appropriate for CD only during the active weight loss intervention (0-6 months). During weight maintenance (7-18 months), Participants in the CD group were provided with energy intake recommendations for weight maintenance based on estimated resting energy expenditure (Mifflin et al., 1990) multiplied by 1.6-1.8 to account for physical activity and provided with examples of meal plans consisting of suggested servings of grains, proteins, fruits and vegetables, dairy and fats based on their maintenance energy requirements. Participants were encouraged to accumulate a minimum of 30 min/day of moderate intensity physical activity 5 days/week (150 min/week). The present authors are aware that this level of physical activity is less than recommended by current guidelines for weight management (Donnelly et al., 2009; Jensen et al., 2014). However, based on experience from our pilot trial in adults with intellectual and developmental disabilities, and other reports in the literature demonstrating the low levels of physical activity in this group (Barnes, Howie, McDermott,& Mann, 2013), accumulating 150 min/week of moderate intensity physical activity represents a reasonable recommendation. Brisk walking was recommended as it is inexpensive, safe, fits easily into the daily routine and can be performed alone or with others. Pedometers (Omron HJ-320, Lake Forest, IL) were provided to all participants as both a motivational tool and to self-monitor physical activity. All education/behavioural sessions were conducted during home visits with both participants and their study partner. The frequency and duration of these sessions was equal for both the eSLD and CD groups across the intervention. All sessions were led by health educators trained to deliver the intervention by shadowing a co-investigator experienced with weight management for adults with intellectual and developmental disabilities and classroom instruction specific to the diet and physical activity components of the intervention. This coinvestigator also supervised health educators during their initial session with participants and study partners and attended a minimum of 4-monthly sessions, at random, to insure the intervention was delivered as intended using a checklist. The co-investigator and health educators met twice per month to discuss and solve any issues regarding the delivery of the intervention that may have occurred. Health educators were assigned to participant/study partners at baseline and delivered both the weight loss (0-6 months) and maintenance interventions (7-18 months) to those individuals. Health educators were assigned to deliver the intervention to participants randomized to the eSLD or CD groups over the same time frame to reduce the potential for health educator effects."
Treatment duration	18 months
Follow-up from baseline	18 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 149 Intervention group/s: eSLD (n=77) Comparator group: CD (n=72)
Mean age ± SD	Intervention: 36.1y (12.0); Control: 37.0y (12.5)
Sex	57.05% female

<table>
<tr><td>Pre-existing medical condition</td><td>Mild-to-moderate intellectual and developmental disabilities. Intellectual and developmental disability diagnoses were verified by the Community Service Provider operating in Kansas under the auspices of a Community Developmental Disability Organization</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>eSLD: 98.4
(23.9)

eSLD: 37.5
(7.6)</td><td>CD: 98.4
(24.9)

CD: 36.4
(8.1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss 5-<10%
Proportion (%)

Weight loss ≥10%
Proportion (%)</td><td>eSLD: 18.5

eSLD: 38.9</td><td>CD: 21.3

CD: 27.6</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)

Change in weight (%)
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)

Change in waist circumference (cm)
Mean (SD)</td><td>eSLD: -6.4
(7.9)

eSLD: -6.7
(8.3)

eSLD: -2.3
(3.2)

eSLD: -4.9
(7.3)</td><td>CD: -6.6
(9.2)

CD: -6.4
(8.6)

CD: -2.3
(3.5)

CD: -4.1
(9.7)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Across the 18-month trial, randomized participants attended 80% and 76% of the monthly scheduled home visit meetings in the eSLD and CD groups, respectively (p = .72). Monthly meeting attendance was 97% in both the eSLD and CD groups among those actively participating in the trial. Across the 18-month trial, randomized participants completed 54% and 61% of requested monthly self-monitoring reports in the eSLD and CD groups, respectively. Completion of monthly reports was significantly higher in the CD (83%) compared with the eSLD group (70%, p = .01) among those actively participating in the trial. Participants randomized to the eSLD group were asked to consume two portion-controlled entrées, two low-calorie shakes and five servings of fruits and vegetables each day. Self-reported compliance with these recommendations was poor. For example, 9% and 10% of participants complied with the entrée, and 17% and 0% complied with the shake recommendations at 6 and 18 months, respectively. Self-reported compliance with the fruit and vegetable recommendation was observed in 28% and 31% participants at 6 and 18 months. Participants randomized to the CD group were asked to consume a lower fat (<30% total energy intake), reduced energy (~500 kcal/day) diet which included five servings of fruits and vegetables per day. Self reports indicated approximately 29% and 38%</td></tr>
</table>

	of participants in the CD group complied with the recommendation for lower fat intake at 6 and 18 months.
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Ptomey, 2023

Guideline record ID: 10588--1

Study characteristics		
Citation	Ptomey, L. T., Washburn, R. A., Goetz, J. R., Sullivan, D. K., Gibson, C. A., Mayo, M. S., Krebill, R., Gorczyca, A. M., Honas, J. J., Rice, A. M., Helsel, B. C., Lee, R. H., & Donnelly, J. E. (2023). A randomized trial comparing diet and delivery strategies for weight management in adolescents with intellectual disabilities. Pediatric Obesity, 18(1), e12972. https://doi.org/10.1111/ijpo.12972	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A randomized trial comparing diet and delivery strategies for weight management in adolescents with intellectual disabilities	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Age 13-21 years with mild-to-moderate ID (IQ 40-74), as verified by a primary care physician, body mass index (BMI) ≥ 85th percentile on CDC growth charts (age ≤ 19 years) or BMI ≥25 kg/m2 (age > 19 years), or waist circumference to height ratio >0.5 which indicates excess central adiposity in children and adolescents and is commonly observed in youth with Down Syndrome, sufficient functional ability to understand directions, communicate through spoken language, living at home with a parent or guardian, and internet access in the home."	
Exclusion criteria	"Type 1 diabetes, or Type 2 diabetes treated with insulin, Prader-Willi Syndrome, participation in a weight management program involving diet and physical activity in the past 6 months, eating disorders, serious food allergies, consuming special diets, or the inability to participate in MVPA. To enhance the generalizability of our findings, individuals who used medications for prevalent conditions associated with obesity or other medications commonly prescribed for individuals with ID were allowed to participate. Clearance from a primary care physician was required for all participants."	
Setting	Home	
Intervention	"Immediately following completion of the previously described 6-month weight loss intervention, participants began a 12-month maintenance intervention continuing in the intervention arm assigned at baseline. Both the weight loss and maintenance interventions were based on the behavioural principles of the Social Cognitive Theory, which considers the influence of individual experiences, the actions of others, and environmental factors on individual health behaviours. Adolescents were required to designate one parent to serve as the primary family contact across the 18-month trial. The parent was asked to attend all behavioural sessions to familiarize themselves with both the diet and physical activity recommendations and the behavioural strategies incorporated in the intervention. The parent was asked to provide support and encouragement, while aiding in following the prescribed diet, promoting physical activity, and self monitoring of diet and physical activity, if necessary. The RD arms were delivered using FaceTime™ on an iPad® provided by the trial (Apple Inc., Cupertino, CA). Recommended energy intake at the initiation of weight maintenance was estimated using the Dietary Reference Intake equation for total daily energy expenditure for overweight boys/girls, based on participant weight at 6 months with consideration for growth and development and adjusted as required based on observed changes in weight across the weight maintenance intervention. Participants in the eSLD arm were encouraged to continue using the eSLD, i.e., a minimum of two entrées (200-270 kcal each), two shakes (~100 kcal each), five one-cup servings of fruits and vegetables each day, and lower energy foods (green/yellow) from a chart/pictures of foods that were colourcoded based on the SLD system. During weight maintenance participants	

	were asked to purchase low calorie entrées and shakes from a list of these items that are readily available at most grocery stores, developed by the health educators. This contrasted with the weight loss intervention where the entrées and shakes recommended for the eSLD arm were provided by the trial and shipped to the participant's homes every other week. Participants randomized to the CD arms were asked to continue using a CD as recommended during weight loss; however, suggested servings of grains, proteins, fruits and vegetables, dairy, and fats were recalculated based on their energy needs for weight maintenance. Participants were asked to continue the physical activity recommendations prescribed for weight loss (0-6 months), i.e., 60 min./day of MVPA least 5 days/week and 10 000 steps/day. Individual education/behavioural counselling sessions (30-45 min) specifically developed for adolescents with ID were delivered to the adolescent and a parent by a trained health educator twice each month during the first 6 months of weight maintenance (7- 12 months), the same session frequency used during weight loss, and once each month during the final 6 months of weight maintenance (13-18 months)."
Control/Comparator	"Immediately following completion of the previously described 6-month weight loss intervention, participants began a 12-month maintenance intervention continuing in the intervention arm assigned at baseline. Both the weight loss and maintenance interventions were based on the behavioural principles of the Social Cognitive Theory, which considers the influence of individual experiences, the actions of others, and environmental factors on individual health behaviours. Adolescents were required to designate one parent to serve as the primary family contact across the 18-month trial. The parent was asked to attend all behavioural sessions to familiarize themselves with both the diet and physical activity recommendations and the behavioural strategies incorporated in the intervention. The parent was asked to provide support and encouragement, while aiding in following the prescribed diet, promoting physical activity, and self monitoring of diet and physical activity, if necessary. the FTF arm was delivered during a home visit. Participants randomized to the CD arms were asked to continue using a CD as recommended during weight loss; however, suggested servings of grains, proteins, fruits and vegetables, dairy, and fats were recalculated based on their energy needs for weight maintenance. Participants were asked to continue the physical activity recommendations prescribed for weight loss (0-6 months), i.e., 60 min./day of MVPA least 5 days/week and 10 000 steps/day. Individual education/behavioural counselling sessions (30-45 min) specifically developed for adolescents with ID were delivered to the adolescent and a parent by a trained health educator twice each month during the first 6 months of weight maintenance (7- 12 months), the same session frequency used during weight loss, and once each month during the final 6 months of weight maintenance (13-18 months). COVID-19 restrictions prohibited FTF contacts with participants between March and June 2020. Therefore, during this period all sessions with participants in the FTF arm were conducted by telephone. Participants who were uncomfortable with attending FTF meetings following the lifting of the COVID-19 restrictions (n = 10) were allowed to continue with telephone meetings from July 2020 through the completion of the trial (May 2021). The content and duration of the education/behavioural counselling sessions were identical in all three intervention arms and included strategies focused on weight maintenance, e.g., making healthy choices when eating out, healthy eating in social situations, resistance training, and maintaining motivation for MVPA etc. Health educator feedback and counselling relative to participants self-monitored dietary intake, MVPA, and body weight were provided during each session. COVID-19 restrictions prohibited FTF contacts with participants between March and June 2020. Therefore, during this period all sessions with participants in the FTF arm were conducted by telephone. Participants who were uncomfortable with attending FTF meetings following the lifting of the COVID-19 restrictions (n = 10) were allowed to continue with telephone meetings from July 2020 through the completion of the trial (May 2021)."
Treatment duration	18 months
Follow-up from baseline	18 months

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 110
Intervention group/s: RD/eSLD (n=35); RD/CD (n=39)

Comparator group: FTF/CD (n=36)</td></tr>
<tr><td>Mean age ± SD</td><td>FTF/CD: 16.3y (2.7); RD/CD: 15.6y (1.7); RD/eSLD: 16.7y (2.5)</td></tr>
<tr><td>Sex</td><td>52.73% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Intellectual disability</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>RD/eSLD: 83.6
(26.4)
RD/CD: 74.9
(16.5)</td><td>FTF/CD: 88.4
(29.5)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>RD/eSLD: 32.7
(7.1)
RD/CD: 31.3
(5.8)</td><td>FTF/CD: 34.1
(8.3)</td></tr>
<tr><td>BMI percentile
Mean (SD)</td><td>RD/eSLD: 96
(4)
RD/CD: 95
(6)</td><td>FTF/CD: 96
(6)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>RD/eSLD: 94.4
(15.3)
RD/CD: 90.5
(11.3)</td><td>FTF/CD: 98.3
(17.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in weight (kg)
Mean (SD)</td><td>RD/eSLD: -5.3
(6.3)
RD/CD: -0.7
(4.6)</td><td>FTF/CD: 1.3
(8.2)</td></tr>
<tr><td>Change in weight (%)
Mean (SD)</td><td>RD/eSLD: -7
(7.8)
RD/CD: -1.1
(6.4)</td><td>FTF/CD: 1.1
(9.1)</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (SD)</td><td>RD/eSLD: -2.2
(2.7)
RD/CD: -0.7
(2.1)</td><td>FTF/CD: -0.5
(2.4)</td></tr>
<tr><td>Change in BMI percentile
Mean (SD)</td><td>RD/eSLD: -7.4
(8.6)</td><td>FTF/CD: -1.6
(7.4)</td></tr>
</table>
</td></tr>
</table>

		RD/CD: -2.6 (7.2)	
	Change in waist circumference (cm) Mean (SD)	RD/eSLD: -5.5 (5.3) RD/CD: -0.8 (4.2)	FTF/CD: -1.6 (6.2)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in weight (kg) Mean (SD)	RD/eSLD: -2.2 (7.4) RD/CD: -0.2 (6.6)	FTF/CD: 1.4 (9.7)
	Change in weight (%) Mean (SD)	RD/eSLD: -2.6 (10.5) RD/CD: -0.5 (8.7)	FTF/CD: 1.6 (12.3)
	Change in BMI (kg/m2) Mean (SD)	RD/eSLD: -1.3 (2.7) RD/CD: -0.6 (2.5)	FTF/CD: -0.1 (3.2)
	Change in BMI percentile Mean (SD)	RD/eSLD: -4.4 (8.9) RD/CD: -2.1 (8.3)	FTF/CD: -0.2 (10.1)
	Change in waist circumference (cm) Mean (SD)	RD/eSLD: -3.2 (5.9) RD/CD: -1.1 (5.7)	FTF/CD: -0.5 (6.6)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Puhkala, 2015

Guideline record ID: 10591--1

Study characteristics		
Citation	Puhkala, J., Kukkonen-Harjula, K., Mansikkamäki, K., Aittasalo, M., Hublin, C., Kärmeniemi, P., Olkkonen, S., Partinen, M., Sallinen, M., Tokola, K., & Fogelholm, M. (2015). Lifestyle counseling to reduce body weight and cardiometabolic risk factors among truck and bus drivers--a randomized controlled trial. Scandinavian Journal of Work, Environment & Health, 41(1), 54-64. https://doi.org/https://dx.doi.org/10.5271/sjweh.3463	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Lifestyle counseling to reduce body weight and cardiometabolic risk factors among truck and bus drivers--a randomized controlled trial	
Location	Finland	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria included: (i) 30-62-year-old male truck or bus driver, (ii) waist circumference ≥100 cm, (iii) irregular working schedules in long-distance service, (iv) absence of sleep apnea diagnosis or medication for diabetes, and (v) little physical activity during leisure (≤2 times weekly for 30 minutes per session). Voluntary participants were recruited by advertisement in service stations, workplaces, and newspapers and through labor unions."	
Exclusion criteria	Not reported	
Setting	Home	
Intervention	"The participants in the LIFE group participated in structured monthly lifestyle counseling for 12 months focusing on diet but including also counseling on physical activity and sleep. The contents of the session-specific counseling are described in table 1. Counseling consisted of six individual face-to-face contacts (allocated time 60 minutes) and seven telephone contacts (30 minutes) with trained counselors (two nutritionists and one physiotherapist). The counselors traveled to the participants for the face-to-face meetings. The contents of session-specific counseling in the lifestyle counseling group. [F=face-to-face; T=telephone; PA=physical activity]: 1st (0) F General: overview of counseling, working methods Diet: checklist for eating habits, based on food diary, meal frequency (establishing goals for next 4 weeks) PA: instructions to measure average daily step count with a pedometer 2nd (1) F Diet: meal frequency (compliance, revision of goals); plate model (establishing goals) PA: current PA and step count results; PA recommendations; establishing the first goal 3rd (2) T Diet: meal frequency and plate model (compliance, revision of goals); food groups and their quality (establishing goals) PA: adverse effects, compliance, revision of goals and modes, stretching exercises 4th (3) F Diet: meal frequency, plate model and food quality (compliance, revision and establishing goals) PA: adverse effects, compliance, revision of goals and modes Sleep: Sleep hygiene (establishing goals) 5th (4) T Diet: as session 4 PA: as session 4 Sleep: Sleep hygiene (compliance, revision of goals) 6th (5) T Diet: as session 4 PA: as session 4 Sleep: Sleep hygiene (compliance, revision of goals), alertness (establishing goals) 7th (6) F Diet: as session 4 PA: as session 4 Sleep: as session 6 8-12th (7-11) 4T, 1F Diet: as session 4 PA: as session 4 Sleep: as session 6 13th (12) F Diet: check list for eating habits, compliance with goals during the year, maintenance, how to continue? (goals) PA: adverse effects, maintenance Sleep: compliance with goals during the year; how to continue?"	
Control/Comparator	"Waitlisted for 12 months. After 12 months, the REF group participated in a shorter 3-month counseling protocol including two face-to-face contacts (at 12 and 15 months after baseline) and three telephone contacts (3, 6, and 9 weeks after 12 months). Counseling	

<table>
<tr><td></td><td>was based on the same elements as those used in the LIFE group but in a shortened version.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 113
Intervention group/s: LIFE (n=55)

Comparator group: REF (n=58)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 47.6y (7.9); Control:46.5y (8.6)</td></tr>
<tr><td>Sex</td><td>100.00% male</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist Circumference (cm)
Mean (SD)

Body Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Fat mass (kg)
Mean (SD)</td><td>LIFE: 113.8
(9.5)

LIFE: 105.8
(16.3)

LIFE: 32.9
(4.3)

LIFE: 37.1
(8.9)</td><td>REF: 114.9
(10.3)

REF: 106.7
(16.4)

REF: 33.1
(4.7)

REF: 38
(9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight at 12 months (kg)
Mean (SD)

Change in waist circumference at 12 months (cm)
Mean (SD)

Change in fat mass at 12 months (kg)
Mean (SD)</td><td>LIFE: -3.4
(6.6)

LIFE: -4.7
(5.8)

LIFE: -2.6
(5.1)</td><td>REF: 0.7
(3.9)

REF: -0.1
(3.6)

REF: 0.6
(3.4)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Purcell, 2014

Guideline record ID: 10592

Study characteristics		
Citation	Purcell, K., Sumithran, P., Prendergast, L. A., Bouniu, C. J., Delbridge, E., & Proietto, J. (2014). The effect of rate of weight loss on long-term weight management: a randomised controlled trial. The Lancet Diabetes & Endocrinology, 2(12), 954-962. https://doi.org/https://doi.org/10.1016/S2213-8587(14)70200-1	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The effect of rate of weight loss on long-term weight management: a randomised controlled trial	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligible patients at screening were obese (BMI 30·0-45·0 kg/m²), otherwise healthy, and aged between 18 and 70 years."	
Exclusion criteria	"Pregnancy or breast-feeding; History of surgical procedures or laxative abuse for weight loss; The use of any VLCD or weight lowering drugs in the past three months; Inability to attend scheduled examinations and visits; For females taking an oral contraceptive pill or hormone replacement: dose must have been stable for the past three months; For participants receiving thyroid hormone replacement: dose must have been stable for the past three months; Surgical intervention planned during the study; Any recent (less than six months) cessation of smoking and current smokers; Participation in another study, or administration of any investigational drug in the past three months; Uncontrolled and clinically significant disease or known malignancy that could interfere with the study conduct; Presence of any clinically significant renal or endocrine disease (including diabetes) according the Investigator or as revealed by screening blood tests; Use of anti-depressant and antiepileptic medications known to have weight gaining effect (refer to Appendix 1); Subjects with known history of alcoholism or drug abuse or dependence within 1 year prior to screening; Subjects who were obese in early childhood will be excluded to avoid monogenetic obesity."	
Setting	Hospital, Home	
Intervention	"In the rapid weight loss programme, participants consumed a commercially available very low energy diet preparation (Optifast, Nestlé Nutrition, Vevey, Switzerland) according to the manufacturer's recommendations, for 12 weeks. This diet contains between 450 and 800 kcal per day. Three meals per day were replaced with Optifast, aiming for 15% weight loss (about 1·5 kg per week) during 12 weeks. All participants received meal replacements at no cost, were given similar dietary education materials, and had appointments with the same qualifi ed dietitian every 2 weeks (six appointments for rapid weight loss and 18 for gradual weight loss participants during phase 1). Personalised projected graphs to track expected and actual weight loss were drawn for every participant. Both groups were prescribed the same overall energy deficit (105 000 kcal) during either 12 (rapid weight loss) or 36 (gradual weight loss) weeks. Adherence to the diets was estimated by the rate at which participants were losing weight. Participants who achieved 12·5% weight loss or more in the allocated timeframe were eligible to enter phase 2. In phase 2, for 144 weeks, participants were instructed to follow an individualised diet for weight maintenance, based on the Australian Guide to Healthy Eating,11 and had individual sessions with the dietitian at weeks 4 and 12, and then every 12 weeks for 144 weeks. During these appointments, adherence to the diet was assessed with the participants' self-reported food intake. Participants regaining their lost weight were advised to follow an energy-reduced diet (400-500 kcal per day defi cit).	

<table>
<tr><td></td><td>Throughout the study, all participants were instructed to undertake 30 min or longer per day of mild- to moderate-intensity exercise (eg, a brisk walk).”</td></tr>
<tr><td>Control/Comparator</td><td>“In the gradual weight loss programme, participants consumed an energy-reduced diet (400-500 kcal per day defi cit), on the basis of recommendations in the Australian Guide to Healthy Eating (15% protein, 25-30% fat, and 55-60% carbohydrate),11 with one to two Optifast meal replacements every day, with the aim of 15% weight loss during 36 weeks (roughly 0·5 kg per week). All participants received meal replacements at no cost, were given similar dietary education materials, and had appointments with the same qualifi ed dietitian every 2 weeks (six appointments for rapid weight loss and 18 for gradual weight loss participants during phase 1). Personalised projected graphs to track expected and actual weight loss were drawn for every participant. Both groups were prescribed the same overall energy deficit (105 000 kcal) during either 12 (rapid weight loss) or 36 (gradual weight loss) weeks. Adherence to the diets was estimated by the rate at which participants were losing weight. Participants who achieved 12·5% weight loss or more in the allocated timeframe were eligible to enter phase 2. In phase 2, for 144 weeks, participants were instructed to follow an individualised diet for weight maintenance, based on the Australian Guide to Healthy Eating,11 and had individual sessions with the dietitian at weeks 4 and 12, and then every 12 weeks for 144 weeks. During these appointments, adherence to the diet was assessed with the participants' self-reported food intake. Participants regaining their lost weight were advised to follow an energy-reduced diet (400-500 kcal per day defi cit). Throughout the study, all participants were instructed to undertake 30 min or longer per day of mild- to moderate-intensity exercise (eg, a brisk walk).”</td></tr>
<tr><td>Treatment duration</td><td>Rapid weight loss: 12 weeks, gradual weight loss: 36 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>Rapid weight loss: 156 weeks, gradual weight loss: 180 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 200
Intervention group/s: Rapid weight loss (n=97)

Comparator group: Gradual weight loss (n=103)</td></tr>
<tr><td>Mean age ± SD</td><td>Rapid weight loss: 49·6y (10·9); Gradual weight loss 50·1y (11·1)</td></tr>
<tr><td>Sex</td><td>74.50% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Rapid weight loss: 97
(13.3)

Rapid weight loss: 35.2
(3.7)

Rapid weight loss: 107.7
(10.1)</td><td>Gradual weight loss: 97
(13.7)

Gradual weight loss: 35.5
(4.1)

Gradual weight loss: 108.1
(10.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td>Change in weight (kg)
Mean (95% CIs)

Change in BMI (kg/m2)
Mean (95% CIs)

Change in waist circumference (cm)
Mean (95% CIs)</td><td>Rapid weight loss: -4.1
(-6.1--2.4)

Rapid weight loss: -1.5
(-2.2-0.2)

Rapid weight loss: -4.4
(-6.4--2.3)</td><td>Gradual weight loss: -4.3
(-6.3--2.4)

Gradual weight loss: -1.6
(-2.2-0.9)

Gradual weight loss: -4.1
(-6.7--1.6)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Quattrin, 2014

Guideline record ID: 10593A -- PARENT

Study characteristics		
Citation	Quattrin, T., Roemmich, J. N., Paluch, R., Yu, J., Epstein, L. H., & Ecker, M. A. (2014). Treatment outcomes of overweight children and parents in the medical home. Pediatrics, 134(2), 290-297. https://doi.org/https://dx.doi.org/10.1542/peds.2013-4084	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Treatment outcomes of overweight children and parents in the medical home	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Children who had a BMI over the 85th percentile for age and gender and having a parent who had a BMI .25 kg/m2 were included."	
Exclusion criteria	"The main exclusion criteria were: small for gestational age, short stature, and child/ parent inability to perform physical activity."	
Setting	Patient Centered Medical Homes (PCMH),	
Intervention	"Summary of Protocol Common to Both Groups: Parents attended thirteen 60-minute group sessions over the 12-month treatment period (4 weekly, 2 biweekly, 4 monthly, and 3 at 8- to 10-week intervals), followed by a 12-month follow-up (3 meetings at month 16, 20, and 24). The Intervention and IC groups were held on different evenings. A PEA assigned to each family telephoned the parent between scheduled meetings 10 times during treatment and 3 times during follow-up. The intervention was delivered through the parents. PEAs cared for the children while parents attended the sessions. Both groups received dietary, physical, and sedentary activity guidelines in keeping with the Expert Committee Recommendations. The child's weight goal was 0.5 to 1 pound/week weight loss. Parents were instructed on the appropriate number of servings for their child from each food group to provide 1000 to 1200 daily kilocalories depending on age,15 and to avoid food with .5 g of fat/ serving, high in sugar, or containing artificial sweeteners because they habituate the child to a high sugary taste and in adults have been shown to increase the risk for metabolic syndrome and type 2 diabetes. The threshold of 5 g of fat/ serving was adapted from the validated Traffic Light Diet.18 Efforts to limit high-sugar foods focused mainly on sugar-sweetened drinks and breakfast food such as commercial cereals (.5 g of sugars/serving). The child's pediatrician reviewed %OBMI changes every 6 months. Between the 6-month visits the PEA prepared a letter outlining the child's progress for the families. Summary of Protocol Components Pertinent Only to the Intervention: In the Intervention behavior modification and education on parenting techniques (ie, positive reinforcement, modeling healthy diet and activity, and stimulus control) were delivered by the group leader during the group meetings and by a PEA, assigned to each family, during brief individual sessions held the same evenings as the group meetings. Parents were instructed to monitor their child and their own weight twice a week and received dietary (1500 and 1800 kcals/ day for mothers and fathers, respectively), physical, and sedentary activity guidelines with the goal of a minimum of 1 pound/week weight loss. A list of foods with portion sizes and energy content information was provided. Parents recorded intake and activity for their child and themselves in a diary by crossing off icons detailing the different food groups and physical and sedentary activity. The number of icons was tailored to the child and parent so that shaping up/down of targeted behaviors could be individualized. and fathers, respectively), physical, and sedentary activity guidelines with the goal of a minimum of 1 pound/week weight loss. A list of foods with portion sizes and energy content information was provided. Parents recorded intake and activity for their child and themselves in a diary by crossing off icons detailing the different food groups and	

<table>
<tr><td></td><td>physical and sedentary activity. The number of icons was tailored to the child and parent so that shaping up/down of targeted behaviors could be individualized.”</td></tr>
<tr><td>Control/Comparator</td><td>“Summary of Protocol Common to Both Groups: Parents attended thirteen 60-minute group sessions over the 12-month treatment period (4 weekly, 2 biweekly, 4 monthly, and 3 at 8- to 10-week intervals), followed by a 12-month follow-up (3 meetings at month 16, 20, and 24). The Intervention and IC groups were held on different evenings. A PEA assigned to each family telephoned the parent between scheduled meetings 10 times during treatment and 3 times during follow-up. The intervention was delivered through the parents. PEAs cared for the children while parents attended the sessions. Both groups received dietary, physical, and sedentary activity guidelines in keeping with the Expert Committee Recommendations. The child's weight goal was 0.5 to 1 pound/week weight loss. Parents were instructed on the appropriate number of servings for their child from each food group to provide 1000 to 1200 daily kilocalories depending on age,15 and to avoid food with .5 g of fat/ serving, high in sugar, or containing artificial sweeteners because they habituate the child to a high sugary taste and in adults have been shown to increase the risk for metabolic syndrome and type 2 diabetes. The threshold of 5 g of fat/ serving was adapted from the validated Traffic Light Diet.18 Efforts to limit high-sugar foods focused mainly on sugar-sweetened drinks and breakfast food such as commercial cereals (.5 g of sugars/serving). The child's pediatrician reviewed %OBMI changes every 6 months. Between the 6-month visits the PEA prepared a letter outlining the child's progress for the families.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 96
Intervention group/s: Intervention (n=46)

Comparator group: IC (n=50)</td></tr>
<tr><td>Mean age ± SD</td><td>4.6y (0.2)</td></tr>
<tr><td>Sex</td><td>66.67% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Parent weight kg
Mean (SE)

Parent BMI
Mean (SE)</td><td>Intervention: 101.5
(0.6)

Intervention: 37.2
(8.3)</td><td>IC: 101.2
(0.6)

IC: 36.2
(6.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Parent weight kg
Mean (SE)</td><td>Intervention: 94.7
(0.6)</td><td>IC: 100.6
(0.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Parent weight kg
Mean (SE)</td><td>Intervention: 95.5
(0.7)</td><td>IC: 101.9
(0.6)</td></tr>
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<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
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<tr><td>Compliance with treatment</td><td>For as long as families were in the study they received 100% of the planned curriculum (missed sessions were always rescheduled)</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Quattrin, 2014

Guideline record ID: 10593B --CHILD

Study characteristics		
Citation	Quattrin, T., Roemmich, J. N., Paluch, R., Yu, J., Epstein, L. H., & Ecker, M. A. (2014). Treatment outcomes of overweight children and parents in the medical home. Pediatrics, 134(2), 290-297. https://doi.org/https://dx.doi.org/10.1542/peds.2013-4084	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Treatment outcomes of overweight children and parents in the medical home	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Children who had a BMI over the 85th percentile for age and gender and having a parent who had a BMI >=25 kg/m2 were included."	
Exclusion criteria	"The main exclusion criteria were: small for gestational age, short stature, and child/ parent inability to perform physical activity."	
Setting	Patient Centered Medical Homes (PCMH)	
Intervention	"Summary of Protocol Common to Both Groups: Parents attended thirteen 60-minute group sessions over the 12-month treatment period (4 weekly, 2 biweekly, 4 monthly, and 3 at 8- to 10-week intervals), followed by a 12-month follow-up (3 meetings at month 16, 20, and 24). The Intervention and IC groups were held on different evenings. A PEA assigned to each family telephoned the parent between scheduled meetings 10 times during treatment and 3 times during follow-up. The intervention was delivered through the parents. PEAs cared for the children while parents attended the sessions. Both groups received dietary, physical, and sedentary activity guidelines in keeping with the Expert Committee Recommendations. The child's weight goal was 0.5 to 1 pound/week weight loss. Parents were instructed on the appropriate number of servings for their child from each food group to provide 1000 to 1200 daily kilocalories depending on age,15 and to avoid food with .5 g of fat/ serving, high in sugar, or containing artificial sweeteners because they habituate the child to a high sugary taste and in adults have been shown to increase the risk for metabolic syndrome and type 2 diabetes. The threshold of 5 g of fat/ serving was adapted from the validated Traffic Light Diet.18 Efforts to limit high-sugar foods focused mainly on sugar-sweetened drinks and breakfast food such as commercial cereals (.5 g of sugars/serving). The child's pediatrician reviewed %OBMI changes every 6 months. Between the 6-month visits the PEA prepared a letter outlining the child's progress for the families. Summary of Protocol Components Pertinent Only to the Intervention: In the Intervention behavior modification and education on parenting techniques (ie, positive reinforcement, modeling healthy diet and activity, and stimulus control) were delivered by the group leader during the group meetings and by a PEA, assigned to each family, during brief individual sessions held the same evenings as the group meetings. Parents were instructed to monitor their child and their own weight twice a week and received dietary (1500 and 1800 kcals/ day for mothers and fathers, respectively), physical, and sedentary activity guidelines with the goal of a minimum of 1 pound/week weight loss. A list of foods with portion sizes and energy content information was provided. Parents recorded intake and activity for their child and themselves in a diary by crossing off icons detailing the different food groups and physical and sedentary activity. The number of icons was tailored to the child and parent so that shaping up/down of targeted behaviors could be individualized. and fathers, respectively), physical, and sedentary activity guidelines with the goal of a minimum of 1 pound/week weight loss. A list of foods with portion sizes and energy content information was provided. Parents recorded intake and activity for their child and themselves in a diary by crossing off icons detailing the different food groups and	

<table>
<tr><td></td><td>physical and sedentary activity. The number of icons was tailored to the child and parent so that shaping up/down of targeted behaviors could be individualized."</td></tr>
<tr><td>Control/Comparator</td><td>"Summary of Protocol Common to Both Groups: Parents attended thirteen 60-minute group sessions over the 12-month treatment period (4 weekly, 2 biweekly, 4 monthly, and 3 at 8- to 10-week intervals), followed by a 12-month follow-up (3 meetings at month 16, 20, and 24). The Intervention and IC groups were held on different evenings. A PEA assigned to each family telephoned the parent between scheduled meetings 10 times during treatment and 3 times during follow-up. The intervention was delivered through the parents. PEAs cared for the children while parents attended the sessions. Both groups received dietary, physical, and sedentary activity guidelines in keeping with the Expert Committee Recommendations. The child's weight goal was 0.5 to 1 pound/week weight loss. Parents were instructed on the appropriate number of servings for their child from each food group to provide 1000 to 1200 daily kilocalories depending on age,15 and to avoid food with .5 g of fat/ serving, high in sugar, or containing artificial sweeteners because they habituate the child to a high sugary taste and in adults have been shown to increase the risk for metabolic syndrome and type 2 diabetes. The threshold of 5 g of fat/ serving was adapted from the validated Traffic Light Diet.18 Efforts to limit high-sugar foods focused mainly on sugar-sweetened drinks and breakfast food such as commercial cereals (.5 g of sugars/serving). The child's pediatrician reviewed %OBMI changes every 6 months. Between the 6-month visits the PEA prepared a letter outlining the child's progress for the families."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 96
Intervention group/s: Intervention (n=46)

Comparator group: IC (n=50)</td></tr>
<tr><td>Mean age ± SD</td><td>4.6y (0.2)</td></tr>
<tr><td>Sex</td><td>66.67% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Child weight, kg
Mean (SE)

Child z-BMI
Mean (SE)</td><td>Intervention: 23.4
(0.3)

Intervention: 2.11
(0.05)</td><td>IC: 23.5
(0.3)

IC: 2.11
(0.05)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Child weight, kg
Mean (SE)

Child z-BMI
Mean (SE)</td><td>Intervention: 25.1
(0.3)

Intervention: 1.66
(0.05)</td><td>IC: 26.4
(0.3)

IC: 1.9
(0.05)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Child weight, kg
Mean (SE)

Child z-BMI
Mean (SE)</td><td>Intervention: 28.9
(0.3)

Intervention: 1.61
(0.06)</td><td>IC: 30.6
(0.3)

IC: 1.86
(0.05)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>For as long as families were in the study they received 100% of the planned curriculum (missed sessions were always rescheduled)</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Raben, 2021

Guideline record ID: 10594--1

Study characteristics		
Citation	Raben, A., Vestentoft, P. S., Brand-Miller, J., Jalo, E., Drummen, M., Simpson, L., Martinez, J. A., Handjieva-Darlenska, T., Stratton, G., Huttunen-Lenz, M., Lam, T., Sundvall, J., Muirhead, R., Poppitt, S., Ritz, C., Pietiläinen, K. H., Westerterp-Plantenga, M., Taylor, M. A., Navas-Carretero, S., . . . Fogelholm, M. (2021). The PREVIEW intervention study: results from a 3-year randomized 2 x 2 factorial multinational trial investigating the role of protein, glycaemic index and physical activity for prevention of type 2 diabetes. Diabetes, Obesity and Metabolism, 23(2), 324-337. https://doi.org/https://dx.doi.org/10.1111/dom.14219	
Design & type	Randomised controlled trial (RCT)	Factorial design
Title	The PREVIEW intervention study: Results from a 3-year randomized 2 x 2 factorial multinational trial investigating the role of protein, glycaemic index and physical activity for prevention of type 2 diabetes	
Location	Denmark; Finland; Netherlands; UK; Spain; Bulgaria; Australia; New Zealand	
Trial name	PREVention of diabetes through lifestyle intervention and population studies In Europe and around the World (PREVIEW)	
Methods		
Inclusion criteria	"Men and women age 25-70 years, body mass index [BMI] ≥ 25 kg/m2) were enrolled pre-diabetes confirmed by an OGTT using the American Diabetes Association (ADA) criteria (13): (i) increased fasting glucose (IFG), with venous plasma glucose concentration of 5.6-6.9 mmol/L when fasted; and/or (ii) impaired glucose tolerance (IGT), with venous plasma glucose concentration of 7.8-11.0 mmol/L at 2 h after oral administration of standard 75 g glucose dose, and fasting plasma glucose <7.0 mmol/L."	
Exclusion criteria	"The main exclusion criteria were T2D, and any illness and/or medication with known or potential effect on compliance (e.g., unable to follow the physical activity program) or the main outcomes."	
Setting	University/research centre	
Intervention	"The Cambridge Weight Plan (Northants, UK) was used for the weight-loss phase.18 Participants who achieved a loss of initial body weight of 8% or higher could continue in the study. The intervention diets targeted different macronutrient compositions: HP 25 energy-% (E%) protein, 30 E% fat, 45 E% carbohydrates, low GI (<50); and moderate protein (MP) 15 E% protein, 30 E% fat, 55 E% carbohydrates, moderate GI (>56).14 Both intervention diets emphasized healthy food choices. The PA groups were: high intensity (HI) PA for 75 minutes per week; moderate intensity (MI) PA for 150 minutes per week as recommended.19 More specifically, the HI group participated in 75 minutes of PA per week at six or more metabolic equivalents of task (METs) (450 MET minutes per week) and the MI group 150 minutes at 3-5.9 METs (450 MET minutes per week). Both PA groups were therefore guided to expend the same amount of energy during PA. The counselling visits (8-12 participants) consisted of specific behavioural modification techniques designed to educate about and support adoption of the new diet and PA strategies (PREMIT).20 The frequency of the visits decreased during weight maintenance. An instructors' network ensured consistency between centres. Before trial start, all staff were trained in the procedures at joint training seminars and via standard operating procedures (SOPs). Instruction material for lifestyle changes, measures and questionnaires were also developed for the participants"	
Control/Comparator	"The Cambridge Weight Plan (Northants, UK) was used for the weight-loss phase.18 Participants who achieved a loss of initial body weight of 8% or higher could continue in the study. The intervention diets targeted different macronutrient compositions moderate	

<table>
<tr><td></td><td>protein (MP) 15 E% protein, 30 E% fat, 55 E% carbohydrates, moderate GI (>56). Both intervention diets emphasized healthy food choices. The PA groups were: high intensity (HI) PA for 75 minutes per week; More specifically, the HI group participated in 75 minutes of PA per week at six or more metabolic equivalents of task (METs) (450 MET minutes per week) Both PA groups were therefore guided to expend the same amount of energy during PA. The counselling visits (8-12 participants) consisted of specific behavioural modification techniques designed to educate about and support adoption of the new diet and PA strategies (PREMIT).20 The frequency of the visits decreased during weight maintenance. An instructors' network ensured consistency between centres. Before trial start, all staff were trained in the procedures at joint training seminars and via standard operating procedures (SOPs). Instruction material for lifestyle changes, measures and questionnaires were also developed for the participants."</td></tr>
<tr><td>Treatment duration</td><td>148 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>156 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 2223
Intervention group/s: HP-MI (n=555); HP-HI (n=556); MP-MI (n=559)

Comparator group: MP-HI (n=553)</td></tr>
<tr><td>Mean age ± SD</td><td>HP-MI: 51.6y (11.5); HP-HI: 51.8y (11.7); MP-MI: 51.4y (11.2); MP-HI: 51.4y (11.8)</td></tr>
<tr><td>Sex</td><td>67.61% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)</td><td>HP-MI: 99.3
(20.8)
HP-HI: 100.6
(21.1)
MP-MI: 101.6
(22.6)</td><td>MP-HI: 98.7
(20.9)</td></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)</td><td>HP-MI: 35.1
(6.5)
HP-HI: 35.7
(6.7)
MP-MI: 35.7
(6.6)</td><td>MP-HI: 35
(6.4)</td></tr>
<tr><td>Waist circumference (cm) - Baseline
Mean (SD)</td><td>HP-MI: 109.7
(14.4)
HP-HI: 111.2
(14.5)
MP-MI: 111.1
(15.4)</td><td>MP-HI: 109.7
(14.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
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</table>

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in BMI (kg/2)
Mean (SE)</td><td>HP-MI: -3.3
(0.1)
HP-HI: -3
(0.1)
MP-MI: -3.2
(0.1)</td><td>MP-HI: -3.2
(0.1)</td></tr>
<tr><td>Change in waist circumference (cm)
Mean (SE)</td><td>HP-MI: -8.2
(0.4)
HP-HI: -7.5
(0.4)
MP-MI: -8.5
(0.5)</td><td>MP-HI: -8.3
(0.5)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Dorenbos, E., Drummen, M., Adam, T., Rijks, J., Winkens, B., Martínez, J. A., Navas-Carretero, S., Stratton, G., Swindell, N., Stouthart, P., Mackintosh, K., Mcnarry, M., Tremblay, A., Fogelholm, M., Raben, A., Westerterp-Plantenga, M., & Vreugdenhil, A. (2021). Effect of a high protein/low glycaemic index diet on insulin resistance in adolescents with overweight/obesity-a PREVIEW randomized clinical trial. Pediatric Obesity, 16(1), e12702. https://doi.org/https://dx.doi.org/10.1111/ijpo.12702</td></tr>
</table>

N/A – Not applicable

Raynor, 2012

Guideline record ID: 10597A

Study characteristics		
Citation	Raynor, H. A., Osterholt, K. M., Hart, C. N., Jelalian, E., Vivier, P., & Wing, R. R. (2012). Efficacy of US paediatric obesity primary care guidelines: two randomized trials. Pediatric Obesity, 7(1), 28-38. https://doi.org/10.1111/j.2047-6310.2011.00005.x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Efficacy of US paediatric obesity primary care guidelines: two randomized trials	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Child eligibility criteria included: aged 4-9 years, 85th percentile for body mass index (BMI) as determined by the Centers for Disease Control (CDC) growth charts (5), and having no dietary or physical activity restrictions."	
Exclusion criteria	"Families were ineligible if the participating parent could not read English, had a psychological disorder that would impair ability to participate or if the family was planning to move out of the area during the programme."	
Setting	Home	
Intervention	"DECREASE used a restrictive approach, commonly used in paediatric weight control interventions, and reduced intake of non-nutrient-dense, energy-dense foods. In Trial 1, children and parents in DECREASE reduced intake of sweet and salty snack foods (i.e. candy, cookies, ice cream, chips, nuts) to 3 servings per week, and sugar-sweetened beverages (i.e. soda, Kool-aid, sweetened tea, non-100% fruit juice, sports drinks) to 3 servings per week. INCREASE: increased healthy foods. INCREASE was encouraged to consume two servings per day of whole fruit, three servings per day of vegetables and two servings per day of low-fat dairy products."	
Control/Comparator	"focused on increasing child growth monitoring and providing feedback to families (GROWTH MONITORING). In this intervention, families received a monthly newsletter with information about healthy eating and leisure-time behaviours, and growth was assessed at 0, 3 and 6 months. Letters providing changes in height, weight, body mass index (BMI), BMI percentile (BMI-for-age percentile chart was also provided) and percent overweight along with interpretation of these changes were mailed to families and the child's primary care physician at each growth assessment. Families were provided with research staff's contact information and encouraged to contact the research staff with any questions about the information in the letter."	
Treatment duration	6 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 101 Intervention group/s: DECREASE (n=35); INCREASE (n=33) Comparator group: GROWTH (n=33)	
Mean age ± SD	7.27 (1.7)	

<table>
<tr><td>Sex</td><td>61.39% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>ZBMI
Mean (SD)</td><td>DECREASE: 2.15
(0.44)
INCREASE: 2.34
(0.52)</td><td>GROWTH: 2.45
(0.86)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in ZBMI
Mean (SD)</td><td>DECREASE: -0.24
INCREASE: -0.25</td><td>GROWTH: -0.17</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Growth monitoring appointments: 72.5%; 6 month ZBMI follow up: 91.9%; 12 month ZBMI follow up: 90.1%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Raynor, 2012

Guideline record ID: 10597B--1

Study characteristics		
Citation	Raynor, H. A., Osterholt, K. M., Hart, C. N., Jelalian, E., Vivier, P., & Wing, R. R. (2012). Efficacy of US paediatric obesity primary care guidelines: two randomized trials. Pediatric Obesity, 7(1), 28-38. https://doi.org/10.1111/j.2047-6310.2011.00005.x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Efficacy of US paediatric obesity primary care guidelines: two randomized trials	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Child eligibility criteria included: aged 4-9 years, 85th percentile for body mass index (BMI) as determined by the Centers for Disease Control (CDC) growth charts (5), and having no dietary or physical activity restrictions."	
Exclusion criteria	"Families were ineligible if the participating parent could not read English, had a psychological disorder that would impair ability to participate or if the family was planning to move out of the area during the programme."	
Setting	Home	
Intervention	"TRADITIONAL: focused on behaviours typically targeted in paediatric weight management programmes, decrease sugar-sweetened beverage intake and increase physical activity. TRADITIONAL encouraged children to reach 60 min day-1 (parents 30 min day-1) of moderate-intensity physical activity most days of the week (14) and for children and parents to consume 3 servings of sugar-sweetened beverages per week-1; SUBSTITUTES: used a behavioural economics approach and changed substitute behaviours for sugar-sweetened beverages (i.e. increase low-fat milk intake) and physical activity (i.e. decrease TV watching). SUBSTITUTES encouraged children and parents to watch two hours of TV day-1 (15) and to consume two servings of low-fat milkday-1"	
Control/Comparator	"focused on increasing child growth monitoring and providing feedback to families (GROWTH MONITORING). In this intervention, families received a monthly newsletter with information about healthy eating and leisure-time behaviours, and growth was assessed at 0, 3 and 6 months. Letters providing changes in height, weight, body mass index (BMI), BMI percentile (BMI-for-age percentile chart was also provided) and percent overweight along with interpretation of these changes were mailed to families and the child's primary care physician at each growth assessment. Families were provided with research staff's contact information and encouraged to contact the research staff with any questions about the information in the letter."	
Treatment duration	6 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 81 Intervention group/s: TRADITIONAL (n=26); SUBSTITUTES (n=26) Comparator group: GROWTH (n=29)	

<table>
<tr><td>Mean age ± SD</td><td>7.1y (1.5)</td></tr>
<tr><td>Sex</td><td>60.49% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>ZBMI
Mean (SD)</td><td>TRADITIONAL: 2.25
(0.38)
SUBSTITUTES: 2.28
(0.67)</td><td>GROWTH: 2.27
(0.71)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in ZBMI
Mean (SD)</td><td>TRADITIONAL: -0.41
SUBSTITUTES: -0.21</td><td>GROWTH: -0.24</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Growth monitoring appointments: 64.2%; 6 month ZBMI follow up: 87.6%; 12 month ZBMI follow up: 91.4%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Raynor, 2012

Guideline record ID: 10598--1

Study characteristics		
Citation	Raynor, H. A., Steeves, E. A., Hecht, J., Fava, J. L., & Wing, R. R. (2012). Limiting variety in non-nutrient-dense, energy-dense foods during a lifestyle intervention: a randomized controlled trial. The American Journal of Clinical Nutrition, 95(6), 1305-1314. https://doi.org/10.3945/ajcn.111.031153	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Limiting variety in non-nutrient-dense, energy-dense foods during a lifestyle intervention: a randomized controlled trial	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"An age of 21 to 65 y and a BMI (in kg/m2) between 27 and 45."	
Exclusion criteria	"Individuals were excluded if they could not walk 2 blocks; reported a heart condition, chest pain during periods of activity or rest, or loss of consciousness on the Physical Activity Readiness Questionnaire (13); were taking weight-loss medications or participating in a weight-loss program; had undergone bariatric surgery; were pregnant, lactating, or 6 mo postpartum or planned to become pregnant during the time frame of the investigation; were allergic to foods used in hedonic measures; and were consuming 5 different types of NND-EDFs."	
Setting	Home	
Intervention	"LV: Lifestyle + The LV prescription was designed to reduce the number of different NND-EDFs consumed to only 2 self-selected, chosen NND-EDFs. NND-EDFs were described to participants as foods that were energy-dense, of low nutrient value, and consumed as any component of a meal or snack and were grouped into the specific food groups from MyPyramid (18). NND-EDFs included baked goods, granola/snack bars, high-fat crackers, and flavored popcorn (bread, cereal, rice, and pasta); flavored dairy drinks, frozen dairy-based desserts, frozen yogurt, ice cream, ice milk, and pudding (milk, yogurt, and cheese); and candy, chips, salty snacks, chocolate, frozen desserts, gelatin desserts, and sherbet (fats, oils, and sweets). Modified NND-EDFs (eg, reduced-fat FIGURE 1. Participant flow. LIMITING VARIETY 1307 Downloaded from https://academic.oup.com/ajcn/article/95/6/1305/4568376 by guest on 06 February 2023 cookies), except for calorie-free modified foods (eg, sugar-free gelatin), were included in this category because they compete with healthier, more nutrient-dense food choices and still can be a significant source of calories. Moreover, they are sensorysimilar to their nonmodified counterparts. Participants were informed that reducing variety in the NND-EDF group helped reduce intake from this food group, which assisted them in meeting daily energy and fat gram goals. During the baseline assessments and before randomization, participants listed all NND-EDFs, including all flavors of the NND-EDFs (ie, chocolate chip cookie rather than just cookie), that they had consumed within the previous 28 d as part of any meal or snack. Participants also reported their liking of each NND-EDF, using a Likert-type scale, and their frequency of consumption of each NND-EDF over the previous 28 d. Each NND-EDF reported consumed received a score, which was the product of the liking · the frequency score. The 6 NND-EDFs with the highest product scores were presented to the participants, and from this list participants were asked to choose 2 that they would like to include in their diet during the intervention. Participants were encouraged to pick NND-EDFs that they felt they could consume while also working toward consuming a low-energy, low-fat diet (ie, they were advised to not choose an NND-EDF in which it would be challenging to consume only one serving at a time). The flavor of NND-EDFs was also	

	defined. For example, rather than just selecting ice cream, participants chose the flavor of ice cream, such as strawberry ice cream. Seventy-nine percent of participants selected a sweet and savory NND-EDF, 19% selected 2 sweet NND-EDFs, and 2% selected 2 savory NND-EDFs for their 2 chosen snack foods. In the initial treatment session, after being made aware of randomization assignment, participants in Lifestyle+LV were reminded of the 2 NND-EDFs that they selected. Participants in this condition were instructed to eat no other NND-EDFs, except the 2 selected, throughout the intervention as any part of a meal or snack. Participants were not given instructions regarding any specific amount of the chosen NND-EDFs to consume or the frequency of consumption of these foods. Participants recorded NND-EDF consumption in the daily diary, indicating whether the NND-EDF was a "chosen" NND-EDF or "other" NND-EDF. Participants were informed that the goal was to limit NND-EDF consumption to only the 2 chosen NND-EDFs."
Control/Comparator	"LIFESTYLE: The 18-mo intervention consisted of 48 group meetings lasting 60 min each. These meetings occurred weekly from month 1 to month 6 and then twice a month from month 7 to month 18. The meetings were led by an experienced research interventionist (either master or doctoral level) with expertise in nutrition, exercise physiology, and behavior modification and were delivered in a research setting. Separate group meetings occurred for the 2 conditions. Sessions covered lessons on behavioral and cognitive skills (self-monitoring, stimulus control, problem-solving, preplanning, goal setting, cognitive restructuring, social support development, and relapse prevention) to help with changing dietary and physical activity behaviors and were modeled after lessons used in the Diabetes Prevention Program (17). Each session began with a group discussion on progress on intervention goals, which was followed by a lesson and the assignment of homework that would assist participants in meeting intervention goals. Participants were instructed to consume a standard energy- and fat-restricted diet. Daily calorie goals were based on study entry weight: with 1200 kcal/d prescribed for an entry weight 90.9 kg (200 lb) and 1500 kcal/d prescribed for an entry weight of .90.9 kg (200 lb). Fat intake was restricted to 30% of energy from fat. A sample meal plan, based on recommendations of MyPyramid (18), was provided to help participants consume a balanced diet while meeting energy and fat goals. Participants used a diary to record their daily energy and fat gram intake from food items and beverages. Diaries were turned in weekly for months 1-6, and twice a month from months 7-18, so that written feedback on food choices, dietary goals, and other problematic eating behaviors could be provided to participants. Participants were also educated on how to adjust caloric intake for weight maintenance, to prevent weight regain, in sessions focused on relapse prevention (eg, increase caloric intake by 100 kcal/d for 1 wk, keeping other aspects of the diet and physical activity the same, until weight maintenance occurred). Participants were instructed to gradually increase moderateintensity physical activity to 40 min/d 5 times/wk. Participants were encouraged to walk briskly and accumulate time spent being physically active by engaging in multiple short bouts (eg, 10 min in length). Participants were also given a pedometer and a goal of 10,000 steps per day (19). Daily steps and minutes of physical activity were recorded in the same diary in which consumption was recorded)."
Treatment duration	18 months
Follow-up from baseline	12 months
Eligible outcome(s) reported	Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 202 Intervention group/s: Lifestyle+LV (n=101) Comparator group: Lifestyle (n=101)
Mean age ± SD	51.3y (9.5)

<table>
<tr><td>Sex</td><td>57.43% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>Lifestyle+LV: 34.5
(4.1)</td><td>Lifestyle: 35.3
(4.5)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Percentage Weight Loss
Mean (SD)</td><td>Lifestyle+LV: -9.9
(7.6)</td><td>Lifestyle: -9.6
(9.2)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Number of sessions attended (31.6 ± 13.1), number of diaries turned in (31.5 ± 21.7), retention rates for follow-up assessments: 97.5%, 95.1%, and 93.1% at 6, 12, and 18 mo, respectively</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Recasens, 2019

Guideline record ID: 10599--1

Study characteristics		
Citation	Recasens, M. A., Xicola-Coromina, E., Manresa, J.-M., Ullmo, P. A., Jensen, B. B., Franco, R., Suarez, A., Nadal, A., Vila, M., Recasens, I., Pérez, M. J., Castell, C., & Llargués, E. (2019). Impact of school-based nutrition and physical activity intervention on body mass index eight years after cessation of randomized controlled trial (AVall study). Clinical Nutrition, 38(6), 2592-2598. https://doi.org/https://dx.doi.org/10.1016/j.clnu.2018.12.029	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Impact of school-based nutrition and physical activity intervention on body mass index eight years after cessation of randomized controlled trial (AVall study)	
Location	Spain	
Trial name	The AVall Study	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	School	
Intervention	"The aim of the intervention was to promote healthy eating habits and physical activity in the school setting, using the investigation, vision, action and change (IVAC) educational methodology during two school years. In the IVAC methodology, children investigated and reflected on how conditions in their environment and in society affected their health and lifestyle and developed actions for change [14,15]. The teacher helped them develop skills and competencies to change the conditions in their environment. At the beginning of the project, the intervention group in each school was offered necessary equipment to promote physical activity during break time (balls, ropes, elastic bands and handkerchiefs to practice traditional games) and educational material on healthy food consisting of a nutritional and physical activity pyramid prepared by the research team, complementary material from public institutions or approved material prepared by food companies. Every classroom used three hours a week for activities related to healthy food habits and/or physical activity. The teachers in each classroom developed activities related to healthy habits that were integrated into regular content (e.g., math, science, language, knowledge of the environment) through means such as posters, food tables, games, crafts, cooking workshops or games on the school playground. Each activity was designed to ensure that children participated. Over the two-year intervention period, six meetings between the research team, teachers and educators took place to monitor activities and plan subsequent actions. The purpose of the meetings was to attempt to standardize the intervention across classes and collect ideas that could be implemented in other schools. The methodology was not rigid; individual classroom teachers adapted the concepts to discuss with students in the different thematic areas. This educational method allowed the inclusion of activities related to healthy eating habits and physical activity in any subject in the curriculum. In addition, an extracurricular intervention that relied on collaboration between schools and participating families was designed."	
Control/Comparator	Not reported	
Treatment duration	2 years	
Follow-up from baseline	10 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 278
Intervention group/s: Intervention (n=156)

Comparator group: Control (n=122)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>46.76% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Prevalence of overweight Proportion (%)

prevalence of obesity Proportion (%)</td><td>Intervention: 17.9

Intervention: 7.7</td><td>Control: 14.8

Control: 7.4</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Prevalence of overweight Proportion (%)

prevalence of obesity Proportion (%)</td><td>Intervention: 15.4

Intervention: 5.8</td><td>Control: 21.3

Control: 6.6</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Redmon, 2010

Guideline record ID: 10600--1

Study characteristics		
Citation	Redmon, J. B., Bertoni, A. G., Connelly, S., Feeney, P. A., Glasser, S. P., Glick, H., Greenway, F., Hesson, L. A., Lawlor, M. S., Montez, M., Montgomery, B., & the Look AHEAD Research Group. (2010). Effect of the look AHEAD study intervention on medication use and related cost to treat cardiovascular disease risk factors in individuals with type 2 diabetes. Diabetes Care, 33(6), 1153-1158. https://doi.org/https://dx.doi.org/10.2337/dc09-2090	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of the look AHEAD study intervention on medication use and related cost to treat cardiovascular disease risk factors in individuals with type 2 diabetes	
Location	USA	
Trial name	Action for Health and Diabetes (Look AHEAD)	
Methods		
Inclusion criteria	"Aged 45-76 years, had a BMI 25 kg/m2 (27 kg/m2 if taking insulin), A1C 11%, blood pressure 160/100 mmHg, and fasting triglyceride level 600 mg/dl. Participants had to successfully complete a baseline maximal graded exercise test reaching a workload of at least four metabolic equivalents (METS)."	
Exclusion criteria	Not reported	
Setting	GP clinic, Hospital, University/research centre	
Intervention	"ILI cohort, which received a program of diet, behavior modification, and increased physical activity with goals of a minimum weight loss of 7% of initial body weight and at least 175 min/week of moderate physical activity (e.g., walking). The initial year of the ILI used frequent individual and group meetings with intervention teams that included registered dietitians, behavior psychologists, and exercise specialists. To assist participants in reducing caloric intake, participants were prescribed portion-controlled diets that included the use of meal-replacement products. Dietary counseling included information on healthy diet composition, including adequate intake of fruits and vegetables and avoidance of excessive caloric intake from fat. After 6 months, participants who had difficulty meeting study weight loss goals received additional study intervention including additional behavior strategies and use of the weight loss medication orlistat in accord with specific study protocols. All study participants received a general diabetes education session prior to randomization."	
Control/Comparator	"usual-care cohort, which received a program of general diabetes support and education (DSE), The DSE cohort was offered three additional diabetes education sessions during the first year."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 5145 Intervention group/s: ILI (n=2570) Comparator group: DSE (n=2575)	

<table>
<tr><td>Mean age ± SD</td><td>ILI: 59y (7); DSE: 59y (7)</td></tr>
<tr><td>Sex</td><td>59.53% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>ILI: 35.9
(6)</td><td>DSE: 36
(5.8)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>ILI: 32.8
(6.1)</td><td>DSE: 35.7
(5.9)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight change (kg)
Mean</td><td>ILI: -8.7</td><td>DSE: -0.8</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Wadden, T. A., Neiberg, R. H., Wing, R. R., Clark, J. M., Delahanty, L. M., Hill, J. O., Krakoff, J., Otto, A., Ryan, D. H., Vitolins, M. Z., & The Look AHEAD Research Group. (2011). Four-year weight losses in the Look AHEAD study: factors associated with long-term success. Obesity, 19(10), 1987-1998. https://doi.org/https://dx.doi.org/10.1038/oby.2011.230; The Look AHEAD Research Group. (2013). Cardiovascular effects of intensive lifestyle intervention in type 2 diabetes. The New England Journal of Medicine, 369(2), 145-154. https://doi.org/10.1056/NEJMoa1212914</td></tr>
</table>

N/A – Not applicable

Reeves, 2021

Guideline record ID: 10601--1

Study characteristics		
Citation	Reeves, M. M., Terranova, C. O., Winkler, E. A. H., McCarthy, N., Hickman, I. J., Ware, R. S., Lawler, S. P., Eakin, E. G., & Demark-Wahnefried, W. (2021). Effect of a remotely delivered weight loss intervention in early-stage breast cancer: randomized controlled trial. Nutrients, 13(11), 4091. https://doi.org/10.3390/nu13114091	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a Remotely Delivered Weight Loss Intervention in Early-Stage Breast Cancer: Randomized Controlled Trial	
Location	Australia	
Trial name	Living Well after Breast Cancer	
Methods		
Inclusion criteria	"Women aged 18-75 years were eligible if they had: a diagnosis of stage I-III breast cancer in the previous two years, a BMI 25-45 kg/m2, and completed primary cancer treatment (excluding endocrine treatment)."	
Exclusion criteria	"Exclusions included pregnancy, contraindications to unsupervised exercise, >5% weight loss within the previous six months, insufficient English, or self-reported anxiety and/or depression that would interfere with participation."	
Setting	Home	
Intervention	"The intervention was remotely delivered via telephone by accredited dietitians (with optional text messages) and aimed for weight loss of 5-10%, by reducing energy intake (1200-1500 kcal/day) and saturated fat (<7% total energy), increasing vegetables and fruit (5 and 2 servings/day, respectively), and limitingalcohol (≤1 serving/day). Additionally, incremental increases in moderate-to-vigorous intensity aerobic activity to 210 min/week and 2-3 resistance exercise sessions/week were encouraged. Intervention participants received a workbook, scale, measuring tape, pedometer, calorie-counter book, and self-monitoring diary. During the first 6 months, participants received up to 16 calls (six weekly then 10 bi-weekly calls) and optional text messages. During the second 6 months, participants received six monthly calls and tailored text messages. Dietitians used a semi-structured approach and motivational interviewing for each call. Participants in both arms received materials after each assessment, including a study newsletter and assessment feedback. For intervention participants, assessment results were compared to guidelines."	
Control/Comparator	"Participants in both arms received materials after each assessment, including a study newsletter and assessment feedback. Participants allocated to usual care received brief feedback on their assessment results."	
Treatment duration	18 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 159 Intervention group/s: Intervention (n=79) Comparator group: Usual care (n=80)	

Mean age ± SD	Intervention: 55.9y (9.1); Usual Care: 54.9y (9.3)
Sex	100.00% female
Pre-existing medical condition	Diagnosis of stage I-III breast cancer in the previous two years
Results	

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Weight (kg) Mean (SD)	Intervention: 83.92 (14.19)	Usual care: 83.64 (13.62)
Total fat mass (kg) Mean (SD)	Intervention: 39 (10.56)	Usual care: 37.36 (10.72)
Waist circumference (cm) Mean (SD)	Intervention: 106.72 (11.7)	Usual care: 104.91 (10.37)
	Intervention: 31.3 (5.2)	Usual care: 31.4 (4.9)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point

Variable	Intervention arm/s	Comparator
Change in weight (%) Mean (95% CIs)	Intervention: -5.01 (-6.51--3.51)	Usual care: -0.3 (-1.82-1.21)
Change in weight (kg) Mean (95% CIs)	Intervention: -4.12 (-5.36--2.88)	Usual care: -0.31 (-1.57-0.95)
Change in total fat mass (kg) Mean (95% CIs)	Intervention: -2.99 (-4.06--1.92)	Usual care: 0.27 (-0.91-1.45)
Change in waist circumference (cm) Mean (95% CIs)	Intervention: -5.56 (-7.23)	Usual care: -2.03 (-3.75--0.31)

Change in outcome measure from baseline to final follow-up/endpoint

Variable	Intervention arm/s	Comparator
Change in weight (%) Mean (95% CIs)	Intervention: -3.66 (-5.26--2.05)	Usual care: -0.65 (-2.32-1.02)
Change in weight (kg) Mean (95% CIs)	Intervention: -3.02 (-4.38--1.65)	Usual care: -0.59 (-2.02-0.84)
Change in total fat mass (kg) Mean (95% CIs)	Intervention: -3.02 (-4.38--1.65)	Usual care: -0.09 (-1.45-1.27)
Change in waist circumference (cm) Mean (95% CIs)	Intervention: -5.36 (-6.93--3.79)	Usual care: -2.28 (-3.9--0.65)

Compliance with treatment	Not reported
Notes	

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Reichard, 2015

Guideline record ID: 10602--1

Study characteristics		
Citation	Reichard, A., Saunders, M. D., Saunders, R. R., Donnelly, J. E., Lauer, E., Sullivan, D. K., & Ptomey, L. (2015). A comparison of two weight management programs for adults with mobility impairments. Disability and Health Journal, 8(1), 61-69. https://doi.org/https://dx.doi.org/10.1016/j.dhjo.2014.08.002	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A comparison of two weight management programs for adults with mobility impairments	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"(a) Had a self-reported mobility impairment, (b) were overweight or obese ((BMI) > 25), (c) qualified or were eligible for Medicaid, and (d) lived within 60 miles of Wichita, KS."	
Exclusion criteria	"Potential participants were excluded if they had a diagnosis of Type 1 diabetes, acute heart disease, cancer, or other medical conditions that would affect energy metabolism, or if they had participated in another weight loss program within the last year."	
Setting	Home, Throughout the project, participants met once a month with project staff, in their homes or other place of their choosing.	
Intervention	"One diet, referred to as the modified Stop Light Diet (SLDm diet), followed the model used successfully by Saunders et al25 with adults with intellectual or developmental disabilities. This diet consisted of: (a) at least 5 daily servings of (fresh, canned or frozen) fruits and vegetables. (b) 2 meal replacement shakes (Provided by Health Management Resources (HMR)). (c) 2 packaged entrees of 300 calories or less, typically found in grocery stores. The SLDm diet program used a visual aid similar to a Stoplight Guide described by Epstein and Squires (1988). This aid listed a typical serving size for approximately 150 food items. Items in the 40e60 calorie range per serving were categorized in the green group, or ''Eat all you want''; items in the 60e100 range in the yellow group, or ''use caution''; and items over 100 calories in the red group ''eat rarely/never.'' Participants were told they if they wanted additional foods, they should choose one from the green group, or occasionally, yellow group on the chart; red foods should only be those found in the packaged entrees. Each participant was randomly assigned to one of the diets with approximately 1200e1500 calories (adjusted upward based on initial weight), both clinically proven to promote weight loss in average adults. All participants were encouraged to regularly drink water or other zero calorie beverages and to exercise. A simple exercise program was recommended for each participant based on his/her physical capabilities. Those that were ambulatory were encouraged to walk. Those that were unable to bear weight but had movement in their legs or arms were encouraged use one of several ergometers available through the project or to purchase one. In addition, exercises employing therabands were taught and interested participants were provided with therabands, with project funds"	
Control/Comparator	Not reported.	
Treatment duration	6 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 126
Intervention group/s: Intervention (n=64)

Comparator group: Control (n=62)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 51.7y (51.4); Control: 45.6y (45.6)</td></tr>
<tr><td>Sex</td><td>84.92% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Median (mean)</td><td>Intervention: 42.5
(43.6)</td><td>Control: 45.9</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Median (mean)</td><td>Intervention: 41.2
(43)</td><td>Control: 46.3
(45.7)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (lbs)
Median (mean)

Change in BMI (kg/m2)
Median (mean)</td><td>Intervention: -17
(-14.6)

Intervention: -2.58
(-2.64)</td><td>Control: -4
(-1.39)

Control: -0.65
(-0.27)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Reid, 2014

Guideline record ID: 10603

Study characteristics		
Citation	Reid, R. D., McDonnell, L. A., Riley, D. L., Mark, A. E., Mosca, L., Beaton, L., Papadakis, S., Blanchard, C. M., Mochari-Greenberger, H., O'Farrell, P., Wells, G. A., Slovinec D'Angelo, M. E., & Pipe, A. L. (2014). Effect of an intervention to improve the cardiovascular health of family members of patients with coronary artery disease: a randomized trial. Canadian Medical Association Journal, 186(1), 23-30. https://doi.org/10.1503/cmaj.130550	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of an intervention to improve the cardiovascular health of family members of patients with coronary artery disease: a randomized trial	
Location	Canada	
Trial name	N/A	
Methods		
Inclusion criteria	“Siblings, children and spouses of patients with CAD who had at least 1 modifiable risk factor (i.e., smoking, physical inactivity, dyslipidemia, hypertension or abdominal obesity) were eligible.”	
Exclusion criteria	“We excluded people with one of the following conditions: established coronary, cerebrovascular or peripheral vascular disease; diabetes; current or planned pregnancy; or fasting blood glucose ≥ 7 mmol/L at screening.”	
Setting	Hospital	
Intervention	“The heart-health intervention included feedback about the results of the baseline and 3-month assessments; goal setting; 17 counselling sessions with a trained health educator; and the communication of reports and recommendations to the participant's primary care physician. Counselling sessions occurred weekly for the first 12 weeks and then at weeks 16, 20, 26, 39 and 52. The first 2 sessions lasted 45 minutes, and the remaining sessions lasted 15-20 minutes. The second counselling session (at week 2) was face-to-face; all others were by telephone. The counselling scripts (available from the corresponding author) were standardized. During the sessions in weeks 1 and 2, participants received feedback about their risk levels relative to recommendations. 13,21-24 The health educators helped participants set goals for reducing their risk and create action plans. An assessment summary and indications for his or her medical care were mailed to the patient's primary care physician. Medical care was suggested if the patient's blood pressure or lipid levels exceeded threshold values (i.e., blood pressure 140/90 mm Hg; 21 low-density lipoprotein [LDL] cholesterol > 2.0 mmol/L if participant's Framingham Risk Score was 20%, LDL cholesterol > 3.5 mmol/L if the Framingham Risk Score was 10%-19%, or LDL cholesterol > 5.0 mmol/L if the Framingham Risk Score was < 10%). Participants received printed materials about smoking cessation, healthy eating, weight management and physical activity. During the phone calls at weeks 3-12 16, 20, 26, 39 and 52, the health educators engaged participants in a dialogue about progress toward their goals and recommended strategies to overcome any barriers. During the week 16 session, participants received the results of their 3-month assessment. The summary of this assessment and recommendations for medical care were mailed to the patient's primary care physician.”	
Control/Comparator	“The control group received printed materials about smoking cessation, healthy eating, weight management and physical activity. A report was sent to the participant's primary care physician if the critical threshold values for blood pressure or lipids were exceeded.”	
Treatment duration	12 months	

<table>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 426
Intervention group/s: Family heart-health intervention (n=211)

Comparator group: Control (n=215)</td></tr>
<tr><td>Mean age ± SD</td><td>51.5y (11.6)</td></tr>
<tr><td>Sex</td><td>61.27% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Family heart-health intervention: 29.2 (5.4)</td><td>Control: 29.6 (6)</td></tr>
<tr><td>Waist Circumference
Mean (SD)</td><td>Family heart-health intervention: 96.3 (13.5)</td><td>Control: 97.4 (15.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Family heart-health intervention: 27.9 (4.8)</td><td>Control: 29 (5.3)</td></tr>
<tr><td>Waist Circumference
Mean (SD)</td><td>Family heart-health intervention: 92.5 (13.4)</td><td>Control: 95.1 (13.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Participants in the intervention group completed a median of 15 of the 17 counselling sessions (range 0-17 sessions; interquartile range 11-17 sessions).</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Reis, 2010

Guideline record ID: 10605--1

Study characteristics		
Citation	Reis, L. O., Favaro, W. J., Barreiro, G. C., de Oliveira, L. C., Chaim, E. A., Fregonesi, A., & Ferreira, U. (2010). Erectile dysfunction and hormonal imbalance in morbidly obese male is reversed after gastric bypass surgery: a prospective randomized controlled trial. International Journal of Andrology, 33(5), 736-744. https://doi.org/https://dx.doi.org/10.1111/j.1365-2605.2009.01017.x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Erectile dysfunction and hormonal imbalance in morbidly obese male is reversed after gastric bypass surgery: a prospective randomized controlled trial	
Location	Brazil	
Trial name	N/A	
Methods		
Inclusion criteria	"Morbidly obese men - BMI > 40."	
Exclusion criteria	"Exclusion criteria were co-morbidities requiring regular drug usage (statin, antihypertensive, oral anti-diabetic), endocrine disease (except mild hypogonadism) or recent hormonal manipulation (thyroid / other hormonal reposition / block in the last 3 months), testicular impairment, previous history of alcohol or tobacco abuse and phosphodiesterase type-5 inhibitor usage."	
Setting	Hospital, University/research centre	
Intervention	"INTERVENTION programme (group A - 10 patients), including weight loss plan with nutritional education for low energy diet and intensive behaviour modification for daily physical activity guided by multidisciplinary team of nutritionist, physical educator, psychologist and subsequent surgery (gastric bypass) The goals of intervention prior to surgery were: a reduction in intake of saturated fatty acid to less than 15% of energy consumed; an increase in intake of monounsaturated fatty acid to 15% or more of energy consumed; an increase in fibre intake to at least 20 g per 1000 kcal; and moderate exercise for at least 30 min / day for at least 5 days/week. Behavioural and psychological counselling was also offered. The dietary advice was tailored to each subject on the basis of 3-day food records. Each subject in the intervention group had weekly sessions with a nutritionist during the first year of the study and monthly thereafter. In group A, surgery was performed as previously described (Scopinaro et al., 1996); briefly, a distal gastrectomy involving three-quarters of the stomach with a 250-300 mL residual stump and Roux-en-Y reconstruction. The alimentary tract was 250 cm long; the common tract, 50 cm long. A prophylactic cholecystectomy was performed. The anamnesis, physical examination, BMI (calculated as body weight divided by height squared - kg / m2), International Index of Erectile Function (IIEF-5) questionnaire and blood test were obtained for hormonal profile once before enrollment (during the initial consultation) - time 0, once before surgery (usually between 3 and 7 days before the operation, which were offered 4 months after enrollment) - time 1 and once after surgery (24 months follow-up) - time 2. Serum total (TT) and free testosterone (FT), oestradiol, prolactin (PRL), luteinizing (LH) and follicle-stimulating (FSH) hormones were measured. A centralized computed-generated randomization was utilized and the person administering the questionnaire was blinded to the surgery."	
Control/Comparator	"CONTROL (group B - 10 patients), which underwent general multidisciplinary team direction and were not arranged to receive intensive programme. For ethical reasons, subjects in the control group were given general, oral and written information about healthy food choices and general guidance on increasing their level of physical activity at	

<table>
<tr><td></td><td>baseline and at subsequent visits, but no specific individualized programme was offered to them. In the final study, the same intervention and surgery were offered to all subjects in the control group. The anamnesis, physical examination, BMI (calculated as body weight divided by height squared - kg／m2), International Index of Erectile Function (IIEF-5) questionnaire and blood test were obtained for hormonal profile once before enrollment (during the initial consultation) - time 0, once before surgery (usually between 3 and 7 days before the operation, which were offered 4 months after enrollment) - time 1 and once after surgery (24 months follow-up) - time 2. Serum total (TT) and free testosterone (FT), oestradiol, prolactin (PRL), luteinizing (LH) and follicle-stimulating (FSH) hormones were measured. A centralized computed-generated randomization was utilized and the person administering the questionnaire was blinded to the surgery.”</td></tr>
<tr><td>Treatment duration</td><td>4 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 20
Intervention group/s: A Group (n=10)

Comparator group: B Group (n=10)</td></tr>
<tr><td>Mean age ± SD</td><td>39.3y (11.3)</td></tr>
<tr><td>Sex</td><td>100.00% male</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg／m2)
Mean (SD)

Weight (kg)
Mean (SD)</td><td>A Group: 55.7
(7.8)

A Group: 168.6
(28.2)</td><td>B Group: 54
(6.1)

B Group: 160.4
(20.1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg／m2)
Mean (SD)

Weight (kg)
Mean (SD)</td><td>A Group: 31
(5.3)

A Group: 94.5
(22.1)</td><td>B Group: 52.3
(5.5)

B Group: 155
(17.6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Rendeli, 2020

Guideline record ID: 10609--1

Study characteristics		
Citation	Rendeli, C., Kuczynska, E., Giuliano, A. C., Chiaretti, A., & Ausili, E. (2020). Dietary approach to prevent obesity risk in Spina Bifida patients. Child's Nervous System, 36(7), 1515-1520. https://doi.org/https://dx.doi.org/10.1007/s00381-019-04471-y	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Dietary approach to prevent obesity risk in Spina Bifida patients	
Location	Italy	
Trial name	N/A	
Methods		
Inclusion criteria	"Spina Bifida patients with BMI ≥ 25."	
Exclusion criteria	Not reported	
Setting	University/research centre	
Intervention	"The "diet" group received a dietary program."	
Control/Comparator	""No diet" group did not receive any program."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 56 Intervention group/s: Diet group (n=26) Comparator group: No diet group (n=30)	
Mean age ± SD	18.39y (5.63)	
Sex	58.93% female	
Pre-existing medical condition	Spina Bifida	
Results		

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
BMI (kg/m2)	Diet group: 29.7 (3.8)	No diet group: 30.3 (4.6)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to

Variable	Intervention arm/s	Comparator

<table>
<tr><td>12 months or closest time point</td><td><table><tr><td>BMI (kg/m2)
Mean (SD)</td><td>Diet group: -27.7
(3.7)</td><td>No diet group: -29.2
(4.7)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Rieger, 2017

Guideline record ID: 10613--1

Study characteristics		
Citation	Rieger, E., Treasure, J., Murray, K., & Caterson, I. (2017). The use of support people to improve the weight-related and psychological outcomes of adults with obesity: a randomised controlled trial. Behaviour Research and Therapy, 94, 48-59. https://doi.org/https://dx.doi.org/10.1016/j.brat.2017.04.012	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The use of support people to improve the weight-related and psychological outcomes of adults with obesity: A randomised controlled trial	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	"18-65 years old, had a body mass index (BMI kg/m2) 30, and had a member from their social network who was able to attend the program for support people. The latter were patient-selected, and comprised diverse relationships such as partners, siblings, adult children, parents, friends, and colleagues."	
Exclusion criteria	"Exclusion criteria for the patients included major psychiatric or medical conditions that would preclude full participation in the study, current treatment for obesity, current treatments known to affect eating or weight, and pregnancy."	
Setting	unclear (group CBT sessions)	
Intervention	"CBT-A treatment + The support people of patients in the CBT-SP condition participated in 10, 90-minute group sessions comprised of support people alone, with 4e6 participants per group. These sessions commenced eight weeks after the start of the patients' program. The program for support people consisted of six fortnightly sessions followed by a four-month period for support people to practice their support skills. An additional three fortnightly sessions were then held. After a further one-month period for support people to practice these additional support skills, the tenth and final session was held. The rationale for starting the support people intervention eight weeks after the commencement of the patient program was two-fold. Firstly, in accordance with the principles of motivational interviewing, the training of the support people sought to emphasise that the patients have the expertise to manage their weight and that the support person's role is to elicit this expertise. Such an emphasis sought to minimise engagement in controlling behaviours on the part of the support person. Thus in the initial eight weeks of the intervention the focus was on helping patients to develop their expertise in fundamental weight management skills. Secondly, after eight weekly groups, the patient groups were held fortnightly. In order to partially compensate for this reduction in support from the clinician and group, this was considered to be an ideal time for meetings between the patient and their support person to commence. The support people program was developed by the authors (ER and JT) on the basis of published manuals on motivational interviewing (Miller & Rollnick, 2013; Rosengren, 2009) and programs for support people in the context of substance misuse (Smith & Meyers, 2004) and eating disorders (Treasure, Smith, & Crane, 2007). The aim of the intervention was to enable support people to become skilled in eliciting self-motivation for weight control from the patients. To help patients increase the importance of weight loss to them, support people were instructed in questions designed to elicit from patients the costs of their eating and weight problems, as well as questions designed to help patients identify the benefits of their eating and weight problems with a view to discussing with their support person alternative (non-food) ways of obtaining these benefits. To help patients increase their selfefficacy for weight loss, support people were instructed in questions designed to elicit from patients statements of confidence in their weight loss	

	abilities. Instruction in communication skills primarily focused on the use of affirmations, asking open-ended questions, avoiding unsolicited advice-giving, and the primacy of good listening skills. Support people were encouraged to have regular support sessions with the patient for reviewing with the patient their weight goals, and identifying the strategies the patient is using to achieve these goals or the obstacles that are impeding goal attainment. Support people were also instructed in problemsolving skills to encourage discussing weight-related problems with the patient in a collaborative manner. Throughout, support people were encouraged to adopt a guiding style and avoid the extremes of being controlling or passive in their support role. A detailed description of each session's content can be seen in Table 5 of Rieger et al. (2014)"
Control/Comparator	"All patients participated in 26, 90-minute group sessions comprised of eight weekly, 16 fortnightly, and two monthly sessions over 12 months, with 6e8 patients per group. Group membership was somewhat flexible in that if patients were unable to attend their usual group due to other commitments, they attended one of the other groups scheduled for that week to ensure that they received the session content. Nine (5%) of the patients who commenced treatment attended a group other than their allocated group during the course of the intervention, usually on only one occasion. Treatment was conducted in a series of cohorts, from August 2010 to November 2013, with the final assessment undertaken in November 2014. The program was developed by the authors (ER and JT) on the basis of published manuals on cognitive-behavioural approaches for obese adults (Beck, 2007; Cooper, Fairburn, & Hawker, 2003) and motivational interviewing (Miller & Rollnick, 2013). It focused on teaching cognitive-behavioural skills for dietary modification and increasing physical activity, and included both a weight loss phase (the initial 8 months) and a weight maintenance phase (the final 4 months). The initial sessions entailed education regarding the recommended caloric intake, rate of weight loss, and structure of eating, as well as instituting daily self-monitoring of eating and physical activity. Subsequent sessions taught a range of cognitive and behavioural skills to assist with weight control such as goalsetting, strategies for managing cravings (e.g., stimulus control, 'urge surfing', and distraction), strategies for managing social situations that trigger overeating (e.g., assertiveness training), strategies for managing emotional triggers of overeating (e.g., pleasant activity scheduling and relaxation training), problem-solving skills, identifying and challenging dysfunctional thoughts that trigger overeating, graded physical activity, and targeting body dissatisfaction. Specific motivational strategies were the focus of seven sessions, and included a focus on increasing the importance of weight loss by (i) increasing awareness of the costs of eating and weight problems (e.g., health concerns) and decreasing the benefits (e.g., mood regulation) by finding non-food ways of achieving the same benefits; (ii) identifying core values and how eating and weight problems may conflict with these values; and (iii) exploring one's future across various life domains in the event of losing or not losing weight. Motivational-enhancement sessions also focused on enhancing self-efficacy for losing weight (e.g., by identifying personal qualities that can be harnessed for successful weight control)."
Treatment duration	12 months
Follow-up from baseline	24 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 201 Intervention group/s: CBT-SP (n=98) Comparator group: CBT-A (n=103)
Mean age ± SD	CBT-SP: 47.1y (11.0), CBT-A: 46.93y (12.01)
Sex	73.63% female

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist (cm)
Mean (SD)</td><td>CBT-SP: 105.17
(20.05)

CBT-SP: 37.78
(6.02)

CBT-SP: 112.05
(13.98)</td><td>CBT-A: 105.99
(21.32)

CBT-A: 37.64
(6.61)

CBT-A: 113.05
(14.86)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist (cm)
Mean (SD)</td><td>CBT-SP: 97.25
(17.7)

CBT-SP: 35
(4.94)

CBT-SP: 103.93
(13.04)</td><td>CBT-A: 100.37
(22.27)

CBT-A: 36
(7.64)

CBT-A: 106.96
(16.03)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight
Mean (SD)</td><td>CBT-SP: -5.76
(6.64)</td><td>CBT-A: -5.13
(6.94)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Risica, 2013

Guideline record ID: 10614--1

Study characteristics		
Citation	Risica, P. M., Gans, K. M., Kumanyika, S., Kirtania, U., & Lasater, T. M. (2013). SisterTalk: final results of a culturally tailored cable television delivered weight control program for Black women. International Journal of Behavioral Nutrition and Physical Activity, 10, 141. https://doi.org/https://dx.doi.org/10.1186/1479-5868-10-141	
Design & type	Randomised controlled trial (RCT)	Factorial design
Title	SisterTalk: final results of a culturally tailored cable television delivered weight control program for Black women	
Location	US	
Trial name	SisterTalk	
Methods		
Inclusion criteria	“Self-identified as African American or Black, aged 18- 70, resided in the catchment area of the cable TV company, planned to stay in the area for at least one year; were not pregnant or less than four months postpartum, had no physical problems that would prevent mild physical activity; had no previous history of treatment for eating disorders; were able to speak and read English; had no participation in any other weight-control research project; and had access to a working telephone, television and VCR as well as availability to watch the SisterTalk cable TV program at its weekly airtime. Women were eligible to participate if they had a BMI ≥ 22.”	
Exclusion criteria	Not reported	
Setting	Home	
Intervention	“(ITV + TS): Participants in this condition received the 12 weekly TV shows and were given a private toll-free number to call in during the "live" sharing component in the last 15 minutes of the show. They also received 12 weekly then 4 monthly social support phone calls delivered by community outreach educators (COEs). The COEs were Black lay women from the local community in Boston who underwent a 20 hour training process. They called participants several days after each show to check in, discuss progress, provide support and help participants problem solve through any barriers that had arisen during the behavior change process, and to encourage participants to continue moving toward their goals. The COEs were trained to answer simple questions regarding the content, but to ask for help from the research staff if something more complicated arose. Interactive TV shows without telephone support (ITV): Participants received the same 12-week interactive TV show intervention with the same toll free call-in number, but did not receive the telephone support calls. Passive TV shows with telephone support (PTV + TS): Participants received the 12 weekly TV shows but their format did not allow them to call in during the sharing segment. They also received 12 weekly and 4 monthly telephone support calls from a COE. Passive TV shows without telephone support (PTV): Participants received the 12 weekly TV shows, but their format did not allow them to call in during the sharing segment and they did not receive telephone support calls. This condition was similar to regular broadcast TV. Participants in all four intervention conditions received biweekly mailings of written education materials that corresponded with the TV shows. After the 12 weekly shows, participants in all four intervention conditions received monthly mailings for four months including educational materials and four booster video-tapes that focused on maintenance of behavior changes and included a compilation of the three most popular "10- Minute Workouts" as an exercise video.”	
Control/Comparator	“Participants received biweekly mailings for 12 weeks and then monthly mailings for four months that contained wellness content unrelated to weight, nutrition or physical activity,	

<table>
<tr><td></td><td>i.e. cancer screening, injury prevention, etc. They received the entire set of 16 SisterTalk videos and written materials after the 12 month follow-up.”</td></tr>
<tr><td>Treatment duration</td><td>12 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 363
Intervention group/s: ITV + TS (n=73); ITV (n=64); PTV + TS (n=73); PTV (n=71)

Comparator group: Comparison (n=82)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>ITV + TS: 35.6
(8.3)
ITV: 35.2
(7.5)
PTV + TS: 34
(7.3)
PTV: 34.1
(7.4)</td><td>Comparison: 34.4
(8.5)</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>ITV + TS: 97.1
(25.4)
ITV: 95.5
(20.4)
PTV + TS: 91.6
(22.6)
PTV: 91.1
(20.3)</td><td>Comparison: 90
(22.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (SD)</td><td>ITV + TS: 0.1
(1.6)
ITV: -0.36
(1.5)
PTV + TS: -0.26
(3.8)
PTV: 0.18
(1.5)</td><td>Comparison: 0.04
(1.6)</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)</td><td>ITV + TS: 0.2
(4.4)
ITV: -1.02</td><td>Comparison: 0.16
(4.2)</td></tr>
</table>
</td></tr>
</table>

		(4.1) PTV + TS: -0.71 (10.6) PTV: 0.45 (4)	
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Robertson, 2017

Guideline record ID: 10619

Study characteristics		
Citation	Robertson, W., Fleming, J., Kamal, A., Hamborg, T., Khan, K. A., Griffiths, F., Stewart-Brown, S., Stallard, N., Petrou, S., Simkiss, D., Harrison, E., Kim, S. W., & Thorogood, M. (2017). Randomised controlled trial and economic evaluation of the 'Families for Health' programme to reduce obesity in children. Archives of Disease in Childhood, 102(5), 416-426. https://doi.org/https://dx.doi.org/10.1136/archdischild-2016-311514	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Randomised controlled trial and economic evaluation of the 'Families for Health' programme to reduce obesity in children	
Location	UK	
Trial name	Families for Health Programme (FFH)	
Methods		
Inclusion criteria	"Eligible families had an overweight (≥91st centile for BMI) or obese (≥98th centile for BMI) child aged 6-11 years, based on the UK 1990 definition11; and at least one parent or guardian willing to take part."	
Exclusion criteria	"Families were excluded if parent or child had insufficient command of English; the child had recognised medical cause of obesity or was unable to participate due to severe learning difficulties and/or behavioural problems."	
Setting	GP clinic	
Intervention	"The FFH V2 manualised programme comprises 10 weekly 2½-hour sessions, with children and parents from 8 to 12 families attending parallel groups. The programme combines information on parenting skills, social and emotional development as well as healthy eating including portion size and physical activity. The plan was to run six FFH courses (two in each site). Parenting compo nents, based on the Nurturing Programme from Family Links,13 aimed to increase parental capacity to implement and maintain lifestyle changes"	
Control/Comparator	"Families assigned to UC were offered 'One Body One Life', 15 a group-based family intervention in site A, Change4Life advisors offering one-to-one support in site B and either (1) a two-step programme, MEND16 and Choose It, with taster sessions for physical activity, healthy eating, or (2) Weight Watchers for young people aged 10+ years or (3) referral to the school nurse for children aged 6-9 years in site C."	
Treatment duration	10 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference	
Participant characteristics		
Number of participants	n= 128 Intervention group/s: Families For Health (n=63) Comparator group: Usual Care (n=65)	
Mean age ± SD	9.44y (1.59)	
Sex	50.78% female	

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI-z score
Mean (95% CIs)

Waist z-score
Mean (95% CIs)

BMI (kg/m2)
Mean (95% CIs)

Waist circumference (cm)
Mean (95% CIs)</td><td>Families For Health: 2.69
(2.52-2.85)

Families For Health: 3.33
(3.17-3.49)

Families For Health: 25.79
(24.67-26.91)

Families For Health: 86.17
(83.24-89.09)</td><td>Usual Care: 2.74
(2.57-2.91)

Usual Care: 3.27
(3.09-3.44)

Usual Care: 25.93
(24.86-26.99)

Usual Care: 86.3
(83.35-89.24)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI-z score
Mean (95% CIs)

Waist z-score
Mean (95% CIs)

BMI (kg/m2)
Mean (95% CIs)

Waist circumference (cm)
Mean (95% CIs)</td><td>Families For Health: 2.72
(2.54-2.89)

Families For Health: 3.32
(3.18-3.47)

Families For Health: 27.3
(25.8-28.81)

Families For Health: 90.36
(86.79-93.92)</td><td>Usual Care: 2.58
(2.37-2.79)

Usual Care: 3.09
(2.87-3.31)

Usual Care: 25.82
(24.69-26.95)

Usual Care: 86.47
(83.13-89.81)</td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
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<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Robinson, 2021

Guideline record ID: 10620--1

Study characteristics		
Citation	Robinson, T. N., Matheson, D., Wilson, D. M., Weintraub, D. L., Banda, J. A., McClain, A., Sanders, L. M., Haskell, W. L., Haydel, K. F., Kapphahn, K. I., Pratt, C., Truesdale, K. P., Stevens, J., & Desai, M. (2021). A community-based, multi-level, multi-setting, multi-component intervention to reduce weight gain among low socioeconomic status Latinx children with overweight or obesity: the Stanford GOALS randomised controlled trial. The Lancet Diabetes & Endocrinology, 9(6), 336-349. https://doi.org/https://dx.doi.org/10.1016/S2213-8587(21)00084-X	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A community-based, multi-level, multi-setting, multi-component intervention to reduce weight gain among low socioeconomic status Latinx children with overweight or obesity: The Stanford GOALS randomised controlled trial	
Location	USA	
Trial name	Stanford GOALS	
Methods		
Inclusion criteria	"Aged 7-11 years on the date of randomisation with a BMI at or above the 85th percentile for age and sex on the 2000 US Centers for Disease Control and Prevention BMI reference."	
Exclusion criteria	"Children were not eligible if they were diagnosed with a medical condition or taking a medication affecting growth; had a condition limiting participation in interventions or assessments; they or their parent or guardian were unable to read, understand, and complete informed consent in English or Spanish; planned to move from the area within 36 months; or were deemed to have another characteristic that made them unsuitable for the study."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The MMM intervention was multi-level, intervening directly with individual children, parents and families, peer groups, primary care clinics, and the home and community environments; multi-component, intervening on eating behaviours, physical activity, screen time, and parenting, via behavioural and environmental interventions; and multi-setting, intervening in homes, community-based after school programmes, and primary care clinics.8 The MMM intervention was grounded in Bandura's social cognitive model11 and delivered over 3 years for each family. It was designed based on previous research and refined with 18 months of community engagement, formative research, and pilot studies.8 Latinx cultural values were incorporated into the intervention, considering both surface structure and deep structure12 regarding psychological and sociocultural influences on health and behaviour.8 We included strategies from recent social psychological science to promote intrinsic motivation,13 alter implicit mindsets,14 and affirm values15 to address psychological barriers to behaviour change. We designed specific intervention content and activities to maximise motivation for participation in the process of behaviour change with stealth intervention principles.16 The MMM intervention was conceptualised holistically as a complex systems intervention, including planned interactions, opportunities for mutual reinforcement, repetition, and positioning complementary elements across the different levels, settings, and components of the intervention, to generate synergistic effects and accommodate individual and family preferences and life experiences over their 3 years of participation.8 GOALS@home included environmental and behavioural interventions delivered to the children, parents or guardians, and other family members in their home by trained, bilingual (Spanish and English) health educators, following a protocol. Five modules were designed to span the 3 years, and each module included a number of levels requiring mastery of specific skills before moving forward. First, a module to alter the home	

	environment (four levels), by replacing plates, bowls, glasses, and serving utensils to promote smaller serving sizes,17 followed by three modules to promote behaviour changes in eating (eight levels), physical activity (seven levels) and screen time (six levels), delivered in an order chosen by the family, and a fifth module on problem solving and maintenance (five levels). The content was adapted from previous interventions,18-20 and consistent with US Preventive Services Task Force recommendations.21 Team GOALS was a community-based after school team sports programme designed for children with overweight and obesity from low socioeconomic status families.22 Team GOALS was offered weekdays, year-round including a 5-6-week summer programme, except school holidays, in partnership with four community centres run by the local Boys and Girls Clubs, the Parks, Recreation and Community Services Department, and Police Activities League. Team GOALS was an environmental intervention, made available in the neighbourhoods where participants were recruited for MMM children to attend as often as they wished. Each session included 1-1·5 h of activity plus time for homework. Four sports, soccer, flag football, basketball, and lacrosse, were rotated seasonally throughout the year with additional sports introduced with community partners during summers (eg, track and field, volleyball, rugby, ultimate frisbee, and swimming). Sessions and activities were structured to keep children moving and coaches were trained by the investigators to provide feedback promoting intrinsic motivation13 and a growth mindset14 for activity. Primary Care GOALS provided brief, self-guided, semiannual reports of GOALS@Home and Team GOALS progress to help primary care medical providers counsel their participating patients and reinforce participation.8 Health educators also reviewed copies of the progress reports with families during GOALS@home visits and encouraged participants to take their copies to primary care medical visits to review with their providers."
Control/Comparator	"The comparison intervention was delivered over the entire 3 years of participation for each family, and included two home counselling visits per year, monthly health education newsletters mailed individually to parents and to children, quarterly neighborhood-based health education or family fun nights, and one to two social field trips per year to the Stanford campus and athletic events.8 Health Education content focused on nutrition, physical activity, screen time, chronic disease prevention, and general health topics. It was designed as a rigorous and ethical active placebo comparison intervention, to limit risks of resentful demoralisation or compensatory rivalry, and include active ingredients, which can influence obesity-related behaviour but differed from the conceptually relevant components in the MMM intervention. Primary care providers and participating families in both the MMM and Health Education interventions also received children's annual blood test results with explanations appropriate for readers with low health literacy."
Treatment duration	3 years
Follow-up from baseline	2 years
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference
Participant characteristics	
Number of participants	n= 241 Intervention group/s: MMM (n=120) Comparator group: HE (n=121)
Mean age ± SD	9.5y (1.4)
Sex	55.60% female
Pre-existing medical condition	No pre-existing medical condition
Results	

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)

Waist circumference (cm) - Baseline
Mean (SD)</td><td>MMM: 25.26
(4.04)

MMM: 86.18
(11)</td><td>HE: 24.86
(3.87)

HE: 84.68
(10.61)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Unadjusted Slope/Change in BMI (kg/m2)
Mean (SD)

Unadjusted sope/change in waist circumference (cm)
Mean (SD)</td><td>MMM: -0.47
(1.49)

MMM: 2.62
(4.19)</td><td>HE: 1.17
(1.15)

HE: 4.34
(3.48)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Unadjusted Slope/Change in BMI (kg/m2)
Mean (SD)

Unadjusted sope/change in waist circumference (cm)
Mean (SD)</td><td>MMM: -1.05
(0.88)

MMM: 3.42
(2.46)</td><td>HE: 1.11
(0.83)

HE: 3.72
(2.37)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Rock, 2010

Guideline record ID: 10622--1

Study characteristics		
Citation	Rock, C. L., Flatt, S. W., Sherwood, N. E., Karanja, N., Pakiz, B., & Thomson, C. A. (2010). Effect of a free prepared meal and incentivized weight loss program on weight loss and weight loss maintenance in obese and overweight women: a randomized controlled trial. JAMA, 304(16), 1803-1810. https://doi.org/https://dx.doi.org/10.1001/jama.2010.1503	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a free prepared meal and incentivized weight loss program on weight loss and weight loss maintenance in obese and overweight women: a randomized controlled trial	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	“Eligibility criteria included age 18 years or older; BMI of 25 to 40 and a minimum of 15 kg over ideal weight as defined by the 1983 Metropolitan Life Insurance tables13; not pregnant or breastfeeding or planning to become pregnant in the next 2 years; willing to participate in any of the 3 study groups over a 2-year period; no eating disorders, food allergies, or intolerances; and willing and able to perform a simple step test for assessing cardiopulmonary fitness.”	
Exclusion criteria	“Women at BMI levels of greater than 40 were excluded because such extreme obesity is associated with more serious comorbid conditions and is more likely to require a higher intensity and more supervised clinical approach to weight loss and exercise. Current active involvement in another diet intervention study or organized weight loss program or having a history or presence of a significant psychiatric disorder or any other condition that in the investigator's judgment would interfere with participation in the trial also disqualified women.”	
Setting	University/research centre	
Intervention	“Participants assigned to the centerbased or telephone-based study groups received all program materials, including free-of-charge prepackaged prepared foods as needed to achieve a meal plan. Interactions between corporatetrained and supervised staff and the participants consisted of brief weekly oneto-one contacts with an in-person or telephone counselor, withfollow-up telephone and e-mail contacts and Web site or message board availability. Counselors were instructed to provide the program as designedfor a regular paying client, although they were not blinded to the identity of study participants. Freeof-charge counseling sessions were offered to participants for the entire 2-year period. The diet component of the program consisted of a nutritionally adequate, low-fat (20%-30% of energy), reducedenergy diet (typically 1200-2000 kcal/d) thatincluded prepackaged preparedfood items with increased amounts of vegetables and fruits to reduce the energy density of the diet. The approach was tailored so that participants could choose regular foods when preferred. Participants were encouraged during the initial period to follow a menu plan with prepackaged foods, which would provide 42% to 68% of energyfor those who choose not to deviate from the plan. Regular foods, such as vegetables, fruit, cereal or grain products, low-fat dairy products, lean meat or the equivalent, and unsaturated fat sources were recommended to achieve the total prescribed energy intake. Over time, participants were transitioned to a meal plan based mainly on food not provided by the commercial program, although participants could choose to include 1 prepackaged meal per day during weight loss maintenance. Prepared foods and counselors were provided by JennyCraig Inc (Carlsbad, California). Increased physical activity was another program component; the goal was 30 minutes of physical activity on 5 or more days per week. Program material and counseling addressed attitudes about weight, food, and physical	

<table>
<tr><td></td><td>activity and included recipes and guidance for eating in restaurants, CDs and DVDs to increase physical activity, and online tools and support.”</td></tr>
<tr><td>Control/Comparator</td><td>“Participants assigned to the usual care group were provided consultation with a research staff dietetics professional, who provided publicly available print material that described dietary and physical activity guidelines to promote weight loss and maintenance atParticipants assigned to the usual care group were provided consultation with a research staff dietetics professional, who provided publicly available print material that described dietary and physical activity guidelines to promote weight loss and maintenance at baseline (after randomization) and again at 6 months. Energy intake level to achieve a weight loss of 10% over a 6-month period was prescribed, aiming for a deficit of 500 to 1000 kcal/ d.14 Sample meal plans based on food groups, recommendations to increase physical activity, and written materials and resources for strategies and skills (eg, reading food labels, estimating serving sizes, eating outside the home) were provided. This 1-hour session was followed by monthly check-in via e-mail or telephone, and progress and strategies were discussed in a follow-up counseling session at 6 months.”</td></tr>
<tr><td>Treatment duration</td><td>2 years</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Weight for height growth chart</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 442
Intervention group/s: Center-based intervention (n=167); Telephone-based intervention (n=164)

Comparator group: Usual care (n=111)</td></tr>
<tr><td>Mean age ± SD</td><td>44y</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight, kg
Mean (95% CIs)</td><td>Center-based intervention:
92.2
(90.7-93.7)
Telephone-based intervention:
92.9
(91.1-94.7)</td><td>Usual care: 91
(89-92.9)</td></tr>
<tr><td>BMI
Mean (95% CIs)</td><td>Center-based intervention:
33.8
(33.3-34.4)
Telephone-based intervention:
33.8
(33.3-34.3)</td><td>Usual care: 34
(33.4-34.6)</td></tr>
<tr><td>Waist circumference, cm
Mean (95% CIs)</td><td>Center-based intervention:
108.9
(107.6-110.3)
Telephone-based intervention:
108.5
(106.9-110)</td><td>Usual care: 108.3
(106.6-110)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight, kg
Mean (95% CIs)</td><td>Center-based intervention: 82.1
(81.3-84.6)
Telephone-based intervention: 84.4
(82.3-86.5)</td><td>Usual care: 88.5
(86.3-90.8)</td></tr>
<tr><td>BMI
Mean (95% CIs)</td><td>Center-based intervention: 30.2
(29.6-30.8)
Telephone-based intervention: 30.7
(30.1-31.4)</td><td>Usual care: 33.2
(32.4-33.9)</td></tr>
<tr><td>Waist circumference, cm
Mean (95% CIs)</td><td>Center-based intervention: 98
(96.5-99.5)
Telephone-based intervention: 99.9
(98.5-101.6)</td><td>Usual care: 103.2
(101.4-105)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight
Mean (95% CIs)</td><td>Center-based intervention: -10.1
(-11.2--9)
Telephone-based intervention: -8.5
(-9.7--7.2)</td><td>Usual care: -2.4
(-3.6--1.2)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Rock, 2015

Guideline record ID: 10621--1

Study characteristics		
Citation	Rock, C. L., Flatt, S. W., Byers, T. E., Colditz, G. A., Demark-Wahnefried, W., Ganz, P. A., Wolin, K. Y., Elias, A., Krontiras, H., Liu, J., Naughton, M., Pakiz, B., Parker, B. A., Sedjo, R. L., & Wyatt, H. (2015). Results of the Exercise and Nutrition to Enhance Recovery and Good Health for You (ENERGY) trial: a behavioral weight loss intervention in overweight or obese breast cancer survivors. Journal of Clinical Oncology, 33(28), 3169-3176. https://doi.org/https://dx.doi.org/10.1200/JCO.2015.61.1095	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Results of the Exercise and Nutrition to Enhance Recovery and Good Health for You (ENERGY) Trial: A Behavioral Weight Loss Intervention in Overweight or Obese Breast Cancer Survivors	
Location	US	
Trial name	Exercise and Nutrition to Enhance Recovery and Good Health for You (ENERGY)	
Methods		
Inclusion criteria	"Inclusion criteria were age 21 years; a history of breast cancer (stage I [1 cm], II, or III) diagnosed within the previous 5 years; completion of initial therapies not including endocrine therapy; body mass index (BMI) of 25 to 45 kg/m2 ; and ability to comply with study procedures."	
Exclusion criteria	"Exclusion criteria included history of malignancies other than initial breast cancer, except nonmelanoma skin cancer; serious psychiatric illness; and any medical condition substantially limiting moderate physical activity."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Intervention details have been reported previously.10 The goal of the intervention was a 7% weight loss at 2 years after random assignment. Briefly, the intervention began with an intensive phase that consisted of 4 months of weekly 1-hour group sessions for closed groups of an average of 15 women, tapering to every other week for 2months. From 6months onward, the groups met monthly for the remainder of the first year. The strategies and guidance discussed in the group sessions were reinforced by brief (10- to 15-minute) personalized guidance delivered by telephone and/or e-mail. The goal of dietary guidance was to promote a reduction in energy intake, aiming for a deficit of 500 to 1,000 kcal a day relative to expenditure. The physical activity goal was an average of at least 60 minutes per day of purposeful exercise at a moderate level of intensity. Tailored print newsletters provided additional support when the groups met less frequently. Newsletters were provided quarterly from 6 to 24 months; were individually tailored based on information about physical activity, dietary intake, and weight; and provided guidance for overcoming barriers to increase physical activity and regulate dietary intake."	
Control/Comparator	"Control group participants were provided weight management resources and materials in the public domain. An individualized diet counseling session was provided at baseline and 6 months, and current physical activity recommendations (at least 30 minutes per day) were advised. Control group participants also received monthly telephone calls and/or e-mails from the study coordinator and were invited to attend optional informational seminars on aspects of healthy living other than weight control every other month during the first year."	
Treatment duration	Intervention: 24 Months; Control: 12 months	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 692
Intervention group/s: Intervention (n=344)

Comparator group: Control (n=348)</td></tr>
<tr><td>Mean age ± SD</td><td>56y (9)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Breast Cancer (diagnosed and treated)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SE)

BMI (kg/m2)
Mean (SE)

Waist circumference (cm)
Mean (SE)</td><td>Intervention: 85
(0.8)

Intervention: 31.6
(0.3)

Intervention: 104.9
(0.7)</td><td>Control: 84.7
(0.7)

Control: 31.4
(0.2)

Control: 103.5
(0.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SE)

BMI (kg/m2)
Mean (SE)

Waist circumference (cm)
Mean (SE)</td><td>Intervention: 79.7
(0.9)

Intervention: 29.7
(0.3)

Intervention: 97.8
(0.7)</td><td>Control: 83.5
(0.9)

Control: 30.9
(0.3)

Control: 100.4
(0.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SE)

BMI (kg/m2)
Mean (SE)

Waist circumference (cm)
Mean (SE)</td><td>Intervention: 81.4
(0.9)

Intervention: 30.3
(0.3)

Intervention: 99.4
(0.7)</td><td>Control: 83.8
(0.9)

Control: 31
(0.3)

Control: 100.4
(0.7)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (%)
Mean (SE)</td><td>Intervention: -6
(0.4)</td><td>Control: -1.5
(0.4)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (%)
Mean (SE)</td><td>Intervention: -3.7
(0.4)</td><td>Control: -1.3
(0.4)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Rodriguez Cristobal, 2012

Guideline record ID: 10832--1

Study characteristics		
Citation	Rodríguez Cristóbal, J. J., Alonso-Villaverde Grote, C., Travé Mercadé, P., Pérez Santos, J. M., Peña Sendra, E., Muñoz Lloret, A., Fernández Pérez, C., Bleda Fernández, D., & the EFAP group. (2012). Randomised clinical trial of an intensive intervention in the primary care setting of patients with high plasma fibrinogen in the primary prevention of cardiovascular disease. BMC Research Notes, 5, 126. https://doi.org/https://dx.doi.org/10.1186/1756-0500-5-126	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Randomised clinical trial of an intensive intervention in the primary care setting of patients with high plasma fibrinogen in the primary prevention of cardiovascular disease	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	"Patients of both genders, aged between 30 and 75 years, in which in two consecutive analyses, separated by a minimum interval of 15 days, with fibrinogen levels > 300 mg/dl and plasma total cholesterol < 250 mg/dl. -Agreement to participate in the study, with written informed consent using procedures reviewed and approved by the EECC review board."	
Exclusion criteria	"Any lipid-lowering therapy (dietary or pharmacological intervention). - Local or generalized infection, either acute or chronic. - History of cardiovascular disease, according to medical records and/or anamnesis. - Fibrinogen lowering therapies (ticlopidine, fibrates, pentoxifylline) - Severe clinical pathology (terminally ill patients, dementia, etc.)."	
Setting	GP clinic, Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"An active follow up of this group of patients was done, consisting of: - Phone calls to get psychologist support, and letters to record each visit with the physician, additional measures to encourage the maintenance of lifestyle modifications, which will be done every 2 months. In each visit, physical activity questionnaires were done, as well as both pharmacological medical recommendations and lifestyle change. A laboratory analysis was done every 8 months. The intensive intervention included: Smoking cessation, Smoking history, degree of dependency, motivation to give up smoking, clear and tailored advice, a follow-up program for those patients who stop smoking and use of TSN or bupropion. Interview about physical activities and classify as, active, partially active or sedentary; advice to start, increase or sustain physical activities. Gradual weight loss 0.51 kg per week, advice healthy diet once objectives are achieved. Dietary measures or pharmacological treatment, according to guidelines for hypertension and diabetes mellitus."	
Control/Comparator	"This subset of patients have received advice about their lifestyle (diet, exercise and smoking cessation) according to the practice guidelines of the 'Institut Català de la Salut'(ICS), following nernational consensus."	
Treatment duration	2 years	
Follow-up from baseline	2 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 300
Intervention group/s: Intensive intervention (n=146)

Comparator group: Standard intervention (n=154)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 56.8y (10.6); Control 58.6y (10.6)</td></tr>
<tr><td>Sex</td><td>63.33% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>High fibrinogen levels > 300 mg/dl</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Proportion obese (%)
Proportion (%)</td><td>Intensive intervention: 75.7 (13.1)

Intensive intervention: 30.3 (5.8)

Intensive intervention: 46.8</td><td>Standard intervention: 76.7 (12.9)

Standard intervention: 30.5 (5.1)

Standard intervention: 55.5</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intensive intervention: 29.6 (4.8)</td><td>Standard intervention: 31.8 (4.9)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Rojo-Tirado, 2021

Guideline record ID: 10624--1

Study characteristics		
Citation	Rojo-Tirado, M. A., Benito, P. J., Ruiz, J. R., Ortega, F. B., Romero-Moraleda, B., Butragueño, J., Bermejo, L. M., Castro, E. A., & Gómez-Candela, C. (2021). Body composition changes after a weight loss intervention: a 3-year follow-up study. Nutrients, 13(1), 164. https://doi.org/10.3390/nu13010164	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Body Composition Changes after a Weight Loss Intervention: A 3-Year Follow-Up Study	
Location	Spain	
Trial name	PRONAF	
Methods		
Inclusion criteria	"18 to 50 years old, had a body mass index (BMI) between 25 and 34.9 kg/m2, were nonsmokers, were sedentary, and had glucose values <5.6 mmol/L (<100 mg/dL) were invited to participate in this study. Women were required to have regular menstrual cycles."	
Exclusion criteria	Not reported	
Setting	Unclear (All exercise training groups (strength, endurance, and combined SE groups) followed an individualized training program, which consisted of three-times-per-week exercise sessions for 22 weeks, carefully supervised by certified personal trainers.)	
Intervention	"Hypocaloric diets (25-30% less energy than TDEE) were prescribed individually by expert dieticians for the 22-week intervention period. Some 29-34% of energy came from fat, 50-55% from carbohydrates, and 20% from protein, according to the Spanish Society of Community Nutrition's recommendations [11], to achieve the body composition benefits observed in different studies and examined in a meta-analysis [12]. All exercise training groups (strength, endurance, and combined SE groups) followed an individualized training program, which consisted of three-times-per-week exercise sessions for 22 weeks, carefully supervised by certified personal trainers. Each training session included a 5 min aerobic warm-up, the session routine, and a 5 min cooldown and stretching exercise. Strength session routines consisted of eight exercises (i.e., shoulder press, squat, barbell row, lateral split, bench press, front split, biceps curl, and French press for triceps). Endurance session routines consisted of self-selected running, cycling, or elliptical. For the combined strength and endurance group, a combination of cycle ergometry, treadmill, or elliptical intercalated with squat, row machine, bench press, and front split was carried out. The volume and intensity of the three training groups were increased progressively. During the adaptation period (i.e., weeks 1-4), the subjects were taught the different exercise routines. During weeks 5 to 8, the exercises were carried out at an intensity of 50% of 15 repetition maximums (RM) and heart rate reserve (HRR), and the subjects performed 2 laps of the circuit (51 min and 15 s in total). During weeks 9 to 14, the intensity was increased to 60% of 15RM and HRR. Finally, during weeks 15 to 24, the volume was increased to 3 circuit laps instead of 2 (64 min in total). In addition, 5 min recovery periods were established between the circuit laps. The S and SE participants performed 15 repetitions (45 s) for each exercise, including a rest period of 15 s between repetitions. Full details of the different protocols developed by the groups are described elsewhere [9]."	
Control/Comparator	"Hypocaloric diets (25-30% less energy than TDEE) were prescribed individually by expert dieticians for the 22-week intervention period. Some 29-34% of energy came from fat, 50-55% from carbohydrates, and 20% from protein, according to the Spanish Society of Community Nutrition's recommendations [11], to achieve the body composition benefits observed in different studies and examined in a meta-analysis [12]. The participants from	

<table>
<tr><td></td><td>the control group followed the dietary intervention and respected the recommendations about physical activity from the American College of Sports Medicine (ACSM) [13]. However, this activity was not supervised, and they were free to do it dail.”</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>3 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 239
Intervention group/s: S (n=60); E (n=60); SE (n=60)

Comparator group: C (n=59)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>55.23% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SE)</td><td>S: 92.3
(2)
E: 85.9
(2)
SE: 83.3
(2.2)</td><td>C: 86.8
(1.9)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SE)</td><td>S: 31.6
(0.5)
E: 30.4
(0.5)
SE: 29
(0.5)</td><td>C: 30.7
(0.5)</td></tr>
<tr><td>Fat mass (%)
Mean (SE)</td><td>S: 41.5
(0.9)
E: 40.5
(0.9)
SE: 38.1
(1)</td><td>C: 41.5
(0.9)</td></tr>
<tr><td>Fat mass (kg)
Mean (SE)</td><td>S: 36.1
(1.3)
E: 33
(1.3)
SE: 29.9
(1.4)</td><td>C: 34
(1.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SE)</td><td>S: 89.1
(2.5)
E: 83.8
(2.5)
SE: 78.6
(2.7)</td><td>C: 85.5
(2.4)</td></tr>
<tr><td>BMI (kg/m2)</td><td>S: 30.7</td><td>C: 30.4</td></tr>
</table>
</td></tr>
</table>

	Mean (SE) Fat mass (%) Mean (SE) Fat mass (kg) Mean (SE)	(0.7) E: 29.8 (0.7) SE: 27.4 (0.8) S: 40.1 (1.3) E: 40.6 (1.3) SE: 33.6 (1.4) S: 33.9 (1.9) E: 33.4 (1.9) SE: 25.8 (2.1)	(0.7) C: 40.9 (1.3) C: 33.1 (1.9)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	75.3% (Adherence over 90% of the training sessions and adherence to diet over 80%)		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Rosas, 2020

Guideline record ID: 10625--1

Study characteristics		
Citation	Rosas, L. G., Lv, N., Xiao, L., Lewis, M. A., Venditti, E. M. J., Zavella, P., Azar, K., & Ma, J. (2020). Effect of a culturally adapted behavioral intervention for Latino adults on weight loss over 2 years: a randomized clinical trial. JAMA Network Open, 3(12), e2027744. https://doi.org/10.1001/jamanetworkopen.2020.27744	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a Culturally Adapted Behavioral Intervention for Latino Adults on Weight Loss Over 2 Years: A Randomized Clinical Trial	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Adult (age 18 years) primary care patients who self-reported Latino ethnicity and ability to speak Spanish (Spanish-only or bilingual) with a BMI 24 or greater and prediabetes, a history of gestational diabetes, or 3 of 5 elements of the metabolic syndrome27 but without type 1 or type 2 diabetes or cardiovascular disease were eligible to participate."	
Exclusion criteria	"Exclusions included significant psychiatric or medical comorbidities (eg, bipolar disorder, active cancer), pregnancy, or planned relocation during the follow-up period."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The intervention, which was delivered by a trained bilingual health coach in Spanish, is a cultural adaptation of the Group Lifestyle Balance curriculum30 derived from the original DPP lifestyle intervention.11 A bilingual health coach who did not have a specialized degree was trained by a certified master trainer for the Group Lifestyle Balance curriculum. The in-depth cultural adaptation included focus groups with Latino patients, key informant interviews with clinicians, and a structured pretest with a Latino Patient Advisory Board.25 As a result of the adaptation, a family-wide orientation session was instituted to increase awareness about intervention goals and best approaches for providing positive social support, including structural, emotional, appraisal, and informational support. Family members were also included in the session that focused on a healthy home environment to promote desirable food and activity changes. Intervention sessions were delivered in person for 1 year. Participants used a wearable activity tracker and mobile application to track their physical activity and the MyFitnessPal web or mobile application to track their dietary intake. The first 6 months, or core phase, included 16 group sessions (12 weekly sessions and then 4 bimonthly sessions). Based on social cognitive theory,31 the sessions used behavioral strategies, such as self-monitoring, goal setting, stress management, and problem solving, to achieve goals. The goals of the intervention were to achieve 7% weight loss and a minimum of 150 minutes per week of moderate-intensity physical activity. In addition, the health coach provided weekly individualized feedback to participants on their physical activity via their fitness tracker application and diet via their diet tracking application. The postcore support phase included an additional 6 monthly group sessions that focused on continued behavior change and other behavior maintenance strategies (eg, relapse control). A healthy meal was offered at each in-person session to model healthy foods and to increase engagement and retention.25 Overall, the first 12 months of the intervention included approximately 23 hours of in-person time with the coach (orientation session plus 22 sessions) as well as feedback via the applications. In the second year, participants were sent monthly emails that reviewed the material from the first year and reminded participants to reach out to the coach for support. All intervention materials were provided in Spanish, with English available on request. Participants could elect to use the smartphone applications in their preferred language."	

<table>
<tr><td>Control/Comparator</td><td>“Participants in both treatment groups continued to receive usual care from their primary care clinicians. Primary care clinicians were not made aware of patients' randomization assignment. Clinicians were neither encouraged nor prevented from offering weight management treatment to patients. Participants were not prevented from accessing weight management services from their primary care clinician or in the community. The health care system offered weight management programs, including bariatric surgery, group-based diabetes prevention programs, and meal replacement.”</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Weight for height growth chart</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 190
Intervention group/s: Intervention (n=91)

Comparator group: Usual care (n=99)</td></tr>
<tr><td>Mean age ± SD</td><td>50.2y (12.2)</td></tr>
<tr><td>Sex</td><td>62.11% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI - Baseline
Mean (SD)

Weight - Baseline
Mean (SD)

Waist circumference - Baseline
Mean (SD)</td><td>Intervention: 32.4
(5.4)

Intervention: 86.6
(17.2)

Intervention: 103.8
(13.7)</td><td>Usual care: 32.4
(6)

Usual care: 87.6
(20.8)

Usual care: 103.9
(15)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of participants achieving 5% weight loss
Proportion (%)</td><td>Intervention: 25.9</td><td>Usual care: 9.2</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of participants achieving 5% weight loss
Proportion (%)</td><td>Intervention: 24.2</td><td>Usual care: 15.2</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight
Mean (SD)

Change in BMI
Mean (SD)

Change in waist circumference
Mean (SD)</td><td>Intervention: -2.6
(6)

Intervention: -1
(2.3)

Intervention: -4.3
(12.6)</td><td>Usual care: -0.3
(4.2)

Usual care: -0.1
(1.6)

Usual care: -1.9
(5.4)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in weight
Mean (SD)

Change in BMI
Mean (SD)

Change in waist circumference
Mean (SD)</td><td>Intervention: -1.1
(5.7)

Intervention: -0.4
(2.2)

Intervention: 0.3
(7.1)</td><td>Usual care: -1.1
(7.1)

Usual care: -0.4
(2.7)

Usual care: -0.1
(7.2)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Rosas, 2022

Guideline record ID: 10626--1

Study characteristics		
Citation	Rosas, L. G., Lv, N., Xiao, L., Venditti, E. M., Lewis, M. A., Azar, K. M. J., Hooker, S. P., Zavella, P., & Ma, J. (2022). HOMBRE: a trial comparing 2 weight loss approaches for Latino men. American Journal of Preventive Medicine, 63(3), 341-353. https://doi.org/https://dx.doi.org/10.1016/j.amepre.2022.03.032	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	HOMBRE: A Trial Comparing 2 Weight Loss Approaches for Latino Men	
Location	US	
Trial name	HOMBRE	
Methods		
Inclusion criteria	"Self-identified as Latino, had a BMI ≥27 kg/m2, and had 1 or more cardiometabolic risk factors (i.e., high waist circumference, high triglycerides, high blood pressure [BP], high fasting plasma glucose, or low highdensity lipoprotein cholesterol)."	
Exclusion criteria	"Patients with severe psychiatric (e.g., active bipolar or psychotic disorder) or medical (e.g., active cancer, organ failure) comorbidities were excluded."	
Setting	GP clinic	
Intervention	"The HOMBRE trial was designed to provide rigorous evidence to patients, their providers, and healthcare systems using a pragmatic, comparative effectiveness design. The 2 interventions were chosen on the basis of patient and stakeholder engagement and in accordance with existing recommendations for behavioral weightloss interventions in primary care.8 The HOMBRE intervention offered participants 3 options for engaging in a 12-month behavioral lifestyle intervention: coach-facilitated group sessions using online video conferencing, coach-facilitated group sessions in person, and prerecorded videos of group sessions available online (Appendix Table 1, available online). All the 3 options included 12 weekly sessions during the intensive phase (Months 1−3) and 8 monthly contacts either by phone or e-mail during the maintenance phase (Months 4−12). In addition, all the 3 options encouraged men to self-monitor using a study-provided digital weight scale, a study-provided wearable activity tracker, and the MyFitnessPal website or Smartphone application for dietary tracking (available in Spanish and English). The videoconference and in-person groups offered a cultural adaptation of the Group Lifestyle Balance (GLB) intervention. GLB is a group-based adaptation of the original Diabetes Prevention Program (DPP) intervention24−26 grounded in Social Cognitive Theory.27 The goal of GLB is to promote 5%−10% weight loss as recommended by obesity treatment guidelines28 and a minimum of 150 minutes per week of moderate-intensity physical activity (e.g., brisk walking). A Latino Patient Advisory Board made up of 15 Latino primary care patients with overweight or obesity culturally adapted the original GLB, which has been previously published.29 Briefly, the Latino Patient Advisory Board met weekly for approximately 2–3 hours for 16 weeks to complete the cultural adaptation process. The Advisory Board members recommended: 1. adding an orientation session before session 1 to provide a brief overview of the intervention for participants and family members; 2. incorporating the MyPlate visual in the orientation and in the early intervention sessions given its effectiveness for communicating the types of food choices recommended by the intervention; and 3. inviting family members to sessions 6 and 12 given the cultural importance of family support. Two full-time trained bilingual coaches facilitated weekly sessions in either English or Spanish at the same time each week on videoconference or in person at the clinic where participants were recruited or in a nearby clinic. For the online video option, men were given access to prerecorded online videos of the GLB that had been tested in previous RCTs.25,30 There were 12 videos for the weekly sessions of the	

<table>
<tr><td></td><td>intensive phase. Each video featured a coach-facilitated group session with actors representing diverse demographic groups, including men and women. The videos were recorded in English and had the option of Spanish subtitles. Men were encouraged to watch the videos weekly with a family member. In addition to the differences in delivery options, the 3 options differed in the level and type of coach feedback (Appendix Table 1, available online). In the videoconference and in-person groups, the lifestyle coach provided real-time interactive feedback on diet and physical activity goals during the intensive phase and monthly phone calls or emails supporting continued goal progress and problem solving for encountered barriers during the maintenance phase. In the online videos option, men received standardized weekly messages from the coach during the intensive phase, with prompts to watch the videos, and standardized monthly messages during the maintenance phase”</td></tr>
<tr><td>Control/Comparator</td><td>“Men randomized to the control condition were given access to the same 12-session program videos that men in the HOMBRE intervention could choose. Men in the minimal-intensity intervention only received coach support if they initiated a contact. On request, coaches answered participants' questions by telephone, e-mail, mobile text messaging, or secure messaging through patient portal in the electronic health record (EHR).”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 424
Intervention group/s: HOMBRE (n=212)

Comparator group: Minimal Intensity (n=212)</td></tr>
<tr><td>Mean age ± SD</td><td>47.0y (11.9)</td></tr>
<tr><td>Sex</td><td>100.00% male</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (% weight loss)
Mean (SD)</td><td>HOMBRE: -2.3
(5.8)</td><td>Minimal Intensity: -1.6
(5.8)</td></tr><tr><td>Change in waist circumference (cm)
Mean (SD)</td><td>HOMBRE: -0.8
(5.7)</td><td>Minimal Intensity: 0
(6.7)</td></tr><tr><td>Change in weight (kg)
Mean (SD)</td><td>HOMBRE: -2.46
(6.6)</td><td>Minimal Intensity: -1.67
(6.16)</td></tr></table></td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Ross, 2012

Guideline record ID: 10628--1

Study characteristics		
Citation	Ross, R., Lam, M., Blair, S. N., Church, T. S., Godwin, M., Hotz, S. B., Johnson, A., Katzmarzyk, P. T., Lévesque, L., & MacDonald, S. (2012). Trial of prevention and reduction of obesity through active living in clinical settings: a randomized controlled trial. Archives of Internal Medicine, 172(5), 414-424. https://doi.org/10.1001/archinternmed.2011.1972	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Trial of prevention and reduction of obesity through active living in clinical settings: a randomized controlled trial	
Location	Canada	
Trial name	Prevention and Reduction of Obesity Through Active Living (PROACTIVE)	
Methods		
Inclusion criteria	"Sedentary (planned activity 1 time/ wk), overweight (body mass index [BMI; calculated as weight in kilograms divided by height in meters squared], 27-39), and abdominally obese (WC, 102 cm in men or 88 cm in women)."	
Exclusion criteria	"Patients with dyslipidemia, type 2 diabetes mellitus, or hypertension were not excluded from participation. Exclusion criteria included serious medical conditions that prevented participants from increasing daily physical activity."	
Setting	GP clinic	
Intervention	"Details of the behavioral intervention are published elsewhere.8 The 2-year, multiphase intervention was designed to promote physical activity concurrent with the consumption of a balanced diet. The intervention included individually tailored counseling based on the transtheoretical model and social cognitive theory.9-11Counseling was delivered by health educators who had degrees in kinesiology and who received behavioral counseling training from a clinical psychologist. Each health educator was assigned to 1 of 3 family medicine clinics and delivered all counseling sessions on site within a private office. Motivational interviewing served as the counseling model.9 During phase 1 of the intervention (months 0-6, 15 sessions), the health educator worked one on one with participants to provide knowledge and skills to increase daily physical activity and consume a healthful diet. Phase 2 (months 7-12, 6 sessions) started at session 16 and encouraged the participants to maintain their current program (45-60 minutes of activity per day and healthy eating patterns). During phase 3 (months 13-24, 12 sessions), contact with health educators continued, but the session duration was determined according to each participant's WC value and physical activity level."	
Control/Comparator	"Participants randomized to usual care received advice from their physicians regarding lifestyle as a strategy for obesity reduction and continued to meet with their physician according to their usual schedule. Physicians were asked not to change their routine counseling approach for obese PROACTIVE patients."	
Treatment duration	24 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 490
Intervention group/s: Intervention (n=249)

Comparator group: Usual Care (n=241)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 51.3y (11.0); Control: 52.4y (11.8)</td></tr>
<tr><td>Sex</td><td>70.20% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)

Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 107.2
(11)

Intervention: 91.2
(14.1)

Intervention: 32.6
(4.1)</td><td>Usual Care: 105.9
(10.8)

Usual Care: 89.2
(14.1)

Usual Care: 32
(4.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in waist circumference (cm)
Mean (SE)

Change in weight (kg)
Mean (SE)

Change in BMI (kg/m2)
Mean (SE)</td><td>Intervention: -2.5
(0.4)

Intervention: -2.41
(0.34)

Intervention: -0.84
(0.13)</td><td>Usual Care: -0.9
(0.4)

Usual Care: -0.85
(0.36)

Usual Care: -0.27
(0.13)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in waist circumference (cm)
Mean (SE)

Change in weight (kg)
Mean (SE)

Change in BMI (kg/m2)
Mean (SE)</td><td>Intervention: -0.9
(0.4)

Intervention: -1.18
(0.42)

Intervention: -0.46
(0.16)</td><td>Usual Care: 0.2
(0.4)

Usual Care: -0.6
(0.41)

Usual Care: -0.23
(0.15)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>73.5%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Ross, 2022

Guideline record ID: 10629--1

Study characteristics		
Citation	Ross, R., Latimer-Cheung, A. E., Day, A. G., Brennan, A. M., & Hill, J. O. (2022). A small change approach to prevent long-term weight gain in adults with overweight and obesity: a randomized controlled trial. Canadian Medical Association Journal, 194(9), E324-E331. https://doi.org/https://dx.doi.org/10.1503/cmaj.211041	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A small change approach to prevent long-term weight gain in adults with overweight and obesity: a randomized controlled trial	
Location	Canada	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria required that participants be between 25 and 70 years old, have a BMI between 25.0 and 39.9, be physically inactive and have a stable weight (within 2 kg of baseline weight) for 6 months before the beginning of the study."	
Exclusion criteria	"We excluded participants if they were current smokers, had a planned pregnancy within 3 years or reported a history of heart disease, stroke or any condition that would prevent them from engaging in exercise."	
Setting	University/research centre	
Intervention	"We asked participants in the SCA group to attend a combination of group and 1-on-1 sessions. The format, frequency and content of intervention sessions is described elsewhere.12 Overall, participants were offered 17 group-based sessions and 9 individual counselling sessions, representing about 20 hours of intervention contact. Initial sessions were interventionist-led, but transitioned to being directed by the participant to foster independent self-regulation of SCA behaviours. The SCA intervention comprised several behaviour techniques. Participants randomized to the SCA group reviewed their progress by examining their diet and physical activity patterns, self-monitoring, setting weekly SCA goals and developing a weekly plan for ongoing maintenance of their small change goals. Participants submitted dietary and physical activity logs and their SCA plan to an interventionist on a weekly basis via electronic or paper form. All participants in the SCA group were asked to wear the pedometers we provided (i.e., self-monitor) and maintain their normal activity pattern during the first week after randomization. After establishing a baseline activity level (measured as steps per day), we asked each SCA participant to increase their daily physical activity by about 2000 steps per day (about 20 minutes) above the baseline value and to maintain this goal as a daily minimum for the duration of the 2-year intervention. The SCA participants selfmonitored their physical activity by recording their daily steps and submitting their records on a weekly basis, electronically or in person. We asked SCA participants to wear the pedometer at 6, 12 and 24 months for comparison with their baseline activity level. We asked SCA participants to reduce their usual diet by 100 kcal/d. Participants recorded their usual diet using daily dietary intake records over the 2-week period immediately after randomization. The study dietitian used diet record information, obtained using established procedures,12 to provide participants with specific, pragmatic examples of how to reduce their usual dietary intake by 100 kcal/d. We asked SCA participants to keep a log each day of the strategies used to reduce caloric intake by 100 kcal/d and to submit their records on a weekly basis, electronically or in person. Participants submitted a full 7-day intake record at 12 and 24 months."	

<table>
<tr><td>Control/Comparator</td><td>“we asked all MA group participants to maintain their usual lifestyle (diet and exercise) for the duration of the 2-year intervention and did not discourage them from adopting a healthy lifestyle for the purposes of preventing or losing weight.”</td></tr>
<tr><td>Treatment duration</td><td>2 years</td></tr>
<tr><td>Follow-up from baseline</td><td>36 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 320
Intervention group/s: Small change approach (n=160)

Comparator group: Monitoring alone (n=160)</td></tr>
<tr><td>Mean age ± SD</td><td>52.6y (10.3)</td></tr>
<tr><td>Sex</td><td>77.19% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight, kg
Mean (SD)

Waist circumference, cm
Mean (SD)

BMI
Mean (SD)</td><td>Small change approach: 90 (14.9)

Small change approach: 106.7 (11.7)

Small change approach: 32.6 (4.3)</td><td>Monitoring alone: 90.7 (14)

Monitoring alone: 108 (11.8)

Monitoring alone: 32.6 (4.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight
Mean (SE)

Change in waist circumference
Mean (SE)</td><td>Small change approach: -2.5 (0.5)

Small change approach: -2.4 (0.5)</td><td>Monitoring alone: -0.6 (0.5)

Monitoring alone: -0.9 (0.5)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight
Mean (SE)

Change in waist circumference
Mean (SE)</td><td>Small change approach: -1.2 (0.8)

Small change approach: -1.3 (0.8)</td><td>Monitoring alone: -0.7 (0.8)

Monitoring alone: -0.7 (0.8)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>SCA: 80%</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Roth, 2011

Guideline record ID: 10834--1

Study characteristics		
Citation	Roth, B., Munsch, S., & Meyer, A. H. (2011). [Long-term evaluation of a psychological training for obese children and their parents (TAKE)]. Praxis der Kinderpsychologie und Kinderpsychiatrie, 60(4), 304-321. https://doi.org/https://doi.org/10.13109/prkk.2011.60.4.304	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	[Long-term evaluation of a psychological training for obese children and their parents (TAKE)]	
Location	Switzerland	
Trial name	Training adipöser Kinder und ihrer Eltern (TAKE)	
Methods		
Inclusion criteria	"Obese children aged eight to twelve."	
Exclusion criteria	"Exclusion criteria were physical illnesses, severe mental disorders requiring treatment, and participation in other weight reduction programs and psychotherapy."	
Setting	University/research centre, child and adolescent psychiatric service	
Intervention	"Mother-Child Condition (A) 10 parent sessions according to the TAKE manual, 3 sessions of nutritional advice, 6 follow-up sessions according to parents TAKE-Manual, 10 children's sessions according to the TAKE manual, 10 lessons of sport for the children, 6 follow-up sessions children according to TAKE-Manual. The TAKE manual was developed according to the latest scientific recommendations, as a behavioral therapy group therapy program. It contains a parent and a child manual, which are coordinated in terms of content and can be carried out both as parent training and parallel as parent-child treatment. This is followed by six monthly follow-up sessions. For the initial treatment phase of ten weekly sessions, the topics of nutrition and eating habits, exercise and psychological factors such as being teased, social skills, self-esteem and body image are dealt with. The procedure is individualized, ie each family can contribute its own requirements and goals to the group, which are worked on using a problem-solving approach. The first ten sessions take place weekly and are held simultaneously and in parallel in the parent-child treatment."	
Control/Comparator	"Mother-Only Condition (B) 10 parent sessions according to the TAKE manual, 3 sessions of nutritional advice, 6 follow-up sessions according to parents TAKE-Manual, 10 sessions of PMR* for the children (*Progressive muscle relaxation (PMR) was included in condition B to eliminate any influence of a therapy dose effect.) The TAKE manual was developed according to the latest scientific recommendations, as a behavioral therapy group therapy program. It contains a parent and a child manual, which are coordinated in terms of content and can be carried out both as parent training and parallel as parent-child treatment. This is followed by six monthly follow-up sessions. For the initial treatment phase of ten weekly sessions, the topics of nutrition and eating habits, exercise and psychological factors such as being teased, social skills, self-esteem and body image are dealt with. The procedure is individualized, ie each family can contribute its own requirements and goals to the group, which are worked on using a problem-solving approach. The first ten sessions take place weekly and are held simultaneously and in parallel in the parent-child treatment. An additional nutritional consultation of three sessions is planned for the parent group."	
Treatment duration	6 months	
Follow-up from baseline	64 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 58
Intervention group/s: Mother-child (n=32)

Comparator group: Mother-only (n=26)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI-SDS
Mean (SD)</td><td>Mother-child: 2.4</td><td>Mother-only: 2.61</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI-SDS
Mean (SD)</td><td>Mother-child: 2.26</td><td>Mother-only: 2.31</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Rubino, 2022

Guideline record ID: 10632--1

Study characteristics		
Citation	Rubino, D. M., Greenway, F. L., Khalid, U., O'Neil, P. M., Rosenstock, J., Sørrig, R., Wadden, T. A., Wizert, A., Garvey, W. T., & Investigators, t. S. (2022). Effect of weekly subcutaneous semaglutide vs daily liraglutide on body weight in adults with overweight or obesity without diabetes: the STEP 8 randomized clinical trial. JAMA, 327(2), 138-150. https://doi.org/https://dx.doi.org/10.1001/jama.2021.23619	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Weekly Subcutaneous Semaglutide vs Daily Liraglutide on Body Weight in Adults With Overweight or Obesity Without Diabetes: The STEP 8 Randomized Clinical Trial	
Location	US	
Trial name	STEP 8	
Methods		
Inclusion criteria	"Participants were eligible to be included in the trial only if all the following criteria applied: • Informed consent obtained before any trial-related activities. Trial-related activities are any procedures that are carried out as part of the trial, including activities to determine suitability for the trial. • Male or female, age ≥18 years at the time of signing informed consent. • Body mass index (BMI) ≥30.0 kg/m2 or ≥27.0 kg/m2 with the presence of at least 1 of the following weight-related comorbidities (treated or untreated): hypertension, dyslipidemia, obstructive sleep apnea, or cardiovascular disease. • History of at least 1 self-reported unsuccessful dietary effort to lose body weight. The criteria were assessed at the investigator's discretion unless otherwise stated."	
Exclusion criteria	"Exclusion Criteria Participants were excluded from the trial if any of the following criteria applied: Glycemia-Related • Hemoglobin A1c (HbA1c) ≥6.5% (48 mmol/mol) as measured by the central laboratory at screening. • History of type 1 or type 2 diabetes (T1/2D). • Treatment with glucose-lowering agent(s) within 90 days before screening. Obesity-Related • A self-reported change in body weight >5 kg (11 lb) within 90 days before screening irrespective of medical records. • Treatment with any medication for the indication of obesity within the past 90 days before screening. • Previous or planned (during the trial period) obesity treatment with surgery or a weight loss device. However, the following were allowed: (1) liposuction and/or abdominoplasty, if performed >1 year before screening; (2) lap banding, if the band has been removed >1 year before screening; (3) intragastric balloon, if the balloon has been removed >1 year before screening; or (4) duodenal-jejunal bypass sleeve, if the sleeve has been removed >1 year before screening. • Uncontrolled thyroid disease, defined as thyroid stimulating hormone >6.0 mIU/L or <0.35 mIU/L as measured by the central laboratory at screening. Mental Health • History of major depressive disorder within 2 years before screening. • Diagnosis of other severe psychiatric disorder (eg, schizophrenia, bipolar disorder). • A Patient Health Questionnaire-9 score ≥15 at screening. • A lifetime history of suicidal attempt. • Suicidal behavior within 30 days before screening. • Suicidal ideation corresponding to type 4 or 5 on the Columbia-Suicide Severity Rating Scale within the past 30 days before screening. General Safety • Presence of acute pancreatitis within the past 180 days prior to the day of screening. • History or presence of chronic pancreatitis. • Calcitonin ≥100 ng/L as measured by the central laboratory at screening. • Personal or first-degree relative history of multiple endocrine neoplasia type 2 or medullary thyroid carcinoma. Renal impairment measured as estimated glomerular filtration rate value of <15 ml/min/1.73 m2 as defined by Kidney Disease: Improving Global Outcomes 20121 by the central laboratory at screening. • History of malignant neoplasms within the past 5 years prior to screening. Basal and squamous cell skin cancer and any carcinoma in-situ are allowed. • Any of the following: myocardial infarction, stroke, hospitalization for unstable angina or transient ischemic attack within the past 60 days prior to screening. • Participant classified as being in New York Heart	

	Association Class IV. • Surgery scheduled for the duration of the trial, except for minor surgical procedures, in the opinion of the investigator. • Known or suspected abuse of alcohol or recreational drugs. • Known or suspected hypersensitivity to trial product(s) or related products. • Previous participation in this trial. Participation is defined as signed informed consent. • Participation in any clinical trial of an approved or non-approved investigational medicinal product within 90 days before screening. • Other individuals from the same household participating in any semaglutide or liraglutide trial. • Female who is pregnant, breast-feeding, or intends to become pregnant or is of child-bearing potential and not using a highly effective contraceptive method. • Any disorder, unwillingness, or inability, not covered by any of the other exclusion criteria, which in the investigator's opinion, might jeopardize the participant's safety or compliance with the protocol. The criteria were assessed at the investigator's discretion unless otherwise stated.”
Setting	Home
Intervention	“Once-weekly subcutaneous semaglutide, 2.4mg, or once-daily subcutaneous liraglutide, 3.0 mg o, for 68 weeks, with a 7-week follow-up. Semaglutide, initiated at 0.25 mg, was escalated to 2.4 mg (maintenance dose) over 16 weeks (eFigure 1 in Supplement 3). A 1.7-mg maintenance dose was permitted if 2.4 mg could not be tolerated; 1 or more attempts to reescalate was advised. Liraglutide was initiated at 0.6 mg and escalated to 3.0 mg over 4 weeks; escalation could be delayed by a week to aid tolerability. Commensurate with the prescribing information,6 treatment was discontinued if liraglutide, 3.0 mg, was not tolerated; treatment could be restarted, with reescalation over 4 weeks. Treatments were administered using a multidose pen injector; the semaglutide (andmatched placebo) group switched to a single-dose pen injector for weeks 44 to 68. All participants received counseling (from qualified health care professionals, every 4-6 weeks, via in-person visits or telephone) to adhere to diet (500-kcal/d deficit relative to baseline estimated energy expenditure) and physical activity recommendations (≥150 minutes/week).”
Control/Comparator	“matching placebo of once-weekly subcutaneous semaglutide, 2.4mg or or once-daily subcutaneous liraglutide, 3.0 mg for 68 weeks, with a 7-week follow-up. The placebo groups also facilitated comparisons of semaglutide and liraglutide vs placebo (secondary trial objectives), allowing evaluation of trial results in the context of previous findings. Treatments were administered using a multidose pen injector; the semaglutide (andmatched placebo) group switched to a single-dose pen injector for weeks 44 to 68. All participants received counseling (from qualified health care professionals, every 4-6 weeks, via in-person visits or telephone) to adhere to diet (500-kcal/d deficit relative to baseline estimated energy expenditure) and physical activity recommendations (≥150 minutes/week).”
Treatment duration	68 weeks
Follow-up from baseline	Week 68
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 338 Intervention group/s: Semaglutide, 2.4 mg (n=126); Liraglutide, 3.0 mg (n=127) Comparator group: Placebo (n=85)
Mean age ± SD	Semaglutide: 48y (14); Liraglutide: 49y (13); Placebo: 51y (12)
Sex	78.40% female

<table>
<tr><td>Pre-existing medical condition</td><td>1 or more weight-related comorbidities (hypertension, dyslipidemia, obstructive sleep apnea, or cardiovascular disease)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Body weight (kg) - Baseline
Mean (SD)</td><td>Semaglutide, 2.4 mg: 102.5 (25.3)
Liraglutide, 3.0 mg: 103.7 (22.5)</td><td>Placebo: 108.8 (23.1)</td></tr>
<tr><td>Waist circumference (cm) - Baseline
Mean (SD)</td><td>Semaglutide, 2.4 mg: 111.8 (16.3)
Liraglutide, 3.0 mg: 113.5 (15)</td><td>Placebo: 115.4 (15.1)</td></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)</td><td>Semaglutide, 2.4 mg: 37 (7.4)
Liraglutide, 3.0 mg: 37.2 (6.4)</td><td>Placebo: 38.8 (6.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Proportion of Participants with ≥10% weight loss
Proportion (%)</td><td>Semaglutide, 2.4 mg: 70.9
Liraglutide, 3.0 mg: 25.6</td><td>Placebo: 15.4</td></tr>
<tr><td>Proportion of Participants with ≥15% weight loss
Proportion (%)</td><td>Semaglutide, 2.4 mg: 55.6
Liraglutide, 3.0 mg: 12</td><td>Placebo: 6.4</td></tr>
<tr><td>Proportion of Participants with ≥20% weight loss
Proportion (%)</td><td>Semaglutide, 2.4 mg: 38.5
Liraglutide, 3.0 mg: 6</td><td>Placebo: 2.6</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in weight (%)
Mean (95% CIs)</td><td>Semaglutide, 2.4 mg: -15.8 (-17.6--13.9)
Liraglutide, 3.0 mg: -6.4 (-8.2--4.6)</td><td>Placebo: -1.9 (-4-0.2)</td></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)</td><td>Semaglutide, 2.4 mg: -15.3 (-17.3--13.4)
Liraglutide, 3.0 mg: -6.8 (-8.8--4.9)</td><td>Placebo: -1.6 (-3.9-0.8)</td></tr>
<tr><td>Change in waist circumference (cm)
Mean (95% CIs)</td><td>Semaglutide, 2.4 mg: -13.2 (-15--11.5)
Liraglutide, 3.0 mg: -6.6 (-8.3--4.9)</td><td>Placebo: -2 (-4-0.1)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Compliance with treatment</td><td>94.4%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from</td><td></td></tr>
</table>

this study that did not contribute additional data	

N/A – Not applicable

Rumbo-Rodriguez, 2022

Guideline record ID: 10633--1

Study characteristics		
Citation	Rumbo-Rodríguez, L., Zaragoza-Marti, A., Sánchez-SanSegundo, M., Ferrer-Cascales, R., Laguna-Pérez, A., & Hurtado-Sánchez, J. A. (2022). Effectiveness of a two-year multicomponent intervention for the treatment of overweight and obesity in older people. Nutrients, 14(22), 4762. https://doi.org/https://dx.doi.org/10.3390/nu14224762	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effectiveness of a Two-Year Multicomponent Intervention for the Treatment of Overweight and Obesity in Older People	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	"The inclusion criteria were (1) being over 60 years of age and having attended a scheduled consultation with a health professional at the health center and (2) having a body mass index (BMI) greater than 25 kg/m2."	
Exclusion criteria	"The exclusion criteria were as follows: (1) patients with a score of three or more errors in the Pfeiffer test (if they had studies) and four or more errors (without studies), (2) having reported difficulties in reading and writing, and (3) having undergone a dietary- nutritional treatment supervised by a nutritionist during the last year."	
Setting	University/research centre	
Intervention	"10 group nutritional education sessions and 17 individual sessions with the following objectives: (1) improve inappropriate eating habits, (2) improve nutritional and health status, (3) promote balanced eating habits and healthy lifestyles, and (4) teach strategies for planning healthy menus with appropriate culinary techniques. In addition, each participant received a weight loss history, self-monitoring diary, food calorie book, and visual atlas of portion sizes. The contents of the intervention were prepared and designed by the multidisciplinary research team: dietitians and nutritionists, doctors, psychology staff, nursing staff, and physiotherapists. Participants in the experimental group received personalized training for weight management, food education, and psychological support and self-care recommendations. The dietary-nutritional intervention was carried out by a trained and qualified dietician-nutritionist. During the individual sessions, a menu adapted to patient needs based on the MD was provided to each participant. In addition, in the follow up individual sessions, the dietitian-nutritionist monitored weight loss by taking anthropometric measurements and evaluated eating behavior by considering questionnaires. During the group sessions, topics related to the MD and its health benefits, the nutritional labeling of packaged foods, the key diet for healthy aging, seasonal diet, the possibility of a healthy gastronomy, diet and cholesterol, diet and hypertension prevention, diet and bone health, healthy snacks and healthy recipes were carried out. In the psychological support sessions, issues related to self-control, anxiety management, emotional feeding, achievements, and difficulties encountered during treatment, review of weekly action plans, relaxation techniques, consolidation of the new image, cognitive distortions, change management, coping with uncertainty, and motivation to change were discussed. The psychological follow-up was carried out by the psychology staff and the follow-up of self-care in health was carried out by the nursing staff. For physical activity, following the recommendations of the World Health Organization (WHO), exercise of at least 150 min per week was recommended."	

<table>
<tr><td>Control/Comparator</td><td>“The control group received nutritional education in a written format on topics such as MD and its benefits, purchasing choices, nutritional food labelling, meal preparation, and healthy culinary techniques.”</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 51
Intervention group/s: Experimental group (n=25)

Comparator group: Control group (n=26)</td></tr>
<tr><td>Mean age ± SD</td><td>4.64</td></tr>
<tr><td>Sex</td><td>88.24% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Experimental group: 82.66 (13.99)</td><td>Control group: 79.09 (11.87)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Experimental group: 32.7 (4.31)</td><td>Control group: 32.17 (3.93)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Experimental group: 101</td><td>Control group: 100.1</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Experimental group: 79.7</td><td>Control group: 78.9</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Experimental group: 31.5</td><td>Control group: 32.1</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Experimental group: 98.7</td><td>Control group: 101.6</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Experimental group: 79.8</td><td>Control group: 78.8</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Experimental group: 31.6</td><td>Control group: 32.1</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Experimental group: 98.5</td><td>Control group: 100.6</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight
Mean (SD)</td><td>Experimental group: -3</td><td>Control group: -0.2</td></tr>
<tr><td>Change in BMI</td><td>Experimental group: -1.2</td><td>Control group: -0.1</td></tr>
</table>
</td></tr>
</table>

	Mean (SD) Change in waist circumference Mean (SD)	Experimental group: -2.3	Control group: 1.5
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in weight Mean (SD)	Experimental group: -2.9	Control group: -0.3
	Change in BMI Mean (SD)	Experimental group: -1.1	Control group: -0.1
	Change in waist circumference Mean (SD)	Experimental group: -2.5	Control group: 0.5
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Rusu, 2013

Guideline record ID: 10635--1

Study characteristics		
Citation	Rusu, E., Jinga, M., Enache, G., Rusu, F., Dragomir, A. D., Ancuta, I., Dragut, R., Parpala, C., Nan, R., Sima, I., Ateia, S., Stoica, V., Cheţa, D. M., & Radulian, G. (2013). Effects of lifestyle changes including specific dietary intervention and physical activity in the management of patients with chronic hepatitis C--a randomized trial. Nutrition Journal, 12, 119. https://doi.org/https://dx.doi.org/10.1186/1475-2891-12-119	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of lifestyle changes including specific dietary intervention and physical activity in the management of patients with chronic hepatitis C--a randomized trial	
Location	Romania	
Trial name	Adipocitokynes, link between virus C hepatitis and type 2 diabetes mellitus (DIADIPOHEP)	
Methods		
Inclusion criteria	"The inclusion criteria were: age over 35 years, BMI over 25 kg/m2 diagnosis of chronic hepatitis C (CHC infection was defined by the presence of antiHCV antibodies for a least 6 months and a positive HCV-viremia)."	
Exclusion criteria	"The exclusion criteria were: patients with other etiology of chronic liver disease, hepatitis B, autoimmune liver disease, hemochromatosis, HIV infection, patients with history of hepatotoxic or steatosis-inducing drug use, currently on interferon treatment or during the last 12 months, patients having an alcohol consumption of more than 20 g/day for women and 30 g/day for men, history of pancreatitis."	
Setting	Home, University/research centre	
Intervention	"Participants were randomized to a normoglucidic low-calorie diet (NGLCD) group, or to a low-fat diet (LFD) group, both with a lifestlye management program. All patients received nutrition counseling (NGLCD or LFD) in individual sessions every week in the first 6 months and every month thereafter until 12 months, with biological reevaluation at 6 and 12 months. All patients were required to submit a food journal at the baseline visit (before group allocation), as well as subsequent journals prior to the 6 month, 12 month, and each monthly visit. No supplements were allowed in this period. Subjects were required to limit alcohol intake to <20 g/week during the intervention period. Normoglucidic low-calorie diet (NGLCD) Dietitian doctors instructed participants to follow a diet comprising approximately 50-60% of daily caloric intake from carbohydrates [16], 25-35% of total calories from fat (less than 7% of total calories from saturated fat, less than 1% trans fatty acids, 10% monounsaturated fatty acids, 5-10% polyunsaturated fatty acids (PUFAs) and less than 300 mg cholesterol per day), proteins 15% of total calories (1.0 to 1.2 g/kg/day) [17], and <5% of caloric intake from simple sugars. Nutrient-rich choices that included whole grains, vegetables and fruit were prioritized. NGLCD was defined as a normoglucidic, normolipidic, normoproteic, low-calorie diet (100-500 kcal less than estimated energy needs). A healthy lifestyle includes regular physical activity (PA). Regular physical activity included 30 minutes of moderate intensity physical activities (e.g. brisk walking, jogging, cycling) for 3-7 days a week, recommended for persons with hepatitis C virus infection without advanced cirrhosis or other metabolic complications. Physical activity: Regular physical activity included 30 minutes of moderate intensity physical activities (e.g. brisk walking, jogging, cycling) for 3-7 days a week, recommended for persons with hepatitis C virus infection without advanced cirrhosis or other metabolic complications. In patients with overweight or obesity, the energy intake was individualized to be 100-500 kcal less than estimated energy needs because we designed it to induce at least a 5-10% weight loss at 6 months and to maintain this weight loss in the subsequent 6 months."	

<table>
<tr><td>Control/Comparator</td><td>“Participants were randomized to a normoglucidic low-calorie diet (NGLCD) group, or to a low-fat diet (LFD) group, both with a lifestlye management program. All patients received nutrition counseling (NGLCD or LFD) in individual sessions every week in the first 6 months and every month thereafter until 12 months, with biological reevaluation at 6 and 12 months. All patients were required to submit a food journal at the baseline visit (before group allocation), as well as subsequent journals prior to the 6 month, 12 month, and each monthly visit. No supplements were allowed in this period. Subjects were required to limit alcohol intake to <20 g/week during the intervention period. Low-fat diet (LFD) Restriction of fat intake to 20% of total daily energy uptake with avoidance of trans-fat and saturated fat, up to 20% of the total calories from proteins and 60-65% carbohydrates. Further recommendation included increasing fibre uptake to 30 g per day, and avoiding liquid monoand disaccharides. Moreover, patients were advised to consume at least 250 to 300 g of fruits, 125 to 150 g of vegetables, and 25 to 50 g of walnuts per day; in addition, they were also encouraged to consume 400 g of whole grains (rice, maize, and wheat) daily and to increase their consumption of olive oil. Compared with normoglucidic low-calorie diet, low-fat diet was defined by a low intake of fat (up to 20% of caloric intake), increased carbohydrate intake up to 60-65% of daily caloric intake, increased fiber intake (30 g/day), and protein intake up to 20%. Physical activity: Regular physical activity included 30 minutes of moderate intensity physical activities (e.g. brisk walking, jogging, cycling) for 3-7 days a week, recommended for persons with hepatitis C virus infection without advanced cirrhosis or other metabolic complications. In patients with overweight or obesity, the energy intake was individualized to be 100-500 kcal less than estimated energy needs because we designed it to induce at least a 5-10% weight loss at 6 months and to maintain this weight loss in the subsequent 6 months.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 110
Intervention group/s: NGLCD (n=58)

Comparator group: LFD (n=52)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>57.27% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Chronic hepatitis C (CHC infection was defined by the presence of antiHCV antibodies for a least 6 months and a positive HCV-viremia).</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>NGLCD: 92.7
(13.6)</td><td>LFD: 92.4
(11.7)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>NGLCD: 29.4
(3.5)</td><td>LFD: 29.4
(3.4)</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>NGLCD: 84.07
(13.2)</td><td>LFD: 83
(11.11)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>NGLCD: 89.5
(11.9)</td><td>LFD: 89
(10.6)</td></tr>
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</td></tr>
</table>

	BMI (kg/m2) Mean (SD) Weight (kg) Mean (SD)	NGLCD: 28.9 (3.6) NGLCD: 80.09 (13.8)	LFD: 28.3 (3.4) LFD: 79.8 (11.5)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in waist circumference (cm) Mean (SD) Change in waist circumference (cm) Mean (95% CIs) Change in BMI (kg/m2) Mean (SD) Change in BMI (kg/m2) Mean (95% CIs) Change in weight (kg) Mean (SD) Change in weight (kg) Mean (95% CIs)	NGLCD: -3.3 (3.6) NGLCD: -3.3 (-4.3--2.3) NGLCD: -1.4 (1.1) NGLCD: -1.4 (-1.7--1.1) NGLCD: -3.9 (3.3) NGLCD: -3.9 (-4.8--3.1)	LFD: -3.4 (3.1) LFD: -3.4 (-6.7--0.96) LFD: -1.1 (0.9) LFD: -1.1 (-1.3--0.8) LFD: -3.1 (2.6) LFD: -3.1 (-3.8--2.3)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Ruusunen, 2012

Guideline record ID: 10636--1

Study characteristics		
Citation	Ruusunen, A., Voutilainen, S., Karhunen, L., Lehto, S. M., Tolmunen, T., Keinänen-Kiukaanniemi, S., Eriksson, J., Tuomilehto, J., Uusitupa, M., & Lindström, J. (2012). How does lifestyle intervention affect depressive symptoms? results from the Finnish Diabetes Prevention Study. Diabetic Medicine, 29(7), e126-e132. https://doi.org/10.1111/j.1464-5491.2012.03602.x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	How does lifestyle intervention affect depressive symptoms? Results from the Finnish Diabetes Prevention Study	
Location	Finland	
Trial name	Finnish Diabetes Prevention Study (DPS)	
Methods		
Inclusion criteria	"BMI over 25 kg／m2, age 40-64 years and impaired glucose tolerance on the basis of the mean values of two oral glucose tolerance tests."	
Exclusion criteria	"Participants diagnosed to have Type 2 diabetes during the intervention were excluded."	
Setting	Home, ace-to-face counselling sessions with the study nutritionist	
Intervention	"Lifestyle intervention group The participants in the intervention group were given detailed advice to achieve the goals: (1) weight reduction of ‡ 5%, (2) < 30% of the daily energy intake from fat, (3) < 10% of energy intake from saturated fat, (4) fibre intake to ‡ 15 g per 1000 kcal and (5) moderate exercise for ‡ 30 min per day. Consumption of wholegrain cereal products, vegetables, fruit, low-fat milk and meat products, soft margarines and vegetable oils rich in unsaturated fatty acids were recommended. The intensive intervention consisted of seven face-to-face counselling sessions with the study nutritionist during the first year of the study and one session every 3 months thereafter. The goal was to equip the participants with necessary knowledge and skills and to achieve gradual, permanent behavioural changes [10]. Exercise intervention was individualized and based on daily physical activities, endurance exercise and no-cost, supervised circuit-type resistance training. Exercise intervention has been described in detail previously"	
Control/Comparator	"Control group The subjects in the control group were given, at baseline, general verbal and written information about diet and exercise. This was carried out either individually or in one group session and the principles of the message were the same as for the intervention group subjects: to reduce weight, increase physical activity and make qualitative changes in diet. Thus, the advice the control group received concerning healthy lifestyle could be regarded as 'a mini-intervention'. Members of the control group visited the research centres once a year."	
Treatment duration	3 years	
Follow-up from baseline	3 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Weight for height growth chart	
Participant characteristics		
Number of participants	n= 140 Intervention group/s: Intervention (n=69) Comparator group: Control (n=71)	

<table>
<tr><td>Mean age ± SD</td><td>Intervention: 57.7y (6.4); Control: 57.4y (6.5)</td></tr>
<tr><td>Sex</td><td>57.86% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intervention: 30.2
(3.4)</td><td>Control: 31.2
(4.7)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)</td><td>Intervention: -3.14
(4.52)

Intervention: -1.16
(1.74)</td><td>Control: -1.18
(5.32)

Control: -0.45
(1.9)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Lindström, J., Peltonen, M., Eriksson, J. G., Ilanne-Parikka, P., Aunola, S., Keinänen-Kiukaanniemi, S., Uusitupa, M., Tuomilehto, J., & the Finnish Diabetes Prevention Study (DPS). (2013). Improved lifestyle and decreased diabetes risk over 13 years: long-term follow-up of the randomised Finnish Diabetes Prevention Study (DPS). Diabetologia, 56(2), 284-293. https://doi.org/https://dx.doi.org/10.1007/s00125-012-2752-5</td></tr>
</table>

N/A – Not applicable

Saelens, 2013

Guideline record ID: 10836--1

Study characteristics		
Citation	Saelens, B. E., Lozano, P., & Scholz, K. (2013). A randomized clinical trial comparing delivery of behavioral pediatric obesity treatment using standard and enhanced motivational approaches. Journal of Pediatric Psychology, 38(9), 954-964. https://doi.org/10.1093/jpepsy/jst054	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A randomized clinical trial comparing delivery of behavioral pediatric obesity treatment using standard and enhanced motivational approaches	
Location	USA	
Trial name	Family Overweight: Comparing Use of Strategies (FOCUS)	
Methods		
Inclusion criteria	"Only 7-11-year-old children at or above the 85th percentile for age- and gender-specific BMI (Kuczmarski et al., 2000), but no >175% above the median BMI for age and gender were eligible. Only children with at least one overweight parent (BMI 25.0) (National Institutes of Health & National Heart Lung and Blood Institute, 1998) were included to ensure targeting a higher risk group (Freedman, Khan, Dietz, Srinivasan, & Berenson, 2001; Whitaker, Wright, Pepe, Seidel, & Dietz, 1997). Parents' participation in other programs targeting their own weight change was not exclusionary (rare), if the behavioral changes recommended were consistent with FOCUS targets. Participating parents and children were required to (a) not have an existing thought disorder, suicidality, or substance abuse disorder, (b) not have disability or illness that would preclude them from engaging in at least moderate-intensity physical activity, (c) be English-speaking and at least at a second-grade reading level, (d) not have a current or prior diagnosed eating disturbance, and (e) live <50 miles from the treatment site."	
Exclusion criteria	"Children with conditions known to promote obesity were excluded (e.g., Prader-Willi), along with those in another weight control program or who had recently started taking weight-affecting medications (e.g., stimulants)."	
Setting	Not reported	
Intervention	"Self-Directed Treatment Condition: Both treatment conditions included 20 weekly sessions across 21 or 22 weeks (one intentional 'skip' week and one holiday skip week in two cohorts), consistent with U.S. Preventive Services Task Force recommendation for moderate- to high-intensity interventions (>25 contact hours) for childhood obesity treatment. For both treatment conditions, weekly treatment consisted of a 20-30-min individual family session where each parent-child dyad met with a family interventionist and 40-50-min separate child and parent group sessions immediately before or after individual family sessions. The self-directed approach also involves interventionist focus on skills use training, feedback, and holding families accountable for consistent skills use during the first 5 weeks of treatment, the same as the prescribed approach. Thereafter, the interventionist shifts toward encouraging more autonomy and self-efficacy around skills use, by acknowledging parental (and child) ambivalence about behavior change and struggles with continued skills use (e.g., common for families to struggle with continuous daily monitoring of food and physical activity). Information provided about healthy eating and physical activity was the same between the treatment conditions throughout treatment. In both treatment conditions, the first 5 weeks were devoted to bringing all parents and children to similar levels of knowledge and skills use for application to the healthy eating and physical activity plan, including food and physical activity monitoring, contingency management, and environmental control. After these first 5 weeks, the two conditions diverged, particularly regarding the accountability and autonomy for behavioral	

	skills use and goal assignment. Families in the self-directed arm were given more autonomy in making choices about skills use (e.g., which skills to use, what goals to have). The self-directed intervention assists the family in developing the ability to set tailored realistic and meaningful goals, guides and facilitates experimentation for families to determine for themselves which skills are feasible that will optimize their long-term behavior change, guided by the family's readiness to change. This includes the interventionist seeking families' input regarding which behavioral goals and which behavioral skills (if any) they want to continue using after week 5, while providing feedback regarding any discrepancy between families' stated goals and skills use (i.e., cannot have a daily calorie goal if not recording calories). The interventionist supports the parent's autonomy and asks the parent (and child) weekly to consider what they are ready to undertake (e.g., changing the weekly weight loss goal, selecting which skills to use), their confidence in their ability to be successful in meeting goals, and their own behavioral expectations. Family autonomy from the interventionist, inherent to this approach and required for long-term implementation (i.e., after treatment ends), is further solidified by starting long-term planning in the self-directed approach in week 12, notably earlier than in the prescribed approach."
Control/Comparator	"Prescribed Treatment Condition: Both treatment conditions included 20 weekly sessions across 21 or 22 weeks (one intentional 'skip' week and one holiday skip week in two cohorts), consistent with U.S. Preventive Services Task Force recommendation for moderate- to high-intensity interventions (>25 contact hours) for childhood obesity treatment. For both treatment conditions, weekly treatment consisted of a 20-30-min individual family session where each parent-child dyad met with a family interventionist and 40-50-min separate child and parent group sessions immediately before or after individual family sessions. Information provided about healthy eating and physical activity was the same between the treatment conditions throughout treatment. In both treatment conditions, the first 5 weeks were devoted to bringing all parents and children to similar levels of knowledge and skills use for application to the healthy eating and physical activity plan, including food and physical activity monitoring, contingency management, and environmental control. After these first 5 weeks, the two conditions diverged, particularly regarding the accountability and autonomy for behavioral skills use and goal assignment. Families in the prescribed arm were encouraged to continue to adhere to treatment standards (i.e., consistent skills implementation). The prescribed approach purports that skills use leads to improved weight outcomes, which then leads to self-efficacy (child and parent), which then leads back to continued skills use, and so on. This approach takes the stance that after initial skills use, training needs to continue thereafter by the interventionist guiding, providing support for, highlighting the importance of, and helping families problem-solve to consistently and comprehensively use behavioral skills. The interventionist sets weekly treatment goals for parent and child, with little or no input from the family or tailoring of goals, and evaluates and holds accountable families for consistent adherence to the behavioral skills use. During weeks 17-20, the interventionist engages families in long-term planning for continued skills use."
Treatment duration	22 weeks
Follow-up from baseline	24 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles
Participant characteristics	
Number of participants	n= 72 Intervention group/s: Self-directed approach (n=35) Comparator group: Prescribed approach (n=37)
Mean age ± SD	Intervention: 9.7y (1.4); Control: 9.8y (1.4)
Sex	66.67% female

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI z-score
Mean (SE)</td><td>Self-directed approach: 2.05 (0.08)</td><td>Prescribed approach: 2.15 (0.06)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI z-score
Mean (SE)</td><td>Self-directed approach: 1.76</td><td>Prescribed approach: 1.85</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI z-score
Mean (SE)</td><td>Self-directed approach: 1.79</td><td>Prescribed approach: 1.94</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Twelve of the 72 families (16%) who attended any treatment session did not attend past session 5, half of which (n = 6) attended only the first treatment session. Of the 60 families attending past session 5 (when treatment conditions began diverging), the median number of sessions attended was 18 out of 20 total sessions in both the prescribed (n = 32) and self-directed (n = 28) approaches.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Sahlman, 2012

Guideline record ID: 10837--1

Study characteristics		
Citation	Sahlman, J., Seppä, J., Herder, C., Peltonen, M., Peuhkurinen, K., Gylling, H., Vanninen, E., Tukiainen, H., Punnonen, K., Partinen, M., Uusitupa, M., & Tuomilehto, H. (2012). Effect of weight loss on inflammation in patients with mild obstructive sleep apnea. Nutrition, Metabolism & Cardiovascular Diseases, 22(7), 583-590. https://doi.org/10.1016/j.numecd.2010.10.007	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of weight loss on inflammation in patients with mild obstructive sleep apnea	
Location	Finland	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were working age (18e65 years), body mass index (BMI) 28e40 kg/m2 and mild OSA (apneaehypopnea index [AHI] 5e15 events/h)."	
Exclusion criteria	"We excluded patients undergoing any kind of active treatment for OSA, as well as pregnant women, those with chronic kidney or liver disease and those with untreated thyroid disease."	
Setting	Home, University/research centre	
Intervention	"The 1-year lifestyle intervention consisted of 14 visits with the study nutritionist. Special emphasis was placed on diet, exercise and modification of lifestyle in general. The intervention was initiated with a 12-week very low calorie diet followed by dietary counseling according to current dietary recommendations. An increase in daily physical activity was recommended and supervised"	
Control/Comparator	"The subjects in the control group were given standard advice consisting of oral and written information about diet and exercise at the baseline and 3-month visit by the study nurse and physician, but no specific individualized programs were offered to them."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 81 Intervention group/s: Intervention group (n=40) Comparator group: Control group (n=41)	
Mean age ± SD	Intervention: 52.5y (8.8); Control: 51.8y (9.0)	
Sex	17.28% female	
Pre-existing medical condition	Mild obstructive sleep apnea	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline Weight, kg
Mean (SD)

Baseline BMI, kg/m2
Mean (SD)

Baseline Waist circumference, cm
Mean (SD)</td><td>Intervention group: 102
(12.9)

Intervention group: 33.5
(3)

Intervention group: 113
(9.2)</td><td>Control group: 91.4
(10.5)

Control group: 31.5
(2.5)

Control group: 105
(6.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Weight, kg
Mean (SD)

Change in BMI, kg/m2
Mean (SD)

Change in Waist circumference, cm
Mean (SD)</td><td>Intervention group: -10.7
(6.1)

Intervention group: -3.53
(2)

Intervention group: -11.6
(6.4)</td><td>Control group: -2.9
(6.5)

Control group: -1.01
(2.2)

Control group: -3.7
(6.6)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Tuomilehto, H., Gylling, H., Peltonen, M., Martikainen, T., Sahlman, J., Kokkarinen, J., Randell, J., Tukiainen, H., Vanninen, E., Partinen, M., Tuomilehto, J., Uusitupa, M., Seppä, J., & Kuopio Sleep Apnea Group. (2010). Sustained improvement in mild obstructive sleep apnea after a diet- and physical activity-based lifestyle intervention: postinterventional follow-up. The American Journal of Clinical Nutrition, 92(4), 688-696. https://doi.org/10.3945/ajcn.2010.29485</td></tr>
</table>

N/A – Not applicable

Saito, 2011

Guideline record ID: 10838--1

Study characteristics		
Citation	Saito, T., Watanabe, M., Nishida, J., Izumi, T., Omura, M., Takagi, T., Fukunaga, R., Bandai, Y., Tajima, N., Nakamura, Y., Ito, M., & the Zensharen Study for Prevention of Lifestyle Diseases Group. (2011). Lifestyle modification and prevention of type 2 diabetes in overweight Japanese with impaired fasting glucose levels: a randomized controlled trial. Archives of Internal Medicine, 171(15), 1352-1360. https://doi.org/https://dx.doi.org/10.1001/archinternmed.2011.275	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Lifestyle modification and prevention of type 2 diabetes in overweight Japanese with impaired fasting glucose levels: a randomized controlled trial	
Location	Japan	
Trial name	N/A	
Methods		
Inclusion criteria	"The inclusion criteria were age 30 to 60 years, fasting plasma glucose level of 100 to 125 mg/dL, and body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) of at least 24.0."	
Exclusion criteria	"Exclusion criteria were having received a diagnosis of diabetes or receiving treatment for diabetes; having a history of ischemic heart disease, stroke, chronic hepatitis, liver cirrhosis, chronic pancreatitis, chronic nephritis, pituitary disease, thyroid disease, adrenal gland disease, mental illness, gastrectomy, or advanced malignant tumor; receiving corticosteroid or thyroid hormone medication; and being judged by the responsible physician of the local study center as unfit to participate in the study (eg, persons with serious diseases not included in the other exclusion criteria)."	
Setting	GP clinic, Hospital	
Intervention	"For 36 months after randomization, each participant in the FINT and control groups received the intervention on different schedules. The FINT group received individual instructions and follow-up support for lifestyle modification from the medical staff at least 9 times (at baseline and 1, 3, 6, 12, 18, 24, 30, and 36 months; if necessary, 2 extra visits could be added at 9 and 15 months as an option). At each visit after a 12-month interval, the responsible physician in the local study center checked whether each participant had any disease or treatment that was inappropriate for study participation or that clearly influenced glucose tolerance. Irrespective of the assigned groups, all the participants were individually instructed to reduce total energy intake and increase physical activity, aiming at a 5% reduction in body weight, through the help of nurses, dieticians, physical therapists, and physicians. We used existing human and material resources of each local study center as much as possible. Nurses and dieticians were mainly involved in the intervention at most local study centers, although it depended on the personnel situation at each center. The participants were given pedometers and pamphlets providing general information on diabetes and lifestyle modifications. The participants in both groups determined their own lifestyle goals, based on the results of the assessments and their motivation. Participants in the FINT group were invited to a series of follow-up visits and worked toward their goals by using selfmonitoring sheets for recording body weight, pedometer counts, and how close they came to attaining their goals. If necessary, they altered their goals or added new goals. The dietary intervention aimed at reducing total energy intake mainly by restricting excess intake of fat or carbohydrates, taking into consideration the Japan Diabetes Society recommendation for diabetic patients, and by controlling fat intake at 20% to 25% of total energy intake and carbohydrate intake at 55% to 60% of total energy intake. Where necessary, additional intake of dietary fiber, appropriate alcohol consumption (23 g/d), and	

	corrective measures for undesirable dietary habits were also set as goals. Practical and feasible goals were proposed to the participants, such as "reducing the frequency of eating sweet foods between meals to less than 3 times per week." Participants who hoped to do any leisure time physical activity were advised on how to gradually increase their physical activity to 200 kcal/d (837.2 kJ/d) (mainly by walking more and walking faster). Sedentary or busy participants were encouraged to increase daily life physical activity by, for example, "getting off the bus at 1 bus stop prior to the destination in order to walk the rest of the way." Such modifications were easier to do and incorporate than was periodic leisure time physical activity (eg, engaging in sports). A common goal for total counts of pedometer steps was set at 70 000 steps per week (10 000 per day)."
Control/Comparator	"For 36 months after randomization, each participant in the FINT and control groups received the intervention on different schedules. The control group received similar individual instructions 4 times only at 12-month intervals (at baseline and 12, 24, and 36 months) and continued to follow the instructions voluntarily without the follow-up support or the use of self-monitoring tools between each visit. At each visit after a 12-month interval, the responsible physician in the local study center checked whether each participant had any disease or treatment that was inappropriate for study participation or that clearly influenced glucose tolerance. Irrespective of the assigned groups, all the participants were individually instructed to reduce total energy intake and increase physical activity, aiming at a 5% reduction in body weight, through the help of nurses, dieticians, physical therapists, and physicians. We used existing human and material resources of each local study center as much as possible. Nurses and dieticians were mainly involved in the intervention at most local study centers, although it depended on the personnel situation at each center. The participants were given pedometers and pamphlets providing general information on diabetes and lifestyle modifications. The participants in both groups determined their own lifestyle goals, based on the results of the assessments and their motivation. The dietary intervention aimed at reducing total energy intake mainly by restricting excess intake of fat or carbohydrates, taking into consideration the Japan Diabetes Society recommendation for diabetic patients, and by controlling fat intake at 20% to 25% of total energy intake and carbohydrate intake at 55% to 60% of total energy intake. Where necessary, additional intake of dietary fiber, appropriate alcohol consumption (23 g/d), and corrective measures for undesirable dietary habits were also set as goals. Practical and feasible goals were proposed to the participants, such as "reducing the frequency of eating sweet foods between meals to less than 3 times per week." Participants who hoped to do any leisure time physical activity were advised on how to gradually increase their physical activity to 200 kcal/d (837.2 kJ/d) (mainly by walking more and walking faster). Sedentary or busy participants were encouraged to increase daily life physical activity by, for example, "getting off the bus at 1 bus stop prior to the destination in order to walk the rest of the way." Such modifications were easier to do and incorporate than was periodic leisure time physical activity (eg, engaging in sports). A common goal for total counts of pedometer steps was set at 70 000 steps per week (10 000 per day)."
Treatment duration	36 months
Follow-up from baseline	12 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 641 Intervention group/s: FINT Group (n=311) Comparator group: Control Group (n=330)
Mean age ± SD	Not reported
Sex	28.55% female

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference, cm
Mean (SD)

Weight, kg
Mean (SD)

BMI
Mean (SD)</td><td>FINT Group: 92.1
(8.1)

FINT Group: 74.1
(10.4)

FINT Group: 26.9
(2.6)</td><td>Control Group: 91.9
(8.5)

Control Group: 74.8
(10.7)

Control Group: 27.1
(2.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>% of participants who had weight reduction >=5%
Proportion (%)</td><td>FINT Group: 32</td><td>Control Group: 15</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Waist circumference, cm
Mean (SD)

Change Weight, kg
Mean (SD)

Change in BMI
Mean (SD)</td><td>FINT Group: -3.1
(4.3)

FINT Group: -2.5
(3.2)

FINT Group: -0.9
(1.2)</td><td>Control Group: -1.3
(4.7)

Control Group: -1.1
(3.2)

Control Group: -0.4
(1.2)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Compliance with treatment</td><td>Overall participation rate in 9 scheduled visits in the FINT group was 92.4%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Salas-Salvadó, 2019

Guideline record ID: 10839

Study characteristics		
Citation	Salas-Salvadó, J., Díaz-López, A., Ruiz-Canela, M., Basora, J., Fitó, M., Corella, D., Serra-Majem, L., Wärnberg, J., Romaguera, D., Estruch, R., Vidal, J., Martínez, J. A., Arós, F., Vázquez, C., Ros, E., Vioque, J., López-Miranda, J., Bueno-Cavanillas, A., Tur, J. A., . . . PREDIMED-Plus investigators. (2019). Effect of a lifestyle intervention program with energy-restricted Mediterranean diet and exercise on weight loss and cardiovascular risk factors: one-year results of the PREDIMED-Plus trial. Diabetes Care, 42(5), 777-788. https://doi.org/10.2337/dc18-0836	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a Lifestyle Intervention Program With Energy-Restricted Mediterranean Diet and Exercise on Weight Loss and Cardiovascular Risk Factors: One-Year Results of the PREDIMED-Plus Trial	
Location	Spain	
Trial name	PREvencion con DIeta MEDiterranea (PREDIMED)-Plus Trial	
Methods		
Inclusion criteria	"Eligible participants were community-dwelling adults (aged 55-75 y in men; 60-75 y in women) with overweight/obesity [body mass index ≥27 and <40 kg/m2], who met at least three components of the MetS according to the updated harmonized criteria of the joint statement from International Diabetes Federation/National Heart, Lung and Blood Institute/American Heart Association (IDF/NHLBI/AHA-2009) (1): hypertriglyceridemia [≥150 mg/dL (≥1.7 mmol/L)] or drug treatment for elevated triglycerides; low concentrations of HDL cholesterol [<50 mg/dL (<1.3 mmol/L) and <40 mg/dL (<1.03 mmol/L) in women and men, respectively] or drug treatment for low HDL cholesterol; elevated blood pressure (systolic ≥130 mmHg and/or diastolic ≥85 mmHg) or being treated for hypertension; high fasting plasma glucose [≥100 mg/dL (≥5.5 mmol/L)] or drug treatment for hyperglycemia; and elevated waist circumference for European individuals (≥88 cm in women and ≥102 cm in men)."	
Exclusion criteria	"Illiteracy or inability/unwillingness to provide with the written informed consent or communicate with study staff. - Documented history of previous CVD, including: angina, myocardial infarction, coronary revascularization procedures, stroke (ischemic or hemorrhagic, including transient ischemic attacks), symptomatic peripheral artery disease that required surgery or was diagnosed with vascular imaging techniques, ventricular arrhythmia, uncontrolled atrial fibrillation, congestive heart failure (New York Heart Association Class III or IV), hypertrophic cardiomyopathy, and history of aortic aneurysm ≥ 5.5 cm in diameter or aortic aneurism surgery. - Institutionalization (the participant is a permanent or long-stay resident in a nursing home). - Active malignant cancer or history of malignancy within the last 5 years (except non-melanoma skin cancer). - Inability to follow the recommended diet (due to religious reasons, swallowing disorders, etc) or to perform physical activity. -A low predicted likelihood to change dietary habits according to the Prochaska and DiClemente Stages of Change Model (Nigg et al., 1999). - Inclusion in another weight loss program (> 5 kg) in the 6 months before the selection visit. -History of surgical procedures for weight loss or intention to undergo bariatric surgery in the next 12 months. -History of small or large bowel resection or inflammatory bowel disease. -Obesity of unknown endocrine origin (except for treated hypothyroidism). -Food allergy to any component of the Mediterranean diet. -Immunodeficiency or HIV-positive status. -Cirrhosis or liver failure. -Serious psychiatric disorders, including schizophrenia, bipolar disorder, eating disorders, and depression with hospitalization within the last 6 months. -Any severe co-morbidity condition with less than 24 months' life expectancy. -Alcohol abuse or addition (or total daily alcohol intake >50g) or drug abuse within the past 6-m. - History of major organ transplantation. - Concurrent therapy with immunosuppressive drugs or	

	cytotoxic agents. - Current treatment with systemic corticosteroids. - Current use of weight loss medication. - Concurrent participation in another randomized clinical trial. - Patients with an acute infection or inflammation (e.g., pneumonia) were allowed to participate in the study 3 months after resolution of such condition. - Any other condition that might interfere with adherence to the study protocol."
Setting	Home, University/research centre
Intervention	"Participants allocated to the intervention group were prescribed an energy-restricted MedDiet, accompanied by physical activity promotion and behavioral support, with the purpose of accomplishing specific weight-loss objectives. These objectives were achieving an average reduction of ≥8% of the initial body weight and an average reduction of ≥5% of initial waist circumference in the first 6-months, and maintaining these reductions throughout the duration of the study. The PREDIMED-Plus final aim targets a between-group average absolute difference in weight-loss and waist circumference reduction of ≥5%. To this end, they attended to monthly individual sessions during the first year, with the purpose of reinforcing individualized dietary and physical activity counseling using problem-solving interviews for successful weight loss. The energy-restricted MedDiet aimed at an energy reduction of 600 kcal/day (about 30% of estimated energy requirements) according to each participants' basal metabolic rate and physical activity level, using the Institute of Medicine equations (http://www.nap.edu/books/0309085373/html/), and with a macronutrient distribution of 40- 45% carbohydrate, 35-40% fat and 20% protein. Qualitatively, the diet promoted the inclusion of food items and their corresponding frequency of consumption according to the 17-point questionnaire. Dietary advice encouraged the consumption of typical and seasonal MedDiet foods and recommends refraining from foods characteristic of the Western dietary pattern. Briefly, it involved the frequent consumption of extra-virgin olive oil, raw nuts, fruits and vegetables, whole grains, legumes, lean meat and fish, and low-fat dairy products. Reduced consumption of animal fats, sugar-sweetened beverages, commercial sweets, pastry and snacks, processed foods and refined grains was encouraged, while wine intake was restricted to one or two glasses/day for women and two or three glasses/day for men. Along with the explanation of the intervention diet, participants in the IG received supporting dietary materials, including general recommendations, a dietary plan, open menus and seasonal recipes, all according to the aimed energy restriction calculated for each participant (energy restricted diets from 1200 to 3000 kcal/day were available). Based on the projected and achieved monthly weight-loss objectives and the accomplishment of the scores achieved in the 17-item questionnaire, the dietitians delivered personalized and updated dietary counseling throughout the entire intervention. Participants were encouraged to gradually increase their level of physical activity to at least 45 minutes per day after 6 months of intervention, and their progress was monitored. The physical activity program included aerobic activities, such as brisk walking or any equivalent activity of moderate intensity (e.g. aquagym, biking, swimming, etc.). The dietitians adapted the recommendations to the participants' preferences and advised them to switch between activities with the same metabolic equivalence of tasks. To progressively increase the time spent in brisk walking, a pedometer (Yamax SW200 Digi-Walker) was provided to each participant to self-monitor steps and enhance motivation. In addition, dietitians encouraged participants to engage in resistance, balance, and flexibility training twice or more a week, for which a leaflet with practical information and types of activities was delivered. In addition, physical activities and resistance, balance, and flexibility training are showed by videos in the group sessions scheduled for this aim. The degree of adherence to these activities was monitored quarterly and problem-solving interviews were carried out to overcome any difficulty. For research purposes only, GENEActive accelerometers were randomly provided to a subsample of participants (at least, to 50% of intervention group participants and 20% of control group participants) to objectively quantify time and intensity of motions during 24-hour periods of one week. Behavioral support included problem-solving strategies and practical tools to facilitate participants' self-control on emotional eating or stress-driven behaviors, such as over intake, consumption of highly palatable foods or engaging in sedentary behaviors. Moreover, it included self-management

<table>
<tr><td></td><td>approaches to improve participants' autonomy and empowerment in order to increase their long-term adherence to the dietary and physical activity recommendations.”</td></tr>
<tr><td>Control/Comparator</td><td>“Participants in the control group received educational sessions with the same content to that used in the PREDIMED study (1). Accordingly, dietitians recommended an energy-unrestricted traditional MedDiet and individual visits and group sessions were programmed every 6 months during the first year. The energyunrestricted traditional MedDiet used in PREDIMED has demonstrated to reduce cardiovascular events (2) when compared to advice on a low-fat diet, while maintaining a steady body weight or a slightly reduced weight in the long term (3). Dietitians explained the traditional MedDiet with emphasis on improving dietary quality (i.e., focusing on food groups and their frequency of consumption). Dietary material and instructions about the traditional MedDiet but unrelated to calorie control were delivered together with material including general lifestyle recommendations for the management of metabolic syndrome. No specific advice for increasing physical activity or losing weight was provided to participants in the control group.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 626
Intervention group/s: Intervention group (n=327)

Comparator group: Control group (n=299)</td></tr>
<tr><td>Mean age ± SD</td><td>65y (5)</td></tr>
<tr><td>Sex</td><td>53.83% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Baseline weight (kg)
Mean (SD)</td><td>Intervention group: 85.8 (13.1)</td><td>Control group: 86.9 (12.7)</td></tr>
<tr><td>Baseline BMI (kg/m2)
Mean (SD)</td><td>Intervention group: 32.3 (3.4)</td><td>Control group: 32.6 (3.6)</td></tr>
<tr><td>Baseline waist circumference (cm)
Mean (SD)</td><td>Intervention group: 106.3 (8.9)</td><td>Control group: 107.3 (9.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Proportion of participants at or below baseline weight
Proportion (%) (95%CI)</td><td>Intervention group: 84.1 (80-88.2)</td><td>Control group: 57.9 (52.2)</td></tr>
<tr><td>Proportion of participants at least 5% below baseline weight
Proportion (%) (95%CI)</td><td>Intervention group: 33.7 (28.4-39.1)</td><td>Control group: 11.9 (8.1-15.7)</td></tr>
<tr><td>Proportion of participants at least 10% below baseline weight</td><td>Intervention group: 6.9 (4.1-9.8)</td><td>Control group: 2.2 (0.4-3.9)</td></tr>
</table>
</td></tr>
</table>

	Proportion (%) (95%CI) Proportion of participants change from baseline BMI >30 to BMI <30 kg/m2 Proportion (%) (95%CI)	Intervention group: 15.7 (11.6-19.7)	Control group: 6.7 (3.7-9.6)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in body weight (kg) Mean (95% CIs)	Intervention group: -3.2 (-3.7--2.8)	Control group: -0.7 (-1.1--0.3)
	Change in body weight (%) Mean (95% CIs)	Intervention group: -3.7 (-4.3--3.2)	Control group: -0.8 (-1.3--0.3)
	Change in BMI (kg/m2) Mean (95% CIs)	Intervention group: -1.2 (-1.4--1)	Control group: -0.3 (-0.4--0.1)
	Change in waist circumference Mean (95% CIs)	Intervention group: -3.1 (-3.8--2.5)	Control group: -0.7 (-1.3-0.03)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	IG attended 75% and 67% of the individual and group sessions, respectively, whereas respective rates for those in the CG were 95% and 78%.		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Salva, 2011

Guideline record ID: 10639--1

Study characteristics		
Citation	Salva, A., Andrieu, S., Fernandez, E., Schiffrin, E. J., Moulin, J., Decarli, B., Rojano-i-Luque, X., Guigoz, Y., Vellas, B., & group, t. N. (2011). Health and nutrition promotion program for patients with dementia (NutriAlz): cluster randomized trial. The Journal of Nutrition, Health & Aging, 15(10), 822-830. https://doi.org/https://doi.org/10.1007/s12603-011-0363-3	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Health and nutrition promotion program for patients with dementia (NutriAlz): cluster randomized trial	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	“Diagnosed with dementia according to DSM IV criteria (50) and were considered to have mild to moderate dementia with MMSE less than or equal to 26. Only ambulatory subjects living at home and who had an identified caregiver were included.”	
Exclusion criteria	“Exclusion criteria included MMSE over 26, residence in an institution, as well as patient having nasal-gastric tube feeding or in a terminal situation, and patient participating in another nutritional intervention study.”	
Setting	Alzheimer outpatients and day care centres	
Intervention	“In the centres of the "intervention" group, a standardised protocol for feeding and nutrition was proposed, which included: 1. A personalized presentation and hand over of a briefcase containing: information about Alzheimer's disease (booklet 1), about nutrition in particular (booklet 2), physical exercise (booklet 3), available aid and services, specifically about the program (booklet 4), schedule for collecting data such as weight and height, coupons for monitoring in a database, etc. This information (briefcase) was given to patients and their relatives with oral information on hotline access, Nutrition Program newsletter. 2. Training for families, caregivers were requested to attend 4 sessions of educational intervention done by a dietician which were divided into the following sessions and topics: - Session 1: Presentation of the participants, presentation of the nutritional support program, presentation of the available resources (hotline, etc.), information on weight loss with Alzheimer's disease, how to carry out nutritional monitoring, how to weigh, how to fill in the nutritional schedule, on lifestyle habits, on a balanced diet and the food pyramid - Session 2: Continuous information on lifestyle habits, on a balanced diet and the food pyramid, and program on creation of menus, conservation of food, cooking methods, how to increase calorific and protein intake, how to substitute foods that are rejected, nutritional support preparations, and nutritional supplements (what they are for, who prescribes them, how and when to take them, where they can be obtained) further motivation for interest in physical exercise - Session 3: Information on Eating behaviour problems (EBP), practical recommendations on how to cope with EBPs, nutrition and medication, nutrition and illnesses or chronic problems, as well as diabetes, constipation, hypertension, and dyslipidemia. - Session 4: General review, practical examples, problemsolving in the creation of menus. 3. Support in weight monitoring. A voluntary individual weight monitoring system was established through the postal dispatch to the Aging Institute (Autonomous University of Barcelona) of coupons with information about the weight of the person affected but without revealing data, which may identify them. According to the evolution of the weight curve written recommendation were sent by mail and if weight loss was identified as susceptible to making the illness worse, they were recommended to visit a doctor. 4. Periodic information for the families. A voluntary system was established (which was accessed through signing a coupon) through which the carers	

<table>
<tr><td></td><td>who so desired could receive general information about nutrition, nutritional needs of those with Alzheimer's or other problems related with nutrition. The resulting register was of the caregivers (not the patients) and complied with all legal requirements. The management of this section was by the Aging Institute (Autonomous University of Barcelona). 5. Action protocols and standardised help decision trees, related to malnutrition risks, for professionals were designed with the participation of at least one person of each intervention centre. Each centre was asked to designate a senior member of the medical and/or nursing staff. The healthcare professionals in the intervention group received training and followed the program recommendations through these forms and action standards."</td></tr>
<tr><td>Control/Comparator</td><td>"Usual care."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 946
Intervention group/s: NutriAlz Program (n=448)

Comparator group: Usual care (n=498)</td></tr>
<tr><td>Mean age ± SD</td><td>79.0y (7.3)</td></tr>
<tr><td>Sex</td><td>68.08% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Dementia</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (95% CIs)

BMI (kg/m2)
Mean (95% CIs)

Baseline weight (kg)
Mean (SD)

BMI at baseline (kg/m2)
Mean (SD)</td><td>NutriAlz Program: 63.5
(62.4-64.7)

NutriAlz Program: 26.6
(26.2-27.1)

NutriAlz Program: 63.5
(12.5)

NutriAlz Program: 26.6
(4.4)</td><td>Usual care: 65.1
(64-66.2)

Usual care: 27.3
(26.9-27.7)

Usual care: 65.1
(12.5)

Usual care: 27.3
(4.6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (95% CIs)

BMI (kg/m2)
Mean (95% CIs)</td><td>NutriAlz Program: 63.9
(62.6-65.3)

NutriAlz Program: 26.8
(26.3-27.3)</td><td>Usual care: 65.5
(64.2-66.8)

Usual care: 27.3
(26.8-27.8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight at 12 months (kg)</td><td>NutriAlz Program: 0.26
(-0.57-1.09)</td><td>Usual care: 0.09
(-0.7-0.52)</td></tr>
</table></td></tr>
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12 months or closest time point	Mean (95% CIs) Change in BMI at 12 months (kg/m2) Mean (95% CIs)	NutriAlz Program: -0.01 (-0.21-0.19)	Usual care: -0.06 (-0.22-0.22)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Santamaria, 2012

Guideline record ID: 10843--1

Study characteristics		
Citation	Santamaria, A., Giordano, D., Corrado, F., Pintaudi, B., Interdonato, M. L., Di Vieste, G., Di Benedetto, A., & D'Anna, R. (2012). One-year effects of myo-inositol supplementation in postmenopausal women with metabolic syndrome. Climacteric, 15(5), 490-495. https://doi.org/10.3109/13697137.2011.631063	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	One-year effects of myo-inositol supplementation in postmenopausal women with metabolic syndrome	
Location	Italy	
Trial name	N/A	
Methods		
Inclusion criteria	"To define metabolic syndrome, we used the criteria of the Adult Treatment Panel (ATP) III of the National Cholesterol Education Programme 6, and all 80 women satisfi ed at least three of the fi ve criteria reported. The other inclusion criteria were age: 50 - 60 years old and at least a 12-month period from the last menstruation."	
Exclusion criteria	"Exclusion criteria were: (1) less than three criteria for defining the metabolic syndrome; (2) age 50 and 60 years old; (3) a period shorter than 12 months from the last menstruation; (4) consumption of drugs lowering blood levels of glucose and/or cholesterol."	
Setting	Home	
Intervention	"All women were treated with a low-energy diet following the Italian guidelines 8, and then they were assigned randomly to myo-inositol 2 g b.i.d. for the fi rst 6 months and subsequently for the other 6 months. The diet was continued throughout the study and compliance was reinforced by a nutritionist, who phoned the women about every 2 months, with the aim of maintaining their adherence to the study . All women were hypertensive and were treated with various antihypertensive agents, but not with other drugs, during the whole study"	
Control/Comparator	"All women were treated with a low-energy diet following the Italian guidelines 8, and then they were assigned to placebo (n 40) for the fi rst 6 months and subsequently for the other 6 months . The diet was continued throughout the study and compliance was reinforced by a nutritionist, who phoned the women about every 2 months, with the aim of maintaining their adherence to the study . All women were hypertensive and were treated with various antihypertensive agents, but not with other drugs, during the whole study."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference	
Participant characteristics		
Number of participants	n= 80 Intervention group/s: Myo-inositol (n=40) Comparator group: Placebo (n=40)	
Mean age ± SD	Intervention: 55.6y (3.2); Control: 55.0y (3.2)	

<table>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Myo-inositol: 31.5
(2.4)

Myo-inositol: 115
(12)</td><td>Placebo: 30.7
(2.5)

Placebo: 110
(11.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Myo-inositol: 29.9
(1.4)

Myo-inositol: 107
(2.8)</td><td>Placebo: 30.2
(1.1)

Placebo: 109
(7.5)</td></tr>
</table>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Santa-Maria, 2020

Guideline record ID: 10842

Study characteristics		
Citation	Santa-Maria, C. A., Coughlin, J. W., Sharma, D., Armanios, M., Blackford, A. L., Schreyer, C., Dalcin, A., Carpenter, A., Jerome, G. J., Armstrong, D. K., Chaudhry, M., Cohen, G. I., Connolly, R. M., Fetting, J., Miller, R. S., Smith, K. L., Snyder, C., Wolfe, A., Wolff, A. C., . . . Stearns, V. (2020). The effects of a remote-based weight loss program on adipocytokines, metabolic markers, and telomere length in breast cancer survivors: the POWER-Remote trial. Clinical Cancer Research, 26(12), 3024-3034. https://doi.org/https://dx.doi.org/10.1158/1078-0432.CCR-19-2935	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Effects of a Remote-based Weight Loss Program on Adipocytokines, Metabolic Markers, and Telomere Length in Breast Cancer Survivors: the POWER-Remote Trial	
Location	US	
Trial name	POWER-Remote Trial	
Methods		
Inclusion criteria	"Eligible participants had stage 0-III breast cancer and completed recommended primary breast surgery, radiation, and/ or chemotherapy prior to enrolling into the trial. Endocrine therapy was allowed if started at least 3 months prior to randomization and if expected to continue for the duration of the study. Concurrent antiHER2 therapy was permitted. Women had to have a body mass index (BMI) ≥25 kg/m2, weigh ≤400 lbs, and be willing to lose at least 5% of their body weight."	
Exclusion criteria	Not reported	
Setting	Web and phone based	
Intervention	"POWER-remote arm The infrastructure of the adapted POWER-remote intervention was similar to that of the original POWER trial; however, educational materials included oncology-relevant information such as lymph edema prevention exercises and general information about breast cancer. In addition, instead of engaging the primary care provider as in the original POWER study, each patient's treating oncologist was involved and received information regarding the patient's weight loss. Participants randomized to POWER-remote received a 12-month behavioral weight loss intervention based on the original POWER study including telephone-based behavioral weight loss coaching and use of a web-based self-monitoring and learning platform developed by Healthways Inc (14). Participants could record dietary intake, exercise, and weight on a web-based platform (Innergy). Dietary recommendations included a reduced calorie, high vegetable and fruit diet based on the Dietary Approaches to Stop Hypertension (DASH) diet (21). Weight goals and behavioral and self-monitoring recommendations are described in Supplementary Table S1. Coaches trained in both behavioral weight loss principles and motivational interviewing reviewed self-monitoring data through the Innergy website and provided behavioral weight loss counseling during telephonic coaching sessions. The website and an accompanying smartphone application allowed participants to track their weight, food and beverage intake, and exercise; the website provided access to the weight loss educational materials for review during coaching calls. Additional platform features included a message center to communicate with the study health coach and a group wall for weight loss support from other participants in the study. Participants were offered 21 phone calls over the 1-year study period (weekly for 3 months, monthly for an additional 9 months). The approximately 20-minute calls were with a designated coach and included review of self-monitoring, problem solving, and identification of barriers and strategies for overcoming these barriers and goal setting. The theoretical framework for the active intervention draws upon behavior change theory related to weight loss, specifically social cognitive theory and	

<table>
<tr><td></td><td>utilized a Motivational Interviewing approach. The health coach had a background in delivering weight loss interventions (including the original POWER trial) and was trained by experienced coinvestigators.”</td></tr>
<tr><td>Control/Comparator</td><td>“Self-directed arm This arm served as the comparison group. It reflected standard medical care, where oncologists encourage participants to achieve and maintain ideal BMI (9). The same coach as in the POWER-remote arm delivered the one-time coaching session to self-directed participants. The content of this call included the importance of gradual weight loss, promoted lifestyle change related to diet and exercise, and encouraged self - monitoring. Participants in this arm were provided the National Heart, Lung, and Blood Institute (NHLBI) publication "Aim for A Healthy Weight," and met with a weight-loss coach one time during the baseline visit (22).”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 96
Intervention group/s: POWER-remote (n=50)

Comparator group: Self-directed (n=46)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Breast Cancer Survivors</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (range)

BMI (kg/m2)
Mean (range)</td><td>POWER-remote: 85.7
(62.9-121.9)

POWER-remote: 32
(26.9-49.2)</td><td>Self-directed: 85
(68.5-114.8)

Self-directed: 32
(29.8-45.3)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight
Mean (SD)

Change in waist circumference
Mean (range)</td><td>POWER-remote: 4.7
(6.3)

POWER-remote: -6.6
(-11.5--1.7)</td><td>Self-directed: 0.4
(4.7)

Self-directed: 0.3
(-2-2.1)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
</table>

Compliance with treatment	Median call completion was 14 of 15 calls in the first 6 months and seven of seven calls from months 7-12. There was a median of 24 weekly logins during the first 6 months and 22.5 weekly logins during months 7-12.
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Santanasto, 2015

Guideline record ID: 10844--1

Study characteristics		
Citation	Santanasto, A. J., Newman, A. B., Strotmeyer, E. S., Boudreau, R. M., Goodpaster, B. H., & Glynn, N. W. (2015). Effects of changes in regional body composition on physical function in older adults: a pilot randomized controlled trial. The Journal of Nutrition, Health & Aging, 19(9), 913-921. https://doi.org/https://dx.doi.org/10.1007/s12603-015-0523-y	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of Changes in Regional Body Composition on Physical Function in Older Adults: A Pilot Randomized Controlled Trial	
Location	US	
Trial name	Wellness for Elders through Lifestyle and Learning (WELL)	
Methods		
Inclusion criteria	"Overweight to moderately obese (BMI 28.0-39.9 kg/m2) older adults (age 70.6±6.1yrs), community dwelling."	
Exclusion criteria	"Inappropriate age and BMI ranges, regular exercise >3x/week and >90 min/week in the past month, having lost more than 10lbs in the past 4 months, taking medication for obesity or unwillingness to be randomized into either intervention group. Participants who were: 1. unable to walk 400m in <15 minutes without an assistance device, 2. deemed by the study nurse practitioner to have severe medical condition(s) precluding safe participation in a diet and/or exercise intervention, or 3. had significant cognitive impairment (known diagnosis of dementia or Modified Mini-Mental State Exam score <80) were also excluded."	
Setting	GP clinic, University/research centre	
Intervention	"Participants in PA+WL (n=21) attended 24 weekly, 2 bi-monthly, and 5 monthly sessions lead by a nutritionist. Strategies to achieve the recommended caloric intake were discussed and performance in the weight loss intervention was evaluated. Based on baseline weight, according to the Diabetes Prevention Program(24), participants were assigned one of the following daily goals: 1200 calories and 33 fat grams, 1500 calories and 42 fat grams, 1800 calories and 50 fat grams, or 2000 calories and 55 fat grams. Total daily fat intake was limited to ~25% of total calories and emphasis was placed on consuming of mono- and polyunsaturated fats while limiting saturated fat and cholesterol. In addition, participants were instructed to include at least 5 servings of fruits or vegetables and 6 servings of grains, especially whole grains, in their daily diet. The goal was to achieve a 7% reduction in body weight by 6-months and to maintain the weight loss for the remainder of the trial. To aid weight loss, participants were weighed once per week and kept food records for at least 6 days/week during the first 6 months and once per month thereafter. All enrollees participated in a physical activity program consisting primarily of treadmill walking, supplemented with lower extremity resistance training using ankle weights and balance exercises. The program was divided into three phases: adoption (weeks 1-8), transition (weeks 9-24), and maintenance (weeks 25-52), designed to transition exercise out of the clinic setting and into the participant's daily routine. During the adoption phase, participants were required to attend 3 center-based exercise sessions per week. For the transition phase, center-based sessions were reduced to 2 sessions per week with the third session to be conducted at home. During the maintenance phase, participants were invited to attend 1 optional exercise session per week; but, were expected to engage in physical activity at least three 3 per week. Rather than assigning participants specific days and times to exercise, an open-door policy was utilized and session length was not capped. Home exercise logs were maintained and collected weekly during all phases of the intervention."	

<table>
<tr><td>Control/Comparator</td><td>“The PA+SA group (n=15) attended 60-minute, once monthly successful aging health education workshops to control for attention. The sessions were based on "The Ten Keys to Healthy Aging™"(25) and the comparison intervention program developed for the Lifestyle Interventions and Independence for Elders Pilot Study. All enrollees participated in a physical activity program consisting primarily of treadmill walking, supplemented with lower extremity resistance training using ankle weights and balance exercises. The program was divided into three phases: adoption (weeks 1-8), transition (weeks 9-24), and maintenance (weeks 25-52), designed to transition exercise out of the clinic setting and into the participant's daily routine. During the adoption phase, participants were required to attend 3 center-based exercise sessions per week. For the transition phase, center-based sessions were reduced to 2 sessions per week with the third session to be conducted at home. During the maintenance phase, participants were invited to attend 1 optional exercise session per week; but, were expected to engage in physical activity at least three 3 per week. Rather than assigning participants specific days and times to exercise, an open-door policy was utilized and session length was not capped. Home exercise logs were maintained and collected weekly during all phases of the intervention.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 35
Intervention group/s: Physical activity plus weight loss (PA+WL) (n=21)

Comparator group: PA plus successful aging (SA) education (n=14)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 70.6y (5.9); Control: 69.9y (6.2)</td></tr>
<tr><td>Sex</td><td>82.86% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Waist Circumference, cm
Mean (SD)</td><td>Physical activity plus weight loss (PA+WL): 108.8
(7.2)</td><td>PA plus successful aging (SA) education: 104.3
(8.3)</td></tr>
<tr><td>Body Weight, kg
Mean (SD)</td><td>Physical activity plus weight loss (PA+WL): 89.8
(10)</td><td>PA plus successful aging (SA) education: 85.3
(6.8)</td></tr>
<tr><td>BMI, kg/m2
Mean (SD)</td><td>Physical activity plus weight loss (PA+WL): 33.6
(3.3)</td><td>PA plus successful aging (SA) education: 32
(3.1)</td></tr>
<tr><td>Percent Body Fat
Mean (SD)</td><td>Physical activity plus weight loss (PA+WL): 43
(5.4)</td><td>PA plus successful aging (SA) education: 42.2
(5.4)</td></tr>
<tr><td>Total Fat Mass, kg
Mean (SD)</td><td>Physical activity plus weight loss (PA+WL): 38
(5.9)</td><td>PA plus successful aging (SA) education: 35.7
(6.7)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>12-month Change Waist Circumference, cm
Mean (SD)</td><td>Physical activity plus weight loss (PA+WL): -2.5
(7.8)</td><td>PA plus successful aging (SA) education: 0.1
(10.5)</td></tr><tr><td>12-month Change Body Weight, kg
Mean (SD)</td><td>Physical activity plus weight loss (PA+WL): -4.9
(6.1)</td><td>PA plus successful aging (SA) education: -0.8
(3)</td></tr><tr><td>12-month Change BMI, kg/m2
Mean (SD)</td><td>Physical activity plus weight loss (PA+WL): -1.7
(2.3)</td><td>PA plus successful aging (SA) education: -0.2
(1.1)</td></tr><tr><td>12-month Change Percent Body Fat
Mean (SD)</td><td>Physical activity plus weight loss (PA+WL): -2.9
(3.4)</td><td>PA plus successful aging (SA) education: -0.8
(1.6)</td></tr><tr><td>12-month Change Total Fat Mass, kg
Mean (SD)</td><td>Physical activity plus weight loss (PA+WL): -4.8
(4.6)</td><td>PA plus successful aging (SA) education: -1.2
(2.2)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>39%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Sarwer, 2012

Guideline record ID: 10642--1

Study characteristics		
Citation	Sarwer, D. B., Moore, R. H., Spitzer, J. C., Wadden, T. A., Raper, S. E., & Williams, N. N. (2012). A pilot study investigating the efficacy of postoperative dietary counseling to improve outcomes after bariatric surgery. Surgery for Obesity and Related Diseases, 8(5), 561-568. https://doi.org/https://dx.doi.org/10.1016/j.soard.2012.02.010	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A pilot study investigating the efficacy of postoperative dietary counseling to improve outcomes after bariatric surgery	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Patients who underwent bariatric surgery at the Hospital of the University of Pennsylvania."	
Exclusion criteria	Not reported	
Setting	Hospital, Home	
Intervention	"RYGB was performed as either an open or a laparoscopic procedure by 1 of 2 surgeons (S.E.R. and N.N.W.) and using essentially the same technique. One surgeon (N.N.W.) performed laparoscopic adjustable gastric banding (LAGB) procedures using the Lap-Band and a standard surgical technique. Postoperative weight loss did not differ by surgeon or technique (open or laparoscopic). Thus, the results from both surgeons were combined for all analyses. Intervention participants received brief (15 min), every-other-week, in-person postoperative dietary counseling sessions with 1 of the bariatric surgery program's registered dietitians for the first 4 months after surgery. The registered dietitian followed a treatment protocol specifically developed for the study. It was designed to assist in the transition through the 4 phases of the postoperative diet (i.e., liquids, pureed, soft foods, and regular diet); to improve adherence to the regular diet; to promote protein intake and decrease sugar and fat intake; and to decrease the incidence of overeating, vomiting, and dumping. Participants were weighed at each in-person visit and were encouraged, but not required, to monitor their food intake with food records that could be reviewed at the counseling sessions. We initially designed the intervention to be delivered as face-to-face visits. We soon realized that patients were having a difficult time returning for scheduled visits. To address this issue, we modified the intervention and provided participants with the option of brief telephone interviews with the registered dietitian when in-person visits were impossible."	
Control/Comparator	"RYGB was performed as either an open or a laparoscopic procedure by 1 of 2 surgeons (S.E.R. and N.N.W.) and using essentially the same technique. One surgeon (N.N.W.) performed laparoscopic adjustable gastric banding (LAGB) procedures using the Lap-Band and a standard surgical technique. Postoperative weight loss did not differ by surgeon or technique (open or laparoscopic). Thus, the results from both surgeons were combined for all analyses. These participants received the standard postoperative care delivered by our program. No formal postoperative nutrition counseling sessions were scheduled, but the dietitian was available to patients, as needed. Participants were encouraged, but not required, to return for monthly support groups."	
Treatment duration	4 months	
Follow-up from baseline	24 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 84
Intervention group/s: Dietary counselling (n=41)

Comparator group: Standard care (n=43)</td></tr>
<tr><td>Mean age ± SD</td><td>42.0y (9.9)</td></tr>
<tr><td>Sex</td><td>63.10% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Percentage change in weight Mean (SD)</td><td>Dietary counselling: -32.3 (2)</td><td>Standard care: 32.4 (2)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Percentage change in weight Mean (SD)</td><td>Dietary counselling: -32.4 (2.4)</td><td>Standard care: 33.6 (2.5)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Saslow, 2017

Guideline record ID: 10643--1

Study characteristics		
Citation	Saslow, L. R., Daubenmier, J. J., Moskowitz, J. T., Kim, S., Murphy, E. J., Phinney, S. D., Ploutz-Snyder, R., Goldman, V., Cox, R. M., Mason, A. E., Moran, P., & Hecht, F. M. (2017). Twelve-month outcomes of a randomized trial of a moderate-carbohydrate versus very low-carbohydrate diet in overweight adults with type 2 diabetes mellitus or prediabetes. Nutrition & Diabetes, 7(12), 304. https://doi.org/https://dx.doi.org/10.1038/s41387-017-0006-9	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Twelve-month outcomes of a randomized trial of a moderate-carbohydrate versus very low-carbohydrate diet in overweight adults with type 2 diabetes mellitus or prediabetes	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligibility criteria included being aged 18 or older, overweight (body mass index (BMI) of 25 or above), with a current glycated hemoglobin (HbA1c) level over 6.0%."	
Exclusion criteria	"We excluded participants who were currently using insulin or taking more than three glucose-lowering agents."	
Setting	Home	
Intervention	"Participants were randomised to a very low-carbohydrate ketogenic (LCK) diet or a moderate-carbohydrate, calorie-restricted, lowfat (MCCR) diet. All participants attended 19 classes over 12 months; Twelve 2-h weekly classes, then three 2-h classes every 2 weeks, followed by four 1.5-h classes every 2 months. LCK: One group leader instructed LCK participants to eat an ad libitum very low-carbohydrate, likely ketogenic diet, by reducing their carbohydrate intake to between 20-50 g of carbohydrates (excluding fiber) a day. We gave them a goal of achieving a blood ketone (betahydroxybutyrate) level of between 0.5 and 3 millimolar (mmol), as measured twice a week for the first several months at home. Starting in week 6, group leaders taught participants in both groups about the importance of sleep and exercise for type 2 diabetes and encouraged them to increase both, if needed. A third group leader also taught all participants supportive behavioral adherence strategies aimed at increasing positive affect and mindful eating, in order to increase intervention adherence."	
Control/Comparator	"Participants were randomised to a very low-carbohydrate ketogenic (LCK) diet or a moderate-carbohydrate, calorie-restricted, lowfat (MCCR) diet. All participants attended 19 classes over 12 months; Twelve 2-h weekly classes, then three 2-h classes every 2 weeks, followed by four 1.5-h classes every 2 months. MCCR: A different group leader instructed the MCCR participants to follow an MCCR diet in which 45-50% of their calories were to be derived from carbohydrates. We also instructed them to lower their fat consumption and eat 500 fewer kilocalories (kcal) per day than their calculated maintenance needs to reduce weight. Starting in week 6, group leaders taught participants in both groups about the importance of sleep and exercise for type 2 diabetes and encouraged them to increase both, if needed. A third group leader also taught all participants supportive behavioral adherence strategies aimed at increasing positive affect and mindful eating, in order to increase intervention adherence."	
Treatment duration	12 months	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 34
Intervention group/s: LCK (n=16)

Comparator group: MCCR (n=18)</td></tr>
<tr><td>Mean age ± SD</td><td>LCK: 64.8y (7.7); MCCR: 55.1y (13.5)</td></tr>
<tr><td>Sex</td><td>73.53% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes or prediabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Estimated marginal mean
(95% CIs)

Weight (kg)
Estimated marginal mean
(95% CIs)</td><td>LCK: 35.9
(32.5-39.2)

LCK: 99.9
(88.4-111.5)</td><td>MCCR: 36.9
(33.7-40.1)

MCCR: 97.5
(86.6-108.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Estimated marginal mean
(95% CIs)

Weight (kg)
Estimated marginal mean
(95% CIs)</td><td>LCK: 33.3
(29.9-36.7)

LCK: 92
(80.5-103.6)</td><td>MCCR: 36
(32.8-39.2)

MCCR: 95.8
(84.9-106.6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (% of initial)
Mean (SD)</td><td>LCK: -8.3
(5.8)</td><td>MCCR: -3.8
(6)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>LCK: 87.5; MCCR: 85.3</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Sattin, 2016

Guideline record ID: 10847--1

Study characteristics		
Citation	Sattin, R. W., Williams, L. B., Dias, J., Garvin, J. T., Marion, L., Joshua, T. V., Kriska, A., Kramer, M. K., & Narayan, K. M. V. (2016). Community Trial of a Faith-Based Lifestyle Intervention to Prevent Diabetes Among African-Americans. Journal of Community Health, 41(1), 87-96. https://doi.org/https://dx.doi.org/10.1007/s10900-015-0071-8	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Community Trial of a Faith-Based Lifestyle Intervention to Prevent Diabetes Among African-Americans	
Location	USA	
Trial name	Fit Body and Soul (FBAS)	
Methods		
Inclusion criteria	“Eligible persons were required to be self-described AAs, ages 20-64 years, who were planning on remaining in the community for 1 year and to meet the following criteria: non-diabetic [fasting plasma glucose (FPG) \126 mg/dl]; a body-mass index (the weight in kilograms divided by the square of the height in meters) of 25.0 or more; no medical contraindications to physical activity (as determined by the Physical Activity Readiness Questionnaire); no history of gastric weight-loss surgery or weight loss of more than 10 % in the past 3 months for any reason other than childbirth; no physical conditions or medications that might affect glucose metabolism; no behaviors that might interfere with participation; no illnesses that would limit life span; and, for females, no current pregnancy or planned pregnancy within the study period.”	
Exclusion criteria	“Those with a FPG of 126 mg/dl or greater at baseline were removed from the study and are excluded from this analysis.”	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	“The FBAS (intervention arm) which is a faith-based adaptation of the GLB program. FBAS was aimed at achieving a weight loss of at least 7 % of baseline by week-12, and to maintain the weight loss at 12-months post-baseline through six booster sessions. Secondary aims initially included: FPG with a mean reduction of at least 3 mg/dl, and physical activity of moderate intensity for at least 150 min per week. Each intervention arm involved participants attending 12-weekly group 1-h core sessions at their respective church. For FBAS, the 12 core sessions comprised the key components of successful weight loss programs such as strategies to reduce calories and dietary fat consumption, encouraging physical activity, and behavioral modification such as stimulus control, goal setting, and problem solving. Church health advisors (CHAs) were members of their respective church's health ministry (e.g., nurses, pharmacists, physicians) and were trained by a co-investigator certified to perform GLB training. CHAs delivered the weekly sessions followed by six monthly 1-h post-core ''booster'' sessions. To conduct fidelity monitoring, a research team member attended each group session to record participant attendance and used an investigator-developed fidelity tool to verify that the content delivered by CHAs was delivered as designed with all core components and in the appropriate manner and context to the appropriate group.”	
Control/Comparator	“Each intervention arm involved participants attending 12-weekly group 1-h core sessions at their respective church. The HE program (comparison arm) developed from the list of topics provided by the Centers for Disease Control and Prevention (CDC) Guide to Community Prevention Services The HE comparison curriculum addressed key health issues facing AAs in Richmond County, Georgia, and investigators developed the selected health topics into a scripted manual and developed participant handouts from information	

<table>
<tr><td></td><td>provided by the American Heart Association, American Cancer Association, American Diabetes Association, Mental Health America, and other national organizations. For HE, the 12 core sessions included information and risk improvement strategies about mental health and stress, heart disease and stroke, diabetes, cancer, smoking, injury and violence, asthma, nutrition, physical activity, HIV/ AIDS, and communicating with one's health provider.”</td></tr>
<tr><td>Treatment duration</td><td>12 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 604
Intervention group/s: FBAS (n=317)

Comparator group: HE (n=287)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 46.6y (10.9); Control: 46.4y (10.9)</td></tr>
<tr><td>Sex</td><td>83.44% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

Body-mass index
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>FBAS: 98.4
(21)

FBAS: 35.8
(7)

FBAS: 107.8
(15)</td><td>HE: 99
(22.1)

HE: 35.6
(7.6)

HE: 106.7
(15.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss (kg)
Mean (SD)

Percentage of weight loss >=3 %
Proportion (%)

Percentage of weight loss >=5 %
Proportion (%)

Percentage of weight loss >=7 %
Proportion (%)</td><td>FBAS: 2.39

FBAS: 0.39

FBAS: 27.0%

FBAS: 19.0%</td><td>HE: -0.47

HE: 22.00%

HE: 13.00%

HE: 8.00%</td></tr>
</table></td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Savoye, 2011

Guideline record ID: 10848--1

Study characteristics		
Citation	Savoye, M., Nowicka, P., Shaw, M., Yu, S., Dziura, J., Chavent, G., O'Malley, G., Serrecchia, J. B., Tamborlane, W. V., & Caprio, S. (2011). Long-term results of an obesity program in an ethnically diverse pediatric population. Pediatrics, 127(3), 402-410. https://doi.org/https://dx.doi.org/10.1542/peds.2010-0697	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-term results of an obesity program in an ethnically diverse pediatric population	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	“Major inclusion criteria included English-speaking, 8- to 16-year old children with a BMI >= 95th percentile.”	
Exclusion criteria	“Exclusion criteria included serious medical conditions that would preclude participation in the program, use of medications that may cause significant weight gain/loss, or involvement in a coexisting weight management program.”	
Setting	School, Community (e.g. sports club, places of worship, commercial weight loss programs), University/research centre	
Intervention	“During the intervention phase of the program, participants randomly assigned to the Bright Bodies group attended the program at a nearby school twice a week for 6 months and then every other week for an additional 6 months. This setting was chosen with respect to the limited transportation options of the socioeconomically diverse families. The program consisted of exercise twice (50 minutes each) and nutrition/behavior modification once (40 minutes each) per week. Parents did not participate in the exercise component. Parents attended classes of nutrition-related topics, but did not attend behavior-modification-related topics with their child (they alternately attended their own parent class). Nutrition and behavior modification topics were based on the Smart Moves Workbook, a curriculum designed for overweight and obese children and written by 1 of the authors (Ms Savoye). Sample topics in the behavior modification component included "Ready, Set, Goal!," "Risky Business: Identifying High-risk Situations," "Mirror, Mirror on the Wall," "Bullies, Teasers, and Other Annoying People," and "Oops I Slipped: Understanding a Relapse." Techniques included selfawareness, goal-setting, stimulus control, coping-skills training, and cognitive behavior strategies. Behavior modification classes were facilitated by the registered dietitian or social worker. Parent classes included topics that reflected the challenges parents verbalized. These classes emphasized the importance of the parents' role in modeling healthy behavior change. The nutrition education component of the program used a nondiet approach that emphasized low-fat, nutrientdense foods of moderate portions. Topics included "Determining Portion Sizes," "Better Food Choices: A NonDiet Approach," "Making Sense of a Food Label," and "Bag It! Pros to Bringing Lunch to School." A favorite nutrition topic for parents and children alike was "Recipes Dear to the Heart," which includes a recipe for collard greens that has been trimmed of calories and fat. The topic also involves sharing traditional family recipes and working together as ateamtomodify itto be healthier. This topic is an example of how the program was tailored to inner-city, ethnically diverse populations. In addition, the dietitian was bilingual (Spanish) for parents who needed additional explanation of nutrition concepts. The exercise component of the program was facilitated by exercise physiologists. Each class consisted of a warm-up, high-intensity aerobic exercise, and cool down. The high-intensity exercise consisted of a variety of children games, obstacle courses, basketball, flag football, sprinting games, and sport drills. The objective of the high intensity exercise was to sustain	

<table>
<tr><td></td><td>65% to 80% of the age-adjusted maximal heart rate for the duration of the exercise. Participants were also encouraged to exercise 3 additional days at home per week and to decrease sedentary behaviors. The minimum activity that each participant completed was 100 minutes per week (2 50-minute sessions) for the first 6 months and 100 minutes twice per month for the last 6 months. After completing 1 year of the program, participants were encouraged to stay active and apply the knowledge gained during the program when making food choices (nondiet approach) throughout the next year. They were referred back to the Yale Pediatric Obesity Clinic for follow-up where end of study assessments were made at 24 months.”</td></tr>
<tr><td>Control/Comparator</td><td>“The control group participants were followed in the Yale Pediatric Obesity Clinic every 6 months and received general diet and exercise counseling (30 minutes) by dietitians and physicians along with brief psychosocial counseling by a social worker (30 minutes). At 24 months, the participants were asked to return for end-of study assessments.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td>Participant characteristics</td><td></td></tr>
<tr><td>Number of participants</td><td>n= 174
Intervention group/s: Weight Management Group (n=105)

Comparator group: Control Group (n=69)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 12.0y (2.5); Control: 12.5y (2.3)</td></tr>
<tr><td>Sex</td><td>60.34% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td>Results</td><td></td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight, kg
Mean (SD)</td><td>Weight Management Group:
87
(25.1)</td><td>Control Group: 91.2
(23.3)</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Weight Management Group:
35.7
(7.5)</td><td>Control Group: 36.2
(6.2)</td></tr>
<tr><td>BMI z score
Mean (SD)</td><td>Weight Management Group:
2.47
(0.34)</td><td>Control Group: 2.48
(0.27)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Weight, kg
Mean (95% CIs)</td><td>Weight Management Group:
0.3
(-1.4-2)</td><td>Control Group: 8.3
(6.1-10.6)</td></tr>
</table>
</td></tr>
</table>

	Change in BMI (kg/m2) Mean (95% CIs) Change in BMI z score Mean (95% CIs)	Weight Management Group: -1.8 (-2.4--1.1) Weight Management Group: -0.21 (-0.25)	Control Group: 1.9 (1.1-2.8) Control Group: 0.01 (-0.04-0.07)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in Weight, kg Mean (95% CIs) Change in BMI (kg/m2) Mean (95% CIs) Change in BMI z score Mean (95% CIs)	Weight Management Group: 5.9 (4-7.9) Weight Management Group: -0.9 (-1.7--0.1) Weight Management Group: -0.2 (-0.25--0.16)	Control Group: 12 (9.5-14.6) Control Group: 1.9 (0.9-2.9) Control Group: -0.05 (-0.1-0.01)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Schauer, 2012

Guideline record ID: 10646--1

Study characteristics		
Citation	Schauer, P. R., Kashyap, S. R., Wolski, K., Brethauer, S. A., Kirwan, J. P., Pothier, C. E., Thomas, S., Abood, B., Nissen, S. E., & Bhatt, D. L. (2012). Bariatric surgery versus intensive medical therapy in obese patients with diabetes. The New England Journal of Medicine, 366(17), 1567-1576. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1200225	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Bariatric surgery versus intensive medical therapy in obese patients with diabetes	
Location	USA	
Trial name	Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE)	
Methods		
Inclusion criteria	"Age of 20 to 60 years, a diagnosis of type 2 diabetes (glycated hemoglobin level, >7.0%), and a BMI of 27 to 43."	
Exclusion criteria	"Patients were excluded if they had undergone previous bariatric surgery or other complex abdominal surgery or had poorly controlled medical or psychiatric disorders."	
Setting	Hospital, Home	
Intervention	"All patients received intensive medical therapy, as defined by American Diabetes Association (ADA) guidelines, including lifestyle counseling, weight management, frequent home glucose monitoring, and the use of newer drug therapies (e.g., incretin analogues) approved by the Food and Drug Administration (FDA).2,12 Every 3 months for the first 12 months, patients returned for study visits with a diabetes specialist at the Cleveland Clinic. Patients were counseled by a diabetes educator and evaluated for bariatric surgery by a psychologist and encouraged to participate in the Weight Watchers program. The goal of medical management was modification of diabetes medications until the patient reached the therapeutic goal of a glycated hemoglobin level of 6.0% or less or became intolerant to the medical treatment. All patients were treated with lipid-lowering and antihypertensive medications, according to ADA guidelines, with the following targets: systolic blood pressure, 130 mm Hg or less; diastolic blood pressure, 80 mm Hg or less; and low-density lipoprotein (LDL) cholesterol, 100 mg per deciliter (2.6 mmol per liter) or less. Bariatric procedures were performed laparoscopically by a single surgeon with the use of instruments provided by Ethicon Endo-Surgery. Gastric bypass consisted of the creation of a 15-to20-ml gastric pouch, a 150-cm Roux limb, and a 50-cm biliopancreatic limb (Fig. S3 in the Supplementary Appendix).13 Sleeve gastrectomy involved a gastric-volume reduction of 75 to 80% by resecting the stomach alongside a 30-French endoscope beginning 3 cm from the pylorus and ending at the angle of His (Fig. S3 in the Supplementary Appendix). Patients who were assigned to undergo bariatric surgery were evaluated by surgical, nutrition, and psychology services as necessary.14 Vitamin and nutrient supplementation after gastric bypass included a multivitamin, iron, vitamin B12, and calcium citrate with vitamin D; after sleeve gastrectomy, such supplementation included a multivitamin and vitamin B12. Patients were assessed for nutritional deficiencies within 12 months after surgery"	
Control/Comparator	"All patients received intensive medical therapy, as defined by American Diabetes Association (ADA) guidelines, including lifestyle counseling, weight management, frequent home glucose monitoring, and the use of newer drug therapies (e.g., incretin analogues) approved by the Food and Drug Administration (FDA).2,12 Every 3 months for the first 12 months, patients returned for study visits with a diabetes specialist at the Cleveland Clinic. Patients were counseled by a diabetes educator and evaluated for bariatric surgery by a	

<table>
<tr><td></td><td>psychologist and encouraged to participate in the Weight Watchers program. The goal of medical management was modification of diabetes medications until the patient reached the therapeutic goal of a glycated hemoglobin level of 6.0% or less or became intolerant to the medical treatment (Fig. S1 and S2 in the Supplementary Appendix, available at NEJM.org). All patients were treated with lipid-lowering and antihypertensive medications, according to ADA guidelines, with the following targets: systolic blood pressure, 130 mm Hg or less; diastolic blood pressure, 80 mm Hg or less; and low-density lipoprotein (LDL) cholesterol, 100 mg per deciliter (2.6 mmol per liter) or less.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 150
Intervention group/s: Gastric bypass (n=50); Sleeve Gastrectomy (n=50)

Comparator group: Intensive Medical Therapy (n=50)</td></tr>
<tr><td>Mean age ± SD</td><td>Medical therapy: 49.7y (7.4); Gastric bypass: 48.3y (8.4); Sleeve Gastrectomy; 47.9y (8.0)</td></tr>
<tr><td>Sex</td><td>66.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Gastric bypass: 106.7 (14.8)
Sleeve Gastrectomy: 100.6 (16.5)</td><td>Intensive Medical Therapy: 104.4 (14.5)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Gastric bypass: 37 (3.3)
Sleeve Gastrectomy: 36.1 (3.9)</td><td>Intensive Medical Therapy: 36.3 (3)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Gastric bypass: 116.4 (9.2)
Sleeve Gastrectomy: 113.6 (10.2)</td><td>Intensive Medical Therapy: 112.9 (8.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Gastric bypass: 77.3 (13)
Sleeve Gastrectomy: 75.5 (12.9)</td><td>Intensive Medical Therapy: 99 (16.4)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Gastric bypass: 26.8 (3.2)
Sleeve Gastrectomy: 27.2 (3.5)</td><td>Intensive Medical Therapy: 34.4 (3.7)</td></tr>
<tr><td>% Excess weight loss
Median (IQR)</td><td>Gastric bypass: 88 (72-101)
Sleeve Gastrectomy: 81 (65-97)</td><td>Intensive Medical Therapy: 13 (0.8-23)</td></tr>
</table>
</td></tr>
</table>

	Waist circumference (cm) Mean (SD)	Gastric bypass: 93.4 (9) Sleeve Gastrectomy: 93.5 (8.8)	Intensive Medical Therapy: 108.8 (10.8)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in body weight from baseline (kg) Mean (SD)	Gastric bypass: -29.4 (8.9) Sleeve Gastrectomy: -25.1 (8.5)	Intensive Medical Therapy: -5.4 (8)
	Change in BMI from baseline (kg/m2) Mean (SD)	Gastric bypass: -10.2 (3.1) Sleeve Gastrectomy: -9 (2.7)	Intensive Medical Therapy: -1.9 (2.9)
	Change in waist circumference from baseline (cm) Mean (SD)	Gastric bypass: -23 (8.3) Sleeve Gastrectomy: -20.1 (9)	Intensive Medical Therapy: -4.1 (8.5)
	% change in waist circumference Mean (SD)	Gastric bypass: -19.6 (6.5) Sleeve Gastrectomy: -17.5 (7.1)	Intensive Medical Therapy: -3.6 (7.4)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data	Kashyap, S. R., Bhatt, D. L., Wolski, K., Watanabe, R. M., Abdul-Ghani, M., Abood, B., Pothier, C. E., Brethauer, S., Nissen, S., Gupta, M., Kirwan, J. P., & Schauer, P. R. (2013). Metabolic effects of bariatric surgery in patients with moderate obesity and type 2 diabetes: analysis of a randomized control trial comparing surgery with intensive medical treatment. Diabetes Care, 36(8), 2175-2182. https://doi.org/10.2337/dc12-1596; Maghrabi, A. H., Wolski, K., Abood, B., Licata, A., Pothier, C., Bhatt, D. L., Nissen, S., Brethauer, S. A., Kirwan, J. P., Schauer, P. R., & Kashyap, S. R. (2015). Two-year outcomes on bone density and fracture incidence in patients with T2DM randomized to bariatric surgery versus intensive medical therapy. Obesity, 23(12), 2344-2348. https://doi.org/https://dx.doi.org/10.1002/oby.21150; Schauer, P. R., Bhatt, D. L., Kirwan, J. P., Wolski, K., Aminian, A., Brethauer, S. A., Navaneethan, S. D., Singh, R. P., Pothier, C. E., Nissen, S. E., Kashyap, S. R., & for the STAMPEDE Investigators. (2017). Bariatric surgery versus intensive medical therapy for diabetes - 5-year outcomes. The New England Journal of Medicine, 376(7), 641-651. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1600869; Schauer, P. R., Bhatt, D. L., Kirwan, J. P., Wolski, K., Brethauer, S. A., Navaneethan, S. D., Aminian, A., Pothier, C. E., Kim, E. S. H., Nissen, S. E., Kashyap, S. R., & for the STAMPEDE Investigators. (2014). Bariatric surgery versus intensive medical therapy for diabetes--3-year outcomes. The New England Journal of Medicine, 370(21), 2002-2013. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1401329		

N/A – Not applicable

Schauer, 2014

Guideline record ID: 10645--1

Study characteristics		
Citation	Schauer, P. R., Bhatt, D. L., Kirwan, J. P., Wolski, K., Brethauer, S. A., Navaneethan, S. D., Aminian, A., Pothier, C. E., Kim, E. S. H., Nissen, S. E., Kashyap, S. R., & for the STAMPEDE Investigators. (2014). Bariatric surgery versus intensive medical therapy for diabetes--3-year outcomes. The New England Journal of Medicine, 370(21), 2002-2013. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1401329	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Bariatric surgery versus intensive medical therapy for diabetes--3-year outcomes	
Location	USA	
Trial name	Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE)	
Methods		
Inclusion criteria	"Eligibility criteria included an age of 20 to 60 years, a glycated hemoglobin level of more than 7.0%, and a body-mass index (BMI, the weight in kilograms divided by the square of the height in meters) of 27 to 43."	
Exclusion criteria	Not reported	
Setting	Hospital, Home	
Intervention	"Gastric bypass + IMT or sleeve gastrectomy + IMT"	
Control/Comparator	"Intensive medical therapy (IMT)."	
Treatment duration	3 years	
Follow-up from baseline	3 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 150 Intervention group/s: Gastric bypass (n=50); Sleeve Gastrectomy (n=50) Comparator group: Intensive Medical Therapy (n=50)	
Mean age ± SD	Not reported in this article	
Sex	Not reported	
Pre-existing medical condition	Type 2 diabetes	
Results		

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Body weight (kg) Mean (SD)	Gastric bypass: 106.8 (14.9) Sleeve Gastrectomy: 100.6 (16.5)	Intensive Medical Therapy: 104.5 (14.2)
Waist circumference (cm) Mean (SD)	Gastric bypass: 116.6 (9.25) Sleeve Gastrectomy: 113.6	Intensive Medical Therapy: 113.3 (9.33)

		(10.21) Gastric bypass: 37.1 Sleeve Gastrectomy: 36.1	 Intensive Medical Therapy: 36.4
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Body weight (kg) Mean (SD) Waist circumference (cm) Mean (SD) BMI (kg/m2) Mean	Gastric bypass: 80.6 (15.5) Sleeve Gastrectomy: 79.3 (15.1) Gastric bypass: 97.2 (9.96) Sleeve Gastrectomy: 98.8 (10) Gastric bypass: 27.9 Sleeve Gastrectomy: 29.2	Intensive Medical Therapy: 100.2 (16.6) Intensive Medical Therapy: 111.9 (12.73) Intensive Medical Therapy: 34.8
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in Body weight from baseline (kg) Mean (SD) % Weight change from baseline Mean (SD) % change in waist circumference Mean (SD)	Gastric bypass: -26.2 (10.6) Sleeve Gastrectomy: -21.3 (9.7) Gastric bypass: -24.5 (9.1) Sleeve Gastrectomy: -21.1 (8.9) Gastric bypass: -16.5 (6.97) Sleeve Gastrectomy: -12.8 (8.72)	Intensive Medical Therapy: -4.3 (8.8) Intensive Medical Therapy: -4.2 (8.3) Intensive Medical Therapy: -1.5 (8)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data	Kashyap, S. R., Bhatt, D. L., Wolski, K., Watanabe, R. M., Abdul-Ghani, M., Abood, B., Pothier, C. E., Brethauer, S., Nissen, S., Gupta, M., Kirwan, J. P., & Schauer, P. R. (2013). Metabolic effects of bariatric surgery in patients with moderate obesity and type 2 diabetes: analysis of a randomized control trial comparing surgery with intensive medical treatment. Diabetes Care, 36(8), 2175-2182. https://doi.org/10.2337/dc12-1596; Maghrabi, A. H., Wolski, K., Abood, B., Licata, A., Pothier, C., Bhatt, D. L., Nissen, S., Brethauer, S. A., Kirwan, J. P., Schauer, P. R., & Kashyap, S. R. (2015). Two-year outcomes on bone density and fracture incidence in patients with T2DM randomized to bariatric surgery versus intensive medical therapy. Obesity, 23(12), 2344-2348. https://doi.org/https://dx.doi.org/10.1002/oby.21150; Schauer, P. R., Bhatt, D. L., Kirwan, J. P., Wolski, K., Aminian, A., Brethauer, S. A., Navaneethan, S. D., Singh, R. P., Pothier, C. E., Nissen, S. E., Kashyap, S. R., & for the STAMPEDE Investigators. (2017). Bariatric surgery		

	versus intensive medical therapy for diabetes - 5-year outcomes. The New England Journal of Medicine, 376(7), 641-651. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1600869; Schauer, P. R., Kashyap, S. R., Wolski, K., Brethauer, S. A., Kirwan, J. P., Pothier, C. E., Thomas, S., Abood, B., Nissen, S. E., & Bhatt, D. L. (2012). Bariatric surgery versus intensive medical therapy in obese patients with diabetes. The New England Journal of Medicine, 366(17), 1567-1576. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1200225

N/A – Not applicable

Schauer, 2017

Guideline record ID: 10644--1

Study characteristics		
Citation	Schauer, P. R., Bhatt, D. L., Kirwan, J. P., Wolski, K., Aminian, A., Brethauer, S. A., Navaneethan, S. D., Singh, R. P., Pothier, C. E., Nissen, S. E., Kashyap, S. R., & for the STAMPEDE Investigators. (2017). Bariatric surgery versus intensive medical therapy for diabetes - 5-year outcomes. The New England Journal of Medicine, 376(7), 641-651. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1600869	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Bariatric Surgery versus Intensive Medical Therapy for Diabetes - 5-Year Outcomes	
Location	USA	
Trial name	Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE)	
Methods		
Inclusion criteria	"Eligibility criteria included an age of 20 to 60 years, a glycated hemoglobin level of more than 7.0%, and a body-mass index (BMI; the weight in kilograms divided by the square of the height in meters) of 27 to 43."	
Exclusion criteria	Not reported	
Setting	Hospital, Home	
Intervention	"Intensive medical therapy plus either gastric bypass or sleeve gastrectomy"	
Control/Comparator	"Intensive medical therapy."	
Treatment duration	5 years	
Follow-up from baseline	5 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 150 Intervention group/s: Gastric bypass (n=50); Sleeve Gastrectomy (n=50) Comparator group: Medical Therapy (n=50)	
Mean age ± SD	Not reported in this article	
Sex	Not reported	
Pre-existing medical condition	Type 2 diabetes	
Results		

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Body weight (kg) Mean (SD)	Gastric bypass: 106.8 (14.9) Sleeve Gastrectomy: 100.4 (16.8)	Medical Therapy: 105 (14.4)
Waist circumference (cm) Mean (SD)	Gastric bypass: 116.5 (9.25) Sleeve Gastrectomy: 113.5	Medical Therapy: 113.7 (9.4)

		(10.35)	
	BMI (kg/m2) Mean	Gastric bypass: 37 Sleeve Gastrectomy: 36	Medical Therapy: 36.4

Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator

Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Body weight (kg) Mean (SD)	Gastric bypass: 83.4 (15.3) Sleeve Gastrectomy: 81.9 (15)	Medical Therapy: 99 (17)
	Waist circumference (cm) Mean (SD)	Gastric bypass: 99.4 (9.23) Sleeve Gastrectomy: 99.3 (9.43)	Medical Therapy: 111.6 (13.09)
	BMI (kg/m2) Mean	Gastric bypass: 28.9 Sleeve Gastrectomy: 29.3	Medical Therapy: 34

Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in weight from baseline (kg) Mean (SD)	Gastric bypass: -23.2 (9.6) Sleeve Gastrectomy: -18.6 (7.5)	Medical Therapy: -5.3 (10.8)
	% change from baseline in body weight Mean (SD)	Gastric bypass: -21.8 (8.3) Sleeve Gastrectomy: -18.5 (6.6)	Medical Therapy: -5 (9.9)
	% change in waist circumference Mean (SD)	Gastric bypass: -14.7 (6.6) Sleeve Gastrectomy: -12.2 (7.96)	Medical Therapy: -1.3 (10.17)

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	Kashyap, S. R., Bhatt, D. L., Wolski, K., Watanabe, R. M., Abdul-Ghani, M., Abood, B., Pothier, C. E., Brethauer, S., Nissen, S., Gupta, M., Kirwan, J. P., & Schauer, P. R. (2013). Metabolic effects of bariatric surgery in patients with moderate obesity and type 2 diabetes: analysis of a randomized control trial comparing surgery with intensive medical treatment. Diabetes Care, 36(8), 2175-2182. https://doi.org/10.2337/dc12-1596; Maghrabi, A. H., Wolski, K., Abood, B., Licata, A., Pothier, C., Bhatt, D. L., Nissen, S., Brethauer, S. A., Kirwan, J. P., Schauer, P. R., & Kashyap, S. R. (2015). Two-year outcomes on bone density and fracture incidence in patients with T2DM randomized to bariatric surgery versus intensive medical therapy. Obesity, 23(12), 2344-2348. https://doi.org/https://dx.doi.org/10.1002/oby.21150; Schauer, P. R., Bhatt, D. L., Kirwan, J. P., Wolski, K., Brethauer, S. A., Navaneethan, S. D., Aminian, A., Pothier, C. E., Kim, E. S. H., Nissen, S. E., Kashyap, S. R., & for the STAMPEDE Investigators. (2014). Bariatric surgery

	versus intensive medical therapy for diabetes--3-year outcomes. The New England Journal of Medicine, 370(21), 2002-2013. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1401329; Schauer, P. R., Kashyap, S. R., Wolski, K., Brethauer, S. A., Kirwan, J. P., Pothier, C. E., Thomas, S., Abood, B., Nissen, S. E., & Bhatt, D. L. (2012). Bariatric surgery versus intensive medical therapy in obese patients with diabetes. The New England Journal of Medicine, 366(17), 1567-1576. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1200225

N/A – Not applicable

Schiavon, 2018

Guideline record ID: 10647--1

Study characteristics		
Citation	Schiavon, C. A., Bersch-Ferreira, A. C., Santucci, E. V., Oliveira, J. D., Torreglosa, C. R., Bueno, P. T., Frayha, J. C., Santos, R. N., Damiani, L. P., Noujaim, P. M., Halpern, H., Monteiro, F. L. J., Cohen, R. V., Uchoa, C. H., de Souza, M. G., Amodeo, C., Bortolotto, L., Ikeoka, D., Drager, L. F., . . . Berwanger, O. (2018). Effects of bariatric surgery in obese patients with hypertension: the GATEWAY randomized Trial (Gastric Bypass to Treat Obese Patients With Steady Hypertension). Circulation, 137(11), 1132-1142. https://doi.org/https://dx.doi.org/10.1161/CIRCULATIONAHA.117.032130	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of Bariatric Surgery in Obese Patients With Hypertension: The GATEWAY Randomized Trial (Gastric Bypass to Treat Obese Patients With Steady Hypertension)	
Location	Brazil	
Trial name	Gastric Bypass to Treat Obese Patients With Steady Hypertension (GATEWAY)	
Methods		
Inclusion criteria	"We included patients 18 to 65 years of age with hypertension, with a body mass index (BMI) ranging from 30.0 to 39.9 kg/m2, and treated with ≥2 antihypertensive drugs at maximum doses or >2 drugs at moderate doses."	
Exclusion criteria	"Exclusion criteria were systolic blood pressure ≥180 mmHg or diastolic blood pressure ≥120 mmHg; cardiovascular disease (myocardial infarction or stroke within 6 months, angina, coronary revascularization, heart failure); severe psychiatric disorders because of increased risk of low compliance with the study procedures; chronic kidney disease (diabetic nephropathy or glomerular filtration rate <30 mL/min); secondary hypertension, except because of sleep apnea; peripheral arterial disease; atrophic gastritis; type 1 diabetes mellitus, latent autoimmune diabetes of adults, or type 2 diabetes mellitus with glycohemoglobin >7.0%; alcoholism or use of illicit drugs; current smoking; previous abdominal surgery; severe hepatic diseases; pregnancy or women of childbearing age not using effective contraceptive methods; cancer in the past 5 years; use of immunosuppressive drugs, chemotherapy, or radiotherapy; or inability to understand or adhere to study procedures."	
Setting	Hospital	
Intervention	"Roux-en-Y gastric bypass plus medical therapy. Medical therapy was standardized for all patients based on office blood pressure. Patients from both groups received nutritional advice based on national statements for hypertension and obesity. A visit to a dietitian from the investigation team followed each medical visit at the hospital to reinforce the nutritional recommendations previously indicated. Nutritional advice in the medical therapy group was mainly directed at weight reduction and blood pressure control. Aimed at progressive weight loss over time, a total daily energy consumption calculated as 20 kcal/kg of ideal body weight per day was recommended among the patients. Similarly, for the improvement of blood pressure control, the ingestion of high-sodium food, such as snacks, sausages, and fast food, was discouraged, and the reduction of salt used for cooking at home or added to already prepared food was encouraged. Fruit and vegetable consumption was also recommended to increase potassium intake. For those patients submitted to Roux-en-Y gastric bypass, the nutritional advice included information about food consistency in the postoperative period. In addition, all patients received psychological and physical activity counseling and were treated for other comorbidities according to current guidelines."	

<table>
<tr><td>Control/Comparator</td><td>“Medical therapy was standardized for all patients based on office blood pressure. Patients from both groups received nutritional advice based on national statements for hypertension and obesity. A visit to a dietitian from the investigation team followed each medical visit at the hospital to reinforce the nutritional recommendations previously indicated. Nutritional advice in the medical therapy group was mainly directed at weight reduction and blood pressure control. Aimed at progressive weight loss over time, a total daily energy consumption calculated as 20 kcal/kg of ideal body weight per day was recommended among the patients. Similarly, for the improvement of blood pressure control, the ingestion of high-sodium food, such as snacks, sausages, and fast food, was discouraged, and the reduction of salt used for cooking at home or added to already prepared food was encouraged. Fruit and vegetable consumption was also recommended to increase potassium intake. In addition, all patients received psychological and physical activity counselling and were treated for other comorbidities according to current guidelines.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 100
Intervention group/s: Gastric Bypass + Medical Therapy (n=50)

Comparator group: Medical Therapy (n=50)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 43.1y (9.2); Control: 44.6y (9.2)</td></tr>
<tr><td>Sex</td><td>76.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Hypertension</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Gastric Bypass + Medical Therapy: 37.4
(2.4)</td><td>Medical Therapy: 36.4
(2.9)</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Gastric Bypass + Medical Therapy: 102
(13.6)</td><td>Medical Therapy: 100.1
(14)</td></tr>
<tr><td>Waist Circumference (cm)
Mean (SD)</td><td>Gastric Bypass + Medical Therapy: 112.2
(7.9)</td><td>Medical Therapy: 111
(8.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Gastric Bypass + Medical Therapy: 26.8
(3.7)</td><td>Medical Therapy: 36.3
(3.9)</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Gastric Bypass + Medical Therapy: 72.7
(12.4)</td><td>Medical Therapy: 99.4
(15.3)</td></tr>
<tr><td>Waist Circumference (cm)
Mean (SD)</td><td>Gastric Bypass + Medical Therapy: 86.9
(8.5)</td><td>Medical Therapy: 109.8
(9.6)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in BMI (kg/m2)
Mean (SD)</td><td>Gastric Bypass + Medical Therapy: -10.8
(3.7)</td><td>Medical Therapy: -0.2
(2.2)</td></tr><tr><td>Change in Weight (kg)
Mean (SD)</td><td>Gastric Bypass + Medical Therapy: -29.5
(11.2)</td><td>Medical Therapy: -0.7
(6)</td></tr><tr><td>Change in Waist Circumference (cm)
Mean (SD)</td><td>Gastric Bypass + Medical Therapy: -25.7
(9.6)</td><td>Medical Therapy: -0.9
(6.3)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>surgical/not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Schiavon, C. A., Bhatt, D. L., Ikeoka, D., Santucci, E. V., Santos, R. N., Damiani, L. P., Oliveira, J. D., Machado, R. H. V., Halpern, H., Monteiro, F. L. J., Noujaim, P. M., Cohen, R. V., de Souza, M. G., Amodeo, C., Bortolotto, L. A., Berwanger, O., Cavalcanti, A. B., & Drager, L. F. (2020). Three-year outcomes of bariatric surgery in patients with obesity and hypertension: a randomized clinical trial. Annals of Internal Medicine, 173(9), 685-693. https://doi.org/10.7326/M19-3781</td></tr>
</table>

N/A – Not applicable

Schiavon, 2020

Guideline record ID: 10648--1

Study characteristics		
Citation	Schiavon, C. A., Bhatt, D. L., Ikeoka, D., Santucci, E. V., Santos, R. N., Damiani, L. P., Oliveira, J. D., Machado, R. H. V., Halpern, H., Monteiro, F. L. J., Noujaim, P. M., Cohen, R. V., de Souza, M. G., Amodeo, C., Bortolotto, L. A., Berwanger, O., Cavalcanti, A. B., & Drager, L. F. (2020). Three-year outcomes of bariatric surgery in patients with obesity and hypertension: a randomized clinical trial. Annals of Internal Medicine, 173(9), 685-693. https://doi.org/10.7326/M19-3781	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Three-Year Outcomes of Bariatric Surgery in Patients With Obesity and Hypertension: A Randomized Clinical Trial	
Location	Brazil	
Trial name	Gastric Bypass to Treat Obese Patients With Steady Hypertension (GATEWAY)	
Methods		
Inclusion criteria	"Aged 18 to 65 years with a BMI between 30.0 and 39.9 kg/m2 and established hypertension treated with at least 2 antihypertensive drugs at maximum doses or more than 2 antihypertensive drugs at moderate doses."	
Exclusion criteria	"Main exclusion criteria included the following: mean systolic BP greater than or equal to 180 mm Hg or diastolic BP greater than or equal to 120 mm Hg; cardiovascular disease (myocardial infarction or stroke within 6 months, angina, coronary revascularization, heart failure); severe psychiatric disorders; secondary hypertension (except sleep apnea); type 1 diabetes, latent autoimmune diabetes of adults, or type 2 diabetes with glycated hemoglobin level greater than 7.0%; and current smoking."	
Setting	Hospital	
Intervention	"Roux-en-Y gastric bypass plus medical therapy. Medical therapy was standardized for all patients based on office blood pressure. Patients from both groups received nutritional advice based on national statements for hypertension and obesity. A visit to a dietitian from the investigation team followed each medical visit at the hospital to reinforce the nutritional recommendations previously indicated. Nutritional advice in the medical therapy group was mainly directed at weight reduction and blood pressure control. Aimed at progressive weight loss over time, a total daily energy consumption calculated as 20 kcal/kg of ideal body weight per day was recommended among the patients. Similarly, for the improvement of blood pressure control, the ingestion of high-sodium food, such as snacks, sausages, and fast food, was discouraged, and the reduction of salt used for cooking at home or added to already prepared food was encouraged. Fruit and vegetable consumption was also recommended to increase potassium intake. In addition, all patients received psychological and physical activity counselling and were treated for other comorbidities according to current guidelines."	
Control/Comparator	"Medical therapy was standardized for all patients based on office blood pressure. Patients from both groups received nutritional advice based on national statements for hypertension and obesity. A visit to a dietitian from the investigation team followed each medical visit at the hospital to reinforce the nutritional recommendations previously indicated. Nutritional advice in the medical therapy group was mainly directed at weight reduction and blood pressure control. Aimed at progressive weight loss over time, a total daily energy consumption calculated as 20 kcal/kg of ideal body weight per day was recommended among the patients. Similarly, for the improvement of blood pressure control, the ingestion of high-sodium food, such as snacks, sausages, and fast food, was discouraged, and the reduction of salt used for cooking at home or added to already	

<table>
<tr><td></td><td>prepared food was encouraged. Fruit and vegetable consumption was also recommended to increase potassium intake. In addition, all patients received psychological and physical activity counselling and were treated for other comorbidities according to current guidelines.”</td></tr>
<tr><td>Treatment duration</td><td>surgical/12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>3 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 100
Intervention group/s: Gastric Bypass + Medical Therapy (n=50)

Comparator group: Medical Therapy (n=50)</td></tr>
<tr><td>Mean age ± SD</td><td>43.9y (9.2)</td></tr>
<tr><td>Sex</td><td>76.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Hypertension</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Weight (kg)
Mean (SD)

Waist Circumference (cm)
Mean (SD)</td><td>Gastric Bypass + Medical Therapy: 37.4
(2.4)

Gastric Bypass + Medical Therapy: 102
(13.6)

Gastric Bypass + Medical Therapy: 112.2
(7.9)</td><td>Medical Therapy: 36.4
(2.9)

Medical Therapy: 100.1
(14)

Medical Therapy: 111
(8.8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Weight (kg)
Mean (SD)

Waist Circumference (cm)
Mean (SD)</td><td>Gastric Bypass + Medical Therapy: 26.8
(3.7)

Gastric Bypass + Medical Therapy: 73.1
(13)

Gastric Bypass + Medical Therapy: 86.1
(9.9)</td><td>Medical Therapy: 36.3
(4.2)

Medical Therapy: 99
(15.1)

Medical Therapy: 111
(11.1)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Total Weight Loss (%) Mean	Gastric Bypass + Medical Therapy: -27.8	Medical Therapy: -0.1
Compliance with treatment	Surgical/not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data	Schiavon, C. A., Bersch-Ferreira, A. C., Santucci, E. V., Oliveira, J. D., Torreglosa, C. R., Bueno, P. T., Frayha, J. C., Santos, R. N., Damiani, L. P., Noujaim, P. M., Halpern, H., Monteiro, F. L. J., Cohen, R. V., Uchoa, C. H., de Souza, M. G., Amodeo, C., Bortolotto, L., Ikeoka, D., Drager, L. F., . . . Berwanger, O. (2018). Effects of bariatric surgery in obese patients with hypertension: the GATEWAY randomized Trial (Gastric Bypass to Treat Obese Patients With Steady Hypertension). Circulation, 137(11), 1132-1142. https://doi.org/https://dx.doi.org/10.1161/CIRCULATIONAHA.117.032130		

N/A – Not applicable

Seimon, 2019

Guideline record ID: 10850

Study characteristics		
Citation	Seimon, R. V., Wild-Taylor, A. L., Keating, S. E., McClintock, S., Harper, C., Gibson, A. A., Johnson, N. A., Fernando, H. A., Markovic, T. P., Center, J. R., Franklin, J., Liu, P. Y., Grieve, S. M., Lagopoulos, J., Caterson, I. D., Byrne, N. M., & Sainsbury, A. (2019). Effect of weight loss via severe vs moderate energy restriction on lean mass and body composition among postmenopausal women with obesity: the TEMPO Diet randomized clinical trial. JAMA Network Open, 2(10), e1913733. https://doi.org/https://dx.doi.org/10.1001/jamanetworkopen.2019.13733	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Weight Loss via Severe vs Moderate Energy Restriction on Lean Mass and Body Composition Among Postmenopausal Women With Obesity: The TEMPO Diet Randomized Clinical Trial	
Location	Australia	
Trial name	Type of Energy Manipulation for Promoting Optimum Metabolic Health and Body Composition in Obesity (TEMPO)	
Methods		
Inclusion criteria	"Key inclusion criteria were postmenopausal women aged 45 to 65 years with body mass index (calculated as weight in kilograms divided by height in meters squared) from 30 to 40, at least 5 years after menopause, with less than 3 hours of structured physical activity per week (ie, sedentary), and living in the Sydney metropolitan area of New South Wales, Australia."	
Exclusion criteria	"Participants with osteoporosis or diabetes and those taking medication affecting body composition were excluded."	
Setting	University/research centre	
Intervention	"The severe intervention involved a severe energy restriction of 65% to 75% relative to estimated energy expenditure for 4 months (16 weeks) or until a body mass index of no lower than 20 was reached, whichever came first. This was achieved using a total meal replacement diet (KicStart meal replacement shakes and soups from Prima Health Solutions) supplemented with a whey protein isolate (Beneprotein; Nestlé HealthCare Nutrition) to achieve the prescribed protein target (described later). This was followed by moderate energy restriction (ie, the moderate intervention) for the remaining period to 12 months (52 weeks). Both diets were individualized for each participant and were nutritionally sound. That is, the diet used in the moderate intervention was designed to meet nutrient requirements with minimum energy intake, while the severe intervention used a commercial total meal replacement product and supplemental protein that rendered it close to the recommended nutrient requirements. For both interventions, a protein intake of 1.0 g/kg of actual body weight per day was prescribed. Participants were encouraged to gradually increase step counts to a total of 8000 to 12 000 steps/d, including 30 to 60 min/d of moderate to vigorous physical activity. Although physical activity was encouraged, it was not supervised. Since the use of food diaries to measure adherence to the prescribed diet is difficult to assess because of missing dietary records and underreporting among participants with overweight and obesity, weight loss was used to monitor adherence to the diets. We expected approximately 1.5 to 2.5 kg/wk weight loss for participants in the severe intervention and approximately 0.5 to 1.0 kg/wk weight loss for participants in the moderate intervention. To increase adherence to the diet, participants attended individual dietary appointments with the trial dietitian approximately every 2 weeks for the first 26 weeks of the intervention (ie, at 1, 2, 4, 6, 8, 10, 12, 15, 16, 18, 20, 25, and 26 weeks relative to commencement of the dietary interventions, plus an	

<table>
<tr><td></td><td>extra appointment at 17 weeks for participants in the severe intervention during their transition to the moderate intervention) and then approximately every month until 52 weeks (ie, at 29, 33, 37, 41, 45, 51, and 52 weeks).”</td></tr>
<tr><td>Control/Comparator</td><td>“The moderate intervention involved a moderate energy restriction of 25% to 35% relative to estimated energy expenditure for a total of 12 months (52 weeks). This was achieved using a food based diet, with recommendations based on the Australian Guide to Healthy Eating.32 The guide provides recommendations on the average number of standard servings of the 5 core food groups (ie, vegetables, fruits, grains and cereals, meat and meat alternatives, and reduced fat dairy) that an individual should consume to meet nutritional requirements based on age and sex. To simplify adherence to the moderate intervention, we defined 6 food groups. The meat and meat alternative and reduced fat dairy food groups were collapsed into a proteins group, and starchy vegetables were incorporated into the grains and cereals group to form a carbohydrates group, while participants also had groups for vegetables, fruits, fats, and discretionary foods. For both interventions, a protein intake of 1.0 g/kg of actual body weight per day was prescribed. Participants were encouraged to gradually increase step counts to a total of 8000 to 12 000 steps/d, including 30 to 60 min/d of moderate to vigorous physical activity. Although physical activity was encouraged, it was not supervised. Since the use of food diaries to measure adherence to the prescribed diet is difficult to assess because of missing dietary records and underreporting among participants with overweight and obesity, weight loss was used to monitor adherence to the diets. We expected approximately 1.5 to 2.5 kg/wk weight loss for participants in the severe intervention and approximately 0.5 to 1.0 kg/wk weight loss for participants in the moderate intervention. To increase adherence to the diet, participants attended individual dietary appointments with the trial dietitian approximately every 2 weeks for the first 26 weeks of the intervention (ie, at 1, 2, 4, 6, 8, 10, 12, 15, 16, 18, 20, 25, and 26 weeks relative to commencement of the dietary interventions, plus an extra appointment at 17 weeks for participants in the severe intervention during their transition to the moderate intervention) and then approximately every month until 52 weeks (ie, at 29, 33, 37, 41, 45, 51, and 52 weeks).”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 101
Intervention group/s: Severe intervention (n=50)

Comparator group: Moderate intervention (n=51)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 58.0y (4.4); Control: 58.0y (4.2)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight, kg
Mean (SD)</td><td>Severe intervention: 90.1 (9.4)</td><td>Moderate intervention: 92.4 (8.3)</td></tr>
<tr><td>Body mass index
Mean (SD)</td><td>Severe intervention: 34.3 (2.5)</td><td>Moderate intervention: 34.6 (2.5)</td></tr>
<tr><td>Whole-body lean mass, kg</td><td>Severe intervention: 44.3</td><td>Moderate intervention: 44.8</td></tr>
</table>
</td></tr>
</table>

	Mean (SD) Waist circumference, cm Mean (SD) Whole-body fat mass, kg Mean (SD)	(4.9) Severe intervention: 108.3 (7.3) Severe intervention: 42.2 (5.6)	(4) Moderate intervention: 108.8 (7) Moderate intervention: 43.5 (5.9)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight change, kg Mean (95% CIs) Weight change, % of baseline Mean (95% CIs) Body mass index change Mean (95% CIs) Change in Whole-body lean mass, kg Mean (95% CIs) Change in Waist circumference, cm Mean (95% CIs) Whole-body fat mass change, kg Mean (95% CIs)	Severe intervention: -15.3 (-18.1--12.5) Severe intervention: -17.3 (-20.3) Severe intervention: -5.81 (-6.89--4.74) Severe intervention: -3.2 (-4.1--2.3) Severe intervention: -14.3 (-17.3--11.3) Severe intervention: -10.2 (-12.1--8.4)	Moderate intervention: -8.4 (-11.4--5.4) Moderate intervention: -8.8 (-12--5.7) Moderate intervention: -3.17 (-4.31--2.02) Moderate intervention: -2.1 (-3.1--1.2) Moderate intervention: -6.9 (-10.1--3.7) Moderate intervention: -5.5 (-7.5--3.4)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Sellman, 2017

Guideline record ID: 10852—1

Study characteristics		
Citation	Sellman, D., Schroder, R., Deering, D., Elmslie, J., Foulds, J., & Frampton, C. (2017). Psychosocial enhancement of the green prescription for obesity recovery: A randomised controlled trial. The New Zealand Medical Journal (Online), 130(1450), 44-54. Retrieved from http://ezproxy.deakin.edu.au/login?url=https://www.proquest.com/scholarly-journals/psychosocial-enhancement-green-prescription/docview/1870216784/se-2	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Psychosocial enhancement of the Green Prescription for obesity recovery: a randomised controlled trial	
Location	New Zealand	
Trial name	N/A	
Methods		
Inclusion criteria	“Inclusion criteria were: 23-65 years old, not currently involved in other weight loss programmes, with no current signifi cant medical condition or undergoing medical treatment likely to signifi cantly affect weight, or which would make weight loss or dietary restriction contraindicated.”	
Exclusion criteria	Not reported	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs), University/research centre	
Intervention	“Green Prescription plus Kia Ākina (KA/ GRx): Green Prescription provides free consultations with a qualified and experienced physical activity coach who helps to support each person to discover suitable physical activity options in their community. Program encourages participants to establish a plan of activity suited to meet individual need and be supported by other participants and Green Prescription staff. Program incorporates instruction about healthy food and eating behaviour "Appetite for Life"- 22 group support and education sessions about healthy living, as well as text and email encouragement. Kia Ākina is an obesity recovery network which utilises six standard addiction treatment strategies: permanent life-style change; safe non-stigmatising venue; motivational enhancement principles; abstinence-based food-rules; harm reduction and care of long-term medical conditions; and self-help recovery group processes. Program involves a combination of Food/diet modification, increased physical Activity and Behavioural strategies, termed the FAB approach. The options include face to face meetings-six monthly workshops (two hours each) and weekly facilitated group discussion meetings (one hour), with topics determined by participants-an ongoing email discussion group based on a weekly email message addressing one of five key principles (Take Control, Get Active, Eat Well, Persist, Enjoy Life), a daily text buddy system and regular motivational text messages. A list of 50 energy-dense, nutrient-poor foods high in fat, sugar and/or containing alcohol, has been developed; referred to as the NEEDNT Food List (Non-Essential, Energy-Dense, Nutritionally-defi cienT).”	
Control/Comparator	“Green Prescription alone (GRx): Green Prescription provides free consultations with a qualified and experienced physical activity coach who helps to support each person to discover suitable physical activity options in their community. Program encourages participants to establish a plan of activity suited to meet individual need and be supported by other participants and Green Prescription staff. Program incorporates instruction about healthy food and eating behaviour "Appetite for Life"- 22 group support and education sessions about healthy living, as well as text and email encouragement.”	
Treatment duration	12 months	

<table>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 108
Intervention group/s: KA/GRx (n=54)

Comparator group: GRx (n=54)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 45.17 (10.9); Control: 42.4y (10.9)</td></tr>
<tr><td>Sex</td><td>84.26% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight kg
Mean (SD)

Baseline BMI
Mean (SD)</td><td>KA/GRx: 111.6
(21.2)

KA/GRx: 41
(7)</td><td>GRx: 110.8
(21.9)

GRx: 40.8
(7.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight kg
Mean (SD)</td><td>KA/GRx: 108
(20.6)</td><td>GRx: 110
(22.6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg) at 12 months
Mean (SD)

% weight loss at 12 months
Mean (SD)

% excess weight loss
Mean (SD)</td><td>KA/GRx: 3.6
(5.7)

KA/GRx: 3.2
(4.8)

KA/GRx: 14.6
(29.3)</td><td>GRx: 0.7
(5)

GRx: 0.7
(4.4)

GRx: 4.1
(20.2)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that</td><td></td></tr>
</table>

did not contribute additional data	

N/A – Not applicable

Serra-Prat, 2022

Guideline record ID: 10855--1

Study characteristics		
Citation	Serra-Prat, M., Terradellas, M., Lorenzo, I., Arús, M., Burdoy, E., Salietti, A., Ramírez, S., Palomera, E., Papiol, M. S., & Pleguezuelo, E. (2022). Effectiveness of a weight-loss intervention in preventing frailty and functional decline in community-dwelling obese older people. A randomized controlled trial. The Journal of Frailty & Aging, 11(1), 91-99. https://doi.org/https://dx.doi.org/10.14283/jfa.2021.38	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effectiveness of a Weight-Loss Intervention in Preventing Frailty and Functional Decline in Community-Dwelling Obese Older People. A Randomized Controlled Trial	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	"Adults aged 65-75 years, with a BMI of 30-39 kg/m2 (inclusive), who had at least one of the following obesity-related clinical conditions for which weight loss is advisable: dyslipidaemia, hypertension, diabetes or insulin resistance, obesity-related physical limitations, or sleep apnoea/hypopnoea."	
Exclusion criteria	"Exclusion criteria were dementia, neurodegenerative diseases, severe psychiatric disorders, cancer diagnoses, lower limb amputation, institutionalization, and life expectancy <6 months."	
Setting	GP clinic, Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The intervention consisted of a 6-month multimodal personalized program combining individual and group sessions. Diet (Personalized eating plans were based on a diet as follows: (a) hypocaloric, with a caloric deficit of 300-400 kcal/day with respect to the DEE, (b) balanced in macronutrients, with around 20%, 50% 27% of total energy delivered in the form of proteins (1.2 g/kg/day), carbohydrates, and fat, respectively, and (c) balanced in micronutrients (vitamins and minerals) according to current recommendations, with supplementation of vitamins (D, B6, B12) and minerals (calcium, magnesium, selenium) if deficient.) + exercise (A multicomponent physical exercise program included the following: (a) 45 minutes of unsupervised daily aerobic exercise (e.g., walking outdoors) on at least 5 days/week, (b) unsupervised strength, balance, and flexibility exercises for 15-20 minutes/day on 3 days a week (adapted to different ailments and with personalized follow up to avoid injuries) to be done at home, and (c) health education by a physiotherapist, consisting of 20 theoretical practical group sessions of 1 hour/week in the primary care centre)"	
Control/Comparator	"Usual care."	
Treatment duration	6 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 305 Intervention group/s: Intervention (n=150)	

	Comparator group: Control (n=155)
Mean age ± SD	Intervention: 69.6y (2.7); Control: 69.9y (2.7)
Sex	65.90% female
Pre-existing medical condition	No pre-existing medical condition
Results	

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Baseline BMI Mean (SD)	Intervention: 34.2 (3.3)	Control: 34 (3.2)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point

Variable	Intervention arm/s	Comparator
MALE Change in weight (kg) Mean (SD)	Intervention: -3.3 (3.7)	Control: -1.2 (4.3)
FEMALE change in weight (kg) Mean (SD)	Intervention: -3.4 (4.4)	Control: -0.04 (3.9)
MALE Change in BMI (kg/m2) Mean (SD)	Intervention: -1.2 (1.3)	Control: -0.4 (1.8)
FEMALE Change in BMI (kgm/m2) Mean (SD)	Intervention: -1.4 (1.8)	Control: -0.04 (1.6)
MALE Change in waist circumference (cm) Mean (SD)	Intervention: -5.1 (5.9)	Control: -2.9 (4.9)
FEMALE change in waist circumference (cm) Mean (SD)	Intervention: -3.1 (5.5)	Control: -1.1 (6.7)

Change in outcome measure from baseline to final follow-up/endpoint

Variable	Intervention arm/s	Comparator
MALE Change in weight (kg) Mean (SD)	Intervention: -2.6 (3.8)	Control: -2.2 (5)
FEMALE change in weight (kg) Mean (SD)	Intervention: -2.8 (3.4)	Control: -1.2 (4.6)
MALE Change in BMI (kg/m2) Mean (SD)	Intervention: -0.9 (1.4)	Control: -0.8 (1.7)
FEMALE Change in BMI (kgm/m2) Mean (SD)	Intervention: -1.2 (1.4)	Control: -0.5 (1.9)
MALE Change in waist circumference (cm) Mean (SD)	Intervention: -2.3 (5.7)	Control: -2.6 (4.9)
	Intervention: -3.5	Control: -1.6

	FEMALE change in waist circumference (cm) Mean (SD)	(6)	(6.2)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Shapiro, 2012

Guideline record ID: 10652--1

Study characteristics		
Citation	Shapiro, J. R., Koro, T., Doran, N., Thompson, S., Sallis, J. F., Calfas, K., & Patrick, K. (2012). Text4Diet: a randomized controlled study using text messaging for weight loss behaviors. Preventive Medicine, 55(5), 412-417. https://doi.org/10.1016/j.ypmed.2012.08.011	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Text4Diet: A randomized controlled study using text messaging for weight loss behaviors	
Location	USA	
Trial name	Text4Diet	
Methods		
Inclusion criteria	"Inclusion criteria consisted of: aged 21 to 65 years, BMI between 25.0 and 39.9, with regular access to the Internet, owns a cell phone and uses SMS, ability to read and speak English, and ability to participate in moderate PA."	
Exclusion criteria	"Exclusion criteria consisted of: currently or has the intention to become pregnant during the trial, plans to move out of San Diego during the trial, and current eating disorder."	
Setting	Home	
Intervention	"The current program, Text4Diet™ ("the intervention") modified Patrick et al.'s (2009) content with: a) expanded content to include sugar-sweetened beverages, sedentary time and PA; b) daily step monitoring via pedometers, c) creation of 2000 non-repetitive SMS; and d) novel online enrollment and automatic baseline survey scoring (assessing healthy/unhealthy behaviors) to support tailored messages on eating behavior topics (EBT). Participants randomized to the intervention received SMS and MMS (multimedia messaging service) 4 times/day for 12 months. SMS included: tips, facts, motivation, messages requesting answers to knowledge questions, or self-monitoring data on weight and steps. MMS included portion control pictures and weight/step graphical feedback over time. SMS for self-monitoring data requested step count (daily) and weight (weekly). Partici pants received personalized feedback on progress via: 1) weekly weight and step graphical MMS charts that depicted the previous 5 weeks; and 2) a daily pe dometer goal for the upcoming week, calculated by averaging the daily steps from the previous week and adding 750 until they reached a daily average of 12,000 steps, recommended for weight loss. Participants also received weekly encouragement regarding their weight change beginning at month 3. Participants received monthly e-newsletters with diet and PA informa tion from credible publicly available sources. They also had access to a website that provided health tips, recipes, food and PA logs, and a personal weight chart. No instruction on dietary composition was given other than USDA recommendations for a balanced diet."	
Control/Comparator	"The control group received the same monthly e-newsletters as the intervention group but they did not receive SMS, MMS, or have access to the intervention website."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 170 Intervention group/s: Intervention (n=81)	

<table>
<tr><td></td><td>Comparator group: Control (n=89)</td></tr>
<tr><td>Mean age ± SD</td><td>41.9Y (11.8)</td></tr>
<tr><td>Sex</td><td>65.29% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (lb)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 202
(37.9)

Intervention: 32.4
(4.2)</td><td>Control: 204.9
(39.5)

Control: 32
(4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (lb)
Mean (SD)</td><td>Intervention: -3.64
(12.01)</td><td>Control: -2.27
(9.39)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Text-messaging adherence was moderately strong (60-69%).</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Siegrist, 2013

Guideline record ID: 10659--1

Study characteristics		
Citation	Siegrist, M., Lammel, C., Haller, B., Christle, J., & Halle, M. (2013). Effects of a physical education program on physical activity, fitness, and health in children: the JuvenTUM project. Scandinavian Journal of Medicine & Science In Sports, 23(3), 323-330. https://doi.org/https://doi.org/10.1111/j.1600-0838.2011.01387.x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of a physical education program on physical activity, fitness, and health in children: The Juven TUM project	
Location	Germany	
Trial name	The JuvenTUM Project	
Methods		
Inclusion criteria	"Inclusion criteria were (1) attendance in the second or third grade and (2) written consent from parents."	
Exclusion criteria	Not reported	
Setting	School	
Intervention	"The program consisted of monthly lessons lasting 45 min with three parts: a warm-up of 10 min with running, playing running games at high intensity, 30 min exercises to improve body awareness and selfesteem with conversation in class about health-related topics, and 5 min relaxation exercises. Worksheets and homework assignments plus monthly newsletters intended to stimulate parent-child interaction and to support physical activity at home and in sports clubs. All materials were comprehensible and colorful to reach as many children and parents as possible and include individuals from a wide range of migration backgrounds and socioeconomic status. Parents participated in two training sessions in which they were given a program overview and practical instruction about health issues (3 h total). They were informed about the development and course of the intervention program, received health-related journals, participated in practical instruction based on increasing motivation to spend more time being active with their children, and were asked to improve health behaviors (e.g. making healthy food choices and less media consumption) with their family.Three teacher trainings (9 h total) were conducted with the objective of increasing their students' physical activity during lessons and breaks and improving physical education within their schools. All trainings contained practical instructions and included games for the classroom and playgrounds as well as for physical education lessons. Additionally, measures were taken to improve the quality of food sold at school snack bars and school stores as well as to arrange the classrooms, halls, and playgrounds in a way to promote more physical activity."	
Control/Comparator	"In the CS, principals were instructed to continue with school activities as usual, without changing policies related to physical activity or nutrition during the study period."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 724
Intervention group/s: IS (n=427)

Comparator group: CS (n=297)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>48.34% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI in overweight children
Mean (SD)

Waist circumference in overweight children
Mean (SD)

SDS-BMI in overweight children
Mean (SD)</td><td>IS: 23.2
(2.8)

IS: 77
(7.8)

IS: 1.96
(0.47)</td><td>CS: 23
(3)

CS: 75.3
(8)

CS: 1.86
(0.46)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI in overweight children
Mean (SD)

Waist circumference in overweight children
Mean (SD)

SDS-BMI in overweight children
Mean (SD)</td><td>IS: 24.2
(2.9)

IS: 76
(8)

IS: 1.93
(0.47)</td><td>CS: 24
(3.3)

CS: 77.4
(8.7)

CS: 1.82
(0.53)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Silva, 2010

Guideline record ID: 10859--1

Study characteristics		
Citation	Silva, M. N., Vieira, P. N., Coutinho, S. R., Minderico, C. S., Matos, M. G., Sardinha, L. B., & Teixeira, P. J. (2010). Using self-determination theory to promote physical activity and weight control: a randomized controlled trial in women. Journal of Behavioral Medicine, 33(2), 110-122. https://doi.org/10.1007/s10865-009-9239-y	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Using self-determination theory to promote physical activity and weight control: a randomized controlled trial in women	
Location	Portugal	
Trial name	Promotion of Exercise and Health in Obesity (PESO)	
Methods		
Inclusion criteria	"To be included in the study they were required to be female, between 25 and 50 years old, premenopausal, not pregnant, have a BMI between 25 and 40 kg/m2, be willing to attend weekly meetings (during 1 year) and be tested regularly (during 3 years), be free from major illnesses and not taking (or having taken in the previous year) medication known to interfere with body weight regulation, namely anti-depressive medication, and willing to not participate in any other formal or informal weight loss program during the first year of the study (intervention group only)."	
Exclusion criteria	Not reported	
Setting	Home, University/research centre	
Intervention	"Group 1: SDT basic tenets, covering PA, eating/nutrition, body image, and other cognitive and behavioral contents"	
Control/Comparator	"Group 2: (control) ''thematic courses'' such as healthy/preventive nutrition, stress management, self-care, and effective communication skills. The interpersonal climate promoted in this condition was similar to that commonly observed in standard health care settings: choices, rationale, and explanations were limited; specific behavioural goals were not set; minimal feedback was provided."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 239 Intervention group/s: Intervention (n=123) Comparator group: Control (n=116)	
Mean age ± SD	Intervention: 38.1y (7.04); Control: 37.1y (6.99)	
Sex	100.00% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline Weight (kg)
Mean (SD)

Baseline Body mass index (kg/m2)
Mean (SD)

Baseline Body fat (%)
Mean (SD)

Baseline Fat mass (kg)
Mean (SD)</td><td>Intervention: 82.1
(11.9)

Intervention: 31.7
(4.24)

Intervention: 43.7
(4.9)

Intervention: 36
(8.42)</td><td>Control: 81.5
(12.1)

Control: 31.3
(4)

Control: 44.1
(4.94)

Control: 36
(8.04)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in fat mass (kg)
Mean (SD)

Change in Percent body fat %
Mean (SD)

Change in BMI
Mean (SD)

Change in weight %
Mean (95% CIs)</td><td>Intervention: -5.6
(4.1)

Intervention: -6.9
(7.9)

Intervention: -2.3
(1.9)

Intervention: -7.29</td><td>Control: -1.5
(4.3)

Control: -2.5
(7.5)

Control: 0.7
(1.9)

Control: -1.74</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Silva, M. N., Markland, D., Carraça, E. V., Vieira, P. N., Coutinho, S. R., Minderico, C. S., Matos, M. G., Sardinha, L. B., & Teixeira, P. J. (2011). Exercise autonomous motivation predicts 3-yr weight loss in women. Medicine & Science in Sports & Exercise, 43(4), 728-737. https://doi.org/10.1249/MSS.0b013e3181f3818f</td></tr>
</table>

N/A – Not applicable

Silva, 2011

Guideline record ID: 10858--1

Study characteristics		
Citation	Silva, M. N., Markland, D., Carraça, E. V., Vieira, P. N., Coutinho, S. R., Minderico, C. S., Matos, M. G., Sardinha, L. B., & Teixeira, P. J. (2011). Exercise autonomous motivation predicts 3-yr weight loss in women. Medicine & Science in Sports & Exercise, 43(4), 728-737. https://doi.org/10.1249/MSS.0b013e3181f3818f	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Exercise Autonomous Motivation Predicts 3-yr Weight Loss in Women	
Location	Portugal	
Trial name	Promotion of Exercise and Health in Obesity (PESO)	
Methods		
Inclusion criteria	"Inclusion: female, between 25 and 50 yr old, premenopausal, have a body mass index (BMI) between 25 and 40 kglmj2, willing to attend weekly meetings (during 1 yr), free from major illnesses, and not taking medications known to interfere with body weight regulation."	
Exclusion criteria	Not reported	
Setting	University/research centre	
Intervention	"Intervention group: 30 sessions, targeted at increasing PA and energy expenditure, adopting a diet consistent with a moderate energy deficit, and integrating exercise and eating patterns that would support weight maintenance"	
Control/Comparator	"Control group: 29-session general health education curriculum (e.g., preventive nutrition, stress management, self-care, and effective communication skills)."	
Treatment duration	12 months	
Follow-up from baseline	36 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= Not reported Intervention group/s: Intervention (n=not reported) Comparator group: Control (n=not reported)	
Mean age ± SD	37.6y (7.0)	
Sex	Not reported	
Pre-existing medical condition	No pre-existing medical condition	
Results		
Outcome measure at baseline	Variable / Intervention arm/s / Comparator	

Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	% weight loss Mean (SD)	Intervention: -7.3% (5.9%)	Control: -1.70%
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	% weight loss Mean (SD)	Intervention: -3.9% (7.6%)	Control: -1.9 (7.4)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data	Silva, M. N., Vieira, P. N., Coutinho, S. R., Minderico, C. S., Matos, M. G., Sardinha, L. B., & Teixeira, P. J. (2010). Using self-determination theory to promote physical activity and weight control: a randomized controlled trial in women. Journal of Behavioral Medicine, 33(2), 110-122. https://doi.org/10.1007/s10865-009-9239-y		

N/A – Not applicable

Silva, 2022

Guideline record ID: 10857--1

Study characteristics		
Citation	Silva, A. M., Nunes, C. L., Jesus, F., Francisco, R., Matias, C. N., Cardoso, M., Santos, I., Carraça, E. V., Finlayson, G., Silva, M. N., Dickinson, S., Allison, D., Minderico, C. S., Martins, P., & Sardinha, L. B. (2022). Effectiveness of a lifestyle weight-loss intervention targeting inactive former elite athletes: the Champ4Life randomised controlled trial. British Journal of Sports Medicine, 56(7), 394-402. https://doi.org/https://dx.doi.org/10.1136/bjsports-2021-104212	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effectiveness of a lifestyle weight-loss intervention targeting inactive former elite athletes: the Champ4Life randomised controlled trial	
Location	Not reported	
Trial name	Champ4Life	
Methods		
Inclusion criteria	"(1) To be a former high-level athlete, aged 18-65 years old; (2) to be inactive (<30 min/day of moderate-intensity PA for at least 5 days per week or <20 min/day of vigorous PA intensity for at least 3 days per week); (3) to have a BMI ≥25 kg/m2 and (4) to be willing to attend the educational sessions at the study site and be ready to modify their diet and their PA habits to lose weight."	
Exclusion criteria	Not reported	
Setting	University/research centre	
Intervention	"Briefly, the IG attended an initial nutrition appointment presented by a certified dietitian to prompt a moderate caloric reduction (~300-500 kcal/day) and to provide a well-balanced personalised diet plan. Follow-up appointments were scheduled to adjust individual energy requirements. Additionally, IG completed 12 educational sessions throughout the 4 months of the intervention. These educational sessions addressed PA, weight management and nutrition."	
Control/Comparator	"Participants from the CG were placed on a waiting list to be offered the Champ4Life programme after they completed all measurements at the three time points: baseline (0 months) and after 4 and 12 months."	
Treatment duration	4 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 94 Intervention group/s: Intervention (n=49) Comparator group: Control (n=45)	
Mean age ± SD	42.4y (7.3)	
Sex	34.04% female	

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SE)

BMI (kg/m2)
Mean (SE)

Waist circumference (cm)
Mean (SE)

Fat mass (kg)
Mean (SE)

Fat mass (%)
Mean (SE)

Fat-free mass (kg)
Mean (SE)

Fat-free mass (%)
Mean (SE)</td><td>Intervention: 91.1
(0.4)

Intervention: 31
(0.2)

Intervention: 103.1
(0.6)

Intervention: 29.6
(0.4)

Intervention: 33.1
(0.3)

Intervention: 60.2
(0.2)

Intervention: 65.9
(0.3)</td><td>Control: 91.2
(0.5)

Control: 31
(0.2)

Control: 103.2
(0.6)

Control: 29.7
(0.4)

Control: 33.1
(0.3)

Control: 60.2
(0.2)

Control: 66
(0.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SE)

BMI (kg/m2)
Mean (SE)

Waist circumference (cm)
Mean (SE)

Fat mass (kg)
Mean (SE)

Fat mass (%)
Mean (SE)

Fat-free mass (kg)
Mean (SE)

Fat-free mass (%)
Mean (SE)</td><td>Intervention: 86.8
(0.5)

Intervention: 29.5
(0.2)

Intervention: 99.5
(0.7)

Intervention: 26.6
(0.4)

Intervention: 30.9
(0.3)

Intervention: 59.1
(0.2)

Intervention: 68.2
(0.3)</td><td>Control: 92.2
(0.5)

Control: 31.2
(0.2)

Control: 104.9
(0.7)

Control: 30.7
(0.4)

Control: 33.9
(0.3)

Control: 59.7
(0.3)

Control: 66.5
(0.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
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<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
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Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Simonson, 2018

Guideline record ID: 10860--1

Study characteristics		
Citation	Simonson, D. C., Halperin, F., Foster, K., Vernon, A., & Goldfine, A. B. (2018). Clinical and patient-centered outcomes in obese patients with type 2 diabetes 3 years after randomization to Roux-en-Y gastric bypass surgery versus intensive lifestyle management: the SLIMM-T2D study. Diabetes Care, 41(4), 670-679. https://doi.org/10.2337/dc17-0487	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Clinical and Patient-Centered Outcomes in Obese Patients With Type 2 Diabetes 3 Years After Randomization to Roux-en-Y Gastric Bypass Surgery Versus Intensive Lifestyle Management: The SLIMM-T2D Study	
Location	UK	
Trial name	Surgery or Lifestyle With Intensive Medical Management in the Treatment of Type 2 Diabetes (SLIMM-T2D)	
Methods		
Inclusion criteria	"Major eligibility criteria included: 1) age 21-65 years for male or female sex; 2) diagnosis of type 2 diabetes for at least 1 year; 3) BMI of 30-42 kg/m2 ; 4) HbA1c >7.0% (53 mmol/mol) regardless of ongoing treatment, or >6.5% (48 mmol/mol) while receiving either two oral antihyperglycemic agents, at greater than or equal to half-maximal dose, or insulin, with a stable medication regimen for .8 weeks; and 5) no clinical or symptomatic evidence of significant cardiovascular or other diseases prohibiting safely exercising or undergoing a RYGB."	
Exclusion criteria	"Individuals were excluded if they had detectable levels of anti-GAD antibodies, a history of diabetic ketoacidosis, uncontrolled type 2 diabetes (HbA1c .12% [.108 mmol/mol]), gastrointestinal disease, malignant disease within 5 years, significant cardiopulmonary or renal disease, an active eating disorder, impaired mental status, weight loss .3% within the previous 3 months, abused drugs/ alcohol, participated in another weight-reduction program, or were using weight reducing medications and/or supplements. Participants had to be nonsmoking for 2 months. Patients with a preference for a bariat ric procedure other than RYGB were not enrolled."	
Setting	Hospital	
Intervention	"The RYGB procedure was performed at Brigham and Women's Hospital using standard operative protocols"	
Control/Comparator	"Participants randomized to the medical arm of the study enrolled in the Why WAIT (Weight Achievement and Intensive Treatment) program, which is designed for clinical practice and conducted quar terly at the Joslin Diabetes Center for groups of 10-15 patients. Two-hour group sessions are conducted weekly during a 12-week initiation phase in which patients receive individual med ication adjustments and participate in supervised group exercise and didactic sessions. Key aspects of Why WAIT in clude weekly medication adjustments; structured modified dietary intervention with a hypocaloric (1,500-1,800 kcal) diet; up to 300 min/week of graded, bal anced, and individualized exercise with emphasis on strength training; cognitive behavioral therapy; and group education. Antidiabetes medications were adjusted according to an algorithm designed to re duce or eliminate medications known to be associated with weight gain or hypo glycemia while initiating or increasing doses of medications that are weight neu tral (10,13). None of the patients received anti-obesity medications during the study. A maintenance phase of individual monthly counseling is provided for the next 9 months, for a total intervention period of 1 year."	

<table>
<tr><td>Treatment duration</td><td>surgical/12 month intensive medical weight loss intervention</td></tr>
<tr><td>Follow-up from baseline</td><td>3 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 38
Intervention group/s: Roux-en-Y gastric bypass (RYGB) (n=19)

Comparator group: Intensive medical diabetes and weight management (IMWM) (n=19)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 50.7y (7.6); Control: 52.6y (4.3)</td></tr>
<tr><td>Sex</td><td>60.53% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 Diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline weight (kg)
Mean (SD)</td><td>Roux-en-Y gastric bypass (RYGB): 104.6
(15.5)</td><td>Intensive medical diabetes and weight management (IMWM): 102.7
(17)</td></tr>
<tr><td>Baseline BMI (kg/m2)
Mean (SD)</td><td>Roux-en-Y gastric bypass (RYGB): 36
(3.5)</td><td>Intensive medical diabetes and weight management (IMWM): 36.5
(3.4)</td></tr>
<tr><td>Baseline Waist Circumference (cm)
Mean (SD)</td><td>Roux-en-Y gastric bypass (RYGB): 117.8
(14.9)</td><td>Intensive medical diabetes and weight management (IMWM): 114.1
(12.2)</td></tr>
</table>
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<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (95% CIs)</td><td>Roux-en-Y gastric bypass (RYGB): -27.9
(-30.2--25.6)</td><td>Intensive medical diabetes and weight management (IMWM): -6.9
(-9.3--4.6)</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (95% CIs)</td><td>Roux-en-Y gastric bypass (RYGB): -9.7
(-10.5--8.8)</td><td>Intensive medical diabetes and weight management (IMWM): -2.3
(-3.1--1.4)</td></tr>
<tr><td>Change in Waist Circumference (cm)
Mean (95% CIs)</td><td>Roux-en-Y gastric bypass (RYGB): -26.9
(-30.5--23.4)</td><td>Intensive medical diabetes and weight management (IMWM): -6.4
(-10.1--2.6)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
</table>
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</table>

	Change in weight (kg) Mean (95% CIs)	Roux-en-Y gastric bypass (RYGB): -24.9 (-29.5--20.4)	Intensive medical diabetes and weight management (IMWM): -5.2 (-10.3--0.2)
	Change in BMI (kg/m2) Mean (95% CIs)	Roux-en-Y gastric bypass (RYGB): -8.7 (-10.3--7.1)	Intensive medical diabetes and weight management (IMWM): -1.8 (-3.5-0)
	Change in Waist Circumference (cm) Mean (95% CIs)	Roux-en-Y gastric bypass (RYGB): -24.8 (-31--18.6)	Intensive medical diabetes and weight management (IMWM): -1 (-8.2-6.2)
Compliance with treatment	Intervention group: surgical		
Notes			
Additional included publications arising from this study that did not contribute additional data	Simonson, D. C., Vernon, A., Foster, K., Halperin, F., Patti, M. E., & Goldfine, A. B. (2019). Adjustable gastric band surgery or medical management in patients with type 2 diabetes and obesity: three-year results of a randomized trial. Surgery for Obesity and Related Diseases, 15(12), 2052-2059. https://doi.org/https://dx.doi.org/10.1016/j.soard.2019.03.038		

N/A – Not applicable

Simonson, 2019

Guideline record ID: 10861--1

Study characteristics		
Citation	Simonson, D. C., Vernon, A., Foster, K., Halperin, F., Patti, M. E., & Goldfine, A. B. (2019). Adjustable gastric band surgery or medical management in patients with type 2 diabetes and obesity: three-year results of a randomized trial. Surgery for Obesity and Related Diseases, 15(12), 2052-2059. https://doi.org/https://dx.doi.org/10.1016/j.soard.2019.03.038	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Adjustable gastric band surgery or medical management in patients with type 2 diabetes and obesity: three-year results of a randomized trial	
Location	UK	
Trial name	Surgery or Lifestyle with Intensive Medical Management in the Treatment of Type 2 Diabetes (SLIMM-T2D)	
Methods		
Inclusion criteria	"Inclusion Criteria: Potential participants will be those with T2DM, with a diagnosis of diabetes of at least one year in duration, BMI 30-45 kg/m^2 for the LAGB compared to intensive medical weight and diabetes management and BMI 30-42 kg/m^2 for LRYGB compared to intensive medical weight and diabetes management, Age 21-65 years, With a strong desire for substantial weight loss, who are free from active cardiovascular or other diseases that would render them unable to partake in a structured exercise program or to undergo a bariatric surgical procedure, and who are committed to life long medical and nutritional follow up."	
Exclusion criteria	"Exclusion Criteria: Detectable levels of glutamic acid decarboxylase (GAD) antibody or a history of diabetic ketoacidosis or uncontrolled T2DM (consistent fasting blood glucose >200 mg/dl or HbA1c above twice normal); Previous gastrointestinal surgery, inflammatory bowel disease, esophageal diseases including severe intractable esophagitis, Barrett's Disease, esophageal dysmotility or other impaired gastric motility (gastroparesis), or hiatal hernia >3 cm in size, chronic or acute bleeding conditions including peptic ulcer disease, portal hypertension (gastric or esophageal varices), chronic pancreatitis, or cirrhosis of the liver; Malignant or debilitating medical conditions, severe cardiopulmonary disease including uncontrolled hypertension (repeated systolic measures >160 or diastolic > 95 mm Hg on more than one day), unstable angina pectoris, recent myocardial infarction within 6 months, history of coronary artery bypass surgery or angioplasty, congestive heart failure, arrhythmia, stroke or transient ischemic attacks, urinary albumin excretion >300 mcg/mg creatinine and/or serum creatinine >1.5 mg/dL (permitting safety of increased dietary protein intake), Any endocrine disorder other than T2DM or thyroid disease which is stable on replacement therapy, including Cushing's syndrome; Any previous history of eating disorders, history of drug and/or alcohol abuse within 2 years of the screening visit, history of impaired mental status as defined by Diagnostic and Statistical Manual, 4th Edition (DSM-4) criteria and including, but not limited to active substance abuse, a history of schizophrenia, borderline personality disorder, uncontrolled depression, suicidal attempts within the past two years or current suicidal tendencies or ideations. Subjects will be excluded if there is a history of significant weight loss (>3%) within the previous 3 months or participation in alternate medically supervised exercise or weight reduction program within the previous 3 months, or with use of prescription or over the counter weight reduction medications or supplements within one month of the Screening Visit and for the duration of study participation. Women who are lactating, planning pregnancy, or unwilling to use contraception during the course of the trial."	
Setting	Hospital	

<table>
<tr><td>Intervention</td><td>“LAGB was performed at Brigham and Women's Hospital using standard operative procedures”</td></tr>
<tr><td>Control/Comparator</td><td>“Participants randomized to DWM enrolled in the "Why WAIT" (Weight Achievement and Intensive Treatment) program designed for clinical practice at the Joslin Diabetes Center. Why WAIT's cognitive behavioral support is based on the Diabetes Prevention Program and LookAHEAD studies but differs by medication adjustment, amount of caloric reduction, dietary composition, exercise type and duration, and group education. The program includes weekly 2-hour group support or didactic method and supervised exercise sessions over 12 weeks (initiation phase), followed by 9 months with individual monthly counseling (maintenance phase).”</td></tr>
<tr><td>Treatment duration</td><td>surgical/12 month DWM intervention</td></tr>
<tr><td>Follow-up from baseline</td><td>3 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 40
Intervention group/s: Laparoscopic adjustable gastric band (LAGB) (n=18)

Comparator group: Diabetes and weight management (DWM) program (n=22)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention (LAGB): 51.0y (12.7); Control (DWM): 51.6y (7.5)</td></tr>
<tr><td>Sex</td><td>45.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline Weight (kg)
Mean (SD)</td><td>Laparoscopic adjustable gastric band (LAGB): 106.8 (10.4)</td><td>Diabetes and weight management (DWM) program: 111.6 (17.9)</td></tr>
<tr><td>Baseline BMI (kg/m2)
Mean (SD)</td><td>Laparoscopic adjustable gastric band (LAGB): 36.4 (3)</td><td>Diabetes and weight management (DWM) program: 36.7 (4.2)</td></tr>
<tr><td>Baseline Waist Circumference (cm)
Mean (SD)</td><td>Laparoscopic adjustable gastric band (LAGB): 115.9 (7.1)</td><td>Diabetes and weight management (DWM) program: 114.4 (9.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Weight (kg)
Mean (95% CIs)</td><td>Laparoscopic adjustable gastric band (LAGB): -13.5 (-16--11)</td><td>Diabetes and weight management (DWM) program: -8.4 (-10.7--6)</td></tr>
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</table>

	Change in BMI (kg/m2) Mean (95% CIs)	Laparoscopic adjustable gastric band (LAGB): -4.6 (-5.4--3.7)	Diabetes and weight management (DWM) program: -2.7 (-3.5--1.9)
	Change in Excess weight loss (%) from baseline Mean (95% CIs)	Laparoscopic adjustable gastric band (LAGB): -41.9 (-50.6--33.3)	Diabetes and weight management (DWM) program: -25.6 (-33.7--17.6)
	Change in Waist Circumference (cm) from baseline Mean (95% CIs)	Laparoscopic adjustable gastric band (LAGB): -8.8 (-12.1)	Diabetes and weight management (DWM) program: -8 (-11.3--4.7)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in Weight (kg) Mean (95% CIs)	Laparoscopic adjustable gastric band (LAGB): -12 (-15.9--8.1)	Diabetes and weight management (DWM) program: -4.8 (-8.6--0.9)
	Change in BMI (kg/m2) Mean (95% CIs)	Laparoscopic adjustable gastric band (LAGB): -3.9 (-5.2--2.6)	Diabetes and weight management (DWM) program: -1.7 (-3--0.4)
	Change in Excess weight loss (%) from baseline Mean (95% CIs)	Laparoscopic adjustable gastric band (LAGB): -38.2 (-52--24.4)	Diabetes and weight management (DWM) program: -17.8 (-31.4--4.2)
	Change in Waist Circumference (cm) from baseline Mean (95% CIs)	Laparoscopic adjustable gastric band (LAGB): -8.8 (-13.6--3.9)	Diabetes and weight management (DWM) program: -3.4 (-8.3-1.4)
Compliance with treatment	surgical		
Notes			
Additional included publications arising from this study that did not contribute additional data	Simonson, D. C., Halperin, F., Foster, K., Vernon, A., & Goldfine, A. B. (2018). Clinical and patient-centered outcomes in obese patients with type 2 diabetes 3 years after randomization to Roux-en-Y gastric bypass surgery versus intensive lifestyle management: the SLIMM-T2D study. Diabetes Care, 41(4), 670-679. https://doi.org/10.2337/dc17-0487		

N/A – Not applicable

Simpson, 2015

Guideline record ID: 10863--1

Study characteristics		
Citation	Simpson, S. A., McNamara, R., Shaw, C., Kelson, M., Moriarty, Y., Randell, E., Cohen, D., Alam, M. F., Copeland, L., Duncan, D., Espinasse, A., Gillespie, D., Hill, A., Owen-Jones, E., Tapper, K., Townson, J., Williams, S., & Hood, K. (2015). A feasibility randomised controlled trial of a motivational interviewing-based intervention for weight loss maintenance in adults. Health Technology Assessment, 19(50). https://doi.org/https://dx.doi.org/10.3310/hta19500	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A feasibility randomised controlled trial of a motivational interviewing-based intervention for weight loss maintenance in adults	
Location	UK	
Trial name	N/A	
Methods		
Inclusion criteria	"Adults aged 18-70 years with a current or previous BMI of ≥ 30 kg/m2 were eligible for inclusion if they had intentionally lost at least 5% body weight (by pharmacological, lifestyle and/or behavioural methods) during the previous 12 months and this weight loss had been independently verified."	
Exclusion criteria	"Exclusion criteria were factors rendering potential participants unable to comply with the protocol, such as previous bariatric surgery (unless fully reversed, e.g. by removal of a gastric balloon), terminal illness, poor competence in English (i.e. inability to complete study materials), living with another study participant or, in the case of women, pregnancy (note: women who became pregnant after recruitment were not excluded, but given a leaflet on exercising safely during pregnancy)."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Group 1: Participants in the intensive intervention group had six one-to-one individually tailored MI sessions. Sessions were delivered by experienced MIPs and were delivered approximately fortnightly for 3 months, lasting around 1 hour. For the final 9 months of the intervention participants received monthly MI telephone calls lasting approximately 20 minutes. Group 2: Participants in the less intensive intervention group received two face-to-face tailored MI sessions 2 weeks apart. Participants also received two MI-based telephone calls at 6 and 12 months lasting around 20 minutes. MI topics comprised self-monitoring, goal-setting and implementation intentions, habits, emotional eating and coping with relapse, diet, physical activity, barriers to maintenance, social support and self-efficacy. Diet and physical activity were discussed in the MI sessions in line with current government guidance. Participants were encouraged to reflect on their values, goals and current behaviour and to develop their own goals and techniques for implementing and maintaining behaviours. Participants in the intervention groups were encouraged by researchers at their baseline assessments to self-monitor by weighing themselves weekly and MIPs encouraged the concept of self-monitoring generally. Participants were able to record all self-monitoring activity, including diet, physical activity, other markers of successful maintenance (e.g. clothes fitting better), goals set at sessions and implementation intentions, in a diary provided by the study team (paper-based and brief online version); however, completion was optional. Diaries provided to participants were intended for their personal use only and were not collected by the study team for outcome assessment. However, participants were asked to record their weekly weight and send this information to the study team via the study website or by text, e-mail or telephone. Participants in both the intensive and the less intensive arms had the opportunity to attend four professional-led peer group support sessions which were planned to occur monthly	

<table>
<tr><td></td><td>lasting 1.5 hours for 4 months and following on from face-to-face MI sessions. The group sessions were to be led by a facilitator with the aim of providing participants with the opportunity to share problems, techniques and tips with peers. The sessions were designed around four themes: (1) barriers to maintenance, emotional eating and coping with relapse, (2) diet, (3) physical activity and (4) intervention-related tasks and activities such as self-monitoring, goal-setting and implementation intentions, social support and habit formation."</td></tr>
<tr><td>Control/Comparator</td><td>"Group 3: control arm received a leaflet advising them on healthy lifestyle."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 166
Intervention group/s: Intensive Intervention (n=54); Less Intensive Intervention (n=54)

Comparator group: Control (n=58)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>84.34% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intensive Intervention: 34.4
(6.19)
Less Intensive Intervention:
34.8
(6.2)</td><td>Control: 33.3
(5.19)</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intensive Intervention: 92.5
(20.02)
Less Intensive Intervention:
93.8
(17.66)</td><td>Control: 90.2
(15.41)</td></tr>
<tr><td>Waist circumference
Mean (SD)</td><td>Intensive Intervention: 104.3
(15.51)
Less Intensive Intervention:
105.4
(14.1)</td><td>Control: 102.5
(11.96)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intensive Intervention: 33.3
(6.5)
Less Intensive Intervention:
33.4
(6.03)</td><td>Control: 33
(5.22)</td></tr>
<tr><td>Augmented BMI at 12 months
Mean (SD)</td><td>Intensive Intervention: 33.3
(6.5)
Less Intensive Intervention:
34.1
(6.22)</td><td>Control: 33
(5.39)</td></tr>
</table>
</td></tr>
</table>

	Weight (kg) Mean (SD) Augmented Weight at 12 months Mean (SD) Waist circumference Mean (SD)	Intensive Intervention: 90.1 (21) Less Intensive Intervention: 91.6 (17.19) Intensive Intervention: 90.1 (21) Less Intensive Intervention: 94.3 (19.97) Intensive Intervention: 102.8 (16.33) Less Intensive Intervention: 103.2 (13.56)	Control: 89.6 (17.21) Control: 90.1 (17.28) Control: 102.7 (14.63)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	87%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Slater, 2022

Guideline record ID: 10661--1

Study characteristics		
Citation	Slater, S., Lambkin, D., Schumacher, T., Williams, A., & Baillie, J. (2022). Testing the effectiveness of a novel, evidence-based weight management and lifestyle modification programme in primary care: the Healthy Weight Initiative. Journal of Primary Health Care, 14(1), 64-73. https://doi.org/https://doi.org/10.1071/HC21065	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Testing the effectiveness of a novel, evidence-based weight management and lifestyle modification programme in primary care: the Healthy Weight Initiative	
Location	Australia	
Trial name	The Healthy Weight Initiative	
Methods		
Inclusion criteria	"Inclusion criteria reflected the study's prevention-focussed hypothesis and were: understanding conversational English; aged 18-65 years; body mass index (BMI) ≥ 25, without a diagnosed pre-existing chronic disease (heart disease, diabetes, cancer and stroke); no history of eating disorders; not currently pregnant or breast feeding."	
Exclusion criteria	Not reported	
Setting	GP clinic	
Intervention	"Both arms received the same week 1 (baseline), week 12 and evaluation assessments and programme resources. The HI arm had 10 additional weekly measurements, evidenced-based education and support sessions on healthy eating, physical activity and lifestyle modification. Programme delivery items for high-intensity trial arms included: Initial assessment; Lifestyle and motivation; Nutrition - Where Are You Now?; Physical Activity and Lifestyle; Nutrition - Making the Right Choices; Progress Review 1; Move More, Sit Less; Nutrition - Portion Control; Progress - Your Physical Activity; Progress Review 2; Managing Setbacks; Final assessment - Celebrate Your Success. The Healthy Weight Initiative programme baseline, final and evaluation health assessments included nutritional and physical activity level assessments, mental health screening using the DASS-21, eating behaviour assessment using the Three Factor Eating questionnaire-R18 and patient goal setting (healthy eating, physical activity and lifestyle choices) focussing on improvement rather than meeting the Australian Guideline for healthy eating and physical activity goals"	
Control/Comparator	"Both arms received the same week 1 (baseline), week 12 and evaluation assessments and programme resources. . The Healthy Weight Initiative programme baseline, final and evaluation health assessments included nutritional and physical activity level assessments, mental health screening using the DASS-21, eating behaviour assessment using the Three Factor Eating questionnaire-R18 and patient goal setting (healthy eating, physical activity and lifestyle choices) focussing on improvement rather than meeting the Australian Guideline for healthy eating and physical activity goals."	
Treatment duration	12 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 695
Intervention group/s: HI (n=390)

Comparator group: LI (n=305)</td></tr>
<tr><td>Mean age ± SD</td><td>45.6y (12.6)</td></tr>
<tr><td>Sex</td><td>78.71% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>HI: 98.7
(19.7)

HI: 35.4
(6.4)

HI: 107.7
(14.1)</td><td>LI: 98.7
(19.3)

LI: 35.5
(5.9)

LI: 108.1
(14.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>HI: 95.3
(19.7)

HI: 34.3
(6.4)

HI: 104.2
(14.2)</td><td>LI: 97.8
(22.2)

LI: 35.4
(7)

LI: 107.2
(16.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)

Change in waist circumference (cm)
Mean (SD)</td><td>HI: -3.4

HI: -3.5</td><td>LI: -0.9

LI: -0.9</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Smith, 2021

Guideline record ID: 10662--1

Study characteristics		
Citation	Smith, J. D., Berkel, C., Carroll, A. J., Fu, E., Grimm, K. J., Mauricio, A. M., Rudo-Stern, J., Winslow, E., Dishion, T. J., Jordan, N., Atkins, D. C., Narayanan, S. S., Gallo, C., Bruening, M. M., Wilson, C., Lokey, F., & Samaddar, K. (2021). Health behaviour outcomes of a family based intervention for paediatric obesity in primary care: a randomized type II hybrid effectiveness-implementation trial. Pediatric Obesity, 16(9), e12780. https://doi.org/https://dx.doi.org/10.1111/ijpo.12780	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Health behaviour outcomes of a family based intervention for paediatric obesity in primary care: A randomized type II hybrid effectiveness-implementation trial	
Location	US	
Trial name	Family Check-Up 4 Health (FCU4Health)	
Methods		
Inclusion criteria	"Inclusion criteria were child age 6 to 12 years and elevated BMI (≥85th percentile for age and gender) to align with USPSTF guidelines,24 (changed to age 5.5 due to enrollment rate challenges and lag between referral and completion of consent/assent and baseline assessment) and a consenting English or Spanish speaking caregiver."	
Exclusion criteria	"No additional exclusion criteria were used to increase acceptability to referrers and external validity."	
Setting	GP clinic, Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Families in the intervention condition were invited to participate in the FCU4Health in addition to receiving usual care through their clinic. The Family Check-Up 4 Health (FCU4Health) focuses on building motivation and providing tailored support to promote children's health. FCU4Health involves a family assessment, feedback and motivation session and individually tailored treatment plan comprised of parenting skill sessions and referrals to services in the community to address the participation and retention challenges that plague obesity interventions. The FCU4Health explicitly provides parents with the skills and support to implement the recommended diet, physical activity and family health routine changes. The baseline, 3-, and 6-month assessments were each followed by a feedback session, conducted by a trained FCU4Health coordinator, and tailored follow-up sessions, focused on parenting skill development, and care coordination to connect families with community-based services. The first feedback discussed caregiver perception of needs, their child's health and health behaviours, the caregivers' motivation to change, and community referrals. The 3- and 6-month feedbacks additionally focused on family progress and problem-solving barriers. Coordinators also conducted phone-based coaching, based on the needs of families and schedule of in-person visits, to maintain contact with the family, problem-solving challenges and reinforce positive changes. In accordance with USPSTF guidelines, the FCU4Health was delivered over a 6-month period with a targeted dosage of 26-50 hours of support. However, given that this is an individually tailored intervention, the dose was highly variable based on family needs (range = 1.40 to 719.20 hours, M = 53.79 hours, SD = 98.61 of total intervention hours including FCU4Health and community services, such as organized physical activity and cooking classes)."	
Control/Comparator	"Families randomized to the services-as-usual arm received information about the same community resources offered to families in the FCU4Health arm. They also continued to receive usual care from their providers with frequency of visits determined by BMI classification and progress toward weight management goals."	

<table>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 240
Intervention group/s: FCU4Health (n=141)

Comparator group: Control (n=99)</td></tr>
<tr><td>Mean age ± SD</td><td>9.5y (2.0)</td></tr>
<tr><td>Sex</td><td>49.17% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)

BMI z-score
Mean (SD)</td><td>FCU4Health: 25.77
(5.04)

FCU4Health: 2.34
(1.5)</td><td>Control: 25.31
(5.37)

Control: 2.05
(1.27)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)

BMI z-score
Mean (SD)</td><td>FCU4Health: 26.92
(5.59)

FCU4Health: 2.24
(1.45)</td><td>Control: 26.72
(5.75)

Control: 1.96
(1.78)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Sniehotta, 2019

Guideline record ID: 10663--1

Study characteristics		
Citation	Sniehotta, F. F., Evans, E. H., Sainsbury, K., Adamson, A., Batterham, A., Becker, F., Brown, H., Dombrowski, S. U., Jackson, D., Howell, D., Ladha, K., McColl, E., Olivier, P., Rothman, A. J., Steel, A., Vale, L., Vieira, R., White, M., Wright, P., & Araújo-Soares, V. (2019). Behavioural intervention for weight loss maintenance versus standard weight advice in adults with obesity: a randomised controlled trial in the UK (NULevel Trial). PLOS Medicine, 16(5), e1002793. https://doi.org/10.1371/journal.pmed.1002793	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Behavioural intervention for weight loss maintenance versus standard weight advice in adults with obesity: A randomised controlled trial in the UK (NULevel Trial)	
Location	UK	
Trial name	NULevel	
Methods		
Inclusion criteria	"Individuals were eligible to take part if they were aged ≥18 years, had a body mass index (BMI) of ≥30 kg/m2 in the 24 months preceding trial entry (≥28 kg/m2 for individuals of South Asian descent), and had lost ≥5% body weight in the 12 months preceding trial entry. Individuals were requested to provide written verification of weight loss from a physician, weight loss counsellor, or friend or family member; if this was unavailable, then participants self-certified their weight loss. To participate, individuals needed to be able to use a standing scale, to be willing and able to attend study visits at Newcastle University, and to have use of an internet-enabled mobile telephone."	
Exclusion criteria	"Individuals were ineligible to take part if they had lost weight through illness or surgical procedures or were pregnant, planning to become pregnant during the study period, or breastfeeding an infant <6 months old. Other exclusion criteria were current involvement in other weight research studies, an inability to understand written or spoken English, a diagnosis of an eating disorder or condition that significantly limited physical activity, a baseline weight of >175 kg (due to capacity limitations of the study scales), and plans to leave the geographical area for a prolonged time during the study period."	
Setting	Home, University/research centre	
Intervention	"We used phone-based mobile internet technology to help participants monitor their weight, set behavioural goals, track goal progress, and plan for risk factors for regain and to provide feedback and reinforcement, drawing on effective behavioural principles. The intervention was delivered using the combination of a single face-to-face meeting with an intervention team member and regular automated short message service (SMS) (at least 1 every 2 days) with embedded links and other content (triggered by participants' weight and weekly online-questionnaire data), along with personalised SMS generated by the intervention team. Individual telephone calls with a member of the research team could be scheduled on participant request.Intervention participants were encouraged to weigh themselves daily and use the online study portal to monitor their weight on a graph showing the weight data sent by their scales. When the intervention software detected weight changes, the online study interface sent participants automated feedback via SMS. Participants met a research team member (psychologist) once, for around an hour, to learn about the intervention and receive support to set and plan for behavioural goals (diet and physical activity), plan for relapse prevention, and to learn how to self-monitor their diet, physical activity, and weight in the transition from weight loss to WLM. Participants were given a pedometer (Omron UK Ltd, Milton Keynes, UK) and prompted to record their progress towards physical activity goals (step counts) and dietary goals in a weekly diary on	

<table>
<tr><td></td><td>the study interface. When data were entered, automated feedback on behavioural goal progress was sent by the online study interface via SMS”</td></tr>
<tr><td>Control/Comparator</td><td>“Participants in the control arm did not receive any instructions regarding frequency of use for the study scales although they were made aware, for ethical reasons, that the study team could see their weight data. Content was drawn from the NHS Choices website (www.nhs.uk/livewell) and included information on healthy food swaps, 100-calorie snacks, healthy breakfasts, and how to read nutritional labels. Other than to arrange follow-up assessment, no further scheduled contact with the control group occurred.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 288
Intervention group/s: Intervention (n=144)

Comparator group: Control (n=144)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 42.0y (11.6); Control: 41.6y (11.4)</td></tr>
<tr><td>Sex</td><td>77.43% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight
Mean (SD)</td><td>Intervention: 85.6
(17.5)</td><td>Control: 85.5
(15.9)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight
Mean (SD)</td><td>Intervention: 86.8
(18.2)</td><td>Control: 87
(16.7)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Spence, 2023

Guideline record ID: 10950--1

Study characteristics		
Citation	Spence, N. D., Newton, A. S., Keaschuk, R. A., Ambler, K. A., Holt, N. L., Jetha, M. M., Mushquash, A. R., Rosychuk, R. J., Sharma, A. M., Spence, J. C., & Ball, G. D. C. (2023). Parents as agents of change in managing pediatric obesity: a randomized controlled trial comparing cognitive behavioral therapy versus psychoeducation interventions. Childhood Obesity, 19(2), 71-87. https://doi.org/https://doi.org/10.1089/chi.2021.0194	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Parents as Agents of Change in Managing Pediatric Obesity: A Randomized Controlled Trial Comparing Cognitive Behavioral Therapy versus Psychoeducation Interventions	
Location	Canada	
Trial name	Parents as Agents of Change in Pediatric Weight Management (PAC)	
Methods		
Inclusion criteria	"8-12 years old with an age- and sex-specific BMI ǂ85th per centile,20 and at least one parent had to agree to participate. Families also needed to be fluent in English (verbal and written). No children in the study had underlying medical conditions or were taking medications that could impact weight change."	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"The CBT intervention (16 group sessions over 16 weeks) focused on the role that cognitive processes play in the maintenance of problem behaviours, mood states, and habits. This intervention emphasized the relationship between thoughts, feelings, and actions, and utilized techniques involving motivation, goal setting, problem-solving, and knowledge/skill acquisition to facilitate sustainable behaviour changes. The skills learned were designed for parents to identify and change the parenting mechanisms that influence children's unhealthy lifestyle habits."	
Control/Comparator	"The PEP intervention (16 group sessions over 16 weeks) was a knowledge-based intervention modelled after traditional nutrition and health education programs. It was a more passive intervention, with limited focus on active skill building. Active integration of learned concepts in goal setting and linking cognitions and behaviours to lifestyle changes was not emphasized. PEP was not a true control group, but its content and delivery were consistent with what many clinicians provide for standard weight management."	
Treatment duration	4 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 52 Intervention group/s: CBT (n=27) Comparator group: PEP (n=25)	
Mean age ± SD	9.8y (1.7)	
Sex	51.92% female	

<table>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline Weight (kg)
Mean (SD)

Baseline BMIz
Mean (SD)</td><td>CBT: 61.5
(15.5)

CBT: 2.3
(0.3)</td><td>PEP: 62.9
(16.1)

PEP: 2.2
(0.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in BMIz score
Mean (95% Cis)</td><td>CBT: 0.00
(-0.17-0.17)</td><td>PEP: -0.14
(-0.33-0.05)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Spring, 2013

Guideline record ID: 10665--1

Study characteristics		
Citation	Spring, B., Duncan, J. M., Janke, E. A., Kozak, A. T., McFadden, H. G., DeMott, A., Pictor, A., Epstein, L. H., Siddique, J., Pellegrini, C. A., Buscemi, J., & Hedeker, D. (2013). Integrating technology into standard weight loss treatment: a randomized controlled trial. JAMA Internal Medicine, 173(2), 105-111. https://doi.org/10.1001/jamainternmed.2013.1221	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Integrating technology into standard weight loss treatment: a randomized controlled trial	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria included a body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) between 25 and 40, weight less than 181.4 kg, and being able to participate in moderate-intensity physical activity."	
Exclusion criteria	"Recent psychiatric hospitalization, current substance abuse, binge eating disorder, or a severe mood disorder were exclusion criteria."	
Setting	Hospital, Mobile personal digital assistant (PDA)	
Intervention	"All participants completed a technology fluency assessment and received a brief (15-minute) training session on how to use a personal digital assistant (PDA) to record food intake, weight, and physical activity. They were loaned a PDA for 2 weeks and asked to upload their data daily. Those who entered their weight and recorded 2 or more meals (with 2 items per meal) per day for at least 7 days underwent an equipoise induction, which detailed the procedures and highlighted the pros and cons of both groups to equalize their desirability and prevent dropout after randomization. Participants were then randomly assigned either to standard-of-care group treatment alone (Standard group) or to the standard plus connective mobile technology system (Mobile group). Participants assigned to the mobile group retained the PDA. During months 1 through 6, both groups attended biweekly MOVE!sessions led by dieticians, psychologists, or physicians. Each session lasted approximately 11⁄2 hours and included discussion of nutrition, physical activity, and behavior change.21 Participants were given a 5% to 10% weight loss goal. They were weighed at each session and encouraged to self-monitor, but personalized feedback was not provided. For participants assigned to the mobile group, a goal feedback thermometer on the PDA was activated at the start of the intervention phase. By recording their foods throughout the day, the thermometer was automatically updated with current caloric intake, and participants used the PDA as a decision support tool to self-regulate energy intake. Participants uploaded their data every day for the first 2 weeks of the intervention and once per week thereafter until the end of month 6. After the first month of treatment, the coach introduced physical activity goals and activated a second goal feedback thermometer to depict progress toward a daily physical activity goal. During the 6-month intervention phase, a paraprofessional coach telephoned participants every 2 weeks to provide 10 to 15 minutes of individualized guidance based on the uploaded data and monitored the uploads to respond to technical difficulties. Calorie goals were tailored according to the participant's baseline weight; activity goals were calculated using current activity level. Progress through the treatment algorithm was mastery based (triggered by accomplishment of each prior goal). If, after meeting calorie goals, participants did not lose weight for 2 consecutive weeks, they were instructed to reduce calories in 100-kcal increments until they reached a calorie intake level that yielded a weight loss rate of 0.5% to 1% of their current weight per week. For safety, no participant was given an intake goal below 1200 kcal/d. Conversely, if the rate of weight loss was too rapid (operationalized as	

<table>
<tr><td></td><td>weight loss of 1.4 kg per week for 4 consecutive weeks), the calorie intake goal was increased in 100-kcal increments until the goal of 0.5 to 0.9 kg of weight loss per week was attained. Daily physical activity goals (in minutes) were assigned by increasing self-reported baseline activity level by 25% after 1 month in the protocol. Subsequent physical activity goals were increased by 25% when participants met their previous goal. Goal activity counts were progressively increased until the criterion of an equivalent of 60 min/d of moderate-intensity physical activity was reached. During the maintenance phase (months 7-12), participants in both groups attended monthly MOVE! support group sessions led by hospital staff. During months 7 to 9, mobile group participants were asked to record and transmit data biweekly; during months 10 to 12, they transmitted 1 week of data per month. Throughout maintenance, coaches telephoned participants only if data were not submitted; they provided no other behavioral feedback."</td></tr>
<tr><td>Control/Comparator</td><td>"All participants completed a technology fluency assessment and received a brief (15-minute) training session on how to use a personal digital assistant (PDA) to record food intake, weight, and physical activity. They were loaned a PDA for 2 weeks and asked to upload their data daily. Those who entered their weight and recorded 2 or more meals (with 2 items per meal) per day for at least 7 days underwent an equipoise induction, which detailed the procedures and highlighted the pros and cons of both groups to equalize their desirability and prevent dropout after randomization. Participants were then randomly assigned either to standard-of-care group treatment alone (Standard group) or to the standard plus connective mobile technology system (Mobile group). Participants assigned to the standard group returned the PDA when the 6-month intervention phase began; During months 1 through 6, both groups attended biweekly MOVE!sessions led by dieticians, psychologists, or physicians. Each session lasted approximately 1 1⁄2 hours and included discussion of nutrition, physical activity, and behavior change. Participants were given a 5% to 10% weight loss goal. They were weighed at each session and encouraged to self-monitor, but personalized feedback was not provided. During the maintenance phase (months 7-12), participants in both groups attended monthly MOVE! support group sessions led by hospital staff."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 69
Intervention group/s: Connective Mobile Group (n=34)

Comparator group: Standard Group (n=35)</td></tr>
<tr><td>Mean age ± SD</td><td>57.7y (11.9)</td></tr>
<tr><td>Sex</td><td>14.49% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight, kg
Mean (SD)</td><td>Connective Mobile Group:
113.7
(16.1)</td><td>Standard Group: 110.1
(15.1)</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Connective Mobile Group:
36.9
(5.4)</td><td>Standard Group: 35.8
(3.8)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>5% or more weight loss Proportion (%)</td><td>Connective Mobile Group: 29.6</td><td>Standard Group: 14.8</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight loss over time Mean (95% CIs)</td><td>Connective Mobile Group: -2.9 (0.5-6.2)</td><td>Standard Group: -0.02 (-2.1-2.1)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>mean number attended, 6.2 meetings in the mobile group vs 5.9 meetings in the standard group. Of the recommended 12 coaching calls, the average mobile participant received 74.4% (mean [SD], 8.9 [2.8] calls; range, 0-15 calls; median, 8 calls), lasting a mean (SD) 125.6 (48.8) minutes (median, 125 minutes) per participant. Total additional time spent on technical support calls averaged a mean (SD) of 15.3 (5.4) minutes (median, 10 minutes) per participant</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Spring, 2017

Guideline record ID: 10666--1

Study characteristics		
Citation	Spring, B., Pellegrini, C. A., Pfammatter, A., Duncan, J. M., Pictor, A., McFadden, H. G., Siddique, J., & Hedeker, D. (2017). Effects of an abbreviated obesity intervention supported by mobile technology: the ENGAGED randomized clinical trial. Obesity, 25(7), 1191-1198. https://doi.org/10.1002/oby.21842	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of an abbreviated obesity intervention supported by mobile technology: The ENGAGED randomized clinical trial	
Location	USA	
Trial name	E-Networks Guiding Adherence to Goals in Exercise and Diet (ENGAGED)	
Methods		
Inclusion criteria	“Eligible participants were between 18 and 60 years old, with BMI between 30 and 40 kg/m2, no weight gain or loss exceeding 11.3 kg for the past 6 months, and not participating in another weight loss program.”	
Exclusion criteria	“Individuals who were pregnant, nursing, had an unstable medical condition, had contraindications to moderate intensity physical activity, or took medications known to cause weight gain or loss were excluded.”	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	“STND: for the first 8 weeks, those assigned to STND or TECH treatment attended weekly 90-minute group sessions led by a psychologist or exercise physiologist and focused on nutrition, MVPA, and behavior change strategies. A 30-minute guided walking exercise was offered after group sessions. STND and SELF participants received the same calorie counting book and paper diaries. Weekly for the first 8 weeks and monthly from months 3 to 6, TECH and STND participants received 10- to 15-minutes calls during which trained coaches with at least a bachelor's degree reviewed self-monitoring and goal attainment and helped participants solve problems.; TECH: for the first 8 weeks, those assigned to STND or TECH treatment attended weekly 90-minute group sessions led by a psychologist or exercise physiologist and focused on nutrition, MVPA, and behavior change strategies. A 30-minute guided walking exercise was offered after group sessions. TECH participants were lent an Android smartphone with studydesigned ENGAGED app and accelerometer for 6 months. They used the app to self-monitor dietary intake and body weight and wore the accelerometer to objectively measure MVPA; these data transmitted wirelessly to their coach. The app's dietary intake "fans" showed traffic-light colors depicting calorie and fat gram allowances remaining for that day. MVPA data, transmitted by the accelerometer, automatically populated an app display, visualizing the remaining MVPA needed to reach the weekly goal. TECH participants used the app's team tab to track their group members' selfmonitoring adherence, post messages to the team, or message individual group members directly. Additionally, TECH participants received two to four personalized messages per week for 6 months. Weekly for the first 8 weeks and monthly from months 3 to 6, TECH and STND participants received 10- to 15-minutes calls during which trained coaches with at least a bachelor's degree reviewed self-monitoring and goal attainment and helped participants solve problems.”	
Control/Comparator	“SELF: Those randomized to SELF attended one 60-minute group session at which treatment assignment was revealed and participants received their weight loss target, a calorie and fat gram counting book (The Complete Book of Food Counts (23)), and 6 months of daily paper self-monitoring diaries. They also received Group Lifestyle Balance (24) DVDs presenting 12 mock group treatment sessions adapted from the original DPP	

<table>
<tr><td></td><td>curriculum (25). SELF participants received no additional in-person sessions or coaching calls.”</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 96
Intervention group/s: STND (n=32); TECH (n=32)

Comparator group: SELF (n=32)</td></tr>
<tr><td>Mean age ± SD</td><td>39.3y (11.7)</td></tr>
<tr><td>Sex</td><td>84.38% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>STND: 96
(14.6)
TECH: 94.7
(11.6)</td><td>SELF: 94.8
(12.4)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Mean (95% CIs)</td><td>STND: -5.6
(-8.5--2.8)
TECH: -3.1
(-5.9--0.3)</td><td>SELF: -2.7
(-5.7--0.4)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Adherence to diet: 5.3% SELF; 3.9% STND; 4.1% TECH. Adherence to physical activity: 2.4% SELF; 4.4% STND; 4.8% TECH. Adherence to weight self-monitoring: 4.6% SELF; 5.0% STND; 1.7% TECH</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Stark, 2011

Guideline record ID: 10872--1

Study characteristics		
Citation	Stark, L. J., Spear, S., Boles, R., Kuhl, E., Ratcliff, M., Scharf, C., Bolling, C., & Rausch, J. (2011). A pilot randomized controlled trial of a clinic and home-based behavioral intervention to decrease obesity in preschoolers. Obesity, 19(1), 134-141. https://doi.org/10.1038/oby.2010.87	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A pilot randomized controlled trial of a clinic and home-based behavioral intervention to decrease obesity in preschoolers	
Location	USA	
Trial name	Learning about Activity and Understanding Nutrition for Child Health (LAUNCH)	
Methods		
Inclusion criteria	"Inclusion criteria were (i) child age between 2 and 5 years; (ii) child ≥95th percentile BMI (12), but not more than 100% above the mean BMI; (iii) at least one parent with a BMI ≥25; and (iv) medical clearance from the child's pediatrician."	
Exclusion criteria	"Exclusion criteria were (i) non-English speaking; (ii) living >50 miles from the medical center; (iii) a disability or illness that would interfere with at least moderate physical activity; (iv) medical condition/medication associated with weight gain; or (v) currently enrolled in another weight-control program."	
Setting	Hospital, Home	
Intervention	"Clinic and home-based behavioral intervention. LAUNCH was designed to produce small decreases or stabilize the rate of children's weight gain, consistent with current recommendations for treatment of preschool obesity (14,15). The 6-month intervention consisted of two phases. Phase 1 (Intensive Intervention) was 12 weekly sessions that alternated between group-based clinic sessions (parent and child concurrent groups) and individual home visits. Phase 2 (Maintenance) was 12 weeks of every other week sessions, alternating between group sessions in clinic and home sessions. Parent-group clinic sessions (90min each) addressed three components: dietary education, physical activity and parenting skills. Dietary education covered the same topics as described for the PC, but recommendations were embedded in separate sessions targeting snack and beverages (Session 2), breakfast/lunch (Session 4), and dinner (Session 6). Parents kept 7-day diet diaries on their and their child's intake during weeks 1-12. Calorie goals were set to gradually achieve an energy intake in the range of 1,000-1,200 per day depending on the child's age, and at a caloric intake commensurate with a weight below a BMI of 25 for parents. Although food choices and barriers continued to be addressed, the primary focus of Sessions 8, 10, and 12 was on decreasing screen time to <2h/day and increasing physical activity to 60min of active play/day. Children and parents were provided with pedometers and given goals of 5,000 and 10,000 steps per day, respectively. Pedometer and diet diary data were used as feedback tools. Throughout treatment, parents were taught to use child behavior management skills (16) to implement dietary and activity changes including: (i) praise and attention to increase healthy eating and physical activity; (ii) ignoring and time-out to manage tantrums; (iii) contingency management; and (iv) modeling. They were also taught stimulus control strategies, such as setting up the food environment to encourage healthy eating by eliminating high calorie/low nutrient foods and having fruits and vegetables in the home. To ensure children were exposed to new vegetables repeatedly, parents were given a 14-day supply of a vegetables at each of six clinic sessions and instructed on how to apply behavioral strategies to effectively conduct a daily taste with their child following the protocol described by Wardle et al. (17). Parents and children were weighed at each clinic visit with the goal of keeping the child's weight stable. The parent	

<table>
<tr><td></td><td>group was conducted by a licensed clinical psychologist following a written manual. Children were seen concurrently in a group format. They received nutrition education through games and art activities, tried new foods during a structured meal, and completed 15min of moderate to vigorous activity. Child groups were conducted by pediatric psychology postdoctoral fellows and a research coordinator. In-home sessions (60-90min each) were designed to support generalization of the clinic-taught skills to the home environment and were conducted by psychology postdoctoral fellows. For example, the home therapist observed the taste-test and provided feedback and/or modeling of skills, such as praise or conducting time-out for tantrums (depending on child behavior). They also conducted home "clean outs" with parents where high-calorie/low-nutrient foods were identified and a plan was made to eliminate them from the home. Therapists assisted parents with setting up a safe place in the home for active play. Phase 2 (Maintenance) sessions focused on helping families continue to make or maintain changes in eating and activity by identifying barriers and problem-solving with the families on using strategies taught during phase 1 to address these barriers. To prepare families for end of treatment diet diary recording was reduced to 3days/week (2 weekdays, 1 weekend) and pedometers were worn but no longer recorded."</td></tr>
<tr><td>Control/Comparator</td><td>"Enhanced standard of care: Pediatricial Counseling. PC was designed to deliver dietary and physical activity recommendations outlined by the American Academy of Pediatrics (13). Following a scripted manual a board-certified pediatrician met each family individually for one 45-min visit to review the child's growth chart and to explain BMI, BMI percentiles, and the child's current BMI percentile. The following recommendations were made in accordance with the Stage 1 Intervention: "Prevention Plus" for obese preschool children (14); (i) ≤2h/day of screen time; (ii) 60min/day of active play; (iii) eliminating soda and limiting juice to 4oz./day); (iv) providing ≥5servings/day of fruits and vegetables; (v) limiting eating out; and (vi) appropriate portion sizes for preschoolers. Each family was given 1-page healthy food and activity brochure created by the Collaboration for Healthy Ohio (http://www. healthyohioprogram.org/healthylife/nutri2/nutrikids2/ounce.aspx)."</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 18
Intervention group/s: LAUNCH (n=8)
Comparator group: Pediatrician counseling (n=10)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 4.4y (0.92); Control: 3.9y (1.1)</td></tr>
<tr><td>Sex</td><td>33.33% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI percentile for age and sex Mean (SD)</td><td>LAUNCH: 99 (0.9)</td><td>Pediatrician counseling: 97.7 (2.5)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in BMI z
Mean (SD)

Change in BMI percentile
Mean (SD)

Change in Weight (kg)
Mean (SD)</td><td>LAUNCH: -0.37
(0.41)

LAUNCH: -1.1
(1.9)

LAUNCH: 0.6
(3.5)</td><td>Pediatrician counseling: 0.4
(0.49)

Pediatrician counseling: 1.6
(2.7)

Pediatrician counseling: 4.8
(1.5)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Children's physical activity was measured by the MTI actigraph that has been validated and calibrated for use with preschool children (25). Actigraphs were worn for 7 days during all waking hours, with re-wearing requested if worn for less than 5 valid days (26). A valid day was a day in which the 60% of the total awake time with valid hours (27) with a valid hour defined as one with less than 10-min of consecutive zero counts. Across all time points, there was 86% compliance in meeting these criteria. Children in both groups engaged in an average of approximately 20min of vigorous activity and 59-75min of moderate activity per day at all time points. (baseline, 6 and 12 months)</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Stark, 2014

Guideline record ID: 10667--1

Study characteristics		
Citation	Stark, L. J., Clifford, L. M., Towner, E. K., Filigno, S. S., Zion, C., Bolling, C., & Rausch, J. (2014). A pilot randomized controlled trial of a behavioral family-based intervention with and without home visits to decrease obesity in preschoolers. Journal of Pediatric Psychology, 39(9), 1001-1012. https://doi.org/10.1093/jpepsy/jsu059	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A pilot randomized controlled trial of a behavioral family-based intervention with and without home visits to decrease obesity in preschoolers	
Location	USA	
Trial name	Learning about Activity and Understanding Nutrition for Child Health (LAUNCH-HV)	
Methods		
Inclusion criteria	“Inclusion criteria were (1) child age of 2-5 years; (2) child 95th percentile BMI (Kuczmarski et al., 2000), but <100% above the mean BMI; (3) one parent with a BMI 25; and (4) medical clearance from the child's pediatrician.”	
Exclusion criteria	“Exclusion criteria were (1) non-English speaking; (2) living 50 miles from the medical center; (3) disability or illness that would interfere with moderate physical activity; (4) medical condition/medication associated with weight gain; or (5) enrolled in a weight control program.”	
Setting	Hospital, Home	
Intervention	“LAUNCH-Home visits: LAUNCH-HV was an 18-session manualized intervention designed to produce small decreases or stabilize the rate of child weight gain, consistent with current recommendations for treatment of preschool obesity (Barlow, 2007). The 6-month intervention consisted of two phases: Phase I (Intensive Intervention), 12 weekly sessions, alternating between group-based clinic sessions (parent and child concurrent groups), and individual home visits and Phase II (Maintenance), 12 weeks of every-other-week sessions, alternating between group clinic, and individual home sessions. Phase I. Months 1-3 of the LAUNCH-HV intervention targeted lifestyle behavior modification and improving parenting skills (see Supplementary Material online for treatment flow and session topics). The parent-group clinic sessions (90 min each) were conducted by a licensed clinical psychologist or second-year psychology postdoctoral fellow and included education on diet (Weeks 2-7), physical activity (Weeks 8-12), and parenting skills (all sessions to facilitate diet and activity goals). Parents kept 7-day diet diaries for themselves and their child (Weeks 1-12). During Phase I, parents were provided vegetables at each session for daily taste tests (14 days) between sessions.In a concurrent session, children participated in a manualized group-based intervention led by a pediatric psychology postdoctoral fellow and a research coordinator. Session topics paralleled the topics covered in the parent group and focused on education about healthy eating, opportunities to try new foods (vegetable taste test, healthy dinners), and engage in physical activity. Home sessions (60-90 min each) were conducted by a pediatric psychology fellow following a manualized protocol to support generalization of clinic-taught skills to the home environment through instruction, therapist modeling and parent rehearsal of dietary changes, physical activity, and behavioral techniques. A ''home clean-out'' was conducted following each clinic session on diet. During the ''home clean-out'', high-calorie low-nutrient foods and beverages were identified, and parents were given the choice to remove items from the home or have an ''eating in moderation'' plan affixed while keeping the items in the home. Phase II. Months 4-6 focused on helping families maintain treatment gains by engaging parents in longterm planning, problem-solving around individual barriers, and use of parenting skills to promote maintenance of diet and activity changes.; LAUNCH-clinic: LAUNCH-clinic intervention	

<table>
<tr><td></td><td>content was identical to LAUNCH-HV clinic sessions including providing parents with vegetables at each session to facilitate daily taste tests (14 days) between sessions, keeping a 7-day diet diary for themselves and their preschooler (Weeks 1-12). In lieu of home visits, parents were provided a ''home clean-out'' box to use on their own to eliminate high-calorie low-nutrient foods from the home. To match LAUNCH-HV on treatment duration (6 months), LAUNCH-clinic sessions were conducted every other week during Months 1-3 and monthly during Months 4-6 of the intervention, for 10 treatment sessions. This intervention conforms to the content, structure, and support recommended by the Expert Committee guidelines for a Stage 3 intervention”</td></tr>
<tr><td>Control/Comparator</td><td>“Pediatrician counseling was a manualized intervention designed to deliver dietary and physical activity recommendations outlined by the American Academy of Pediatrics (Spear et al., 2007). A board-certified pediatrician met each family individually for one 45 min visit to explain BMI, BMI percentiles and to review the child's growth chart. Modeled on the Stage 1 Intervention ''Prevention Plus'' (Barlow, 2007), the pediatrician recommended (1) screen time 2 h daily; (2) active play 60 min daily; (3) eliminating soda and 4 ounces daily; (4) fruits and vegetables 5 servings daily; (5) limiting eating out; and (6) appropriate portion sizes for preschoolers. Each family was given a one-page healthy food and activity brochure created by the Collaboration for Healthy Ohio (Toolkit, 2007).”</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 33
Intervention group/s: LAUNCH-HV (n=10); LAUNCH-clinic (n=11)

Comparator group: PC (n=12)</td></tr>
<tr><td>Mean age ± SD</td><td>LAUNCH-HV: 4.7y (1.3); LAUNCH-Clinic: 4.2y (1.1); PC: 4.8y (0.7)</td></tr>
<tr><td>Sex</td><td>69.70% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>LAUNCH-HV: 24.6
(4.8)
LAUNCH-clinic: 26.6
(8.9)</td><td>PC: 26.1
(5.7)</td></tr>
<tr><td>BMI z-score
Mean (SD)</td><td>LAUNCH-HV: 2.1
(0.2)
LAUNCH-clinic: 2.5
(0.8)</td><td>PC: 2.4
(0.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI z-score change</td><td>LAUNCH-HV: -0.5</td><td>PC: -0.03</td></tr>
</table>
</td></tr>
</table>

12 months or closest time point	Mean (SD) BMI percentile change Mean (SD) Weight change (kg) Mean (SD)	(0.43) LAUNCH-clinic: -0.59 (0.75) LAUNCH-HV: -4 (3.9) LAUNCH-clinic: -5.1 (11.3) LAUNCH-HV: 0.8 (2.5) LAUNCH-clinic: 2.3 (3.1)	(0.36) PC: 0.2 (1.1) PC: 5.2 (2.6)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Stark, 2019

Guideline record ID: 10871--1

Study characteristics		
Citation	Stark, L. J., Filigno, S. S., Kichler, J. C., Bolling, C., Ratcliff, M. B., Robson, S. M., Simon, S. L., McCullough, M. B., Clifford, L. M., Stough, C. O., Zion, C., & Mara, C. A. (2019). Maintenance following a randomized trial of a clinic and home-based behavioral intervention of obesity in preschoolers. The Journal of Pediatrics, 213, 128-128.e123. https://doi.org/https://doi.org/10.1016/j.jpeds.2019.05.004	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Maintenance Following a Randomized Trial of a Clinic and Home-based Behavioral Intervention of Obesity in Preschoolers	
Location	USA	
Trial name	Learning about Activity and Understanding Nutrition for Child Health (LAUNCH)	
Methods		
Inclusion criteria	"Child inclusion criteria (active patient, aged 2-5 years, and BMI percentile ³95th)."	
Exclusion criteria	"Exclusion criteria (developmental disability, medical condition promoting obesity or condition that precluded full participation, weight affecting medication, enrolled in a weight-management program, or non-English speaking)."	
Setting	Home, Medical facility; Paediatritian	
Intervention	"LAUNCH and motivational interviewing were designed to follow the Expert Committee Recommendations for reducing obesity in pre-schoolers by either stabilizing or slowing the rate of children's weight gain or producing a gradual weight loss of 1 lb/month. On the basis of the Expert Committee Recommendations, both LAUNCH and motivational interviewing targeted: (1) limiting portion size; (2) limiting consumption of energy-dense foods; (3) limiting eating out; (4) consumption of ³5 servings of fruit and vegetables per day; (5) minimizing or eliminating sugar-sweetened beverages; (6) limiting screen time to £2 hours per day, and no TV in room where child sleeps; and (7) achieving ³1 hour of moderate-to-vigorous physical activity (MVPA) per day. LAUNCH and motivational interviewing were delivered over 18 sessions (weekly in months 1-3; every other week in months 4-6). LAUNCH was a family-based, behavioral intervention delivered in sessions that alternated weekly between group clinic sessions (90 minutes) at a medical facility and individual home visits (60 minutes). The clinic sessions included simultaneous parent and child groups. Parent-group sessions provided nutrition education, problem-solving around/monitoring of dietary intake for children and parents and physical activity changes, and child behavior management strategies (across all sessions) such as differential attention (eg, ignoring complaints about food, praising trying vegetables), contingency management (eg, rewarding healthy behaviors), limit setting, effective use of time-out to manage tantrums, shaping (eg, gradually introducing change) and exposure to introduce new foods, and implementing stimulus control measures to improve food choices and physical activity. Child groups provided nutrition education about healthy eating, opportunities to try new foods during a structured meal, and engagement in MVPA. Home visits were designed to support the generalization of the clinic-taught skills to the home including parenting skills and changing the home environment. Parent clinic group sessions were conducted by a PhD-licensed psychologist. The child group and home visits were conducted by a postdoctoral fellow in pediatric psychology or nutrition. Motivational interviewing was conducted with caregivers and targeted improvement in the child's dietary and activity behaviors. At the first visit, caregivers met with a pediatrician trained in motivational interviewing, at which time they completed questionnaires to assess their values and motivation for change and were given information about their child's weight and BMI percentile and a packet of publicly available materials/brochures from the	

<table>
<tr><td></td><td>American Academy of Pediatrics "Let's Go" program. Following the tenets of motivational interviewing, caregivers were asked about their concern with their preschoolers' weight, diet, and physical activity and asked about their desired child outcome, motivation, and confidence to make changes in any area of concern. If receptive, they were asked to select a nutrition or physical activity behavior as a primary target of discussion from a menu of the American Academy of Pediatrics recommendations and the "Let's Go" materials. Subsequent motivational interviewing intervention sessions were delivered by a licensed clinical psychologist trained in motivational interviewing in either the family's home (3 sessions) or over the telephone (14 sessions). These sessions consisted of a discussion of previous goals selected by the caregiver, exploration of the caregiver's perception of their success in reaching these goals, determination of caregiver's confidence and willingness to continue working on existing goal(s) vs establishing new behavioral goals, enhancement of motivation to address ambivalence and readiness to change behaviors in the caregivers, and identification of self-selected strategies for goal attainment."</td></tr>
<tr><td>Control/Comparator</td><td>"Participants in the standard care group received routine care from their pediatrician and were only seen by the study team at the assessment visits."</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 151
Intervention group/s: LAUNCH (n=47); Motivational interviewing (n=50)

Comparator group: Standard care (n=54)</td></tr>
<tr><td>Mean age ± SD</td><td>55.14mo (11.19)</td></tr>
<tr><td>Sex</td><td>56.95% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI%95th
Mean (SD)</td><td>LAUNCH: 114.72
(13.134)
Motivational interviewing:
113.79
(13.08)</td><td>Standard care: 115.27
(14.4)</td></tr>
<tr><td>Weight
Mean (SD)</td><td>LAUNCH: 26.15
(6.16)
Motivational interviewing:
25.91
(5.02)</td><td>Standard care: 25.97
(5.47)</td></tr>
<tr><td>BMI%ile
Mean (SD)</td><td>LAUNCH: 98.6
(1.22)
Motivational interviewing:
98.52
(1.31)</td><td>Standard care: 98.57
(1.3)</td></tr>
<tr><td>BMIz
Mean (SD)</td><td>LAUNCH: 2.41
(0.53)</td><td>Standard care: 2.48
(0.7)</td></tr>
</table>
</td></tr>
</table>

		Motivational interviewing: 2.41 (0.55)	

Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	BMI%95th Mean (SD)	LAUNCH: 112.15 (15.25) Motivational interviewing: 112.17 (12.98)	Standard care: 115.03 (16.29)
	Weight Mean (SD)	LAUNCH: 29.18 (6.98) Motivational interviewing: 30.1 (5.42)	Standard care: 29.79 (6.36)
	BMI%ile Mean (SD)	LAUNCH: 96.9 (3.41) Motivational interviewing: 97.6 (2.52)	Standard care: 97.77 (2.67)
	BMIz Mean (SD)	LAUNCH: 2.19 (0.7) Motivational interviewing: 2.17 (0.48)	Standard care: 2.28 (0.59)

Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator

Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in BMI%95th Mean (SD)	LAUNCH: -1.73 (8.58) Motivational interviewing: 1.15 (7.47)	Standard care: 2.06 (8.41)
	Change in Weight Mean (SD)	LAUNCH: 3.42 (2.68) Motivational interviewing: 4.46 (2.49)	Standard care: 4.52 (2.33)
	Change in BMI%ile Mean (SD)	LAUNCH: -1.64 (3.04) Motivational interviewing: -0.66 (1.93)	Standard care: -0.67 (2.33)
	Change in BMIz Mean (SD)	LAUNCH: -0.2 (0.54) Motivational interviewing: -0.12 (0.31)	Standard care: -0.13 (0.4)

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator

Compliance with treatment	Not reported

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Steele, 2012

Guideline record ID: 10873

Study characteristics		
Citation	Steele, R. G., Aylward, B. S., Jensen, C. D., Cushing, C. C., Davis, A. M., & Bovaird, J. A. (2012). Comparison of a family-based group intervention for youths with obesity to a brief individual family intervention: a practical clinical trial of positively fit. Journal of Pediatric Psychology, 37(1), 53-63. https://doi.org/https://dx.doi.org/10.1093/jpepsy/jsr057	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Comparison of a family-based group intervention for youths with obesity to a brief individual family intervention: a practical clinical trial of positively fit	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligibility criteria for participation in the study included: (a) the participating child or adolescent was between 7 and 17 years of age; (b) the participant's body mass index (BMI) percentile was categorized as over weight (i.e., BMI 85th percentile) or obese (i.e., BMI 95th percentile); (c) a parent was willing to partic ipate in the intervention; (d) the participant had no reported serious mental illness (i.e., those requiring current inpatient psychiatric care) or developmental delay that would prevent participation in the group intervention; (e) the parent and child spoke English; (f) the parent provided written informed consent; and (g) the child verbally assented to participation."	
Exclusion criteria	Not reported	
Setting	University/research centre	
Intervention	"10 weekly group treatment sessions. Separate sessions were held for children (7-12) and adolescents (13-17), in order to accommodate varied developmental levels. Approximately 40 min of each treatment session consisted of nutrition/physical activity education followed by 40 min of behavioral intervention, with a 10-min summary and goal-setting period at the conclusion of each session. Parents and children attended separate meetings for both nutritional/physical activity education and behavioral components of the treatment and reconvened for the concluding goal-setting portion of the session. Nutritional sessions focused on un derstanding nutritional information and portion control, planning for special occasions, and increasing knowledge of and participation in physical activity. Behavioral treatment sessions addressed topics including stimulus control, rewards for change, modeling, goal setting, social support, and maintenance of lifestyle change"	
Control/Comparator	"families received three 60-min individual face-to-face visits with one of two registered dietitians involved in the study. These visits were approximately evenly spaced over a 10-week period. Families in this condition received the Trim Kids manual at initial (pretreatment) assessment and were instructed to read the first four chapters prior to their first meeting with the dietitian. Additional chapters were assigned at the first and second sessions. Topics discussed in the BFI condition included meal planning, basic nutri tional principles, physical activity, and energy balance principles."	
Treatment duration	10 weeks	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 93
Intervention group/s: Positively Fit (n=47)

Comparator group: BFI - Trim Kids (n=46)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 11.63y (2.48); Control: 11.52y (2.82)</td></tr>
<tr><td>Sex</td><td>59.14% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>zBMI
Mean (SD)

BMI percentile
Mean (SD)</td><td>Positively Fit: 2.2
(0.34)

Positively Fit: 98.13
(1.92)</td><td>BFI - Trim Kids: 2.24
(0.36)

BFI - Trim Kids: 98.24
(1.67)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Stettler, 2015

Guideline record ID: 10874--1

Study characteristics		
Citation	Stettler, N., Wrotniak, B. H., Hill, D. L., Kumanyika, S. K., Xanthopoulos, M. S., Nihtianova, S., Shults, J., Leff, S. S., Pinto, A., Berkowitz, R. I., & Faith, M. S. (2015). Prevention of excess weight gain in paediatric primary care: beverages only or multiple lifestyle factors. The Smart Step Study, a cluster-randomized clinical trial. Pediatric Obesity, 10(4), 267-274. https://doi.org/https://dx.doi.org/10.1111/ijpo.260	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Prevention of excess weight gain in paediatric primary care: beverages only or multiple lifestyle factors. The Smart Step Study, a cluster-randomized clinical trial	
Location	USA	
Trial name	Smart Step Study	
Methods		
Inclusion criteria	"Subjects were selected with a BMI between the 75th and the 95th percentile based on their last clinic visit when weight and height were measured.18 At the baseline visit, some subjects were measured to be outside of this range, but were included, as they were still considered at risk for excess weight gain, based on their BMI at the previous clinic visit. Other inclusion criteria were: age 8.0-12.9 years, consulting at the selected practice in the past three years, and consuming an average of at least 4 oz. of sugar sweetened beverages (see definition in Table 1) per day, to insure relevance of the beverage only intervention."	
Exclusion criteria	"Exclusion criteria were serious physical or psychiatric conditions or medications potentially interfering with nutrition or physical activity, as determined by the primary care pediatrician. Home-schooled patients were excluded, so that the control intervention (bullying prevention) would be relevant to those randomized to it."	
Setting	Pediatric primary care	
Intervention	"Details on the content of the beverage-only (modified from part of the "We Can!" program): Progressively reduce intake of "Whoa" beverages (modified from the "We Can!"a categories: regular soda, sweetened iced teas and lemonade, fruit drinks with less than 100% fruit juice, and sports drinks) to ≤ 1 to 2 12-oz. serving/day • Progressively increase intake of "Go" beverages (modified from the "We Can!" categories: water, fat free milk, and 1% milk) to ≥ 6 12-oz. servings of per day (based on current recommendations for water intake). Details on the content of the multiple behavior (changes in multiple aspects of diet, physical activity, and sedentary activity): Progressively reduce intake of "Whoa" beverages (modified from the "We Can!" categories: regular soda, sweetened iced teas and lemonade, fruit drinks with less than 100% fruit juice, and sports drinks) to ≤ 1-2 12- oz. servings/day • Progressively increase intake of "Go" beverages (modified from the "We Can!" categories: water, fat-free milk, and 1% milk) to ≥ 6 12-oz. servings of per day (based on current recommendations for water intake) • Progressively increase pedometer counts to 15,000 steps per day • Progressively reduce screen time to ≤ 2 hours per day. Twelve 15-25 minute clinician, child, and parent/guardian encounters on a weekly (session 1-4), bi-weekly (session 5 and 6), monthly (sessions 7 and 8), and then bi-monthly (session 9-12) basis over 12 months. A 5-hour behavioral-specialist-led training workshop, providing continuing medical education credits but no financial compensation, was held for the clinicians, who were then certified to deliver the arm of the intervention to which their practice was randomized to. The conceptual framework, aims and activities for each session, clinician's manuals, selfmonitoring booklets, behavioral contracts, educational materials, and, when available, electronic medical record data entry fields to document session adherence were reviewed and role play of select sessions were conducted. The theory-based (behavioral economics), family-based, culturally- and developmentally-	

<table>
<tr><td></td><td>appropriate intervention consisted of twelve 15 - 25 minute clinician, child, and at least one parent or guardian encounters over 12 months. Children earned points, based on session attendance and goal achievements, which they could exchange for small prizes selected from a study catalogue. The clinical practice or clinician was compensated a $35 flat fee for each competed session. Regular conference calls of the clinicians with the research team took place and behaviorally-trained research staff was available to support the clinical staff in implementing the intervention.”</td></tr>
<tr><td>Control/Comparator</td><td>“Details on the content of the control (bullying prevention or Friendship Making intervention): Develop strategies for improving friendship making skills and anger management abilities • Identify internal and external cues in understanding when one is becoming angry or upset • Developing strategies to stay calm in challenging social situations (e.g., deep breathing, counting to 10, visual imagery) • Developing strategies for generating and evaluating choices in handling potential peer conflict situations • Improving empathy awareness and perspective taking skills. Twelve 15-25 minute clinician, child, and parent/guardian encounters on a weekly (session 1-4), bi-weekly (session 5 and 6), monthly (sessions 7 and 8), and then bi-monthly (session 9-12) basis over 12 months. A 5-hour behavioral-specialist-led training workshop, providing continuing medical education credits but no financial compensation, was held for the clinicians, who were then certified to deliver the arm of the intervention to which their practice was randomized to. The conceptual framework, aims and activities for each session, clinician's manuals, selfmonitoring booklets, behavioral contracts, educational materials, and, when available, electronic medical record data entry fields to document session adherence were reviewed and role play of select sessions were conducted. The theory-based (behavioral economics), family-based, culturally- and developmentally-appropriate intervention consisted of twelve 15 - 25 minute clinician, child, and at least one parent or guardian encounters over 12 months. Children earned points, based on session attendance and goal achievements, which they could exchange for small prizes selected from a study catalogue. The clinical practice or clinician was compensated a $35 flat fee for each competed session. Regular conference calls of the clinicians with the research team took place and behaviorally-trained research staff was available to support the clinical staff in implementing the intervention.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 172
Intervention group/s: Beverage-only (n=76); Multiple behaviour (n=63)

Comparator group: Control (n=33)</td></tr>
<tr><td>Mean age ± SD</td><td>Beverage-only: 10.8y (1.4); Multiple behavior: 10.7y (1.3); Control: 10.8y (1.4)</td></tr>
<tr><td>Sex</td><td>52.33% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Prevalence obesity (%)
Proportion (%)</td><td>Beverage-only: 18.0%
Multiple behaviour: 17.0%</td><td>Control: 21.0%</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Prevalence obesity (%)
Proportion (%)</td><td>Beverage-only: 15.0%
Multiple behaviour: 15.0%</td><td>Control: 38.0%</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Study subjects attended a median of 8 sessions without statistically significant differences between groups.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Stookey, 2017

Guideline record ID: 10875--1

Study characteristics		
Citation	Stookey, J. D., Evans, J., Chan, C., Tao-Lew, L., Arana, T., & Arthur, S. (2017). Healthy apple program to support child care centers to alter nutrition and physical activity practices and improve child weight: a cluster randomized trial. BMC Public Health, 17, 965. https://doi.org/https://doi.org/10.1186/s12889-017-4951-y	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Healthy apple program to support child care centers to alter nutrition and physical activity practices and improve child weight: a cluster randomized trial	
Location	US	
Trial name	Healthy Apple Program (HAP)	
Methods		
Inclusion criteria	"All child care centers that participated in CCHP nutrition screenings in 2011-2012 were eligible for the HAP pilot. The CCHP provides services to child care centers that primarily serve low income children in San Francisco and do not have federal, state or school district funding. The target population inclusion criteria did not change after trial commencement. Child care centers that were eligible in 2011-2012 remained eligible for the duration of the pilot, even if they declined CCHP services in interim years. The target population included all children, ages 2 to 5y, enrolled at eligible child care centers."	
Exclusion criteria	"Child care centers that were closed in Autumn 2012 or declined CCHP services for 2012-2013 before the randomization were ineligible for the HAP pilot. Child care centers with funding from Head Start, the San Francisco Unified School District, or Community College District were ineligible to receive CCHP screenings, and excluded from the HAP pilot. Child care centers that declined one or both BMI screenings in any given year were excluded from evaluation analyses for that year, because of missing data regarding the primary outcome of interest, annual change in BMI between the Autumn and Spring screenings. Children who declined one or both screenings or were absent on the date(s) of screening in any given year were excluded from evaluation analyses for that year."	
Setting	Childcare centres	
Intervention	"CCHP + HAP centers were offered the same services provided to CCHP + HAP Delayed centers. During Implementation year 1, in addition to the routine services, CCHP + HAP child care centers were invited to participate in the HAP pilot. CCHP public health nurses or health workers introduced the HAP resources and process, in-person, to child care center staff. They delivered the HAP invitation packet to the child care center, and spent up to 16 h per child care center, providing one-on-one support to each child care provider regarding the HAP self-assessment, goal setting, action plans to achieve the goal(s), Tip Sheets and online Technical Assistance resources. The CCHP staff had written instructions and form templates to standardize the delivery of one-on-one support (see Additional files 4 and 5). In Summer 2013, the San Francisco Children's Council offered two workshops to address needs identified by the HAP participants. A nutrition workshop addressed ideas for seasonal menu planning, child nutrition education resources for parents, and policies for food for holidays or celebrations. A physical activity workshop addressed how to integrate age-appropriate physical activity and academic learning for preschoolers (http://www.pkimbrell.com/). CCHP and HAP staff extended verbal and/ or email invitations to the staff contact at each child care center for any of the center staff to attend the workshops. Child care centers were invited to participate, but not required, because all CCHP services are optional and voluntary. Child care center staff were not paid to attend the workshops. In Autumn 2013, child care providers who completed the initial self-assessment were invited to re-take the self-assessment. Their most recent self-assessment	

<table>
<tr><td></td><td>scores were used to determine HAP award eligibility. A ceremony in Autumn 2013 recognized child care providers who met criteria for a HAP award (http:// healthyapple.arewehealthy.com/ HealthyAppleAward.aspx). In Spring and Summer 2014, while the HAP pilot data and program structure were reviewed, CCHP staff did not offer HAP materials to any child care centers. HAP resources were made available to child care centers in the CCHP + HAP Delayed group, beginning in Autumn 2014."</td></tr>
<tr><td>Control/Comparator</td><td>"Throughout the evaluation period, routine CCHP services were given to centers allocated to the CCHP + HAP Delayed group. These services included public health nurse consultation, health education, and hearing, vision, dental, and nutrition screenings and referrals. Each academic year, in Autumn and Spring, the same two trained health workers visited all child care centers that accepted the free CCHP BMI screening. The protocol was essentially the same each year. Screening data were collected as described below (see measures section). Child-specific weight status reports were given to the child care centers to send home to the parents or caregivers. The current prevalence of overweight or obese children at the child care center was reported to the child care provider. In Autumn 2013, CCHP protocol also included drinking water promotion for all child care centers. The promotion included distribution of a pamphlet about the benefits of drinking water for child obesity prevention and child-sized water pitchers for all centers (Help-Yourself Pitchers, Lakeshore Learning, San Leandro, CA). In Implementation year 2, 2014- 2015, CCHP + HAP Delayed centers were invited to participate in the HAP, and given HAP resources as described below."</td></tr>
<tr><td>Treatment duration</td><td>9 months</td></tr>
<tr><td>Follow-up from baseline</td><td>30 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 791
Intervention group/s: CCHP +HAP (n=430)

Comparator group: CCHP +HAP Delayed (n=361)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Prevalence of overweight or obesity in the Autumn
Proportion (%)</td><td>CCHP +HAP: 22</td><td>CCHP +HAP Delayed: 33</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Prevalence of overweight or obesity in the Autumn
Proportion (%)</td><td>CCHP +HAP: 27</td><td>CCHP +HAP Delayed: 28</td></tr>
<tr><td>Incidence of overweight or obesity between Autumn and Spring
Proportion (%)</td><td>CCHP +HAP: 5.2</td><td>CCHP +HAP Delayed: 6.7</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td>Prevalence of overweight or obesity in the Autumn
Proportion (%)

Incidence of overweight or obesity between Autumn and Spring
Proportion (%)</td><td>CCHP +HAP: 26

CCHP +HAP: 6</td><td>CCHP +HAP Delayed: 29

CCHP +HAP Delayed: 1.6</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Ströbl, 2013

Guideline record ID: 10669--1

Study characteristics		
Citation	Ströbl, V., Knisel, W., Landgraf, U., & Faller, H. (2013). A combined planning and telephone aftercare intervention for obese patients: effects on physical activity and body weight after one year. Journal of Rehabilitation Medicine, 45(2), 198-205. https://doi.org/https://doi.org/10.2340/16501977-1095	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A COMBINED PLANNING AND TELEPHONE AFTERCARE INTERVENTION FOR OBESE PATIENTS: EFFECTS ON PHYSICAL ACTIVITY AND BODY WEIGHT AFTER ONE YEAR	
Location	Germany	
Trial name	N/A	
Methods		
Inclusion criteria	"Patients were eligible if they had obesity (International Classification of Diseases 10 (ICD-10) E66) and had a body mass index (BMI) of between 30 and 44 kg/m2, had started inpatient medical rehabilitation with the goal of reducing their body weight, and were between 18 and 65 years of age."	
Exclusion criteria	"They were excluded if they had type 1 diabetes or a disorder precluding participation in sports therapy. Other co-morbidities were allowed, as they are frequent among obese patients. Patients who had had or were planning to have bariatric surgery were also excluded. Patients who were not able to see, hear, read or understand German or who had severe psychiatric disorders, such as psychotic and substance abuse disorders, were also excluded."	
Setting	Home, Rehabilitation clinic	
Intervention	"All study participants received the standard medical inpatient rehabilitation treatment for morbidly obese patients (usual care), as provided by a rehabilitation clinic of the German Statutory Pension Insurance (Rehazentrum Bad Kissingen der Deutschen Rentenversicherung Bund, Klinik Saale, Bad Kissingen, Germany). This 3-week multimodal, structured, interdisciplinary treatment aims at weight management and is based on nutrition therapy, physical exercise, and psychoeducation. The intervention group additionally received a planning intervention provided in a group setting (50 min), followed by an individual counselling session (10 min) 1 week later, before discharge, and 6 phone calls of 5-10 min duration for up to 6 months after discharge. Based on existing intervention programmes (11, 17), manuals were developed for each of the 3 intervention components, covering definition of goals, didactic methods, and media, including a booklet for patients entitled "My Activity Schedule". In the group counselling session of 4-10 participants, the transfer of physical activity behaviours into everyday life after discharge from inpatient rehabilitation was addressed. To strengthen their self-management skills, patients were encouraged to reflect on suitable types of physical activity they would like to perform for 45 min each on 5 days a week. Patients were then taught how to plan the implementation of the behaviours selected. Participants also discussed what obstacles they might encounter and how to cope with them. They were shown how to monitor their behaviour and adapt their plans if necessary. The intervention techniques used in the planning intervention were coded according to the classification of Abraham & Michie (18) as follows: provide general information on behaviour-health link, prompt intention formation, prompt barrier identification, prompt specific goal setting, and prompt self-monitoring of behaviour. At the end of the group session, patients were given their booklets and invited to make individual physical activity and coping plans for the time after discharge. Up to 3 activity behaviours could be selected. Patients were offered templates for the individual plans as well as for self-monitoring of behaviours. After 5-7 days, each patient received an	

<table>
<tr><td></td><td>individual counselling session to review the plan they had made. In this session, the time point for the first phone call was also arranged. The telephone aftercare comprised 6 phone calls within 6 months after discharge from inpatient medical rehabilitation. These calls aimed to enhance compliance with the physical activity plans patients had made and to increase patients' self-management skills. The phone calls started 2 weeks after discharge and were provided at a decreasing rate to gradually shift responsibility back to the patient. Thus, follow-up calls were scheduled at 2, 5, 9, 13, 18 and 24 weeks after the end of inpatient rehabilitation. The patients' experiences with the implementation of their exercise plans were discussed. In particular, patients reported on their exercise behaviour, the obstacles they had met, and the coping strategies they had employed. For each activity, the plans were reinforced and, at times, generalized, reduced, or otherwise adapted, as needed. The intervention techniques applied were classified as follows (18): provide general encouragement, prompt review of behavioural goals, provide feedback on performance, use of follow-up prompts, relapse prevention. The phone calls were provided by the sports therapist (UL), who had also led the group and individual counselling sessions at the clinic."</td></tr>
<tr><td>Control/Comparator</td><td>"All study participants received the standard medical inpatient rehabilitation treatment for morbidly obese patients (usual care), as provided by a rehabilitation clinic of the German Statutory Pension Insurance (Rehazentrum Bad Kissingen der Deutschen Rentenversicherung Bund, Klinik Saale, Bad Kissingen, Germany). This 3-week multimodal, structured, interdisciplinary treatment aims at weight management and is based on nutrition therapy, physical exercise, and psychoeducation. Control group received no further intervention."</td></tr>
<tr><td>Treatment duration</td><td>Intervention: 27 weeks; Control: 3 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 467
Intervention group/s: Intervention (n=228)

Comparator group: Control (n=239)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 48.54y (9.77); Control: 48.03y (9.77)</td></tr>
<tr><td>Sex</td><td>44.75% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>Intervention: 109.8
(15.6)</td><td>Control: 109.7
(16.1)</td></tr>
<tr><td>BMI, physician measurement, kg/m2
Mean (SD)</td><td>Intervention: 36.41
(3.56)</td><td>Control: 36.26
(3.44)</td></tr>
<tr><td>BMI, self-report, kg/m2
Mean (SD)</td><td>Intervention: 36.41
(3.56)</td><td>Control: 36.26
(3.44)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI, physician measurement, kg/m2
Mean (SD)

BMI, self-report, kg/m2
Mean (SD)</td><td>Intervention: 105.4
(16.1)

Intervention: 35.19
(4)

Intervention: 34.81
(3.95)</td><td>Control: 105.8
(17.2)

Control: 35.26
(3.98)

Control: 34.86
(4.09)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Stumm, 2016

Guideline record ID: 10670--1

Study characteristics		
Citation	Stumm, G., Blaik, A., Kropf, S., Westphal, S., Hantke, T. K., & Luley, C. (2016). Long-term follow-up of the telemonitoring weight-reduction program "Active Body Control". Journal of Diabetes Research, 2016, 3798729. https://doi.org/https://dx.doi.org/10.1155/2016/3798729	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-Term Follow-Up of the Telemonitoring Weight-Reduction Program "Active Body Control"	
Location	Germany	
Trial name	The Active Body Control (ABC) program	
Methods		
Inclusion criteria	"Patients recruited met the criteria for diagnosis of the metabolic syndrome according to the recommendations of the International Diabetes Federation."	
Exclusion criteria	"The exclusion criteria were as follows: age below 30 or above 60 years and presence of diabetes mellitus, coronary heart disease, chronic heart failure, cerebrovascular disorders, or other conditions possibly also having a bearing on physical activity or body weight, such as psychiatric disorders, use of antidepressants, neuroleptic or cortisol therapy, thyroid dysfunction, active cancer or other severe diseases, disabling disorders of the motor system, pregnancy, or changes in oral contraception. None of these patients had taken part in an earlier study carried out by the authors."	
Setting	Hospital, Telemonitoring	
Intervention	"One year prior to randomisation, all patients attended an initial 2-hour instruction meeting including an explanation of the Magdeburg Dual Diet. This consists of conventional calorie restriction, with reduction in the calorie intake by 500 kcal/day and preference for carbohydrates with low glycemic index. The importance of daily moderate but regular physical activity was emphasized. To this end, the patients were provided with the Aipermotion 440 model from Aipermon GmbH (Munich, Germany). The accelerometers were programmed individually for each patient and calculated the daily walking distances and daily exercise-related energy expenditure in kilocalories and in addition recorded meal calories in a simplified form. The study was then continued for a second year. All 49 patients who had finished the first year were randomized to one of two groups. In this first intervention group the counselling was continued, but with lower intensity than during the first year ("ABC continued" group, n = 25). During the first year all patients had received counselling letters every week. This frequency was reduced during the second year to one letter per month."	
Control/Comparator	"One year prior to randomisation, all patients attended an initial 2-hour instruction meeting including an explanation of the Magdeburg Dual Diet. This consists of conventional calorie restriction, with reduction in the calorie intake by 500 kcal/day and preference for carbohydrates with low glycemic index. The importance of daily moderate but regular physical activity was emphasized. To this end, the patients were provided with the Aipermotion 440 model from Aipermon GmbH (Munich, Germany). The accelerometers were programmed individually for each patient and calculated the daily walking distances and daily exercise-related energy expenditure in kilocalories and in addition recorded meal calories in a simplified form. The study was then continued for a second year. All 49 patients who had finished the first year were randomized to one of two groups. In this second group both telemonitoring and feedback by counselling letters were completely	

<table>
<tr><td></td><td>discontinued ("ABC discontinued" group, n = 24). At the end of the second year both groups were invited for a final medical examination.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 49
Intervention group/s: ABC continued (n=25)

Comparator group: ABC discontinued (n=24)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 50y (8); Control: 52y (7)</td></tr>
<tr><td>Sex</td><td>32.65% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight regain(%) - difference between end point and randomisation
Mean (95% CIs)</td><td>ABC continued: 2.8
(4.3-1.4)</td><td>ABC discontinued: 4.4
(2.8-6.1)</td></tr><tr><td>Weight regain(kg)- difference between end point and randomisation
Mean (95% CIs)</td><td>ABC continued: 2.9
(1.5-4.4)</td><td>ABC discontinued: 4.7
(3-6.5)</td></tr><tr><td>BMI (kg/m2) regain- difference between end point and randomisation
Mean (95% CIs)</td><td>ABC continued: 1
(-0.5--1.5)</td><td>ABC discontinued: 1.5
(-0.9--2)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Sullivan, 2017

Guideline record ID: 10671--1

Study characteristics		
Citation	Sullivan, S., Swain, J. M., Woodman, G., Antonetti, M., De La Cruz-Muñoz, N., Jonnalagadda, S. S., Ujiki, M., Ikramuddin, S., Ponce, J., Ryou, M., Reynoso, J., Chhabra, R., Sorenson, G. B., Clarkston, W. K., Edmundowicz, S. A., Eagon, J. C., Mullady, D. K., Leslie, D., Lavin, T. E., & Thompson, C. C. (2017). Randomized sham-controlled trial evaluating efficacy and safety of endoscopic gastric plication for primary obesity: the ESSENTIAL trial. Obesity, 25(2), 294-301. https://doi.org/https://dx.doi.org/10.1002/oby.21702	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Randomized sham-controlled trial evaluating efficacy and safety of endoscopic gastric plication for primary obesity: The ESSENTIAL trial	
Location	US	
Trial name	ESSENTIAL	
Methods		
Inclusion criteria	"Male and female subjects between 22 and 60 years old, with a body mass index (BMI) of ≥30 kg/m2 and <35 kg/m2 with at least one non-severe comorbid obesity-related condition (uncontrolled or drug dependent hypertension, type 2 DM, or hyperlipidemia) or a BMI ≥35 kg/m2 and <40 kg/m2 with or without a non-severe obesity-related comorbid condition, were included in the study. Obesity-related comorbidities were defined as severe if symptoms caused severe discomfort or compromised performance of daily activities and/or the condition was not entirely controlled with prescription drug therapy. The following levels were used to determine eligibility for patients not on prescription drug therapy: systolic blood pressure >160 mm Hg, diastolic blood pressure >100 mm Hg, HbA1c >7.0, or on any antidiabetic medication other than metformin, fasting LDL cholesterol 160 mg/dL, fasting triglycerides 400 mg/dL, or fasting total cholesterol 350 mg/dL. Eligible subjects could not have taken prescription or over-the-counter weight loss medication for 6 months before enrollment and had to agree to abstain from both weight loss medications for 12 months and additional weight loss interventional procedures or liposuction for 24 months post-enrollment."	
Exclusion criteria	"Subjects were excluded if they had a history of prior bariatric, gastric, or esophageal surgery or if they had severe systemic disease, esophageal stricture or other condition that would limit passage of endolumenal instruments, severe gastroesophageal reflux disease, hiatal hernia >3 cm, inflammatory disease of the gastrointestinal tract, past or present use of insulin for diabetes treatment, history of type 2 DM >10 years, or a known hormonal or genetic cause for obesity."	
Setting	Hospital	
Intervention	"The active treatment (pose procedure) utilized the g-Cath EZ Delivery Catheter with Snowshoe Suture Anchors and its accessories (gProxVR EZ Endoscopic Grasper, the g-LixTM Endoscopic Grasper, and the TransPortVR Endoscopic Access Device). For active subjects, the access device was passed endoscopically into the stomach. Approximately eight to ten g-Cath suture anchors were placed in the gastric fundus and an additional three to four suture anchors were placed in the distal gastric body near the antral inlet. Each subject was given daily calorie guidelines based on his or her start weight. Lifestyle therapy visits consisted of a brief diet history, goal setting, and an educational topic. Both groups received identical post-treatment diet and exercise counseling."	
Control/Comparator	"Sham treatment involved the placement of a 54 F (18 mm) "bougie" dilator after a screening endoscopy. The dilator remained inserted for 45 minutes with repositioning every 15 minutes to prevent it from sticking to mucosal tissue, after which the dilator was	

<table>
<tr><td></td><td>removed and the patient was extubated and moved to recovery. Each subject was given daily calorie guidelines based on his or her start weight. Lifestyle therapy visits consisted of a brief diet history, goal setting, and an educational topic. Both groups received identical post-treatment diet and exercise counseling.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 332
Intervention group/s: Active (n=221)

Comparator group: Sham (n=111)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 44.2y (8.6); Control: 45.3y (9.1)</td></tr>
<tr><td>Sex</td><td>89.16% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>Active: 99.7
(12.2)</td><td>Sham: 98.7
(11.6)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Proportion of population with 5% TBWL (total body weight loss)
Proportion % (95% CI)</td><td>Active: 41.55
(34.83-48.26)</td><td>Sham: 22.11
(13.76-30.45)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% TBWL (total body weight loss)
Mean (SD)

% TBWL (total body weight loss)
Median (95% CI)</td><td>Active: -4.95
(7.04)

Active: -3.89
(-7.73-30.85)</td><td>Sham: -1.38
(5.58)

Sham: -0.69
(-13.7-22.97)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Sundfør, 2018

Guideline record ID: 10672--1

Study characteristics		
Citation	Sundfør, T. M., Svendsen, M., & Tonstad, S. (2018). Effect of intermittent versus continuous energy restriction on weight loss, maintenance and cardiometabolic risk: a randomized 1-year trial. Nutrition, Metabolism & Cardiovascular Diseases, 28(7), 698-706. https://doi.org/https://doi.org/10.1016/j.numecd.2018.03.009	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of intermittent versus continuous energy restriction on weight loss, maintenance and cardiometabolic risk: A randomized 1-year trial	
Location	Norway	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria included waist circumference 94/ 80 cm (men/women) and 1 additional metabolic syndrome component: circulating levels of TG 1.7 mmol/l, HDL cholesterol 1.0/1.3 (men/women), blood pressure 130/85 mmHg or use of antihypertensive drugs or fasting glucose 5.6 mmol/l, and weight stability within 3 kg during the last three months."	
Exclusion criteria	"Exclusion criteria were diabetes if treated with insulin or incretin analogues, bariatric surgery, use of anti-obesity drugs or other drugs affecting body weight, eating disorder, or psychiatric illness, or alcohol or drug abuse that could contribute to difficulties with study procedures."	
Setting	Hospital, Home	
Intervention	"We estimated baseline energy requirements using the Mifflin formula [15], and multiplied baseline energy Effect of intermittent versus continuous energy restriction 699 requirements with physical activity level (PAL) estimated according to self-reported physical activity to calculate the total daily energy expenditure (TDEE). Participants in the intermittent energy restriction group were advised to consume 400/600 (female/male) on each of two nonconsecutive days a week and to consume food as usual the remaining five days a week. Both groups received individualized dietary plans including educational materials and individual counselling sessions. All participants were encouraged to follow the general principles of a Mediterranean type diet (30e35% fat, w20% protein and 45e50% carbohydrates, mostly unrefined) emphasizing more vegetables, fruits, legumes, fish, poultry, nuts, fermented dairy products, and olive oil and restricting processed meats, red meat and sweets. Participants in the intermittent energy restriction group were recommended fasting on Mondays and Thursdays, but were given the opportunity to adapt this from week to week, as long as they had at least one "normal" day between the fasting days. They received menus that recommended w50 g protein/day from chicken breast, lean meat, lean fish, fat free yoghurt, cottage cheese, egg or legumes and vegetables to increase satiety on fasting days. The participants in the intermittent energy group were given the choice of consuming one meal providing 400/600 kcal (women/men) or splitting their assigned energy for the day into two snacks of 200/300 kcal (woman/men) or three snacks 100/150 kcal (woman/men). In addition to dietary counselling both groups were similarly counselled in cognitive behavioral methods to improve compliance. All the participants were advised about factors shown to improve weight loss maintenance [16]. These factors included planning meals and activity schedules, improving step-wise problem-solving-skills to handle barriers and stronger stimulus control to minimize overeating and to create positive cues for healthy eating, homework exercises regarding high-risk situations for overeating, distinguishing between hunger and cravings and individualized consultations of 30 and 60 min at each follow-up. They were encouraged to maintain a consistent eating pattern, to focus on how to maintain life-style changes, to be satisfied with achieved weight	

<table>
<tr><td></td><td>loss and to have confidence in their ability to maintain weight-loss without professional help.”</td></tr>
<tr><td>Control/Comparator</td><td>“Participants in the continuous energy restriction group were advised to reduce their energy intake evenly seven days a week so the total weekly energy reduction was equivalent in both groups. The energy intake for participants in this group was based on the calculation of total weekly energy expenditure and its reduction if the participant fasted two days a week: Energy expenditure per week (TDEE x 7) minus total reduction in energy intake per week (TDEE minus 400/600 kcal [female/male] x 2)/7. Both groups received individualized dietary plans including educational materials and individual counselling sessions. All participants were encouraged to follow the general principles of a Mediterranean type diet (30e35% fat, w20% protein and 45e50% carbohydrates, mostly unrefined) emphasizing more vegetables, fruits, legumes, fish, poultry, nuts, fermented dairy products, and olive oil and restricting processed meats, red meat and sweets. The continuous energy reduction group received meal plans with suggestions for breakfast, lunch, dinner and snacks in line with their individualized energy recommendations. In addition to dietary counselling both groups were similarly counselled in cognitive behavioral methods to improve compliance. All the participants were advised about factors shown to improve weight loss maintenance [16]. These factors included planning meals and activity schedules, improving step-wise problem-solving-skills to handle barriers and stronger stimulus control to minimize overeating and to create positive cues for healthy eating, homework exercises regarding high-risk situations for overeating, distinguishing between hunger and cravings and individualized consultations of 30 and 60 min at each follow-up. They were encouraged to maintain a consistent eating pattern, to focus on how to maintain life-style changes, to be satisfied with achieved weight loss and to have confidence in their ability to maintain weight-loss without professional help.”</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 112
Intervention group/s: Intermittent (n=54)

Comparator group: Continuous (n=58)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 49.9y (10.1); Control: 47.5y (11.6)</td></tr>
<tr><td>Sex</td><td>50.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight(kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intermittent: 108.6
(16.3)

Intermittent: 35.1
(3.9)

Intermittent: 116
(10)</td><td>Continuous: 107.5
(16.1)

Continuous: 35.3
(3.5)

Continuous: 116
(10)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Proportion of participants achieving 5-10% weight loss (%)
Proportion (%)

Proportion of participants achieving >10% weight loss (%)
Proportion (%)</td><td>Intermittent: 31.5

Intermittent: 31.5</td><td>Continuous: 34.5

Continuous: 34.5</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight change (kg)
Mean (SD)

Waist circumference change (cm)
Mean (SD)</td><td>Intermittent: -8
(6.5)

Intermittent: -8.7
(5.9)</td><td>Continuous: -9
(7.1)

Continuous: -9.6
(6.3)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Svetkey, 2015

Guideline record ID: 10675--1

Study characteristics		
Citation	Svetkey, L. P., Batch, B. C., Lin, P.-H., Intille, S. S., Corsino, L., Tyson, C. C., Bosworth, H. B., Grambow, S. C., Voils, C., Loria, C., Gallis, J. A., Schwager, J., & Bennett, G. G. (2015). Cell phone intervention for you (CITY): a randomized, controlled trial of behavioral weight loss intervention for young adults using mobile technology. Obesity, 23(11), 2133-2141. https://doi.org/https://dx.doi.org/10.1002/oby.21226	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Cell phone intervention for you (CITY): A randomized, controlled trial of behavioral weight loss intervention for young adults using mobile technology	
Location	US	
Trial name	Cell Phone Intervention for You (CITY)	
Methods		
Inclusion criteria	"Individuals were eligible if they were aged 18-35 years, had overweight or obesity (BMI ≥25 kg/m2), and used a mobile telephone."	
Exclusion criteria	"Individuals were excluded if they were taking weight loss medications or corticosteroids, had weight loss surgery, weighed more than 440 lbs (the limit of study scales), or had any condition deemed unsafe for the study."	
Setting	University/research centre	
Intervention	"In CP, the smartphone was used for both intervention delivery and self-monitoring. Specifically, the intervention was delivered exclusively through an investigator-designed smartphone app which included goal setting, challenge games, and social support through a "buddy system" that allowed exchange of pre-determined messages to a randomly assigned buddy participant. Self-management behaviors for CP were regularly and frequently prompted by the app according to a protocol-driven schedule; participants did not have a choice in the timing or frequency of prompts. Tailoring within the CP intervention occurred mainly via setting personal goals. Self-monitoring by smartphone was achieved by tracking weight, dietary intake, and physical activity, with frequent prompts to self-monitor and feedback on the results.; PC: the PC intervention was delivered primarily by an interventionist during six weekly group sessions followed by monthly phone contacts. Intervention elements such as goal setting, challenges, and social support were delivered through these personal coaching interactions, with extensive tailoring during the conversations with the interventionist. The smartphone was used exclusively for self-monitoring, with tracking of weight, dietary intake, and physical activity initiated by the participant (i.e., without smartphone prompts), transmitted to the interventionist, and incorporated by the interventionist into the coaching sessions. The PC interventionists were dietitians trained in Motivational Interviewing."	
Control/Comparator	"Participants randomized to the Control group were given three handouts on healthy eating and physical activity from the Eat Smart Move More NC program (http://www.eatsmartmovemorenc.com/) but otherwise received no intervention and were not asked to selfmonitor. Use of these materials was not monitored."	
Treatment duration	24 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 365
Intervention group/s: CP (n=122); PC (n=120)

Comparator group: Control (n=123)</td></tr>
<tr><td>Mean age ± SD</td><td>29.4y (4.3)</td></tr>
<tr><td>Sex</td><td>69.59% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight
Mean (SD)</td><td>CP: 102.4
(25.2)
PC: 99.3
(23.4)</td><td>Control: 101.3
(22.6)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Proportion (%) with weight loss at least 5%
Proportion (%)</td><td>CP: 25.5
PC: 27.5</td><td>Control: 22</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight
Mean (SD)</td><td>CP: -1.48
PC: -3.58</td><td>Control: -2.25</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight
Mean (SD)</td><td>CP: -0.99
PC: -2.45</td><td>Control: -1.44</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>The CP group self-weighed an average of 4.0 times/week for the first 6 months and continued at 2.1 times/week during months 13 through 24. CP participants interacted with the study app in other ways an average of 4.6 times/day in the first 6 months and 0.7 times/day in the final year. The PC group self-weighed an average of 2.2 times/week in the first 6 months and 1.0 times/week in the final year of intervention. Excluding weighing, the PC group interacted with the study app an average of 1.8 times/day in the first 6 months and 0.4 times/day in the final year. In addition, over 90% completed all expected coaching contacts in the first 6 months and more than 87% of monthly calls from months 13 through 24.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Taheri, 2020

Guideline record ID: 10677--1

Study characteristics		
Citation	Taheri, S., Zaghloul, H., Chagoury, O., Elhadad, S., Ahmed, S. H., El Khatib, N., Amona, R. A., El Nahas, K., Suleiman, N., Alnaama, A., Al-Hamaq, A., Charlson, M., Wells, M. T., Al-Abdulla, S., & Abou-Samra, A. B. (2020). Effect of intensive lifestyle intervention on bodyweight and glycaemia in early type 2 diabetes (DIADEM-I): an open-label, parallel-group, randomised controlled trial. The Lancet Diabetes & Endocrinology, 8(6), 477-489. https://doi.org/https://dx.doi.org/10.1016/S2213-8587(20)30117-0	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of intensive lifestyle intervention on bodyweight and glycaemia in early type 2 diabetes (DIADEM-I): an open-label, parallel-group, randomised controlled trial	
Location	Qatar	
Trial name	Diabetes Intervention Accentuating Diet and Enhancing Metabolism (DIADEM-I)	
Methods		
Inclusion criteria	"Eligible participants were those who provided written informed consent, were aged 18-50 years, reported a diagnosis of type 2 diabetes within the previous 3 years (as confirmed from available medical records), had a BMI of 27·0 kg/m² or more, originated from the Middle East and north Africa region, and who were resident in Qatar."	
Exclusion criteria	"Individuals were excluded if they: had type 1 diabetes, had had an ischaemic cardiovascular event in the previous 6 months, had stage 3b or higher chronic kidney disease, were pregnant, lactating, or planning a pregnancy, had any condition precipitating fluid overload, such as heart failure or liver cirrhosis, had been diagnosed with a severe psychiatric disorder, had uncontrolled depression, had uncontrolled epilepsy, had known lactose intolerance, had severe arthritis that prevented walking, had active gout, or had active gallstone disease or known asymptomatic gallstones."	
Setting	GP clinic, Community healthcare centre	
Intervention	"Participants in the intensive lifestyle intervention group were supported by a team of trained dietitians, personal trainers, and physicians, who followed a standard intervention delivery protocol. After randomisation, participants underwent a 12-week total diet replacement phase, in which they were given formula low-energy (800-820 kcal/day) diet meal replacement products (57% carbohydrate, 14% fat, 26% protein, and 3% fibre; Cambridge Weight Plan, Northants, UK), followed by a 12-week structured food reintroduction phase. Thereafter, participants managed their own energyrestricted food intake and lifestyle changes for 6 months. Eating raw vegetables and salad was permitted in the total diet replacement phase, if required. Participants were advised to drink 2 L or more of water daily. If required, a fibre supplement was recommended for constipation. When food was reintroduced, a regular meal pattern with a similar distribution of macronutrients as the meal replacement products was recommended. Participants were advised to aim for low-glycaemic index carbohydrates. Physical activity support initially focused on walking (with an aim of at least 10000 steps per day), followed by the recommendation of increasing unsupervised activity to at least 150 min/week."	
Control/Comparator	"Participants in the control group received usual medical diabetes care according to clinical guidelines.15 Adjustments to medication were made to aid individualised glycaemic, lipid, and blood pressure control, and to facilitate weight loss or weight maintenance. Standard diet and activity advice, and diabetes education were provided."	
Treatment duration	12 months	

<table>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 147
Intervention group/s: Intervention (n=70)

Comparator group: Control (n=77)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 41.9y (5.4); Control: 42.3 (5.8)</td></tr>
<tr><td>Sex</td><td>27.21% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes diagnosed within last 3 years</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 100.64
(16.95)

Intervention: 113.21
(12.45)</td><td>Control: 101.68
(19.26)

Control: 113.24
(12.78)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 90.3
(16.85)

Intervention: 102.87
(14.04)</td><td>Control: 96.85
(17.13)

Control: 108.4
(11.73)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)

Change in waist circumference
Mean (SD)</td><td>Intervention: -11.98
(9.46)

Intervention: -11.44
(9.9)</td><td>Control: -3.98
(5.29)

Control: -4.03
(5.68)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Tapsell, 2014

Guideline record ID: 10679--1

Study characteristics		
Citation	Tapsell, L. C., Batterham, M. J., Thorne, R. L., O'Shea, J. E., Grafenauer, S. J., & Probst, Y. C. (2014). Weight loss effects from vegetable intake: a 12-month randomised controlled trial. European Journal of Clinical Nutrition, 68(7), 778-785. https://doi.org/https://doi.org/10.1038/ejcn.2014.39	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight loss effects from vegetable intake: a 12-month randomised controlled trial	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were healthy adults 18-65 years with a body mass index 25-35 kg/m2."	
Exclusion criteria	"Exclusion factors were major illnesses, diabetes mellitus, thyroid abnormalities, heavy alcohol consumption, recent acute or chronic disease, changing medications affect weight, weight loss >5 kg in last 3 months, fluctuating exercise patterns, strenuous exercise >1 h per day, pregnancy or lactation, dietary limitations, and dislike of vegetables."	
Setting	Home	
Intervention	"An accredited practising dietitian provided participants with a personalised diet prescription based on core food groups from the Australian Guide to Healthy Eating,20 that is, vegetables, fruit, grain foods, meat/fish/eggs/ cheese, milk/yoghurt and nuts/seeds/spreads/oils, providing ~ 80% energy requirements for age, weight and sex as per the Mifflin equation.21 The energy intake of the diets was managed by careful dietary modelling of all food groups including vegetables. All participants were requested to consume at least five servings of vegetables each day but the servings were different between control vs comparator. Comparator (1 cup cooked, 2.0 cups raw). Foods high in saturated fat and added sugars (cakes, biscuits and soft drinks) were discouraged, in keeping with the ADG including the 2013 update.17 Initial consultations lasted 1 h, with 30-min follow-up at months 1, 2, 3, 6, 9 and 12 by the same dietitian. E-mail messages were sent 2 weeks before clinic visits. Short message service was sent to participants' mobile phones with reminders of appointments and encouragement to maintain study requirements. Booklets outlining the recommended number of servings of food groups per day and a 4-day estimated food record (including one weekend day) were provided. The high vegetable group were given extra support and materials on use of vegetables."	
Control/Comparator	"An accredited practising dietitian provided participants with a personalised diet prescription based on core food groups from the Australian Guide to Healthy Eating,20 that is, vegetables, fruit, grain foods, meat/fish/eggs/ cheese, milk/yoghurt and nuts/seeds/spreads/oils, providing ~ 80% energy requirements for age, weight and sex as per the Mifflin equation.21 The energy intake of the diets was managed by careful dietary modelling of all food groups including vegetables. All participants were requested to consume at least five servings of vegetables each day, but the servings were different between control vs comparator. Control 0.5 cup cooked, 1 cup of raw. Foods high in saturated fat and added sugars (cakes, biscuits and soft drinks) were discouraged, in keeping with the ADG including the 2013 update.17 Initial consultations lasted 1 h, with 30-min follow-up at months 1, 2, 3, 6, 9 and 12 by the same dietitian. E-mail messages were sent 2 weeks before clinic visits. Short message service was sent to participants' mobile phones with reminders of appointments and encouragement to maintain study requirements. Booklets outlining the recommended number of servings of food groups per day and a 4-day estimated food record (including one weekend day) were provided."	

<table>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 113
Intervention group/s: Comparator (n=58)

Comparator group: Control (n=55)</td></tr>
<tr><td>Mean age ± SD</td><td>48.9y (9.3)</td></tr>
<tr><td>Sex</td><td>75.22% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Comparator: 84.6
(13.05)

Comparator: 30.11
(2.89)

Comparator: 97.44
(9.32)</td><td>Control: 84.89
(9.86)

Control: 29.84
(2.57)

Control: 98.48
(9.39)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Comparator: 77.02
(10.74)

Comparator: 27.51
(2.57)

Comparator: 90.77
(9.4)</td><td>Control: 79.02
(9.32)

Control: 27.79
(2.35)

Control: 92.8
(8.13)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>98%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Tapsell, 2017

Guideline record ID: 10680--1

Study characteristics		
Citation	Tapsell, L. C., Lonergan, M., Batterham, M. J., Neale, E. P., Martin, A., Thorne, R., Deane, F., & Peoples, G. (2017). Effect of interdisciplinary care on weight loss: a randomised controlled trial. BMJ Open, 7(7), e014533. https://doi.org/https://dx.doi.org/10.1136/bmjopen-2016-014533	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of interdisciplinary care on weight loss: a randomised controlled trial	
Location	Australia	
Trial name	HealthTrack	
Methods		
Inclusion criteria	"Inclusion criteria were: permanent residents of the Illawarra region, adults aged 25- 54 years, and with a BMI in the range 25-40 kg/m2 ."	
Exclusion criteria	"Exclusion criteria were: unable to communicate in English; have severe medical con ditions, an impaired ability to participate in study; or have other medical conditions thought to limit survival to 1 year; suffer from immunodeficiency; have reported illegal drug use or regular alcohol intake associated with alcoholism (N50 g/day); or have difficulties or major impediments to participating in the components of the study."	
Setting	GP clinic	
Intervention	"Participants were randomly assigned to usual care (C, general advice), intervention (I, interdisciplinary advice) and intervention + food supplement (IW, I+30 g walnuts/ day). Assessment and treatment protocols were devised by the research team including physicians, dietitians, exercise physiologists and psychologists. Participants received an interdisciplinary intervention on weight loss in overweight and obese adults [19]. An intensive phase was conducted for three months (monthly clinic visits), followed by quarterly follow up visits to 12 months. All groups received dietary advice based on the food groups forming the Australian Guide to Healthy Eating (AGHE) [20], namely vegetables, fruit, cereals/grains, lean meat and alternatives (including fish and seafood), and low-fat dairy foods. The diet plans for participants in the I and IW groups were individualized with a prescribed number of serves of each food group to meet energy intake targets, and the dietary advice was delivered by Accredited Practising Dietitians (APDs). For the IW group, the diet plan included the free sample of 30g walnuts/day provided for the duration of the study. The energy value of the walnuts was modelled into the overall diet plan. The advice was accompanied by menu-style suggestions. Consultations with APDs (I and IW groups) also included categorical exercise advice, again following the National Physical Activity Guidelines and supported by an exercise physiologist if requested. Participants in both intervention groups also received quarterly phone calls from a trained health coach, who counselled participants on Acceptance and Commitment therapy via a printed workbook. In the intervention counselling session an accredited practising dietitian negotiated changes in specific food choices based on a diet history assessment and materials that referred to the food groups outlined in AGHE (vegetables, fruits, grains, protein rich foods, dairy foods, oils). This consultation included advice to increase physical activity and reduce sedentary behaviour by identifying opportunities in leisure, occupation and household activities, with additional categorical guidance prepared by the exercise physiologist following exercise assessment. The psychologist developed a workbook for participants and trained health coaches to deliver related scripted calls of short (15min) duration at quarterly intervals. The psychological coaching component was based on principles from Acceptance and Commitment Therapy and involved clarification of underlying values to increase motivation related to weight loss,	

<table>
<tr><td></td><td>increasing mindfulness and awareness to facilitate better health choices, and self-compassion to promote continued valued-action even in the presence of setbacks."</td></tr>
<tr><td>Control/Comparator</td><td>"Participants were randomly assigned to usual care (C, general advice), intervention (I, interdisciplinary advice) and intervention + food supplement (IW, I+30 g walnuts/ day). Control group received the same dietary advice based on the food groups forming the Australian Guide to Healthy Eating (AGHE) [20], namely vegetables, fruit, cereals/grains, lean meat and alternatives (including fish and seafood), and low-fat dairy foods. The C group was given general advice from a practice nurse with reference to standard servings from AGHE related pamphlets, as well as receiving National Physical Activity Guidelines."</td></tr>
<tr><td>Treatment duration</td><td>3 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 377
Intervention group/s: Intervention (n=125); Intervention + Walnuts (n=126)

Comparator group: Control (n=126)</td></tr>
<tr><td>Mean age ± SD</td><td>45 years (IQR 37, 51)</td></tr>
<tr><td>Sex</td><td>73.74% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>Intervention: 91.9 (15.2)
Intervention + Walnuts: 91.4 (15.6)</td><td>Control: 91.8 (14.7)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight (kg)
Mean (SD)</td><td>Intervention: 86.5 (17.8)
Intervention + Walnuts: 87.9 (14.2)</td><td>Control: 87.8 (14.9)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	Neale, E. P., Tapsell, L. C., Martin, A., Batterham, M. J., Wibisono, C., & Probst, Y. C. (2017). Impact of providing walnut samples in a lifestyle intervention for weight loss: a secondary analysis of the HealthTrack trial. Food & Nutrition Research, 61(1). https://doi.org/10.1080/16546628.2017.1344522

N/A – Not applicable

Tarraga Marcos, 2014

Guideline record ID: 10681--1

Study characteristics		
Citation	Tárraga Marcos, M. L., Rosich, N., Panisello Royo, J. M., Gálvez Casas, A., Serrano Selva, J. P., Rodríguez-Montes, J. A., & Tárraga López, P. J. (2014). [Efficacy of motivational interventions in the treatment of overweight and obesity]. Nutrición Hospitalaria, 30(4), 741-748. https://doi.org/https://dx.doi.org/10.3305/nh.2014.30.4.7704	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	[Efficacy of motivational interventions in the treatment of overweight and obesity]	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	"1. Patients of both genders who are overweight (BMI >25) or obese (BMI > 30), registered in the Clinical Record (Hª C) or diagnosed again 2.- Age from 30 to 70 years. 3.- That they are in the same phase of change. 4.- Accept to participate in the study."	
Exclusion criteria	"Exclusion Criteria: 1. Patients with serious pathology. 2.- Patients with morbid obesity. 3.- Patients with severe psychic or sensory alterations that may interfere with taking advantage of the motivational intervention (uncorrected severe deafness, intense visual deficits, etc.)."	
Setting	Home, Health centre	
Intervention	"Action as in the control group, plus group motivation intervention every 2 weeks from 1 to 12 and monthly from 13 to 32, following the Guide for the Prevention and Treatment of Overweight and Obesity of the SEEDO'2000 consensus11"	
Control/Comparator	"Strategy in the Control group: Usual intervention according to the protocols of each center: visits every 3 months, which include advice on lifestyle changes, physical exercise, hypocaloric diet 1200-1500 kcal and anthropometric measurements (weight, height and head circumference). waist). Assessment by the health professional of the blood analysis at the beginning, one year and at the end of the study."	
Treatment duration	32 weeks	
Follow-up from baseline	2 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 696 Intervention group/s: Study (n=319) Comparator group: Control (n=377)	
Mean age ± SD	Not reported	
Sex	77.16% female	
Pre-existing medical condition	No pre-existing medical condition	
Results		

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Study: 85.5
(13.9)

Study: 34.05
(4.8)

Study: 107.6
(10.8)</td><td>Control: 87.11
(14.8)

Control: 34.1
(4.8)

Control: 107.69
(11.5)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Study: 33.5
(4.9)</td><td>Control: 33.8
(4.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Study: 33.3
(5)</td><td>Control: 33.6
(4.9)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI change (kg/m2)
Mean (SD)</td><td>Study: -1.4
(5.8)</td><td>Control: -1.8
(4.9)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Percentage weight loss (%)
Mean (SD)

BMI change (kg/m2)
Mean (SD)</td><td>Study: -2.5

Study: -0.9
(6.9)</td><td>Control: -1

Control: -2.4
(7.3)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Tarro, 2014

Guideline record ID: 10876--1

Study characteristics		
Citation	Tarro, L., Llauradó, E., Albaladejo, R., Moriña, D., Arija, V., Solà, R., & Giralt, M. (2014). A primary-school-based study to reduce the prevalence of childhood obesity - the EdAl (Educació en Alimentació) study: a randomized controlled trial. Trials, 15, 58. https://doi.org/https://doi.org/10.1186/1745-6215-15-58	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A primary-school-based study to reduce the prevalence of childhood obesity--the EdAl (EducaciÃ³ en AlimentaciÃ³) study: a randomized controlled trial	
Location	Spain	
Trial name	Educació en Alimentació (EDAl)	
Methods		
Inclusion criteria	“Inclusion criteria were name, gender, date, place of birth and parental consent.”	
Exclusion criteria	Not reported	
Setting	School	
Intervention	“One diet, referred to as the modified Stop Light Diet (SLDm diet), followed the model used successfully by Saunders et al25 with adults with intellectual or developmental disabilities. This diet consisted of: (a) at least 5 daily servings of (fresh, canned or frozen) fruits and vegetables. (b) 2 meal replacement shakes (Provided by Health Management Resources (HMR)). (c) 2 packaged entrees of 300 calories or less, typically found in grocery stores. The SLDm diet program used a visual aid similar to a Stoplight Guide described by Epstein and Squires (1988). This aid listed a typical serving size for approximately 150 food items. Items in the 40e60 calorie range per serving were categorized in the green group, or ''Eat all you want''; items in the 60e100 range in the yellow group, or ''use caution''; and items over 100 calories in the red group ''eat rarely/never.'' Participants were told they if they wanted additional foods, they should choose one from the green group, or occasionally, yellow group on the chart; red foods should only be those found in the packaged entrees. Each participant was randomly assigned to one of the diets with approximately 1200e1500 calories (adjusted upward based on initial weight), both clinically proven to promote weight loss in average adults. All participants were encouraged to regularly drink water or other zero calorie beverages and to exercise. A simple exercise program was recommended for each participant based on his/her physical capabilities. Those that were ambulatory were encouraged to walk. Those that were unable to bear weight but had movement in their legs or arms were encouraged use one of several ergometers available through the project or to purchase one. In addition, exercises employing therabands were taught and interested participants were provided with therabands, with project funds”	
Control/Comparator	“control group did not receive any type of intervention.”	
Treatment duration	28 months	
Follow-up from baseline	28 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 2350 Intervention group/s: Intervention group (n=1550)	

<table>
<tr><td></td><td>Comparator group: Control group (n=800)</td></tr>
<tr><td>Mean age ± SD</td><td>8.4y (0.6)</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Proportion of participants overweight (%)
Proportion (%)

Proportion of participants obese (%)
Proportion (%)</td><td>Intervention group: 21.03

Intervention group: 9.04</td><td>Control group: 14.41

Control group: 7.49</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Proportion of participants overweight (%)
Proportion (%)

Proportion of participants obese (%)
Proportion (%)</td><td>Intervention group: 22.03

Intervention group: 7.02</td><td>Control group: 22.49

Control group: 7.93</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>% Change in proportion of overweight participants based on BMI (%)
Proportion (%)

% Change in proportion obese participants (%)
Proportion (%)</td><td>Intervention group: 1.27

Intervention group: -2.02</td><td>Control group: 8.08

Control group: 0.44</td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Llauradó, E., Tarro, L., Moriña, D., Aceves-Martins, M., Giralt, M., & Solà, R. (2018). Follow-up of a healthy lifestyle education program (the EdAl study): four years after cessation of randomized controlled trial intervention. BMC Public Health, 18, 104. https://doi.org/10.1186/s12889-017-5006-0</td></tr>
</table>

N/A – Not applicable

Taveras, 2011

Guideline record ID: 10682--1

Study characteristics		
Citation	Taveras, E. M., Gortmaker, S. L., Hohman, K. H., Horan, C. M., Kleinman, K. P., Mitchell, K., Price, S., Prosser, L. A., Rifas-Shiman, S. L., & Gillman, M. W. (2011). Randomized controlled trial to improve primary care to prevent and manage childhood obesity: the High Five for Kids study. Archives of Pediatrics & Adolescent Medicine, 165(8), 714-722. https://doi.org/10.1001/archpediatrics.2011.44	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Randomized controlled trial to improve primary care to prevent and manage childhood obesity: the high five for kids study	
Location	USA	
Trial name	High Five for Kids	
Methods		
Inclusion criteria	"Participants comprised children aged 2.0 to 6.9 years whose BMI (calculated as weight in kilograms divided by height in meters squared) was in the 95th percentile or higher or whose BMI was in the 85th to less than 95th percentile if at least 1 parent was overweight (BMI 25) and who received their pe diatric care at Harvard Vanguard Medical Associates between August 2006 and October 2008."	
Exclusion criteria	"We excluded (1) children whose parent or guardian could not respond to interviews in English or Spanish, (2) children whose families were planning to leave Harvard Vanguard Medical Associates, (3) families for whom the primary care clinician thought the intervention was not ap propriate, and (4) children with chronic medical conditions."	
Setting	GP clinic, Primary care paediatric offices of Harvard Vanguard Medi cal Associates, a multisite group practice in Massachusetts	
Intervention	"We trained the paediatric nurse practitioners to be the key intervening clinicians and to use motivational interviewing during four 25-minute, in-person chronic disease management visits and three 15-minute telephone calls in the first year of the intervention. We developed several resources to assist the physicians and nurse practitioners in supporting participants and their family in behaviour change. For the patient waiting rooms, we created posters highlighting our targeted behaviours to encourage dialogue during well-child care visits. For the chronic disease management visits with the nurse practitioners, we developed educational modules targeting television viewing and fast food and sugar-sweetened beverage intake that were matched to a family's stage of readiness to change; printed and electronic tools for self-management support; lists of local resources for physical activity; and an interactive Web site with educational materials, recipes, and other features. To further support behaviour change, the nurse practitioners provided small incentives such as water bottles, books, and snack containers. In addition, the nurse practitioners offered interested families an electronic television monitoring device to assist with the goal of reducing television viewing."	
Control/Comparator	"Participants randomized to usual care received the current standard of care offered by their paediatric practice. This included well-child care visits and follow-up appointments for weight checks with their paediatrician or a subspecialist (e.g., nutritionist). Visits for families in the usual care group included the baseline and annual well-child care visits."	
Treatment duration	12 months	
Follow-up from baseline	12 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 475
Intervention group/s: Intervention (n=271)

Comparator group: Usual care (n=204)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SE)</td><td>Intervention: 19.2
(0.2)</td><td>Usual care: 19.1
(0.1)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SE)</td><td>Intervention: 19.5
(0.2)</td><td>Usual care: 19.6
(0.2)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in BMI
Mean (SE)</td><td>Intervention: 0.31
(0.09)</td><td>Usual care: 0.49
(0.1)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Taveras, 2015

Guideline record ID: 10877--1

Study characteristics		
Citation	Taveras, E. M., Marshall, R., Kleinman, K. P., Gillman, M. W., Hacker, K., Horan, C. M., Smith, R. L., Price, S., Sharifi, M., Rifas-Shiman, S. L., & Simon, S. R. (2015). Comparative effectiveness of childhood obesity interventions in pediatric primary care: a cluster-randomized clinical trial. JAMA Pediatrics, 169(6), 535-542. https://doi.org/10.1001/jamapediatrics.2015.0182	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Comparative effectiveness of childhood obesity interventions in pediatric primary care: a cluster-randomized clinical trial	
Location	US	
Trial name	Study of Technology to Accelerate Research (STAR)	
Methods		
Inclusion criteria	"Children's eligibility criteria for the STAR trial included 6.0 to 12.9 years of age, BMI at the 95th percentile or greater for age and sex, and receipt of well-child care at Harvard Vanguard Medical Associates within the 15 months before enrollment."	
Exclusion criteria	Not reported	
Setting	Home, Pediatric offices	
Intervention	"Computerized CDS System In the 10 practices randomized to the 2 intervention arms (CDS and CDS + coaching), we modified the existing electronic health record to deploy a computerized, point-of-care CDS alert to pediatric clinicians at the time of a well-child visit for a child with aBMI at the 95th percentile or greater.The alert contained links to growth charts, evidence-based childhood obesity screening and management guidelines,3and a pre populated standardized note template specific for obesity that included options for (1)documenting and coding for the BMI percentile, (2)documenting and coding for nutrition and physical activity counseling, (3) placing referrals for weight management programs, (4) placing orders for laboratory studies if appropriate, and (5) printing educational materials. In these 10 practices, we also trained the clinicians to use brief motivational interviewing to negotiate a follow-up weight management plan with the patient and their family.These training sessions were conducted in person at each of the 10 sites during regularly scheduled clinical meetings and were led by expert faculty (E.M.T. and R.M.) and information technology specialists. Educational Materials and Intervention for Self-Guided Behavior Change for Families To augment the clinical intervention and to support families in behavior change, we developed a comprehensive set of educational materials for pediatric clinicians to provide to their patients at well-child and follow-up visits that focused on individual- and family-level behaviors (eFigure in Supplement 2). These behaviors included (1) decreases in screen time, (2) decreases in consumption of sugar-sweetened beverages, (3) increases in moderate and vigorous physical activity, and (4) improvement of sleep duration and quality. Families in the CDS arm also received 4 newsletters throughout the intervention period encouraging self-guided behavior change. Individualized Family Coaching In the CDS + coaching intervention arm, families were assigned a health coach who used motivational interviewing to support families by telephone at 1, 3, 6, and 9 months. Parents were also invited to participate in an interactive text message program. Any parent who chose not to receive texts had the option to receive the same messages by email. Texts received twice weekly during the 1-year follow-up provided support for behavior change for the patient and their family. A previous STAR investigation described the procedures and content of the text message program."	

<table>
<tr><td>Control/Comparator</td><td>“Participants at practices randomized to the control arm received the current standard of care offered by their pediatric office. No new decision support tools for obesity were made available in the electronic health records of the 4 usual care practices.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 549
Intervention group/s: CDS (n=194); CDS + Coaching (n=171)

Comparator group: Usual care (n=184)</td></tr>
<tr><td>Mean age ± SD</td><td>9.8y (1.9)</td></tr>
<tr><td>Sex</td><td>46.81% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)

BMI z score, U</td><td>CDS: 25.6
(4.5)
CDS + Coaching: 26
(4.2)

CDS: 2.04
(0.3)
CDS + Coaching: 2.08
(0.3)</td><td>Usual care: 25.7
(4.2)

Usual care: 2.05
(0.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)

BMI z score, U</td><td>CDS: 26.3
(4.6)
CDS + Coaching: 26.8
(4.6)

CDS: 1.93
(0.39)
CDS + Coaching: 1.99
(0.35)</td><td>Usual care: 26.9
(4.6)

Usual care: 2.01
(0.33)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI change (kg/m2)
Mean

BMI z score U change
Mean</td><td>CDS: 0.7
CDS + Coaching: 0.9

CDS: -0.1
CDS + Coaching: -0.08</td><td>Usual care: 1.2

Usual care: -0.04</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

Compliance with treatment	Among the 171 participants in the CDS + coaching arm, 116 (67.8%) completed all of these activities and were categorized as having high fidelity to the intervention protocol; 55 (32.2%) did not complete all of these activities and were categorized as having low fidelity.
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Taveras, 2017

Guideline record ID: 10878--1

Study characteristics		
Citation	Taveras, E. M., Marshall, R., Sharifi, M., Avalon, E., Fiechtner, L., Horan, C., Gerber, M. W., Orav, E. J., Price, S. N., Sequist, T., & Slater, D. (2017). Comparative effectiveness of clinical-community childhood obesity interventions: a randomized clinical trial. JAMA Pediatrics, 171(8), e171325. https://doi.org/https://dx.doi.org/10.1001/jamapediatrics.2017.1325	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Comparative Effectiveness of Clinical-Community Childhood Obesity Interventions: A Randomized Clinical Trial	
Location	USA	
Trial name	Connect for Health	
Methods		
Inclusion criteria	"Eligibility included the following: (1) child age 2 to 12.9 years, (2) BMI in the 85th or greater percentile, and (3) family not planning to leave HVMA within the study time frame."	
Exclusion criteria	Not reported	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Enhanced Primary Care Plus Coaching In the enhanced primary care plus coaching arm, families received individualized health coaching tailored to their socio-environmental context. Four trained health coaches contacted families every other month for 1 year using telephone, videoconference (Vidyo), or in-person visits, according to parent preference. These contacts were approximately 15 to 20 minutes. Details of the coaching training and quality assurance have been previously described.15 Families also received twice-weekly text messages or emails, as well as mailings following each coaching session with educational materials to support families' behavior change goals. Health coaches used a motivational interviewing style of counseling and shared decision-making techniques to provide family-centered care in addressing childhood obesity risk factors and management. At each contact, health coaches used an online community resource map developed for the study to identify resources within each family's community that could support behavior change. In addition, health coaches offered families a 1-month free family membership to area YMCAs to encourage physical activity and community connections. Families were also invited to attend a healthy grocery shopping program led by Cooking Matters (https://cookingmatters.org/). To engage parents and children in setting behavior change goals, health coaches used a behavior change decision aid tool, developed by our study team, that helped families identify outcomes that mattered most to them and potential motivators for engaging in behavior change."	
Control/Comparator	"Enhanced Primary Care (Control) Participants randomized to the enhanced primary care group were exposed to the clinical best practices described here. In addition, participants received monthly text messages that contained links to publicly available resources to support behavior change (eg, links to the Let's Move! program). Participants also received a Neighborhood Resource Guide listing places that support healthy living in their community."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	

<table>
<tr><td colspan="4">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td colspan="3">n= 721
Intervention group/s: Enhanced Primary Care Plus Coaching (n=360)

Comparator group: Enhanced Primary Care (n=361)</td></tr>
<tr><td>Mean age ± SD</td><td colspan="3">8.0y (3.0)</td></tr>
<tr><td>Sex</td><td colspan="3">51.04% female</td></tr>
<tr><td>Pre-existing medical condition</td><td colspan="3">No pre-existing medical condition</td></tr>
<tr><td colspan="4">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td colspan="3"><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Enhanced Primary Care Plus Coaching: 23 (4.9)</td><td>Enhanced Primary Care: 22.8 (4.6)</td></tr>
<tr><td>BMI z Score
Mean (SD)</td><td>Enhanced Primary Care Plus Coaching: 1.87 (0.56)</td><td>Enhanced Primary Care: 1.91 (0.56)</td></tr>
<tr><td>Proportion in Overweight BMI Category (85th percentile to <95th percentile)
Proportion (%)</td><td>Enhanced Primary Care Plus Coaching: 38.1</td><td>Enhanced Primary Care: 34.9</td></tr>
<tr><td>Proportion obese BMI Category (95th percentile to <120% of the 95th percentile)
Proportion (%)</td><td>Enhanced Primary Care Plus Coaching: 40.6</td><td>Enhanced Primary Care: 43.4</td></tr>
<tr><td>Proportion in severe obesity BMI Category (120% of the 95th percentile)
Proportion (%)</td><td>Enhanced Primary Care Plus Coaching: 21.4</td><td>Enhanced Primary Care: 21.6</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td colspan="3"><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI z Score
Mean (SD)</td><td>Enhanced Primary Care Plus Coaching: 1.79 (0.58)</td><td>Enhanced Primary Care: 1.85 (0.58)</td></tr>
<tr><td>Proportion in Overweight BMI Category (85th percentile to <95th percentile)
Proportion (%)</td><td>Enhanced Primary Care Plus Coaching: 28.5</td><td>Enhanced Primary Care: 28.4</td></tr>
<tr><td>Proportion obese BMI Category (95th percentile to <120% of the 95th percentile)
Proportion (%)</td><td>Enhanced Primary Care Plus Coaching: 37.4</td><td>Enhanced Primary Care: 39.4</td></tr>
<tr><td>Proportion in severe obesity BMI Category (120% of the 95th percentile)
Proportion (%)</td><td>Enhanced Primary Care Plus Coaching: 22.5</td><td>Enhanced Primary Care: 22.8</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td colspan="3"><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Changes in BMI z Score Mean (95% CIs)</td><td>Enhanced Primary Care Plus Coaching: -0.09 (-0.13--0.05)</td><td>Enhanced Primary Care: -0.06 (-0.1--0.02)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td colspan="2">Among the 360 participants in the enhanced primary care plus coaching group, 65% completed all 6 visits with a health coach; 96% reported receiving neighborhood resource information and 76% were very satisfied with the information. Eighty-one parents (23%) reported joining their local YMCA and 64 parents (18%) reported attending one of the Cooking Matters workshops.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td colspan="2"></td></tr>
</table>

N/A – Not applicable

Tay, 2016

Guideline record ID: 10743--1

Study characteristics		
Citation	Tay, J., Zajac, I. T., Thompson, C. H., Luscombe-Marsh, N. D., Danthiir, V., Noakes, M., Buckley, J. D., Wittert, G. A., & Brinkworth, G. D. (2016). A randomised-controlled trial of the effects of very low-carbohydrate and high-carbohydrate diets on cognitive performance in patients with type 2 diabetes. British Journal of Nutrition, 116(10), 1745-1753. https://doi.org/10.1017/S0007114516004001	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A randomised-controlled trial of the effects of very low-carbohydrate and high-carbohydrate diets on cognitive performance in patients with type 2 diabetes	
Location	Australia	
Trial name	N/A	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	"Type 1 diabetes; abnormal renal or liver function; any significant endocrinopathy (other than stable treated thyroid disease); history of malignancy or respiratory, gastrointestinal, cerebrovascular, peripheral or CVD; pregnancy or lactation; severe depression and current depression (Beck Depression Inventory Score≥29); history of/or current eating disorder; or smoking."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Hypoenergetic (2092-4184 kJ/d deficit (500-1000 kcal/d deficit)) LC, high-unsaturated/ low-saturated-fat diet (n 57; 14 % energy as carbohydrate (CHO <50 g/d), 28 % protein (PRO), 58 % fat (<10 % SFA)). To achieve the targeted macronutrient profile, specific foods and quantities were listed in a food record that was completed daily by participants. Diet plans were personalised for energy requirements and participants received dietetic counselling biweekly for the first 12 weeks, and monthly for the remainder of the study. To facilitate compliance, participants were provided with key foods (approximately 30 % total energy) that reflected the assigned diet profiles for the initial 12 weeks, and for the remainder of study were provided with key foods or a $50AUD voucher on alternating months. All participants also undertook the same supervised moderate-intensity aerobic/resistance exercise sessions (60 min, 3 d/week), consistent with diabetes management guidelines(13). These group-based exercise classes were conducted in local community centres, and participants from both diet groups attended classes together."	
Control/Comparator	"energy-matched HC diet (n 58; 53 % CHO, 17 % PRO, 30 % fat (<10 % SFA)) that reflected conventional dietary guidelines. To achieve the targeted macronutrient profile, specific foods and quantities were listed in a food record that was completed daily by participants. Diet plans were personalised for energy requirements and participants received dietetic counselling biweekly for the first 12 weeks, and monthly for the remainder of the study. To facilitate compliance, participants were provided with key foods (approximately 30 % total energy) that reflected the assigned diet profiles for the initial 12 weeks, and for the remainder of study were provided with key foods or a $50AUD voucher on alternating months. All participants also undertook the same supervised moderate-intensity aerobic/resistance exercise sessions (60 min, 3 d/week), consistent with diabetes management guidelines(13). These group-based exercise classes were conducted in local community centres, and participants from both diet groups attended classes together."	
Treatment duration	52 weeks	

<table>
<tr><td>Follow-up from baseline</td><td>52 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 115
Intervention group/s: LC diet (n=58)

Comparator group: HC diet (n=57)</td></tr>
<tr><td>Mean age ± SD</td><td>58y (7)</td></tr>
<tr><td>Sex</td><td>42.61% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg) - Baseline Mean (SD)

BMI (kg/m2) - Baseline Mean (SD)</td><td>LC diet: 101.7 (34.2)

LC diet: 34.2 (4.5)</td><td>HC diet: 101.6 (15.8)

HC diet: 35.1 (4.1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg) Mean (95% CIs)</td><td>LC diet: -9.8 (-11.7--7.9)</td><td>HC diet: -10.1 (-12--8.2)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Taylor, 2015

Guideline record ID: 10879--1

Study characteristics		
Citation	Taylor, R. W., Cox, A., Knight, L., Brown, D. A., Meredith-Jones, K., Haszard, J. J., Dawson, A. M., Taylor, B. J., & Williams, S. M. (2015). A tailored family-based obesity intervention: a randomized trial. Pediatrics, 136(2), 282-289. https://doi.org/https://doi.org/10.1542/peds.2015-0595	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A Tailored Family-Based Obesity Intervention: A Randomized Trial	
Location	New Zealand	
Trial name	Motivational Interviewing and Treatment (MInT)	
Methods		
Inclusion criteria	"All families with children 4 to 8 years of age, identified as overweight or obese (BMI ≥85th percentile) at screening."	
Exclusion criteria	"Medical conditions affecting growth."	
Setting	Home, University/research centre	
Intervention	"The TP condition consisted of a single multidisciplinary consultant session (usually both parents, mentor, dietitian, exercise specialist, and clinical psychologist all together) followed by regular, brief contact (predominantly mothers only) with a MInT mentor (1 nutritionist, 1 exercise trainer) over the 2-year intervention. The intervention was family-based rather than solely targeting the overweight child. An extensive report was generated before the consultant session using the baseline data and compared with guidelines or published data. All specialists used this report to identify potential targets for change, specific to each family, to guide prioritization. These could be specific (dietary goals) or general (approaches to parenting). The consultant sessions were 1 to 2 hours long in total, with the family taking the lead in identifying targets for change. Each family then met with their MInT mentor, monthly in year 1 and every 3 months in year 2, typically alternating between face to-face sessions (30-40 minutes) at the university or in their home and phone calls (5-10 minutes). In these sessions, individual goals were negotiated and relevant resources, based on well-established behavioral strategies, were discussed (Table 2). Resources were provided as required rather than providing all families with every resource. Frequency of contact was purposely reduced in year 2 to assess how families managed by themselves with more limited contact. These sessions provided personalized support to each family, while allowing continued monitoring and adjustment to target behaviors over time. Estimated total intervention contact time over the 2-year intervention was 6 to 7 hours per family. The consultants did not meet with the families again, but both mentors were supervised fortnightly by the clinical psychologist. These sessions involved self-review by the mentors, and assistance with intervention plans and problem solving for families"	
Control/Comparator	"UC families (predominantly mothers only) met with a trained researcher at baseline and 6 months. The first appointment lasted 30 to 45 minutes, and parents received individualized feedback about their child's diet and activity habits, based on the comprehensive data collected at the screening and baseline appointments. The child's results were compared with guidelines (eg, 2 hours of screen time each day, participate in at least 1 hour of physical activity) or published data (eg, recommended scores for the dietary questionnaire). Generalized advice using publicly available resources suitable for children of this age was then provided about healthy eating, physical activity, and sleep. Parents could ask questions and discuss any aspect in more detail. A second appointment at 6 months reviewed progress, provided support and answered queries. No new information/resources	

<table>
<tr><td></td><td>were provided, and these sessions lasted 15 to 30 minutes. Estimated total intervention contact time per family over the 2-year intervention was 45 to 75 minutes.”</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 206
Intervention group/s: TP (n=104)

Comparator group: UC (n=102)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 6.5y (1.4); Control: 6.4y (1.4)</td></tr>
<tr><td>Sex</td><td>55.34% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI z score
Mean (SD)

Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>TP: 1.69
(0.5)

TP: 30.4
(8.8)

TP: 19.8
(2.5)</td><td>UC: 1.54
(0.42)

UC: 27.4
(6.9)

UC: 19
(2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI z score
Mean (SD)

Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>TP: 1.5
(0.53)

TP: 33.3
(9.8)

TP: 19.9
(2.8)</td><td>UC: 1.46
(0.43)

UC: 30.9
(7.9)

UC: 19.4
(2.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI z score
Mean (SD)

Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>TP: 1.42
(0.56)

TP: 37.9
(11.5)

TP: 20.6
(3.3)</td><td>UC: 1.42
(0.45)

UC: 35.5
(8.8)

UC: 20.2
(2.5)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</table>

<table>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Attendance at intervention sessions was high: all but 2 usual-care participants attended baseline and 90% attended the 6-month session. Families in the TP condition should have received ~14 sessions; the median attended was 11.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Teixeira, 2010

Guideline record ID: 10880--1

Study characteristics		
Citation	Teixeira, P. J., Silva, M. N., Coutinho, S. R., Palmeira, A. L., Mata, J., Vieira, P. N., Carraça, E. V., Santos, T. C., & Sardinha, L. B. (2010). Mediators of weight loss and weight loss maintenance in middle-aged women. Obesity, 18(4), 725-735. https://doi.org/https://dx.doi.org/10.1038/oby.2009.281	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Mediators of weight loss and weight loss maintenance in middle-aged women	
Location	Portugal	
Trial name	Promotion of Exercise and Health in Obesity (PESO)	
Methods		
Inclusion criteria	"To be included in the study, participants had to be female, between 25-50 years old, premenopausal, have a BMI between 25 and 40kg/ m2, be willing to attend weekly meetings (during 1 year), be free from major illnesses, and not take medications known to interfere with body weight regulation."	
Exclusion criteria	"Started taking medication susceptible to affect weight (e.g., antidepres sants, anxiolytics, and antiepileptics; n = 10), had a serious chronic dis ease diagnosis or severe illness/injury (n = 4), became pregnant (n = 2), or entered menopause (n = 3)."	
Setting	University/research centre	
Intervention	"Primary targets of the intervention included increasing physi cal activity (PA) and energy expenditure, adopting a diet consistent with a moderate energy deficit, and ultimately establishing exercise and eating patterns that would support weight maintenance. Cogni tive and behavioral aspects such as identifying personal resistances, overcoming lapses, establishing adequate goals, and implementing self monitoring were emphasized. Intervention sessions covered topics such as emotional and external eating, its detection and prevention, as well as improving body acceptance and body image (19). The program's principles and style of intervention were based on Self-Determination Theory (20,21) with a special focus on increasing competence and internal regulation toward exercise and weight control. Guiding prin ciples of the intervention included providing participants with adequate structure and a range of options to choose from, supporting their auto nomous decisions during the program, and encouraging participants explore their own motivations for treatment and define their personal treatment goals, while limiting external contingencies and controls (e.g., outcomes-based rewards or praise, external monitoring of behaviors and body weight)."	
Control/Comparator	"The control group received a general health education curriculum based on several educational courses on various topics (e.g., preventive nutrition, stress management, self-care, and effective communication skills)."	
Treatment duration	12 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 225 Intervention group/s: Intervention (n=114)	

<table>
<tr><td></td><td>Comparator group: Control (n=111)</td></tr>
<tr><td>Mean age ± SD</td><td>37.6y (7.0)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight %
Mean (SD)</td><td>Intervention: -7.3
(5.9)</td><td>Control: -1.7
(5)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight %
Mean (SD)</td><td>Intervention: -5.5
(5)</td><td>Control: -2.2
(7.5)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Tejera, 2022

Guideline record ID: 10881--1

Study characteristics		
Citation	Tejera, C., Porca, C., Rodriguez-Carnero, G., Andújar, P., Casanueva, F. F., Bellido, D., & Crujeiras, A. B. (2022). Reducing metabolic syndrome through a group educational intervention program in adults with obesity: IGOBE program. Nutrients, 14(5), 1066. https://doi.org/https://dx.doi.org/10.3390/nu14051066	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Reducing Metabolic Syndrome through a Group Educational Intervention Program in Adults with Obesity: IGOBE Program	
Location	Spain	
Trial name	Group Intervention in OBEsity (IGOBE)	
Methods		
Inclusion criteria	“Men and women, individuals aged ≥18 years, individuals who were obese (body mass index of ≥30 kg/m2), individuals motivated to maintain healthy lifestyle habits, and individuals who attended scheduled meetings and control visits were eligible for this study.”	
Exclusion criteria	“Participants who had obesity induced by endocrine problems, were diagnosed with mental illness or other health problems that could alter their response to treatment, with drug-abuse problems or consumed alcohol, use weight loss drugs, planned to get pregnant or were pregnant during the study period, previously underwent weight-loss surgery, had special dietary restrictions, and acquired an HIV infection were excluded.”	
Setting	Hospital, Home	
Intervention	“The participants allocated to the IG followed a structured program of habit change and exercise. This program included a baseline visit, an intensive program of six weekly 1 h sessions, and two follow-up visits at 6 and 12 months. If the entire session had an attendance rate of 80%, the program was considered successful. In the IG, the nutritionists and nurses conducted the six weekly 1 h sessions with 15 patients per group using the active-participation method, encouraging communication and interactive learning (see IGOBE program previous publication for more details [17]). The topics discussed during the sessions were preparation of menus, healthy recipes, preparation of healthy eating plans, knowledge about labeling, methods of managing emotional hunger, and registration of weekly activities. Workout involved the performance for 360 min of weekly physical activity or 10,000 steps/day and included strength work. In all sessions, 15 min were allotted for performing exercise. During the session, behavioral therapy was performed, and discussion groups was conducted to maximize the "halo effect" of peer interaction on eating habits, exercise, and healthy lifestyle. The weekly sessions aimed at providing the patients with knowledge and tools to promote healthy habits and resources in order to encourage patients to maintain a healthy lifestyle. In this session, false beliefs were discussed, and real-life experiences were provided as examples on how the theory is applied to day-to-day life. In addition, the IG was provided with a social support system through the establishment of an e-mail support and a website containing information and healthy recipes (www.foroactua.com, accessed on 21 February 2022), incorporated as part of the program; received e-mails to reinforce the message; and underwent continuous training by following the information posted on the website. Participants were encouraged to register in paper or mobile phone apps the food they consumed, training they received, and their feelings to track their improvements and to provide them with tips and strategies to help them achieve success. After finishing the six sessions, the participants attended two more reinforced sessions at 6 and 12 months after the beginning of the program.”	

<table>
<tr><td>Control/Comparator</td><td>“Participants allocated to the CG received the standard of care for obesity while admitted in the hospital; their clinical treatment was revised by an endocrinologist and endocrinology nurse at 6 and 12 months after the baseline visit, with a mandatory visit at 12 months. During this visit, the patients were encouraged to change their unhealthy lifestyle, adhere to the prescribed diet, provide their medical records, and ensure weight and body composition control. In the usual practice, after basal evaluation, the doctors and nurses provided a written prescription of the recommended diet and exercise. The patients returned for body weight control and body composition control at 6 and 12 months after the baseline visit. No other contact or considerations were made during follow-up.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 456
Intervention group/s: Intervention group (n=232)

Comparator group: Control group (n=224)</td></tr>
<tr><td>Mean age ± SD</td><td>48.8y (12.8)</td></tr>
<tr><td>Sex</td><td>78.07% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Intervention group: 107.8
(23.9)</td><td>Control group: 102.6
(18.3)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intervention group: 40.5
(7.9)</td><td>Control group: 39.2
(5.6)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Intervention group: 115.8
(16)</td><td>Control group: 111.5
(15.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Intervention group: 99.7
(21.3)</td><td>Control group: 105.6
(19.4)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Intervention group: 37.4
(6.8)</td><td>Control group: 40.4
(6.1)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Intervention group: 107
(14.4)</td><td>Control group: 116.5
(14.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change (%)
Mean (SD)</td><td>Intervention group: -7.06
(7.26)</td><td>Control group: 2.96
(6.13)</td></tr>
<tr><td>BMI Change (%)
Mean (SD)</td><td>Intervention group: -7.33
(7.7)</td><td>Control group: 2.9
(6.25)</td></tr>
</table>
</td></tr>
</table>

	Waist circumference change (%) Mean (SD)	Intervention group: -7.37 (6.9)	Control group: 4.85 (6.43)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data	Nguyen, B., Shrewsbury, V. A., O'Connor, J., Steinbeck, K. S., Hill, A. J., Shah, S., Kohn, M. R., Torvaldsen, S., & Baur, L. A. (2013). Two-year outcomes of an adjunctive telephone coaching and electronic contact intervention for adolescent weight-loss maintenance: the Loozit randomized controlled trial. International Journal of Obesity, 37(3), 468-472. https://doi.org/10.1038/ijo.2012.74		

N/A – Not applicable

Ter Bogt, 2011

Guideline record ID: 10683--1

Study characteristics		
Citation	ter Bogt, N. C. W., Milder, I. E. J., Bemelmans, W. J. E., Beltman, F. W., Broer, J., Smit, A. J., & van der Meer, K. (2011). Changes in lifestyle habits after counselling by nurse practitioners: 1-year results of the Groningen Overweight and Lifestyle study. Public Health Nutrition, 14(6), 995-1000. https://doi.org/10.1017/S1368980010003708	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Changes in lifestyle habits after counselling by nurse practitioners: 1-year results of the Groningen Overweight and Lifestyle study	
Location	Netherlands	
Trial name	Groningen Overweight and Lifestyle (GOAL)	
Methods		
Inclusion criteria	"Eligible participants had a BMI between 25 and 40 kg/m2 and either hypertension or dyslipidaemia, or both. Hypertension was defined as mean systolic blood pressure >140 mmHg and/or diastolic >90 mmHg (based on two measurements on at least two different visits) or current use of blood pressure-lowering medication, and dyslipidaemia was defined as a total serum cholesterol >5.5 mmol/l or low HDL cholesterol (male: <0.9 mmol/l; female: <1.1 mmol/l) or a ratio of total to HDL cholesterol >6 mmol/l and/or current use of cholesterol-lowering medication."	
Exclusion criteria	"Exclusion criteria were diabetes mellitus, hypothyroidism, pregnancy, liver or kidney disease, current treatment for malignancy, severely shortened life expectancy, mental illness and addiction to alcohol or drugs."	
Setting	GP clinic, Hospital	
Intervention	"In the first year, the lifestyle intervention of the NP consisted of four individual visits (1, 2, 3 and 8 months after baseline) and one feedback session by telephone (5 months after baseline). During these contact sessions the NP was guided by the standardized computerized software program, which contains instructions on lifestyle counselling according to (inter)national guidelines(3,13,14) and allows data entry of the measurements. The NP (contracted by the GP) followed a training programme (four sessions of 4 h each) and received an individual instruction about the software program. The primary aim was to prevent weight gain and lose 5-10 % weight if patients were motivated."	
Control/Comparator	"The participants in the control group were offered one visit with their GP to discuss results from the screening and thereafter received usual GP care (mean number of visits was 2.0 (SD 1.7)). According to National GP Guidelines(2), this implies low intensive or absent care (regarding focus on lifestyle) for a large majority."	
Treatment duration	1 year	
Follow-up from baseline	1 year	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 341 Intervention group/s: NP (n=169) Comparator group: GP-UC (n=172)	

<table>
<tr><td>Mean age ± SD</td><td>NP Group: 55.2y (7.7); GP-UC Group: 57.1y (7.7)</td></tr>
<tr><td>Sex</td><td>53.08% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Hypertension and/or dyslipidaemia</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2) - Baseline Mean (SD)

Weight (kg) - Baseline Mean</td><td>NP: 29.4 (3.1)

NP: 88</td><td>GP-UC: 29.5 (3.7)

GP-UC: 87</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg) Mean</td><td>NP: -1.9</td><td>GP-UC: -0.9</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Driehuis, F., Barte, J. C. M., ter Bogt, N. C. W., Beltman, F. W., Smit, A. J., van der Meer, K., & Bemelmans, W. J. E. (2012). Maintenance of lifestyle changes: 3-year results of the Groningen Overweight and Lifestyle study. Patient Education and Counseling, 88(2), 249-255. https://doi.org/https://dx.doi.org/10.1016/j.pec.2012.03.017</td></tr>
</table>

N/A – Not applicable

Thomas, 2017

Guideline record ID: 10684--1

Study characteristics		
Citation	Thomas, J. G., Raynor, H. A., Bond, D. S., Luke, A. K., Cardoso, C. C., Foster, G. D., & Wing, R. R. (2017). Weight loss in Weight Watchers Online with and without an activity tracking device compared to control: a randomized trial. Obesity, 25(6), 1014-1021. https://doi.org/https://doi.org/10.1002/oby.21846	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight loss in Weight Watchers Online with and without an activity tracking device compared to control: A randomized trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Eligibility criteria included the following: age 18 to 70 years old, BMI of 27 to 40 kg/m2, English fluency, access to the Internet via a personal computer (PC), and basic computer skills."	
Exclusion criteria	"Exclusion criteria included the following: report of a contraindication for weight loss or unsupervised exercise; pregnancy, breastfeeding, or a plan to become pregnant within 12 months of enrollment; a plan to move away from the geographic region of the research center within 12 months of enrollment; use of a commercial weight loss program or weight loss of 5% of initial body weight within the previous 6 months; current use of prescription weight loss medication; previous bariatric surgery; chemotherapy or radiation for cancer within 6 months of enrollment; and report of any lifetime eating disorder diagnosis, excluding binge eating disorder."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Weight watchers online (WWO): Participants assigned to the WWO condition received 12 months of access to WWO at no cost. Participants were instructed to access WWO via their personal computers but could access resources for tracking daily food intake and PA, and weekly tracking of body weight, via a mobile application (app) for smartphones and tablets. The WWO program used the PointsPlusVR dietary plan and tracking system and the activity PointsPlus PA tracking system, both aimed at fostering a healthy diet, increased PA, and gradual weight loss. Participants recorded their food and beverage consumption using this system, which assigns a PointsPlus value to each item. Upon first accessing the WWO system, participants entered their weight, height, and PA level (sedentary to very active). This information was used to set an individualized daily PointsPlus dietary goal. By recording PA, participants could accrue activity PointsPlus values to spend on food.; WWO+ Active Link (WWO+AL): Participants assigned to the WWO plus ActiveLink (WWO1AL) condition received 12 months of access to WWO at no cost. Participants were instructed to access WWO via their personal computers but could access resources for tracking daily food intake and PA, and weekly tracking of body weight, via a mobile application (app) for smartphones and tablets. The WWO program used the PointsPlusVR dietary plan and tracking system and the activity PointsPlus PA tracking system, both aimed at fostering a healthy diet, increased PA, and gradual weight loss. Participants recorded their food and beverage consumption using this system, which assigns a PointsPlus value to each item. Upon first accessing the WWO system, participants entered their weight, height, and PA level (sedentary to very active). This information was used to set an individualized daily PointsPlus dietary goal. By recording PA, participants could accrue activity PointsPlus values to spend on food. Additionally, participants in WWO+AL received an ActiveLink PA tracking device with related software at no cost. The ActiveLink is a thumb-sized device containing an accelerometer that can be worn on the waist, chest, or wrist and, in combination with	

<table>
<tr><td></td><td>accompanying software, monitors PA. The ActiveLink could be connected to a PC to upload data to the WWO platform, which converted estimates of PA into activity PointsPlus values. The ActiveLink software also provided participants with PA goals based on their current PA level and encouraging messages as they monitored their progress toward goals.”</td></tr>
<tr><td>Control/Comparator</td><td>“The Control condition consisted of online newsletters made available weekly for 3 months, then biweekly for 3 months, then monthly for 6 months. The newsletters contained general educational information on the benefits of losing weight and healthy eating and PA habits.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 271
Intervention group/s: WWO (n=94); WWO+AL (n=91)

Comparator group: Control (n=86)</td></tr>
<tr><td>Mean age ± SD</td><td>WWO: 55.1y (11.5); WWO+AL: 54.9y (11.9); Control: 54.9y (11.3)</td></tr>
<tr><td>Sex</td><td>77.49% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>WWO: 93.4
(14)
WWO+AL: 91.9
(14.1)

WWO: 34.3
(3.6)
WWO+AL: 33.8
(4.1)</td><td>Control: 88.8
(13.8)

Control: 33.5
(3.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion of participants achieved >5% weight loss (%)
Proportion (%)</td><td>WWO: 25.5
WWO+AL: 14.3</td><td>Control: 12.9</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss (kg)
Mean (95% CIs)</td><td>WWO: -2.1
(1.1-3)
WWO+AL: -1.6
(0.6-2.6)</td><td>Control: -1.2
(0.2-2.3)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Thomas, 2019

Guideline record ID: 10883--1

Study characteristics		
Citation	Thomas, J. G., Bond, D. S., Raynor, H. A., Papandonatos, G. D., & Wing, R. R. (2019). Comparison of smartphone-based behavioral obesity treatment with gold standard group treatment and control: a randomized trial. Obesity, 27(4), 572-580. https://doi.org/https://dx.doi.org/10.1002/oby.22410	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Comparison of Smartphone-Based Behavioral Obesity Treatment With Gold Standard Group Treatment and Control: A Randomized Trial	
Location	US	
Trial name	Live SMART	
Methods		
Inclusion criteria	"English-fluent and literate participants (30% men and 30% racial/ethnic minorities), aged 18-70 years old, with overweight/obesity (body mass index [BMI] of 25-45 kg/m2) who were willing to use electronic resources for weight loss if assigned to SMART."	
Exclusion criteria	"The exclusion criteria included: currently in another weight loss program; taking weight loss medication; weight loss of ≥ 5% of body weight during the past 6 months; currently pregnant, lactating, less than 6 months postpartum, or plans to become pregnant during the next 18 months; report of a heart condition, chest pain during periods of activity or rest, or loss of consciousness on the Physical Activity Readiness Questionnaire (PAR-Q);15 report of a medical condition that would affect the safety of participating in unsupervised PA; inability to walk 2 blocks without stopping; history of bariatric surgery; report of conditions that in the opinion of the investigators would render the participant potentially unlikely to follow the protocol including terminal illness, plans to relocate, or a history of substance abuse, bulimia nervosa, or other significant uncontrolled or untreated psychiatric problem."	
Setting	Home, University/research centre, Mobile phone based	
Intervention	"Treatment in each condition began with a one-hour group session to set goals for weight loss, dietary intake, and PA, and to learn the procedures for self-monitoring and feedback. All participants were given an initial weight loss goal of 10% of their current body weight. To achieve this goal, participants were instructed to follow a low-calorie diet of 1,200-1,800 kcal/day depending on their baseline body weight, and gradually work towards performing 200 minutes of moderate-to-vigorous PA per week, with an emphasis on walking performed in bouts of ≥10 minutes. Participants assigned to GROUP attended treatment sessions in groups of 15-20 participants weekly for 6 months, bi-weekly for the following 6 months, and monthly for the final 6 months. Group interventionists were masters-level dieticians and exercise physiologists; two were assigned to lead each group. They weighed each participant privately before the group meeting and tracked their weight loss progress on a graph. The format and content of the group meetings followed the approach used in the behavioral interventions of the Diabetes Prevention Program (DPP) and Look Ahead trials.16,17 The early sessions were focused on dietary education and skills training, which emphasized following a low-fat diet (< 30% of calories from fat). Participants were instructed to build a PA habit starting with 10 minutes on at least 5 days/week, and gradually increase in increments of 10 minutes/day until reaching 200 minutes/week. Behavioral skills such as stimulus control, meal planning, and problem solving were taught to facilitate adherence and to address common barriers to weight loss.1 The end of each session involved setting a personal behavioral goal (e.g., limit fried food to once per week, try exercising with a friend), and the start of the next session involved a review of progress towards goals. Participants were instructed to self-monitor their daily weight, dietary intake	

	(noting the calorie and fat content of each food), and minutes spent physically active (only on days that PA was performed) using paper diaries and a nutritional reference book provided to them. The paper diaries were submitted at each treatment session and the interventionists returned them at the following session with brief written feedback consisting of praise, suggestions for further behavior change, and encouragement. Participants assigned to SMART received the same general content as GROUP via 5-minute skills training videos delivered 3 times weekly for 6 months, then twice weekly for 6 months, and weekly for the final 6 months (144 lessons total). This content was developed specifically for the purposes of this research study and it was delivered via a study application ("app") for smartphone devices. Once a video became available to a participant, it remained accessible until the end of their participation. Participants were instructed to use the free commercially available MyFitnessPal app for self-monitoring of daily weight, dietary intake, and PA minutes. The study interventionists that led the GROUP treatment retrieved these records electronically and used the study app to provide feedback at the same frequency as in the GROUP condition, with similar content and overall length. The study app also allowed participants in SMART to set up to three simultaneous behavioral goals to target, receive timed reminders, and report on their adherence (e.g., a participant setting a goal to prepare a lunch before leaving for work would receive a reminder in the morning and then indicate whether they prepared their lunch as planned). These data were available to the interventionist providing feedback. Lastly the app allowed participants to post brief messages that could be seen by all other SMART participants. Study interventionists conducted monthly individual weigh-ins with SMART participants lasting ≤10 minutes focused on evaluating progress toward the weight loss goal."
Control/Comparator	"Participants assigned to CONTROL attended monthly weigh-ins lasting ≤10 minutes with study interventionists to evaluate progress towards the weight loss goals. At each visit, brief printed information pertaining to the benefits of weight loss and healthy eating and PA habits, but not behavioral strategies for weight loss or behavior change, was provided. As in the GROUP condition, participants were instructed to selfmonitor their daily weight, dietary intake (noting the calorie and fat content of each food), and minutes spent physically active using paper diaries and a nutritional reference book provided to them. The paper diaries were mailed to a study interventionist who returned them by mail with brief written feedback mirroring the content and frequency of the feedback provided in GROUP and SMART."
Treatment duration	18 months
Follow-up from baseline	18 months
Eligible outcome(s) reported	Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 276 Intervention group/s: GROUP (n=106); SMART (n=114) Comparator group: CONTROL (n=56)
Mean age ± SD	55.1y (9.9)
Sex	82.97% female
Pre-existing medical condition	No pre-existing medical condition
Results	

<table>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight Loss, kg
Mean (95% CIs)

Weight Loss, %
Mean (95% CIs)</td><td>GROUP: -7.3
(5.8-8.8)
SMART: -6.6
(5.1-8)

GROUP: 7.6
(6-9.2)
SMART: 6.8
(5.3-8.4)</td><td>CONTROL: 6.7
(4.3-9)

CONTROL: 6.9
(4.5-9.4)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight Loss, kg
Mean (95% CIs)

Weight Loss, %
Mean (95% CIs)</td><td>GROUP: -5.9
(4.5-7.4)
SMART: 5.5
(3.9-7.1)

GROUP: 6.2
(4.7-7.7)
SMART: 5.7
(4.1-7.4)</td><td>CONTROL: 6.4
(3.7-9.2)

CONTROL: 6.7
(3.8-9.6)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td colspan="2">GROUP attended a mean 59.0% (95% CI 54.1 to 63.9) of 56 scheduled visits. Out of 19 scheduled visits, SMART attended 68.8% (95% CI 63.9 to 73.7) and CONTROL attended 61.1% (95% CI 52.4 to 69.8). Participants assigned to SMART viewed 72.4 (95% CI 57.8 to 87.0) video lessons across 18 months. Rates of self-monitoring body weight were significantly lower in GROUP (21.2%; 95% CI 17.9 to 25.9) than in SMART (30.7%; 95% CI 26.2 to 37.2) and in CONTROL (29.7%; 95% CI 21.7 to 37.7).</td></tr>
<tr><td>Notes</td><td colspan="2"></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td colspan="2"></td></tr>
</table>

N/A – Not applicable

Thompson, 2017

Guideline record ID: 10884--1

Study characteristics		
Citation	Thompson, C. C., Abu Dayyeh, B. K., Kushner, R., Sullivan, S., Schorr, A. B., Amaro, A., Apovian, C. M., Fullum, T., Zarrinpar, A., Jensen, M. D., Stein, A. C., Edmundowicz, S., Kahaleh, M., Ryou, M., Bohning, M. J., Ginsberg, G., Huang, C., Tran, D. D., Glaser, J. P., . . . Aronne, L. J. (2017). Percutaneous gastrostomy device for the treatment of class II and class III obesity: results of a randomized controlled trial. The American Journal of Gastroenterology, 112(3), 447-457. https://doi.org/https://dx.doi.org/10.1038/ajg.2016.500	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Percutaneous Gastrostomy Device for the Treatment of Class II and Class III Obesity: Results of a Randomized Controlled Trial	
Location	US	
Trial name	Pivotal Aspiration Therapy with Adjusted Lifestyle (PATHWAY)	
Methods		
Inclusion criteria	"Key eligibility criteria were age 21-65 years old and a body mass index (BMI; the weight in kilograms divided by the square of the height in meters) of 35.0-55.0 kg/m 2."	
Exclusion criteria	"Key exclusion criteria were history of gastrointestinal disease or previous abdominal surgery that would increase the risk of endoscopic A-tube placement, previous bariatric surgery, chronic abdominal pain, serious cardiovascular disease (including acute coronary syndrome or New York Heart Association class III or IV heart failure), use of medications that cause clinically signifi cant weight gain or loss, or a history of major depressive or other severe psychiatric disorders. In addition, potential participants were excluded if they had a history of an eating disorder (binge eating disorder, bulimia nervosa or night eating syndrome) or evidence of an eating disorder evaluated by using the Questionnaire on Eating and Weight Patterns-Revised (7) and by conducting an Eating Disorder Examination (8), which provide a self-reported measure and an interview-based assessment of binge eating, purging and disordered attitudes and behaviors related to eating, bodyshape, and weight."	
Setting	Hospital, Community (e.g. sports club, places of worship, commercial weight loss programs), University/research centre	
Intervention	"Participants randomized to therapy with AspireAssist underwent endoscopic placement of a specially designed gastrostomy tube, known as the A-tube, which has a 15-cm fenestrated intragastric portion to allow aspiration of gastric contents. The endoscopic procedure is analogous to the placement of a percutaneous endoscopic gastrostomy tube (9) (details of the procedure are provided in the Supplementary Appendix), which is typically performed on an outpatient basis and takes approximately 15-20 min to complete. After the gastrostomy matured, at approximately 10-14 days following A-tube placement, at the week-0 visit, the proximal end of the A-tube was cut to within 1 cm of the abdominal wall and attached to a Skin-Port. Participants were then trained on how to aspirate after meals and instructed to chew very thoroughly, to avoid A-tube blockage, and to aspirate about 20 min after each of three main meals daily. The components of the AspireAssist device and the aspiration procedure are shown in Figure 1 . The aspiration process involves flushing food particles out of the stomach and through the A-Tube by infusing water into the stomach from the reservoir and then reversing the flow by opening the clamp on the Companion component to allow gastric contents to drain out of the stomach into a lavatory. This process is repeated (typically 3-8 infusions) until food particles are no longer seen in the aspirate. The aspiration process usually takes 10-15 min to perform. The counter mechanism within the Connector counts down by 1 count, from 115 initial counts,	

<table>
<tr><td></td><td>each time the Connector opens the Skin Port valve. When the Counter reaches "0" counts (usually after ~5 weeks of therapy), the Connector can no longer open the Skin Port valve, preventing additional aspiration procedures without being seen by the research team to obtain a new Connector. Participants in both treatment groups completed a 10-session behavioral and diet education weight loss program (details provided in the Supplementary Appendix) delivered to participants over 52 weeks. Participants in both treatment groups were seen by the study team for medical monitoring, lifestyle counseling, and blood tests at weeks 0, 2, 6, 10, 14, 20, 24, 28, 32, 36, 40, 44, 48, and 52. An assessment of eating behaviors (assessed by the Questionnaire on Eating and Weight Patterns-Revised and the Eating Disorder Examination) was made at baseline and at weeks 28 and 52, in both treatment groups, and an additional assessment at week 14 in the AspireAssist group.”</td></tr>
<tr><td>Control/Comparator</td><td>“Participants in both treatment groups completed a 10-session behavioral and diet education weight loss program (details provided in the Supplementary Appendix) delivered to participants over 52 weeks. Participants in both treatment groups were seen by the study team for medical monitoring, lifestyle counseling, and blood tests at weeks 0, 2, 6, 10, 14, 20, 24, 28, 32, 36, 40, 44, 48, and 52. An assessment of eating behaviors (assessed by the Questionnaire on Eating and Weight Patterns-Revised and the Eating Disorder Examination) was made at baseline and at weeks 28 and 52, in both treatment groups.”</td></tr>
<tr><td>Treatment duration</td><td>52 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>52 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 171
Intervention group/s: AspireAssist group (n=111)

Comparator group: Lifestyle Counseling group (n=60)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 42.4y (10.0); Control: 46.8y (11.6)</td></tr>
<tr><td>Sex</td><td>87.13% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Body mass index-kg/m 2
Mean (SD)</td><td>AspireAssist group: 42
(5.1)</td><td>Lifestyle Counseling group:
40.9
(3.9)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>10% or more of initial body weight lost
Proportion (%)

At least 25% of excess body weight lost
Proportion (%)</td><td>AspireAssist group: 58.6

AspireAssist group: 58.6</td><td>Lifestyle Counseling group: 22

Lifestyle Counseling group: 22</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr></table></td></tr>
</table>

12 months or closest time point	Percent body weight loss Mean (SD) Change in weight Mean (SD) Excess body weight lost Mean (SD)	AspireAssist group: 12.1 (9.6) AspireAssist group: 14.2 (11.3) AspireAssist group: 31.5 (26.7)	Lifestyle Counseling group: 3.5 (6) Lifestyle Counseling group: 4.1 (7.2) Lifestyle Counseling group: 9.8 (15.5)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Successful endoscopic placement of the A-tube was achieved in 97% of attempts (111 of 114 endoscopies performed in 112 participants).		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Thorndike, 2021

Guideline record ID: 10886--1

Study characteristics		
Citation	Thorndike, A. N., McCurley, J. L., Gelsomin, E. D., Anderson, E., Chang, Y., Porneala, B., Johnson, C., Rimm, E. B., & Levy, D. E. (2021). Automated behavioral workplace intervention to prevent weight gain and improve diet: the ChooseWell 365 randomized clinical trial. JAMA Network Open, 4(6), e2112528. https://doi.org/10.1001/jamanetworkopen.2021.12528	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Automated Behavioral Workplace Intervention to Prevent Weight Gain and Improve Diet: The ChooseWell 365 Randomized Clinical Trial	
Location	US	
Trial name	ChooseWell 365	
Methods		
Inclusion criteria	"Employees were potentially eligible for the study if they were between the ages of 20 and 75 years and used their ID for cafeteria purchases on the main campus at least 4 times a week for at least 6 weeks over a 12-week period prior to enrollment."	
Exclusion criteria	"Exclusion criteria were plans to leave employment in the next year (eg, retirement), current pregnancy, desire to gain weight, history of eating disorder, weight loss surgery in prior 6 months or planned in the upcoming year, current enrollment in a weight loss program, and working in the MGH cafeteria or in the Translational and Clinical Research Center (TCRC), where study visits took place."	
Setting	Hospital	
Intervention	"Development of the study intervention has been described in detail elsewhere. After the baseline visit, participants randomized to the intervention group were emailed a result letter that included their daily calorie budget, calculated using the measured resting energy expenditure and physical activity levels and accounted for a participant's desire to lose or maintain weight. The letter also included fasting glucose, hemoglobin A1c (HbA1c), and lipid profile results. Participants received 2 emails per week that were automatically generated by the ChooseWell 365 software platform developed for this study. The first email, sent on Tuesdays, provided a log of all cafeteria items purchased during the prior week. The email included a colored summary graphic, as well as a list of daily items, calories, and remaining calories for each day (daily calorie goal minus total purchased calories) to provide a benchmark to guide future food choices. The second email, sent on Thursdays, provided 2 personalized tips about healthy eating, physical activity, or disease prevention, as well as a simple and healthy recipe. Prior to the study start, a database of more than 350 messages was developed by the study dietitian (E.D.G.) and physician (A.N.T.) using 6 predetermined domains: weight and energy balance, disease risk, workplace food, home food, barriers to healthy eating, and physical activity. The software platform pulled messages from the database that were triggered by participants' weekly cafeteria purchases, baseline survey responses, and health measurements (eTable 1 in Supplement 2). Participants received a monthly letter in the mail that included a graph illustrating the participant's monthly proportion of green, yellow, and red cafeteria items purchased, compared with all MGH employees and with the healthiest MGH employees, defined as employees with 80% or more green purchases. The letter also provided a green goal to earn a financial incentive by increasing green purchases in the next month. A reward of $20 could be earned for passing 40%, 60%, or 80% monthly green purchase thresholds. Each threshold could only be rewarded once. If a participant maintained green purchases above a new threshold (but did not pass the next threshold), or if they maintained greater than 80% green, they earned $5 for the month. Employees with the	

<table>
<tr><td></td><td>least healthy purchasing at baseline (ie, <40% green) could earn the most money over 12 months (maximum $115)”</td></tr>
<tr><td>Control/Comparator</td><td>“Participants assigned to the control group received a letter by email after the baseline visit with blood test results (glucose, HbA1c, and lipids). During the 12-month intervention period, control participants did not receive any emails; they received a monthly letter with standard healthy lifestyle tips, such as the benefits of eating vegetables and exercising regularly. To ensure that the intervention group received the same standard lifestyle information as the control group, one of the intervention group emails each month provided the same message.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 602
Intervention group/s: Intervention (n=299)

Comparator group: Control (n=303)</td></tr>
<tr><td>Mean age ± SD</td><td>43.6y (12.2)</td></tr>
<tr><td>Sex</td><td>79.40% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight category - Overweight (BMI 25-29.9)
Proportion (%)</td><td>Intervention: 30.8</td><td>Control: 33</td></tr>
<tr><td>Weight category - Obese (BMI ≥30)
Proportion (%)</td><td>Intervention: 32.8</td><td>Control: 27.7</td></tr>
<tr><td>Weight, kg
Mean (SD)</td><td>Intervention: 79.8
(18.8)</td><td>Control: 77
(18.3)</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Intervention: 28.6
(6.6)</td><td>Control: 28
(6.5)</td></tr>
<tr><td>Waist, cm
Mean (SD)</td><td>Intervention: 95.6
(17.8)</td><td>Control: 93.4
(16.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Weight, kg
Mean (95% CIs)</td><td>Intervention: 0.6
(0.1-1.1)</td><td>Control: 0.4
(-0.1-0.9)</td></tr>
</table>
</td></tr>
</table>

	Change in BMI Mean (95% CIs) Change in Waist, cm Mean (95% CIs)	Intervention: 0.2 (0.1-0.4) Intervention: 1 (-0.3-2.4)	Control: 0.2 (0-0.4) Control: 1.3 (0.5-2.2)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Change in Weight, kg Mean (95% CIs) Change in BMI Mean (95% CIs) Change in Waist, cm Mean (95% CIs)	Intervention: 1.5 (0.7-2.2) Intervention: 0.5 (0.3-0.8) Intervention: 1.3 (0-2.7)	Control: 0.9 (0.2-1.6) Control: 0.4 (0.1-0.6) Control: 1.8 (0.9-2.6)
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Topham, 2021

Guideline record ID: 10891A--OVERWEIGHT

Study characteristics		
Citation	Topham, G. L., Washburn, I. J., Hubbs-Tait, L., Kennedy, T. S., Rutledge, J. M., Page, M. C., Swindle, T., Shriver, L. H., & Harrist, A. W. (2021). The Families and Schools for Health Project: a longitudinal cluster randomized controlled trial targeting children with overweight and obesity. International Journal of Environmental Research and Public Health, 18(16), 8744. https://doi.org/https://dx.doi.org/10.3390/ijerph18168744	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Families and Schools for Health Project: A Longitudinal Cluster Randomized Controlled Trial Targeting Children with Overweight and Obesity	
Location	USA	
Trial name	Families and Schools for Health (FiSH)	
Methods		
Inclusion criteria	“Families with a 1st grade child (ages 6-7) who were at the 75th percentile or higher for BMI-for-age.”	
Exclusion criteria	“Children below the 75%ile were excluded from analyses.”	
Setting	School, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	“Family psychoeducational groups (FL and FL + FD) were held in the evenings at elementary school buildings or community centers during the spring of children's 1st grade year. Each family psychoeducational group was facilitated by one graduate and one advanced undergraduate student, one from the field of nutrition and one from either human development and family science or psychology. Concurrent parent and child groups were conducted in separate rooms. Childcare, snacks, and a small participant payment were offered to participating families. The psychoeducational groups included a total of 12 weekly, 90-min sessions (see Table 3). The Family Lifestyle (FL) component was based on the interventions designed by Epstein and Squires [24] and Satter [25], with a focus on developing healthy food and exercise habits to promote a healthy weight in participating children [26]. Parents and children met in separate groups for the first half of FL sessions and, during the second half, parents and children came together to make and eat a healthy snack. For the Family Lifestyle and Family Dynamics (FL + FD) groups, the first half mirrored the first half of the FL intervention sessions. However, in the FL + FD groups, parents and children remained separate during the second half and participated in the FD content. The FD component focused on general parenting and healthy family relationships (parent) and healthy emotion management and problem solving (child). The parent FD component was developed as an adaptation of the Love, Limits, and Latitude program [27]. Treatment fidelity was maximized by following manualized session scripts, conducting weekly staff meetings, and completing an independent review of a sample of session audio recordings. Fidelity was assessed by independent raters who reviewed randomly assigned audio recordings of group sessions (60% of sessions) and who assessed whether each topic in the intervention manual was covered. Across the 12 sessions for the child and parent FL groups, adherence to the manual was 91% and 90%, respectively. Across the 12 sessions for the child and parent FD groups, adherence to the manual was 88% and 90%, respectively. The Peer Group (PG) Intervention (received in FL + PG and FL + FD + PG conditions) involved implementation of a curriculum developed and piloted by the last author [28]. The intervention was based on the book, You Can't Say, 'You Can't Play!' (YCSYCP, [29]), which promotes teaching children to accept each other by disallowing rejection at school. YCSYCP facilitators were pairs of graduate and undergraduate students who conducted 12, 30-min weekly sessions across the spring semester in participant children's 1st grade classrooms (see Table 1). All children in the class received the PG component, regardless of whether	

<table>
<tr><td></td><td>they were enrolled in the FiSH Project. To support the intervention in the classroom when the project facilitators were not present, teachers were given Paley's book to read, were oriented to the YCSYCP curriculum by the last author, and were present when the PG intervention sessions were conducted."</td></tr>
<tr><td>Control/Comparator</td><td>"The control group consisted of children in 1st grade classrooms in schools randomly assigned to the control condition. As was the case for intervention children, anthropometric data were collected during each wave; however, no classroom or family interventions were offered or conducted with children in control schools."</td></tr>
<tr><td>Treatment duration</td><td>3.3 years</td></tr>
<tr><td>Follow-up from baseline</td><td>3.3 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 538
Intervention group/s: FL (n=117); FL + FD (n=87); FL + PG (n=124); FL + FD + PG (n=129)

Comparator group: Control (n=81)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>48.33% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Intervention effect vs control on Raw BMI - Overweight group
Beta coefficient</td><td>FL: 0.01
(0.02)
FL + FD: 0.03
(0.02)
FL + PG: 0.02
(0.02)
FL + FD + PG: -0.01
(0.02)</td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Across the 12 sessions for the child and parent FL groups, adherence to the manual was 91% and 90%, respectively. Across the 12 sessions for the child and parent FD groups, adherence to the manual was 88% and 90%, respectively.</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Topham, 2021

Guideline record ID: 10891B--OBESITY

Study characteristics		
Citation	Topham, G. L., Washburn, I. J., Hubbs-Tait, L., Kennedy, T. S., Rutledge, J. M., Page, M. C., Swindle, T., Shriver, L. H., & Harrist, A. W. (2021). The Families and Schools for Health Project: a longitudinal cluster randomized controlled trial targeting children with overweight and obesity. International Journal of Environmental Research and Public Health, 18(16), 8744. https://doi.org/https://dx.doi.org/10.3390/ijerph18168744	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Families and Schools for Health Project: A Longitudinal Cluster Randomized Controlled Trial Targeting Children with Overweight and Obesity	
Location	USA	
Trial name	Families and Schools for Health (FiSH)	
Methods		
Inclusion criteria	“Families with a 1st grade child (ages 6-7) who were at the 75th percentile or higher for BMI-for-age.”	
Exclusion criteria	“Children below the 75%ile were excluded from analyses.”	
Setting	School, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	“Family psychoeducational groups (FL and FL + FD) were held in the evenings at elementary school buildings or community centers during the spring of children's 1st grade year. Each family psychoeducational group was facilitated by one graduate and one advanced undergraduate student, one from the field of nutrition and one from either human development and family science or psychology. Concurrent parent and child groups were conducted in separate rooms. Childcare, snacks, and a small participant payment were offered to participating families. The psychoeducational groups included a total of 12 weekly, 90-min sessions (see Table 3). The Family Lifestyle (FL) component was based on the interventions designed by Epstein and Squires [24] and Satter [25], with a focus on developing healthy food and exercise habits to promote a healthy weight in participating children [26]. Parents and children met in separate groups for the first half of FL sessions and, during the second half, parents and children came together to make and eat a healthy snack. For the Family Lifestyle and Family Dynamics (FL + FD) groups, the first half mirrored the first half of the FL intervention sessions. However, in the FL + FD groups, parents and children remained separate during the second half and participated in the FD content. The FD component focused on general parenting and healthy family relationships (parent) and healthy emotion management and problem solving (child). The parent FD component was developed as an adaptation of the Love, Limits, and Latitude program [27]. Treatment fidelity was maximized by following manualized session scripts, conducting weekly staff meetings, and completing an independent review of a sample of session audio recordings. Fidelity was assessed by independent raters who reviewed randomly assigned audio recordings of group sessions (60% of sessions) and who assessed whether each topic in the intervention manual was covered. Across the 12 sessions for the child and parent FL groups, adherence to the manual was 91% and 90%, respectively. Across the 12 sessions for the child and parent FD groups, adherence to the manual was 88% and 90%, respectively. The Peer Group (PG) Intervention (received in FL + PG and FL + FD + PG conditions) involved implementation of a curriculum developed and piloted by the last author [28]. The intervention was based on the book, You Can't Say, 'You Can't Play!' (YCSYCP, [29]), which promotes teaching children to accept each other by disallowing rejection at school. YCSYCP facilitators were pairs of graduate and undergraduate students who conducted 12, 30-min weekly sessions across the spring semester in participant children's 1st grade classrooms (see Table 1). All children in the class received the PG component, regardless of whether	

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<tr><td>Control/Comparator</td><td>“The control group consisted of children in 1st grade classrooms in schools randomly assigned to the control condition. As was the case for intervention children, anthropometric data were collected during each wave; however, no classroom or family interventions were offered or conducted with children in control schools.”</td></tr>
<tr><td>Treatment duration</td><td>3.3 years</td></tr>
<tr><td>Follow-up from baseline</td><td>3.3 years</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 538
Intervention group/s: FL (n=117); FL + FD (n=87); FL + PG (n=124); FL + FD + PG (n=129)

Comparator group: Control (n=81)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>48.33% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Intervention effect vs control on Raw BMI - Obese group Beta coefficient</td><td>FL: -0.05
(0.02)
FL + FD: -0.02
(0.02)
FL + PG: -0.02
(0.02)
FL + FD + PG: -0.05
(0.02)</td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Across the 12 sessions for the child and parent FL groups, adherence to the manual was 91% and 90%, respectively. Across the 12 sessions for the child and parent FD groups, adherence to the manual was 88% and 90%, respectively.</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Tremblay, 2019

Guideline record ID: 10892

Study characteristics		
Citation	Tremblay, A., Dutheil, F., Drapeau, V., Metz, L., Lesour, B., Chapier, R., Pereira, B., Verney, J., Baker, J. S., Vinet, A., Walther, G., Obert, P., Courteix, D., & Thivel, D. (2019). Long-term effects of high-intensity resistance and endurance exercise on plasma leptin and ghrelin in overweight individuals: the RESOLVE Study. Applied Physiology, Nutrition, and Metabolism, 44(11), 1172-1179. https://doi.org/https://doi.org/10.1139/apnm-2019-0019	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-term effects of high-intensity resistance and endurance exercise on plasma leptin and ghrelin in overweight individuals: the RESOLVE Study	
Location	France	
Trial name	REverse metabolic SyndrOme by Lifestyle and Various Exercises (RESOLVE)	
Methods		
Inclusion criteria	"Aged between 50 and 70 years; diagnosed with metabolic syndrome (Alberti et al. 2005); were overweight and sedentary; maintained a stable body weight and medical treatment over the last 6 months; women were postmenopausal; did not have restricted diet over the previous year; and completed a satisfactory maximal oxygen uptake ($\dot{V}$O2max) test.Additionally, the participants had to be exempt from some diseases that had the potential to interfere with the metabolic outcome of this study and had to be free of any previous medical surgery that could have impacted the studied metabolism, such as bariatric surgery."	
Exclusion criteria	Not reported	
Setting	Home, participants stayed in a residential establishment	
Intervention	"Phase 1 This phase elapsed over 3 weeks during which participants stayed in a residential establishment where their exercise program and food intake were supervised. In each condition, participants had to perform 15-20 h of exercise per week that included 90 min of daily aerobic exercise plus four 90-min weekly resistance exercise sessions. As indicated above, the conditions differed by the relative intensity of either resistance or endurance exercise. A Polar S810 system (Polar Electro Oy, Kempele, Finland) was used to record and store heart rate values. Endurance training included aquagym, cycling, and walking whereas resistance training was based on 8 exercises with free weights and traditional muscular development equipment. For each exercise, participants had to perform 3 series of 10 repetitions. Maximal tests were realized at baseline to determine the individual capacities of each participant. Regarding the resistance intervention, tests were realized for each of the selected exercises to determine the participants' 10RM. The training intensity increased from 65% to 85% of 10RM for Re, whereas rE and re remained at 30% of 10RM. Resistance training was done 4 times a week and comprised a 15-min warm-up followed by height exercises with free weights and traditional muscle building equipment. Exercises were high pulley machine (lower back), seated row (upper back and trapezius), bench press (chest), chest fly (chest), squat press (legs), leg extension machine (quadriceps), dumbbell curl (biceps brachial), and triceps pushdown on high pulley (triceps brachial). Each exercise was performed for 3 sets of 10 repetitions with a 1-min rest interval. A $\dot{V}$O2peak test was also realized by each participant at baseline. Intensity of the endurance sessions increased gradually from 40% to 75% of $\dot{V}$O2max from week 1 to week 3 for rE, whereas Re remained at 30% of $\dot{V}$O2max. Throughout the residential program, participants received both standard and personalized meals prescribed by dietitians. Protein intake was set at 1.2 g/(kg body weight·day) and accounted for 15%-20% daily energy intake. Lipid and carbohydrate intake provided 30%-35% and 45%-55% daily energy intake, respectively (as requested by the national nutrition guideline, French Nutrition and Health National Plan;	

	PNNS). Total daily energy intake was calculated to promote a 500-kcal daily negative energy balance. Phase 2 This phase covered the remaining part of the 1-year intervention, i.e., between D21 and the end of M12. During this period, participants were requested to maintain the same training program individually while relying on guidelines and exercise prescription that they had received in phase 1"
Control/Comparator	"This phase elapsed over 3 weeks during which participants stayed in a residential establishment where their exercise program and food intake were supervised. In each condition, participants had to perform 15-20 h of exercise per week that included 90 min of daily aerobic exercise plus four 90-min weekly resistance exercise sessions. As indicated above, the conditions differed by the relative intensity of either resistance or endurance exercise. A Polar S810 system (Polar Electro Oy, Kempele, Finland) was used to record and store heart rate values. Endurance training included aquagym, cycling, and walking whereas resistance training was based on 8 exercises with free weights and traditional muscular development equipment. For each exercise, participants had to perform 3 series of 10 repetitions. Maximal tests were realized at baseline to determine the individual capacities of each participant. Regarding the resistance intervention, tests were realized for each of the selected exercises to determine the participants' 10RM. The training intensity increased from 65% to 85% of 10RM for Re, whereas rE and re remained at 30% of 10RM. Resistance training was done 4 times a week and comprised a 15-min warm-up followed by height exercises with free weights and traditional muscle building equipment. Exercises were high pulley machine (lower back), seated row (upper back and trapezius), bench press (chest), chest fly (chest), squat press (legs), leg extension machine (quadriceps), dumbbell curl (biceps brachial), and triceps pushdown on high pulley (triceps brachial). Each exercise was performed for 3 sets of 10 repetitions with a 1-min rest interval. A $\dot{V}$ O2peak test was also realized by each participant at baseline. Intensity of the endurance sessions remained at 30% of $\dot{V}$ O2max. Throughout the residential program, participants received both standard and personalized meals prescribed by dietitians. Protein intake was set at 1.2 g/(kg body weight·day) and accounted for 15%-20% daily energy intake. Lipid and carbohydrate intake provided 30%-35% and 45%-55% daily energy intake, respectively (as requested by the national nutrition guideline, French Nutrition and Health National Plan; PNNS). Total daily energy intake was calculated to promote a 500-kcal daily negative energy balance. Phase 2 This phase covered the remaining part of the 1-year intervention, i.e., between D21 and the end of M12. During this period, participants were requested to maintain the same training program individually while relying on guidelines and exercise prescription that they had received in phase 1."
Treatment duration	12 months
Follow-up from baseline	12 months
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 100 Intervention group/s: Re (n=34); rE (n=32) Comparator group: re (n=34)
Mean age ± SD	Not reported
Sex	56.00% female
Pre-existing medical condition	No pre-existing medical condition
Results	

<table>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Re: 32.1
(3.9)
rE: 34.4
(4.2)</td><td>re: 33.9
(4)</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Re: 85.4
(12.4)
rE: 94
(13.7)</td><td>re: 89
(12.7)</td></tr>
<tr><td>Fat mass (kg)
Mean (SD)</td><td>Re: 27.7
(7.6)
rE: 32.2
(7.7)</td><td>re: 33.9
(4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>Re: 29.9
(3.9)
rE: 31.3
(4)</td><td>re: 31.8
(4)</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Re: 79.2
(11.9)
rE: 84.9
(12.9)</td><td>re: 82.5
(12.7)</td></tr>
<tr><td>Fat mass (kg)
Mean (SD)</td><td>Re: 22.7
(7)
rE: 26.7
(8.1)</td><td>re: 31.8
(4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
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</table></td></tr>
<tr><td>Compliance with treatment</td><td>During phase 2, the mean compliance scores were 54.6% ± 22.1% for Re, 52.7% ± 26.1% for rE, and 52.1% ± 18.1% for re.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Dutheil, F., Lac, G., Lesourd, B., Chapier, R., Walther, G., Vinet, A., Sapin, V., Verney, J., Ouchchane, L., Duclos, M., Obert, P., & Courteix, D. (2013). Different modalities of exercise to reduce visceral fat mass and cardiovascular risk in metabolic syndrome: the RESOLVE randomized trial. International Journal of Cardiology, 168(4), 3634-3642. https://doi.org/https://dx.doi.org/10.1016/j.ijcard.2013.05.012</td></tr>
</table>

N/A – Not applicable

Trepanowski, 2017

Guideline record ID: 10893--1

Study characteristics		
Citation	Trepanowski, J. F., Kroeger, C. M., Barnosky, A., Klempel, M. C., Bhutani, S., Hoddy, K. K., Gabel, K., Freels, S., Rigdon, J., Rood, J., Ravussin, E., & Varady, K. A. (2017). Effect of alternate-day fasting on weight loss, weight maintenance, and cardioprotection among metabolically healthy obese adults: a randomized clinical trial. JAMA Internal Medicine, 177(7), 930-938. https://doi.org/10.1001/jamainternmed.2017.0936	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Alternate-Day Fasting on Weight Loss, Weight Maintenance, and Cardioprotection Among Metabolically Healthy Obese Adults: A Randomized Clinical Trial	
Location	US	
Trial name	N/A	
Methods		
Inclusion criteria	"Individuals included were men and women between 18 and 65 years of age, with a body mass index between 25.0 and 39.9 (calculated as weight in kilograms divided by height in meters squared) who had previously been sedentary (<60 minutes per week of light activity for the 3 months prior to the study)."	
Exclusion criteria	"Exclusion criteria were a history of cardiovascular disease or type 1 or 2 diabetes, use ofmedications that could affect study outcomes, unstable weight for 3 months prior to the beginning of the study (>4-kg weight loss or gain), perimenopause or otherwise irregular menstrual cycle, pregnancy, and currently smoking."	
Setting	Home, University/research centre	
Intervention	"The active trial duration was 1 year and consisted of a baseline phase (1 month), a weight-loss phase (6 months), and a weight-maintenance phase (6 months). We chose this design because weight loss typically peaks at 6 months during a lifestyle intervention. During the baseline phase, all participants ate their usual diet and maintained a stable weight. Baseline total energy expenditure was measured using doubly labeled water. All participants were instructed not to change their physical activity habits throughout the trial (eg, not to join a gym) to avoid potential confounding. Weight-Loss Phase Participants in the alternate-day fasting group and those in the daily calorie restriction group were provided with all meals during the first 3 months of the trial and received dietary counseling thereafter. During the 6-month weight-loss phase, the intervention groups were instructed to reduce their energy intake by a mean of 25% per day. To achieve this reduction, the alternate-day fasting group was instructed to consume 25% of baseline energy intake as a lunch (between 12 pm and 2 pm) on fast days and 125% of baseline energy intake split between 3 meals on alternating feast days. The daily calorie restriction group was instructed to consume 75% of baseline energy intake split between 3 meals every day. The provided meals were in accordance with the American Heart Association guidelines for macronutrient intake, with 30% of energy as fat, 55% as carbohydrate, and 15% as protein. From months 4 to 6, when food was no longer provided, intervention participants met individually with a dietician or nutritionist weekly to learn how to continue with their diets on their own. Weight-Maintenance Phase At the beginning of the 6-month weight-maintenance phase, total daily energy expenditure was reassessed using doubly labeled water. Participants were instructed to maintain their body weight during this phase. Participants in the alternate-day fasting group were instructed to consume 50% of energy needs as a lunch on fast days and 150% of energy needs split between 3 meals on alternating feast days. Participants in the daily calorie restriction group were instructed to consume 100% of energy needs split between 3 meals every day. Intervention participants met with the dietician individually each month to learn cognitive behavioral strategies to	

<table>
<tr><td></td><td>prevent weight regain and received personalized energy targets for weight maintenance based on results from doubly labeled water.”</td></tr>
<tr><td>Control/Comparator</td><td>“Control Group Protocol Participants in the control group were instructed to maintain their weight throughout the trial and not to change their eating or physical activity habits. Controls received no food or dietary counseling but visited the research center at the same frequency as the intervention participants (to provide outcome measurements). Controls who completed the 12-month trial received 3 months of free weight-loss counseling and a 12-month gym membership at the end of the study.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 100
Intervention group/s: Alternate-Day Fasting Group (n=34); Daily Calorie Restriction Group (n=35)

Comparator group: Control Group (n=31)</td></tr>
<tr><td>Mean age ± SD</td><td>44y (11)</td></tr>
<tr><td>Sex</td><td>86.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight, kg
Mean (SD)</td><td>Alternate-Day Fasting Group: 95
(13)
Daily Calorie Restriction Group: 101
(16)</td><td>Control Group: 92
(16)</td></tr>
<tr><td>Fat mass
Mean (SD)</td><td>Alternate-Day Fasting Group: 38
(7)
Daily Calorie Restriction Group: 40
(7)</td><td>Control Group: 36
(10)</td></tr>
<tr><td>BMI
Mean (SD)</td><td>Alternate-Day Fasting Group: 34
(4)
Daily Calorie Restriction Group: 35
(4)</td><td>Control Group: 34
(4)</td></tr>
<tr><td>Waist circumference
Mean (SD)</td><td>Alternate-Day Fasting Group: 102
(10)
Daily Calorie Restriction Group: 108
(11)</td><td>Control Group: 104
(12)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in ADF - Change in Control, Body weight, % change
Mean (95% CIs)

Change in ADF - Change in Control, Fat mass, kg
Mean (95% CIs)

Change in DCR - Change in Control, Body weight, % change
Mean (95% CIs)

Change in DCR - Change in Control, Fat mass, kg
Mean (95% CIs)</td><td>Alternate-Day Fasting Group:
-6
(-8.5--3.6)

Alternate-Day Fasting Group:
-2
(-4.4-0.5)

Alternate-Day Fasting Group:
-5.3
(-7.6)

Alternate-Day Fasting Group:
-2
(-4.4-0.4)</td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Trief, 2016

Guideline record ID: 10686--1

Study characteristics		
Citation	Trief, P. M., Fisher, L., Sandberg, J., Cibula, D. A., Dimmock, J., Hessler, D. M., Forken, P., & Weinstock, R. S. (2016). Health and psychosocial outcomes of a telephonic couples behavior change intervention in patients with poorly controlled type 2 diabetes: a randomized clinical trial. Diabetes Care, 39(12), 2165-2173. https://doi.org/https://doi.org/10.2337/dc16-0035	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Health and Psychosocial Outcomes of a Telephonic Couples Behavior Change Intervention in Patients With Poorly Controlled Type 2 Diabetes: A Randomized Clinical Trial	
Location	USA	
Trial name	Diabetes Support Project (DSP)	
Methods		
Inclusion criteria	“Couples were eligible if patients, with a willing partner able to speak and read English, met the following criteria: had a diagnosis of type 2 diabetes for >1 year (diagnosis confirmed by medical record and/or A1C level); baseline A1C level of ≥7.5% (58 mmol/mol); ≥21 years of age; able to speak and read English; in a self-defined committed relationship for ≥1 year; no severe medical or psychiatric conditions that might interfere with participation; and telephone access.”	
Exclusion criteria	Not reported	
Setting	Home, University/research centre	
Intervention	“INTERVENTIONS - Couples calls (CC) and Individual calls (IC): All groups participated in two telephone sessions (mean length of calls: 75 min) of comprehensive diabetes education. CC and IC interventions had 10 additional calls (mean length: CC 57 min/call). These behavioural interventions, based on social learning theory (which included knowledge development, goal setting, self-monitoring, and behavioural contracting), promoted changes in diet, activity, medication adherence, and blood glucose testing. The CC intervention was also based on Interdependence Theory; partners were actively involved in calls and homework. Couples were encouraged to provide mutual support for change, using collaborative problem solving techniques and recognizing their interdependence (i.e., reciprocal effects on one another). Two sessions were relationship focused, as follows: couples practiced the "speaker-listener technique" (partner shares concern, the other restates it until partner feels understood, then they switch roles) and communication/conflict management around a diabetes-related issue. Workbooks included precall readings, content for discussion, goal-setting forms, and diet/blood glucose/activity self-monitoring logs. Educators followed a "script," but tailored interventions to participants' cultural preferences and cognitive abilities.; IC: All groups participated in two telephone sessions (mean length of calls: 75 min) of comprehensive diabetes education. CC and IC interventions had 10 additional calls (mean length: IC 50 min/call). . These behavioural interventions, based on social learning theory (which included knowledge development, goal setting, self-monitoring, and behavioural contracting), promoted changes in diet, activity, medication adherence, and blood glucose testing. . In the IC arm, partners were not involved, and the two CC relationship-focused calls addressed individual problem solving. Workbooks included precall readings, content for discussion, goal-setting forms, and diet/blood glucose/activity self-monitoring logs. Educators followed a "script," but tailored interventions to participants' cultural preferences and cognitive abilities.”	

<table>
<tr><td>Control/Comparator</td><td>“CONTORL - Diabetes education (DE): All groups participated in two telephone sessions (mean length of calls: 75 min) of comprehensive diabetes education. In the DE arm, there was no further intervention.”</td></tr>
<tr><td>Treatment duration</td><td>CC: 12 weeks; IC: 12 weeks; DE: 2 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 268
Intervention group/s: CC (n=97); IC (n=93)

Comparator group: DE (n=78)</td></tr>
<tr><td>Mean age ± SD</td><td>56.8y (10.9)</td></tr>
<tr><td>Sex</td><td>38.43% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes >1 year</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>CC: 35.7
(6.3)
IC: 36
(8.2)

CC: 118.7
(15.2)
IC: 117.3
(18.3)</td><td>DE: 36
(8.1)

DE: 118.3
(18)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>CC: 35.2
(6.7)
IC: 36.1
(6.7)

CC: 116.8
(15.5)
IC: 116.9
(15.5)</td><td>DE: 35.6
(6.5)

DE: 116.6
(15.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
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<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Tuomilehto, 2010

Guideline record ID: 10900--1

Study characteristics		
Citation	Tuomilehto, H., Gylling, H., Peltonen, M., Martikainen, T., Sahlman, J., Kokkarinen, J., Randell, J., Tukiainen, H., Vanninen, E., Partinen, M., Tuomilehto, J., Uusitupa, M., Seppä, J., & Kuopio Sleep Apnea Group. (2010). Sustained improvement in mild obstructive sleep apnea after a diet- and physical activity-based lifestyle intervention: postinterventional follow-up. The American Journal of Clinical Nutrition, 92(4), 688-696. https://doi.org/10.3945/ajcn.2010.29485	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Sustained improvement in mild obstructive sleep apnea after a diet- and physical activity-based lifestyle intervention: postinterventional follow-up	
Location	Finland	
Trial name	N/A	
Methods		
Inclusion criteria	"The inclusion criteria for the initial trial were 1) age 18-65 y, 2) body mass index (BMI; in kg/m2) 28-40, and 3) an apnea-hypopnea index (AHI) of 5 to 15 events/h."	
Exclusion criteria	"Excluded patients were considered simple snorers (ie, snoring reported as the only symptom and an AHI, 5 in sleep recordings)."	
Setting	Home, University/research centre	
Intervention	"The dietary intervention had several main goals, including the reduction of dietary fat to 30% of total energy; an increase in the intake of fruit, vegetables, poultry, fish, and lean meat; and the limitation of dairy fats, fatty meat, and desserts. The clinical nutritionist provided dietary and lifestyle counselling at each of the 14 visits, specifically focusing on eating behaviour. Body weight was measured at each visit, and the patients were asked about the lifestyle changes they had undertaken. The intervention was initiated with a 12-wk VLCD providing 600-800 kcal/d via Nutrilett (Nycomed Pharma, Oslo, Norway), Modifast (Novartis, Basel, Switzerland), Nutrifast (Leiras, Turku, Finland), or Naturdiet (Vitamex, Norrko¨ping, Sweden), which was followed by advice on how to improve the daily diet according to the current dietary recommendations. The nutritionist provided face-to-face counseling individually tailored to each patient in the intervention group and also participated in the group sessions. In addition to dietary counseling, the subjects in the intervention group were advised to increase their overall level of daily physical activity and endurance exercise (such as walking, skiing, jogging, or swimming). The possible changes undertaken and the frequency of physical activity of the participants were self-reported at the follow-up."	
Control/Comparator	"The subjects in the control group were given standard care consisting of general oral and written information about diet and exercise at the baseline and 3- and 12-mo visits by the study nurse and physician without any specific individualized advice. During the second year, no intervention or advice was offered to either of the study groups, and the study nurse checked regularly that the participants did not receive any co-intervention for OSA other than that specified in the study design."	
Treatment duration	12 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 81
Intervention group/s: Intervention group (n=40)

Comparator group: Control group (n=41)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 51y (9.0); Control: 51.7y (8.8)</td></tr>
<tr><td>Sex</td><td>22.22% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Mild obstructive sleep apnea (OSA) with an apnea-hypopnea index (AHI) of 5 to 15 events/h</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention group: 100.8
(12)

Intervention group: 33.4
(2.8)

Intervention group: 112.5
(8.7)</td><td>Control group: 92.3
(11.4)

Control group: 31.6
(2.8)

Control group: 105.8
(7.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Weight (kg)
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)

Change in Waist circumference (cm)
Mean (SD)</td><td>Intervention group: -7.3
(6.5)

Intervention group: -2.4
(2.1)

Intervention group: -7.7
(6.7)</td><td>Control group: -2.9
(7.5)

Control group: -1
(2.6)

Control group: -3.5
(7.3)</td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>During the intervention period, the rate of participation in these sessions varied from 70% to 80%, and actual compliance with the intervention was achieved in 83% (29/35) of the patients.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Sahlman, J., Seppä, J., Herder, C., Peltonen, M., Peuhkurinen, K., Gylling, H., Vanninen, E., Tukiainen, H., Punnonen, K., Partinen, M., Uusitupa, M., & Tuomilehto, H. (2012). Effect of weight loss on inflammation in patients with mild obstructive sleep apnea. Nutrition, Metabolism & Cardiovascular Diseases, 22(7), 583-590. https://doi.org/10.1016/j.numecd.2010.10.007</td></tr>
</table>

N/A – Not applicable

Tur, 2013

Guideline record ID: 10901--1

Study characteristics		
Citation	Tur, J. J., Escudero, A. J., Alos, M. M., Salinas, R., Terés, E., Soriano, J. B., Nicola, G., Urgelés, J. R., Pagán, A., Cortes, B., González, X., & Burguera, B. (2013). One year weight loss in the TRAMOMTANA study. A randomized controlled trial. Clinical Endocrinology, 79(6), 791-799. https://doi.org/https://dx.doi.org/10.1111/cen.12109	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	One year weight loss in the TRAMOMTANA study. A randomized controlled trial	
Location	Spain	
Trial name	Multidisciplinary treatment of morbid obesity: medication, behavioral therapy, nutritional support, and physical activity (TRAMOMTANA)	
Methods		
Inclusion criteria	"Inclusion criteria were: (1). Age between 18 and 65 years. (2). Men or women of any ethnic group with BMI >40 kg/m2 . (3). Arterial pressure <160/100 mmHg. (4). A fasting triglycerides levels greater than 600 mg/dl and a <11% glycosylated haemoglobin (HbA1C) level. The patients had voluntarily signed and dated the informed consent after being explained the nature of the study and after having given them the opportunity to ask questions."	
Exclusion criteria	"The exclusion criteria included pregnancy, enrolment in another obesity intervention, prior bariatric surgery, drug or alcohol abuse and mental disorders (Depression and anxiety which was considered manageable by the investigator was not a criteria for exclusion) and/or physical impairment, or any other which could interfere with the ability to comply with treatment."	
Setting	Hospital, University/research centre	
Intervention	"Intensive life style intervention (ILI) group. A total of 60 subjects were assigned to receive intensive life style behavioural modification. They attended weekly group meetings from weeks 1 through to 12, sessions were conducted biweekly from weeks 13 to 52. Meetings included 10-12 subjects, lasted 90 min, and were led by a registered nurse, Master in nutrition. The group sessions were focused on the qualitative aspects of the dietary habits, as the distribution of energy intake, frequency of consumption and food choices. We provided information on the benefits of the Mediterranean diet and encouraged our patients to follow this diet. There were no restrictions in calorie intake. Nutrition education strategies took into account the patients' social, economic and cultural life of their personalities, their habits, customs and preferences, recognizing their personal circumstances and situations. The nutritional evaluation assessed food intake and identified eating triggers (e.g. times of emotional upset). Subjects were instructed to complete weekly homework assignments during a 72-h period -to develop perspectives on food preferences and meal patterns (e.g. how many meals, when, where, with whom, duration) and physical activity. We also addressed their difficulties (e.g. physical, economical and social limitations) in carrying out the life style changes that we were asking them to slowly develop. Records were reviewed at weekly meetings. A physician, sports medicine specialist, prescribed daily exercise (led by a physiotherapist), physical self-checks and stretching without resistance in sets of 2 min every 4-6 h, coordinated with breath control, before moving to aerobic exercise. This pattern served as recognition of the limitations of the body as a tool and relied heavily on home-based exercise with gradual progression towards a goal of 175 min of moderate-intensity physical activity per week, and programmes were tailored based on the results of a baseline physical fitness test and safety concerns. Patients could receive treatment with weight loss medicines, such as orlistat or antidepressants at the physician's discretion. Forty per cent of the patients included in this	

<table>
<tr><td></td><td>group received treatment with sibutramine for a period of 1-2 months until it was withdrawn from the market in January of 2010”</td></tr>
<tr><td>Control/Comparator</td><td>“Conventional Obesity Therapy (COT) group. The Conventional Obesity Therapy (COT) (n = 33) group received the standard available nutritional education, medical treatment and follow-up available for patients with morbid obesity following the protocols approved by the Spanish Endocrine Society (Table 3). Patients had regular clinic visits with an endocrinologist and a dietician every 3-6 months throughout the duration of the study. Medical therapies, including the use of drugs, were determined by their endocrinologist on an individual basis.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 106
Intervention group/s: ILI (n=60)

Comparator group: COT (n=46)</td></tr>
<tr><td>Mean age ± SD</td><td>46.5y (10.7)</td></tr>
<tr><td>Sex</td><td>67.92% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (Kg)
Mean (SD)

Body-mass index (Kg/m2)
Mean (SD)</td><td>ILI: 122.24
(20.05)

ILI: 45.79
(4.97)</td><td>COT: 126.02
(17.9)

COT: 46.76
(4.62)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (Kg)
Mean (SD)

Body-mass index (Kg/m2)
Mean (SD)</td><td>ILI: 108.09
(18.56)

ILI: 40.15
(5.33)</td><td>COT: 125.52
(18.71)

COT: 46.37
(4.83)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight Mean (%)
Mean %

Change in BMI
Mean %</td><td>ILI: -11.58

ILI: -12.32</td><td>COT: -0.4

COT: -0.83</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
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</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Turner-McGrievy, 2023

Guideline record ID: 10951--1

Study characteristics		
Citation	Turner-McGrievy, G. M., Wilcox, S., Frongillo, E. A., Murphy, E. A., Hutto, B., Wilson, M., Davey, M., Bernhart, J. A., Okpara, N., Bailey, S., & Hu, E. (2023). Effect of a plant-based vs omnivorous soul food diet on weight and lipid levels among African American adults: a randomized clinical trial. JAMA Network Open, 6(1), e2250626. https://doi.org/10.1001/jamanetworkopen.2022.50626	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a Plant-Based vs Omnivorous Soul Food Diet on Weight and Lipid Levels Among African American Adults: A Randomized Clinical Trial	
Location	USA	
Trial name	Nutritious Eating With Soul (NEW Soul)	
Methods		
Inclusion criteria	"Aged 18 to 65 years with overweight or obesity (defined as body mass index [BMI; calculated as weight in kilograms divided by height in meters squared] of 25.0-49.9) who self-identify as African American."	
Exclusion criteria	"Currently following a vegan diet, pregnant or planning a pregnancy within 2 years, currently participating a weight loss program or taking weight loss medications, weight loss >10lbs in the last 6 months, type 2 diabetes controlled with medications or uncontrolled thyroid condition."	
Setting	University/research centre	
Intervention	"Vegan diet with a focus on soul food and traditional African cuisine, and both emphasize plant-rich, low-fat eating styles (Table 3). The vegan diet recommends a whole food, plant-based dietary approach [16, 17], meaning a focus on minimally processed plant foods and avoiding refined foods, including oils. Participants are encouraged to meet their fat requirements through whole foods (e.g., nuts, nut butters, avocados, and seeds). All classes included a review of the previous class's SMART (Specific, Measurable, Achievable, Relevant, and Time-Bound) goal24; a discussion of successes and challenges from the previous week led by a community facilitator; a presentation of a nutrition topic (eg, greens, making a meal plan, and protein); a cooking demonstration by a community soul food chef, NEW Soul nutrition interventionist (M.D.), or hands-on in groups; a physical activity or stress management activity; and setting of the next SMART goal. Participants were provided with a binder with the food group recommendations, example meal ideas, and starter recipes. At each class, participants received additional handouts related to the topics covered in class and recipes."	
Control/Comparator	"The omni diet follows the Therapeutic Lifestyle Changes dietary guidelines in order to have guidance on portion sizes for foods like lean meats [18]. Both diets are guided by the Oldways African Heritage Pyramid [19], which emphasizes intake of fruits, vegetables, particularly leafy greens and tubers, and whole grains. The omni diet also included the intake of fish, poultry, and low-fat dairy, and modest amounts of red meat, as outlined by the Oldways pyramid. All classes included a review of the previous class's SMART (Specific, Measurable, Achievable, Relevant, and Time-Bound) goal24; a discussion of successes and challenges from the previous week led by a community facilitator; a presentation of a nutrition topic (eg, greens, making a meal plan, and protein); a cooking demonstration by a community soul food chef, NEW Soul nutrition interventionist (M.D.), or hands-on in groups; a physical activity or stress management activity; and setting of the next SMART goal. Participants were provided with a binder with the food group recommendations,	

<table>
<tr><td></td><td>example meal ideas, and starter recipes. At each class, participants received additional handouts related to the topics covered in class and recipes.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 159
Intervention group/s: Vegan (n=77)

Comparator group: Omnivorous (n=82)</td></tr>
<tr><td>Mean age ± SD</td><td>48.4y (10.6)</td></tr>
<tr><td>Sex</td><td>79.25% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Body mass index
Mean (SD)</td><td>Vegan: 37
(6.3)</td><td>Omnivorous: 36.8
(7.5)</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Vegan: 102.9
(18.9)</td><td>Omnivorous: 102.8
(23.2)</td></tr>
<tr><td>Total percentage body fat
Mean (SD)</td><td>Vegan: 45.2
(6.7)</td><td>Omnivorous: 44.2
(8.1)</td></tr>
<tr><td>Total lean mass
Mean (SD)</td><td>Vegan: 54.4
(9.4)</td><td>Omnivorous: 54.9
(11.6)</td></tr>
<tr><td>Waist circumference, cm
Mean (SD)</td><td>Vegan: 106.5
(15.3)</td><td>Omnivorous: 107.2
(17)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight change (kg)
Mean (SE)</td><td>Vegan: -2.39
(0.55)</td><td>Omnivorous: -2.03
(0.53)</td></tr>
<tr><td>Change in total percentage body fat at 12 months
Mean (SE)</td><td>Vegan: -0.32
(0.3)</td><td>Omnivorous: -0.29
(0.29)</td></tr>
<tr><td>Change in total lean mass, kg, over 12 months
Mean (SE)</td><td>Vegan: -1.51
(0.3)</td><td>Omnivorous: -1.26
(0.3)</td></tr>
</table>
</td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	Weight change (kg) Mean (SE)	Vegan: -2.46 (0.6)	Omnivorous: -2.02 (0.56)
Compliance with treatment	Intervention: 35%; Control: 26% at 12 months		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Unick, 2017

Guideline record ID: 10903--1

Study characteristics		
Citation	Unick, J. L., Lang, W., Williams, S. E., Bond, D. S., Egan, C. M., Espeland, M. A., Wing, R. R., Tate, D. F., & SNAP Research Group. (2017). Objectively-assessed physical activity and weight change in young adults: a randomized controlled trial. International Journal of Behavioral Nutrition and Physical Activity, 14, 165. https://doi.org/https://dx.doi.org/10.1186/s12966-017-0620-x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Objectively-assessed physical activity and weight change in young adults: a randomized controlled trial	
Location	USA	
Trial name	Study of Novel Approaches to Weight Gain Prevention (SNAP)	
Methods		
Inclusion criteria	"Participants were normal weight (BMI: 21 to <25 kg/m2) or overweight (BMI: 25 to 30 kg/m2), between the ages of 18 and 35, English speaking, and had no medical conditions that would limit their ability to make dietary or PA changes."	
Exclusion criteria	"Exclusion Criteria: 1. Untreated hypertension, hyperlipidemia, or type 2 diabetes, unless permission is provided by their health care provider. 2. Heart disease, heart problems or report being prescribed drugs for blood pressure or a major heart condition, unless permission is provided by their health care provider. 3. Type 1 diabetes or treatment of type 2 diabetes with insulin or oral medication that may cause hypoglycemia. 4. Health problems which may influence the ability to walk for physical activity (e.g. lower limb amputation) or other reasons why a person should not do physical activity, unless permission is provided from their health care provider. Health problems that may be associated with unintentional weight change or affect the safety of a weight loss program, including report of a heart attack or stroke, chest pain during periods of activity or rest, loss of consciousness, active tuberculosis, HIV, chronic hepatitis B or C, inflammatory bowel disease requiring treatment within the past year, thyroid disease, renal disease, liver disease, hospitalization for asthma in the past year, or cancer within the past 5 years (except for non-melanoma skin cancers or early stage cervical cancer) or chronic use of steroid medication. 6. Report of a past diagnosis of or treatment for a Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition-Text Revision (DSM-IV-TR) eating disorder (anorexia nervosa or bulimia nervosa) or meet criteria for anorexia or bulimia nervosa during screening for this trial. 7. Report of a past diagnosis of or current symptoms of alcohol or substance dependence. 8. Currently pregnant, pregnant within the past 6 months, or planning to become pregnant within the next 6 months. 9. History of schizophrenia, manic depression, or bipolar disorder. 10. Hospitalization for depression or other psychiatric disorder within the past 12 months. 11. Having lost and maintained a weight loss of 10 pounds or more within the past 6 months or are currently participating in a weight loss program, trying to gain weight, using steroids for muscle mass or weight gain, taking weight loss medication, or have had surgery for weight loss. 12. Participation in another weight loss or physical activity study that would interfere with this study. 13. Another member of the household (or roommate) is a participant or staff member on this trial. 14. Reason to suspect that the participant would not adhere to the study intervention or assessment schedule (i.e., can't come to group on a regular basis; will be away for more than two weeks during initial intervention phase or planning to move from the area within next year). 15. Not able to speak and understand English. 16. Residence or place of work further than 30 miles from the intervention site. 17. Perceived inability to attend the 2 year data collection visit. 18. Does not have Internet access on a regular basis."	

<table>
<tr><td>Setting</td><td>Hospital, University/research centre</td></tr>
<tr><td>Intervention</td><td>“Small changes: Participants randomized to SC were instructed to make daily, small changes in diet and PA in order to prevent weight gain. Dietary recommendations focused on reducing calorie intake by 100 cal per day through 'small' behavior modifications, such as reducing portion sizes or selecting lower calorie alternatives. Further, SC participants were given pedometers and instructed to increase daily steps by 2000 steps/day above their baseline level (equivalent to 1 mile of walking) through changes in lifestyle activities (e.g., parking further from the store or using the stairs). Participants were given a monthly chart to record their daily weight, steps, and whether they made any small changes to their diet. This was completed daily during the first 16 weeks and during refresher courses. These were reviewed by interventionists and feedback was provided. Large changes: Participants randomized to LC were instructed to make lar ger changes to their diet and PA to create a 5 to 10 pound buffer against future weight gain within the first 4 months [18]. Participants were instructed to reduce calorie intake by 500-1000 kcals/day (depending upon initial body weight) and increase PA gradually to ≥250 min/week of MVPA. Once this 'buffer' was created, participants were instructed to gradually increase calorie intake to maintain their reduced weight and to maintain this high level of PA throughout the remainder of the study. If at any point a participant's weight exceeded their baseline weight, it was recommended that they return to their initial calorie intake and recreate another 5-10 lb. buffer. Participants were instructed to record their weight, diet, and minutes of PA daily. These diaries were reviewed by an interventionist and feedback was provided”</td></tr>
<tr><td>Control/Comparator</td><td>“Self-guided (control condition) Participants in the control condition attended one in-person group session and were provided with general information on weight gain in young adults, which included basicguidelines for self-weighing and a brief overview of both SC and LC approaches. They were then encouraged to select the approach that would work best for them and apply these strategies over the course of the study. Participants were sent quarterly newsletters via postal mail and were provided with links to internet resources via a study website but received no additional contact from intervention staff.”</td></tr>
<tr><td>Treatment duration</td><td>4 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 595
Intervention group/s: Small Changes (n=199); Large Changes (n=195)

Comparator group: Control (n=201)</td></tr>
<tr><td>Mean age ± SD</td><td>27.7y (4.4)</td></tr>
<tr><td>Sex</td><td>77.98% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight at Baseline (kg) Mean (SD)</td><td>Small Changes: 71.9 (11)
Large Changes: 70.8 (11)</td><td>Control: 71.4 (10.2)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Least square mean (95% CIs)</td><td>Small Changes: -1.4
(-2--0.7)
Large Changes: -2.5
(-3.1--1.9)</td><td>Control: -0.4
(-1-0.3)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight (kg)
Least square mean (95% CIs)</td><td>Small Changes: -1
(-1.8--0.3)
Large Changes: -1.6
(-2.3--0.8)</td><td>Control: 0.7
(0-1.4)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Compliance to wearing the armband was excellent at baseline (7.1 ± 0.9 days for 14.1 ± 1.5 h/day) and remained high at 4 months (6.6 ± 1.3 days for 13.7 ± 1.8 h/day), 1 year (6.6 ± 1.4 days for 13.7 ± 1.8 h/day) and 2 years (6.6 ± 1.4 days for 13.6 ± 1.6 h/day). 28.4% of participants averaging the national recommendation for daily steps (≥10,000 steps/ day). Attendance at face-to-face intervention meetings did not differ between SC (86.0%) and LC (87.4%)</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Valero-Perez, 2020

Guideline record ID: 10904--1

Study characteristics		
Citation	Valero-Pérez, M., Bermejo, L. M., López-Plaza, B., García, M. A., Palma-Milla, S., & Gómez-Candela, C. (2020). Regular consumption of Lipigo® promotes the reduction of body weight and improves the rebound effect of obese people undergo a comprehensive weight loss program. Nutrients, 12(7), 1960. https://doi.org/https://dx.doi.org/10.3390/nu12071960	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Regular Consumption of Lipigo R Promotes the Reduction of Body Weight and Improves the Rebound Effect of Obese People Undergo a Comprehensive Weight Loss Program	
Location	Spain	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were as follows: age between 18 and 65 years, BMI of ≥2 7 and <40 kg/m2, willing to follow a balanced hypocaloric diet to lose weight and perform regulated physical activity, absence of familial or social environment that prevents compliance with dietary treatment, having a suitable understanding of the clinical trial, agreeing to voluntarily participate in the study, and signing the informed consent form."	
Exclusion criteria	"The exclusion criteria were as follows: treatment for CV risk (dyslipidemia, hypertension, diabetes mellitus, and others), mental illness or low cognitive ability, history of severe liver or kidney disease or cancer, pregnancy or lactation, plans to stop smoking or to lose weight, allergy to any of the compounds of Lipigo® as well as subjects who consumed >30 g/day alcohol, subjects were also excluded if they had participated in any program or clinical trials of weight control within the last 6 months."	
Setting	Hospital	
Intervention	"The intervention was divided in two phases: a weight-loss intervention phase (WLP) (12 weeks) in which all subjects were included in a dietary program controlled in 6 visits taking place every two weeks (V0-V6); and a follow-up post-weight lost intervention phase (P-WLP) (40 weeks) controlled in 3 visits taking place every three months (V7-V9). During both phases (WLP and P-WLP) participants were randomized with sex stratification to consume 3 sticks/day of Lipigo® or Placebo (2 sticks just before the lunch and 1 stick just before the dinner). Hypocaloric diets (between 1500 and 3000 Kcal) were prescribed individually for all participants by a dietician expert at the Department of Nutrition of La Paz University Hospital, Madrid. Diets were designed to provide 30% less energy than the total energy expenditure (TEE) at baseline being 1500 kcal the lower limit for caloric restriction. Basal metabolic rate (BMR) was measured by bioelectric impedance Electro Fluid Graph + (EFG) (Akern s.r.l., Florence, Italy). BMR and TEE calculations were corrected according to physical activity and sex as recommended by the World Health Organization (WHO). Proposed hypocaloric diet consisted of 50-55% carbohydrates from total energy intake (added sugars <10%) and 29-34% fat (saturated fatty acids <10%, polyunsaturated fatty acids 5-10% and monounsaturated fatty acids, mainly from virgin olive oil, to complete the lipid profile), according to the recommendations of the Spanish Society of Community Nutrition (SENC, according to its Spanish initials, [22]). Proteins represented 20% of total energy intake (between 0.9-1.8 g/kg of body weight/day), based on body composition benefits observed in a recent meta-analysis [23]. The food intake was distributed in 5 meals: 3 main meals (breakfast, lunch, and dinner) and 2 snacks (mid-morning (11:00 a.m.-11:29 a.m.), and afternoon (5:00-5:29 p.m.)). The hypocaloric dietary program was prescribed at baseline (V0) of the WLP: participants received a 7-day-meal plan as an example of the individualized diet designed for each one. Moreover, each participant received a food exchange list, allowing the personalization of diet plans according to individual preferences,	

	but ensuring that the resulting menu would provide the individual nutritional requirements calculated. Further dietary counseling was given every two weeks (V1-V5) until the end of the WLP (12th week, V6). Dieticians used all these visits to resolve questions and to motivate participants sufficiently to comply with dietary advice. All subjects were given recommended portion sizes and information on possible food swaps. Moreover, nutrition education and motivational sessions were given by the dietician. In V0 subjects were instructed to perform moderate physical activity for 1 h at least 3 times a week. The subjects began according to their level of physical activity and gradually increased until they achieved 3 sessions per week or more at the end of WLP. During the WLP, participants attended 5 nutrition and health education sessions (visits 1 to 5) goals to promote healthy eating and physical activity. During the WLP and P-WLP, subjects consumed 3 sticks/day of Lipigo® or Placebo (2 sticks just before the lunch and 1 stick just before the dinner) Lipigo® is a fiber combination obtained from S. cerevisiae from the brewery industry. Each stick contained a polysaccharide-rich fraction (909 mg β-glucan, 91 mg chitin-chitosan) and 400 mg excipients. The polysaccharide fraction was obtained by a specific hydrolysis procedure of residual S. cerevisiae from brewery patented by DAMM S.A (El Prat del Llobregat, Barcelona, Spain). The nutritional composition per 100 g of dry product was: protein, 1.6 g; fat, 3.7 g; carbohydrates 58.7 g; dietary fiber, 29.9 g; and sodium 0.6 g."
Control/Comparator	"The intervention was divided in two phases: a weight-loss intervention phase (WLP) (12 weeks) in which all subjects were included in a dietary program controlled in 6 visits taking place every two weeks (V0-V6); and a follow-up post-weight lost intervention phase (P-WLP) (40 weeks) controlled in 3 visits taking place every three months (V7-V9). During both phases (WLP and P-WLP) participants were randomized with sex stratification to consume 3 sticks/day of Lipigo® or Placebo (2 sticks just before the lunch and 1 stick just before the dinner). Hypocaloric diets (between 1500 and 3000 Kcal) were prescribed individually for all participants by a dietician expert at the Department of Nutrition of La Paz University Hospital, Madrid. Diets were designed to provide 30% less energy than the total energy expenditure (TEE) at baseline being 1500 kcal the lower limit for caloric restriction. Basal metabolic rate (BMR) was measured by bioelectric impedance Electro Fluid Graph + (EFG) (Akern s.r.l., Florence, Italy). BMR and TEE calculations were corrected according to physical activity and sex as recommended by the World Health Organization (WHO). Proposed hypocaloric diet consisted of 50-55% carbohydrates from total energy intake (added sugars <10%) and 29-34% fat (saturated fatty acids <10%, polyunsaturated fatty acids 5-10% and monounsaturated fatty acids, mainly from virgin olive oil, to complete the lipid profile), according to the recommendations of the Spanish Society of Community Nutrition (SENC, according to its Spanish initials, [22]). Proteins represented 20% of total energy intake (between 0.9-1.8 g/kg of body weight/day), based on body composition benefits observed in a recent meta-analysis [23]. The food intake was distributed in 5 meals: 3 main meals (breakfast, lunch, and dinner) and 2 snacks (mid-morning (11:00 a.m.-11:29 a.m.), and afternoon (5:00-5:29 p.m.)). The hypocaloric dietary program was prescribed at baseline (V0) of the WLP: participants received a 7-day-meal plan as an example of the individualized diet designed for each one. Moreover, each participant received a food exchange list, allowing the personalization of diet plans according to individual preferences, but ensuring that the resulting menu would provide the individual nutritional requirements calculated. Further dietary counseling was given every two weeks (V1-V5) until the end of the WLP (12th week, V6). Dieticians used all these visits to resolve questions and to motivate participants sufficiently to comply with dietary advice. All subjects were given recommended portion sizes and information on possible food swaps. Moreover, nutrition education and motivational sessions were given by the dietician. In V0 subjects were instructed to perform moderate physical activity for 1 h at least 3 times a week. The subjects began according to their level of physical activity and gradually increased until they achieved 3 sessions per week or more at the end of WLP. During the WLP, participants attended 5 nutrition and health education sessions (visits 1 to 5) goals to promote healthy eating and physical activity. Placebo was composed of 1000 mg maltodextrine and 400 mg excipients. DAMM S.A. prepared the Lipigo® and the Placebo sticks specifically for this study. Both types of sticks were packaged in box packs of 30 sticks. The packs were labeled as either L1 or L2 to maintain blinded conditions. During every visit in the WLP, subjects received all the sticks needed until the next visit every two weeks. At baseline of the P-WLP

<table>
<tr><td></td><td>(V6) and in the V7 and V8, subjects received all the sticks need to complete three months to the next visit. The sticks received by each participant were assigned according to the randomization.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 73
Intervention group/s: Lipigo (n=37)

Comparator group: Placebo (n=36)</td></tr>
<tr><td>Mean age ± SD</td><td>50.9y (8.9)</td></tr>
<tr><td>Sex</td><td>91.78% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Lipigo: 82.65
(12.48)

Lipigo: 31.18
(3.28)

Lipigo: 98.18
(11.05)</td><td>Placebo: 82.65
(12.48)

Placebo: 31.21
(3.65)

Placebo: 97.35
(11.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Lipigo: 79.67
(13.01)

Lipigo: 29.79
(3.32)

Lipigo: 93.94
(10.66)</td><td>Placebo: 80.18
(12.49)

Placebo: 30.27
(3.62)

Placebo: 91.4
(17.54)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Weight (kg)
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)

Change in Waist circumference (cm)
Mean (SD)</td><td>Lipigo: -3.36
(3.36)

Lipigo: -1.4
(1.58)

Lipigo: -3.48
(3.25)</td><td>Placebo: -2.47
(3.41)

Placebo: -0.94
(1.32)

Placebo: -3.08
(3.44)</td></tr>
</table>
</td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	<table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table>
Compliance with treatment	Compliance was measured by comparing the number of sticks provided and the number of empty sticks returned. A subject was considered compliant when he/she consumed ≥80% of the sticks provided. 88.2 ± 8.04% of the participants showed proper adherence to treatment.
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

van der Aa, 2016

Guideline record ID: 10905--1

Study characteristics		
Citation	van der Aa, M. P., Elst, M. A. J., van de Garde, E. M. W., van Mil, E. G. A. H., Knibbe, C. A. J., & van der Vorst, M. M. J. (2016). Long-term treatment with metformin in obese, insulin-resistant adolescents: results of a randomized double-blinded placebo-controlled trial. Nutrition & Diabetes, 6(8), e228. https://doi.org/https://dx.doi.org/10.1038/nutd.2016.37	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-term treatment with metformin in obese, insulin-resistant adolescents: results of a randomized double-blinded placebo-controlled trial	
Location	Netherlands	
Trial name	N/A	
Methods		
Inclusion criteria	"Age 10-16 years; BMI-SDS >2.3; HOMA-IR >=3.4; Caucasian decent; Written informed consent."	
Exclusion criteria	"T2DM; PCOS; Endocrine disorders treated with corticosteroids; Height <1.3 SD from target height; Syndromal disorders; Pregnancy; (History of) alcohol abuse; Impaired renal function (GFR <80ml/min); Impaired hepatic function (ALT>150% of normal value for age); Insufficient knowledge of Dutch language."	
Setting	Hospital, Home	
Intervention	"Medication Participants received immediate-release metformin 500 mg tablets (Centrapharm, Etten-Leur, The Netherlands) or identical placebo tablets (Apotheek Haagse Ziekenhuizen, Den Haag, The Netherlands) in an increasing dosing regimen, with a maximum dose of two tablets twice daily in the fourth study week. Subjects were advised to take the medication during or after breakfast and dinner. In case of gastrointestinal complaints, the dosage was reduced to the last well-tolerated dose. After symptoms had disappeared, the dosage was again increased to the maximum of two tablets twice daily, if tolerated. To estimate medication compliance, pill counts were performed on returned medication packages during each hospital visit (every 3 months). Physical training. Physical training by a physical therapist was offered twice weekly to all participants. During the monthly phone calls and three monthly visits participants were encouraged to attend these trainings"	
Control/Comparator	"Medication Participants received identical placebo tablets (Apotheek Haagse Ziekenhuizen, Den Haag, The Netherlands) in an increasing dosing regimen, with a maximum dose of two tablets twice daily in the fourth study week. Subjects were advised to take the medication during or after breakfast and dinner. In case of gastrointestinal complaints, the dosage was reduced to the last well-tolerated dose. After symptoms had disappeared, the dosage was again increased to the maximum of two tablets twice daily, if tolerated. To estimate medication compliance, pill counts were performed on returned medication packages during each hospital visit (every 3 months). Physical training. Physical training by a physical therapist was offered twice weekly to all participants. During the monthly phone calls and three monthly visits participants were encouraged to attend these trainings."	
Treatment duration	18 months	
Follow-up from baseline	18 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 42
Intervention group/s: Metformin (n=23)

Comparator group: Placebo (n=19)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 13.6y; Control: 12.0y</td></tr>
<tr><td>Sex</td><td>66.67% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Insulin resistance: HOMA-IR ≥3.4</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Median (IQR)

BMI-SDS
Median (IQR)

Weight (kg)
Median (IQR)</td><td>Metformin: 29.8
(28.1-34.5)

Metformin: 3.1
(2.72-3.52)

Metformin: 82.2
(75.4-92.7)</td><td>Placebo: 30.5
(28.7-38.6)

Placebo: 3.38
(3.1-4.2)

Placebo: 86.1
(74-103)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI
Median (IQR)

BMI-SDS
Median (IQR)

Weight (kg)
Median (IQR)</td><td>Metformin: 29.9
(26.3-33.6)

Metformin: 2.9
(2.34-3.39)

Metformin: 83.4
(76.6-94.2)</td><td>Placebo: 32.8
(29.3-40.4)

Placebo: 3.29
(3.02-4.18)

Placebo: 96.7
(79-111)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in BMI
Median (IQR)

Change in BMI-SDS
Median (IQR)

Change in weight (kg)
Median (IQR)</td><td>Metformin: 0.2
(-2.9-1.3)

Metformin: -0.12
(-0.5-0.08)

Metformin: 1.6
(-4.2-5.9)</td><td>Placebo: 1.2
(-0.3-2.4)

Placebo: 0.04
(-0.24-0.1)

Placebo: 12
(2.7-17)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>In the metformin group 74% (17/22 participants) returned their medication boxes at least 4 times, versus 69% in the placebo group (13/18 participants). The returned boxes contained on average 28% and 24% of its content for the metformin and placebo groups, respectively.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

van der Baan-Slootweg, 2014

Guideline record ID: 10906--1

Study characteristics		
Citation	van der Baan-Slootweg, O., Benninga, M. A., Beelen, A., van der Palen, J., Tamminga-Smeulders, C., Tijssen, J. G. P., & van Aalderen, W. M. C. (2014). Inpatient treatment of children and adolescents with severe obesity in the Netherlands: a randomized clinical trial. JAMA Pediatrics, 168(9), 807-814. https://doi.org/10.1001/jamapediatrics.2014.521	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Inpatient treatment of children and adolescents with severe obesity in the Netherlands: a randomized clinical trial	
Location	Netherlands	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were 8 to 18 years of age and a BMI z score of at least 2.3, corresponding to the 98.9th percentile, according to the growth curves based on the fourth Dutch National Growth Study of 1997 (calculated via http://groeiweb .pgdata.nl/calculator.asp), with obesity-related comorbidity (eg, obstructive sleep apnea syndrome, elevated insulin levels, type 2 diabetes mellitus, liver function disorders, hypertension, dyslipidemia, joint problems) or a BMI z score of at least 3.0 (corresponding to the 99.9th percentile)."	
Exclusion criteria	"Exclusion criteria consisted of severe psychiatric disorder, intellectual disability, obesity caused by endocrine disorders (eTable in the Supplement), use of medication that could cause significant weight gain or weight loss, and/or participation in a concomitant weight management program."	
Setting	Hospital	
Intervention	"Patients randomized to the inpatient treatment program were hospitalized for 26 weeks. They followed a program during weekdays and returned home for the weekends with homework assignments. The program consisted of an exercise schedule 4 days per week (30 to 60 minutes each day, with a mean duration of 45 minutes for each exercise session) and nutrition/behavior modification once per week (60 minutes for each session). Patients and caregivers received comparable information about nutrition and behavior, but the 1-hour lessons were held separately, at 3 times during the treatment period. A child psychologist facilitated the behavior modification element of the weight management program in individual and group sessions. Topics included self-regulation, self-awareness, goal setting, stimulus control, coping skills training, cognitive behavioral strategies, contingency management, and positive reinforcement formeeting (self-imposed) goals.Behaviormodification classes for caregivers included the same topic, with additional topics that reflected the challenges verbalized by the parents (eg, preparing healthy meals, implementing physical activity in the family's routine, how to help the child when the caregiver fails to change their own habits). Aside from group sessions, individual meetings with a dietician, a psychologist, or a social worker were organized as needed. An exercise therapist led the exercise component of the weight management program. The standardized training sessionswith high-intensity aerobic exercise (indoor, outdoor, and swimming activities) occurred in groups (n ≤ 10). Besides these organized activities, patients were encouraged to participate in outside activities daily, with other patients or on their own, to change their sedentary behavior. Thenutritional educational component of the programused a nondiet approach, focusing on improving the quality of the dietary intake and on trying to establish controlled yet flexible eating behaviors. A stable and predictive pattern of eating was promoted, and children were encouraged to try unfamiliar foods. By creating more awareness of their feelings of hunger and satisfaction, physical regulation of food intake was stimulated. The nutritional education of the parents included	

<table>
<tr><td></td><td>the above-mentioned components with more in-depth knowledge of nutrition, such as understanding food labels.”</td></tr>
<tr><td>Control/Comparator</td><td>“Patients randomized to the ambulatory treatment program and their caregivers attended the program for 12 visits at increasing time intervals for a 6-month period. After weighing, the children exercised for an hour (swimming and gymnastics). Children and parents were also encouraged to exercise at home on 3 additional days per week and to reduce sedentary behaviors. After physical exercise, the children attended an educational program for 1 hour and a nutritional educational session for half an hour. In parallel sessions, caregivers were given detailed instructions on nutrition and nutritional behavior. The classes emphasized the importance of the parents' role in inducing changes in health behaviors. The exercise counseling was given by exercise therapists who delivered exercise classes to the patients. The content of the nutrition classes, behavioral modification classes, and homework assignments for children and parents/caregivers was identical to that given during the inpatient treatment program.”</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>30 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 90
Intervention group/s: Inpatient (n=45)

Comparator group: Ambulatory (n=45)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 13.8y (2.3); Control: 13.9y (2.5)</td></tr>
<tr><td>Sex</td><td>57.78% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI z score
Mean (SD)

Waist circumference
Mean (SD)</td><td>Inpatient: 3.35
(0.56)

Inpatient: 105.01
(16.83)</td><td>Ambulatory: 3.35
(0.56)

Ambulatory: 103.42
(17.24)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI z score
Mean (SD)</td><td>Inpatient: 2.85
(0.84)</td><td>Ambulatory: 3.1
(0.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI z score
Mean (SD)

Waist circumference
Mean (SD)</td><td>Inpatient: 3.13
(1.1)

Inpatient: 105.01
(20.76)</td><td>Ambulatory: 3.3
(1.17)

Ambulatory: 105.77
(23.1)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>% Change in BMI z Score
Mean</td><td>Inpatient: -14.7</td><td>Ambulatory: -7.6</td></tr>
</table></td></tr>
</table>

Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
	% Change in BMI z Score Mean	Inpatient: -6.3	Ambulatory: -1.5
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

van Gemert, 2015

Guideline record ID: 10908--1

Study characteristics		
Citation	van Gemert, W. A., Monninkhof, E. M., May, A. M., Peeters, P. H., & Schuit, A. J. (2015). Effect of exercise on insulin sensitivity in healthy postmenopausal women: the SHAPE study. Cancer Epidemiology, Biomarkers & Prevention, 24(1), 81-87. https://doi.org/https://dx.doi.org/10.1158/1055-9965.EPI-14-0722	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of exercise on insulin sensitivity in healthy postmenopausal women: the SHAPE study	
Location	Netherlands	
Trial name	Sex Hormones And Physical Exercise (SHAPE)	
Methods		
Inclusion criteria	"Eligible women were of ages 50 to 69 years, postmenopausal and sedentary. Postmenopausal was defined as 12 months since last menses. Being sedentary was defined as being engaged in less than 2 h/wk of moderate or vigorous physical activities. Furthermore, women had to be nonsmokers and had to have nondiabetic fasting glucose levels (<7 mmol/L)."	
Exclusion criteria	"Main exclusion criteria were having diabetes (type I or II), ever diagnosed with cancer in the 5 years preceding recruitment, and use of exogenous hormones."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The 1-year exercise program comprised 2.5 hours of moderate to vigorous intensity physical activity [average metabolic equivalent (MET) of 7; ref. 26] per week. Women were strictly advised to perform the 2.5 hours of exercise in addition to their usual physical activity pattern. Supervised group sessions of 1 hour combined aerobic and strength exercise were provided twice a week. In addition, participants were instructed to perform one 30-minute home-based session of individual aerobic exercise. The group sessions were provided in a nearby fitness center by qualified sports instructors. Fifteen to 20 women were included in one group. Classes started with a 10-minute warming-up and ended with a 5-minute cooling down. Heart rate monitors were worn to ensure an intensity of 60% to 85% of the age-predicted maximum heart rate during the 30-minute aerobic exercise. The 25-minute strength training consisted of sets of eight to 12 repetitions of exercises for each major muscle group. The intensity and number of sets were gradually increased during the study period. The exercise program is described in more detail in the Supplementary Data. Compliance to the exercise program was monitored by the sports instructors, who registered attendance, and by study personnel who visited the exercise sites regularly. Women were asked to record their home-based exercise activities (type, duration, and average heart rate) in an exercise diary."	
Control/Comparator	"Controls were asked to maintain their habitual physical activity level. All participants were asked to maintain their usual diet."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 189
Intervention group/s: Exercise group (n=96)

Comparator group: Control group (n=93)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 58.9y (4.6); Control: 58.4y (4.2)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Fat mass (kg)
Mean (SD)

Body fat %
Mean (SD)</td><td>Exercise group: 73.6
(8.2)

Exercise group: 26.6
(2.9)

Exercise group: 28.3
(5.7)

Exercise group: 39.8
(4.5)</td><td>Control group: 74.8
(10.8)

Control group: 27.3
(3.6)

Control group: 29.9
(8)

Control group: 40.9
(5.8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)

Change in fat mass (kg)
Mean (95% CIs)

Change in body fat %
Mean (95% CIs)</td><td>Exercise group: -0.66

Exercise group: -0.33
(-0.66-0.005)

Exercise group: -0.43
(-0.74--0.13)</td><td>Control group: -0.34

N/A

N/A</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>63%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Van Name, 2016

Guideline record ID: 10909--1

Study characteristics		
Citation	Van Name, M. A., Camp, A. W., Magenheimer, E. A., Li, F., Dziura, J. D., Montosa, A., Patel, A., & Tamborlane, W. V. (2016). Effective translation of an intensive lifestyle intervention for Hispanic women with prediabetes in a community health center setting. Diabetes Care, 39(4), 525-531. https://doi.org/https://dx.doi.org/10.2337/dc15-1899	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effective Translation of an Intensive Lifestyle Intervention for Hispanic Women With Prediabetes in a Community Health Center Setting	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Women between 18 and 65 years of age with at least one risk factor for diabetes, including BMI >= kg/m2, a family history of type 2 diabetes, a history of gestational diabetes mellitus, a child born .9 pounds (4 kg), or a diagnosis of hypertension, dyslipidemia, or cardiovascular disease."	
Exclusion criteria	"Subjects were excluded from the study if they were pregnant or planning to become pregnant, were taking medications that would affect weight or glucose metabolism, or had chronic medical or psychiatric disorders that would interfere with their ability to participate in the exercise or other components of the ILI program."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The FHCHC ILI is a modified version of the National Institute of Diabetes and Digestive and Kidney Diseases DPP intervention. It consists of a familycentered 14-week group program held in the classrooms and cafeteria of a public school near the health center. Participants attend a 1-h lifestyle class one evening per week, which focuses on healthy food choices, behavior change, and weight loss. The curriculum closely follows the sequence and materials from the DPP Research Group (11). The curriculum was enhanced for a population with lower literacy with a hands-on learning approach including weekly cooking demonstrations using fresh ingredients harvested from FHCHC's community garden, group learning sessions at the local grocery store, and encouragement to participate in the neighborhood community farm. The weekly program is led and supervised by a bilingual nurse practitioner from the CHC, who received training in the DPP curriculum at the University of Pittsburgh's Diabetes Prevention Support Center. Classes are conducted in both English and Spanish, and all handouts and presentation materials are also bilingual. A 1-h, trainer-led group exercise class occurs 2-3 nights per week, with 1 night per week offered immediately after the lifestyle class. For facilitation of class attendance and a family-based approach at home, participants are encouraged to attend with family members, including children and babies. A parallel program of play-based physical activity for children and adolescents and child care for the youngest are offered simultaneously at the school."	
Control/Comparator	"Subjects randomized to the usual care group continued to receive follow-up care by their primary care provider at the FHCHC. In addition, they received one-time diabetes prevention counseling by study staff who recommended they lose 7% of their body weight and increase physical activity to 150 min/week. Follow-up dietary counseling by the center's nutritionist was offered. This is the standard care provided to patients diagnosed with prediabetes in this CHC. At the end of 12 months upon study conclusion, these subjects were offered entry into the ILI program."	

<table>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 130
Intervention group/s: ILI (n=65)

Comparator group: Usual care (n=65)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 43.8y (10.8); Control: 43.0 (9.7)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight, kg
Mean (SD)

BMI, kg/m2
Mean (SD)

Waist circumference, cm
Mean (SD)</td><td>ILI: 84.8
(24.8)

ILI: 35.4
(8.5)

ILI: 106.9
(15.4)</td><td>Usual care: 87.1
(22.8)

Usual care: 35.2
(7.3)

Usual care: 109
(15)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Weight, kg
Least squares mean and CI

Change in weight, %
Least squares mean and CI

Change in BMI, kg/m2
Least squares mean and CI

Change in Waist circumference, cm
Least squares mean and CI</td><td>ILI: -3.8
(-4.6--3)

ILI: -4.4
(-5.4--3.5)

ILI: -1.6
(-2--1.3)

ILI: -3.3
(-5.2--1.4)</td><td>Usual care: 1.4
(0.6-2.2)

Usual care: 1.6
(0.7-2.6)

Usual care: 0.6
(0.2-0.9)

Usual care: -0.2
(-2.1-1.7)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

van Wier, 2011

Guideline record ID: 10912--1

Study characteristics		
Citation	van Wier, M. F., Dekkers, J. C., Hendriksen, I. J. M., Heymans, M. W., Ariëns, G. A. M., Pronk, N. P., Smid, T., & van Mechelen, W. (2011). Effectiveness of phone and e-mail lifestyle counseling for long term weight control among overweight employees. Journal of Occupational and Environmental Medicine, 53(6), 680-686. https://doi.org/10.1097/JOM.0b013e31821f2bbb	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effectiveness of Phone and E-Mail Lifestyle Counseling for Long Term Weight Control Among Overweight Employees	
Location	Netherlands	
Trial name	ALIFE@Work	
Methods		
Inclusion criteria	"BMI (calculated as weight in kilograms divided by height in meters squared) ≥ 25 kg/m2; paid employment ≥ 8 hours/week; able to read and write Dutch; access to the Internet (at work or at home); minimum age 18 years; not pregnant; no diagnosis or treatment for disorders that would make physical activity difficult."	
Exclusion criteria	"Employees with a BMI < 25 kg/m2, as calculated from the measurements, were excluded."	
Setting	Hospital, Home	
Intervention	"All groups received self-help brochures about overweight, healthy diet, and physical activity. In addition, the phone group and the Internet group had access to a lifestyle intervention program, adapted from previous research carried out by HealthPartners in Minnesota.20 On the basis of the principles of behavior modification,21 it consisted of ten modules. These modules provided information on nutrition and physical activity and explained behavior modification strategies (eg, self-monitoring, goal-setting). The phone group received the program in the form of a workbook. The Internet group accessed the program through an interactive Web site composed of personalized Web pages. No diet or exercise prescription was given, but participants were encouraged to set their own behavioral goals toward the Dutch dietary and physical activity guidelines. After finishing each module, the participants were contacted by their personal counselor, depending on group allocation, either by phone or e-mail. The counseling was provided by four trained counselors (two dieticians and two physical activity scientists), according to a standardized protocol, for a maximum of 6 months.18"	
Control/Comparator	"Control received self-help brochures about overweight, healthy diet, and physical activity."	
Treatment duration	6 months	
Follow-up from baseline	2 years	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 1386 Intervention group/s: Phone (n=462); Internet (n=464) Comparator group: Control (n=460)	
Mean age ± SD	43y (8.6)	

<table>
<tr><td>Sex</td><td>32.97% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Phone: 93.6
(14)
Internet: 92.9
(14.4)</td><td>Control: 93
(13.4)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Phone: 102.4
(9.7)
Internet: 101.5
(9.9)</td><td>Control: 101.3
(9.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Phone: 92.1
(13.7)
Internet: 91.0
(14.4)</td><td>Control: 92.0
(13.2)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Phone: 99.8
(10.1)
Internet: 99.4
(10.4)</td><td>Control: 99.5
(9.7)</td></tr>
<tr><td>≥5% weight loss
Proportion (%)</td><td>Phone: 22.1
Internet: 22.4</td><td>Control: 15.9</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Participants in the phone group, 34% completed all counseling sessions, compared to 18% in the Internet group</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Gussenhoven, A. H. M., van Wier, M. F., Bosmans, J. E., Dekkers, J. C., & van Mechelen, W. (2013). Cost-effectiveness of a distance lifestyle counselling programme among overweight employees from a company perspective, ALIFE@Work: a randomized controlled trial. Work, 46(3), 337-346. https://doi.org/10.3233/WOR-121555</td></tr>
</table>

N/A – Not applicable

Verduci, 2021

Guideline record ID: 10914--1

Study characteristics		
Citation	Verduci, E., Banderali, G., Di Profio, E., Vizzuso, S., Zuccotti, G., & Radaelli, G. (2021). Effect of individual- versus collective-based nutritional-lifestyle intervention on the atherogenic index of plasma in children with obesity: a randomized trial. Nutrition & Metabolism, 18, 11. https://doi.org/10.1186/s12986-020-00537-w	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of individual- versus collective-based nutritional-lifestyle intervention on the atherogenic index of plasma in children with obesity: a randomized trial	
Location	Italy	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria: BMI z-score>2, based on the WHO references [21], age 6 - 12 years, gestational age 37-42 weeks, body weight at birth ≥2500 g and <4000 g, single birth, white parents, family living in Milan or neighbourhood (≤30 km)."	
Exclusion criteria	"Exclusion criteria: child having syndromic, organic and/or hormonal conditions besides obesity, child on a diet and/or medication that could afect body weight, child needing hospital admission."	
Setting	Hospital	
Intervention	"Individual- The study protocol planned to administer the participants to an individual-intervention promoting a normo-caloric diet and physical activity. General dietary recommendations were balanced and age- and sex-adjusted in accordance with the national guidelines for treatment of childhood obesity [22] and the Italian Society of Human Nutrition [23], that are Daily Energy Intake (En) 1372-2499 kcal (depending on age and sex); protein: 0.94-0.97 g/kg/die; carbohydrates: 45%-60% En, sugar<15% En; fats: 20%-35% En (of which saturated fatty acids <10% En, polyunsaturated fatty acids 5-10% En); fiber: 8.4 g/1000 kcal [22, 23]. Any child was further requested to engage in at least 60 min of moderate to vigorous daily physical activity (MVPA) [24]. The children and their parents were trained in the hospital during an educational two-hours session held by the same expert paediatrician assisted by a nutritionist. he training course was organized to be held individually (individual intervention), and instructed them and parents about regulation of energy expenditure, body composition, physical activity, consequences of sedentary lifestyle, principles of nutrition, food sources, glycemic index and glucose metabolism. In the individual intervention, recommendations were refined and personalized on the child's preferences regarding food and lifestyle, and a series of supplementary behaviour modification techniques were recommended in accordance to the Coventry, Aberdeen and London-Refined (CALO-RE) taxonomy (items 1, 2, 5, 6, 8, 16, 21, and 26) [25]. Written guidelines were given to the parents, including general nutritional advice, food choice lists, recommended average servings for principal food categories, according to Italian Dietary Reference Values [23]. General nutritional advices included increasing fruit and vegetables (>400 g/ die, or five portions [26]), legume and fish intakes while decreasing meat consumption, avoiding sugar-sweetened beverages and limiting sweets and introducing more whole grain food, also according to the principles of the Mediterranean diet [27]. An illustrated brochure explaining potential benefits of daily physical activity and a diary for daily recording physical activity of the child in terms of type, frequency, duration and intensity were given to parents. The paediatrician invited parents to contact the hospital staff throughout the intervention period when needed or desired, in any case whenever any adverse event occurred. The educational session was repeated 6 months after starting the intervention. Compliance with nutritional intervention was	

<table>
<tr><td></td><td>estimated at 12 months by the rate of daily dietary energy intake within the recommended range, and compliance with physical activity by the rate of MPVA longer than 60 min.”</td></tr>
<tr><td>Control/Comparator</td><td>“Collective - The study protocol planned to administer the participants to a collective-based intervention promoting a normo-caloric diet and physical activity. Both in individual and collective intervention, general dietary recommendations were balanced and age- and sex-adjusted in accordance with the national guidelines for treatment of childhood obesity [22] and the Italian Society of Human Nutrition [23], that are Daily Energy Intake (En) 1372-2499 kcal (depending on age and sex); protein: 0.94-0.97 g/kg/die; carbohydrates: 45%-60% En, sugar<15% En; fats: 20%-35% En (of which saturated fatty acids <10% En, polyunsaturated fatty acids 5-10% En); fiber: 8.4 g/1000 kcal [22, 23]. Any child was further requested to engage in at least 60 min of moderate to vigorous daily physical activity (MVPA) [24]. The children and their parents were trained in the hospital during an educational two-hours session held by the same expert paediatrician assisted by a nutritionist. The training course was organized to be held in a class of 4 children (collective intervention) and instructed them and parents about regulation of energy expenditure, body composition, physical activity, consequences of sedentary lifestyle, principles of nutrition, food sources, glycemic index and glucose metabolism. Written guidelines were given to the parents, including general nutritional advice, food choice lists, recommended average servings for principal food categories, according to Italian Dietary Reference Values [23]. General nutritional advices included increasing fruit and vegetables (>400 g/ die, or five portions [26]), legume and fish intakes while decreasing meat consumption, avoiding sugar-sweetened beverages and limiting sweets and introducing more whole grain food, also according to the principles of the Mediterranean diet [27]. An illustrated brochure explaining potential benefits of daily physical activity and a diary for daily recording physical activity of the child in terms of type, frequency, duration and intensity were given to parents. The paediatrician invited parents to contact the hospital staff throughout the intervention period when needed or desired, in any case whenever any adverse event occurred. The educational session was repeated 6 months after starting the intervention. Compliance with nutritional intervention was estimated at 12 months by the rate of daily dietary energy intake within the recommended range, and compliance with physical activity by the rate of MPVA longer than 60 min.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 153
Intervention group/s: Individual (n=76)

Comparator group: Collective (n=77)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 10.0y (2.4); Control: 9.9y (2.3)</td></tr>
<tr><td>Sex</td><td>52.29% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body mass index z-score Mean (95% CIs)</td><td>Individual: 3.21 (3.1-3.32)</td><td>Collective: 3.13 (3-3.2)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body mass index z-score
Mean (95% CIs)</td><td>Individual: 2.58
(2.46-2.7)</td><td>Collective: 2.72
(2.61-2.83)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Body mass index z-score
Mean (95% CIs)</td><td>Individual: -0.63
(-0.72--0.54)</td><td>Collective: -0.41
(-0.51--0.31)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Compliance with the intervention was 90.8% and 88.3% in children who underwent individual or collective intervention respectively</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Vermunt, 2012

Guideline record ID: 10916--1

Study characteristics		
Citation	Vermunt, P. W. A., Milder, I. E. J., Wielaard, F., de Vries, J. H. M., Baan, C. A., van Oers, J. A. M., & Westert, G. P. (2012). A lifestyle intervention to reduce type 2 diabetes risk in Dutch primary care: 2.5-year results of a randomized controlled trial. Diabetic Medicine, 29(8), e223-231. https://doi.org/https://dx.doi.org/10.1111/j.1464-5491.2012.03648.x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A lifestyle intervention to reduce Type 2 diabetes risk in Dutch primary care: 2.5-year results of a randomized controlled trial	
Location	Netherlands	
Trial name	Active Prevention in High Risk individuals Of Diabetes Type 2 in and around Eindhoven (APHRODITE)	
Methods		
Inclusion criteria	"A Dutch translation of the Finnish FINDRISC [16] was sent to patients aged ‡ 40 years and £ 70 years (n = 16 032). Individuals with a score ‡ 13 points were invited to participate in the study."	
Exclusion criteria	"Four exclusion criteria: known diabetes, terminal disease or physical or mental disabilities making active participation in the study impossible."	
Setting	GP clinic	
Intervention	"The intervention was based on the transtheoretical model [18] and was designed to be consistent with general practitioner's and nurse practitioners' daily routine. Five intervention objectives were specified: weight reduction of 5% or more if overweight; physical exercise of moderate to high intensity for at least 30 minutes a day for at least 5 days a week; dietary fat intake less than 30%; saturated fat intake less than 10% of total energy intake; and dietary fibre intake of at least 3.4 g per MJ. Stage transition was supported by the use of behavioural change techniques to influence participant motivation (motivational interviewing, decisional balance), action (goal setting, developing action plans, barrier identification) and maintenance (relapse prevention) [19]. After the admission interview with the general practitioner [17], 11 consultations of 20 min were scheduled over 2.5 years alternately with the nurse practitioner and the general practitioner. In addition, five group meetings were organized by dieticians and physiotherapists to provide more detailed information on diet and exercise. Moreover, participants in the intervention group were invited for a 1-h consultation with a dietician, in which a 3-day food record was discussed."	
Control/Comparator	"During the admission interview, usual care group participants received oral and written information about Type 2 diabetes and a healthy lifestyle. The nurse practitioner was visited only for measurements at baseline and after 6, 18 and 30 months. Apart from the admission interview participants did not have study-related encounters with the general practitioner."	
Treatment duration	2.5 years	
Follow-up from baseline	2.5 years	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 925
Intervention group/s: Intervention group (n=479)

Comparator group: Usual Care group (n=446)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)

BMI (kg/m2) - Baseline
Mean (SD)

Waist circumference (cm) - Baseline
Mean (SD)</td><td>Intervention group: 84.3 (15.9)

Intervention group: 29 (4.4)

Intervention group: 99.9 (11.7)</td><td>Usual Care group: 82.1 (14.5)

Usual Care group: 28.5 (4.2)

Usual Care group: 98.7 (10.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)

Change in waist circumference (cm)
Mean (SD)</td><td>Intervention group: -0.6 (5.1)

Intervention group: -0.2 (1.7)

Intervention group: -0.3 (6.4)</td><td>Usual Care group: -0.3 (4.5)

Usual Care group: -0.1 (1.6)

Usual Care group: 0.2 (5.6)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Attendance at individual consultations ranged from 80% to 89% for consultations with the general practitioner and from 86% to 97% for consultations with the nurse practitioner</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Verrastro, 2023

Guideline record ID: 12024--1

Study characteristics		
Citation	Verrastro, O., Panunzi, S., Castagneto-Gissey, L., De Gaetano, A., Lembo, E., Capristo, E., Guidone, C., Angelini, G., Pennestrì, F., Sessa, L., Vecchio, F. M., Riccardi, L., Zocco, M. A., Boskoski, I., Casella-Mariolo, J. R., Marini, P., Pompili, M., Casella, G., Fiori, E., . . . Mingrone, G. (2023). Bariatric-metabolic surgery versus lifestyle intervention plus best medical care in non-alcoholic steatohepatitis (BRAVES): a multicentre, open-label, randomised trial. The Lancet, 401(10390), 1786-1797. https://doi.org/https://doi.org/10.1016/S0140-6736(23)00634-7	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Bariatric-metabolic surgery versus lifestyle intervention plus best medical care in non-alcoholic steatohepatitis (BRAVES): a multicentre, open-label, randomised trial	
Location	Italy	
Trial name	BRAVES	
Methods		
Inclusion criteria	“We included participants with obesity (BMI 30-55 kg/m²), with or without type 2 diabetes, with histologically confirmed NASH (NAFLD activity score of at least 1 in each single item) and no evidence of another form of liver disease.”	
Exclusion criteria	“Coronary event or procedure (myocardial infarction, unstable angina, coronary artery bypass, surgery or coronary angioplasty) in the previous 6 months; Liver cirrhosis; End stage renal failure; Any other life-threatening non-cardiac disease; Pregnancy; Inability to give informed consent; Substantial alcohol consumption (>20g/day for women or >30g/day for men); Wilson's disease; Lipodystrophy; Parenteral nutrition; Abetalipoproteinemia; Interfering medications (e.g., amiodarone, methotrexate, tamoxifen, corticosteroids); Participation in any other concurrent therapeutic clinical trial. Specific exclusion criteria for subjects with T2D: HbA1c≥10.0%; recurrent major hypoglycaemia or hypoglycaemic unawareness as judged by the principal investigators (PIs).”	
Setting	Hospital, Home	
Intervention	“Roux-en-Y Gastric Bypass RYGB involves the use of a surgical stapler to create a small and vertically oriented gastric pouch with a volume of 30 ml. The upper pouch was completely divided by the gastric remnant and is anastomosed to the jejunum, 75 cm distally to the Treitz's ligament, through a narrow antecolic antegastric gastrojejunal anastomosis in a Roux-en-Y fashion. Bowel continuity was restored by an L-L enteroentero anastomosis, between the excluded biliary limb and the alimentary limb, performed at 100 cm from the gastrojejunostomy. Lifestyle modification counselling was provided to each patient. Sleeve Gastrectomy A complete skeletonization of the greater curvature of the stomach was performed until the dissection of the left pillar. The SG was created using a linear stapler with sequential 60mm firings starting at 4-6 cm from pylorus. . The stapler was applied alongside a 48-Fr calibrating bougie in order to obtain a complete "fundectomy". The resection line was performed avoiding the ''critical area'' by resecting the fundus 1.5 cm from the angle of His. The resected stomach was grasped at the antral tip by a laparoscopic grasper and retrieved through one of the trocar sites. A methylene blue dye test by a nasogastric tube was routinely performed at the end of the procedure. The residual gastric remnant capacity was 60-80 ml. Drains were not routinely placed, and the nasogastric tube was removed at the end of the procedure. Upper gastrointestinal contrast (Gastrografin) study was performed on the first/second postoperative day. Lifestyle modification counselling was provided to each patient.”	

<table>
<tr><td>Control/Comparator</td><td>“LM plus best medical care Patients were advised to follow a structured lifestyle intervention program including diet and physical activity. All participants received vitamin E 800 IU/day. All people with T2D also underwent pharmacotherapy with pioglitazone and a GLP1-RA (1.8 mg liraglutide), plus SGLT2-inhibitors or other anti-diabetes medications as needed. The choice of vitamin E23, pioglitazone21 and liraglutide22 as add on to lifestyle modification was based on evidence of their positive effects on NASH. Vitamin E, pioglitazone and liraglutide were not administered in the surgical groups. Alcohol consumption was assessed at the screening and then every 3 months by the alcohol use disorders identification test (AUDIT)24. Diet Resting calorie requirements were calculated via the Harris-Benedict equation25 and an activity factor, and subjects were instructed not to change their activity level other than that suggested by physicians during the study. The diet contained 1/3 kcal less than the calculated energy expenditure and 30% fat of which 10% saturated, 55% low glycaemic index carbohydrates and 15% proteins. Compliance with the diet was estimated by assessing 3-day food diaries recorded every week for the first 6 months and then every month until 1 year. Physical Activity Participants were encouraged to gradually increase their walking to achieve 10,000 steps per day. A moderate intensity physical activity program of 1 hour of aerobic exercise 2-3 hours per week was 4 also recommended. Physical activity was assessed using the International Physical Activity Questionnaire - Short Form (IPAQ-SF) 26.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 288
Intervention group/s: Roux-en-Y gastric bypass (n=96); Sleeve gastrectomy (n=96)

Comparator group: Lifestyle modification (n=96)</td></tr>
<tr><td>Mean age ± SD</td><td>Roux-en-Y gastric bypass: 47.23y (8.30); Sleeve gastrectomy: 47.21y (8.97); Lifestyle modification: 47.81y (10.24)</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>Histologically confirmed NASH (NAFLD activity score of at least 1 in each single item) and no evidence of another form of liver disease.</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Bodyweight, kg
Mean (SD)</td><td>Roux-en-Y gastric bypass:
127.69
(19.54)
Sleeve gastrectomy: 118.84
(18.68)</td><td>Lifestyle modification: 116.07
(22.9)</td></tr>
<tr><td>BMI, kg/m2
Mean (SD)</td><td>Roux-en-Y gastric bypass:
43.39
(4.14)
Sleeve gastrectomy: 40.76
(3.74)</td><td>Lifestyle modification: 41.16
(6.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Bodyweight, kg
Mean (SD)</td><td>Roux-en-Y gastric bypass:
87.02
(15.66)
Sleeve gastrectomy: 89.77</td><td>Lifestyle modification: 109.82
(24.15)</td></tr>
</table>
</td></tr>
</table>

	BMI, kg/m2 Mean (SD)	(16.45) Roux-en-Y gastric bypass: 29.7 (4.26) Sleeve gastrectomy: 30.82 (4.08)	Lifestyle modification: 39.07 (7.55)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported.		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Versteegden, 2023

Guideline record ID: 12025--1

Study characteristics		
Citation	Versteegden, D. P. A., Van Himbeeck, M. J. J., Luyer, M. D., van Montfort, G., de Zoete, J.-P. J. G. M., Smulders, J. F., & Nienhuijs, S. W. (2023). A randomized clinical trial evaluating eHealth in bariatric surgery. Surgical Endoscopy, 37(10), 7625-7633. https://doi.org/https://doi.org/10.1007/s00464-023-10211-w	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A randomized clinical trial evaluating eHealth in bariatric surgery	
Location	Netherlands	
Trial name	BePATIENT	
Methods		
Inclusion criteria	"Adult patients with severe obesity who had approval of the multidisciplinary team, conform IFSO criteria, were eligible [24]. Only patients undergoing a primary laparoscopic gastric sleeve or bypass were included. The choice between both procedures was based on informed consultation between patient and treatment team. Further inclusion criteria were access to internet and a smartphone; ability to understand the Dutch language; and a signed informed consent."	
Exclusion criteria	Not reported	
Setting	Hospital	
Intervention	"In addition to the control group, patients in the online group received access to an eHealth platform. The platform was an institutional-specific patient platform, accessible with an internet browser or dedicated app. It was produced in collaboration with a digital health developer (Bepatient SAS, Paris, France) with the purpose of educating and preparing the patient to improve outcomes. It contained information about obesity, the treatment options, dietary information, and exercise. Information was available in the form of written text, images, videos, and quizzes. The preparation phase section was developed to instruct and prepare patients for the operation and aftercare program. In the Frequently-asked-questions section, the common questions were answered. The platform was updated regularly with new information or advice in the sections Question of the Week and Tip of the Week. In the Prevention of weight regain section patients were able to find information about weight regain and how to prevent this. Experiences of former and current patients were displayed at the Patient testimonials section. In the Sports program section instructional videos of several exercises were shown. Patients received access to personal accounts which could only be accessed using a self-chosen password. Patients received a demonstration on how to utilize the platform after inclusion. Furthermore, during follow-up meetings the medical staff, dieticians, and psychologist referred to the platform routinely and advised to use it as additional support."	
Control/Comparator	"Patients in the control group received standard care. This consisted of a preoperative screening and preconditioning program followed by a five-year follow-up period. Patients received informational handouts with written information about weight management, bariatric surgery, the obesity center, and the care pathway. In the first two years after surgery, participants were scheduled to have 13 appointments with a bariatric surgeon, obesity nurse, dietician, psychologist, and physiotherapist, of which 3 were group meetings. In the second year, less consultations were planned but they could be increased on request or if necessary."	
Treatment duration	2 years	

<table>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 153
Intervention group/s: Online (n=50)

Comparator group: Control (n=103)</td></tr>
<tr><td>Mean age ± SD</td><td>Online: 43.7y; Control: 44.2y</td></tr>
<tr><td>Sex</td><td>74.51% female</td></tr>
<tr><td>Pre-existing medical condition</td><td></td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% Total Weight Loss
Mean (SD)</td><td>Online: -29.6
(9.5)</td><td>Control: 31.2
(7.8)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>% Total Weight Loss
Mean (SD)</td><td>Online: -28.8
(10.7)</td><td>Control: 29.8
(9.1)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Actively used platform, 90%; Mean number of connections, 22.1; Mean number of page views 103.8 (See table 4, usage of eHealth solutions)</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Verweij, 2013

Guideline record ID: 10918--1

Study characteristics		
Citation	Verweij, L. M., Proper, K. I., Weel, A. N. H., Hulshof, C. T. J., & van Mechelen, W. (2013). Long-term effects of an occupational health guideline on employees' body weight-related outcomes, cardiovascular disease risk factors, and quality of life: results from a randomized controlled trial. Scandinavian Journal of Work, Environment & Health, 39(3), 284-294. https://doi.org/https://dx.doi.org/10.5271/sjweh.3341	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Long-term effects of an occupational health guideline on employees' body weight-related outcomes, cardiovascular disease risk factors, and quality of life: results from a randomized controlled trial	
Location	Netherlands	
Trial name	Balance@Work	
Methods		
Inclusion criteria	"Employees were considered eligible to participate in the RCT when they: (i) had unhealthy levels of daily physical activity or dietary behavior (ie, not complying with public health physical activity or nutrition recommendations) (22-24) and/or were overweight (ie, waist circumference >80 cm for women and >94 cm for men); (ii) had completed a questionnaire in Dutch at baseline; (iii) were not on sick leave for >21 days; and (iv) were not pregnant or had a disease or condition that would make physical activity impossible."	
Exclusion criteria	Not reported	
Setting	Workplace	
Intervention	"Occupational physicians (OP) in the intervention group were additionally asked to provide guideline-based care. The development of the draft occupational health practice guideline has been described in detail elsewhere. Briefly, the guideline consists of three sections: (i) prevention at the environmental level (advice for the employer); (ii) prevention at the individual level (advice for the employee); and (iii) evaluation and maintenance. For the first section, an environment scan was developed that provided an overview of environmental risk factors that could contribute to the prevention of weight gain (eg, availability of bike sheds and shower facilities, pricing strategies in cafeteria). Based on this overview, environmental goals could be prioritized, and feasibility and barriers for implementation could be discussed with the employer and the workers' representative council at baseline and 6-months follow-up. For the second section, prevention at the individual level, a minimal intervention strategy was developed for OP on how to promote the employee's healthy lifestyle in five 20-30 minute counseling sessions during six months. For this purpose, OP were trained over two days in applying behavioral change counseling, an adapted form of motivational interviewing suitable for brief consultations in healthcare settings. After having discussed their risk profile and current health status, employees could choose the target behavior they would like to discuss (increasing physical activity, decreasing sedentary behavior, increasing fruit consumption, or reducing the energy intake derived from snacks) in the first counseling session. Next, ambivalence and motivation for change was assessed by discussing pros and cons of behavioral change, and willingness, importance, and perceived confidence to change behavior. OP then guided employees to make a decision on what behavior they needed to change and increased perceived behavioral control by asking employees to formulate a maximum of three implementation intentions. Last, employees set shortand long-term goals. In subsequent sessions, progress and barriers were discussed and short-term goals were adjusted if necessary. No specific weight loss advice was provided as the guideline aimed to prevent weight gain by improving employees' physical activity and healthy dietary behavior. Moreover, obese	

	employees could be referred to the Dutch guideline for treatment of obesity (26). To monitor their behavior, employees were provided with a toolkit containing a waist circumference measure tape, a pedometer, a diary, and leaflets on physical activity and nutrition from the Dutch Heart Foundations and the Netherlands Nutrition Centre."
Control/Comparator	"Occupational physicians (OP) in the control group were asked to provide care as usual, which generally consisted of a health risk appraisal with anthropometric measurements and subsequent health advice."
Treatment duration	6 months
Follow-up from baseline	18 months
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 523 Intervention group/s: Intervention (n=274) Comparator group: Control (n=249)
Mean age ± SD	47y (8)
Sex	37.09% female
Pre-existing medical condition	No pre-existing medical condition
Results	

Outcome measure at baseline

Variable	Intervention arm/s	Comparator
Proportion Overweight (≥25-<30 kg/m2) Proportion (%)	Intervention: 40.0%	Control: 45.0%
Proportion Obese (≥30 kg/m2) Proportion (%)	Intervention: 27.0%	Control: 29.0%
Waist circumference (cm) Mean (SD)	Intervention: 94.5 (13.1)	Control: 98 (13.5)
Body weight (kg) Mean (SD)	Intervention: 86 (16.8)	Control: 87.5 (17)
Body mass index (kg/m2) Mean (SD)	Intervention: 27.6 (5)	Control: 28 (4.9)

Outcome measure at 12 months or closest time point

Variable	Intervention arm/s	Comparator
Waist circumference (cm) Mean (SD)	Intervention: 95.1 (13)	Control: 97.2 (12.5)
Body weight (kg) Mean (SD)	Intervention: 83 (15.6)	Control: 87.1 (16.4)
Body mass index (kg/m2) Mean (SD)	Intervention: 27 (4.7)	Control: 27.6 (4.6)

Outcome measure at final follow-up/endpoint

Variable	Intervention arm/s	Comparator
Waist circumference (cm) Mean (SD)	Intervention: 93.3 (12.7)	Control: 96.8 (12.2)

	Body weight (kg) Mean (SD) Body mass index (kg/m2) Mean (SD)	Intervention: 84.6 (16) Intervention: 27 (4.6)	Control: 86.7 (15.8) Control: 27.4 (4.4)
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Viester, 2018

Guideline record ID: 10694--1

Study characteristics		
Citation	Viester, L., Verhagen, E. A. L. M., Bongers, P. M., & van der Beek, A. J. (2018). Effectiveness of a worksite intervention for male construction workers on dietary and physical activity behaviors, body mass index, and health outcomes: results of a randomized controlled trial. American Journal of Health Promotion, 32(3), 795-805. https://doi.org/https://doi.org/10.1177/0890117117694450	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effectiveness of a Worksite Intervention for Male Construction Workers on Dietary and Physical Activity Behaviors, Body Mass Index, and Health Outcomes: Results of a Randomized Controlled Trial	
Location	Netherlands	
Trial name	N/A	
Methods		
Inclusion criteria	“The research population consisted of consenting blue-collar workers of a construction company who attended the PHS.”	
Exclusion criteria	“The exclusion criterion was being on sick leave for >4 weeks at baseline. Sickness absence data were collected over a 2-year period, starting 12 months prior to baseline.”	
Setting	Workplace	
Intervention	“The "VIP in construction" program is a tailored program including personal health coaching, information, and tools to support changes in PA and dietary behavior. The program was offered at the worksite during working hours. According to the study protocol, the intervention commenced within 2 weeks after the baseline measurements delivered by study-trained health professionals (personal health coaches) during initial face-to-face and follow-up telephone health coaching sessions, consisting of a minimum of 2 and a maximum of 4 sessions. During the coaching sessions, participants received personalized feedback on their health screening and current lifestyle behavior, received training instruction, and were supported in self-monitoring of behavior, goal setting, and evaluation. Participants also received personal energy plan forms to record their goals and action plans, forms they could also use during the follow-up health coaching sessions. The intervention was tailored to the participant's weight status (BMI and waist circumference), PA level, and stage of change. The intervention program focused on improving PA levels and healthy dietary behavior and in addition to the coaching sessions consisted of tailored information, training instruction for core stability and strengthening exercises, and the VIP in construction toolbox (overview of the company health-promoting facilities, waist circumference-measuring tape, pedometer, BMI calculator, calorie guide, recipes, and knowledge tests).”	
Control/Comparator	“The control group received care as usual and was only contacted for the baseline and follow-up measurements.”	
Treatment duration	6 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 314
Intervention group/s: Intervention (n=162)

Comparator group: Control (n=152)</td></tr>
<tr><td>Mean age ± SD</td><td>46.6y (9.7)</td></tr>
<tr><td>Sex</td><td>100.00% male</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 88.3
(12.3)

Intervention: 27.3
(3.5)

Intervention: 99.2
(10)</td><td>Control: 89.1
(15.1)

Control: 27.5
(4)

Control: 100.3
(12.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 88.7
(12.4)

Intervention: 27.5
(3.5)

Intervention: 97.9
(9.7)</td><td>Control: 90.2
(15.2)

Control: 27.9
(4)

Control: 99.9
(11.8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Villareal, 2011

Guideline record ID: 10695

Study characteristics		
Citation	Villareal, D. T., Chode, S., Parimi, N., Sinacore, D. R., Hilton, T., Armamento-Villareal, R., Napoli, N., Qualls, C., & Shah, K. (2011). Weight loss, exercise, or both and physical function in obese older adults. The New England Journal of Medicine, 364(13), 1218-1229. https://doi.org/https://dx.doi.org/10.1056/NEJMoa1008234	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight loss, exercise, or both and physical function in obese older adults	
Location	US	
Trial name	Weight Loss and Exercise in Obese, Physically Limited, Older Women and Men	
Methods		
Inclusion criteria	"Volunteers were eligible for inclusion in the study if they were 65 years of age or older and obese (BMI [the weight in kilograms divided by the square of the height in meters] of 30 or more), if they had a sedentary lifestyle, if their body weight had been stable during the previous year (i.e., had not fluctuated more than 2 kg), and if their medications had been stable for 6 months before enrollment. All participants had to have mild-to-moderate frailty, on the basis of meeting at least two of the following operational criteria8,19,20: a score on the modified Physical Performance Test (in which the total score ranges from 0 to 36, with higher scores indicating better physical status) of 18 to 32; a peak oxygen consumption (VO2peak) of 11 to 18 ml per kilogram of body weight per minute; or difficulty in performing two instrumental activities of daily living or one basic activity of daily living."	
Exclusion criteria	"Persons who had severe cardiopulmonary disease; musculoskeletal or neuromuscular impairments that preclude exercise training; visual, hearing, or cognitive impairments; or a history of cancer, as well as persons who were receiving drugs that affect bone health and metabolism or who were current smokers, were excluded."	
Setting	Home, University/research centre	
Intervention	"Diet: Participants assigned to the diet group were prescribed a balanced diet that provided an energy deficit of 500 to 750 kcal per day from their daily energy requirement. The diet contained approximately 1 g of high-quality protein per kilogram of body weight per day. Participants met weekly as a group with a dietitian for adjustments of their caloric intake and for behavioral therapy. They were instructed to set weekly behavioral goals and attend weekly weigh-in sessions. Food diaries were reviewed, and new goals were set on the basis of diary reports. The goal was to achieve a weight loss of approximately 10% of their baseline body weight at 6 months and to maintain that weight loss for an additional 6 months.; Exercise: Participants in the exercise group were given information regarding a diet that would maintain their current weight and participated in three group exercise-training sessions per week. Each session was approximately 90 minutes in duration and consisted of aerobic exercises, resistance training, and exercises to improve flexibility and balance. The exercise sessions were led by a physical therapist. The aerobic exercises included walking on a treadmill, stationary cycling, and stair climbing. The participants exercised so that their heart rate was approximately 65% of their peak heart rate and gradually increased the intensity of exercise so that their heart rate was between 70 and 85% of their peak heart rate. The progressive resistance training included nine upper-extremity and lower-extremity exercises with the use of weight-lifting machines. Participants performed 1 or 2 sets at a resistance of approximately 65% of their one-repetition maximum, with 8 to 12 repetitions of each exercise; they gradually increased the intensity to 2 to 3 sets at a resistance of approximately 80% of their one-repetition maximum, with 6 to 8 repetitions of each exercise.; Diet-Exercise: Participants in the diet-	

<table>
<tr><td></td><td>exercise group participated in both the weight-management and exercise programs. They were were prescribed a balanced diet that provided an energy deficit of 500 to 750 kcal per day from their daily energy requirement. The diet contained approximately 1 g of high-quality protein per kilogram of body weight per day. Participants met weekly as a group with a dietitian for adjustments of their caloric intake and for behavioral therapy. They were instructed to set weekly behavioral goals and attend weekly weigh-in sessions. Food diaries were reviewed, and new goals were set on the basis of diary reports. The goal was to achieve a weight loss of approximately 10% of their baseline body weight at 6 months and to maintain that weight loss for an additional 6 months. They were also given information regarding a diet that would maintain their current weight and participated in three group exercise-training sessions per week. Each session was approximately 90 minutes in duration and consisted of aerobic exercises, resistance training, and exercises to improve flexibility and balance. The exercise sessions were led by a physical therapist. The aerobic exercises included walking on a treadmill, stationary cycling, and stair climbing. The participants exercised so that their heart rate was approximately 65% of their peak heart rate and gradually increased the intensity of exercise so that their heart rate was between 70 and 85% of their peak heart rate. The progressive resistance training included nine upper-extremity and lower-extremity exercises with the use of weight-lifting machines. Participants performed 1 or 2 sets at a resistance of approximately 65% of their one-repetition maximum, with 8 to 12 repetitions of each exercise; they gradually increased the intensity to 2 to 3 sets at a resistance of approximately 80% of their one-repetition maximum, with 6 to 8 repetitions of each exercise. All participants were given supplements to ensure an intake of approximately 1500 mg of calcium per day and approximately 1000 IU of vitamin D per day”</td></tr>
<tr><td>Control/Comparator</td><td>“Participants assigned to the control group did not receive advice to change their diet or activity habits and were prohibited from participating in any weight-loss or exercise program. They were provided general information about a healthy diet during monthly visits with the staff.”</td></tr>
<tr><td>Treatment duration</td><td>52 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 107
Intervention group/s: Diet (n=26); Exercise (n=26); Diet-Exercise (n=28)

Comparator group: Control (n=27)</td></tr>
<tr><td>Mean age ± SD</td><td>Diet: 70y (4); Exercise: 70y (4); Diet-Exercise: 70y (4); Control: 69y (4)</td></tr>
<tr><td>Sex</td><td>62.62% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Mild-to-moderate frailty</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)</td><td>Diet: 104.1
(15.3)
Exercise: 99.2
(17.4)
Diet-Exercise: 99.1
(16.8)

Diet: 37.2</td><td>Control: 101
(16.3)

Control: 37.3</td></tr>
</table>
</td></tr>
</table>

	Mean (SD) Fat Mass (kg) Mean (SD)	(4.5) Exercise: 36.9 (5.4) Diet-Exercise: 37.2 (5.4) Diet: 42.8 (6.6) Exercise: 41.6 (9.4) Diet-Exercise: 41.9 (11.5)	(4.7) Control: 43.8 (9.9)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight change (kg) Mean (SD) Fat mass change (kg) Mean (SD) Weight loss % Mean	Diet: -9.7 (5.4) Exercise: -0.5 (3.6) Diet-Exercise: -8.6 (3.8) Diet: -7.1 (3.9) Exercise: -1.8 (1.9) Diet-Exercise: -6.3 (2.8) Diet: -10 Exercise: -1 Diet-Exercise: -9	Control: -0.1 (3.5) Control: 1.2 (5.1) Control: <1
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	97.2%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Vimalananda, 2016

Guideline record ID: 10922--1

Study characteristics		
Citation	Vimalananda, V., Damschroder, L., Janney, C. A., Goodrich, D., Kim, H. M., Holleman, R., Gillon, L., & Lutes, L. (2016). Weight loss among women and men in the ASPIRE-VA behavioral weight loss intervention trial. Obesity, 24(9), 1884-1891. https://doi.org/https://doi.org/10.1002/oby.21574	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight loss among women and men in the ASPIRE-VA behavioral weight loss intervention trial	
Location	USA	
Trial name	Aspiring to Lifelong Health in VA (ASPIRE-VA)	
Methods		
Inclusion criteria	“Inclusion Criteria: Current patient at Ann Arbor or Cleveland medical center. Current provider- or self-referral to MOVE! program and eligible to participate in MOVE! 18 years of age and older Able to communicate in English Report being able to walk 10 minutes continuously without sitting down to rest Competent to provide written informed consent. Eligible veterans were men and women referred to the MOVE! program [body mass index (BMI) >30 kg/m2 or a BMI between 25 and 30 kg/m2 with at least one obesity-related chronic health condition, without contraindications for weight loss].”	
Exclusion criteria	“We excluded individuals already enrolled in a weight loss study, who were receiving weight loss treatment, or who were pregnant.”	
Setting	GP clinic, Home	
Intervention	“ASPIRE small-changes approach. The two ASPIRE programs (phone and group) used a small-changes approach. Rather than prescribing a preset goal such a daily calorie target, the small-changes approach encouraged participants to set personalized goals for weight loss that were feasible within an individual's life context. Goals were designed to achieve a modest daily caloric deficit (100-200 fewer calories) through increased physical activity and modifications to eating patterns that were attainable and self-reinforcing. Logbooks were provided to track food intake and pedometers were provided to track daily step count. Diet choices were guided by a modified Stoplight Food Guide, which categorized foods as "Green," "Yellow," and "Red" without having to count calories. The small changes are designed to be cumulative over time, yielding slower but longer-term weight loss that is more likely to be maintained given participants' enhanced sense of self-efficacy and mastery of self-regulatory lifestyle habits. ASPIRE-Group sessions were weekly for 90 min in the active treatment phase of the first 3 months. The maintenance phase in months 4 to 12 comprised biweekly 60-min sessions for 6 months, and then monthly 60-min sessions for the next 3 months. The total treatment dose was 33 h. ASPIRE-Phone sessions were up to 30 min in the first 3 months and 20 min in the maintenance phase, for a total treatment dose of 11 h. The small-changes intervention approach remained consistent over time. ASPIRE was a manualized intervention in which the coach sought to elicit active engagement and discussion with participants regarding key self-regulatory topics and skills based on social cognitive theory (5), problem-solving therapy (30), and motivational interviewing (31). Sessions encouraged participants to receive feedback and support on self-monitored progress toward personal goal attainment. Those in ASPIRE-Group typically met in small groups with five to eight participants and the lifestyle coach at prescheduled times at the medical center. These groups were closed to new participants after the program began. ASPIRE-Phone participants had individual phone calls with the lifestyle coach arranged at mutually convenient times. ASPIRE-Group sessions were weekly for 90 min in the active treatment phase of the first 3 months. The maintenance phase in months	

<table>
<tr><td></td><td>4 to 12 comprised biweekly 60-min sessions for 6 months, and then monthly 60-min sessions for the next 3 months. The total treatment dose was 33 h. ASPIRE-Phone sessions were up to 30 min in the first 3 months and 20 min in the maintenance phase, for a total treatment dose of 11 h. The small-changes intervention approach remained consistent over time."</td></tr>
<tr><td>Control/Comparator</td><td>"MOVE! weight management program (control arm). As noted, though national guidelines for MOVE! exist, local contextual features often determine specifics of the design and delivery of the program at individual sites. About three-quarters of MOVE sessions in VHA are delivered in group formats, and MOVE! at our study sites were delivered predominantly via groups. Groups were open; new participants could join any time, though they were not included in our study sample. MOVE! provided individualized handouts on health behavior change topics, counseling and behavior modification support. Psychoeducation topics in MOVE! were discussed didactically. Sessions were led by an interdisciplinary group of providers, including dietitians, health psychologists, and physical therapists who rotated from session to session. A pedometer and an optional self-monitoring log were provided. MOVE! participants were offered 90-min weekly sessions in the active treatment phase, during months 1 to 3. In the maintenance phase in months 4 to 12, both sites offered drop-in follow-up groups. Maintenance sessions in months 4 to 12 were 90 min every 3 months at one site, and 60 min every 2 weeks at the other site. Overall, veterans in MOVE! were offered a total treatment dose of 22 to 35 h. The intervention approach remained consistent over time."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 481
Intervention group/s: Aspire-Phone (n=162); Aspire-Group (n=160)

Comparator group: MOVE Usual Care (n=159)</td></tr>
<tr><td>Mean age ± SD</td><td>55.0y (10.0)</td></tr>
<tr><td>Sex</td><td>14.97% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline weight (kg) - Women Mean (SD)</td><td>Aspire-Phone: 96.1 (17)
Aspire-Group: 102.6 (24.2)</td><td>MOVE Usual Care: 99 (16.7)</td></tr>
<tr><td>Baseline weight (kg) Men Mean (SD)</td><td>Aspire-Phone: 115.7 (22.2)
Aspire-Group: 114.3 (20.8)</td><td>MOVE Usual Care: 116.2 (23.7)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td>Weight change at 12 months (kg) – Women
Mean (95% CIs)</td><td>Aspire-Phone: 0.2
(-2-2.4)
Aspire-Group: -2.7
(-5--0.5)</td><td>MOVE Usual Care: -2.6
(-5.2--0.1)</td></tr><tr><td>Weight change at 12 months (%) - Women
Mean (95% CIs)</td><td>Aspire-Phone: 0.2
(-2.1-2.5)
Aspire-Group: -2.6
(-4.8--0.5)</td><td>MOVE Usual Care: -2.7
(-5.2- -0.1)</td></tr><tr><td>12-month weight change (kg) - Men
Mean (95% CIs)</td><td>Aspire-Phone: -1.8
(-2.8--0.8)
Aspire-Group: -2.8
(-3.8--1.8)</td><td>MOVE Usual Care: -1.2
(-2.1--0.2)</td></tr><tr><td>12-month weight change (%) - Men
Mean (95% CIs)</td><td>Aspire-Phone: -1.5
(-2.4--0.7)
Aspire-Group: -2.5
(-3.3--1.7)</td><td>MOVE Usual Care: -1
(-1.8--0.2)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Lutes, L. D., Cummings, D. M., Littlewood, K., Dinatale, E., & Hambidge, B. (2017). A community health worker-delivered intervention in African American women with type 2 diabetes: a 12-month randomized trial. Obesity, 25(8), 1329-1335. https://doi.org/https://dx.doi.org/10.1002/oby.21883</td></tr>
</table>

N/A – Not applicable

Voils, 2017

Guideline record ID: 10926--1

Study characteristics		
Citation	Voils, C. I., Olsen, M. K., Gierisch, J. M., McVay, M. A., Grubber, J. M., Gaillard, L., Bolton, J., Maciejewski, M. L., Strawbridge, E., & Yancy, W. S., Jr. (2017). Maintenance of weight loss after initiation of nutrition training: a randomized trial. Annals of Internal Medicine, 166(7), 463-471. https://doi.org/https://doi.org/10.7326/M16-2160	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Maintenance of Weight Loss After Initiation of Nutrition Training: A Randomized Trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"To be included in the study, patients had to be aged 18 to 75 years, have a body mass index (BMI) of 30 kg/m2 or greater, have a primary care provider, agree to attend visits, and have access to a telephone and reliable transportation."	
Exclusion criteria	"Exclusion criteria included liver disease; type 1 diabetes; most recent hemoglobin A1c in past 6 months 12% or greater; average systolic blood pressure over the past year and most recent blood pressure 160 mm Hg or greater; history of weight loss surgery; dementia, severe psychiatric illness, or substance abuse; weight loss of 10 lb or more in the previous 3 months; current enrollment in a lifestyle program; current weight loss medication; pregnancy or plans to become pregnant in the next 6 months; breastfeeding; lack of birth control if premenopausal; organ transplant recipient; heart issues in the past 3 months; cancer not in remission; pacemaker or defibrillator (because of the use of a bio-electronic impedance scale); emotional problems that would impede intervention adherence or interacting in a group environment; and inability to stand for measurements."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"The maintenance intervention involved transitions from initiation to maintenance skills and from group visits to individual telephone calls, as well as decreased frequency of contact (18). The intervention period was 42 weeks, followed by 14 weeks of no contact. Group visits occurred at weeks 2, 6, and 10. Individual telephone calls were made at weeks 4, 8, 12, 16, 20, 24, 32, and 40. Group sessions addressed maintenance caloric intake, weight selfmonitoring, increasing and maintaining physical activity, obtaining social support from friends and family, and relapse prevention. All calls had a uniform structure that focused on 4 maintenance constructs outlined in our theoretical model and were deemed acceptable in a pilot test: satisfaction with outcomes, relapse-prevention planning, self-monitoring, and social support (19). To make salient satisfaction with outcomes, participants reviewed "before" and "after" photographs and were asked to discuss outcomes of weight loss that continued to motivate them. They then identified high-risk situations in which relapse might occur and developed a plan to navigate those situations. Next, they specified a frequency of self-weighing and used a 1.36-kg (3-lb) regain relapse threshold. If relapse occurred, the registered dietitian guided the patient to reinitiate and self-monitor his or her diet or physical activity. Finally, participants identified a primary support person and supportive behaviors and were encouraged to share their plans with their support person. The group sessions and telephone calls were delivered by 1 of 2 registered dieticians. Training included a review of theoretical principles and calls with mock participants, with feedback from the investigators. A co-investigator attended each group session and used a fidelity checklist to ensure that all protocoled elements were addressed. All maintenance telephone calls were recorded. Each week, the principal investigator, at least 1 coinvestigator, and the registered dietitians met for 1 hour to review	

<table>
<tr><td></td><td>randomly selected intervention calls, and the investigators completed fidelity checklists and provided feedback.”</td></tr>
<tr><td>Control/Comparator</td><td>“Usual care was chosen as the comparator to mimic the typical patient experience of no further intervention after participating in a weight loss program. The VA's MOVE! clinical weight loss program (20) was not used as a comparator because it focuses on weight loss. MOVE! and referral to a nutritionist were available as part of usual care. Participants in the intervention group were asked not to enroll in MOVE! or other lifestyle programs or to consult a nutritionist during the intervention, whereas usual care participants were told they could do both. In a post hoc chart review, we determined that 2 participants randomly assigned to usual care and 3 to the intervention group attended a MOVE! orientation visit but had no further involvement in the program during the 56-week maintenance phase.”</td></tr>
<tr><td>Treatment duration</td><td>42 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>56 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 222
Intervention group/s: Maintenance (n=110)

Comparator group: Usual Care (n=112)</td></tr>
<tr><td>Mean age ± SD</td><td>61.8y (8.3)</td></tr>
<tr><td>Sex</td><td>15.32% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Model-estimated weights (Kg)
Usual care vs Intervention
Mean (95% CIs)</td><td>Maintenance: 103.57
(100.86-106.28)</td><td>Usual Care: 103.57
(100.86-106.28)</td></tr>
<tr><td>Weight, kg
Mean (SD)</td><td>Maintenance: 102.1
(19.8)</td><td>Usual Care: 105
(21)</td></tr>
<tr><td>Waist circumference, inches
Mean (SD)</td><td>Maintenance: 43.5
(5.4)</td><td>Usual Care: 44.5
(6)</td></tr>
<tr><td>BMI, kg/m2
Mean (SD)</td><td>Maintenance: 33.3
(5.7)</td><td>Usual Care: 34.6
(6.4)</td></tr>
<tr><td>BMI ≥35 kg/m2
Proportion (%)</td><td>Maintenance: 29.1%</td><td>Usual Care: 39.3%</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Model-estimated weights (Kg)
Usual care vs Intervention
Mean (95% CIs)</td><td>Maintenance: 104.32
(101.41-107.23)</td><td>Usual Care: 105.93
(103.03-108.82)</td></tr>
<tr><td>Estimated differences in weights
Mean (95% CIs)</td><td>Maintenance: 1.6
(0.07-3.13)</td><td></td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Patients in the intervention group attended 0 to 3 maintenance meetings (mean, 2.07 [SD, 1.06]) and participated in 2 to 8 telephone calls (mean, 7.34 [SD, 1.43]). Retention for week-56 assessments in the usual care and maintenance groups was 90% and 80% for weight (Figure 1), 78% and 76% for FFQ, and 89% and 79% for IPAQ, respectively.</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

von Gruenigen, 2012

Guideline record ID: 10927

Study characteristics		
Citation	von Gruenigen, V., Frasure, H., Kavanagh, M. B., Janata, J., Waggoner, S., Rose, P., Lerner, E., & Courneya, K. S. (2012). Survivors of uterine cancer empowered by exercise and healthy diet (SUCCEED): a randomized controlled trial. Gynecologic Oncology, 125(3), 699-704. https://doi.org/https://dx.doi.org/10.1016/j.ygyno.2012.03.042	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Survivors of uterine cancer empowered by exercise and healthy diet (SUCCEED): a randomized controlled trial	
Location	USA	
Trial name	Survivors of Uterine CanCer Empowered by Exercise and Healthy Diet (SUCCEED)	
Methods		
Inclusion criteria	"Women with histologically confirmed Stage I or II EC following surgery consisting of a total abdominal hysterectomy, bilateral salpingo-oophorectomy (TAH, BSO), with no evidence of disease and diagnosed within the prior 3 years were eligible. Additional eligibility criteria included body mass index (BMI) ≥25 (overweight/obese), a performance status of 0-2, medical clearance from the patient's primary care physician and approval for contact by the patient's treating gynecologic oncologist."	
Exclusion criteria	"Exclusion criteria included: individuals unable to read the consent form, patients with severe depression, dementia or cognitive deficits, participants unavailable for longitudinal follow-up assessments, pre-existing medical conditions that were a barrier for participation in unsupervised walking, and women who participated in a structured weight loss or exercise program during the previous 6 months."	
Setting	Not reported	
Intervention	"The SUCCEED group received 6 months of group and individual counseling with a weight loss goal of 5% [7,10-15]. A multidisciplinary approach, including a physician, psychologist, registered dietitian (RD), and physical therapist was used and is endorsed by the NIH [7]. The RD provided continued contact from 6 to 12 months with intervention participants via telephone, email, and newsletters. Sixteen group sessions were conducted (10 weekly followed by 6 bi-weekly) in the SUCCEED group. Physician face-to-face counseling visits occurred at 3, 6 and 12 months. Group topics included PA, nutrition and improving diet quality and behavior modification designed to increase women's self-efficacy. Sessions were 60 min in length with 8-10 women per group. The RD weighed participants in private at the beginning of each session and weekly food/activity records were reviewed. After 6 months when the group sessions ended, additional feedback and support was provided by the RD via newsletters, telephone and email [7]. Newsletter topics included holiday recipes, reinforcement of goals for increasing calcium, decreasing sodium, and ways to increase PA. The intervention followed a stepwise, phased approach using strategies outlined by social cognitive theory, indicating that the optimal intervention for a major behavior change should focus on establishing short-term goals, enabling the person to build selfefficacy [7]. The weight loss goal was 5% in six months [17,18]. The nutritional component of the intervention included improving diet quality by increasing fruits, vegetables, lean protein, whole grains and low-fat dairy intake, while reducing saturated fat, simple carbohydrates and low nutrient/high calorie foods. Additional topics addressed were grocery shopping, portion sizes, meal planning, food labels, and social eating. The intervention focused on the adoption of lifelong lifestyle changes rather than caloric restriction. At the first session, the RD provided participants with individualized weight loss goals. Education and skill development to increase PA and PA self-efficacy were included using a guide previously developed for breast cancer survivors [19,20]. Patients were encouraged to add activities	

<table>
<tr><td></td><td>that they enjoyed or to begin a walking program or other exercise activity. Group PA goals were 150 min/week (5 times/week for 30 min) for months 1-2, 225 min/week (5 times/week for 45 min) for months 3-4 and 300 min/week (5 times/week for 60 min) for months 5-6 [19]. Long-term changes in everyday activities (for example, climbing stairs instead of taking elevators) and moderate aerobic activity were emphasized [21]. Participants were given pedometers to provide immediate feedback and reinforcement to patients and to provide objective assessment of PA. A goal of 10,000 steps/day or an increase of 2000 steps/day from baseline was used [22]. Patients were given three-pound hand and adjustable ankle weights and instructed in the proper form and procedure for performing resistance exercises. Heart rate monitors were provided to facilitate monitoring of target heart rate goals. Physician counseling visits (conducted by the PI) at 3, 6, and 12 months focused on nutrition and PA goals for SUCCEED participants in order to augment the group sessions and provide individualized attention."</td></tr>
<tr><td>Control/Comparator</td><td>"Patients randomized to the UC group received an informational brochure ("Healthy Eating & Physical Activity Across Your Lifespan, Better Health and You"). Physician visits for the UC group consisted of overall health concerns, review of medications and co-morbidities."</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 75
Intervention group/s: SUCCEED (n=41)

Comparator group: CONTROL (n=34)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 57y (8.6); Control: 58.9y (10.9)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Survivors of uterine cancer</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body mass index
Mean (SD)</td><td>SUCCEED: 36.4
(5.5)</td><td>CONTROL: 36.5
(9.6)</td></tr>
<tr><td>Body mass index category - Overweight (25.0-29.9)
Proportion (%)</td><td>SUCCEED: 14.6</td><td>CONTROL: 29.4</td></tr>
<tr><td>Body mass index category - Class I obesity (30.0-34.9)
Proportion (%)</td><td>SUCCEED: 24.4</td><td>CONTROL: 17.6</td></tr>
<tr><td>Body mass index category - Class II obesity (35.0-39.9)
Proportion (%)</td><td>SUCCEED: 31.7</td><td>CONTROL: 17.6</td></tr>
<tr><td>Body mass index category - Class III obesity (>40.0)
Proportion (%)</td><td>SUCCEED: 29.3</td><td>CONTROL: 35.3</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>SUCCEED: 95.7
(19)</td><td>CONTROL: 94
(23)</td></tr>
</table>
</td></tr>
</table>

	Waist circumference (in.) Mean (SD)	SUCCEED: 42.1 (4.9)	CONTROL: 41.6 (5.9)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight (kg) Mean (SD) Waist circumference (in.) Mean (SD)	SUCCEED: 92.7 (20.1) SUCCEED: 41.1 (5)	CONTROL: 95.4 (25.4) CONTROL: 40.8 (6.3)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Weight change (kg) Mean (SD) Percent weight change (%) Mean (SD)	SUCCEED: -3 SUCCEED: -3	CONTROL: 1.4 CONTROL: 1.4
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Adherence (attendance): 84.1%		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Vos, 2012

Guideline record ID: 10699--1

Study characteristics		
Citation	Vos, R. C., Huisman, S. D., Houdijk, E. C. A. M., Pijl, H., & Wit, J. M. (2012). The effect of family-based multidisciplinary cognitive behavioral treatment on health-related quality of life in childhood obesity. Quality of Life Research, 21(9), 1587-1594. https://doi.org/https://dx.doi.org/10.1007/s11136-011-0079-1	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The effect of family-based multidisciplinary cognitive behavioral treatment on health-related quality of life in childhood obesity	
Location	Netherlands	
Trial name	N/A	
Methods		
Inclusion criteria	"Children with obesity (according to Cole et al. [2]) aged 8-17 years, living in the Hague and in the area around the Hague and referred to a pediatrician, are invited to participate. Reasons for referral are overweight or obesity, and increased risk of co-morbidity (e.g. hypertension, family history of diabetes mellitus and/or hypercholesterolemia and/or cardiovascular disease before the age of 55, Hindustani ethnicity)."	
Exclusion criteria	"Potential participants are excluded if their knowledge of the Dutch language, intelligence or social skills are insufficient to participate in the group. Other exclusion criteria are use of medication that might have an effect on weight loss, medical co-morbidities that could affect participation, or previous enrollment in another cognitive behavioral treatment program with the focus on reducing obesity."	
Setting	Hospital	
Intervention	"The multidisciplinary cognitive behavioral treatment of the intervention group consisted of a screening phase (of 3 months), followed by an intensive phase (of 3 months) and booster sessions thereafter for a total period of 2 years. In the screening phase the children with their parents were seen at two separate occasions individually by a dietitian (45 min/occasion), a child-physiotherapist (45 min/occasion), a child-psychologist (90 min/occasion), and once by a social worker (90 min). During the screening phase, a dietician provided nutritional advice on reducing caloric intake and, more importantly, on learning healthy eating behavior. A 3-day dietary recall (1 weekend day included) was used to get more insight into dietary habits of the children. Information was provided about nutrition and healthy eating behavior according to the traffic light nutritional list [22]. The traffic light nutritional list identifies several main food groups (fruits, vegetables, grains, milk and other dairy products, meat, fish, and others). Foods within each group are colorcoded reflecting the caloric density per average serving and Dutch standards for healthy nutrition. The colors are green for ''go,'' orange for ''approach with caution,'' and red for ''stop.'' A child-physiotherapist evaluated the physical activity level of the children in the intervention group, based on a physical activity 3-day recall (1 weekend day included). The information from this recall was used for advice on how to increase and optimize physical activity during everyday life and to reduce sedentary activities. The role of the child-psychologist was to help the children not only to reduce weight by learning cognitive behavioral techniques, but also to deal with and accept their own body. The intensive phase of the treatment consisted of 7 group meetings for the children, 5 separate parent meetings, and 1 meeting for parents together with their children. Meetings of 2 h were given biweekly. The main focus of the first two meetings with the children was on nutritional information of energy balance and healthy eating. During the remaining meetings with the children, several cognitive behavioral techniques were taught on self-control, coping, and self-image, in order to maintain long-term lifestyle change and body	

<table>
<tr><td></td><td>weight reduction. The parent meetings addressed the topics of motivation for treatment of their children, including information on healthy nutrition, setting boundaries, and how to help their children by giving positive feedback.”</td></tr>
<tr><td>Control/Comparator</td><td>“The control group was given an initial advice on physical activity and nutrition. After 1 year, the children in the control group were offered to participate in the multidisciplinary cognitive behavioral treatment. The normal weight control group was measured only once at the beginning of the study.”</td></tr>
<tr><td>Treatment duration</td><td>3 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 81
Intervention group/s: Intervention (n=41)

Comparator group: Control (n=40)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 13.3y (2.0); Control: 13.1y (1.9)</td></tr>
<tr><td>Sex</td><td>51.85% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI-SDS
Mean (SD)</td><td>Intervention: 4.2
(0.7)</td><td>Control: 4.3
(0.6)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI-SDS
Mean (SD)</td><td>Intervention: 3.8
(1.1)</td><td>Control: 4.2
(0.7)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Wadden, 2011

Guideline record ID: 10702--1

Study characteristics		
Citation	Wadden, T. A., Foreyt, J. P., Foster, G. D., Hill, J. O., Klein, S., O'Neil, P. M., Perri, M. G., Pi-Sunyer, F. X., Rock, C. L., Erickson, J. S., Maier, H. N., Kim, D. D., & Dunayevich, E. (2011). Weight loss with naltrexone SR/bupropion SR combination therapy as an adjunct to behavior modification: the COR-BMOD trial. Obesity, 19(1), 110-120. https://doi.org/https://doi.org/10.1038/oby.2010.147	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight loss with naltrexone SR/bupropion SR combination therapy as an adjunct to behavior modification: The COR-BMOD trial	
Location	US	
Trial name	COR-BMOD	
Methods		
Inclusion criteria	"Participation was open to persons 18-65 years of age who had a BMI of 30-45kg/m2, or a BMI of 27-45kg/m2 in the presence of controlled hypertension and/or dyslipidemia. Women of child-bearing potential were required to use effective contraception throughout the study."	
Exclusion criteria	"Exclusion criteria included: type 1 or 2 diabetes mellitus; significant cerebrovascular, cardiovascular, hepatic, or renal disease; obesity of known endocrine origin; previous surgical (or device) intervention for obesity; loss or gain of >4kg within the previous 3 months; use of medications known to affect body weight; a history of seizures; treatment with bupropion or naltrexone within the previous 12 months; and a history of drug or alcohol abuse within the previous 12 months. Current smokers and those who had used tobacco or other nicotine products within 6 months before screening were excluded, as were individuals with serious psychiatric illness (e.g., bipolar disorder, schizophrenia, bulimia, or conditions requiring psychotropic medications other than low doses of sedative hypnotics)."	
Setting	Home, University/research centre	
Intervention	"NB32 + intensive group behavior modification (BMOD): Naltrexone SR 32mg/day combined with bupropion SR 360mg/day (NB32). NB32 was provided as a single tablet (with 8mg naltrexone SR and 90mg bupropion SR), and participants were instructed to take two tablets twice daily (i.e., morning and evening). Medication was initiated at one-quarter of the daily maintenance dose and increased weekly over the first 4 weeks (with the maintenance dose reached at the beginning of the fourth week). All participants were instructed to consume a balanced deficit diet of conventional foods that provided ~15-20% of energy from protein, 30% or less energy from fat, and the remainder from carbohydrate. Individual goals for energy intake were based on initial body weight. Participants who weighed ≤249 lb were prescribed 1,200kcal/day, whereas those 250-299 lb were prescribed 1,500kcal/day, with higher allotments for heavier individuals (i.e., 300-349 lb, 1,800kcal/day; ≥350 lb, 2,000kcal/ day). Participants were instructed in measuring portion sizes, counting calories (with a calorie counter provided), and keeping detailed daily records of their food intake. They also were encouraged, during the first 6 months, to gradually increase to 180min/week of planned moderately vigorous physical activity (typically brisk walking). Participants were further instructed to keep daily records of their activity, to increase their lifestyle activity, and to engage in strength training, if desired. During months 7-12, they were encouraged to aim for up to 360min of activity per week. Group sessions typically began with a review of participants' eating and activity records and other homework assignments. Group leaders then introduced a new topic in weight control which, during the first 16 weeks, included meal planning, stimulus control, slowing eating,	

	problem solving, social support, and coping with high risk situations. Subsequent sessions covered skills required for maintaining lost weight. Treatment sessions were led following detailed treatment manuals that incorporated materials from the LEARN Program for Weight Management (18), the Diabetes Prevention Program (19), and other handouts used by the authors (G.D.F., P.M.O., C.L.R., and T.A.W.) in prior trials."
Control/Comparator	"Placebo + intensive group behavior modification (BMOD):Placebo was provided as a single tablet, and participants were instructed to take two tablets twice daily (i.e., morning and evening). Medication was initiated at one-quarter of the daily maintenance dose and increased weekly over the first 4 weeks (with the maintenance dose reached at the beginning of the fourth week). All participants were instructed to consume a balanced deficit diet of conventional foods that provided ~15-20% of energy from protein, 30% or less energy from fat, and the remainder from carbohydrate. Individual goals for energy intake were based on initial body weight. Participants who weighed ≤249 lb were prescribed 1,200kcal/day, whereas those 250-299 lb were prescribed 1,500kcal/day, with higher allotments for heavier individuals (i.e., 300-349 lb, 1,800kcal/day; ≥350 lb, 2,000kcal/ day). Participants were instructed in measuring portion sizes, counting calories (with a calorie counter provided), and keeping detailed daily records of their food intake. They also were encouraged, during the first 6 months, to gradually increase to 180min/week of planned moderately vigorous physical activity (typically brisk walking). Participants were further instructed to keep daily records of their activity, to increase their lifestyle activity, and to engage in strength training, if desired. During months 7-12, they were encouraged to aim for up to 360min of activity per week. Group sessions typically began with a review of participants' eating and activity records and other homework assignments. Group leaders then introduced a new topic in weight control which, during the first 16 weeks, included meal planning, stimulus control, slowing eating, problem solving, social support, and coping with high risk situations. Subsequent sessions covered skills required for maintaining lost weight. Treatment sessions were led following detailed treatment manuals that incorporated materials from the LEARN Program for Weight Management (18), the Diabetes Prevention Program (19), and other handouts used by the authors (G.D.F., P.M.O., C.L.R., and T.A.W.) in prior trials."
Treatment duration	56 weeks
Follow-up from baseline	56 weeks
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)
Participant characteristics	
Number of participants	n= 793 Intervention group/s: NB32 + BMOD (n=591) Comparator group: Placebo + BMOD (n=202)
Mean age ± SD	Intervention: 45.9y (10.4); Control: 45.6y (11.4)
Sex	89.91% female
Pre-existing medical condition	No pre-existing medical condition
Results	
Outcome measure at baseline	

Variable	Intervention arm/s	Comparator
Weight (kg) - Baseline Mean (SD)	NB32 + BMOD: 100.2 (15.4)	Placebo + BMOD: 101.9 (15)
Waist circumference (cm) Mean (SD)	NB32 + BMOD: 109.3 (11.4)	Placebo + BMOD: 109 (11.8)

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight loss ≥5% at week 56 (mITT)
Proportion (%)</td><td>NB32 + BMOD: 66.4</td><td>Placebo + BMOD: 42.5</td></tr>
<tr><td>Weight loss ≥10% at week 56 (mITT)
Proportion (%)</td><td>NB32 + BMOD: 41.5</td><td>Placebo + BMOD: 20.2</td></tr>
<tr><td>Weight loss ≥15% at week 56 (mITT)
Proportion (%)</td><td>NB32 + BMOD: 29.1</td><td>Placebo + BMOD: 10.9</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>NB32 + BMOD: 99.1
(12.8)</td><td>Placebo + BMOD: 102
(13.1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in weight (%)
Mean (SE)</td><td>NB32 + BMOD: -9.3
(0.4)</td><td>Placebo + BMOD: -5.1
(0.6)</td></tr>
<tr><td>Change in waist circumference (cm)
Mean (95% CIs)</td><td>NB32 + BMOD: -6.8
(-8.3)</td><td>Placebo + BMOD: -10
(-10.9--9)</td></tr>
<tr><td>% change in waist circumference
Mean (95% CIs)</td><td>NB32 + BMOD: -9.1
(-9.9--8.2)</td><td>Placebo + BMOD: -6.1
(-7.5--4.7)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>41.6% placebo + BMOD discontinued study drug; 42.1% of NB32 + BMOD discontinued drug.</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Wadden, 2011

Guideline record ID: 10704--1

Study characteristics		
Citation	Wadden, T. A., Neiberg, R. H., Wing, R. R., Clark, J. M., Delahanty, L. M., Hill, J. O., Krakoff, J., Otto, A., Ryan, D. H., Vitolins, M. Z., & The Look AHEAD Research Group. (2011). Four-year weight losses in the Look AHEAD study: factors associated with long-term success. Obesity, 19(10), 1987-1998. https://doi.org/https://dx.doi.org/10.1038/oby.2011.230	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Four-year weight losses in the Look AHEAD study: factors associated with long-term success	
Location	US	
Trial name	Action for Health and Diabetes (Look AHEAD)	
Methods		
Inclusion criteria	"Participation was open to persons with type 2 diabetes who were 45-76 years of age and had a BMI ≥25kg/m2 (or ≥27kg/m2 if taking insulin). All applicants completed a graded exercise test, described elsewhere (2,24), to ensure that they could safely adhere to the physical activity program prescribed in the ILI. In addition, they were required to pass a test of behavioral adherence which involved recording their food intake and physical activity for 2 consecutive weeks (25). Candidates who did not keep satisfactory records for at least 12 of 14 days were not eligible to participate."	
Exclusion criteria	Not reported	
Setting	GP clinic, Hospital, University/research centre	
Intervention	"ILI. In year 1, participants in this group were provided a comprehensive intervention designed to induce an average loss ≥7% of initial weight. Individual participants were given a goal of losing ≥10% in order to increase their likelihood of meeting the 7% study-wide goal. The lifestyle intervention was adapted from the Diabetes Prevention Program (DPP) (26,27) and was delivered to groups of ~10-20 persons by experienced lifestyle counselors (i.e., interventionists). During the first 6 months, participants were provided group sessions for the first 3 weeks of each month. The fourth week, they had an individual meeting (20-30min) with their interventionist, and group sessions were not held this week. During months 7-12, participants continued to have a monthly individual meeting with their interventionist but the number of group sessions was reduced from three to two per month. Interventionists included registered dietitians, psychologists, and exercise specialists, all of whom delivered group treatment following detailed protocols. As described previously (25), they attended studywide trainings to receive instruction in intervention delivery and were certified yearly (at their home institution) based on their demonstrated adherence to the protocol"	
Control/Comparator	"DSE. During each of the first 4 years, participants in DSE were invited to attend three 1-h group meetings per year that discussed diet, physical activity, and social support, respectively (1,2). These sessions provided information but not specific behavioral strategies for adopting the diet and activity recommendations. Participants who desired more help in losing weight were told to speak with their own primary care providers, who were permitted to recommend whatever treatments they thought were appropriate."	
Treatment duration	4 years	
Follow-up from baseline	4 years	
Eligible outcome(s) reported	Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 5145
Intervention group/s: ILI (n=2570)

Comparator group: DSE (n=2575)</td></tr>
<tr><td>Mean age ± SD</td><td>ILI: 58.6y (6.8); DSE: 58.9y (6.9)</td></tr>
<tr><td>Sex</td><td>59.53% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline weight (kg) - Females
Mean (SD)

Baseline weight (kg) - Males
Mean (SD)

Baseline BMI (kg/m2) - Females
Mean (SD)

Baseline BMI (kg/m2) - Males
Mean (SD)</td><td>ILI: 94.8
(17.9)

ILI: 108.9
(19)

ILI: 36.3
(6.2)

ILI: 35.3
(5.7)</td><td>DSE: 95.4
(17.3)

DSE: 109
(18)

DSE: 36.3
(6)

DSE: 35.1
(5.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss (kg) per year</td><td>ILI: 8.7
(0.2)</td><td>DSE: 0.8
(0.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Redmon, J. B., Bertoni, A. G., Connelly, S., Feeney, P. A., Glasser, S. P., Glick, H., Greenway, F., Hesson, L. A., Lawlor, M. S., Montez, M., Montgomery, B., & the Look AHEAD Research Group. (2010). Effect of the look AHEAD study intervention on medication use and related cost to treat cardiovascular disease risk factors in individuals with type 2 diabetes. Diabetes Care, 33(6), 1153-1158. https://doi.org/https://dx.doi.org/10.2337/dc09-2090; The Look AHEAD Research Group. (2013). Cardiovascular effects of intensive lifestyle intervention in type 2 diabetes. The New England Journal of Medicine, 369(2), 145-154. https://doi.org/10.1056/NEJMoa1212914</td></tr>
</table>

N/A – Not applicable

Wadden, 2013

Guideline record ID: 10703--1

Study characteristics		
Citation	Wadden, T. A., Hollander, P., Klein, S., Niswender, K., Woo, V., Hale, P. M., & Aronne, L. (2013). Weight maintenance and additional weight loss with liraglutide after low-calorie-diet-induced weight loss: the SCALE Maintenance randomized study. International Journal of Obesity, 37(11), 1443-1451. https://doi.org/https://doi.org/10.1038/ijo.2013.120	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight maintenance and additional weight loss with liraglutide after low-calorie-diet-induced weight loss: the SCALE Maintenance randomized study	
Location	US; Canada	
Trial name	Satiety and Clinical Adiposity - Liraglutide Evidence (SCALE) Maintenance	
Methods		
Inclusion criteria	"Informed consent obtained before any trial-related activities. (Trial-related activities are any procedure that would not have been performed during the normal management of the participant). BMI ≥30 kgm-2, or BMI ≥ 27 kgm-2 with presence of co-morbidities of treated or untreated dyslipidemia and/or hypertension. Untreated dyslipidemia was defined as low-density lipoprotein (LDL) ≥160 mgdl-1, or triglycerides ≥150 mgdl-1, or high-density lipoprotein (HDL) < 40 mgdl-1 for men and < 50 mgdl-1 for women. Untreated hypertension was defined as systolic blood pressure ≥140 and/or diastolic blood pressure ≥90 mmHg. Stable body weight during the previous 3 months (<5 kg self-reported weight change) Age ≥18 years Previously undergone dietary weight loss and not able to maintain reduced weight."	
Exclusion criteria	"Any clinically significant disease which in the Investigators' opinion could interfere with the safety of trial participants or with the results of the trial. Diagnosis of type 1 or type 2 diabetes per the judgment of the Investigator. FPG ≥ 126 mgdl-1 (7 mmoll-1) at start of run-in period. Previous treatment with GLP-1 receptor agonists (including liraglutide or exenatide) within the last 3 months. Visit 1 thyroid-stimulatory hormone outside of the range of 0.4-6.0 mIUl-1. History of chronic pancreatitis or idiopathic acute pancreatitis. Obesity induced by other endocrinological disorders (e.g., Cushing syndrome). Current or history of treatment with medications that may cause significant weight gain within 3 months prior to screening visit, including systemic corticosteroids (except for a short course of treatment, i.e., 7-10 days), tri-cyclic antidepressants, atypical antipsychotic and mood stabilisers (e.g., imipramine, amitriptyline, mirtazapin, phenelzine, chlorpromazine, thioridazine, clozapine, olanzapine, valproic acid and its derivatives, and lithium). Current participation in an organized diet reduction program (or within the last 3 months). Currently using or have used within the last 3 months before screening for this trial: pramlintide, sibutramine, orlistat, zonisamide, topiramate, phentermine, or metformin (either by prescription or as part of a clinical trial). Diet attempts using herbal supplements or over-the-counter medications within 3 months before screening for this trial. Participation in a clinical trial of weight control within the last 3 months prior to screening for this trial. Previous surgical treatment for obesity (excluding liposuction if performed >1 year before study entry). 14. History of major depressive disorder or a PHQ-9 >15 within the last 2 years (completed at visit 1) or history of other severe psychiatric disorders (e.g., schizophrenia or bipolar disorder) or diagnosis of an eating disorder such as restrained eating, binge eating, or bulimia (based on Questionnaire for Diagnosing Binge Eating Disorder and Bulimia Nervosa completed at visit 1). Participants with a lifetime history of a suicide attempt or history of any suicidal behavior within the past month before entry into the trial. Surgery scheduled for the trial duration period, except for minor surgical procedures, at the discretion of the Investigator. Impaired liver function, defined as screening aspartate aminotransferase or alanine aminotransferase ≥2.5 times upper normal range (one re-test analyzed at the central laboratory within 1 week is permitted with the	

	last sample being conclusive). Impaired renal function defined as serum creatinine ≥152 µmoll-1 (≥1.72 mgdl-1) (one retest within one week through the central laboratory is permitted with the result of the last sample conclusive). Known clinically significant active cardiovascular disease, including history of unstable angina, acute coronary event, other significant cardiac events (including history of arrhythmias, myocardial infarction (MI), or conduction delays on electrocardiogram [ECG]), or cerebral stroke within the past 6 months and/or heart failure (New York Heart Association [NYHA] Class III or IV) at the discretion of the Investigator. Uncontrolled treated/untreated hypertension (systolic blood pressure ≥160 mmHg and/or diastolic blood pressure ≥100 mmHg). If white-coat hypertension is suspected at the screening visit a repeated measurement at run-in prior to other trial-related activities is allowed. Cancer (past or present, except basal cell skin cancer or squamous cell skin cancer), which in the Investigator's opinion could interfere with the results of the trial. Known or suspected allergy to trial product(s) or related products. Previous participation in the run-in or randomized phase of this trial. Re-screening is allowed once within the limit of the recruitment period. Known or suspected abuse of alcohol or narcotics. Language barrier, mental incapacity, unwillingness or ability to understand and being able to complete the mental health questionnaire in the provided language. Participants from the same household participating in the trial. Women of childbearing potential who are pregnant, breast-feeding or intend to become pregnant or are not using adequate contraceptive methods (abstinence and/or the following methods: diaphragm with spermicide, condom with spermicide (by male partner), intrauterine device, sponge, spermicide, Norplant, Depo-Provera or oral contraceptives). Positive screening for hepatitis B antigen, hepatitis C antibodies, positive human immunodeficiency virus (HIV) antibodies 29. The receipt of any investigational drug within four weeks prior to screening for this trial."
Setting	Home, University/research centre
Intervention	"To qualify for randomization, participants had to lose X5% of initial body weight during a variable-length (4-12 weeks) LCD run-in period. During this period, participants were prescribed 1200-1400 kcal per day, which included the daily use of up to three liquid meal replacements (for example, Boost, Ensure and Glucerna). To facilitate dietary adherence, participants met face-to-face, every other week with a nutritionist and had telephone calls on alternate weeks. They were encouraged to exercise regularly (recommended 150 min per week of brisk walking) and were provided with pedometers. As soon as individuals lost X5% of screening body weight, they were randomized to receive once-daily liraglutide 3.0 mg (n ¼ 212). Liraglutide (6.0 mg per ml) were provided in modified FlexPen devices (Novo Nordisk A/S, Bagsvaerd, Denmark) and administered by subcutaneous injection in the abdomen, thigh or upper arm. Dosing was initiated at 0.6 mg per day, increasing weekly by 0.6 mg per day throughout a 4-week dose escalation (maximum 5 weeks) to the 3.0 mg dose. At randomization, participants were prescribed a 500 kcal per day deficit diet, based on estimated 24-h energy expenditure. Recommended macronutrient intake was 30% of energy from fat, 20% from protein and 50% from carbohydrate. Liquid meal replacements were not recommended during this time. Participants were instructed to continue the recommended physical activity. Face-to-face lifestyle counseling visits (15-20 min) were provided at weeks 0, 1, 2, 3 and 4 (during drug escalation) and weeks 6, 10, 14, 18, 22, 26, 30, 34, 38, 42, 46 and 52, for a total of 17 visits over 56 weeks. Following medication discontinuation at week 56, participants completed a 12-week follow-up assessment, which included monthly visits."
Control/Comparator	"To qualify for randomization, participants had to lose X5% of initial body weight during a variable-length (4-12 weeks) LCD run-in period. During this period, participants were prescribed 1200-1400 kcal per day, which included the daily use of up to three liquid meal replacements (for example, Boost, Ensure and Glucerna). To facilitate dietary adherence, participants met face-to-face, every other week with a nutritionist and had telephone calls on alternate weeks. They were encouraged to exercise regularly (recommended 150 min per week of brisk walking) and were provided with pedometers. As soon as individuals lost X5% of screening body weight, they were randomized to receive a placebo (n ¼ 210). Placebos were provided in modified FlexPen devices (Novo Nordisk A/S, Bagsvaerd,

<table>
<tr><td></td><td>Denmark) and administered by subcutaneous injection in the abdomen, thigh or upper arm. Dosing was initiated at 0.6 mg per day, increasing weekly by 0.6 mg per day throughout a 4-week dose escalation (maximum 5 weeks) to the 3.0 mg dose. At randomization, participants were prescribed a 500 kcal per day deficit diet, based on estimated 24-h energy expenditure. Recommended macronutrient intake was 30% of energy from fat, 20% from protein and 50% from carbohydrate. Liquid meal replacements were not recommended during this time. Participants were instructed to continue the recommended physical activity. Face-to-face lifestyle counseling visits (15-20 min) were provided at weeks 0, 1, 2, 3 and 4 (during drug escalation) and weeks 6, 10, 14, 18, 22, 26, 30, 34, 38, 42, 46 and 52, for a total of 17 visits over 56 weeks. Following medication discontinuation at week 56, participants completed a 12-week follow-up assessment, which included monthly visits.”</td></tr>
<tr><td>Treatment duration</td><td>56 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>68 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 422
Intervention group/s: Liraglutide 3.0 mg (n=212)

Comparator group: Placebo (n=210)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 45.9y (11.9); Control: 46.5y (11)</td></tr>
<tr><td>Sex</td><td>81.52% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)

BMI (kg/m2) - Baseline
Mean (SD)

Waist circumference (cm) - Baseline
Mean (SD)</td><td>Liraglutide 3.0 mg: 100.4 (20.8)

Liraglutide 3.0 mg: 36 (5.9)

Liraglutide 3.0 mg: 109.4 (15.3)</td><td>Placebo: 98.7 (21.2)

Placebo: 35.2 (5.9)

Placebo: 107.8 (15.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion maintaining >5% run-in weight loss
Proportion (%)

Proportion with >5% weight loss
Proportion (%)

Proportion with >10% weight loss
Proportion (%)</td><td>Liraglutide 3.0 mg: 81.4

Liraglutide 3.0 mg: 50.5

Liraglutide 3.0 mg: 26.1</td><td>Placebo: 48.9

Placebo: 21.8

Placebo: 6.3</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (% change)
Mean (SD)

Change in Body weight (kg)
Mean (SD)

Change in BMI (kg/m 2)
Mean (SD)

Change in Waist circumference (cm)
Mean (SD)</td><td>Liraglutide 3.0 mg: -6.2
(7.3)

Liraglutide 3.0 mg: -6
(7.3)

Liraglutide 3.0 mg: -2.1
(2.6)

Liraglutide 3.0 mg: -4.7
(7.4)</td><td>Placebo: -0.2
(7)

Placebo: -0.1
(6.9)

Placebo: 0
(2.3)

Placebo: -1.2
(6.4)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (% change)
Mean (SD)</td><td>Liraglutide 3.0 mg: -4.1
(8.2)</td><td>Placebo: 0.3
(7.7)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>96%</td></tr>
<tr><td>Notes</td><td></td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Wadden, 2019

Guideline record ID: 10707--1

Study characteristics		
Citation	Wadden, T. A., Walsh, O. A., Berkowitz, R. I., Chao, A. M., Alamuddin, N., Gruber, K., Leonard, S., Mugler, K., Bakizada, Z., & Tronieri, J. S. (2019). Intensive behavioral therapy for obesity combined with liraglutide 3.0 mg: a randomized controlled trial. Obesity, 27(1), 75-86. https://doi.org/https://doi.org/10.1002/oby.22359	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Intensive Behavioral Therapy for Obesity Combined with Liraglutide 3.0 mg: A Randomized Controlled Trial	
Location	USA	
Trial name	Lifestyle Modification and Liraglutide (MODEL)	
Methods		
Inclusion criteria	"Eligibility criteria included the following: ages 21 to 70 years; BMI of 30 to 55 kg/m2 ; prior lifetime weight loss effort with diet and exercise (before considering antiobesity medication) (20); and agreement to participate for 1 year."	
Exclusion criteria	"Exclusion criteria included personal or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome; types 1 or 2 diabetes; renal, hepatic, or recent cardiovascular disease; blood pressure ≥160/100 mmHg; medications that substantially affect body weight (e.g., corticosteroids); substance abuse; current major depression, suicidal ideation, or history of suicide attempts; bariatric surgery; use of weight loss medications or products, as well as weight loss ≥4.5 kg in past 3 months; and pregnancy/tered dietitians in the first 6 months of the Diabetes Prevention Program (DPP) (13).] Patients who lose ≥ 3 kg at month 6 are eligible for additional monthly visits through month 12. The specific schedule and length (15 minutes) of counseling visits proposed by CMS has never been tested in a randomized controlled trial in which PCPs provided IBT, as required by CMS for coverage. Mean 1-year weight losses achieved with this approach were compared with those of two other interventions that included the same background of IBT, provided by the same PCPs. Participants in a second group received IBT combined with liraglutide 3.0 mg/d, a glucagon-like peptide-1 receptor agonist approved for chronic weight management (7,14,15). A meta-analysis found that the addition of liraglutide 3.0 mg/d to approximately monthly lifestyle counseling increased weight loss by approximately 5.2 kg compared with the same counseling with placebo (9). Based on findings of the DPP, we anticipated that participants in the present study who received IBT-alone would lose a mean of 5% of baseline weight at 1 year, which would be approximately doubled by the addition of liraglutide 3.0 mg/d (9,13). Participants in a third group received IBT, liraglutide, and the addition, for 12 weeks, of a portion-controlled diet that provided 1,000 to 1,200 kcal/d. Meal replacements (including liquid shakes, meal bars, and prepared entrées) increase weight loss by approximately 3% to 5% in 12 weeks, compared with consumption of an isocaloric diet composed of conventional foods (16,17). This study assessed whether the provision of a portion-controlled diet would increase weight loss further when added to IBT plus liraglutide. Methods Trial design and setting This was a single-site, open-label, parallel-group-design, randomized trial, conducted at The University of Pennsylvania, whose institutional review board approved the study protocol (ClinicalTrials.gov identifier NCT02911818). The trial was supported by an InvestigatorInitiated Study award from Novo Nordisk. The company had no role in the design, execution, analysis, or reporting of the study, which was conceived by the first author. The last author analyzed the data, the first author wrote the initial draft of the manuscript, and all authors contributed to study implementation and the final draft. We used an open-label design to test IBT as it is delivered in clinical practice, without placebo. In addition, the efficacy of liraglutide 3.0 mg/d, compared with placebo, has been demonstrated in numerous double-blind, randomized trials (15,18,19), reducing the need for another such study. Participants	

	Eligibility criteria included the following: ages 21 to 70 years; BMI of 30 to 55 kg/m2 ; prior lifetime weight loss effort with diet and exercise (before considering antiobesity medication) (20); and agreement to participate for 1 year. Exclusion criteria included personal or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome; types 1 or 2 diabetes; renal, hepatic, or recent cardiovascular disease; blood pressure ≥160/100 mmHg; medications that substantially affect body weight (e.g., corticosteroids); substance abuse; current major depression, suicidal ideation, or history of suicide attempts; bariatric surgery; use of weight loss medications or products, as well as weight loss ≥4.5 kg in past 3 months; and pregnancy/ lactation. Antidepressant medications were permitted, except for those associated with marked weight gain (e.g., paroxetine) or loss (e.g., bupropion)."
Setting	Home, University/research centre
Intervention	"IBT-liraglutide. These participants received the same program of lifestyle counseling as those in IBT-alone. However, starting at week 1, they also were prescribed liraglutide as a once-daily, self-administered subcutaneous injection (14). A study physician or NP taught participants to inject in their abdomen, thigh, or upper arm. To reduce the likelihood of gastrointestinal symptoms (e.g., nausea), the medication was initiated at 0.6 mg/d for 1 week and increased by 0.6 mg/d in weekly intervals until 3.0 mg/d was achieved. Medical staff helped participants develop a medication schedule to facilitate adherence. Multicomponent: These participants received the same treatment as those in IBT-liraglutide, with one exception. At week 4, they were prescribed, for 12 weeks, a 1,000- to 1,200-kcal/d diet that provided four servings daily of a liquid shake (Health Management Resources, 160 kcal per shake) and an evening meal of a frozen food entrée (250-300 kcal), with a serving of fruit and salad (24). As with liraglutide, all Health Management Resources products were provided free of charge; participants were responsible for purchasing frozen food entrées and other foods.; Participants in all three groups received the same 21 sessions of IBT, delivered on the schedule recommended by CMS: 4 initial weekly visits, followed by 10 every-other-week sessions (through month 6), followed by 7 additional visits, delivered every 4 weeks, through month 12. Departing from the CMS protocol, all participants were provided counseling in the second 6 months, regardless of whether they had lost ≥ 3 kg at month 6. (This was done principally for statistical purposes, to maintain an approximately equal number of participants in the three groups at the primary outcome assessment at month 12.) Counseling sessions lasted 15 minutes and were delivered following a detailed protocol (23), adapted from the DPP (13). Participants who weighed<113.6 kg (250 lb) were prescribed a diet of 1,200 to 1,499 kcal/d, composed of conventional foods, with approximately 15% to 20% kcal from protein, 20% to 35% from fat, and the remainder from carbohydrate. Participants who weighed ≥113.6 kg were prescribed 1,500 to 1,800 kcal/d. Participants were instructed to record their food and calorie intake daily, using applications (e.g., MyFitnessPal) or paper diaries (24). They were provided lists of breakfast, lunch, and dinner options (of conventional foods) to be used, as in prior studies (13,25), if they had trouble selecting their meals. Participants were instructed to engage in low- to moderate-intensity physical activity (principally walking) 5 d/wk, gradually building to ≥180 min/wk by week 24 (24). This increased to ≥ 225 min/wk from weeks 25 to 52, consistent with targets for weight loss maintenance (25). Treatment sessions included examining participants' weight change since the last visit, reviewing calorie intake and physical activity for the most recent week, and discussing a new topic from the behavior-change curriculum (23). All participants also had seven brief (5 min) medical visits over the year (i.e., weeks 1, 4, 8, 16, 24, 40, and 52) to review vital signs and any health concerns. These visits were included principally to monitor liraglutide-treated participants but also were provided to the IBT-alone participants to maintain consistency of treatment contact."
Control/Comparator	"Participants in all three groups received the same 21 sessions of IBT, delivered on the schedule recommended by CMS: 4 initial weekly visits, followed by 10 every-other-week sessions (through month 6), followed by 7 additional visits, delivered every 4 weeks, through month 12. Departing from the CMS protocol, all participants were provided counseling in the second 6 months, regardless of whether they had lost ≥ 3 kg at month 6.

<table>
<tr><td></td><td>(This was done principally for statistical purposes, to maintain an approximately equal number of participants in the three groups at the primary outcome assessment at month 12.) Counseling sessions lasted 15 minutes and were delivered following a detailed protocol (23), adapted from the DPP (13). Participants who weighed<113.6 kg (250 lb) were prescribed a diet of 1,200 to 1,499 kcal/d, composed of conventional foods, with approximately 15% to 20% kcal from protein, 20% to 35% from fat, and the remainder from carbohydrate. Participants who weighed ≥113.6 kg were prescribed 1,500 to 1,800 kcal/d. Participants were instructed to record their food and calorie intake daily, using applications (e.g., MyFitnessPal) or paper diaries (24). They were provided lists of breakfast, lunch, and dinner options (of conventional foods) to be used, as in prior studies (13,25), if they had trouble selecting their meals. Participants were instructed to engage in low- to moderate-intensity physical activity (principally walking) 5 d/wk, gradually building to ≥180 min/wk by week 24 (24). This increased to ≥ 225 min/wk from weeks 25 to 52, consistent with targets for weight loss maintenance (25). Treatment sessions included examining participants' weight change since the last visit, reviewing calorie intake and physical activity for the most recent week, and discussing a new topic from the behavior-change curriculum (23). All participants also had seven brief (5 min) medical visits over the year (i.e., weeks 1, 4, 8, 16, 24, 40, and 52) to review vital signs and any health concerns. These visits were included principally to monitor liraglutide-treated participants but also were provided to the IBT-alone participants to maintain consistency of treatment contact.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 150
Intervention group/s: IBT-liraglutide (n=50); Multicomponent (n=50)

Comparator group: IBT-alone (n=50)</td></tr>
<tr><td>Mean age ± SD</td><td>47.6y (11.8)</td></tr>
<tr><td>Sex</td><td>79.33% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)</td><td>IBT-liraglutide: 107.8
(17.9)
Multicomponent: 111.7
(19.4)</td><td>IBT-alone: 105.8
(14.7)</td></tr>
<tr><td>BMI (kg/m2) - Baseline
Mean (SD)</td><td>IBT-liraglutide: 38.5
(5.4)
Multicomponent: 38.8
(5)</td><td>IBT-alone: 38
(4.3)</td></tr>
<tr><td>Waist circumference (cm) - Baseline
Mean (SD)</td><td>IBT-liraglutide: 116.7
(10.4)
Multicomponent: 120.1
(11.8)</td><td>IBT-alone: 116.7
(11.6)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td>Change in weight (%)
Mean (SE)</td><td>IBT-liraglutide: -11.5
(1.3)
Multicomponent: -11.8
(1.3)</td><td>IBT-alone: -6.1
(1.3)</td></tr><tr><td>Change in weight (kg)
Mean (SE)</td><td>IBT-liraglutide: -12.2
(1.3)
Multicomponent: -13.3
(1.3)</td><td>IBT-alone: -6.6
(1.3)</td></tr><tr><td>Change in BMI (kg/m2)
Mean (SE)</td><td>IBT-liraglutide: -4.3
(0.5)
Multicomponent: -4.6
(0.5)</td><td>IBT-alone: -2.3
(0.5)</td></tr><tr><td>Change in waist circumference (cm)
Mean (SE)</td><td>IBT-liraglutide: -11.1
(1.3)
Multicomponent: -12.6
(1.3)</td><td>IBT-alone: -6.5
(1.3)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Participants in the IBT-alone, IBT-liraglutide, and Multicomponent interventions attended a mean (± standard deviation) of 72.4 ± 35.1%, 91.2 ± 16.8%, and 89.0 ± 22.6% of 21 scheduled counseling visits, respectively.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Wadden, 2020

Guideline record ID: 10705--1

Study characteristics		
Citation	Wadden, T. A., Tronieri, J. S., Sugimoto, D., Lund, M. T., Auerbach, P., Jensen, C., & Rubino, D. (2020). Liraglutide 3.0 mg and intensive behavioral bherapy (IBT) for obesity in primary care: the SCALE IBT randomized controlled trial. Obesity, 28(3), 529-536. https://doi.org/https://doi.org/10.1002/oby.22726	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Liraglutide 3.0 mg and Intensive Behavioral Therapy (IBT) for Obesity in Primary Care: The SCALE IBT Randomized Controlled Trial	
Location	USA	
Trial name	Satiety and Clinical Adiposity-Liraglutide Evidence in individuals with and without diabetes (SCALE IBT)	
Methods		
Inclusion criteria	“Eligible participants were aged ≥18 years, with stable body weight (maximum 5-kg self-reported weight change within 90 days before screening) and BMI≥30 kg/m2 .”	
Exclusion criteria	“Key exclusion criteria were glycated hemoglobin (HbA1c)≥6.5%, type 1 or 2 diabetes, use of medications (in the past 90 days) known to induce significant weight loss or gain, inadequately treated hypertension, pregnancy or breastfeeding, history of cardiovascular disease, severe congestive heart failure, second-degree or greater heart block, medullary thyroid carcinoma, multiple endocrine neoplasia type 2, pancreatitis, major depressive disorder within the past 2 years, history of suicide attempt, or malignancy within the past 5 years.”	
Setting	Home, University/research centre	
Intervention	“Liraglutide was self-administered once daily by subcutaneous injection. During the first 4 weeks post randomization, the dose was escalated in weekly increments of 0.6 mg to reach the final dose of 3.0mg. Throughout the 56 weeks, participants had clinic visits to monitor their response to treatment and received 23 brief (~15-minute) CMS-based IBT counseling sessions. Visits were weekly for the first month, every 2 weeks in months 2 to 6, and monthly from months 7 to 13, regardless of whether participants lost ≥ 3 kg during the first 6 months (the CMS requirement for continued treatment after month 6). The CMS-based IBT program followed an abbreviated lifestyle counseling protocol adapted from the Diabetes Prevention Program (DPP) (16) for delivery in primary care settings (9,17,18). The program was delivered by RDs, which is permitted by CMS if they work "incident to" the primary care providers described previously (8). The RDs were either contractors hired for this specific study or they were already employed at the individual sites. The program included recommendations for diet, physical activity, and behavior change. Participants were encouraged to attend the counseling visits regardless of whether they discontinued study medication. Participants who weighed <91 kg (<200 lb) at randomization were prescribed 1,200 kcal/d; the caloric prescription for those who weighed 91 to 136 kg (200-300 lb) was calculated by body weight (pounds)×6 (kilocalories per pound), and participants who weighed >136 kg (>300 lb) were prescribed 1,800 kcal/d (1). Diet recommendations were based on current guidance from the US Department of Agriculture, including approximately 15% to 20% of kilocalories from protein, 20% to 35% from fat, and the remainder from carbohydrates (19). All participants were initially prescribed 100 min/wk of moderate-intensity physical activity (e.g., brisk walking). They were encouraged to be physically active in bouts of 10 minutes or more (20) and to spread their activity across 4 to 5 days each week. Physical activity was increased by 25 minutes every 4 weeks, with an ultimate goal of 250 min/wk.”	

<table>
<tr><td>Control/Comparator</td><td>“Placebo was self-administered once daily by subcutaneous injection. During the first 4 weeks post randomization, the dose was escalated in weekly increments of 0.6 mg to reach the final dose. Throughout the 56 weeks, participants had clinic visits to monitor their response to treatment and received 23 brief (~15-minute) CMS-based IBT counseling sessions. Visits were weekly for the first month, every 2 weeks in months 2 to 6, and monthly from months 7 to 13, regardless of whether participants lost ≥ 3 kg during the first 6 months (the CMS requirement for continued treatment after month 6). The CMS-based IBT program followed an abbreviated lifestyle counseling protocol adapted from the Diabetes Prevention Program (DPP) (16) for delivery in primary care settings (9,17,18). The program was delivered by RDs, which is permitted by CMS if they work "incident to" the primary care providers described previously (8). The RDs were either contractors hired for this specific study or they were already employed at the individual sites. The program included recommendations for diet, physical activity, and behavior change. Participants were encouraged to attend the counseling visits regardless of whether they discontinued study medication. Participants who weighed <91 kg (<200 lb) at randomization were prescribed 1,200 kcal/d; the caloric prescription for those who weighed 91 to 136 kg (200-300 lb) was calculated by body weight (pounds)×6 (kilocalories per pound), and participants who weighed >136 kg (>300 lb) were prescribed 1,800 kcal/d (1). Diet recommendations were based on current guidance from the US Department of Agriculture, including approximately 15% to 20% of kilocalories from protein, 20% to 35% from fat, and the remainder from carbohydrates (19). All participants were initially prescribed 100 min/wk of moderate-intensity physical activity (e.g., brisk walking). They were encouraged to be physically active in bouts of 10 minutes or more (20) and to spread their activity across 4 to 5 days each week. Physical activity was increased by 25 minutes every 4 weeks, with an ultimate goal of 250 min/wk.”</td></tr>
<tr><td>Treatment duration</td><td>56 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>56 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 282
Intervention group/s: Liraglutide-IBT (n=142)

Comparator group: Placebo-IBT (n=140)</td></tr>
<tr><td>Mean age ± SD</td><td>Liraglutide-IBT: 45.4y (11.6); Placebo-IBT: 49.0y (11.2)</td></tr>
<tr><td>Sex</td><td>83.33% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg) - Baseline Mean (SD)</td><td>Liraglutide-IBT: 108.5 (22.1)</td><td>Placebo-IBT: 106.7 (22)</td></tr>
<tr><td>BMI (kg/m2) - Baseline Mean (SD)</td><td>Liraglutide-IBT: 39.3 (6.8)</td><td>Placebo-IBT: 38.7 (7.2)</td></tr>
<tr><td>Waist circumference (cm) Mean (SD)</td><td>Liraglutide-IBT: 116 (14.4)</td><td>Placebo-IBT: 115 (15.6)</td></tr>
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</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Proportion of participants who achieved ≥5% weight loss
Proportion (%)</td><td>Liraglutide-IBT: 61.5</td><td>Placebo-IBT: 38.8</td></tr>
<tr><td>Proportion of participants who achieved >10% weight loss
Proportion (%)</td><td>Liraglutide-IBT: 30.5</td><td>Placebo-IBT: 19.8</td></tr>
<tr><td>Proportion of participants who achieved >15% weight loss
Proportion (%)</td><td>Liraglutide-IBT: 18.1</td><td>Placebo-IBT: 8.9</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in body weight from baseline (%)
Mean</td><td>Liraglutide-IBT: -7.5</td><td>Placebo-IBT: -4</td></tr>
<tr><td>Change in waist circumference from baseline (cm)
Mean</td><td>Liraglutide-IBT: -9.4</td><td>Placebo-IBT: -6.7</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Liraglutide-IBT and placebo-IBT participants attended a mean of 22.5 and 21.2 visits, respectively, of 23 possible treatment visits, corresponding to mean (SD) adherence rates of 97.8% (9.7%) and 92.1% (18.1%). In the liraglutide-IBT group, 89% of participants attended all visits, compared with 74% in the placebo-IBT group.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Wadden, 2021

Guideline record ID: 10700

Study characteristics		
Citation	Wadden, T. A., Bailey, T. S., Billings, L. K., Davies, M., Frias, J. P., Koroleva, A., Lingvay, I., O'Neil, P. M., Rubino, D. M., Skovgaard, D., Wallenstein, S. O. R., Garvey, W. T., & for the STEP 3 Investigators. (2021). Effect of subcutaneous semaglutide vs placebo as an adjunct to intensive behavioral therapy on body weight in adults with overweight or obesity: the STEP 3 randomized clinical trial. JAMA, 325(14), 1403-1413. https://doi.org/https://dx.doi.org/10.1001/jama.2021.1831	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of Subcutaneous Semaglutide vs Placebo as an Adjunct to Intensive Behavioral Therapy on Body Weight in Adults With Overweight or Obesity: The STEP 3 Randomized Clinical Trial	
Location	US	
Trial name	STEP 3	
Methods		
Inclusion criteria	"Eligible participants were aged 18 years or older, reported 1 or more unsuccessful dietary efforts to lose weight, and had either body mass index (BMI) of 27 or higher with at least 1 weight-related comorbidity (cardiovascular disease, dyslipidemia, hypertension, or obstructive sleep apnea) or BMI of 30 or higher."	
Exclusion criteria	"Participants were excluded if they had diabetes, glycated hemoglobin levels of 6.5% or more (≥48 mmol/mol), selfreported body weight change greater than 5 kg within 90 days before screening, or prior or planned obesity treatment with surgery or a weight loss device."	
Setting	Home, University/research centre	
Intervention	"Semaglutide was initiated at 0.25 mg, with dose escalation every 4 weeks until the target dose of 2.4 mg/wk was reached at week 16. If participants did not tolerate the 2.4-mg dose, they were permitted to receive 1.7 mg instead (at the investigator's discretion) and encouraged to make at least 1 attempt to reescalate to the 2.4-mg dose. For the first 8 weeks after randomization, participants received a low-calorie diet (1000-1200 kcal/d) provided as meal replacements (eg, liquid shakes, meal bars, portioncontrolled meals [provided by Nutrisystem, supplied by the sponsor]). Participants subsequently transitioned to a hypocaloric diet (1200-1800 kcal/d) of conventional food for the remainder of the 68 weeks, with prescribed calorie intake based on randomization body weight. At randomization, participants were prescribed 100 minutes of physical activity per week (spread across 4-5 days), which increased by 25 minutes every 4 weeks, to reach 200min/wk. During the 68 weeks, participants were provided with 30 individual intensive behavioral therapy visits with a registered dietitian, who instructed them in diet, physical activity, and behavioral strategies."	
Control/Comparator	"Visually identical placebo for 68 weeks. For the first 8 weeks after randomization, participants received a low-calorie diet (1000-1200 kcal/d) provided as meal replacements (eg, liquid shakes, meal bars, portioncontrolled meals [provided by Nutrisystem, supplied by the sponsor]). Participants subsequently transitioned to a hypocaloric diet (1200-1800 kcal/d) of conventional food for the remainder of the 68 weeks, with prescribed calorie intake based on randomization body weight. At randomization, participants were prescribed 100 minutes of physical activity per week (spread across 4-5 days), which increased by 25 minutes every 4 weeks, to reach 200min/wk. During the 68 weeks, participants were provided with 30 individual intensive behavioral therapy visits with a	

<table>
<tr><td></td><td>registered dietitian, who instructed them in diet, physical activity, and behavioral strategies.”</td></tr>
<tr><td>Treatment duration</td><td>68 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>68 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 611
Intervention group/s: Semaglutide 2.4mg (n=407)

Comparator group: Placebo (n=204)</td></tr>
<tr><td>Mean age ± SD</td><td>46y (13)</td></tr>
<tr><td>Sex</td><td>81.01% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)

BMI (kg/m2) - Baseline
Mean (SD)

Waist circumference (cm) - Baseline
Mean (SD)</td><td>Semaglutide 2.4mg: 106.9 (22.8)

Semaglutide 2.4mg: 38.1 (6.7)

Semaglutide 2.4mg: 113.6 (15.1)</td><td>Placebo: 103.7 (22.9)

Placebo: 37.8 (6.9)

Placebo: 111.8 (16.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion with ≥5% weight loss
Proportion (%)

Proportion with ≥10% weight loss
Proportion (%)

Proportion with ≥ 15% weight loss
Proportion (%)

Proportion with ≥20% weight loss
Proportion (%)</td><td>Semaglutide 2.4mg: 86.6

Semaglutide 2.4mg: 75.3

Semaglutide 2.4mg: 55.8

Semaglutide 2.4mg: 35.7</td><td>Placebo: 47.6

Placebo: 27

Placebo: 13.2

Placebo: 3.7</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>% change in body weight
Mean

Change in waist circumference (cm)</td><td>Semaglutide 2.4mg: -16

Semaglutide 2.4mg: -14.6</td><td>Placebo: -5.7

Placebo: -6.3</td></tr>
</table>
</td></tr>
</table>

	Mean Change in weight (kg) Mean Change in BMI (kg/m2) Mean	 Semaglutide 2.4mg: -16.8 Semaglutide 2.4mg: -6	 Placebo: -6.2 Placebo: -2.2
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Wadden, 2023

Guideline record ID: 12026--1

Study characteristics		
Citation	Wadden, T. A., Chao, A. M., Machineni, S., Kushner, R., Ard, J., Srivastava, G., Halpern, B., Zhang, S., Chen, J., Bunck, M. C., Ahmad, N. N., & Forrester, T. (2023). Tirzepatide after intensive lifestyle intervention in adults with overweight or obesity: the SURMOUNT-3 phase 3 trial. Nature Medicine, 29(11), 2909-2918. https://doi.org/https://doi.org/10.1038/s41591-023-02597-w	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Tirzepatide after intensive lifestyle intervention in adults with overweight or obesity: the SURMOUNT-3 phase 3 trial	
Location	Argentina; Brazil; US	
Trial name	SURMOUNT-3	
Methods		
Inclusion criteria	"Intensive lifestyle intervention lead-in period. A total of 972 participants were assessed for eligibility at screening, of whom 806 were enrolled into the 12-week intensive lifestyle intervention lead-in period. Of the 806 participants enrolled, 579 (71.8%) who achieved ≥5% weight reduction at the end of the lead-in period and were otherwise eligible to proceed to the next phase of the study were randomized to either tirzepatide maximum tolerated dose (MTD, n=287) or placebo (n=292)."	
Exclusion criteria	Not reported	
Setting	Not reported	
Intervention	"Tirzepatide maximum tolerated dose (10 or 15 mg) once weekly for 72 weeks"	
Control/Comparator	"placebo once weekly for 72 weeks."	
Treatment duration	72 weeks	
Follow-up from baseline	72 weeks	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 579 Intervention group/s: Tirzepatide MTD (n=287) Comparator group: Placebo (n=292)	
Mean age ± SD	45.6y (12.2)	
Sex	62.87% female	
Pre-existing medical condition		
Results		
Outcome measure at baseline	Variable / Intervention arm/s / Comparator ( ) / ( ) / ( )	

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Waist circumference (cm)
Mean (SE)

Body weight (kg)
Mean (SE)

BMI (kg/m2)
Mean (SE)</td><td>Tirzepatide MTD: -14.6
(0.7)

Tirzepatide MTD: -21.5
(0.7)

Tirzepatide MTD: -7.7
(0.2)</td><td>Placebo: 0.2
(1)

Placebo: 3.5
(0.7)

Placebo: 1.2
(0.2)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Wake, 2013

Guideline record ID: 10708A--MOTHERS

Study characteristics		
Citation	Wake, M., Lycett, K., Clifford, S. A., Sabin, M. A., Gunn, J., Gibbons, K., Hutton, C., McCallum, Z., Arnup, S. J., & Wittert, G. (2013). Shared care obesity management in 3-10 year old children: 12 month outcomes of HopSCOTCH randomised trial. BMJ, 346, f3092. https://doi.org/https://dx.doi.org/10.1136/bmj.f3092	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Shared care obesity management in 3-10 year old children: 12 month outcomes of HopSCOTCH randomised trial	
Location	Australia	
Trial name	Shared Care Obesity Trial in Children (HopSCOTCH)	
Methods		
Inclusion criteria	"Practice staff invited children aged 3-10 years (up to but not including their 11th birthday) attending each practice to be weighed and measured to determine eligibility. Children were eligible if they were obese but not receiving an ongoing weight management programme."	
Exclusion criteria	"Exclusion criteria included a known endocrine or chromosomal cause for obesity, major health and developmental conditions, and insufficient English to comprehend sessions or complete questionnaires."	
Setting	GP clinic, Hospital, Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Approximately two months after enrolment, intervention children attended a one hour appointment with a specialist tertiary weight management service at Melbourne's Royal Children's Hospital. each child was seen by both a paediatrician and a dietitian provided with summarised child/family details pre-extracted from baseline questionnaire data. The clinicians took further history; did an examination and investigations to identify comorbidities of obesity; and discussed relevant dietary, physical activity, and family/child lifestyle changes. Before leaving, the family and clinicians agreed on an initial care plan and specific goals. Information from all these steps was entered into the shared care, web based software. The research team then scheduled a "long" appointment with the child's general practitioner, to be followed by regular four to eight weekly "standard" consultations to review lifestyle and body mass index progress, identify and solve problems, and set new goals by using brief solution focused techniques. The HopSCOTCH web based, shared care software software enabled a structured intervention at each consultation for each visit, comprising five standardised sequential steps: recording anthropometry; reviewing change in body mass index, using an online chart to plot and track body mass index visually over time against centile charts; assessing and tracking progress and motivation; reviewing the care plan (for example, identifying problems and revising goals); and providing educational resources."	
Control/Comparator	"Participants in the usual care (control) arm were free to seek assistance from their general practitioner or from any other service."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 303
Intervention group/s: Intervention (n=166)

Comparator group: Control (n=137)</td></tr>
<tr><td>Mean age ± SD</td><td>Children: Intervention: 7.2y (2.3); Control: 7.4 (2.2); Parents age not reported</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Mother BMI (kg/m2) Mean (SD)</td><td>Intervention: 26.9 (5.7)</td><td>Control: 28 (7.1)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Mother BMI (kg/m2) Mean (SD)</td><td>Intervention: 28.6 (7.6)</td><td>Control: 30.2 (8.8)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Wake, 2013

Guideline record ID: 10708B--CHILD

Study characteristics		
Citation	Wake, M., Lycett, K., Clifford, S. A., Sabin, M. A., Gunn, J., Gibbons, K., Hutton, C., McCallum, Z., Arnup, S. J., & Wittert, G. (2013). Shared care obesity management in 3-10 year old children: 12 month outcomes of HopSCOTCH randomised trial. BMJ, 346, f3092. https://doi.org/https://dx.doi.org/10.1136/bmj.f3092	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Shared care obesity management in 3-10 year old children: 12 month outcomes of HopSCOTCH randomised trial	
Location	Australia	
Trial name	Shared Care Obesity Trial in Children (HopSCOTCH)	
Methods		
Inclusion criteria	"Practice staff invited children aged 3-10 years (up to but not including their 11th birthday) attending each practice to be weighed and measured to determine eligibility. Children were eligible if they were obese but not receiving an ongoing weight management programme."	
Exclusion criteria	"Exclusion criteria included a known endocrine or chromosomal cause for obesity, major health and developmental conditions, and insufficient English to comprehend sessions or complete questionnaires."	
Setting	GP clinic, Hospital, Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Approximately two months after enrolment, intervention children attended a one hour appointment with a specialist tertiary weight management service at Melbourne's Royal Children's Hospital. each child was seen by both a paediatrician and a dietitian provided with summarised child/family details pre-extracted from baseline questionnaire data. The clinicians took further history; did an examination and investigations to identify comorbidities of obesity; and discussed relevant dietary, physical activity, and family/child lifestyle changes. Before leaving, the family and clinicians agreed on an initial care plan and specific goals. Information from all these steps was entered into the shared care, web based software. The research team then scheduled a "long" appointment with the child's general practitioner, to be followed by regular four to eight weekly "standard" consultations to review lifestyle and body mass index progress, identify and solve problems, and set new goals by using brief solution focused techniques. The HopSCOTCH web based, shared care software software enabled a structured intervention at each consultation for each visit, comprising five standardised sequential steps: recording anthropometry; reviewing change in body mass index, using an online chart to plot and track body mass index visually over time against centile charts; assessing and tracking progress and motivation; reviewing the care plan (for example, identifying problems and revising goals); and providing educational resources."	
Control/Comparator	"Participants in the usual care (control) arm were free to seek assistance from their general practitioner or from any other service."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 303
Intervention group/s: Intervention (n=166)

Comparator group: Control (n=137)</td></tr>
<tr><td>Mean age ± SD</td><td>Children: Intervention: 7.2y (2.3); Control: 7.4 (2.2); Parents age not reported</td></tr>
<tr><td>Sex</td><td>45.76% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Child BMI (kg/m2)
Mean (SD)

Child BMI z-score
Mean (SD)</td><td>Intervention: 22.3
(2.7)

Intervention: 2.2
(0.5)</td><td>Control: 22.8
(3.6)

Control: 2.1
(0.3)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Child BMI (kg/m2)
Mean (SD)

Child BMI z-score
Mean (SD)</td><td>Intervention: 23.2
(3.8)

Intervention: 2
(0.5)</td><td>Control: 23.6
(4.6)

Control: 2
(0.4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Wake, 2013

Guideline record ID: 10708C--FATHERS

Study characteristics		
Citation	Wake, M., Lycett, K., Clifford, S. A., Sabin, M. A., Gunn, J., Gibbons, K., Hutton, C., McCallum, Z., Arnup, S. J., & Wittert, G. (2013). Shared care obesity management in 3-10 year old children: 12 month outcomes of HopSCOTCH randomised trial. BMJ, 346, f3092. https://doi.org/https://dx.doi.org/10.1136/bmj.f3092	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Shared care obesity management in 3-10 year old children: 12 month outcomes of HopSCOTCH randomised trial	
Location	Australia	
Trial name	Shared Care Obesity Trial in Children (HopSCOTCH)	
Methods		
Inclusion criteria	"Practice staff invited children aged 3-10 years (up to but not including their 11th birthday) attending each practice to be weighed and measured to determine eligibility. Children were eligible if they were obese but not receiving an ongoing weight management programme."	
Exclusion criteria	"Exclusion criteria included a known endocrine or chromosomal cause for obesity, major health and developmental conditions, and insufficient English to comprehend sessions or complete questionnaires."	
Setting	GP clinic, Hospital, Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Approximately two months after enrolment, intervention children attended a one hour appointment with a specialist tertiary weight management service at Melbourne's Royal Children's Hospital. each child was seen by both a paediatrician and a dietitian provided with summarised child/family details pre-extracted from baseline questionnaire data. The clinicians took further history; did an examination and investigations to identify comorbidities of obesity; and discussed relevant dietary, physical activity, and family/child lifestyle changes. Before leaving, the family and clinicians agreed on an initial care plan and specific goals. Information from all these steps was entered into the shared care, web based software. The research team then scheduled a "long" appointment with the child's general practitioner, to be followed by regular four to eight weekly "standard" consultations to review lifestyle and body mass index progress, identify and solve problems, and set new goals by using brief solution focused techniques. The HopSCOTCH web based, shared care software software enabled a structured intervention at each consultation for each visit, comprising five standardised sequential steps: recording anthropometry; reviewing change in body mass index, using an online chart to plot and track body mass index visually over time against centile charts; assessing and tracking progress and motivation; reviewing the care plan (for example, identifying problems and revising goals); and providing educational resources."	
Control/Comparator	"Participants in the usual care (control) arm were free to seek assistance from their general practitioner or from any other service."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 303
Intervention group/s: Intervention (n=166)

Comparator group: Control (n=137)</td></tr>
<tr><td>Mean age ± SD</td><td>Children: Intervention: 7.2y (2.3); Control: 7.4 (2.2); Parents age not reported</td></tr>
<tr><td>Sex</td><td>100.00% male</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Father BMI
Mean (SD)</td><td>Intervention: 27.8
(6.9)</td><td>Control: 29.8
(4.9)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Father BMI
Mean (SD)</td><td>Intervention: 29.9
(5.2)</td><td>Control: 31.5
(6.7)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Walburg, 2023

Guideline record ID: 12027

Study characteristics		
Citation	Walburg, F. S., van Meijel, B., Hoekstra, T., Kol, J., Pape, L. M., de Joode, J. W., van Tulder, M., & Adriaanse, M. (2023). Effectiveness of a lifestyle intervention for people with a severe mental illness in dutch outpatient mental health care: a randomized clinical trial. JAMA Psychiatry, 80(9), 886-894. https://doi.org/10.1001/jamapsychiatry.2023.1566	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effectiveness of a Lifestyle Intervention for People With a Severe Mental Illness in Dutch Outpatient Mental Health Care: A Randomized Clinical Trial	
Location	Netherlands	
Trial name	The Severe Mental Illness Lifestyle Evaluation (SMILE)	
Methods		
Inclusion criteria	"Eligibility criteria for participantswere age 18 years or older, active FACT team care, and body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) of 27 or more (chosen to include those with a higher risk of cardiometabolic disorders, as in the STRIDE study19)."	
Exclusion criteria	"Exclusion criteria included experiencing cognitive impairment that could interfere with active participation, contraindications for participation (eg, acute psychiatric crisis or stroke), inability to communicate in Dutch, and pregnant, breastfeeding, or planning pregnancy."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"A total of 21 flexible assertive community treatment (FACT) teams from 8 mental health care centers in the Netherlands participated in the trial. FACT teams are the most common Dutch outpatient mental health care service for long-term care for community dwelling people with SMI.17 A Dutch FACT team is an extended version of an assertive community treatment (ACT) model. Like ACT, FACT teams are outreaching and multidisciplinary, including a psychiatrist, clinical nurse specialist, a psychologist, a mental health nurse who functions as case manager, expert-by-experience, and a supported employment specialist. Also similar to ACT, FACT care includes illness management, symptom treatment, guidance and practical assistance in daily living, rehabilitation, and recovery support. FACT teams differ from ACT teams primarily in that the former are designed to serve the broad range of people with SMIs whereas the latter are provided mainly to a subgroup of similar persons with a history of high acute care service utilization or housing instability. FACT teams have treatment responsibility for all clients with SMI in a specific region, each covering 200 to 250 outpatients. FACT teams offer 2 levels of care: individual case management for most clients and full ACT when there is a need for shared caseload and assertive outreach. The SMILE intervention is primarily modelled after the successful STRIDE intervention. The STRIDE lifestyle intervention was developed for persons with severe mental illness (SMI). In turn, STRIDE was based on prior research, ie, the PREMIER clinical trial,20 behaviour change theories, such as the transtheoretical model,21,22 and motivational theory.23-25 In the SMILE study, the session content of the STRIDE intervention program materials was used (eMethods in Supplement 2).26The lifestyle intervention was adapted to fit Dutch food standards and customs. Participants wanting to stop smoking were offered referral for external support, for example, by general practitioners. The lifestyle intervention was carried out by 2 trained mental health workers who were members of that team. The lifestyle intervention's duration was 12months and consisted of (1) the initial intervention, with 24 sessions of weekly 2-hour group meetings delivered over the first 6 months, and (2) the maintenance phase, which included 6 monthly group sessions (sessions 25 to 30) focusing on maintaining weight loss. Maintenance sessions were, if needed, supplemented	

<table>
<tr><td></td><td>with monthly individual telephone sessions (about 15 minutes) with mental health workers. More information regarding the lifestyle intervention can be found elsewhere.”</td></tr>
<tr><td>Control/Comparator</td><td>“FACT teams in the control group provided treatment as usual (TAU) without structured lifestyle interventions or advice on lifestyle changes.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 224
Intervention group/s: Lifestyle intervention (n=126)

Comparator group: TAU (n=98)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 47.6y (11.4); Control: 47.6y (10.8)</td></tr>
<tr><td>Sex</td><td>61.16% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Severe mental illness (SMI)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>≥5% weight loss at 12 months after baseline
Proportion (%)

≥10% weight loss at 12 months after baseline
Proportion (%)</td><td>Lifestyle intervention: 27.0%

Lifestyle intervention: 16.0%</td><td>TAU: 17.0%

TAU: 6.0%</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Body weight (kg)
Mean (SD)</td><td>Lifestyle intervention: -2.6
(8.4)</td><td>TAU: 0.04
(7.1)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>The SMILE study was an ambitious trial in this population, with the inclusion of 224 people with SMI within 1 year, with an almost complete range of sessions offered by professionals (98%) and with a patient participation rate of 52%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Walc, 2023

Guideline record ID: 12028--1

Study characteristics		
Citation	Walc, A., Latimer-Cheung, A. E., Day, A. G., Brennan, A. M., Hill, J. O., & Ross, R. (2023). A small change approach on adiposity, lean mass and bone mineral density in adults with overweight and obesity: a randomized controlled trial. Clinical Obesity, 13(4), e12587. https://doi.org/https://doi.org/10.1111/cob.12587	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A small change approach on adiposity, lean mass and bone mineral density in adults with overweight and obesity: A randomized controlled trial	
Location	Canada	
Trial name		
Methods		
Inclusion criteria	"Participants were originally recruited to participate in a randomized controlled trial with a primary objective to evaluate the utility of the SCA to prevent weight gain.15 In this secondary analysis, we included participants from the primary trial who completed a dual-energy x-ray absorptiometry (DXA) scan at baseline with at least one follow-up measure. The principal study was a 3-year, single centre, two arm, longitudinal randomized controlled trial, wherein 320 sedentary individuals with obesity or overweight were randomized to SCA or usual care (UC)."	
Exclusion criteria	"Participants were excluded if they already engaged in two or more planned exercise sessions per week, reported a history of heart disease, stroke or any condition that would prevent them from exercise, had planned for pregnancy within 3 years, or if they were a current smoker."	
Setting	University/research centre	
Intervention	"The trial included two phases. Phase I was a 24-month intervention, wherein the SCA participants attended both group and individual counselling sessions to help them make small changes to their diet and physical activity habits. The Phase I intervention emphasized the development of self-regulatory skills based on key constructs from usual care theory,16 health action process approach,17 self-determination theory18 and social cognitive theory.19,20 The SCA group was required to monitor their progress by examining physical activity patterns, setting new weekly SCA goals, developing a weekly plan for on-going maintenance of their goals and submitting these plans to an interventionist weekly. Participants also attended 18 group and 8 one-on-one counselling sessions to support their adoption of the SCA. The treatment strategy was separated into three phases with Phase IA and B lasting 6 months in duration and Phase IC lasting 12 months. To foster self-regulation, these sessions began more frequently and interventionist-led but transitioned to less frequent and more participant directed towards the end of the intervention. To monitor changes in physical activity, all SCA participants were asked to wear a StepsCount pedometer for a week following randomization to establish their average physical activity (daily step count) at baseline. The participants were then asked to increase their daily physical activity by about 2000 steps per day above their baseline value throughout the intervention. Participants were asked to wear the pedometer again for 1 week at 6, 12, 18 and 24 months to compare to baseline activity and were asked to submit self-recorded physical activity records to trial interventionists weekly. SCA participants were asked to submit 7-day dietary intake records to help determine usual diet at baseline following randomization. SCA participants were also asked to reduce their dietary intake by about 100 kcal/day below their baseline value throughout the intervention. SCA participants were asked to keep a log of the strategies they implemented to reduce caloric intake and to submit their records on a weekly basis electronically or in person. Unfortunately, too few	

<table>
<tr><td></td><td>records were submitted and generation of dietary intake data was not possible. Phase II (months: 25-36) was a 1-year passive follow up, wherein all participants had a single contact with trial staff for a body weight assessment at 30 months. For this report, 36-month data are not reported since few DXA scans were obtained at 36 months due to budgetary constraints.”</td></tr>
<tr><td>Control/Comparator</td><td>“UC participants were asked to maintain their usual lifestyle and were not discouraged from losing weight or adopting healthy behaviours. Phase II (months: 25-36) was a 1-year passive follow up, wherein all participants had a single contact with trial staff for a body weight assessment at 30 months. For this report, 36-month data are not reported since few DXA scans were obtained at 36 months due to budgetary constraints.”</td></tr>
<tr><td>Treatment duration</td><td>24 months</td></tr>
<tr><td>Follow-up from baseline</td><td>24 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 289
Intervention group/s: SCA (n=144)

Comparator group: UC (n=145)</td></tr>
<tr><td>Mean age ± SD</td><td>52.7y (10.4)</td></tr>
<tr><td>Sex</td><td>77.85% female</td></tr>
<tr><td>Pre-existing medical condition</td><td></td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Total body fat, kg
Mean (SE)</td><td>SCA: -1.7
(0.3)</td><td>UC: -0.6
(0.3)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Total body fat, kg
Mean (SE)</td><td>SCA: -0.7
(0.4)</td><td>UC: -0.8
(0.4)</td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Adherence to the intervention for SCA, defined as the percentage of sessions attended with intervention staff averaged 81.7% (81% for men and 82% for women).</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from</td><td></td></tr>
</table>

this study that did not contribute additional data	

N/A – Not applicable

Waling, 2010

Guideline record ID: 10709--1

Study characteristics		
Citation	Waling, M., Lind, T., Hernell, O., & Larsson, C. (2010). A one-year intervention has modest effects on energy and macronutrient intakes of overweight and obese Swedish children. The Journal of Nutrition, 140(10), 1793-1798. https://doi.org/https://dx.doi.org/10.3945/jn.110.125435	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A one-year intervention has modest effects on energy and macronutrient intakes of overweight and obese Swedish children	
Location	Sweden	
Trial name	N/A	
Methods		
Inclusion criteria	"To be included in the study, the children had to be born between 1995 and 1998, have an age- and gender-adjusted BMI $ 25 kg/m2 (16), have access to the Internet, and have no chronic diseases affecting metabolic variables and no attention deficit disorder diagnosis."	
Exclusion criteria	Not reported	
Setting	Home, University/research centre	
Intervention	"The intervention group participated in a program aimed at improving food and physical activity habits. The program comprised 14 group sessions with different themes during 1 y at the Department of Food and Nutrition, Umea˚University. The group sessions were held once or twice per month with breaks during holidays. Five of the meetings had food habits as a theme and the remaining meetings focused on physical activity, behavioral changes, and self esteem. The physical activity part will be evaluated elsewhere. Both parents and children were invited to the 1- to 1.5-h-long sessions. To evaluate the effect of the intervention on dietary habits, the intake of the children was compared with national dietary recommendations for SFA [#10 percentage of total energy intake (E%)] dietary fiber (2-3 g/MJ) and refined sugar, e.g. sucrose, glucose, fructose, and starch hydrolysates (#10 E%) (17). In the present study, sucrose was the only refined sugar that could be calculated in the nutritional calculation program used and therefore represents refined sugar. To reach these nutritional goals, the families were provided with different tools to help them make dietary choices in accordance with the intervention goals. To increase the fruit and vegetable intake, as well as dietary fiber intake, children and parents were introduced to the SAPERE-method, which aims at helping children increase preferences for new foods (18). To encourage the families to meet the nutritional goals of the intervention, they were advised to consume foods labeled with the "key hole" created by the Swedish Food Administration. The aim of the key hole is to guide consumers in finding food items that contain more dietary fiber and less salt, sugar, and SFA compared with similar food items. During a majority of the sessions, the parents and the children were separated into different groups to enable discussions and activities suitable from their respective viewpoints. The groups were then reunited at the end of the session for a final discussion. To encourage changes in the participants' everyday lives, a majority of the sessions were of practical character with active participation of both parents and children, e.g. cooking food and tasting different foods. The sessions concerning food habits were led by MW and a registered dietician. Between the meetings, the children, together with the parents, worked with home assignments related to the theme of the next meeting. Our intention with the assignments was to encourage the families to make behavioral changes regarding dietary choices and other lifestyle habits in their home setting"	

<table>
<tr><td>Control/Comparator</td><td>“The children allocated to the control group attended 1 meeting at the beginning of the study where they were informed about the measurements they were expected to participate in during the study. Apart from these measurements, the children had no further contact with the research team.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 83
Intervention group/s: Intervention (n=43)

Comparator group: Control (n=40)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 10.4y (1.09); Control: 10.5y (1.06)</td></tr>
<tr><td>Sex</td><td>51.81% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Body Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 51.1
(9.49)

Intervention: 23.1
(0.83)</td><td>Control: 50.1
(10.4)

Control: 22.6
(0.84)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Body Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 53.9
(11)

Intervention: 23.1
(2.65)</td><td>Control: 55.4
(12.3)

Control: 23
(2.97)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Body weight change (kg)
Mean (SD)

BMI change (kg/m2)
Mean (SD)</td><td>Intervention: 3.6
(3.56)

Intervention: 0.21
(1.07)</td><td>Control: 4.93
(7.59)

Control: 0.31
(1.25)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Wani, 2020

Guideline record ID: 10928

Study characteristics		
Citation	Wani, K., Alfawaz, H., Alnaami, A. M., Sabico, S., Khattak, M. N. K., Al-Attas, O., Alokail, M. S., Alharbi, M., Chrousos, G., Kumar, S., & Al-Daghri, N. M. (2020). Effects of a 12-month intensive lifestyle monitoring program in predominantly overweight/obese Arab adults with prediabetes. Nutrients, 12(2), 464. https://doi.org/https://doi.org/10.3390/nu12020464	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of a 12-Month Intensive Lifestyle Monitoring Program in Predominantly Overweight/Obese Arab Adults with Prediabetes	
Location	Saudi Arabia	
Trial name	N/A	
Methods		
Inclusion criteria	“Adults (≥20 years) were enrolled if they had impaired glucose tolerance (FBG 5.6-6.9 mmol/L).”	
Exclusion criteria	“The exclusion criteria were: Expatriates; pregnant women; those with established type 1 or T2DM and/or those on anti-hyperglycemic drugs; and those with chronic medical conditions, such as renal, hepatic, and cardiac complications.”	
Setting	University/research centre	
Intervention	“Both groups (GA and IG) had an orientation session conducted by a dietician and a physician at the respective study centers. Participants were educated about the risks of prediabetes, overweight/obesity and associated complications, the current scenario of diabetes worldwide and in Saudi Arabia, as well as benefits of modifying lifestyle through dietary changes and increased in physical activity. Pamphlets and booklets containing information on healthy food and lifestyle choices, nutritional components of foods, "Healthy Eating Plate (HEP)", sedentary behavior, and the benefits of physical activity, were explained and distributed to all participants. The session lasted an hour and was conducted for a group of 3-10 newly recruited participants. Aside from the orientation session, seminars and workshops on related topics presided by the investigators were conducted in each center every four months, and all participants were invited to attend. IG group were additionally given an intensive lifestyle modification support, Dietary counseling -Individual consultation with a dietician - Follow up through phone call/email/short message service - Assessment of food intake - Special dietary charts - Ways to reduce total dietary fat <30% of energy - Ways to increase fiber consumption to 15 g/1000 Kcal and Physical activity counseling - Individual consultation with a physical therapist - Pedometers supplied - Recommended at least 5000 steps/day - Follow up through phone call/email/short message service - Assessment of physical activity levels - Special physical activity/exercise/yoga charts - Concept of calorie burn - Concept of Metabolic Equivalents (MET) - Saudi guidelines for management of obesity”	
Control/Comparator	“Both groups (GA and IG) had an orientation session conducted by a dietician and a physician at the respective study centers. Participants were educated about the risks of prediabetes, overweight/obesity and associated complications, the current scenario of diabetes worldwide and in Saudi Arabia, as well as benefits of modifying lifestyle through dietary changes and increased in physical activity. Pamphlets and booklets containing information on healthy food and lifestyle choices, nutritional components of foods, "Healthy Eating Plate (HEP)", sedentary behavior, and the benefits of physical activity, were explained and distributed to all participants. The session lasted an hour and was conducted for a group of 3-10 newly recruited participants. Aside from the orientation session, seminars and workshops on related topics presided by the investigators were conducted in	

<table>
<tr><td></td><td>each center every four months, and all participants were invited to attend. Participants in the GA group received only the intervention, as described above.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 300
Intervention group/s: IG (n=150)

Comparator group: GA (n=150)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 43.10y (9.4); Control: 43.75 (10.9)</td></tr>
<tr><td>Sex</td><td>69.33% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Prediabetes - impaired glucose tolerance (FBG 5.6-6.9 mmol/L)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>IG: 81.26
(15.5)</td><td>GA: 81.95
(14.3)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>IG: 31.71
(6)</td><td>GA: 32.92
(6)</td></tr>
<tr><td>Waist (cm)
Mean (SD)</td><td>IG: 96.45
(13.4)</td><td>GA: 96.96
(8.6)</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>IG: 80.71
(15.7)</td><td>GA: 82.56
(13.8)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>IG: 31.67
(6)</td><td>GA: 33.13
(5.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)</td><td>IG: 78.01
(15.8)</td><td>GA: 83.27
(13.7)</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)</td><td>IG: 30.57
(6.3)</td><td>GA: 33.39
(5.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight
Mean (SD)</td><td>IG: -1.96</td><td>GA: 0.57</td></tr>
<tr><td>Change in BMI (kg/m2)
Mean (SD)</td><td>IG: -0.76</td><td>GA: 0.24</td></tr>
<tr><td>>5% Weight decrease
Proportion (%)</td><td>IG: 37.2</td><td>GA: 12.3</td></tr>
<tr><td>1-5% weight decrease</td><td>IG: 33.3</td><td>GA: 5.8</td></tr>
</table>
</td></tr>
</table>

	Proportion (%) 1-5% Weight increase Proportion (%) >5% Weight increase Proportion (%) Weight <1% increase/<1% reduce Proportion (%)	 IG: 8.5 IG: 3.1 IG: 17.8	 GA: 44.9 GA: 8 GA: 29
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Warnakulasuriya, 2018

Guideline record ID: 10713

Study characteristics		
Citation	Warnakulasuriya, L. S., Fernando, M. M. A., Adikaram, A. V. N., Thawfeek, A. R. M., Anurasiri, W.-M. L., Silva, R. R., Sirasa, M. S. F., Rytter, E., Forslund, A. H., Samaranayake, D. L., & Wickramasinghe, V. P. (2018). Metformin in the management of childhood obesity: a randomized control trial. Childhood Obesity, 14(8), 553-565. https://doi.org/https://doi.org/10.1089/chi.2018.0043	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Metformin in the Management of Childhood Obesity: A Randomized Control Trial	
Location	Sri Lanka	
Trial name	N/A	
Methods		
Inclusion criteria	"Obese (BMI/Age-SDS >=+2SD, WHO 2007)22 8- to 16- year-old children."	
Exclusion criteria	"People of non-Sri Lankan origin, planning to migrate within a year, or having a secondary cause for obesity were excluded."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"Protocol I comprised structured diet+physical activity+metformin. A trained nutritionist gave dietary advice based on foodbased dietary guidelines published by the Ministry of Health, Government of Sri Lanka.26 Age-based portion size guide was provided to parents and children to guide them on the variety and volume they should be eating. Physical activity training was conducted by a qualified physical activity instructor. A daily physical activity routine of 20-30 minutes was given to each child. The workout program was changed to one of four workout plans every month to break the monotony. Weekly physical activity sessions of 1-hour duration were conducted for the participants of both groups. Participants were given a physical activity diary to maintain and to ensure adherence to the physical activity plan at home. During the weekly sessions, the adherence to physical activity plan was assessed and ensured. Children, 8-10.99 years, received metformin 250 mg daily for a week and increased to 250 mg twice daily for a week and thereafter 500 mg twice daily. Eleven- to 16-year-old children received 500 mg of metformin daily for 1 week and increased to 500 mg twice daily for a week and thereafter 1 g twice daily. Children were asked to take metformin with their morning and evening meals to reduce gastrointestinal side effects and risk of hypoglycemia. The children were reviewed 2 weeks after commencement of therapy. Thereafter, they were reviewed monthly to ensure compliance and identify and address any adverse events, and medication was dispensed. In addition, they were contacted via telephone, weekly during the first month and fortnightly afterward to address concerns/issues and also to motivate them to maintain compliance at the highest level. Participants maintained a medication diary and recorded the medication intake there. They were reviewed at the clinic monthly, during which the compliance was assessed and reinforced. At each monthly visits, anthropometry and body composition were assessed, while blood investigations were repeated at 6 and 12 months"	
Control/Comparator	"Protocol II comprised structured diet+physical activity+placebo A trained nutritionist gave dietary advice based on foodbased dietary guidelines published by the Ministry of Health, Government of Sri Lanka.26 Age-based portion size guide was provided to parents and children to guide them on the variety and volume they should be eating. Physical activity training was conducted by a qualified physical activity instructor. A daily physical activity routine of 20-30 minutes was given to each child. The workout program was changed to one of four workout plans every month to break the monotony. Weekly physical activity sessions of 1-hour duration were conducted for the participants of both groups.	

<table>
<tr><td></td><td>Participants were given a physical activity diary to maintain and to ensure adherence to the physical activity plan at home. During the weekly sessions, the adherence to physical activity plan was assessed and ensured. The children were reviewed 2 weeks after commencement of therapy. Thereafter, they were reviewed monthly to ensure compliance and identify and address any adverse events, and medication was dispensed. In addition, they were contacted via telephone, weekly during the first month and fortnightly afterward to address concerns/issues and also to motivate them to maintain compliance at the highest level. Participants maintained a medication diary and recorded the medication intake there. They were reviewed at the clinic monthly, during which the compliance was assessed and reinforced. At each monthly visits, anthropometry and body composition were assessed, while blood investigations were repeated at 6 and 12 months.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 150
Intervention group/s: Metformin (n=68)

Comparator group: Placebo (n=82)</td></tr>
<tr><td>Mean age ± SD</td><td>12.12y (2.28)</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight, kg
Mean (SD)

BMI, kg/m2
Mean (SD)

BMI/Age-standard deviation score
Mean (SD)

Waist Circumference, cm
Mean (SD)

Waist Circumference/Age-standard deviation score
Mean (SD)</td><td>Metformin: 63.44
(15.5)

Metformin: 27.44
(2.7)

Metformin: 2.58
(0.39)

Metformin: 86.8
(9.2)

Metformin: 2.96
(0.48)</td><td>Placebo: 63.51
(14.37)

Placebo: 27.44
(2.96)

Placebo: 2.54
(0.41)

Placebo: 88.05
(9.14)

Placebo: 3.01
(0.44)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight, kg
Mean (SD)

BMI, kg/m2
Mean (SD)

BMI/Age-standard deviation score
Mean (SD)</td><td>Metformin: 64.05
(14.8)

Metformin: 26.58
(3.58)

Metformin: 2.21
(0.52)</td><td>Placebo: 66.55
(14.12)

Placebo: 27.39
(2.98)

Placebo: 2.32
(0.46)</td></tr>
</table>
</td></tr>
</table>

	Waist Circumference, cm Mean (SD) Waist Circumference/Age-standard deviation score Mean (SD)	Metformin: 83.4 (7.8) Metformin: 2.46 (0.53)	Placebo: 86.4 (9.19) Placebo: 2.62 (0.5)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Change in Weight, kg Mean (95% CIs) Change in BMI (kg/m2) Mean (95% CIs) Change in BMI/Age-SDS Mean (95% CIs) Change in Waist circumference (CM) Mean (95% CIs) Change in Waist circumference /Age SDS Mean (95% CIs)	Metformin: 0.603 (0.443-1.649) Metformin: -0.854 (-1.225--0.482) Metformin: -0.37 (-0.44--0.303) Metformin: -3.436 (-4.353--2.519) Metformin: -0.473 (-0.555--0.39)	Placebo: 3.044 (2.091-3.996) Placebo: -0.059 (-0.398-0.279) Placebo: -0.222 (-0.284--0.159) Placebo: -1.51 (-2.345--0.675) Placebo: -0.337 (-0.412-0.261)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Warschburger, 2016

Guideline record ID: 10714--1

Study characteristics		
Citation	Warschburger, P., Kroeller, K., Haerting, J., Unverzagt, S., & van Egmond-Fröhlich, A. (2016). Empowering Parents of Obese Children (EPOC): a randomized controlled trial on additional long-term weight effects of parent training. Appetite, 103, 148-156. https://doi.org/https://doi.org/10.1016/j.appet.2016.04.007	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Empowering Parents of Obese Children (EPOC): A randomized controlled trial on additional long-term weight effects of parent training	
Location	Germany	
Trial name	Empowering Parents of Obese Children (EPOC)	
Methods		
Inclusion criteria	"The inclusion and exclusion criteria were as follows: All parents of obese children (BMI > 97th percentile) aged 7 to 12 were asked to participate at the beginning of their child's stay in an inpatient rehabilitation clinic specialising in childhood obesity. Due to recruitment problems, the age range was later extended up to 13 years."	
Exclusion criteria	"Parents who had already completed parent training and those with inadequate language skills or severe mental disorder (e.g. depression, psychosis) as well as children with secondary causes of obesity or those suffering from severe mental health problems (e.g. ADHD, eating disorder) were excluded."	
Setting	Hospital	
Intervention	"The children stayed in a specialized out-of-home inpatient facility for around 3e6 weeks, and were not accompanied by their parents. During this time, all children participated in a multidisciplinary lifestyle intervention encompassing nutrition education, diet modification, controlled meal options, scheduled activity sessions several times a week, and cognitive-behavioral group training (CBT) and when necessary individual counseling sessions. The CBT encompassed e.g., self-monitoring, cue-control strategies, goal-setting, token programs. The parents were allowed to visit their child at weekends at their own expense, but there was no mandatory parental visitation or treatment involvement. Parents received a compact (10 units over 2 days) cognitive-behaviorally oriented training course in a group setting (8-12 parents) based on the treatment manual "Gemeinsam Fit" [Fit together]. The training focused on how to support the child at home in critical behavioral tasks (limiting television consumption and video games, increasing physical activity, dietary changes) once their rehabilitation stay far from the family home had ended. The sessions were conducted by trained professionals and parents were educated in cognitive behavioral principles such as (self-) monitoring (e.g. food records), stimulus control, modeling, food management and reinforcement principles (e.g. using a structured reward system) through psychoeducation, individualized worksheets, group discussions, role-playing and video feedback. All parents of the CBT group received a short parent guide (incl. video material) and 2 telephone booster sessions after one (T3) and 3 months (T4) following the discharge of their child. The booster sessions focused on the individual intentions and practical problems in their implementation."	
Control/Comparator	"The children stayed in a specialized out-of-home inpatient facility for around 3e6 weeks, and were not accompanied by their parents. During this time, all children participated in a multidisciplinary lifestyle intervention encompassing nutrition education, diet modification, controlled meal options, scheduled activity sessions several times a week, and cognitive-behavioral group training (CBT) and when necessary individual counseling sessions. The CBT encompassed e.g., self-monitoring, cue-control strategies, goal-setting, token	

<table>
<tr><td></td><td>programs. The parents were allowed to visit their child at weekends at their own expense, but there was no mandatory parental visitation or treatment involvement. Parents received a brief written parent guide summarizing what their child had learned during their stay and giving advice on how to further support their child. The booklet encompassed the same contents that the CBT training group received during the training weekend but in a more condensed format. The information-only group received a telephone interview after 3 months (T4) focusing on their child's current behavior and their own dealing with weight-related problems.”</td></tr>
<tr><td>Treatment duration</td><td>3 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 686
Intervention group/s: CBT training (n=336)

Comparator group: Information-only (n=350)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI-SDS (standard deviation score)
Mean (SD)</td><td>YOUTH-intervention: 2.9 (0.54)</td><td>TAU: 2.93 (0.45)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI-SDS (standard deviation score)
Mean (SD)</td><td>YOUTH-intervention: 2.48 (0.58)</td><td>TAU: 2.43 (0.58)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Warschburger, 2019

Guideline record ID: 10715--1

Study characteristics		
Citation	Warschburger, P., & Zitzmann, J. (2019). Does an age-specific treatment program augment the efficacy of a cognitive-behavioral weight loss program in adolescence and young adulthood? Results from a controlled study. Nutrients, 11(9), 2053. https://doi.org/https://doi.org/10.3390/nu11092053	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Does an Age-Specific Treatment Program Augment the Efficacy of a Cognitive-Behavioral Weight Loss Program in Adolescence and Young Adulthood? Results from a Controlled Study	
Location	Germany	
Trial name	YOUTH	
Methods		
Inclusion criteria	“BMI > 30 with accompanying diseases), aged 16 to 21 years, seeking weight loss treatment.”	
Exclusion criteria	“Participants with inadequate language skills, with severe cognitive impairments, or with secondary causes of obesity were excluded.”	
Setting	rehabilitation clinic specializing in the treatment of children and adolescents.	
Intervention	“The Youth intervention (IG) and treatment as usual (TAU) were comparable in all general treatment services offered for adolescents and young adults in a quality assured multidisciplinary lifestyle intervention (e.g., nutrition counselling, physical activity program, and leisure activities). In general, the rehabilitation stays lasted around 5 to 6 weeks with opportunity to extend it upon reasonable request. Besides nutrition education and scheduled activity sessions, cognitive-behaviourally oriented group interventions were applied. In addition, some of the clinics offered special vocational consultations provided by the job center. The YOUTH-program was conceptualized as an age-specific group intervention program for adolescents and young adults with obesity. Based on both a qualitative and a quantitative survey examining the needs of the target group, the program content and methodological approach were compiled. The program was pilot-tested in a small group and discussed with several experienced practitioners in that field. The manualized program encompassed 9 sessions. It was delivered once or twice a week and carried out in closed groups (3-8 participants each group, 90-min sessions), only open for obese adolescents aged 16 years or older. Before the implementation of the intervention, we conducted a two-day train-the-trainer seminar. While the CBT sessions were conducted by experienced psychologists or educationalists, sessions referring to nutritional contents were supported by experienced nutritionists. Regarding the program content, attention is paid to ensure a direct relevance to everyday life of adolescents and young adults with obesity. Therefore, the YOUTH-intervention covers different topics such as diet, eating behaviors, stress management, problem-solving, interaction with the parents, asking for social support, school and profession, social competence and dealing with potential relapse. With a particular emphasis on the enhancement of self-esteem and self-management skills as important individual resources, we aimed to promote long-term treatment success (i.e., stabilization of the attained weight loss during rehabilitation). Therefore, cognitive-behavioral principles, such as goal-setting, self-monitoring, cue-control and reinforcement strategies were delivered through psychoeducation, group discussion, video-material, role-playing, individualized worksheets and "home-work" assignments. In addition, the YOUTH-program explicitly focuses on building up respective strengthening the motivation for change. After each lesson, participants rated on a 6-point Likert scale (from	

<table>
<tr><td></td><td>1 'not important/useful' to 6 'very important/useful') their satisfaction with the intervention.”</td></tr>
<tr><td>Control/Comparator</td><td>“The Youth intervention (IG) and treatment as usual (TAU) were comparable in all general treatment services offered for adolescents and young adults in a quality assured multidisciplinary lifestyle intervention (e.g., nutrition counselling, physical activity program, and leisure activities). In general, the rehabilitation stays lasted around 5 to 6 weeks with opportunity to extend it upon reasonable request. Besides nutrition education and scheduled activity sessions, cognitive-behaviorally oriented group interventions were applied. In addition, some of the clinics offered special vocational consultations provided by the job center. In contrast to the IG, TAU participants took part in an intervention program that was not specially designed for this age group and was delivered across age groups (i.e., younger children and older adolescents were trained together, and all participants received the same age-unspecific education material). Due to organizational reasons, those age-heterogeneous groups (e.g., with children from the age of 12 and adolescents up to the age of 18 or 21) are a common practice in Germany. The concrete education materials slightly differed from clinic to clinic, but all programs pursued the same objective-the building up of self-management skills. Comparable to the YOUTH-intervention, education of nutrition and eating behaviour was provided, whereas no special focus was laid on adolescent-specific issues, such as autonomy from the parents, how to cope with (future) job applications or self-management via consequent goal pursuit.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 266
Intervention group/s: YOUTH-intervention (n=141)

Comparator group: TAU (n=125)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 17.64y (1.10); Control: 17.33y (1.12)</td></tr>
<tr><td>Sex</td><td>65.41% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI-SDS (standardised BMI) Mean (SD)</td><td>CBT training: 2.59 (0.4)</td><td>Information-only: 2.53 (0.37)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI-SDS (standardised BMI) Mean (SD)</td><td>CBT training: 2.38 (0.5)</td><td>Information-only: 2.3 (0.48)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
</table>

<table>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Washburn, 2021

Guideline record ID: 10716--1

Study characteristics		
Citation	Washburn, R. A., Szabo-Reed, A. N., Gorczyca, A. M., Sullivan, D. K., Honas, J. J., Mayo, M. S., Krebill, R., Goetz, J., Ptomey, L. T., Lee, J., & Donnelly, J. E. (2021). A randomized trial evaluating exercise for the prevention of weight regain. Obesity, 29(1), 62-70. https://doi.org/https://dx.doi.org/10.1002/oby.23022	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A Randomized Trial Evaluating Exercise for the Prevention of Weight Regain	
Location	USA	
Trial name	Midwest Exercise Trial for the Prevention of Weight Regain (METPOWeR)	
Methods		
Inclusion criteria	"Participants were adults (BMI = 25-44.9 kg/m2, age 21-55 years) who were able to exercise and willing to be randomized to one of three exercise groups. Clearance from their primary care physician was required."	
Exclusion criteria	"Exclusion criteria included participating in a research project involving WL or exercise in the previous 6 months; currently participating in a regular exercise program (i.e., >500 kcal/wk) of planned activity assessed by questionnaire (20); not being weight stable (±4.5 kg) for 3 months prior to intake; being pregnant during the previous 6 months, currently lactating, or planned pregnancy in the following 15 months; having a serious medical risk such as type 1 diabetes, cancer, or recent cardiac event (heart attack, angioplasty, etc.); having an eating disorder, current treatment for psychological issues, or taking psychotropic medications; taking medications known to affect weight; adhering to specialized diets; not having access to grocery shopping and meal preparation (military, college students with cafeteria plan, etc.)."	
Setting	Home, University/research centre	
Intervention	"Participants who lost ≥5% of their baseline weight (−3 to 0 months) began a 12-month maintenance intervention that included energy intake to maintain WL and increased exercise and behavioural strategies to facilitate adherence to these recommendations (1). Participants were stratified by sex and magnitude of WL (5%-9.9%, 10%-14.9%, and ≥15%) and were randomized to one of three exercise groups (G150, G225, G300) in a 1:1:1 ratio. Daily meal plans including suggested servings of grains, proteins, fruits, vegetables, dairy, and fats, based on participants energy requirements and in compliance with the United States Department of Agriculture and Health and Human Services Dietary Guidelines for Americans, were provided to all participants. Continued consumption of a minimum of two portion-controlled entrées, three low-calorie shakes, and five servings of fruits and vegetables per day were encouraged, but not required, and portion-controlled entrées and shakes were no longer provided by the trial. Participants were asked to purchase portion-controlled entrées and shakes with acceptable energy and macronutrient content available at local supermarkets from a list provided by the trial. Exercise groups represented a spectrum of exercise volume from that recommended by the US Department of Health and Human Services to improve health in adults (150 min/wk), which, although not specifically recommend for weight maintenance, have been interpreted as such, to 300 min/wk as recommend by professional organizations to promote WL maintenance (5-7). Exercise progressed from 100 min/wk to the prescribed goal (150, 225, or 300 min/wk at 70% of HRmax) at month 2 and remained at the prescribed goal for the duration of the 12-month intervention. The average exercise minutes across the 12-month maintenance intervention was calculated as the average exercise minutes per week (supervised+unsupervised) divided by the number of weeks with exercise data. Requirements for exercise mode, supervision, and HR monitoring were identical to those for exercise during WL, as	

<table>
<tr><td></td><td>previously described. Group behavioural sessions were held weekly during the first 3 months (in person) and twice per month (phone conference call) over the final 9 months of the maintenance intervention. The session format during maintenance was identical to that during WL; however, topics such as meal planning, environmental control, eating on the go, and maintaining motivation for diet and exercise were included. Session attendance was tracked by health educators. Participants self-monitored diet and exercise as previously described; however, over the final 9 months when behavioural sessions were conducted by phone, body weight was self-reported using an online Web form."</td></tr>
<tr><td>Control/Comparator</td><td>"All aspects of the intervention were the same across the three groups apart from exercise. The arm with lowest exercise is the G150 group I which participants were prescribed 150 min/wk exercise."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 235
Intervention group/s: G225 (n=80); G300 (n=79)

Comparator group: G150 (n=76)</td></tr>
<tr><td>Mean age ± SD</td><td>42.3y (8.3)</td></tr>
<tr><td>Sex</td><td>81.70% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in weight
Mean (SD)</td><td>G225: 3.2
(5.7)
G300: 2.8
(6.9)</td><td>G150: 1.1
(6.5)</td></tr><tr><td>Change in weight (%)
Mean (SD)</td><td>G225: 3.4
(6.3)
G300: 3.1
(7.4)</td><td>G150: 1.2
(7.1)</td></tr><tr><td>Change in BMI (kg/m2)
Mean (SD)</td><td>G225: 1.1
(2)
G300: 1
(2.4)</td><td>G150: 0.4
(2.4)</td></tr></table></td></tr>
</table>

	Change in Waist circumference (cm) Mean (SD)	G225: 2 (6.8) G300: 2.3 (5.9)	G150: 0.2 (6.5)
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Approximately 60% of weekly exercise minutes were completed under supervision. Completion of prescribed exercise minutes was poor, with 11, 2, and 1 participant averaging 150, 225, and 300 min/wk across the 12-month intervention. Participants attended ~70% of the 30 scheduled behavioral sessions across 12 months: G150=72.4%, G225=67.9%, and G300=69.2%.		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Watson, 2015

Guideline record ID: 10717--1

Study characteristics		
Citation	Watson, S., Woodside, J. V., Ware, L. J., Hunter, S. J., McGrath, A., Cardwell, C. R., Appleton, K. M., Young, I. S., & McKinley, M. C. (2015). Effect of a web-based behavior change program on weight loss and cardiovascular risk factors in overweight and obese adults at high risk of developing cardiovascular disease: randomized controlled trial. Journal of Medical Internet Research, 17(7), e177. https://doi.org/10.2196/jmir.3828	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of a Web-Based Behavior Change Program on Weight Loss and Cardiovascular Risk Factors in Overweight and Obese Adults at High Risk of Developing Cardiovascular Disease: Randomized Controlled Trial	
Location	Ireland	
Trial name	N/A	
Methods		
Inclusion criteria	"Participants were eligible if they were older than 18 years, had a body mass index (BMI) between 27 and 40 kg/m2, were inactive or moderately inactive assessed by the General Practice Physical Activity Questionnaire (GPPAQ) [11] and had 1 or more CVD risk factors: high blood pressure ≥140/90 mmHg, total cholesterol ≥5.0 mmol/L, or type 2 diabetes mellitus. All participants were required to have access to the Internet, email, and a telephone and were asked not to participate in another behavioral change weight loss program throughout the study period."	
Exclusion criteria	"Participants were excluded if they had established CVD, type 1 diabetes mellitus, were pregnant, or consumed excessive amounts of alcohol."	
Setting	Home	
Intervention	"Imperative Health is a service owned by AXA PPP Healthcare Limited that consists of a Web-based program and human (email and telephone) support that assists in lifestyle change, with a particular focus on improving diet and nutrition, increasing physical activity, and managing weight and other CVD risk factors. It combines objective monitoring of weight and physical activity with automated, tailored feedback and support by physiologists by telephone and email. For this particular study, only the Web-based program component of the service was evaluated to determine its specific impact (i.e., the human support [telephone and email] component of the service was removed for the purposes of this trial). Initial Setup of Imperative Health (Web-Based Program) At the end of the baseline appointment, the intervention group participants were provided with the Imperative Health package that contained the self-monitoring devices (Bluetooth-enabled weighing scales and an accelerometer activity band) and basic written instructions to set up an online account at home. The Web-based program encourages daily engagement by allowing the upload of daily weight and physical activity data and by the entry of daily food diaries (described in detail subsequently). The Imperative Health system generated personalized daily targets (weight loss, physical activity, and dietary targets) for each participant to achieve over 12 weeks. Automated weekly feedback on their performance, assessed by the self-monitoring devices (weighing scales and accelerometer) and the food diary was provided. After 12 weeks, to encourage further progress, it was requested that the participants start a new program by completing introductory health questionnaires again and setting new goals. The Web-based program encompassed supportive components to help facilitate lifestyle change. These components of the Web-based program were developed based on well-recognized behaviour change strategies, such as planning, self-monitoring, goal setting, and structured feedback, which were all used within the Diabetes Prevention Program to promote weight loss."	

<table>
<tr><td>Control/Comparator</td><td>“Control group were requested to continue with their usual self and medical care.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 65
Intervention group/s: Intervention (n=32)

Comparator group: Control (n=33)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 51.4y (7.59); Control:52.9y (7.27)</td></tr>
<tr><td>Sex</td><td>55.38% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Intervention: 95.2
(16.7)

Intervention: 32.9
(3.07)

Intervention: 103.5
(11.2)</td><td>Control: 91.9
(13.4)

Control: 32.4
(2.74)

Control: 102.5
(9.47)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight change (kg)
Mean (95% CIs)

Percentage weight loss (%)
Mean (95% CIs)

BMI change (kg/m2)
Mean (95% CIs)

Waist circumference change (cm)
Mean (95% CIs)</td><td>Intervention: -2.38
(-3.48--0.97)

Intervention: -2.42
(-3.93--0.91)

Intervention: -0.78
(-1.26--0.31)

Intervention: -2.31
(-3.84--0.79)</td><td>Control: -1.8
(-3.15--0.44)

Control: -1.94
(-3.26--0.39)

Control: -0.65
(-1.12-0.19)

Control: -1.8
(-3.02--0.58)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Weghuber, 2022

Guideline record ID: 11062--1

Study characteristics		
Citation	Weghuber D, Barrett T, Barrientos-Pérez M, Gies I, Hesse D, Jeppesen OK, Kelly AS, Mastrandrea LD, Sørrig R, Arslanian S; STEP TEENS Investigators. Once-Weekly Semaglutide in Adolescents with Obesity. N Engl J Med. 2022 Dec 15;387(24):2245-2257. doi: 10.1056/NEJMoa2208601. Epub 2022 Nov 2. PMID: 36322838; PMCID: PMC9997064.	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Once-Weekly Semaglutide in Adolescents with Obesity	
Location	USA; Austria; Belgium; Croatia; Ireland; Mexico; Russia; UK	
Trial name	STEP TEENS	
Methods		
Inclusion criteria	"Informed consent of parent(s) or legally acceptable representative of subject and child assent, as appropriate obtained before any trial-related activities. Trial-related activities are any procedures that are carried out as part of the trial, including activities to determine suitability for the trial, Male or female, ages 12 to below 18 years at the time of signing informed consent, BMI equal to or above 95th percentile OR equal to or above 85th percentile (on gender and age-specific growth charts (CDC.gov)) with 1 or more weight related comorbidity (treated or untreated): hypertension, dyslipidaemia, obstructive sleep apnoea or type 2 diabetes, History of at least one self-reported unsuccessful dietary effort to lose weight For subjects with type 2 diabetes at screening the following inclusion criteria apply in addition: - HbA1c equal to or below 10.0% (86 mmol/mol) as measured by central laboratory at screening."	
Exclusion criteria	"Prepubertal subjects (Tanner stage 1), History of type 1 diabetes, A self-reported (or by parent(s)/legally acceptable representative where applicable) change in body weight above 5 kg (11 lbs) within 90 days before screening irrespective of medical records, Subjects with secondary causes of obesity (i.e., hypothalamic, monogenic or endocrine causes), For subjects with type 2 diabetes only: Uncontrolled and potentially unstable diabetic retinopathy or maculopathy. Verified by a fundus examination performed within the past 90 days prior to screening. Pharmacological pupil-dilation is a requirement unless using a digital fundus photography camera specified for non-dilated examination."	
Setting	GP clinic, University/research centre	
Intervention	"Participants will receive semaglutide s.c. once weekly for a dose escalation period of 16 weeks and a maintenance period of 52 weeks. 2.4 mg or maximum tolerated dose (MTD) injected subcutaneously (under the skin, s.c.) once weekly."	
Control/Comparator	"Participants will receive semaglutide placebo s.c. once weekly for a total of 68 weeks."	
Treatment duration	68 weeks	
Follow-up from baseline	68 weeks	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 201 Intervention group/s: Semaglutide (n=134) Comparator group: Placebo (n=67)	

<table>
<tr><td>Mean age ± SD</td><td>15.4y (1.6)</td></tr>
<tr><td>Sex</td><td>62.19% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Baseline Body weight - kg
Mean (SD)</td><td>Semaglutide: 109.9
(25.2)</td><td>Placebo: 102.6
(22.3)</td></tr>
<tr><td>Baseline BMI
Mean (SD)</td><td>Semaglutide: 37.7
(6.7)</td><td>Placebo: 35.7
(5.4)</td></tr>
<tr><td>Baseline Waist circumference - cm
Mean (SD)</td><td>Semaglutide: 111.9
(16.9)</td><td>Placebo: 107.3
(13.4)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>BMI reduction of ≥5% - no. of participants/total no.(%)
Proportion (%)</td><td>Semaglutide: 76.0%</td><td>Placebo: 23%</td></tr>
<tr><td>≥10% reduction in body weight - no. of participants/total no. (%)
Proportion (%)</td><td>Semaglutide: 62.0%</td><td>Placebo: 8%</td></tr>
<tr><td>≥15% reduction in body weight - no. of participants/total no. (%)
Proportion (%)</td><td>Semaglutide: 53.0%</td><td>Placebo: 5%</td></tr>
<tr><td>≥20% reduction in body weight - no. of participants/total no. (%)
Proportion (%)</td><td>Semaglutide: 37.0%</td><td>Placebo: 3%</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to
12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Change in BMI - %
Mean (SD)</td><td>Semaglutide: -16.1
(-1.1)</td><td>Placebo: 0.1
(-0.1)</td></tr>
<tr><td>Change in body weight: Absolute change - kg
Mean (SD)</td><td>Semaglutide: -15.3</td><td>Placebo: 2.4</td></tr>
<tr><td>Change in body weight: Relative change - %
Mean (SD)</td><td>Semaglutide: -14.7</td><td>Placebo: 2.7</td></tr>
<tr><td>Change in waist circumference - cm
Mean (SD)</td><td>Semaglutide: -12.7</td><td>Placebo: -0.6</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
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</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Werkman, 2010

Guideline record ID: 10929

Study characteristics		
Citation	Werkman, A., Hulshof, P. J. M., Stafleu, A., Kremers, S. P. J., Kok, F. J., Schouten, E. G., & Schuit, A. J. (2010). Effect of an individually tailored one-year energy balance programme on body weight, body composition and lifestyle in recent retirees: a cluster randomised controlled trial. BMC Public Health, 10, 110. https://doi.org/https://dx.doi.org/10.1186/1471-2458-10-110	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of an individually tailored one-year energy balance programme on body weight, body composition and lifestyle in recent retirees: a cluster randomised controlled trial	
Location	Netherlands	
Trial name	Wageningen Approach against fat Accumulation and weight Gain (WAAG)	
Methods		
Inclusion criteria	"Recent retirees (date of retirement maximum six months before or after baseline measurement), aged 55-65 years, and not undergoing any medical treatment that might affect body composition."	
Exclusion criteria	Not reported	
Setting	Home, Online, computer based	
Intervention	"Five programme modules were provided to participants of the intervention group during the one year intervention period as shown in Figure 2. Participants could freely choose to make use of the modules or not. Modules 1 and 2 aimed to increase awareness of the energy balance concept and module 3 aimed to improve dietary and/or physical activity behaviour. Module 1 (sent within two weeks after the baseline measurement) was provided as a toolbox and included an information leaflet and several energy balance tools, e.g. a pedometer and a waist tape. Module 2 (sent 3 months after baseline) was a CD-ROM providing individually computertailored feedback on BMI, its health consequences and energy balance behaviour. In module 3 participants could receive computer-tailored feedback regarding: physical activity, fibre consumption, portion sizes of energy dense foods and fat consumption. This module was sent 6 months after baseline. Participants without access to a computer (n = 22) were interviewed (AW) and received printed feedback by mail. Modules 4 and 5 were accessible via the study website which was available during the two-year study period. After login, participants could find more information about diet and physical activity behaviour, participate in a forum and use links to other websites (module 4). Module 5 was an interactive weight maintenance programme (Weight Co@ch [16]) that provided a written tailored advice based on reported body weight, a food frequency questionnaire and a physical activity questionnaire [16]. Finally, the intervention group received newsletters every 2-3 months that contained study information, information about diet and physical activity and encouragements to use the modules."	
Control/Comparator	"During the total study period of two years, the control group was provided with newsletters with general information about the study, such as study progress, and information about art exhibitions and city trips for instance. They could not login to the website and had access to the general information about the study design only."	
Treatment duration	12 months	
Follow-up from baseline	24 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 352
Intervention group/s: Intervention (n=174)

Comparator group: Control (n=178)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 59.5y (2.5); Control: 59.4y (2.3)</td></tr>
<tr><td>Sex</td><td>100.00% male</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Waist circumference, cm
Mean (SD)

Body weight, kg
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Intervention: 99.2
(9.5)

Intervention: 85.1
(11.9)

Intervention: 26.7
(3.6)</td><td>Control: 100.4
(9.2)

Control: 86.1
(11.4)

Control: 27.3
(3.1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Waist circumference, cm
Mean (SD)

Change in body weight, kg
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)</td><td>Intervention: -2.32
(3.24)

Intervention: -1.86
(3.08)

Intervention: -0.49
(1.01)</td><td>Control: -1.9
(3.06)

Control: -1.62
(3.03)

Control: -0.43
(0.98)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in Waist circumference, cm
Mean (SD)

Change in body weight, kg
Mean (SD)

Change in BMI (kg/m2)
Mean (SD)</td><td>Intervention: -1.06
(3.48)

Intervention: -1.47
(3.66)

Intervention: -0.37
(1.12)</td><td>Control: -1.08
(3.6)

Control: -1.58
(3.96)

Control: -0.4
(1.29)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>The toolbox (module 1) was used by 82% of the group, the first CD-ROM (module 2) by 72% and the second CD-ROM (module 3) by 41% of the group. The exposure to the website (module 4) and its interactive component (Weight Co@ch (module 5)) was lower, 54% and 16% respectively.</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

West, 2011

Guideline record ID: 10722--1

Study characteristics		
Citation	West, D. S., Gorin, A. A., Subak, L. L., Foster, G., Bragg, C., Hecht, J., Schembri, M., Wing, R. R., & for the Program to Reduce Incontinence by Diet and Exercise (PRIDE) Research Group. (2011). A motivation-focused weight loss maintenance program is an effective alternative to a skill-based approach. International Journal of Obesity, 35(2), 259-269. https://doi.org/https://dx.doi.org/10.1038/ijo.2010.138	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A motivation-focused weight loss maintenance program is an effective alternative to a skill-based approach	
Location	USA	
Trial name	Program to Reduce Incontinence through Diet and Exercise (PRIDE)	
Methods		
Inclusion criteria	"Women were eligible to participate if they were at least 30 years of age, had a body mass index between 25 and 50 kgm2, reported 10 or more episodes of urinary incontinence on a 7-day voiding diary, and were able to walk for exercise."	
Exclusion criteria	"Exclusion criteria included medical conditions that contraindicated weight loss, pregnancy or parturition in the previous 6 months or history of current or persistent urinary tract infection or other medical conditions of the genitourinary tract."	
Setting	Home, Clinic	
Intervention	"Participants in the weight loss arm were further randomized to receive either the novel motivation-focused weight maintenance program, or a skill-based maintenance program. The same 6-month weight loss program was offered to all individuals randomized to behavioural weight control regardless of maintenance condition. The 24-session program was modelled after the Diabetes Prevention Program16 and the Look AHEAD lifestyle interventions. Weekly group sessions included an individual weigh in and followed a structured protocol. Participants were encouraged to lose 10% of their baseline body weight. A reduced calorie balanced diet was prescribed and meal replacement product coupons (Slimfast, Slim-Fast Foods Company, Englewood, NJ, USA) were provided to replace two meals and one snack per day. Graded exercise goals that progressed to 200min/week or more of moderate physical activity were provided and participants were given pedometers to promote increased daily steps. To encourage adoption of the dietary and physical activity recommendations, training in specific behavioural skills was provided, including self-monitoring, stimulus control, problem-solving, assertiveness training, social support, goal setting, cognitive restructuring and relapse prevention. Common elements of skill-based and motivation-focused maintenance programs: After the initial weight loss program, all lifestyle participants received a 12-month weight maintenance intervention with bi-weekly group meetings. Group meetings were 60 min in length and were conducted by dietitians, exercise physiologists, nurses and psychologists following a structured protocol. The overall aim for both programs was to maintain at least a 10% weight loss. Exercise goals remained at 200 min/week for both conditions and reduced calorie goals were recommended until 10% weight loss goal was achieved, and then dietary intake goals focused on weight stability. Meal replacement coupons (one meal and one snack) continued to be provided to both groups. Skill-based maintenance program: The standard behavioural weight maintenance program reflected current lifestyle program recommendations and focused on reviewing and refining behavioural skills in problem solving, goal setting, social support and relapse prevention. New skill development topics introduced included reversing small weight gains, improving body image and self-esteem, and expanding exercise options. Motivation-focused maintenance program: This novel	

<table>
<tr><td></td><td>maintenance intervention focused on increasing and sustaining motivation to use the dietary, physical activity and behavioural skills introduced in the initial weight loss phase rather than on improving and fine-tuning those skills. The behavioural goals remained the same as in the standard skill-based maintenance and the intervention sought to promote these goals using strategies derived from motivational theories and methods by: (1) strengthening satisfaction with progress; (2) cultivating an identity as a successful weight loser; (3) eliciting personal motivations for engaging in long-term behaviour change efforts and supporting autonomous self-regulation; and (4) developing an enriched array of non-food related reinforcements and self-care activities to increase motivation to engage in non-food related activities."</td></tr>
<tr><td>Control/Comparator</td><td>"Education control group: Women randomized to the control group were offered seven education sessions that provided general information about physical activity, healthy eating habits and weight loss, following a structured protocol. Behavioural weight control: weight loss induction."</td></tr>
<tr><td>Treatment duration</td><td>18 months</td></tr>
<tr><td>Follow-up from baseline</td><td>18 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 338
Intervention group/s: Motivation-focused (n=113); Skill-based (n=113)

Comparator group: Control (n=112)</td></tr>
<tr><td>Mean age ± SD</td><td>53y (10)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Weight loss (kg)
Mean (95% CIs)

Percent weight change (%)</td><td>Motivation-focused: 2.55
(1.02-4.08)
Skill-based: 2.66
(1.41-3.9)

Motivation-focused: 2.83</td><td>Control: -0.31
(-1.68-1.06)

Control: -1.51</td></tr></table></td></tr>
</table>

	Mean (95% CIs)	(1.09-4.57) Skill-based: 2.75 (1.41-4.09)	(-3.3-0.28)
Compliance with treatment	Individuals receiving motivation-focused maintenance attending an average of 17 sessions during the initial 6-month program (71%) and those in the standard skill based maintenance attending 18 (75%).		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

West, 2016

Guideline record ID: 10723--1

Study characteristics		
Citation	West, D. S., Harvey, J. R., Krukowski, R. A., Prewitt, T. E., Priest, J., & Ashikaga, T. (2016). Do individual, online motivational interviewing chat sessions enhance weight loss in a group-based, online weight control program? Obesity, 24(11), 2334-2340. https://doi.org/10.1002/oby.21645	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Do individual, online motivational interviewing chat sessions enhance weight loss in a group-based, online weight control program?	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"To be eligible, individuals had to be in generally good health, be at least 18 years old, and have a body mass index (BMI; kg/m2) between 25 and 50 kg/m2."	
Exclusion criteria	"Individuals were ineligible if they took medications that might affect weight loss, reported substantial recent weight loss, had a history of bariatric surgery, were enrolled in another weight reduction program, or had a condition for which weight loss was contraindicated."	
Setting	Home	
Intervention	"Internet behavioral weight control treatment (BT) plus motivational interviewing (MI):Group behavioral weight control intervention The 18-month manual intervention focused on changing dietary and physical activity patterns using self-management skills and other behavioral strategies. One-hour online, synchronous chat sessions of 12 to 19 participants were moderated by experienced behavioral weight control counselors. Chats were offered weekly during the first 6 months and monthly for 12 additional months and combined participants from both clinical sites. Participants had access to a secure, password-protected, dynamic website with behavioral lessons posted to accompany each chat session, a bulletin board for group communications, educational resources, regularly updated weight loss tips and healthy recipes, and notices of local physical activity events (16). A self-monitoring tool with a personalized dietary monitoring feature and a weight graphing feature and a compendium of physical activities with associated caloric expenditure information were also available on the website. Participants were instructed to record dietary intake, minutes of physical activity, and weight daily in the online journal. Group counselors provided a weekly email with tailored feedback to participants based on this online journaling. A calorie-restricted diet and dietary fat goal corresponding to 25% of calories from fat were prescribed, and graded exercise goals that progressed to 200 min/week of moderate to vigorous exercise were provided. Pedometers were given to assist in selfmonitoring steps and a goal of 10,000 steps/day was provided. Behavioral strategies to assist in making habit changes included selfmonitoring, goal setting, problem solving, and relapse prevention. Weekly homework corresponding to the lesson topic and facilitating enactment of the featured behavioral strategy was assigned. The same group-based, goal-directed intervention was provided to both conditions. Online MI intervention The online MI intervention has been described in detail previously (14). Briefly, six individual MI sessions using an interactive, synchronous form of private chat integrated within the same website as the group weight loss program were offered to participants randomized to the BT 1 MI condition. The text-based chat was selected because many participants lived in rural areas without consistent access to the technology required to support alternatives like video chat. Chats were designed to last approximately 30 min, followed a protocol which allowed flexibility in session flow, and provided content tailored to the participant's treatment engagement and weight change experience, while	

	standardizing the session across individuals. The first MI session was conducted before the group program started. The second MI session was after session 5 of the weekly group program, when early indications that individuals may be struggling with behavior change efforts or weight loss can emerge (17,18). The next five MI chats were offered at 3-month intervals. There are no empirical data examining different patterns of MI delivery in obesity treatment to guide the number or timing of MI sessions; therefore, we mirrored the approach taken in successful in-person programs (8). MI counselors were clinical psychologists who had delivered MI for weight management in previous studies and/or in clinical practice. All MI counselors received training and ongoing supervision in MI from the first author, a MI network trainer and a clinical psychologist who has conducted MI in conjunction with behavioral weight control for two decades (19). MI chat transcripts were reviewed and constructive feedback provided to refine therapist skills. Group telephonic coaching was provided weekly with a focus on maintaining an MI spirit (6), adhering to the protocol, and role-playing around difficulties encountered during MI chats. MI sessions were synchronous, conducted in a private chat room on the study website, and focused on the four processes of MI (6), with initial emphasis on engaging the participant and establishing rapport. Due to the nature of the study enrollment screening process, the desired outcome of weight loss had been established prior to the MI chats; therefore, initial chats emphasized personalized reasons underlying this desire and related behavior changes. Eliciting and elaborating change talk and collaboratively identifying behavior change strategies which the individual recognized as helpful were key elements of early MI sessions. Reflective statements and summaries were used to clarify, reinforce, and promote further elaboration. Each chat concluded with a collaboratively identified goal, if appropriate. The goals could be a behavior change strategy previously recommended within the group-based program, such as engaging in self-monitoring using the online journal, or something else the participant identified as likely to be effective for him/her. Participants were asked to rate their confidence in their ability to accomplish the goal and how important they believed the self-selected short-term goal to be in relation to their overall weight loss goals. Counselors reflected both importance and confidence when a participant's confidence was high and focused on reflecting importance of the goal when confidence was low (6). A semi-structured interview guided each MI chat.”
Control/Comparator	“Group behavioral weight control intervention The 18-month manual intervention focused on changing dietary and physical activity patterns using self-management skills and other behavioral strategies. One-hour online, synchronous chat sessions of 12 to 19 participants were moderated by experienced behavioral weight control counselors. Chats were offered weekly during the first 6 months and monthly for 12 additional months and combined participants from both clinical sites. Participants had access to a secure, password-protected, dynamic website with behavioral lessons posted to accompany each chat session, a bulletin board for group communications, educational resources, regularly updated weight loss tips and healthy recipes, and notices of local physical activity events (16). A self-monitoring tool with a personalized dietary monitoring feature and a weight graphing feature and a compendium of physical activities with associated caloric expenditure information were also available on the website. Participants were instructed to record dietary intake, minutes of physical activity, and weight daily in the online journal. Group counselors provided a weekly email with tailored feedback to participants based on this online journaling. A calorie-restricted diet and dietary fat goal corresponding to 25% of calories from fat were prescribed, and graded exercise goals that progressed to 200 min/week of moderate to vigorous exercise were provided. Pedometers were given to assist in selfmonitoring steps and a goal of 10,000 steps/day was provided. Behavioral strategies to assist in making habit changes included selfmonitoring, goal setting, problem solving, and relapse prevention. Weekly homework corresponding to the lesson topic and facilitating enactment of the featured behavioral strategy was assigned. The same group-based, goal-directed intervention was provided to both conditions.”
Treatment duration	18 months
Follow-up from baseline	18 months

<table>
<tr><td>Eligible outcome(s) reported</td><td>Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 398
Intervention group/s: BT+MI (n=199)

Comparator group: BT (n=199)</td></tr>
<tr><td>Mean age ± SD</td><td>48.4y (10.1)</td></tr>
<tr><td>Sex</td><td>89.70% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>BT+MI: 98.4
(19)

BT+MI: 35.9
(6)</td><td>BT: 98.2
(18.4)

BT: 36.1
(6.1)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Proportion (%) of participants meeting weight loss goal of >5%
Proportion (%)

Proportion (%) of participants meeting weight loss goal of >10%
Proportion (%)</td><td>BT+MI: 33.2

BT+MI: 19.6</td><td>BT: 29.7

BT: 17.1</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss (kg)
Mean (SD)</td><td>BT+MI: -3.5
(7.7)</td><td>BT: -3.3
(7.1)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>28.6%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Wharton, 2021

Guideline record ID: 11065A--DPP-4i subgroup

Study characteristics		
Citation	Wharton, S., Yin, P., Burrows, M., Gould, E., Blavignac, J., Christensen, R. A. G., Kamran, E., Camacho, F., & Barakat, M. (2021). Extended-release naltrexone/bupropion is safe and effective among subjects with type 2 diabetes already taking incretin agents: a post-hoc analysis of the LIGHT trial. International Journal of Obesity, 45(8), 1687-1695. https://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med20&AN=34083744https://library.deakin.edu.au/resserv?sid=OVID:medline&id=pmid:34083744&id=doi:10.1038%2Fs41366-021-00831-4&issn=0307-0565&isbn=&volume=45&issue=8&spage=1687&pages=1687	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Extended-release naltrexone/bupropion is safe and effective among subjects with type 2 diabetes already taking incretin agents: a post-hoc analysis of the LIGHT trial	
Location	Canada; USA	
Trial name	LIGHT Trial	
Methods		
Inclusion criteria	"Individuals ≥50 years of age (women) or ≥45 years of age (men), Body mass index (BMI) ≥27 kg/m2 and ≤50 kg/m2, Waist circumference ≥88 cm (women) or ≥102 cm (men), At increased risk of adverse cardiovascular outcomes: Cardiovascular disease (confirmed diagnosis or at high likelihood of cardiovascular disease) with at least one of the following: History of documented myocardial infarction >3 months prior to screening History of coronary revascularization History of carotid or peripheral revascularization Angina with ischemic changes (resting ECG), ECG changes on a graded exercise test (GXT), or positive cardiac imaging study Ankle brachial index <0.9 (by simple palpation) within prior 2 years ≥50% stenosis of a coronary, carotid, or lower extremity artery within prior 2 years, ND/OR Type 2 diabetes mellitus with at least 2 of the following: Hypertension (controlled with or without pharmacotherapy at <145/95 mm Hg) Dyslipidemia requiring pharmacotherapy Documented low HDL cholesterol (<50 mg/dL in women or <40 mg/dL in men) within prior 12 months, Current tobacco smoker."	
Exclusion criteria	"Myocardial infarction within 3 months prior to screening Angina pectoris Grade III or IV as per the Canadian Cardiovascular Society grading scheme Clinical history of cerebrovascular disease (stroke) History of tachyarrhythmia other than sinus tachycardia Planned bariatric surgery, cardiac surgery, or coronary angioplasty History of seizures (including febrile seizures), cranial trauma, or other conditions that predispose the subject to seizures History of mania or current diagnosis of active psychosis, active bulimia or anorexia nervosa (binge eating disorder is not exclusionary) Any condition with life expectancy anticipated to be less than 4 years (e.g., congestive heart failure NYHA Class 3 or 4)."	
Setting	Hospital	
Intervention	"Drug: NB32 Naltrexone SR 32 mg/Bupropion SR 360 mg/day. Administered in addition to the weight management program. Other Names: CONTRAVE Behavioral: Weight Management Program A comprehensive weight management program will be administered in addition to the subject's study medication assignment. The program includes internet counseling by an accredited health and fitness professional and a nutrition and exercise program with goal setting and educational and tracking tools. Other Names: WeightMate (Tm)"	
Control/Comparator	"Drug: PBO Placebo. Administered in addition to the weight management program. Behavioral: Weight Management Program A comprehensive weight management program will be administered in addition to the subject's study medication assignment. The program includes internet counseling by an accredited health and fitness professional and a nutrition	

	and exercise program with goal setting and educational and tracking tools. Other Names: WeightMate (Tm)."		
Treatment duration	12 months		
Follow-up from baseline	12 months		
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)		
Participant characteristics			
Number of participants	n= 1317 Intervention group/s: Extended-release naltrexone/bupropion (NB) (n=684) Comparator group: Placebo (n=633)		
Mean age ± SD	60.7 (7.0) years		
Sex	55.13% female		
Pre-existing medical condition	Type 2 diabetes		
Results			
Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	Baseline BMI - DPP-4i subgroup Mean (SD) Weight, kg - DPP-4i subgroup Mean (SD) Waist circumference, cm - DPP-4i subgroup Mean (SD)	Extended-release naltrexone/bupropion (NB): 36.9 (5.2) Extended-release naltrexone/bupropion (NB): 105.1 (19.2) Extended-release naltrexone/bupropion (NB): 119.2 (13.2)	Placebo: 37.3 (5.1) Placebo: 106.2 (18.5) Placebo: 119.5 (12.3)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Proportions achieving 5% weight loss - DPP-4i subgroup Proportion (%) Proportions of achieving 10% reduction - DPP-4i subgroup Proportion (%)	Extended-release naltrexone/bupropion (NB): 64.2% Extended-release naltrexone/bupropion (NB): 20.2%	Placebo: 25.0% Placebo: 5.4%
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Absolute Weight Change (kg) from Baseline - DPP-4i subgroup Mean (95% CIs)	Extended-release naltrexone/bupropion (NB): -5.89 (-6.76)	Placebo: -0.88 (-1.94-0.18)
Change in outcome measure from baseline	Variable	Intervention arm/s	Comparator

to final follow-up/endpoint			
Compliance with treatment	not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Wharton, 2021

Guideline record ID: 11065B--GLP-1RA subgroup

Study characteristics		
Citation	Wharton, S., Yin, P., Burrows, M., Gould, E., Blavignac, J., Christensen, R. A. G., Kamran, E., Camacho, F., & Barakat, M. (2021). Extended-release naltrexone/bupropion is safe and effective among subjects with type 2 diabetes already taking incretin agents: a post-hoc analysis of the LIGHT trial. International Journal of Obesity, 45(8), 1687-1695. https://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med20&AN=34083744https://library.deakin.edu.au/resserv?sid=OVID:medline&id=pmid:34083744&id=doi:10.1038%2Fs41366-021-00831-4&issn=0307-0565&isbn=&volume=45&issue=8&spage=1687&pages=1687	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Extended-release naltrexone/bupropion is safe and effective among subjects with type 2 diabetes already taking incretin agents: a post-hoc analysis of the LIGHT trial	
Location	Canada; USA	
Trial name	LIGHT Trial	
Methods		
Inclusion criteria	"Individuals ≥50 years of age (women) or ≥45 years of age (men), Body mass index (BMI) ≥27 kg/m2 and ≤50 kg/m2, Waist circumference ≥88 cm (women) or ≥102 cm (men), At increased risk of adverse cardiovascular outcomes: Cardiovascular disease (confirmed diagnosis or at high likelihood of cardiovascular disease) with at least one of the following: History of documented myocardial infarction >3 months prior to screening History of coronary revascularization History of carotid or peripheral revascularization Angina with ischemic changes (resting ECG), ECG changes on a graded exercise test (GXT), or positive cardiac imaging study Ankle brachial index <0.9 (by simple palpation) within prior 2 years ≥50% stenosis of a coronary, carotid, or lower extremity artery within prior 2 years, ND/OR Type 2 diabetes mellitus with at least 2 of the following: Hypertension (controlled with or without pharmacotherapy at <145/95 mm Hg) Dyslipidemia requiring pharmacotherapy Documented low HDL cholesterol (<50 mg/dL in women or <40 mg/dL in men) within prior 12 months, Current tobacco smoker."	
Exclusion criteria	"Myocardial infarction within 3 months prior to screening Angina pectoris Grade III or IV as per the Canadian Cardiovascular Society grading scheme Clinical history of cerebrovascular disease (stroke) History of tachyarrhythmia other than sinus tachycardia Planned bariatric surgery, cardiac surgery, or coronary angioplasty History of seizures (including febrile seizures), cranial trauma, or other conditions that predispose the subject to seizures History of mania or current diagnosis of active psychosis, active bulimia or anorexia nervosa (binge eating disorder is not exclusionary) Any condition with life expectancy anticipated to be less than 4 years (e.g., congestive heart failure NYHA Class 3 or 4)."	
Setting	Hospital	
Intervention	"Drug: NB32 Naltrexone SR 32 mg/Bupropion SR 360 mg/day. Administered in addition to the weight management program. Other Names: CONTRAVE Behavioral: Weight Management Program A comprehensive weight management program will be administered in addition to the subject's study medication assignment. The program includes internet counseling by an accredited health and fitness professional and a nutrition and exercise program with goal setting and educational and tracking tools. Other Names: WeightMate (Tm)"	
Control/Comparator	"Drug: PBO Placebo. Administered in addition to the weight management program. Behavioral: Weight Management Program A comprehensive weight management program will be administered in addition to the subject's study medication assignment. The program	

	includes internet counseling by an accredited health and fitness professional and a nutrition and exercise program with goal setting and educational and tracking tools. Other Names: WeightMate (Tm).”		
Treatment duration	12 months		
Follow-up from baseline	12 months		
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)		
Participant characteristics			
Number of participants	n= 1317 Intervention group/s: Extended-release naltrexone/bupropion (NB) (n=684) Comparator group: Placebo (n=633)		
Mean age ± SD	60.7 (7.0) years		
Sex	55.13% female		
Pre-existing medical condition	Type 2 diabetes		
Results			
Outcome measure at baseline	Variable	Intervention arm/s	Comparator
	Baseline BMI - GLP-1RA subgroup Mean (SD) Weight, kg - GLP-1RA subgroup Mean (SD) Waist circumference, cm - GLP-1RA subgroup Mean (SD)	Extended-release naltrexone/bupropion (NB): 37.9 (5.5) Extended-release naltrexone/bupropion (NB): 107.7 (19.4) Extended-release naltrexone/bupropion (NB): 121 (13.3)	Placebo: 38 (5.6) Placebo: 106.2 (18.5) Placebo: 121.4 (13.5)
Outcome measure at 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Proportions achieving 5% weight loss - GLP-1RA subgroup Proportion (%) Proportions of achieving 10% reduction - GLP-1RA subgroup Proportion (%)	Extended-release naltrexone/bupropion (NB): 53.3% Extended-release naltrexone/bupropion (NB): 16.7%	Placebo: 23.4% Placebo: 6.9%
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	Absolute Weight Change (kg) from Baseline - GLP-1RA subgroup Mean (95% CIs)	Extended-release naltrexone/bupropion (NB): -5.38 (-6.26--4.51)	Placebo: 0.65 (-0.47-1.76)
Change in outcome measure from baseline	Variable	Intervention arm/s	Comparator

to final follow-up/endpoint	
Compliance with treatment	not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Wild, 2015

Guideline record ID: 10727--1

Study characteristics		
Citation	Wild, B., Hünnemeyer, K., Sauer, H., Hain, B., Mack, I., Schellberg, D., Müller-Stich, B. P., Weiner, R., Meile, T., Rudofsky, G., Königsrainer, A., Zipfel, S., Herzog, W., & Teufel, M. (2015). A 1-year videoconferencing-based psychoeducational group intervention following bariatric surgery: results of a randomized controlled study. Surgery for Obesity and Related Diseases, 11(6), 1349-1360. https://doi.org/https://dx.doi.org/10.1016/j.soard.2015.05.018	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	A 1-year videoconferencing-based psychoeducational group intervention following bariatric surgery: results of a randomized controlled study	
Location	Germany	
Trial name	Bariatric Surgery and Education (BaSE)	
Methods		
Inclusion criteria	"Inclusion criteria were adult patients aged >18 years; severe obesity (BMI >40 kg/m2 or BMI >35 kg/m2 with somatic co-morbidities); indication for gastric sleeve or gastric bypass surgery; and informed consent."	
Exclusion criteria	"Exclusion criteria were severe mental health problems (i.e., suffering from a psychotic disorder or suicidal ideation), language or cognitive disability, no Internet access, and age 465 years."	
Setting	Hospital, Home	
Intervention	"Participants in the experimental condition received a videoconferencing-based psychoeducational group intervention. The manual for the intervention was developed by a team of specialists in psychosomatics, bariatric surgery, sports medicine, and nutrition, based on the current state of evidence. A 1-year group program that included face-to-face and videoconferencing sessions was designed as published elsewhere [25,26]. The program began with 5 face-to-face group interventions (up to 6 patients, 90 min) followed by 6 videoconferencing sessions in smaller groups (3 patients, 50 min) and was followed up by 3 face-to-face group sessions.The overall aim of the psychoeducational intervention was to enable the patients to implement long-term lifestyle changes. Besides patient education in nutrition and exercise, the program aimed at training strategies and skills to improve adjustment, stress management, self-monitoring, self-efficacy and self-esteem, and social competence. We assumed that the positive changes induced by the program should be associated with improvement in regard to weight loss, quality of life, self-efficacy, and reduction in depressive symptoms as well as the patient's eating disorder pathology"	
Control/Comparator	"Participants in the control condition received conventional surgical visits as implemented in the ongoing clinical routine. These visits comprised weight monitoring, clinical examination, detailed symptom history taking (including nutrition and eating behavior), and screening for malnourishment. The routine visits were carried out by a surgeon and scheduled at 1, 3, 6, and 12 months after surgery."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 117
Intervention group/s: Experimental condition (n=59)

Comparator group: Conventional condition (n=58)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline Weight (kg)
Mean (SD)

Baseline BMI (kg/m2)
Mean (SD)</td><td>Experimental condition: 150.7 (24.2)

Experimental condition: 50.1 (6.6)</td><td>Conventional condition: 144.2 (22.7)

Conventional condition: 49.4 (6.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Follow-up weight (kg)
Mean (SE)

Follow-up BMI (kg/m2)
Mean (SE)</td><td>Experimental condition: 99.1 (2.8)

Experimental condition: 33.5 (0.9)</td><td>Conventional condition: 99.8 (2.5)

Conventional condition: 33.7 (0.8)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>%Excess weight loss
Mean (SE)

%Total weight loss
Mean (SE)</td><td>Experimental condition: -67.1 (3.6)

Experimental condition: -32.9 (1.8)</td><td>Conventional condition: -65.9 (3.3)

Conventional condition: -32.5 (1.6)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Wild, B., Hünnemeyer, K., Sauer, H., Schellberg, D., Müller-Stich, B. P., Königsrainer, A., Weiner, R., Zipfel, S., Herzog, W., & Teufel, M. (2017). Sustained effects of a psychoeducational group intervention following bariatric surgery: follow-up of the randomized controlled BaSE study. Surgery for Obesity and Related Diseases, 13(9), 1612-1618. https://doi.org/https://dx.doi.org/10.1016/j.soard.2017.03.034</td></tr>
</table>

N/A – Not applicable

Wild, 2017

Guideline record ID: 10728--1

Study characteristics		
Citation	Wild, B., Hünnemeyer, K., Sauer, H., Schellberg, D., Müller-Stich, B. P., Königsrainer, A., Weiner, R., Zipfel, S., Herzog, W., & Teufel, M. (2017). Sustained effects of a psychoeducational group intervention following bariatric surgery: follow-up of the randomized controlled BaSE study. Surgery for Obesity and Related Diseases, 13(9), 1612-1618. https://doi.org/https://dx.doi.org/10.1016/j.soard.2017.03.034	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Sustained effects of a psychoeducational group intervention following bariatric surgery: follow-up of the randomized controlled BaSE study	
Location	Germany	
Trial name	Bariatric Surgery and Education (BaSE)	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	Hospital, Home	
Intervention	"In addition, participants of the experimental group were offered a psychoeducational group intervention. The program began with 5 face-to-face group interventions (up to 6 patients, for 90 min each) followed by 6 videoconferencing sessions in smaller groups (3 patients, 50 min each) and 3 face-to-face group sessions. Sessions were structured according to topics that have been demonstrated to be important for postsurgery patients: information, postoperative nutrition, coping with stress, relaxation, body image, physical activity, and self-care. Self-monitoring was implemented to facilitate an in-depth analysis of relevant topics. Formulations and coping strategies were discussed. To support patients in reporting early risk-associated eating behavior, such as loss-of-control eating, night eating, and grazing, food diaries and scheduled group discussions about problems associated with eating behavior were introduced."	
Control/Comparator	"Participants of the control group received conventional surgical visits as implemented in the ongoing clinical routine. These visits comprised weight monitoring, clinical examination, detailed symptom history-taking (including nutrition and eating behavior), and screening for malnourishment. The routine visits were scheduled at 1, 3, 6, and 12 months after surgery."	
Treatment duration	12 months	
Follow-up from baseline	Mean 37.9 months (SD 8.2 mo)	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 114 Intervention group/s: Experimental condition (n=58) Comparator group: Conventional condition (n=56)	
Mean age ± SD	Not reported	

<table>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Baseline weight (kg)
Mean (SD)

Baseline BMI (kg/m2)
Mean (SD)</td><td>Experimental condition: 150.7 (24.2)

Experimental condition: 50.1 (6.6)</td><td>Conventional condition: 144.2 (22.7)

Conventional condition: 49.4 (6.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Follow-up weight (kg)
Mean (SE)

Follow-up BMI (kg/m2)
Mean (SE)</td><td>Experimental condition: 104.3 (1.9)

Experimental condition: 35.2 (0.5)</td><td>Conventional condition: 103.6 (2.0)

Conventional condition: 35.0 (0.5)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>%Excess weight loss
Mean (SE)

% Total weight loss
Mean (SE)</td><td>Experimental condition: -60.3 (3.6)

Experimental condition: -30.0 (1.3)</td><td>Conventional condition: -62.1 (3.3)

Conventional condition: -29.4 (1.3)</td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Wild, B., Hünnemeyer, K., Sauer, H., Hain, B., Mack, I., Schellberg, D., Müller-Stich, B. P., Weiner, R., Meile, T., Rudofsky, G., Königsrainer, A., Zipfel, S., Herzog, W., & Teufel, M. (2015). A 1-year videoconferencing-based psychoeducational group intervention following bariatric surgery: results of a randomized controlled study. Surgery for Obesity and Related Diseases, 11(6), 1349-1360. https://doi.org/https://dx.doi.org/10.1016/j.soard.2015.05.018</td></tr>
</table>

N/A – Not applicable

Wilding, 2021

Guideline record ID: 11066--1

Study characteristics		
Citation	Wilding, J. P. H., Batterham, R. L., Calanna, S., Davies, M., Van Gaal, L. F., Lingvay, I., McGowan, B. M., Rosenstock, J., Tran, M. T. D., Wadden, T. A., Wharton, S., Koutaro, Y., Zeuthen, N., Kushner, R. F., & Yokote, K. (2021). Once-Weekly Semaglutide in Adults with Overweight or Obesity. New England Journal of Medicine, 384(11), 989-1002. https://doi.org/10.1056/NEJMoa2032183	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Once-Weekly Semaglutide in Adults with Overweight or Obesity	
Location	USA; Argentina; Belgium; Bulgaria; Canada; Denmark; Finland; France; Germany; India; Japan; Mexico; Poland; Puerto Rico; Russia; Taiwan; UK	
Trial name	STEP 1	
Methods		
Inclusion criteria	"Male or female, age greater than or equal to 18 years at the time of signing informed consent Body mass index (BMI) greater than or equal to 30.0 kg/sqm or greater than or equal to 27.0 kg/sqm with the presence of at least one of the following weight-related comorbidities (treated or untreated): hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease. History of at least one self-reported unsuccessful dietary effort to lose body weight."	
Exclusion criteria	"Key exclusion criteria were diabetes, a glycated hemoglobin level of 48 mmol per mole (6.5%) or greater, a history of chronic pancreatitis, acute pancreatitis within 180 days before enrollment, previous sur gical obesity treatment, and use of antiobesity medication within 90 days before enrollment."	
Setting	University/research centre	
Intervention	"Participants received semaglutide at a dose of 2.4 mg administered subcutaneously once a week for 68 weeks in addition to lifestyle intervention; this 68-week period was followed by a 7-week period without receipt of semaglutide or placebo or lifestyle intervention. Semaglutide, administered with a prefilled pen injector, was initiated at a dose of 0.25 mg once weekly for the first 4 weeks, with the dose increased every 4 weeks to reach the maintenance dose of 2.4 mg weekly by week 16 (lower maintenance doses were permitted if participants had unacceptable side effects with the 2.4-mg dose) (Fig. S1 in the Supplementary Appendix). Participants received individual coun seling sessions every 4 weeks to help them adhere to a reduced-calorie diet (500-kcal defi cit per day relative to the energy expenditure estimated at the time they underwent random ization) and increased physical activity (with 150 minutes per week of physical activity, such as walking, encouraged). Both diet and activity were recorded daily in a diary or by use of a smartphone application or other tools and were reviewed during counseling sessions."	
Control/Comparator	"Participants received a matching placebo, in addition to lifestyle intervention. . Participants received individual counseling sessions every 4 weeks to help them adhere to a reduced-calorie diet (500-kcal defi cit per day relative to the energy expenditure estimated at the time they underwent random ization) and increased physical activity (with 150 minutes per week of physical activity, such as walking, encouraged). Both diet and activity were recorded daily in a diary or by use of a smartphone application or other tools and were reviewed during counseling sessions."	
Treatment duration	68 weeks	
Follow-up from baseline	68 weeks	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 1961
Intervention group/s: Semaglutide (n=1306)

Comparator group: Placebo (n=655)</td></tr>
<tr><td>Mean age ± SD</td><td>Semaglutide: 46y (13); Placebo: 47y (12)</td></tr>
<tr><td>Sex</td><td>74.09% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight
Mean (SD)</td><td>Semaglutide: 105.4
(22.1)</td><td>Placebo: 105.2
(21.5)</td></tr>
<tr><td>Body-mass index
Mean (SD)</td><td>Semaglutide: 37.8
(6.7)</td><td>Placebo: 38
(6.5)</td></tr>
<tr><td>Waist circumference - cm
Mean (SD)</td><td>Semaglutide: 114.6
(14.8)</td><td>Placebo: 114.8
(14.4)</td></tr>
<tr><td>Total fat mass, kg
Mean (SD)</td><td>Semaglutide: 42.1
(10.1)</td><td>Placebo: 43.3
(9.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Participants with body-weight reduction ≥5% at wk 68 - % Proportion (%)</td><td>Semaglutide: 86.4%</td><td>Placebo: 31.5%</td></tr>
<tr><td>Participants with body-weight reduction ≥10% at wk 68 - % Proportion (%)</td><td>Semaglutide: 69.1</td><td>Placebo: 12</td></tr>
<tr><td>Participants with body-weight reduction ≥15% at wk 68 - % Proportion (%)</td><td>Semaglutide: 50.5</td><td>Placebo: 4.9</td></tr>
<tr><td>Participants with body-weight reduction ≥20% at wk 68 - % Proportion (%)</td><td>Semaglutide: 32.0%</td><td>Placebo: 1.7%</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Percent body-weight change from baseline to wk 68
Mean (95% CIs)</td><td>Semaglutide: -14.85</td><td>Placebo: -2.41</td></tr>
<tr><td>Change from baseline to wk 68 -Waist circumference - cm
Mean (SD)</td><td>Semaglutide: -13.54</td><td>Placebo: -4.13</td></tr>
<tr><td>Change from baseline to wk 68: Body weight - kg</td><td>Semaglutide: -15.3</td><td>Placebo: -2.6</td></tr>
</table>
</td></tr>
</table>

	Mean (SD) Change from baseline to wk 68: Body-mass index Mean (SD) Total fat mass, Kg change Mean (SD)	 Semaglutide: -5.54 Semaglutide: -10.4	 Placebo: -0.92 Placebo: -1.17
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	Not reported		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Wilding, 2022

Guideline record ID: 11067—1

Study characteristics		
Citation	Wilding, J. P. H., Batterham, R. L., Davies, M., Van Gaal, L. F., Kandler, K., Konakli, K., Lingvay, I., McGowan, B. M., Oral, T. K., Rosenstock, J., Wadden, T. A., Wharton, S., Yokote, K., & Kushner, R. F. (2022). Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension. Diabetes, Obesity & Metabolism, 24(8), 1553-1564. https://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med22&AN=35441470https://library.deakin.edu.au/resserv?sid=OVID:medline&id=pmid:35441470&id=doi:10.1111%2Fdom.14725&issn=1462-8902&isbn=&volume=24&issue=8&spage=1553&pages=1553-1564&dat	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension	
Location	USA; Argentina; Belgium; Bulgaria; Canada; Denmark; Finland; France; Germany; India; Japan; Mexico; Poland; Puerto Rico; Russia; Taiwan; UK	
Trial name	STEP-1	
Methods		
Inclusion criteria	"Main phase: Male or female, age greater than or equal to 18 years at the time of signing informed consent. Body mass index (BMI) greater than or equal to 30.0 kg/sqm or greater than or equal to 27.0 kg/sqm with the presence of at least one of the following weight-related comorbidities (treated or untreated): hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease History of at least one self-reported unsuccessful dietary effort to lose body weight. Extension phase: Informed consent for the extension phase obtained before any trial related activities for the extension phase commenced. On randomised treatment on the target dose at week 68, i.e. treated with 2.4 mg semaglutide once-weekly or semaglutide placebo."	
Exclusion criteria	"Main phase: Glycated haemoglobin (HbA1C) greater than or equal to 48 mmol/mol (6.5%) as measured by the central laboratory at screening A self-reported change in body weight greater than 5 kg (11 lbs) within 90 days before screening irrespective of medical records Extension phase: Female who is pregnant or intends to become pregnant during the extension phase Any disorder, unwillingness or inability, not covered by any of the other exclusion criteria, which in the investigator's opinion, might jeopardise the subject's compliance with the extension of the trial."	
Setting	University/research centre	
Intervention	"Participants will receive semaglutide subcutaneous (s.c.; under the skin) injection(s) once-weekly as well as diet and physical activity counselling for 68 weeks. Dose escalation of semaglutide will take place as follows: 0.25 mg from week 1 to 4, 0.5 mg from week 5 to 8, 1.0 mg from week 9 to 12, 1.7 mg from week 13 to 16 and 2.4 mg from week 17 to week 68. In the extension phase Approximately 300 participants will continue in the extension phase in the following countries only: Canada, Germany, the UK and selected sites in the US and Japan. These participants will be in the study for about 2.5 years.They will not receive treatment, but will attend another 5 follow-up visits with the study doctor."	
Control/Comparator	"Participants will receive semaglutide matching placebo s.c. injection(s) once-weekly as well as diet and physical activity counselling for 68 weeks. in the extension phase Approximately 300 participants will continue in the extension phase in the following countries only: Canada, Germany, the UK and selected sites in the US and Japan. These	

<table>
<tr><td></td><td>participants will be in the study for about 2.5 years.They will not receive treatment, but will attend another 5 follow-up visits with the study doctor.”</td></tr>
<tr><td>Treatment duration</td><td>68 weeks</td></tr>
<tr><td>Follow-up from baseline</td><td>120 weeks</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 327
Intervention group/s: Semaglutide (n=228)

Comparator group: Placebo (n=99)</td></tr>
<tr><td>Mean age ± SD</td><td>Semaglutide: 48y (12); Placebo: 50y (11)</td></tr>
<tr><td>Sex</td><td>66.97% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (KG)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Semaglutide: 105.6
(21.8)

Semaglutide: 37.6
(7)</td><td>Placebo: 105.4
(25.6)

Placebo: 105.4
(25.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (KG)
Mean (SD)

BMI (kg/m2)
Mean (SD)</td><td>Semaglutide: 87.5
(21.4)

Semaglutide: 31.2
(7.2)</td><td>Placebo: 103.2
(25.6)

Placebo: 103.2
(25.6)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from</td><td></td></tr>
</table>

this study that did not contribute additional data	

N/A – Not applicable

Williams, 2019

Guideline record ID: 10730--1

Study characteristics		
Citation	Williams, C. F., Bustamante, E. E., Waller, J. L., & Davis, C. L. (2019). Exercise effects on quality of life, mood, and self-worth in overweight children: the SMART randomized controlled trial. Translational Behavioral Medicine, 9(3), 451-459. https://doi.org/https://doi.org/10.1093/tbm/ibz015	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Exercise effects on quality of life, mood, and self-worth in overweight children: The SMART randomized controlled trial	
Location	USA	
Trial name	SMART	
Methods		
Inclusion criteria	"Inclusion criteria: 8-11 years old overweight or obese (BMI ≥ 85th percentile for age and sex) children, who were sedentary (no regular participation in an exercise program more than 1 hr/week)."	
Exclusion criteria	"They were excluded if they had any medical conditions or took medications that could affect growth, physical activity, nutritional status, or metabolism."	
Setting	University/research centre	
Intervention	"Participants in both the exercise and control groups were offered an after-school program including a snack and ½ hr of supervised homework time every school day for about 8 months (average number of days offered = 138, SD = 9) in 2008-2012. Participants were transported by bus daily to the Georgia Prevention Institute for the after-school intervention and bused back to their neighborhoods after each session. Lead instructors were rotated between the two groups every 2 weeks, and assistant instructors were rotated between the two groups every week. Both groups could earn points that were redeemed for small prizes weekly for desired behaviors. The reward schedule was periodically calibrated to keep rewards similar between groups. The groups differed in that they were offered either an exercise or sedentary program. The aerobic exercise group engaged in playful instructor-led aerobic activities for 40 min per day. Each session included vigorous aerobic activities and games (e.g., running games, ball games, and jump rope), interspersed with brief rest periods. Games were selected based on interest and ability to elicit vigorous activity. Children wore heart rate monitors every day (S610i; Polar Electro, Oy, Finland) with which they could monitor their own performance and from which data were collected daily. Points in the exercise group were earned for a daily average heart rate above 150 beats per minute, with more points for higher average heart rates."	
Control/Comparator	"Participants in both the exercise and control groups were offered an after-school program including a snack and ½ hr of supervised homework time every school day for about 8 months (average number of days offered = 138, SD = 9) in 2008-2012. Participants were transported by bus daily to the Georgia Prevention Institute for the after-school intervention and bused back to their neighborhoods after each session. Lead instructors were rotated between the two groups every 2 weeks, and assistant instructors were rotated between the two groups every week. Both groups could earn points that were redeemed for small prizes weekly for desired behaviors. The reward schedule was periodically calibrated to keep rewards similar between groups. The groups differed in that they were offered either an exercise or sedentary program. The attention control group engaged in instructor-led sedentary activities (e.g., board games, puzzles, art, and music). Points in the control group were earned for participation and good behavior."	

<table>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 175
Intervention group/s: Exercise group (n=90)

Comparator group: Sedentary control group (n=85)</td></tr>
<tr><td>Mean age ± SD</td><td>9.7y (0.9)</td></tr>
<tr><td>Sex</td><td>61.14% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Body fat (%)
Mean (SD)</td><td>Exercise group: 38.3 (6.9)</td><td>Sedentary control group: 36.7 (7.3)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Body fat (%)
Mean (SD)</td><td>Exercise group: 36.2 (7.7)</td><td>Sedentary control group: 36.2 (8)</td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Attendance was similar in control and exercise groups 64% ± 30% vs. 59% ± 28%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Wilson, 2016

Guideline record ID: 10930--1

Study characteristics		
Citation	Wilson, M. G., DeJoy, D. M., Vandenberg, R., Padilla, H., & Davis, M. (2016). FUEL Your Life: a translation of the Diabetes Prevention Program to worksites. American Journal of Health Promotion, 30(3), 188-197. https://doi.org/https://doi.org/10.4278/ajhp.130411-QUAN-169	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	FUEL Your Life: A Translation of the Diabetes Prevention Program to Worksites	
Location	USA	
Trial name	FUEL Your Life	
Methods		
Inclusion criteria	Not reported	
Exclusion criteria	Not reported	
Setting	Workplace	
Intervention	"The FYL program manual contained the same content as the DPP Lifestyle Change Program manual, but the formatting (i.e., larger print, more readable), graphics (varying colours and headers), pictures (gender neutral), and examples (pertinent to both genders) were modified to make the manual more tailored to male workers and reader friendly. Similar to DPP, at the end of each lesson participants were asked to write down their weight, physical activity levels, and foods eaten. These served as a self-monitoring exercise to create awareness of their behaviours and reinforce goals. Participants in the program were expected to work through the program lessons on their own, at the same pace as they would for DPP (16 lessons over 24 weeks). DPP was a high intensity intervention with regular one on-one meetings between participants and their lifestyle coach and access to considerable resources to support participant change efforts (up to $200 per participant). Site coordinators conducted six group sessions that lasted approximately 10 minutes each and made weekly announcements in safety meetings through the first 6 months of the program. At baseline, an initial one-on-one session was conducted by a master's-level dietitian or health educator with each participant in a private setting to discuss the participant's weight loss and physical activity goals (which were similar to those for DPP: 7% body weight loss and 150 minutes of physical activity a week) and daily dietary fat intake goal (which was chosen based on their starting weight). Participants were also instructed on how to use the fat counter to measure their daily fat intake and given an overview of the participant manual and program components. Worksite environmental supports consisted of (1) saturating the environment with messages through posters and information during safety meetings, (2) carefully adhering to company policies requiring healthy food options in vending machines and company-sponsored events, and (3) encouraging peer support through the health coaches and other participants. Home environmental supports were activated that included (1) sending home a packet of materials that described the program and ways the family could support the participant; (2) providing access to a Web site that included copies of all materials, a chat room, family support strategies, and additional information and recipes; and (3) allowing spouses of participants to take part in the program themselves. DPP did involve participants' spouses in the intervention, so the primary difference between DPP and FYL would be the worksite environmental support."	
Control/Comparator	"The study used an experimental control group design to test the effectiveness of the FYL weight managem ent program. Six sites were matched based on the num ber of employees and randomly assigned to treatm ent or control groups. The control sites had no planned	

<table>
<tr><td></td><td>intervention but may have had health and safety activities ongoing as part of their normal operations.”</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 916
Intervention group/s: Treatment (n=459)

Comparator group: Control (n=457)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 44y; Control: 47y</td></tr>
<tr><td>Sex</td><td>5.90% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight, pounds
Mean (SD)</td><td>Treatment: 218.43</td><td>Control: 206.13</td></tr>
<tr><td>% Overweight (BMI 25-29.9)
Proportion (%)</td><td>Treatment: 32.9</td><td>Control: 43.5</td></tr>
<tr><td>% Obese (BMI 30 or greater)
Proportion (%)</td><td>Treatment: 59.4</td><td>Control: 42.8</td></tr>
<tr><td>Body mass index
Mean (SD)</td><td>Treatment: 31.9
(5.38)</td><td>Control: 29.9
(5.56)</td></tr>
<tr><td>Body weight, pounds
Mean (SD)</td><td>Treatment: 220.1
(44.9)</td><td>Control: 201.4
(45.04)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body mass index
Mean (SD)</td><td>Treatment: 31.8
(5.79)</td><td>Control: 30.2
(5.49)</td></tr>
<tr><td>Body weight, pounds
Mean (SD)</td><td>Treatment: 218.5
(46.41)</td><td>Control: 204.5
(45.98)</td></tr>
<tr><td>Percentage Body Weight Change - No Loss/Weight Gain
Proportion (%)</td><td>Treatment: 44.8</td><td>Control: 64.8</td></tr>
<tr><td>Percentage Body Weight Change - 0.01 %-4.9% Loss
Proportion (%)</td><td>Treatment: 44</td><td>Control: 26.8</td></tr>
<tr><td>Percentage Body Weight Change - 5%-9.9% Loss
Proportion (%)</td><td>Treatment: 10.3</td><td>Control: 5.6</td></tr>
<tr><td>Percentage Body Weight Change - >10% Loss
Proportion (%)</td><td>Treatment: 0.9</td><td>Control: 3</td></tr>
</table>
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</table>

<table>
<tr><td></td><td><table><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in Body mass index
Mean (SD)

Change in Body weight, pounds
Mean (SD)</td><td>Treatment: -0.1

Treatment: -1.6</td><td>Control: 0.3

Control: 3.1</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Wing, 2013

Guideline record ID: 10732--1

Study characteristics		
Citation	The Look AHEAD Research Group. (2013). Cardiovascular effects of intensive lifestyle intervention in type 2 diabetes. The New England Journal of Medicine, 369(2), 145-154. https://doi.org/10.1056/NEJMoa1212914	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Cardiovascular effects of intensive lifestyle intervention in type 2 diabetes	
Location	USA	
Trial name	Action for Health and Diabetes (Look AHEAD)	
Methods		
Inclusion criteria	"To be eligible for participation in the trial, patients were required to be 45 to 75 years of age and to meet all the following criteria: self-reported type 2 diabetes, as verified by the use of glucose-lowering medication, a physician's report, or glucose levels; a body-mass index (the weight in kilograms divided by the square of the height in meters) of 25.0 or more (27.0 or greater in patients taking insulin); a glycated hemoglobin level of 11% or less; a systolic blood pressure of less than 160 mm Hg; a diastolic blood pressure of less than 100 mm Hg; a triglyceride level of less than 600 mg per deciliter (6.77 mmol per liter); the ability to complete a valid maximal exercise test, suggesting it was safe to exercise; and an established relationship with a primary care provider. Patients could be using any type of glucose-lowering medication, but the percentage of those receiving insulin allowed in the trial was limited to less than 30%. Patients with and those without a history of cardiovascular disease were included to increase the generalizability of the results."	
Exclusion criteria	Not reported	
Setting	GP clinic, Hospital, University/research centre	
Intervention	"The intensive lifestyle intervention was aimed at achieving and maintaining weight loss of at least 7% by focusing on reduced caloric intake and increased physical activity. The program included both group and individual counseling sessions, occurring weekly during the first 6 months, with decreasing frequency over the course of the trial. Specific intervention strategies included a calorie goal of 1200 to 1800 kcal per day (with <30% of calories from fat and >15% from protein), the use of meal-replacement products, and at least 175 minutes of moderate-intensity physical activity per week. A toolbox of strategies was available for patients having difficulty achieving the weight loss goals"	
Control/Comparator	"Diabetes support and education featured three group sessions per year focused on diet, exercise, and social support during years 1 through 4. In subsequent years, the frequency was reduced to one session annually."	
Treatment duration	10 years	
Follow-up from baseline	Median 9.6 years	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 5145 Intervention group/s: ILI (n=2570) Comparator group: DSE (n=2575)	

<table>
<tr><td>Mean age ± SD</td><td>ILI: 58.6y (6.8); DSE: 58.9y (6.9)</td></tr>
<tr><td>Sex</td><td>59.53% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (95% CIs)

Waist circumference (cm)
Mean (95% CIs)

Baseline BMI (kg/m2)
Mean (SD)</td><td>ILI: 100
(99.7-101)

ILI: 114
(113-114)

ILI: 35.9
(6)</td><td>DSE: 101
(100-101)

DSE: 114
(114-115)

DSE: 36
(5.8)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg)
Mean (95% CIs)

Waist circumference (cm)
Mean (95% CIs)</td><td>ILI: 93.6
(92.8-94.4)

ILI: 112
(111-112)</td><td>DSE: 96.2
(95.4-97)

DSE: 113
(113-114)</td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>% Weight loss from Baseline
Mean</td><td>ILI: -6.0</td><td>DSE: -3.5</td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td>Redmon, J. B., Bertoni, A. G., Connelly, S., Feeney, P. A., Glasser, S. P., Glick, H., Greenway, F., Hesson, L. A., Lawlor, M. S., Montez, M., Montgomery, B., & the Look AHEAD Research Group. (2010). Effect of the look AHEAD study intervention on medication use and related cost to treat cardiovascular disease risk factors in individuals with type 2 diabetes. Diabetes Care, 33(6), 1153-1158. https://doi.org/https://dx.doi.org/10.2337/dc09-2090; Wadden, T. A., Neiberg, R. H., Wing, R. R., Clark, J. M., Delahanty, L. M., Hill, J. O., Krakoff, J., Otto, A., Ryan, D. H., Vitolins, M. Z., & The Look AHEAD Research Group. (2011). Four-year weight losses in the Look AHEAD study: factors associated with long-term success. Obesity, 19(10), 1987-1998. https://doi.org/https://dx.doi.org/10.1038/oby.2011.230</td></tr>
</table>

N/A – Not applicable

Winters-Stone, 2015

Guideline record ID: 10932--1

Study characteristics		
Citation	Winters-Stone, K. M., Dieckmann, N., Maddalozzo, G. F., Bennett, J. A., Ryan, C. W., & Beer, T. M. (2015). Resistance exercise reduces body fat and insulin during androgen-deprivation therapy for prostate cancer. Oncology Nursing Forum, 42(4), 348-356. https://doi.org/10.1188/15.ONF.348-356	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Resistance Exercise Reduces Body Fat and Insulin During Androgen-Deprivation Therapy for Prostate Cancer	
Location	USA	
Trial name	Prevent Osteoporosis With Impact and Resistance (POWIR)	
Methods		
Inclusion criteria	"Inclusion criteria were having a diagnosis of prostate cancer, currently receiving ADT, no concurrent chemotherapy, no known bone metastases in the hip or spine, no detectable osteoporosis, no regular (more than twice per week with 30 minutes per session) participation in moderate-tovigorous resistance training, and no contraindications for exercise."	
Exclusion criteria	Not reported	
Setting	University/research centre	
Intervention	"Participants in both groups were prescribed an exercise program consisting of two one-hour supervised classes and one 30- to 45-minute home-based session per week for 12 months. POWIR was based on prior interventions in people without cancer (Winters & Snow, 2000) and followed American College of Sports Medicine's recommendations for preserving bone health and muscle strength in older adults (Chodzko-Zajko et al., 2009; Kohrt, Bloomfield, Little, Nelson, & Yingling, 2004). Resistance training used free weights (e.g., dumbbells, barbells, weighted vest) for 1-3 sets per exercise at a weight that could be lifted for 8-12 repetitions (about 60%-80% of one repetition maximum [RM]). Impact exercises were included to place a load on the skeleton by generating ground reaction forces and consisted of 50 two-footed jumps from the ground with weighted vests. An exercise session consisted of wall-sits, squats, dead lifts, lunges, rows, chest presses, lateral raise, push-ups, and two-footed jumps."	
Control/Comparator	"Participants in both groups were prescribed an exercise program consisting of two one-hour supervised classes and one 30- to 45-minute home-based session per week for 12 months. Participants in the control group (FLEX) performed whole-body stretching and relaxation exercises in a seated or prostrate position to minimize muscle forces and energy expenditure. Aside from FLEX, participants in this group were encouraged to maintain habitual physical activity levels throughout the intervention."	
Treatment duration	12 months	
Follow-up from baseline	12 months	
Eligible outcome(s) reported	Dual energy X-ray absorptiometry (DXA), Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 51 Intervention group/s: POWIR (n=29)	

<table>
<tr><td></td><td>Comparator group: FLEX (n=22)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention (POWIR): 69.9y (9.3); Control (FLEX): 70.5y (7.8)</td></tr>
<tr><td>Sex</td><td>100.00% male</td></tr>
<tr><td>Pre-existing medical condition</td><td>Prostate cancer</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Fat mass (kg)
Mean (SD)

Percent body fat
Mean (SD)

Total body mass (kg)
Mean (SD)</td><td>POWIR: 28.4
(4.1)

POWIR: 24.3
(7.7)

POWIR: 28.7
(5.1)

POWIR: 83.6
(15)</td><td>FLEX: 29.6
(4.8)

FLEX: 28.4
(11.1)

FLEX: 31.6
(7)

FLEX: 83.6
(13.4)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Fat mass (kg)
Mean (SD)

Percent body fat
Mean (SD)

Total body mass (kg)
Mean (SD)</td><td>POWIR: 23.9
(7)

POWIR: 28.4
(4.3)

POWIR: 83.2
(15)</td><td>FLEX: 29.9
(12.8)

FLEX: 32.4
(6.6)

FLEX: 84.2
(14.2)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in fat mass (%)
Mean (SD)

Change in percent body fat
Mean (SD)

Change in total body mass (%)
Mean (SD)</td><td>POWIR: -0.2

POWIR: -1.1

POWIR: -0.4</td><td>FLEX: 5.3

FLEX: 2.5

FLEX: 0.7</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>The median attendance for supervised classes was 84% for POWIR and 74% for FLEX, and median attendance to home-based sessions was 43% for POWIR and 51% for FLEX.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Wylie-Rosett, 2018

Guideline record ID: 10739--1

Study characteristics		
Citation	Wylie-Rosett, J., Groisman-Perelstein, A. E., Diamantis, P. M., Jimenez, C. C., Shankar, V., Conlon, B. A., Mossavar-Rahmani, Y., Isasi, C. R., Martin, S. N., Ginsberg, M., Matthan, N. R., & Lichtenstein, A. H. (2018). Embedding weight management into safety-net pediatric primary care: randomized controlled trial. International Journal of Behavioral Nutrition and Physical Activity, 15, 12. https://doi.org/https://dx.doi.org/10.1186/s12966-017-0639-z	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Embedding weight management into safety-net pediatric primary care: randomized controlled trial	
Location	USA	
Trial name	Comprehensive Approach to Family Weight Management	
Methods		
Inclusion criteria	"Inclusion criteria were age 7 to 12 years and BMI ≥85th United States CDC BMI percentile [22] for age and sex."	
Exclusion criteria	"Exclusion criteria included chronic illness (e.g., diabetes), impairments that would affect ability or safety to follow the study protocols, treatment with medications known to affect body weight, and enrollment in another weight management program within 2 years."	
Setting	Hospital	
Intervention	"The Standard Care paediatrician visit procedures were the same for both of the treatment arms however, the Standard Care + Enhanced Program included a behavioural change component (eight skill-building core sessions and monthly post-core support sessions focused on dietary modification and increased physical activity). The Enhanced Program added components was provided by a bilingual multidisciplinary staff (dietitian, social worker, and fitness instructor). The components included a Skill Building Core (eight weekly sessions) and Post-Core Support (monthly sessions). Motivational enhancement based on Motivation Interviewing (MI) principles was used to engage both parent and child to evoke "their" reasons for changing unhealthy lifestyle behaviors [19]. The staff skill training taught by coauthor (YMR), a member of the international Motivational Interviewing Network of Trainers (MINT), focused on - open-ended questions, affirmations, reflections and summary (ORAS) and using empathic guiding to develop goals collaboratively."	
Control/Comparator	"Standard Care Alone (quarterly paediatrician visits to address weight management recommendations). The Standard Care intervention was based on the American Academy of Paediatrics evidence-based recommendations using intervention materials selected during pilot testing [1-3]. Two bilingual primary care paediatricians, who were embedded in the practice, provided the Standard Care intervention for all the study families. Kid-WAVE introduction to foster early engagement children were given the Kid-Weight, Activity, Variety, and Excess (WAVE) Get Healthy card game [23]. The 12-item WAVE card game includes questions adapted from the Youth Behavioural Risk Factor Survey [23-25] to help children choose behavioural targets (e.g., playing active video games, eating more vegetables, avoiding super-sizing or drinking water rather than sugar-sweetened beverages). The paediatrician visits were provided quarterly in designated clinical sessions reserved for the weight management study patients. Paediatrician visit procedures were the same for both treatment arms. The initial visit was a comprehensive, structured 40-min appointment to assess weight-related issues and to engage both the child(ren) and parent(s)/guardian(s) in developing intervention goals collaboratively. Assessments were used for making referrals to the registered dietitian and guiding the paediatricians' use of New York City Department of Health and Mental Hygiene weight management tools.	

<table>
<tr><td></td><td>Follow-up paediatrician appointments were brief (~15 min) quarterly visits to review the assessment themes and collaborative goals identified at the initial visit. The paediatricians elicited the perspective of both the child(ren) and parent/guardian regarding progress toward goals and concerns.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 360
Intervention group/s: Standard Care + Enhanced Program (n=178)

Comparator group: Standard Care Alone (n=182)</td></tr>
<tr><td>Mean age ± SD</td><td>9.3y (1.7)</td></tr>
<tr><td>Sex</td><td>51.39% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI Z-score
Mean (SD)</td><td>Standard Care + Enhanced Program: 1.95
(0.42)</td><td>Standard Care Alone: 2.02
(0.39)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in body mass index Z-score
Mean (SE)</td><td>Standard Care + Enhanced Program: -0.15
(0.03)</td><td>Standard Care Alone: -0.12
(0.03)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>The Standard Care Alone arm had a median of three visits during the 12-month period (range: 1-4). A subgroup analysis within the Standard Care Alone arm suggested no significant effect of number of contacts (≤ 2, 3, 4) on the rate of change (slope) of BMI Z-score (p = 0.27). The Standard Care + Enhanced Program arm had a median of six contacts with Enhanced Program multidisciplinary staff and completed 5.7 ± 2.2 (mean ± SD) Skill Building Core modules. Eighty-five percent of the families completed all eight core modules during 5.2 ± 1.5 (mean ± SD) contacts.</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Xiang, 2018

Guideline record ID: 10740--1

Study characteristics		
Citation	Xiang, A. H., Trigo, E., Martinez, M., Katkhouda, N., Beale, E., Wang, X., Wu, J., Chow, T., Montgomery, C., Nayak, K. S., Hendee, F., Buchanan, T. A., & RISE Consortium. (2018). Impact of gastric banding versus metformin on β-cell function in adults with impaired glucose tolerance or mild type 2 diabetes. Diabetes Care, 41(12), 2544-2551. https://doi.org/https://dx.doi.org/10.2337/dc18-1662	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Impact of Gastric Banding Versus Metformin on beta-Cell Function in Adults With Impaired Glucose Tolerance or Mild Type 2 Diabetes	
Location	USA	
Trial name	BetaFat	
Methods		
Inclusion criteria	"Main inclusion criteria were aged 21-65 years; BMI 30-40 kg/m2 despite at least 2 months on a diet, exercise, and lifestyle modification program; fasting glucose .90 mg/dL, 2-h glucose $140 mg/dL on 75-g oral glucose tolerance test (OGTT), and HbA1c #7.0%; and for participants with diabetes, known duration,1 year; and no history of antidiabetes medication use except during pregnancy."	
Exclusion criteria	"Exclusion criteria detailed in the study protocol included conditions likely to affect study participation or outcomes, contraindications to interventions or assessments, recent weight loss, and inability to provide informed consent."	
Setting	Hospital	
Intervention	"All participants received 1 h of nutrition and lifestyle education. Participants randomized to gastric banding received additional education about the procedure and associated dietary restrictions and had medical and psychological screening prior to surgery. Gastric bands (LAP-BAND; Allergan Corporation, Irvine, CA, and Apollo Endosurgery, Austin, TX) were placed laparoscopically by an experienced bariatric surgeon. Fluid was introduced into band ports 2 months following surgery, and participants were scheduled for band adjustments every 2 months during the first year, then every 3 months. Adjustments were conducted according to an established protocol based on body weight, weight change, and symptoms of satiety and discomfort. Body weight was obtained at each follow-up visit; participants who gained weight compared with the prior visit were counseled on compliance with the prescribed diet by a bariatric dietitian."	
Control/Comparator	"All participants received 1 h of nutrition and lifestyle education. Individuals randomized to metformin received open-label metformin titrated from 500 mg/day to 1,000 mg twice daily over 1 month. Follow-up visits followed the same schedule as for band patients. Medication adherence (pill counts on returned medication bottles) and adverse effects were assessed at each visit; doses were reduced as needed. Metformin was withheld on the morning of all study visits until that visit's procedures were completed."	
Treatment duration	24 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	Body weight (kgs or lbs)	
Participant characteristics		

<table>
<tr><td>Number of participants</td><td>n= 88
Intervention group/s: Gastric band (n=44)

Comparator group: Metformin (n=44)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 47y (10); Control: 51y (9)</td></tr>
<tr><td>Sex</td><td>78.41% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Impaired Glucose Tolerance or Mild Type 2 Diabetes</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg) - Baseline Mean (SD)

BMI (kg/m2) - Baseline Mean (SD)</td><td>Gastric band: 97.5 (12.2)

Gastric band: 35.7 (2.9)</td><td>Metformin: 96.1 (10.9)

Metformin: 35 (2.9)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight loss (kg) Mean (SE)</td><td>Gastric band: -10.7 (2.2)</td><td>Metformin: -1.7 (0.2)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Median pill compliance was 72.4%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Yackobovitch-Gavan, 2018

Guideline record ID: 10741--1

Study characteristics		
Citation	Yackobovitch-Gavan, M., Wolf Linhard, D., Nagelberg, N., Poraz, I., Shalitin, S., Phillip, M., & Meyerovitch, J. (2018). Intervention for childhood obesity based on parents only or parents and child compared with follow-up alone. Pediatric Obesity, 13(11), 647-655. https://doi.org/https://dx.doi.org/10.1111/ijpo.12263	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Intervention for childhood obesity based on parents only or parents and child compared with follow-up alone	
Location	Israel	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were age 5-11 years and body mass index (BMI) between the 85th and 98th percentiles for age and sex."	
Exclusion criteria	"Exclusion criteria were chronic conditions (e.g. diabetes mellitus, cardiac or renal problems, uncontrolled hypertension, liver enzyme levels more than threefold above the upper normal limit, genetic-syndromes and organic diseases associated with obesity), use of medication that might influence weight."	
Setting	Hospital	
Intervention	"The family-based intervention included 12 once weekly group meetings of 60 min each (12-15 participants per meeting) with a dietician and psychologist and focused on cognitive behavioural changes in the family lifestyle. In the parents-only group, at least one parent attended the meetings, and in the parents-child group, at least one parent and child attended separate group meetings. Each meeting focused on a different nutritional or lifestyle goal, including eating in accordance with the food pyramid, adequate fruit and vegetable consumption and abstention from sweetened beverages, the importance of drinking water, reducing fast-food consumption, limiting the time spent watching television or using the computer, increasing the time spent in physical activity, special dietary consideration during parties and vacations and strategies to implement an active lifestyle in the family. All participants underwent the same evaluation by a paediatric endocrinologist at baseline and at 3, 12 and 24 months."	
Control/Comparator	"The control group did not participate in group meetings. All participants underwent the same evaluation by a pediatric endocrinologist at baseline and at 3, 12 and 24 months."	
Treatment duration	3 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	BMI or BMI z-score/BMI-for-age centiles	
Participant characteristics		
Number of participants	n= 247 Intervention group/s: Parents - child (n=84); Parents - only (n=89) Comparator group: Control (n=74)	
Mean age ± SD	8.4y (1.5)	

<table>
<tr><td>Sex</td><td>67.21% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI -SDS - Baseline
Mean (SD)</td><td>Parents - child: 1.78
(0.34)
Parents - only: 1.8
(0.3)</td><td>Control: 1.78
(0.31)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Changes in adjusted BMI-SDS
Mean (95% CIs)</td><td>Parents - child: -0.17
(-0.27--0.08)
Parents - only: -0.05
(-0.15-0.05)</td><td>Control: -0.1
(-0.2-0.01)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Median (inter-quartile range) attendance in the group meetings was 6 (2, 9) in the parents-only group and 7 (3, 10) in the parents-child group (P = .092).</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Yadav, 2016

Guideline record ID: 10933

Study characteristics		
Citation	Yadav, V., Marracci, G., Kim, E., Spain, R., Cameron, M., Overs, S., Riddehough, A., Li, D. K. B., McDougall, J., Lovera, J., Murchison, C., & Bourdette, D. (2016). Low-fat, plant-based diet in multiple sclerosis: a randomized controlled trial. Multiple Sclerosis and Related Disorders, 9, 80-90. https://doi.org/https://dx.doi.org/10.1016/j.msard.2016.07.001	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Low-fat, plant-based diet in multiple sclerosis: A randomized controlled trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were as follows: RRMS (McDonald criteria (McDonald et al., 2001; Polman et al., 2011)); abnormal brain MRI consistent with MS; MS duration o15 years; EDSS r6.0 (Kurtzke, 1983); age 18-70 years; documented clinical relapse or active disease by MRI in the previous 2 years; baseline diet with over 30% of total daily caloric intake from fat as determined by the self-administered Nutrition Quests Block 2005 Food Frequency Questionnaire (FFQ) (Block et al., 1994). Subjects were allowed to be on a DMT during the trial if they were on a stable dose for at least 6 months prior to screening and maintained stable treatment throughout the study."	
Exclusion criteria	"We excluded subjects who were pregnant or breastfeeding and those with any clinically significant MS exacerbation or systemic corticosteroid use within 30 days of screening."	
Setting	Home, University/research centre, Over the phone, online	
Intervention	"The study diet was based on starchy plant foods (beans, breads, corn, pastas, potatoes, sweet potatoes, and rice with the addition of fruits and non-starchy vegetables). Approximately 10% of calories were derived from fat, 14% from protein and 76% from carbohydrate (Anonymous, 2014). Meat, fish, eggs, dairy products and vegetable oils (such as corn and olive oil) were prohibited. We used monthly FFQ and telephone contact to assess diet adherence. Subjects were considered diet adherent if they consumed 20% or less of calories from fat at least 80% of the time during the study. Additional counseling in clinic or by telephone by a trained dietician was used to help subject adherence. Diet group subjects were allowed to discuss dietary challenges with other diet group subjects or the un-blinded study team members via a secure, online discussion board or in-person meetings. The un-blinded study team members documented all correspondence between subjects. Subjects deemed to be having difficulty with diet adherence were not excluded or disqualified after consent. Exercise Subjects in both groups were encouraged to perform at least 30 min of moderate intensity activity at least five days a week, as recommended by the American Heart Association (Anonymous, 2014). Exercise activity (intensity, duration, and frequency) and adherence were assessed using the RAPA questionnaire completed at each clinic visit. Exercise adherence was defined as, "consistently active more than 30 min (RAPA score45) for at least 80% of the clinic visits"."	
Control/Comparator	"The control group received no diet training at study onset and continued their usual diet throughout the study. After study exit at 12 months, control group subjects were offered the 10-day residential diet training at no cost. After the baseline visit, the control group received an exercise education seminar conducted by a licensed physical therapist within three weeks of the baseline visit. Subsequent visits occurred at months 1, 3, 6, 9, and 12 and included physical exams, MSFC, FFQ, FSS, MSQLI, BDI, RAPA, concomitant medications check, and adverse events (AEs) reporting. EDSS was completed at months 3, 6, 9 and 12. Subjects in both groups were encouraged to perform at least 30 min of moderate intensity	

<table>
<tr><td></td><td>activity at least five days a week, as recommended by the American Heart Association (Anonymous, 2014). Exercise activity (intensity, duration, and frequency) and adherence were assessed using the RAPA questionnaire completed at each clinic visit. Exercise adherence was defined as, "consistently active more than 30 min (RAPA score45) for at least 80% of the clinic visits".”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 61
Intervention group/s: Diet group (n=32)

Comparator group: Control group (n=29)</td></tr>
<tr><td>Mean age ± SD</td><td>Intervention: 40.8y (8.86); Control: 40.9y (8.48)</td></tr>
<tr><td>Sex</td><td>93.44% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>people with relapsing-remitting MS (RRMS)</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>BMI (kg/m2)
Mean (SD)</td><td>Diet group: 29.3
(7.42)</td><td>Control group: 28.4
(6.76)</td></tr></table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Rate of BMI change (kg/m2 per month) (over 12 months)
Mean</td><td>Diet group: -0.1746</td><td>Control group: 0.01723</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td>Importantly, 85% (22/26) of the diet group subjects were diet adherent during the 12 month study (% caloric intake as fat across 12 months: mean=14.4% ± 6.13%; median=12.8%; interquartile range [IQR=(10.6-16.7%); Fig. 2]</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Yaskolka Meir, 2021

Guideline record ID: 10935--1

Study characteristics		
Citation	Yaskolka Meir, A., Rinott, E., Tsaban, G., Zelicha, H., Kaplan, A., Rosen, P., Shelef, I., Youngster, I., Shalev, A., Blüher, M., Ceglarek, U., Stumvoll, M., Tuohy, K., Diotallevi, C., Vrhovsek, U., Hu, F., Stampfer, M., & Shai, I. (2021). Effect of green-Mediterranean diet on intrahepatic fat: the DIRECT PLUS randomised controlled trial. Gut, 70(11), 2085-2095. https://doi.org/https://dx.doi.org/10.1136/gutjnl-2020-323106	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effect of green-Mediterranean diet on intrahepatic fat: the DIRECT PLUS randomised controlled trial	
Location	Israel	
Trial name	Dietary Intervention Randomized Controlled Trial Polyphenols Unprocessed (DIRECT PLUS)	
Methods		
Inclusion criteria	"Inclusion criteria: age >30 years with abdominal adiposity (waist circumference: men > 102 cm, women > 88 cm) or dyslipidemia (TG>150mg/dl and HDL-c <40mg/dL for men and <50mg/dL for women)."	
Exclusion criteria	"Individuals who may not be able to partake in PA in the gym; TGs>400 mg/dL; serum creatinine>2 mg/dL; disturbed liver function; major illness that might require hospitalization; pregnant or lactating women; presence of active cancer, is receiving or received chemotherapy in the last three years; participation in another trial; participants who are treated with Coumadin (warfarin) - given its interaction with vitamin K and high level of this vitamin in "Mankai" green shake; pacemaker or platinum implant, because of the impossibility of MRI screening."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs), University/research centre	
Intervention	"MED group: In addition to PA, participants were instructed to adopt a calorie-restricted MED diet. The MED diet assigned was rich in vegetables, with poultry and fish replacing beef and lamb. The diet also included 28g/day of walnuts (containing 440mg polyphenols/day; gallic acid equivalents (GAE), including, mostly, ellagitannins, ellagic acid and its derivatives. Green-MED group: In addition to PA and the provision of 28g/day walnuts, the green-MED diet was restricted in processed and red meat and was richer in plants and polyphenols. The participants were guided to further consume the following provided items: 3-4 cups/day of green tea and 100g/day of frozen Wolffia globosa (Mankai strain) plant frozen cubes, as a green shake replacing dinner. Both green tea and Mankai together provided additional daily intake of 800mg polyphenols ((GAE), including catechins (flavanols)) beyond the polyphenol content in the prescribed MED diet. Both the MED and green-MED diets were equally calorie-restricted (1500-1800 kcal/day for men and 1200-1400 kcal/ day for women). All the participants received free gym memberships and educational sessions to engage in moderate-intensity PA, 18~80% of which included an aerobic component."	
Control/Comparator	"HDG group: In addition to PA, participants received standard nutritional counselling to promote a healthy diet and to achieve a similar intervention intensity."	
Treatment duration	18 months	
Follow-up from baseline	18 months	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	

<table>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 294
Intervention group/s: Green-MED (n=98); MED (n=98)

Comparator group: HDG (n=98)</td></tr>
<tr><td>Mean age ± SD</td><td>51.1y (10.5)</td></tr>
<tr><td>Sex</td><td>11.90% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>NAFLD</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Weight (kg)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Green-MED: 31.3
(4.2)
MED: 31.3
(4)

Green-MED: 93.6
(14.9)
MED: 94.5
(13.5)

Green-MED: 109.3
(8.7)
MED: 110
(9.5)</td><td>HDG: 31.2
(3.8)

HDG: 92.9
(14.7)

HDG: 109.9
(10.3)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (kg)
Mean (SD)

Change in Waist Circumference (cm)
Mean (SD)</td><td>Green-MED: -3.7
(6.3)
MED: -2.7
(5.6)

Green-MED: -6.1
(6.2)
MED: -5.3
(5.7)</td><td>HDG: -0.4
(4.7)

HDG: -4
(5.6)</td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>89.8%</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not</td><td></td></tr>
</table>

contribute additional data	

N/A – Not applicable

Yates, 2011

Guideline record ID: 10936--1

Study characteristics		
Citation	Yates, T., Davies, M. J., Sehmi, S., Gorely, T., & Khunti, K. (2011). The Pre-diabetes Risk Education and Physical Activity Recommendation and Encouragement (PREPARE) programme study: are improvements in glucose regulation sustained at 2 years? Diabetic Medicine, 28(10), 1268-1271. https://doi.org/https://dx.doi.org/10.1111/j.1464-5491.2011.03357.x	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The Pre-diabetes Risk Education and Physical Activity Recommendation and Encouragement (PREPARE) programme study: are improvements in glucose regulation sustained at 2 years?	
Location	UK	
Trial name	Pre-diabetes Risk Education and Physical Activity Recommendation and Encouragement (PREPARE)	
Methods		
Inclusion criteria	"Overweight and obese individuals with impaired glucose tolerance were recruited from population-based Type 2 diabetes screening programmes between September 2006 and March 2007."	
Exclusion criteria	Not reported	
Setting	unclear (3-h group-based structured education programme, delivered by two trained educators to groups of up to 10 individuals)	
Intervention	"Group 2 (education; n = 31) received a standard 3-h group-based structured education programme, delivered by two trained educators to groups of up to 10 individuals. The programme was aimed at promoting increased physical activity, particularly walking activity, to levels that were consistent with minimum recommendations for health; specifically 30 min of moderate-intensity physical activity on at least 5 days per week [4]. The programme was designed to address key perceptions and knowledge of impaired glucose tolerance and to target the perceived effectiveness of exercise as a treatment for impaired glucose tolerance, walking self-efficacy beliefs, barriers to walking and self-regulatory strategies such as action planning and goal setting. Group 3 (education with pedometer; n = 33) received the same 3-h structured education programme, but with an enhanced self-regulation section that incorporated personalized steps⁄day targets and pedometer use to aid goal setting and self-monitoring. Both intervention conditions also received brief one-to-one counselling at 3 and 6 months, no further counselling was provided beyond this time point."	
Control/Comparator	"Group 1 (control; n = 34) received an advice leaflet."	
Treatment duration	24 months	
Follow-up from baseline	24 months	
Eligible outcome(s) reported	Waist Circumference, Body weight (kgs or lbs)	
Participant characteristics		
Number of participants	n= 73 Intervention group/s: Intervention 1: Education (n=29); Intervention 2: Education with pedometer (n=22)	

<table>
<tr><td></td><td>Comparator group: Control (n=22)</td></tr>
<tr><td>Mean age ± SD</td><td>65y (8)</td></tr>
<tr><td>Sex</td><td>35.62% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Intervention 1: Education: 80.4
(15.3)
Intervention 2: Education with pedometer: 81.3
(16.9)</td><td>Control: 80.8
(15.5)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Intervention 1: Education: 103
(13)
Intervention 2: Education with pedometer: 101
(12)</td><td>Control: 103
(9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Body weight (kg)
Mean (SD)</td><td>Intervention 1: Education: 79.4
(15.5)
Intervention 2: Education with pedometer: 82
(15.4)</td><td>Control: 80
(15.9)</td></tr>
<tr><td>Waist circumference (cm)
Mean (SD)</td><td>Intervention 1: Education: 100
(13)
Intervention 2: Education with pedometer: 100
(12)</td><td>Control: 101
(9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
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<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable

Yavari, 2012

Guideline record ID: 10937--1

Study characteristics		
Citation	Yavari, A., Najafipoor, F., Aliasgarzadeh, A., Niafar, M., & Mobasseri, M. (2012). Effect of aerobic exercise, resistance training or combined training on glycaemic control and cardiovascular risk factors in patients with type 2 diabetes. Biology of Sport, 29(2), 135-143. https://www.termedia.pl/Original-paper-EFFECT-OF-AEROBIC-EXERCISE-RESISTANCE-TRAINING-OR-COMBINED-TRAINING-ON-GLYCAEMIC-CONTROL-AND-CARDIO-VASCULAR-RISK-FACTORS-IN-PATIENTS-WITH-TYPE-2-DIABETES,78,23385,1,1.html	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	EFFECT OF AEROBIC EXERCISE, RESISTANCE TRAINING OR COMBINED TRAINING ON GLYCAEMIC CONTROL AND CARDIO-VASCULAR RISK FACTORS IN PATIENTS WITH TYPE 2 DIABETES	
Location	Iran	
Trial name	N/A	
Methods		
Inclusion criteria	"Inclusion criteria were as follows: established T2DM for more than one year duration, treatment only with oral hypoglycaemic agents (not taking insulin), an inactive previous lifestyle, A1c level < 11%."	
Exclusion criteria	"Exclusion criteria were BMI 43, age over 70 years, severe retinopathy, nephropathy and neuropathy, history of serious cerebrovascular or cardiovascular diseases, and severe musculoskeletal problems restricting physical activity."	
Setting	Unclear (The exercise sessions were regularly held two or three times a week with the close supervision of the project staff and trainers)	
Intervention	"The exercise sessions were regularly held two or three times a week with the close supervision of the project staff and trainers. All types of exercise training were done according to the ACSM guidelines. All sessions included 10-15 minutes of stretching and AEROBIC EXERCISE PROTOCOL: Participants of this group performed their activities using treadmill, elliptical or bicycle ergometers three times per week (on non consecutive days). Time of exercise was increased from 20 minutes per session (at 60% of maximum heart rate) to 60 minutes (at 75% of maximum heart rate) per session.; RESISTANT TRAINING PROGRAM: This programme was performed on different weight machines. Correct training techniques were instructed and supervised by professional trainers. The protocol was started on 2 days of the week during the first month and was increased to 3 non-consecutive days per week. Training was started during weeks 1 and 2 with intensity 60% one repetition maximum (1RM) and was progressed to intensity 75-80% 1RM. The number of sets was 1-2 during the first month. This programme included 10 different exercises for upper and lower body. Participants performed 3 sets of 8-10 repetitions (with a 90- 120 s rest between sets) of the following exercises: bench press, seated row, shoulder press, chest press, lateral pulldown, abdominal crunches, leg press, leg extension, triceps pushdown and seated bicep curls. COMBINED EXERCISE TRAINING PROGRAM: The subjects of this group did the aerobic exercise plus resistance training programmes 3 times a week. After a warm-up stage, they worked for 20-30 minutes on a treadmill or bicycle plus 2 sets of each of 8 exercises with 8-10 repetitions on weight machines"	
Control/Comparator	"subjects of the control group were instructed to maintain their present lifestyle until the end of the project."	
Treatment duration	12 months	

<table>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 80
Intervention group/s: Aerobic exercise (n=20); Resistance (n=20); Combined Training (n=20)

Comparator group: Control group (n=20)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>Not reported</td></tr>
<tr><td>Pre-existing medical condition</td><td>Type 2 diabetes mellitus</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight
Mean (SD)

BMI
Mean (SD)</td><td>Aerobic exercise: 68.6
(12.6)
Resistance: 84.1
(9)
Combined Training: 82.6
(16.6)

Aerobic exercise: 29.4
(5.7)
Resistance: 30.3
(4)
Combined Training: 28.8
(5.4)</td><td>Control group: 75.2
(12.7)

Control group: 32
(4.9)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight
Mean (SD)

BMI
Mean (SD)</td><td>Aerobic exercise: 69.3
(12.4)
Resistance: 82.9
(9.4)
Combined Training: 81.1
(14.4)

Aerobic exercise: 28.5
(4.7)
Resistance: 29.7
(3.9)
Combined Training: 27.8
(4.9)</td><td>Control group: 75.2
(12.8)

Control group: 31.3
(5.2)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

Compliance with treatment	Not reported
Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Yin, 2016

Guideline record ID: 10939--1

Study characteristics		
Citation	Yin, X., Yan, L., Lu, Y., Jiang, Q., Pu, Y., & Sun, Q. (2016). Correction of hypovitaminosis D does not improve the metabolic syndrome risk profile in a Chinese population: a randomized controlled trial for 1 year. Asia Pacific Journal of Clinical Nutrition, 25(1), 71-77. https://doi.org/https://dx.doi.org/10.6133/apjcn.2016.25.1.06	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Correction of hypovitaminosis D does not improve the metabolic syndrome risk profile in a Chinese population: a randomized controlled trial for 1 year	
Location	China	
Trial name	N/A	
Methods		
Inclusion criteria	"The participants were 35-60 years old, living in Jinan (latitude 36.6) for more than 5 years, employed in an office setting, and had >13 years of education, free of known diabetes, cardiovascular disease and hypertension, no use of vitamin D and calcium supplementation within 60 days of screening, <1 period of 20 minutes of strenuous physical activity per week, general good health, no smoking, no use of medication that influence body weight. Metabolic syndrome was identified using the updated National Cholesterol Education Program Adult Treatment Panel III criteria for Asian Americans. 18 Vitamin D nutritional status was based on 25(OH)D levels, which were assessed as "deficient" (<20 ng/mL); "insufficient" (20 ng/mL to 30 ng/mL) or "sufficient" (≥30 ng/mL). 19 On the basis of measurement of anthropometric variables and the results of biochemical profile, we choose participants suffered from both metabolic syndrome and vitamin D deficiency."	
Exclusion criteria	"Subjects with diabetes, serum calcium >2.55 mmol/L, males with serum creatinine >129 mmol/L and females with serum creatinine >104 mmol/L were excluded."	
Setting	Hospital, Home	
Intervention	"126 participants suffering from metabolic syndrome and hypovitaminosis D, otherwise healthy, were initially enrolled and randomly assigned to receive either vitamin D treatment (vitamin D treatment group) or placebo (control group). Participants took separate pills containing 700 IU cholecalciferol (vitamin D3) or separate matching placebo tablets containing microcrystalline cellulose. The subjects came to visit every second month for new supply and return of unused medication. During the 12-month trial, 3 participants discontinued treatment (2 and 1 from vitamin D treatment and control groups, respectively); 2 stopped for personal reasons (e.g. they lost interest), 1 subject experienced intestinal discomfort when taking the supplement and decided to stop participation. At the end of the 12th month 123 participants returned for evaluation of the same parameters measured at baseline."	
Control/Comparator	"126 participants suffering from metabolic syndrome and hypovitaminosis D, otherwise healthy, were initially enrolled and randomly assigned to receive either vitamin D treatment (vitamin D treatment group) or placebo (control group). Participants took separate pills containing 700 IU cholecalciferol (vitamin D3) or separate matching placebo tablets containing microcrystalline cellulose. The subjects came to visit every second month for new supply and return of unused medication. During the 12-month trial, 3 participants discontinued treatment (2 and 1 from vitamin D treatment and control groups, respectively); 2 stopped for personal reasons (e.g. they lost interest), 1 subject experienced intestinal discomfort when taking the supplement and decided to stop participation. At the	

<table>
<tr><td></td><td>end of the 12th month 123 participants returned for evaluation of the same parameters measured at baseline.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 126
Intervention group/s: Treatment group (n=63)

Comparator group: Control group (n=63)</td></tr>
<tr><td>Mean age ± SD</td><td>49.5y (8.72)</td></tr>
<tr><td>Sex</td><td>46.03% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Treatment group: 75.7
(3.5)

Treatment group: 27
(1.08)

Treatment group: 95.2
(3.27)</td><td>Control group: 75.5
(4.26)

Control group: 27.2
(0.96)

Control group: 93.3
(3.84)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Mean (SD)

BMI (kg/m2)
Mean (SD)

Waist circumference (cm)
Mean (SD)</td><td>Treatment group: 74.1
(3.48)

Treatment group: 26.5
(1.07)

Treatment group: 93.5
(3.04)</td><td>Control group: 74.8
(4.32)

Control group: 26.9
(1.01)

Control group: 92.6
(3.89)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>The compliance rate for vitamin D/placebo capsules was 95% in both groups.</td></tr>
</table>

Notes	
Additional included publications arising from this study that did not contribute additional data	

N/A – Not applicable

Yin, 2018

Guideline record ID: 10940--1

Study characteristics		
Citation	Yin, Z., Perry, J., Duan, X., He, M., Johnson, R., Feng, Y., & Strand, M. (2018). Cultural adaptation of an evidence-based lifestyle intervention for diabetes prevention in Chinese women at risk for diabetes: results of a randomized trial. International Health, 10(5), 391-400. https://doi.org/https://dx.doi.org/10.1093/inthealth/ihx072	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Cultural adaptation of an evidence-based lifestyle intervention for diabetes prevention in Chinese women at risk for diabetes: results of a randomized trial	
Location	China	
Trial name	Pathway to Health (PATH)	
Methods		
Inclusion criteria	"The study eligibility criteria were female residents aged 25-65 y, pre-diabetes (based on a previous health exam), overweight or obese (body mass index [BMI]≥24), not physically active (based on a short physical activity [PA] screening)9 and expressed interest in lifestyle changes."	
Exclusion criteria	"Individuals who had diagnosed diabetes or reported the use of medication for diabetes were excluded from the study."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"PATH intervention The PATH was a group-based lifestyle intervention built on the DPP Group Lifestyle Balance program13 and a feasibility study of a community-based lifestyle modification program for diabetes risk reduction in Mexican American women at risk for diabetes in San Antonio, TX, USA.14 PATH was a goal-based behavioral intervention with three goals: 5% weight loss, ≥30 min of MPA (3000-4000 moderate-intensity steps/d or an equivalent amount of other forms of PA) on most days of the week and a reduction in weekly caloric intake of 1000-1400 calories (200 calories/d) by adopting healthy eating practices (limiting foods high in fat and starch and increasing vegetables and fruits). PATH participants received training to individualize the three goals into short- and long-term goals and re-evaluate the goals with the support of Community Health Educators (CHEs). For example, each participant identified the 5% weight goal based on her weight at baseline and developed short-term weight loss goals. Intervention activities were adapted to address differences in lifestyle and culture, traditional values associated with foods (e.g., preference for high starch foods), cooking practices, resources available and healthcare practices in China. We also modified the nutritional messages and recommendations based on the Chinese Food Guide Pagoda.15 PATH program materials are available for public use at http://www.pathdpp.com. The 6-mo intervention included 12 large-group health education sessions on nutrition, PA, behavioral monitoring/goal setting; 10 small-group sessions for goal setting and evaluation, counselling and social support; and a final celebration party. The intervention was delivered by CHEs who were recruited from the chronic disease management team in the two CHCs. The CHEs received 50 h of training in lifestyle interventions, PA, nutrition and community-based health promotion. At the beginning of the intervention the participants established their personalized behavioral goals and identified strategies to achieve the goals under the guidance of the CHEs in a PATH Participant's Handbook, which included a PATH description, individual goal worksheets, weekly logs and class handouts. The participants received training on walking with a pedometer and strengthening exercises with a resistance band, an exercise DVD for exercise at home, an oil and salt measuring cup to monitor the amount of oil and salt used in cooking and information on healthy cooking with recipes for reducing starch and fat intake. The class topics and schedules are shown in Table 1. Participant's weight was	

<table>
<tr><td></td><td>recorded at each meeting. CHEs also made weekly phone calls to the participants for problem solving and support if they missed a session. The participants used the PATH Handbook to record their goal progress and monitor their weekly dietary and physical activities. All intervention sessions lasted 60 min and were conducted at two CHCs and a health screening center. The health education session began with a weigh-in and review of the step count for the previous week, followed by a review of the previous class content, a 30-min lecture (using participatory teaching methods) and finally a discussion. Small-group meetings were attended by three to five participants and included a review of previous material, discussion of issues related to topics of previous lectures, sharing of problem-solving strategies and evaluation of individual goals. Voluntary resistance band exercise sessions were offered 30 min before class time from week 8. Participants in the intervention group were allowed to make up missed health classes at a later time.”</td></tr>
<tr><td>Control/Comparator</td><td>“Comparison group: general healthy lifestyle education Participants in the comparison group received a counselling session with a nurse to review the results of the baseline testing, a package with information on nutrition and PA, a pedometer with instructions, an oil and salt measuring cup and a notebook for taking notes at health classes and for tracking weight and PA, but they were not given specific counselling or reinforcement to do so. The participants were invited to attend six general health education classes on PA, nutrition, chronic diseases (obesity, diabetes, heart diseases) and menopause at the same venue as the intervention group. The sessions were 3-4 wk apart and lasted about 1 h. The participants did not have small-group meetings or group exercise sessions.”</td></tr>
<tr><td>Treatment duration</td><td>6 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 184
Intervention group/s: Intervention group (n=109)

Comparator group: Comparison group (n=75)</td></tr>
<tr><td>Mean age ± SD</td><td>51.96y (7.22)</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>No pre-existing medical condition</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)
Estimated marginal means (M) and (SE)

BMI (kg/m2)
Estimated marginal means (M) and (SE)

Waist circumference (cm)
Estimated marginal means (M) and (SE)</td><td>Intervention group: 67.13 (0.88)

Intervention group: 27.2 (0.28)

Intervention group: 94.14 (0.74)</td><td>Comparison group: 67.51 (1.13)

Comparison group: 27.19 (0.34)

Comparison group: 95.58 (0.87)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (kg)</td><td>Intervention group: 66.07 (0.92)</td><td>Comparison group: 66.82 (1.17)</td></tr>
</table>
</td></tr>
</table>

	Estimated marginal means (M) and (SE) BMI (kg/m2) Estimated marginal means (M) and (SE) Waist circumference (cm) Estimated marginal means (M) and (SE)	 Intervention group: 26.8 (0.31) Intervention group: 92.84 (0.75)	 Comparison group: 26.94 (0.37) Comparison group: 95.08 (0.89)
Outcome measure at final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Change in outcome measure from baseline to 12 months or closest time point	Variable	Intervention arm/s	Comparator
	≥5% weight loss Proportion (%)	Intervention group: 28.6	Comparison group: 15
Change in outcome measure from baseline to final follow-up/endpoint	Variable	Intervention arm/s	Comparator
Compliance with treatment	The average attendance of the 23 sessions was 67.5%, with 66 intervention participants attending 70% or more of the sessions.		
Notes			
Additional included publications arising from this study that did not contribute additional data			

N/A – Not applicable

Zamorano, 2021

Guideline record ID: 10744--1

Study characteristics		
Citation	Zamorano, A. S., Wilson, E. M., Liu, J., Leon, A., Kuroki, L. M., Thaker, P. H., McCourt, C. K., Fuh, K. C., Powell, M. A., Mutch, D. G., Evanoff, B. A., Colditz, G. A., & Hagemann, A. R. (2021). Text-message-based behavioral weight loss for endometrial cancer survivors with obesity: a randomized controlled trial. Gynecologic Oncology, 162(3), 770-777. https://doi.org/https://dx.doi.org/10.1016/j.ygyno.2021.06.007	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Text-message-based behavioral weight loss for endometrial cancer survivors with obesity: A randomized controlled trial	
Location	USA	
Trial name	N/A	
Methods		
Inclusion criteria	“Endometrial cancer survivors over the age of 18 years with a BMI ≥ 30 kg/m2 . To be included, patients must have completed all surgical, chemotherapy, or radiation treatment for endometrial cancer and must have had a life expectancy of at least one year with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2. Additionally, patients must have had access to a phone capable of receiving text messages and must not have been participating in another formal weight loss program.”	
Exclusion criteria	Not reported	
Setting	Home, University/research centre	
Intervention	“Initially, each patient in the intervention group received a BodyTrace scale, which used cellular technology to connect to and transmit information to the third-party vendor, ScaleDown™. ScaleDown™ then used advanced algorithms to monitor trends in weight change trajectories. In response to daily weighing, the system then asked questions via text message and gave each participant personalized weight loss advice. Proprietary algorithms in ScaleDown's™ behavioral phenotyping engine personalized this content, which became more personalized with time. However, three months into participant randomization, ScaleDown™ was sold, and the company was abruptly no longer able to provide services to our participants.Participants already in the text-message intervention arm (n = 16) kept the scale they had received from ScaleDown™, were immediately advised of the plan to replace this intervention and were encouraged to continue using it daily without text messaging support in the intervening time. The third-party intervention was replaced with Interactive Obesity Treatment Approach (iOTA), a Washington University-based intervention that was in development as a workplace intervention. In brief, iOTA includes one-on-one counseling with a health coach, tailored behavioral goals, skills training, and behavior self-monitoring delivered by daily text messaging. Our research assistant (AL) was trained as a health coach as we implemented this new intervention. New participants randomized to the intervention arm after implementation of iOTA received a Balance High Accuracy Digital Body Fat Scale at the time of enrollment and randomization. This digital scale did not connect directly to iOTA; instead, participants were asked to text their weight to iOTA weekly. A health coach (AL) met with each iOTA participant, either in-person or by phone, to review that individual's health risk assessment and to choose three behavior change goals related to healthy eating and physical activity. Participants had weekly "check-ins" by text message, prompting them to reply with data on their weight and their chosen behavior goals. Participants then immediately received individually tailored self-monitoring feedback messages and motivational strategies.”	

<table>
<tr><td>Control/Comparator</td><td>“Participants in the enhanced usual care group received a brief inperson counseling session by the research assistant and received handouts based on American Cancer Society guidelines on healthy eating and exercise. These materials encouraged weight loss through counting calories, recording dietary intake, and a walking exercise program. Participants' efforts were not reinforced or monitored by study staff.”</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>BMI or BMI z-score/BMI-for-age centiles, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 80
Intervention group/s: Text-message based intervention (n=40)

Comparator group: Enhanced Usual Care (n=40)</td></tr>
<tr><td>Mean age ± SD</td><td>Not reported</td></tr>
<tr><td>Sex</td><td>100.00% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Endometrial cancer survivors</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (lbs)
Least square means (95% CI)</td><td>Text-message based intervention: 239.1 (225.6-252.6)</td><td>Enhanced Usual Care: 254.3 (233.5-275.1)</td></tr>
<tr><td>BMI (kg/m2)
Median (min, max)</td><td>Text-message based intervention: 39 (30.3-60.4)</td><td>Enhanced Usual Care: 38.4 (30.1-73.7)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight (lbs)
Least square means (95% CI)</td><td>Text-message based intervention: 244 (226.9-261.1)</td><td>Enhanced Usual Care: 245.9 (228.3-263.6)</td></tr>
</table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Change in weight (lbs)
Least square means (95% CI)</td><td>Text-message based intervention: 4.9 (-3.3-13.1)</td><td>Enhanced Usual Care: -8.4 (-16.8-0)</td></tr>
</table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Compliance with treatment</td><td>Not reported</td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from</td><td></td></tr>
</table>

this study that did not contribute additional data	

N/A – Not applicable

Zelicha, 2022

Guideline record ID: 10746--1

Study characteristics		
Citation	Zelicha, H., Kloting, N., Kaplan, A., Yaskolka Meir, A., Rinott, E., Tsaban, G., Chassidim, Y., Bluher, M., Ceglarek, U., Isermann, B., Stumvoll, M., Quayson, R. N., von Bergen, M., Engelmann, B., Rolle-Kampczyk, U. E., Haange, S.-B., Tuohy, K. M., Diotallevi, C., Shelef, I., . . . Shai, I. (2022). The effect of high-polyphenol Mediterranean diet on visceral adiposity: the DIRECT PLUS randomized controlled trial. BMC Medicine, 20, 327. https://doi.org/https://dx.doi.org/10.1186/s12916-022-02525-8	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	The effect of high-polyphenol Mediterranean diet on visceral adiposity: the DIRECT PLUS randomized controlled trial	
Location	Israel	
Trial name	Dietary Intervention Randomized Controlled Trial Polyphenols Unprocessed (DIRECT PLUS)	
Methods		
Inclusion criteria	"Inclusion Criteria: age >30 years with abdominal adiposity (waist circumference: men > 102 cm, women > 88 cm) or dyslipidemia (TG>150mg/dl and HDL-c <40mg/dL for men and <50mg/dL for women)."	
Exclusion criteria	"Individuals who may not be able to partake in PA in the gym; TGs>400 mg/dL; serum creatinine>2 mg/dL; disturbed liver function; major illness that might require hospitalization; pregnant or lactating women; presence of active cancer, is receiving or received chemotherapy in the last three years; participation in another trial; participants who are treated with Coumadin (warfarin) - given its interaction with vitamin K and high level of this vitamin in "Mankai" green shake; pacemaker or platinum implant, because of the impossibility of MRI screening."	
Setting	Community (e.g. sports club, places of worship, commercial weight loss programs), University/research centre	
Intervention	"MED group: In addition to PA, participants were instructed to adopt a calorie-restricted MED diet. The MED diet assigned was rich in vegetables, with poultry and fish replacing beef and lamb. The diet also included 28g/day of walnuts (containing 440mg polyphenols/day; gallic acid equivalents (GAE), including, mostly, ellagitannins, ellagic acid and its derivatives. Green-MED group: In addition to PA and the provision of 28g/day walnuts, the green-MED diet was restricted in processed and red meat and was richer in plants and polyphenols. The participants were guided to further consume the following provided items: 3-4 cups/day of green tea and 100g/day of frozen Wolffia globosa (Mankai strain) plant frozen cubes, as a green shake replacing dinner. Both green tea and Mankai together provided additional daily intake of 800mg polyphenols ((GAE), including catechins (flavanols)) beyond the polyphenol content in the prescribed MED diet. Both the MED and green-MED diets were equally calorie-restricted (1500-1800 kcal/day for men and 1200-1400 kcal/ day for women). All the participants received free gym memberships and educational sessions to engage in moderate-intensity PA, 18~80% of which included an aerobic component."	
Control/Comparator	"HDG group: In addition to PA, participants received standard nutritional counselling to promote a healthy diet and to achieve a similar intervention intensity."	
Treatment duration	18 months	
Follow-up from baseline	18 months	

<table>
<tr><td>Eligible outcome(s) reported</td><td>Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 286
Intervention group/s: Green-MED (n=92); MED (n=96)

Comparator group: HDG (n=98)</td></tr>
<tr><td>Mean age ± SD</td><td>51.1y (10.6)</td></tr>
<tr><td>Sex</td><td>11.89% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>NAFLD</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>BMI (kg/m2)
Mean (SD)

Waist circumference - Women (cm)
Mean (SD)

Waist Circumference - Men (cm)
Mean (SD)</td><td>Green-MED: 31.2
(4)
MED: 31.2
(4)

Green-MED: 100.8
(9.9)
MED: 104.9
(10)

Green-MED: 110
(7.3)
MED: 110.7
(9.4)</td><td>HDG: 31.2
(3.8)

HDG: 103.8
(9.7)

HDG: 110.7
(10.1)</td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td>
<table>
<tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr>
<tr><td>Weight Change (%)
Mean (SD)

Change in Waist Circumference (%)
Mean (SD)</td><td>Green-MED: -3.9
(6.5)
MED: -2.7
(5.6)

Green-MED: -5.7
(5.7)
MED: -4.7
(5)</td><td>HDG: -0.4
(5)

HDG: -3.6
(5.1)</td></tr>
</table>
</td></tr>
<tr><td>Compliance with treatment</td><td>89.8%</td></tr>
<tr><td colspan="2">Notes</td></tr>
</table>

Additional included publications arising from this study that did not contribute additional data	Yaskolka Meir, A., Rinott, E., Tsaban, G., Zelicha, H., Kaplan, A., Rosen, P., Shelef, I., Youngster, I., Shalev, A., Blüher, M., Ceglarek, U., Stumvoll, M., Tuohy, K., Diotallevi, C., Vrhovsek, U., Hu, F., Stampfer, M., & Shai, I. (2021). Effect of green-Mediterranean diet on intrahepatic fat: the DIRECT PLUS randomised controlled trial. Gut, 70(11), 2085-2095. https://doi.org/https://dx.doi.org/10.1136/gutjnl-2020-323106

N/A – Not applicable

Zhang, 2016

Guideline record ID: 10748

Study characteristics		
Citation	Zhang, H.-J., He, J., Pan, L.-L., Ma, Z.-M., Han, C.-K., Chen, C.-S., Chen, Z., Han, H.-W., Chen, S., Sun, Q., Zhang, J.-F., Li, Z.-B., Yang, S.-Y., Li, X.-J., & Li, X.-Y. (2016). Effects of moderate and vigorous exercise on nonalcoholic fatty liver disease: a randomized clinical trial. JAMA Internal Medicine, 176(8), 1074-1082. https://doi.org/https://dx.doi.org/10.1001/jamainternmed.2016.3202	
Design & type	Randomised controlled trial (RCT)	Parallel design
Title	Effects of Moderate and Vigorous Exercise on Nonalcoholic Fatty Liver Disease: A Randomized Clinical Trial	
Location	China	
Trial name	N/A	
Methods		
Inclusion criteria	"Subjects with NAFLD determined by 1H MRS (intrahepatic triglyceride content 5%); 40-65 years old; Waist circumference >90cm for men and >85cm for women."	
Exclusion criteria	"Consumed more than an average of 140 grams of ethanol (10 alcoholic drinks) per week in men and 70 grams of ethanol (five drinks) in women during the past six 9 months; A history of acute or chronic viral hepatitis, drug-induced liver diseases, and autoimmune hepatitis; Myocardial infarction in the past six months; Biliary obstructive diseases; Uncontrolled hypertension (i.e. systolic BP>180 mmHg, and/or diastolic DBP >100 mmHg); Chronic kidney disease (serum creatinine •1.5 mg/dL in men and •1.3 mg/dL in women); Heart failure (New York Heart Association III or IV); Currently participating in weight loss programs; Currently pregnant or planning to be pregnant; Having any medical condition that would affect metabolism (i.e. diabetes, known hyperthyroidism or hypothyroidism); Having a medical condition that would limit exercise participation and taking medication that would affect metabolism or weight loss (i.e. thyroid medication and glucocorticoids) or would alter the heart rate response during exercise (i.e. B-blockers); Unable to participate in the follow-up examination."	
Setting	Home, Community (e.g. sports club, places of worship, commercial weight loss programs)	
Intervention	"VIGOROUS-MODERATE EXERCISE: Participants were instructed to participate in a 6-month vigorous exercise program followed by a 6-month moderate exercise program. During the vigorous exercise sessions, participants jogged on a treadmill and gradually increased exercise intensity so that their heart rate was 65% to 80% of their maximum predicted heart rate (equivalent to 8.0-10.0metabolic equivalents). They were instructed to exercise at this intensity for 30 minutes. Their heart rates were monitored by a wireless heart rate monitor (BH Fitness). The maximum predicted heart rate was calculated as 220/min (210/min for women) minus the participant's age. Participants were required to participate in 5 vigorous exercise sessions each week supervised by a study physician at a local community health center. After 6 months of vigorous exercise, participants switched to moderate exercise for another 6 months. Participants received follow-up telephone calls from study staff twice per week to assess their adherence to the program and provide suggestions for improvement. Before starting the vigorous and moderate exercise programs, participants were trained for 2 to 4 weeks to achieve the appropriate exercise intensity. MODERATE EXERCISE: Participants assigned to the moderate exercise program were instructed to participate in a 12-month moderate exercise program. In the moderate exercise program, participants were instructed to briskly walk at approximately 120 steps per minute so that their heart rate was 45% to 55% of their maximum predicted heart rate (equivalent to 3.0-6.0 metabolic equivalents) for 30 minutes per session and 5 sessions per week. Participants in the moderate exercise program were required to wear pedometers	

<table>
<tr><td></td><td>(Omron Healthcare) and record their daily exercise in a log, which was reviewed weekly by study staff. Participants received follow-up telephone calls from study staff twice per week to assess their adherence to the program and provide suggestions for improvement. Before starting the vigorous and moderate exercise programs, participants were trained for 2 to 4 weeks to achieve the appropriate exercise intensity. BOTH: participants attended group health education sessions, which were held biweekly in the first 6 months and monthly in the last 6 months of the intervention. Health education content (eg, general health knowledge of NAFLD and metabolic diseases, smoking cessation, and elements of a healthy lifestyle) was identical among the randomization groups, with the exception of a behavioral component on adherence to exercise programs that was conducted only in the intervention groups. All study participants were instructed to not change their diet."</td></tr>
<tr><td>Control/Comparator</td><td>"CONTROL: Participants in the control group were instructed to not change their physical activity routine. All participants attended group health education sessions,which were held biweekly in the first 6 months and monthly in the last 6 months of the intervention. Health education content (eg, general health knowledge of NAFLD and metabolic diseases, smoking cessation, and elements of a healthy lifestyle) was identical among the randomization groups. All study participants were instructed to not change their diet."</td></tr>
<tr><td>Treatment duration</td><td>12 months</td></tr>
<tr><td>Follow-up from baseline</td><td>12 months</td></tr>
<tr><td>Eligible outcome(s) reported</td><td>Dual energy X-ray absorptiometry (DXA), BMI or BMI z-score/BMI-for-age centiles, Waist Circumference, Body weight (kgs or lbs)</td></tr>
<tr><td colspan="2">Participant characteristics</td></tr>
<tr><td>Number of participants</td><td>n= 220
Intervention group/s: Vigorous-Moderate Exercise (n=73); Moderate Exercise (n=73)

Comparator group: Control (n=74)</td></tr>
<tr><td>Mean age ± SD</td><td>53.9y (7.1)</td></tr>
<tr><td>Sex</td><td>67.73% female</td></tr>
<tr><td>Pre-existing medical condition</td><td>Nonalcoholic fatty liver disease</td></tr>
<tr><td colspan="2">Results</td></tr>
<tr><td>Outcome measure at baseline</td><td>
<table>
<tr><th>Variable</th><th>Intervention arm/s</th><th>Comparator</th></tr>
<tr><td>Weight (kg) - Baseline
Mean (SD)</td><td>Vigorous-Moderate Exercise:
71.7
(10.1)
Moderate Exercise: 71.1
(10.1)</td><td>Control: 72.1
(8.5)</td></tr>
<tr><td>Waist circumference (cm) - Baseline
Mean (SD)</td><td>Vigorous-Moderate Exercise:
95.2
(7.4)
Moderate Exercise: 95.7
(6.7)</td><td>Control: 96.1
(6.9)</td></tr>
<tr><td>BMI - Baseline
Mean (SD)</td><td>Vigorous-Moderate Exercise:
27.9
(2.7)
Moderate Exercise: 28.1
(3.3)</td><td>Control: 28
(2.7)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Outcome measure at 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Outcome measure at final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to 12 months or closest time point</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td>Change in body fat mass (kg)
Mean (95% CIs)</td><td>Vigorous-Moderate Exercise: -1.66
(-2.1--1.21)
Moderate Exercise: -0.51
(-0.95--0.08)</td><td>Control: -0.23
(-0.66-0.19)</td></tr><tr><td>Change in weight (kg)
Mean (95% CIs)</td><td>Vigorous-Moderate Exercise: -3.19
(-3.82--2.55)
Moderate Exercise: -2.61
(-3.24--1.98)</td><td>Control: -1.11
(-1.72--0.5)</td></tr><tr><td>Change in waist circumference (cm)
Mean (95% CIs)</td><td>Vigorous-Moderate Exercise: -2.85
(-3.72--1.98)
Moderate Exercise: -2.02
(-2.87--1.16)</td><td>Control: -0.25
(-1.08-0.58)</td></tr></table></td></tr>
<tr><td>Change in outcome measure from baseline to final follow-up/endpoint</td><td><table><tr><td>Variable</td><td>Intervention arm/s</td><td>Comparator</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Compliance with treatment</td><td></td></tr>
<tr><td colspan="2">Notes</td></tr>
<tr><td>Additional included publications arising from this study that did not contribute additional data</td><td></td></tr>
</table>

N/A – Not applicable