Appendix 5

Data from included studies

Studies are listed alphabetically.

Burke et al.

Study details	Participants	Outcome measures
Author: Burke *et al.*[71] (Burke *et al.*[104]) Year: 2008 Country: USA Study design: RCT Number of centres: one Funding: National Institutes of Health, Center for Research in Chronic Disorders, Obesity and Nutrition Research Center, Heinz Nutrition Laboratory, General Clinical Research Center, University of Pittsburgh Recruitment dates: three cohorts recruited between September 2002 and May 2004 Setting: university Length of follow-up: 18 months	Number of participants randomised: 200 Intervention 1 – preference for standard diet (pref STD-D) ($n=48$) Intervention 2 – preference for lacto-ovo-vegetarian diet (pref LOV-D) ($n=35$) Intervention 3 – no preference for standard diet (no pref STD-D) ($n=48$) Intervention 4 – no preference for lacto-ovo-vegetarian diet (no pref LOV-D) ($n=45$) Sample attrition/dropout: 44 were lost to follow-up or dropped out of the groups as follows: pref STD-D – 12 pref LOV-D – 7 no pref STD-D – 14 no pref LOV-D – 11 Plus 15 'discarded' from intervention one, and nine excluded after becoming ineligible following randomisation. Total attrition rate was 68 (34%) Attendance at sessions measured: yes Other measures of adherence: yes Sample crossovers: none Inclusion criteria for study entry: Age 18–55 years, BMI of 27–43 kg/m^2, willingness to be randomised to one of two treatment preference conditions and one of two dietary conditions, successful completion of a 5-day food diary, willingness and ability to provide informed consent Exclusion criteria for study entry: current medical condition requiring physician supervision of diet or physical activity, physical limitation restricting exercise ability, pregnancy or intention to become pregnant during the study, current treatment with a medication that might affect weight, alcohol intake >4 drinks/day, participation in a weight loss programme or use of weight loss medication in past 6 months, abstention from eating meat, poultry or fish in the past month Characteristics of participants: Gender, M : F, *n* (%): pref STD-D – 6 (12.5) : 42 (87.5); pref LOV-D – 7 (20) : 28 (80); no pref STD-D – 6 (12.5) : 42 (87.5); no pref LOV-D – 4 (9) : 41 (91) Age (years), mean (SD): pref STD-D – 43.2 (9.4); pref LOV-D – 44.3 (8.4); no pref STD-D – 43.2 (8.4); no pref LOV-D – 43.2 (8.6) Ethnicity – white : non-white, n (%): pref STD-D – 34 (71) : 14 (29); pref LOV-D – 25 (71) : 10 (29); no pref STD-D – 34 (71) : 14 (29); no pref LOV-D – 31 (69) : 14 (31) Paffenbarger Activity Questionnaire (kilocalories expended/week), mean (SD) 1942.20 (2291.78)[a] BMI kg/m^2, mean (SD): pref STD-D – 34.5 (3.9); pref LOV-D – 34.1 (3.5); no pref STD-D – 32.9 (4.1); no pref LOV-D – 33.7 (4.3) Weight (kg), mean (SD): pref STD-D – 97.2 (12.9); pref LOV-D – 96.7 (12.1); no pref STD-D – 92.4 (16.1); no pref LOV-D – 91.8 (15.4)	Primary outcomes: change in body weight from baseline to 18 months Secondary outcomes: BMI, high- and low-density lipoprotein cholesterol, triglycerides, glucose levels, insulin levels, BP, waist circumference Facilitators and barriers: Barriers to Healthy Eating Scale (22-item questionnaire), Correlates of Maintenance to a Low-Fat Diet (25-item scale), Hunger Satiety Scale (6-item), Self-Efficacy in Weight Management (measures of adherence) Methods of assessing outcomes: weight measured on the Tanita Digital Scale. Height measured on a wall mounted stadiometer

	Baseline data are provided for the following factors, but have not been extracted here: low- and high-density lipoprotein cholesterol, triglycerides, glucose levels, insulin levels, BP, waist circumference, Beck Depression Inventory-II scores, physical and psychological function scores, hunger satiety, weight efficacy lifestyle scores, employment status, educational attainment, marital status, total energy, total fat, carbohydrates, animal protein, vegetable protein and fibre Comorbid conditions, *n* (%):[b] coronary heart disease – 2 (1.0); hypertension – 48 (26.4); elevated cholesterol – 35 (19.2); history of emotional/psychological problems – 11 (6.0) % weight lost before starting: not reported

The PREFER study

Aim or goal: weight loss phase (up to 12 months) based on standard weight loss treatment goal of 1–2 lb per week. Weight maintenance phase (months 13–18)

Study hypothesis is that choice of either a standard calorie and fat-restricted diet (STD-D) or a calorie- and fat-restricted (LOV-D) would result in greater weight loss compared with having one of these diets randomly assigned. Secondary hypothesis is LOV-D results in greater weight loss than STD-D

Intervention details

Randomised group 1 – dietary preference		**Randomised group 2 – no dietary preference**	
Participants choose between STD-D and LOV-D		**Participants randomised to STD-D and LOV-D**	
No pref STD-D	**No pref LOV-D**	**STD-D**	**LOV-D**
(*n* = 48)	**(*n* = 45)**	**(*n* = 48)**	**(*n* = 35)**
Diet:	*Diet:*	*Diet:*	*Diet:*
Details, type of diet: calorie and fat restriction	*Details, type of diet:* calorie and fat restriction, and elimination of meat, poultry and fish consumption by the sixth week. Participants were instructed to eliminate these foods at breakfast, then lunch, then dinner and to record in their diaries when they ate meals containing these foods. Four sessions by a vegetarian nutritionist who advised participants on how to adopt the eating plan as well as including family members. Otherwise the content and behavioural strategies taught were the same as intervention 1	As intervention 1	As intervention 2
Calories: reduce maximum daily calorie intake to 1200 kcal (women) 1500 kcal (men) for those weighing < 90.5 kg at baseline; 1500 kcal (women) 1800 kcal (men) for those weighing > 90.5 kg at baseline. Minimum daily intake was 1000 kcal		*Exercise:*	*Exercise:*
Proportions of diet:		As intervention 1	As intervention 1
Reduce fat intake to 25% of total kilocalorie intake, but not less than 10% fat		*Behaviour modification:*	*Behaviour modification:*
Monitoring: participants recorded their calorie and fat content of foods eaten in a weekly diary. At each session a new diary was provided and completed diaries were collected and returned at the next session after interventionists reviewed and annotated the diaries		As intervention 1	As intervention 1
Exercise:		*Ongoing support:*	*Ongoing support:*
Mode: instruction to exercise given during group meetings, with the actual exercise to be done individually		As intervention 1	As intervention 1
Type: mostly walking			
Frequency and length of each session and total number sessions: participants encouraged to walk at least 50 minutes per week initially, gradually increasing to at least 150 minutes per week by week 6			

Delivered: exercise physiologist *Level of supervision:* not reported *Monitoring:* daily recording of exercise in diaries, as above under 'diet' *Behaviour modification:* *Mode:* group, 10–20 participants *Type:* standard cognitive behaviour therapy. Based on several models of motivation and behavioural change, such as Social Cognitive Theory *Content:* environmental modification, problem solving, modelling, relapse prevention, goal-setting, self-monitoring, self-reinforcement, cognitive restructuring, stimulus control, social assertion, and skill development. A cooking class and shopping tour was also given *Frequency and length of each session and total number sessions:* 32 treatment sessions (lasting 60 minutes) over 12 months. Sessions held in the evening weekly for first 6 months, then every 2 weeks for months 7–9 and monthly for months 10–12 *Delivered:* master's prepared dietitian, exercise physiologist, or nurse behavioural scientist. Intervention manuals provided to ensure integrity of protocol *Ongoing support:* None. After 12 months the maintenance phase began and no further contact was made with participants until the final 18 month assessment *Other details:* Participants received *Cooking Light* magazine as an incentive	*Calories:* as intervention 1 *Proportions of diet:* as intervention 1 *Monitoring:* as intervention 1 *Exercise:* As intervention 1 *Behaviour modification:* As intervention 1 *Ongoing support:* As intervention 1 *Other details:* Participants received *Vegetarian Times* magazine as an incentive

a Only mentioned in relation to food diary data entered into the Nutrition Data System-Research software as a measure of adherence.
b Based on a baseline sample of 182 participants (all randomised groups combined) as reported in Burke and colleagues.[105] (Note: this is a different denominator to the $n=176$ for whom baseline data were presented in Burke and colleagues.[71])

Results

Outcomes	Pref STD-D ($n=48$)	Pref LOV-D ($n=35$)	No pref STD-D ($n=48$)	No pref LOV-D ($n=45$)	p-value, 95% CI
% weight change (baseline to 18 months), mean (SD)	–3.9 (6.1)	–5.3 (6.2)	–8.0 (7.8)	–7.9 (8.1)	0.30
Maintenance of weight loss					
Weight change (baseline to 12 months), kg[a]	–7.6	–7.9	–9.7	–9.7	
Weight change (12–18 months maintenance phase), kg[a]	+2.9	+3.3	+2.4	+1	
% change in BMI kg/m^2, mean (SD)	–3.9 (5.9)	–4.5 (7.4)	–7.8 (7.9)	–7.9 (8.2)	Not reported for between group comparisons
Other intermediate outcomes	Between months 6 and 18 there was a significant difference in weight regain between preference groups. Participants who chose their diet (i.e. pref STD-D or pref LOV-D) regained 4.5% (95% CI –5.8 to –3.2), while those with assigned diets (i.e. no pref STD-D or no pref LOV-D) regained 2.1% (95% CI –3.4 to –0.8), $p<0.001$ Over time there was no preference × diet interaction, $p=0.34$ Comments: results also presented for changes in cholesterol, glucose levels, insulin levels, kilocalorie consumption, fat consumption, carbohydrate consumption, animal protein consumption, vegetable protein consumption, and fibre consumption but not extracted here				

a Calculated by reviewer.

Methodological comments/notes

- Allocation to treatment groups: no information is given on the methods of the randomisation procedure. Two-stage randomisation process after stratification on basis of gender, ethnicity and diet preference: (i) participants were randomised to the dietary preference and no dietary preference groups in a 3 : 2 ratio. The choice of ratio as based on a pilot study in which 29%–34% of the participants selected the vegetarian diet. It was projected that the ratio of participants who would prefer the STD-D to the LOV-D diet would therefore be 2 : 1. To ensure an adequate number of participants who preferred the LOV-D in the dietary preference group a 3 : 2 ratio was therefore used. Those in the dietary preference group who preferred the LOV-D received this option; those who preferred the STD-D underwent a random selection process with 50% probability of being included in the study (done to obtain a fair balance in size across the four groups). This resulted in 15 randomised participants being excluded from the study due to the STD-D being oversubscribed. (ii) Participants randomised to the no preference diet group were then further randomised between the LOV-D and STD-D on a 1 : 1 ratio. Therefore in terms of randomised comparison of weight loss interventions only the preference groups were randomised
- Blinding: not reported except in relation to food diary data entered into the Nutrition Data System-Research software as a measure of adherence
- Comparability of treatment groups: statistically significant differences between the dietary preference and no dietary preference conditions at baseline on mean weight [98.14 kg (SD 12.7) vs 93.64 kg (SD 16.4) respectively, $p = 0.01$]. It is also mentioned that cholesterol differed between preference groups. Both weight and cholesterol were included in the mixed model as a covariate (see below). No significant differences were reported for demographic variables
- Method of data analysis: outcomes were assessed at 6, 12 and 18 months. Analysis of variance (ANOVA), Kruskal–Wallis test, chi-square analysis and Fisher's exact test were used to compare preference groups (yes/no), diet groups and their combinations on participant characteristics and response variables at baseline. Mixed models were estimated for each outcome using the restricted maximum likelihood method. The effects included in the mixed model included fixed effects for diet, preference, time and their interactions and a random effect for participant and cohort
- ITT analysis: states that an ITT analysis was to be conducted which would include all randomised participants. In actuality the analysis excludes 24 of the randomised population (15 who were excluded from the STD-D subgroup of the dietary preference intervention, and nine who were excluded because they no longer met the eligibility criteria). Participants who dropped out over the course of the intervention were retained in the analysis. Mentions that missing data were handled through maximum likelihood estimation using all available data
- Sample size/power calculation: fixed effects ANOVA indicated that 33 participants in each of the four groups would provide 80% power to detect a modest effect size for the interaction between diet and preference at a significance level of 0.05. To test the main effects of diet and preference using two-sided sample *t*-tests with a significance level of 0.05, 66 participants in both diet groups and both preference groups would provide 80% power to detect a 2.2 kg difference between the groups assuming a common SD of 4.4 kg
- Attrition/dropout: reasons given. No statistically significant difference among the groups in attrition rates ($p = 0.82$). Nine participants were excluded on the grounds of ineligibility postrandomisation that may introduce a bias

General comments

- Generalisability: participants recruited through database of individuals seeking weight loss treatment at the Obesity Nutrition Research Centre at the University of Pittsburgh, the university and medical centre audio announcement system and direct mailing from purchased mailing lists. The results are generalisable to predominantly white, obese but otherwise healthy middle-aged women of reasonable socioeconomic status (in terms of employment, education and household income)
- Outcome measures: none
- Facilitators/barriers not reported as outcomes: not reported. Eligible individuals were asked their preference for the two dietary interventions prior to randomisation. For those not in their preferred intervention this may have affected their adherence to the diet (as noted by the reviewers, not the authors)
- Intercentre variability: not applicable
- Conflict of interests: none reported

Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Unclear
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	No
4. Were outcome assessors blinded to the treatment allocation?	Unclear
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	No
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	Yes
9. (i) Did the analysis include an intention to treat analysis?	No
(ii) If so, was this defined?	
10. (i) Did the analysis account for missing data?	No
(ii) If so, were the methods appropriate?	

Dubbert and Wilson

Study details	Participants	Outcome measures
Author: Dubbert and Wilson[68] Year: 1984 Country: USA Study design: RCT Number of centres: not reported Funding: not reported. The research was based on the first author's doctoral dissertation Recruitment dates: not reported Setting: not reported Length of follow-up: 30 months after end of treatment (~ 34 months after randomisation)	Number of participants: Individual treatment with weekly (distal) goals: number not reported Individual treatment with daily (proximal) goals: number not reported Couples' treatment with weekly (distal) goals: number not reported Couples' treatment with daily (proximal) goals: number not reported Total randomised: 62 Sample attrition/dropout: Not reported separately by intervention but stated that attrition was spread evenly across the interventions *Completed treatment:* overall 47 (75.8%) *Completed 30-month follow-up:* overall 45 (72.6%) Attendance at sessions measured: yes Other measures of adherence: yes Sample crossovers: none reported. However, the authors observed from questionnaire responses that some participants assigned daily goals reported that they were actually setting weekly goals, and vice versa (sample sizes not reported) Inclusion/exclusion criteria for study entry: *Inclusion:* responders to newspaper advertisements and public service announcements on local radio; married and currently living with spouse; at least 15 lb overweight (Metropolitan Life Insurance norms, US Department of Health, Education and Welfare); not more than 100% overweight; no medical problems other than obesity; not taking medications affecting appetite or weight; spouse willing to attend at least eight sessions, including four group sessions; physician consultation indicating diet, exercise and step testing were not contraindicated *Exclusion:* failure to meet the above inclusion criteria; schedule conflicts (assumed to mean participants unable to attend sessions as scheduled because of other commitments); failure to complete the application Characteristics of participants (sample sizes, parameter and variance estimates not reported): *Risk factors noted:* none reported	Primary outcomes: weight; percentage of participants overweight; percentage of body fat Secondary outcomes: reported, but not stated explicitly that these were secondary outcomes; data not extracted Cardiovascular fitness; BP; marital satisfaction; spouse weight; spouse co-operation; body image; satisfaction; depression; aerobic fitness; binge eating Facilitators and barriers: none reported Methods of assessing outcomes: weight measured using a balance beam scale. Per cent overweight calculated from Metropolitan Life Insurance Company norms for medium frame men or women of the participants' height (reference cited). Per cent body fat estimated from skinfold sums (reference cited) *Subgroup analyses:* none reported

	1. Individual/distal	2. Individual/proximal	3. Group/distal	4. Group/proximal
Weight (units not stated, assumed lb):	207.7[a]	208.9[a]	190.4[a]	195.0[a]
Per cent overweight:	53.6[a]	51.4[a]	47.9[a]	39.6[a]
Estimated per cent body fat:	41.2[a]	42.7[a]	44.0[a]	41.3[a]
Age (years), mean ± SD:	Not reported	Not reported	Not reported	Not reported
Gender, M : F (% M : F):	Overall 14 : 48 (23 : 77) (not reported separately by intervention)			
BMI kg/m^2, *n* (%):	Not reported	Not reported	Not reported	Not reported
% weight lost before starting:	Not reported	Not reported	Not reported	Not reported
Duration of overweight/obesity:	Not reported	Not reported	Not reported	Not reported
Previous weight loss attempts:	Not reported	Not reported	Not reported	Not reported
Physical activity level:	Not reported	Not reported	Not reported	Not reported
Ethnicity:	Not reported	Not reported	Not reported	Not reported
Socioeconomic position:	Not reported	Not reported	Not reported	Not reported

Intervention details

1. Individual treatment with weekly (distal) goals: *n* not reported

Aim or goal: participants to lose 1 lb weight per week and change selected eating and exercise behaviours (individually set)

Diet:

Type of diet: calorie restriction in which participants monitored, modelled and reinforced improved eating habits, adherence to self-monitoring and adherence to calorie restriction

Frequency and length of each session and total number sessions: as reported below for behaviour modification. Specific weekly (distal) calorie-counting prescriptions given to participants at first individual session (week 5)

Level of supervision: small groups supervised by 1–4 therapists but numbers of participants and therapists/group not stated

Calories: as for intervention 3

Proportions of diet: not reported

Monitoring: as for intervention 3

Exercise:

Mode: small groups (size not reported). Individual-based goal-setting

Type: as for intervention 3

Frequency and length of each session and total number sessions: as reported below for behaviour modification. Prescription for exercise programme given in week 5

Delivered: as reported below

Level of supervision: as reported above for diet

Monitoring: weekly records of activities including type, duration and exercise heart rate

Behaviour modification:

Mode: small groups (size not reported)

Type: individual-based problem solving and goal-setting for weight management. No specific instructions for spouse co-operative behaviours were provided (participants attended intervention sessions alone; spouses were involved only in assessment sessions)

2. Individual treatment with daily (proximal) goals: *n* not reported

Aim or goal: same as intervention 1

Diet:

Type of diet: same as intervention 1

Frequency and length of each session and total number sessions: as reported below for behaviour modification. Specific daily (proximal) calorie-counting prescriptions given to participants at first individual session (week 5)

Level of supervision: same as intervention 1

Calories: as for intervention 4

Proportions of diet: not reported

Monitoring: as for intervention 4

Exercise:

Mode: as for intervention 1

Type: as for intervention 4

Frequency and length of each session and total number sessions: as for intervention 1

Delivered: as for intervention 1

Level of supervision: as for intervention 1

Monitoring: daily records of activities including type, duration and exercise heart rate

Behaviour modification:

Mode: same as intervention 1

3. Couples' treatment with weekly (distal) goals: *n* not reported

Aim or goal: same as intervention 1 but goals set by participant and their spouse

Diet:

Type of diet: same as intervention 4

Frequency and length of each session and total number sessions: as reported below for behaviour modification. Specific weekly (distal) calorie-counting prescriptions given to participants at first couple session (week 5)

Level of supervision: same as intervention 1

Calories: participants were encouraged to set weekly calorie goals, equivalent to the weekly sums of the same number of days' calories for the proximal goal (intervention 4) (i.e. 8500 kcal for women or 10,675 kcal for men)

Proportions of diet: not reported

Monitoring: participants recorded their weight weekly; more frequent weighing was discouraged

Exercise:

Mode: As for intervention 4

Type: as for intervention 4 except that the flexibility of arranging activities to meet a weekly goal was emphasised instead of a daily expenditure goal

Frequency and length of each session and total number sessions: as for intervention 1

Delivered: as for intervention 1

Level of supervision: as for intervention 1

4. Couples' treatment with daily (proximal) goals: *n* not reported

Aim or goal: same as intervention 3

Diet:

Type of diet: calorie restriction in which spouses monitored, modelled and reinforced improved eating habits, adherence to self-monitoring and adherence to calorie restriction

Frequency and length of each session and total number sessions: as reported below for behaviour modification. Specific daily (proximal) calorie-counting prescriptions given to participants at first couple session (week 5)

Level of supervision: same as intervention 1

Calories: from week 5 recommended 1215 kcal/day for women or 1525 kcal/day for men. Participants were encouraged to set daily calorie goals and to divide these into subgoals for portions of the day (calorie recording forms were designed to assist this)

Proportions of diet: not reported

Monitoring: participants recorded their weight daily

Exercise:

Mode: small groups. Exercise goals were set by the participant and their spouse

Type: aerobic exercise walking programme with calorie monitoring in which participants monitored, modelled and reinforced improved adherence to exercise. From week 5, daily minimal caloric-expenditure goals were recommended, starting at 145 kcal/day above initial baseline (equivalent to 1.5 mile walk or 1.5 hours active housework). Goals were increased each week by 25 kcal/day (equivalent to walking 5–10 extra minutes), but only if participants met the previous week's goals on at least 4 days. In addition to calorie expenditure goals, participants were instructed to walk for at least 30 minutes on 5 days/week and to monitor their heart rate so they could exercise in the recommended range for improving fitness (70%–80% of their age-predicted heart rate) (reference cited). Adherence to the walking programme enabled participants to meet ≥ 50% of their daily caloric expenditure requirements

Content: facts about weight reduction; basic nutrition; techniques for controlling eating; safely increasing exercise; coping with negative emotions and self-defeating cognitions; asserting oneself to obtain necessary support from significant others; importance of keeping records and setting goals. Some of eating behaviour change suggestions based on existing manuals (references cited) *Weeks 1–4:* education and goal-setting. Participants instructed to identify 1–2 eating and exercise behaviours they wanted to change, and to set goals to accomplish this. Also advised to reduce calorie intake while increasing daily activity *Weeks 5–16:* implementation of diet, exercise and behaviour goal prescriptions. Participants received an individualised computer printout showing their progress at weeks 5, 10 and post-treatment *Frequency and length of each session and total number sessions:* *Weeks 1–4:* 2-hour lectures and small-group discussion meetings *Week 5:* individual sessions of 15–20 minutes duration commenced, with one/week during weeks 5–7 then fortnightly thereafter. In alternate weeks participants weighed in and their calorie records were collected *Delivered:* by four (two male, two female) clinical psychology graduate student therapists (one experienced in behavioural weight-control treatment; three had been or were overweight) *Monitoring:* not reported specifically for behaviour modification component All sessions comprised weigh-in by research assistant, review of previous week's records, new information or treatment prescriptions, problem-solving discussion concerning actual or anticipated difficulties with meeting calorie intake or expenditure goals, and distribution of new self-monitoring forms *Ongoing support:* None reported	*Type:* individual-based problem solving and goal-setting for weight management with limited spouse support. Same as intervention 1, except that participants were told to solicit support from their spouses and other significant others. With the exception of a brief discussion of assertiveness, no explicit directions were given as to how to get spouse support (participants attended intervention sessions alone; spouses were involved only in assessment sessions) *Content: s*ame as intervention 1 *Frequency and length of each session and total number sessions:* same as intervention 1 *Delivered:* as for intervention 1 *Monitoring:* same as intervention 1 *Ongoing support:* None reported	*Monitoring:* same as intervention 1 *Behaviour modification:* *Mode:* same as intervention 1 *Type:* same as intervention 4 *Content:* same as intervention 1 *Frequency and length of each session and total number sessions:* same as intervention 1 *Delivered:* as for intervention 1 *Monitoring:* same as intervention 4 *Ongoing support:* None reported	*Frequency and length of each session and total number sessions:* same as intervention 1 *Delivered:* as for intervention 1 *Level of supervision:* as for intervention 1 *Monitoring:* same as intervention 2 *Behaviour modification:* *Mode:* same as intervention 1 *Type:* spouse-assisted problem solving and goal-setting for weight management. Participants and their spouses were encouraged to be inventive in applying the techniques discussed during the educational phase to meet their goals. Spouses were instructed to praise their weight-reducing partner for goal attainment and day-to-day adherence to the calorie plan and expenditure. In the presence of the participant, therapists instructed spouses to try to follow the same eating and exercise habit changes prescribed for their partner; educational materials were also provided to spouses. In the first 4 weeks spouses were asked to keep records of their own and of their weight-reducing partner's adherence. From week 5 onwards couples were asked to identify specific spouse behaviour changes which would assist the weight-reducing partner's effort *Content:* same as intervention 1 *Frequency and length of each session and total number sessions:* same as intervention 1 *Delivered:* as for intervention 1 *Monitoring:* as for intervention 1. In addition a simple contract form was provided and spouses were encouraged to make a written as well as verbal commitment to the specified behaviour changes *Ongoing support:* None reported
Other details			
Financial deposits/fees/incentives: non-refundable US$15 registration fee. Refundable US$50 deposit with partial or full refunds contingent on the number of sessions and assessments attended *Training/supervision of trainers:* therapists received 2 hours of training in behavioural weight-control techniques, including role playing interactions with participants and spouses. Throughout the programme they had regular meetings with clinical psychology faculty supervisors (timing not stated). Therapist sessions did not deviate from the treatment protocol (checked by audio-taping sessions)			

a Stated differences between interventions not statistically significant; no *p*-values reported.

Results

Outcomes (*n* = 47)	1. Individual; distal goals (*n* not reported)	2. Individual; proximal goals (*n* not reported)	3. Couples; distal goals (*n* not reported)	4. Couples; proximal goals (*n* not reported)	*p*-value, 95% CI
Weight (lb) at 30 months[a]	200	194	176	185	Not reported
Weight (lb) change from baseline[a]	–7.7	–14.9	–14.4	–10	Not reported
Facilitators	None reported	None reported	None reported	None reported	None reported
Barriers	None reported	None reported	None reported	None reported	None reported
Other intermediate outcomes: not reported for 30 months	*Attendance at sessions:* after excluding dropouts, individual-treatment participants attended on average 16.5 (97%) of the sessions while couples-treatment participants attended 15.5 (91%) of the sessions (*t*-test, $p < 0.05$). Spouses in the couples' treatment attended on average 11.9 sessions (70%) *Other measures of adherence:* food and exercise calorie self-monitoring records (including records for dropouts) were not reported separately by intervention but indicated Adherence to record keeping was best during week 2 then declined and stabilised for several weeks and then declined rapidly after about week 9. Seventy-five per cent of participants in both spouse-involvement conditions reported adherence to aerobic exercise programmes during the first week but adherence declined thereafter. At 6-month follow-up only half of participants reported at least three exercise sessions/week and at 12-month follow-up exercise adherence was only slightly above pre-treatment level On average calorie records were kept for 10.5 of the 16 weeks 29% of participants followed instructions to record their heart rate during exercise 57.1% of spouses were willing to make written behaviour change contracts (i.e. a notable proportion failed to adhere formally to the goal-setting and contracting components of the couples treatment package) The total numbers of days for which participants recorded calorie intake and output were each significantly associated with weight change during treatment ($p < 0.05$)				

a Estimated by reviewer from graph (quantitative data not reported).

Methodological comments/notes

- Allocation to treatment groups: subjects were assigned to the four interventions and to four therapists by a stratified randomisation procedure. Stated that the participants were first ranked in order of per cent overweight and that with the exception of a few (unexplained) scheduling restrictions assignments were random from each same-sex set of four individuals or couples. There were seven couples with both husband and wife participating and these were distributed among the four interventions. Also stated that subjects were then randomly assigned to four therapists. Overall, it is difficult from these descriptions to follow exactly how the randomisation process worked. No sample sizes per intervention were provided to assist interpretation
- Blinding: not reported
- Comparability of treatment groups: the groups did not differ in initial weight, proportion overweight, % body fat, or age. No other baseline characteristics were reported
- Method of data analysis: repeated measures ANOVA. Stated that analyses were performed including those who failed to complete the treatment programme (using last available weights) then with dropouts excluded, but not reported for 30 months' follow-up. The results were reported for 47 participants who completed the research requirements
- ITT analysis: not reported
- Sample size/power calculation: not reported. Small sample size (mean of approximately 15 participants per intervention, of which only one to two per intervention were husband and wife couples)
- Attrition/dropout: not reported separately by intervention but stated that attrition was spread evenly across the interventions. Reasons for dropout not fully reported. Stated that there were no significant differences between the dropouts and those who completed the programme for pre-treatment weight, per cent body fat, age, reported age of obesity onset, or weight loss goal

General comments

- Generalisability: predominantly (77%) female population. Participants had answered a newspaper or local radio advertisement and paid a US$15 non-refundable registration fee and a US$50 refundable deposit. This may have had an impact on those taking part
- Outcome measures: reported only graphically for 30 months' follow-up
- Facilitators/barriers not reported as outcomes: none reported
- Intercentre variability: not reported
- Conflict of interests: none reported

Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Unclear
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	Unclear
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis?	Not reported
(ii) If so, was this defined?	
10. (i) Did the analysis account for missing data?	No
(ii) If so, were the methods appropriate?	

Jeffery et al.

Study details	Participants	Outcome measures
Author: Jeffery *et al.*[76] Year: 1998 Country: USA Study design: RCT Number of centres: two Funding: National Heart, Lung and Blood Institute Recruitment dates: not given Setting: clinic, possibly university Length of follow-up: 18 months	Number of participants: abstract states 193, but *n*'s per group = 196 and description of participants states 196 Standard behavioural therapy (SBT): *n* = 40 SBT + supervised exercise (SBTE): *n* = 41 SBT + trainer (SBTT): *n* = 42 SBT + incentive (SBTI): *n* = 37 SBT + trainer + incentive (SBTTI): *n* = 36 Sample attrition/dropout: states that 78% completed the 18-month evaluation, no details of dropout by intervention group Attendance at sessions measured: yes Other measures of adherence: no Sample crossovers: none reported Inclusion/exclusion criteria for study entry: Between 14 and 32 kg overweight according to 1983 insurance industry standards, 25–55 years of age, free of serious diseases, able to walk for exercise and willing to be randomised Characteristics of participants: Any risk factors noted: none reported Gender (M : F), *n* (%): SBT 7 : 33 (18 : 82); SBTE 7 : 34 (17 : 83); SBTT 9 : 33 (21 : 79); SBTI 5 : 32 (14 : 86); SBTTI 5 : 31(14/86) Age (years), mean (SE): SBT 40.0 (1.3); SBTE 41.5 (1.3); SBTT 41.0 (1.3); SBTI 42.6 (1.4); SBTTI 40.7 (1.4) BMI, kg/m^2, mean (SE): SBT 31.4 (0.3); SBTE 31.5 (0.3); SBTT 31.4 (0.3); SBTI 31.5 (0.4); SBTTI 30.6 (0.4) Body weight (kg), mean (SE): SBT 85.6 (1.7); SBTE 87.1 (1.6); SBTT 84.7 (1.6); SBTI 87.7 (1.7); SBTTI 85.7 (1.7) Ever in a weight programme (%): SBT 45; SBTE 71; SBTT 62; SBTI 68; SBTTI 58 Exercise (kcal/week) mean (SE): SBT 681 (103); SBTE 725 (113); SBTT 699 (108); SBTI 768 (128); SBTTI 628 (99) Ethnicity (% white): SBT 82; SBTE 71; SBTT 88; SBTI 73; SBTTI 86 % weight lost before starting: not reported Duration of overweight/obesity: not reported Also reports baseline education status, marital status, energy intake, fat intake, Beck Depression Inventory score, Gormally Binge Eating Questionnaire eating score and perceived barriers to adherence	Primary outcomes: exercise behaviours (Paffenbarger Physical Activity Questionnaire not extracted here), weight Secondary outcomes: also attendance at walks (where relevant by intervention); habitual energy and fat intake (by Block Food Frequency questionnaire), depression (by Beck Depression Inventory), and binge eating (by Gormally Binge Eating Questionnaire) but these were not data extracted here Facilitators and barriers: perceived barriers to adherence Methods of assessing outcomes: Weight measured on a balance beam scale with participant wearing light clothing without shoes Barriers to adherence were assessed by a 15-item questionnaire devised to assess participants' perceptions of practical, social, and interpersonal barriers to successful behaviour change. Reference to authors' own work, unclear if validated in any way

Intervention details

1. SBT

(*n* = 40)

Aim or goal: not stated

Diet:

Details: type of diet: not defined

Calories: 1000 kcal/day if weight was < 91kg and 1500 kcal/day if weight was ≥ 91 kg

Proportions of diet: restrict fat to 20% or less of calories (22 g/day for 1000 kcal and 33g/day for 1500 kcal). Given menus for five breakfasts and dinners per week along with grocery shopping lists

Monitoring: recorded calorie and fat intake every day for the first 24 weeks and 1 week per month thereafter

Exercise:

Mode: assume individual

Type: primarily walking or cycling

Frequency and length of each session and total number sessions: to exercise to the equivalent of 250 kcal/week and to gradually increase to a minimum of 1000 kcal/week

Delivered: by same group leaders as noted below

Level of supervision: none specifically

Monitoring: recorded distances walked in the daily food record

Behaviour modification:

Mode: group (approximately 20)

Type: not stated

Content: stimulus control techniques, problem solving strategies, social assertion, short-term goal-setting and techniques for enhancing motivation, cognitive strategies for altering self-defeating thoughts, relapse prevention, and social support

Frequency and length of each session and total number sessions: weekly for 24 weeks and once per month thereafter

Delivered: led by trained interventionists with advanced degrees in nutrition or behavioural sciences

Ongoing support:

Not stated except for as part of the programme described above (monthly meetings after first 24 weeks)

2. SBTE

(*n* = 41)

Aim or goal: not stated

Diet:

As SBT intervention

Exercise:

Mode: group and individual

Type: primarily walking or cycling. Supervised walking (see below) initially 0.5 miles (0.8 km), increased over first 3 months to 2.5 miles (4.0 km)

Frequency and length of each session and total number sessions: to exercise to at least 1000 kcal/week. Regular attendance at supervised sessions would produce approximately 750 kcal/week

Delivered: by same group leaders as noted below

Level of supervision: mixture of supervised and unsupervised – three supervised walking sessions per week. One at same time and day as group session, two on other days but at the same time of day and location

Monitoring: assume as per SBT

Behaviour modification:

As SBT intervention

Ongoing support:

As per SBT

3. SBTT

(*n* = 42)

Aim or goal: not stated

Diet:

As SBT intervention

Exercise

Mode: group and individual

Type: primarily walking or cycling. Supervised walking as per SBTE

Frequency and length of each session and total number sessions: assume as per SBTE

Delivered: personal trainer (student or staff assistant) assigned to work with three or four participants

Level of supervision: The personal trainer walked with the participants, made reminder telephone calls, and scheduled walking sessions to accommodate participants' own schedules

Monitoring: assume as per SBT

Behaviour modification:

As SBT intervention

Ongoing support:

As per SBT

4. SBTI

(*n* = 37)

Aim or goal: not stated

Diet:

As SBT intervention

Exercise

Mode: group and individual

Type: primarily walking or cycling. Supervised walking as per SBTE

Frequency and length of each session and total number sessions: assume as per SBTE

Delivered: assume as per SBTE

Level of supervision: assume as per SBTE. Also financial award based on the number of walks attended at the end of each month. These were modest and increased in value with increments in cumulative attendance. Participants were paid per walk: US$1 for their first 25 walks, US$1.50 for the next 50 walks, US$2 for the next 50 walks, and US$3 for any remaining walks

Monitoring: assume as per SBTE

Behaviour modification:

As SBT intervention

Ongoing support:

As per SBT

5. SBTTI

(*n* = 36)

Aim or goal: not stated

Diet:

As SBT intervention

Exercise

Mode: group and individual

Type: primarily walking or cycling. Supervised walking as per SBTE

Frequency and length of each session and total number sessions: assume as per SBTE

Delivered: personal trainer as per SBTT

Level of supervision: as per SBTT and SBTI

Monitoring: assume as per SBTE

Behaviour modification:

As SBT intervention

Ongoing support:

As per SBT

Results

Outcomes	SBT ($n=40$ at baseline)	SBTE ($n=41$ at baseline)	SBTT ($n=42$ at baseline)	SBTI ($n=37$ at baseline)	SBTTI ($n=36$ at baseline)	*p*-value
Weight change in kg, mean (SE)	–7.6 (1.1)	–3.8 (1.3)	–2.9 (1.1)	–4.5 (1.2)	–5.1 (1.3)	$p=0.03$[a]
Perceived barriers	Data not reported	Data not reported	Data not reported	Data not reported	Data not reported	Not significant[b]

a Adjusted analysis for baseline weight, gender and centre. Reports $p<0.03$ in the text but $p=0.03$ in the table. The difference was reported to be attributed to the greater weight losses in the SBT group compared with the other four groups. There was also a main effect for centre ($p<0.03$) where those in Minneapolis lost more weight than those in Pittsburgh but no treatment by centre interaction effect.
b Based on the text that states that two analyses of secondary outcomes were significant and perceived barriers were not the two reported.

Methodological comments/notes

- Allocation to treatment groups: states participants were randomised within each centre to one of five treatment groups
- Blinding: no details
- Comparability of treatment groups: states treatment groups did not differ significantly on any of the baseline variables, no description of any significance testing undertaken is provided
- Method of data analysis: analyses conducted to assess changes from baseline to 18 months using general linear modelling to include baseline values, treatment group, centre, and gender as factors in the model. To try to maximise completeness of follow-up at 18 months, participants who were unwilling to attend clinic visits were asked to report their weight by telephone, of which 15 did. Analyses with and without these 15 is reported to have been undertaken which ascertained no differences in the pattern of the results and thus the analyses presented in the paper were for those attending clinic only
- ITT analysis: not reported
- Sample size/power calculation: not reported
- Attrition/dropout: reasons were not provided for the dropouts, and no numbers given by treatment group. Merely states attrition did not differ by treatment group

General comments

- Generalisability: participants recruited through a media advertisement. Came from two urban communities in the USA. Were mostly white, educated and had been in weight control programmes previously. Study primarily set up to assess the effect on exercise level achieved
- Outcome measures: weight changes also reported at 6 months' follow-up. Adherence to walking sessions reported for four study groups (not SBT) over different time periods and showed a decrease in all groups ($p<0.001$) with differences between the groups also reported. Suggests moderately correlated with overall weight change ($r=-0.35$, $p<0.0001$). Also reports average level of total exercise achieved by each treatment group at 6 and 18 months
- Facilitators/barriers not reported as outcomes: none
- Intercentre variability: not reported as such, centre was a factor within the analysis of study outcomes which showed that there was an effect of centre which suggests there probably was intercentre variability
- Conflict of interests: none reported

Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Unclear
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	Unclear
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis?	No
(ii) If so, was this defined?	
10. (i) Did the analysis account for missing data?	No
(ii) If so, were the methods appropriate?	

Jeffery and Wing

Study details	Participants	Outcome measures
Author: Jeffery and Wing;[75] Jeffery *et al.*[106] Country: USA Study design: RCT Number of centres: two Funding: National Institutes of Health grants HL41332 and HL41330 Recruitment dates: not reported Setting: not reported Length of follow-up: 30 months	Number of participants: 202 (equal numbers of men and women), randomised to five groups: Control (C): $n=40$ Standard behavioural treatment (SBT): $n=40$ SBT + food provision (SBT + FP): $n=40$ SBT + incentives (SBT + I): $n=41$ SBT + FP + I: $n=41$ Sample attrition/dropout: 177 (88%) completed the 30-month follow-up evaluation. No differences among treatment groups, centres, or sex in the per cent of participants lost to follow-up. Number by treatment group not reported. 85% (172, calculated by reviewer) completed the 18-month follow-up. Overall attrition at 6 and 12 months also reported Attendance at sessions measured: yes Other measures of adherence: yes Sample crossovers: not reported Inclusion/exclusion criteria for study entry: between 14 kg and 32 kg overweight according to 1983 insurance industry standards, 25–45 years of age, non-smokers, drank fewer than three alcoholic drinks per day, not on a special diet or allergic to any foods, able to exercise, free of current serious disease, not taking prescription medications including oral contraceptives, and agreeable to conditions of participation Characteristics of participants: Any risk factors noted: no Paper does not indicate if data reported are means, and no measures of variance reported Gender (M : F), *n* (%): not reported by group Age (years): C 35.7; SBT 37.5; SBT + FP 38.5; SBT + I 38.1; SBT + FP + I 37.6 BMI (kg/m^2) C 31.1; SBT 30.9; SBT + FP 30.8; SBT + I 31.1; SBT + FP + I 31.1 Mean weight (kg): C 88.2; SBT 89.4; SBT + FP 88.1; SBT + I 92.3; SBT + FP + I 91.1 % weight lost before starting: not reported Duration of overweight/obesity: not reported Previous weight loss attempts (%): C 50.0; SBT 57.5; SBT + FP 62.5; SBT + I 63.4; SBT + FP + I 58.5 Physical activity level (kcal/week): C 1032.4; SBT 1445; SBT + FP 820; SBT + I 1,103; SBT + FP + I 1039 Ethnicity white (%): C 92.5; SBT 87.5; SBT + FP 97.5; SBT + I 90.2; SBT + FP + I 92.7 Socioeconomic position: not reported Pre-existing medical condition: not reported *p*-values reported, all not statistically significant Baseline data for each group also reported on: non-college graduate; married, weight, nutrient intake (kcal/day; calories from fat); total barriers to adherence; eating behaviours inventory; knowledge (15-item test; calorie estimates)	Primary outcomes: change in obesity (weight and BMI) Secondary outcomes: nutrient intake (total energy intake, % of energy from fat); exercise – not data extracted Facilitators and barriers: process measures (potential mediators of weight change) were assessed – attendance at treatment sessions and weigh-ins; adherence; perceived barriers to adherence; adherence to behavioural weight control strategies; nutritional knowledge Methods of assessing outcomes: Adherence: calculated from completion of the 7-day food diaries that were requested at each group treatment session. The number of completed days was divided by the number of assigned days. No indication that this measure was validated in any way Perceived barriers to adherence: derived from a 15-item questionnaire designed specifically for this study. Covered practical and motivational barriers rated on a 5-point scale from 'not at all a problem for me (1)' to 'a very important problem for me (5)' Adherence to behavioural weight control strategies: the 26-item eating behaviours inventory of weight control practices (reference provided) Nutritional knowledge: a 15-item multiple-choice true–false test, and a test to estimate the caloric content of 22 food items

Intervention details: study reports a weight management (weight loss) intervention (duration of intervention 18 months) with participants followed up for a further year after the end of the intervention (to determine how well weight loss maintained, but no intervention or contact with study staff in this period)

Intervention details

SBT (*n* = 40)	Control (*n* = 40)	SBT + FP + I (*n* = 41)	SBT + FP (*n* = 40)	SBT + I (*n* = 41)
Aim or goal: subjects selected a weight loss goal (14, 18 or 23 kg) to try to achieve during the programme. Exercise goals increased to a final goal of 1000 calories a week *Diet:* *Details, type of diet:* emphasised the importance of remaining below caloric goals, but restriction of fat and increasing consumption of complex carbohydrates also stressed *Calories:* either 1000 or 1500 calories per day on the basis of baseline body weight. Goal derived by multiplying baseline body weight by 12, subtracting 1000 calories per day, and rounding to the closest caloric goal to produce an estimated weight loss of about 1 kg per week *Proportions of diet:* not stated *Monitoring:* recorded caloric intake in daily food records for the first 20 weeks and for 1 week each month thereafter Subjects who reached their weight loss goal during treatment had their caloric goals adjusted upward to a level estimated to maintain this body weight *Exercise:* *Mode:* individual (not explicitly stated) *Type:* based on walking or cycling *Frequency and length of each session and total number sessions:* an amount equivalent to 50 calories per day for 5 days a week *Delivered:* self-directed (not explicitly stated) *Level of supervision:* none (not explicitly stated) *Monitoring:* recorded distances walked or duration of bicycling *Behaviour modification:* *Mode:* group of about 20 *Type:* not stated *Content:* included stimulus control techniques, problem solving strategies, social assertion, short-term goal-setting and reinforcement techniques for enhancing motivation, cognitive strategies for replacing negative thinking, relapse prevention, social support *Frequency and length of each session and total number sessions:* met weekly for first 20 weeks and then once a month *Delivered:* trained interventionists with advanced degrees in nutrition or the behavioural sciences *Ongoing support:* Not specifically mentioned but content of group meetings seem to fill this role *Mode:* group of about 20 *Type:* behavioural counselling. Included a weigh-in, presentations of information by the interventionist, group discussion and a review of progress. During the period of monthly group sessions, participants were also encouraged to attend weekly weigh-in session to monitor progress *Frequency and length of each session and total number sessions:* met weekly for first 20 weeks and then once a month Other details None	No intervention. Participants could do whatever they wished to lose weight on their own	Aim or goal: as described for SBT group *Diet:* as described for SBT group *Exercise:* as described for SBT group *Behaviour modification:* as described for SBT group *Ongoing support:* as described for SBT group *Other details* *Food provision:* food provided for five breakfasts and five dinners a week. Pre-packaged breakfasts consisted of cereal, milk, juice, and fruit. Dinners typically consisted of lean meat, potato or rice, and vegetable. For 1 or 2 days a week, a frozen dinner, such as a Weight Watchers® or Lean Cuisine meal, was provided. A meal plan outlined what foods were to be eaten for which meals. Recipes were provided to guide food preparation. Recommendations for lunches were provided *Incentives:* cash payments received based on the amount of weight lost each week in relation to the weight loss goal. Minimum payment of US$2.50 if participants did not gain weight; US$12.50 if weight loss was 50% of goal. Maximum of US$25 if goal reached and maintained. Incentives paid weekly by cheque at time of weigh-in	Aim or goal: unclear if meeting same goals as other group. *Diet:* as described for SBT group *Exercise:* as described for SBT group *Behaviour modification:* as described for SBT group *Ongoing support:* as described for SBT group *Other details:* *Food provision:* as described for SBT + FP + I group	Aim or goal: weight loss goals as SBT + FP + I. Unclear if had the same exercise goal *Diet:* identical to SBT but without any FP *Exercise:* as described for SBT group *Behaviour modification:* as described for SBT group *Ongoing support:* as described for SBT group *Other details* *Incentives:* as described for SBT + FP + I group

Results

Outcomes	SBT + FP + I (*n* = 41)	SBT+I (*n* = 41)	SBT + FP (*n* = 40)	SBT (*n* = 40)	Control (*n* = 40)	*p*-value, 95% CI
Weight change, baseline to 18 months, mean kg, *n* contributing data	–6.4, *n* = 34	–4.0, *n* = 35	–6.6, *n* = 36	–4.6, *n* = 26	0.0, *n* = 28	Not reported
(data estimated from figure and *n* contributing data calculated by reviewer)						
Weight loss, baseline to 30 months, mean[a] kg (SD)	1.6 (6.3)	1.6 (5.5)	2.2 (6.6)	1.4 (7.2)	Gain 0.6 (5.3)	No overall difference between treatment groups ANOVA $p > 0.45$
Loss of ≥ 9 kg from baseline to 30 months, % of participants	Ranged from 8% to 17% in the active treatment groups No detail by group reported.				0%	Not tested
BMI kg/m^2 – baseline, *n*	31.26, *n* = 41	30.77, *n* = 41	30.66, *n* = 40	30.85, *n* = 40	30.88, *n* = 40	Not reported
18 months, *n* (calculated by reviewer)	28.95, *n* = 34	29.28, *n* = 35	28.17, *n* = 36	29.10, *n* = 26	30.67, *n* = 28	
Maintenance of weight loss	The proportion maintaining some weight loss ranged from 51% to 73%				53%	Not tested
Other intermediate outcomes:	The post hoc planned contrast analyses indicated an effect, comparing all treatment groups with the no-treatment group, which approached conventional levels of statistical significance, ($F1, 157 = 3.14$, $p < 0.08$). No adjustment of *p*-value for significance due to multiple comparisons however. Mean weight losses of the SBT groups (all SBT groups) were 4.1 kg at 18 months; in the groups provided with food, mean weight losses increased to 6.4 kg at 18 months. For 18 months, data are based on the analysis restricted to subjects who attended all assessment sessions. The percentage of participants who completed all three follow-ups to provide 18 month data differed by treatment group ($p = 0.03$)					

ANOVA, analysis of variance.

a Paper does not state mean value, just says average. But as standard deviation is also presented, the average given is most likely to be the mean value.

Methodological comments/notes

- Allocation to treatment groups: states randomised but details not reported. But note that randomisation was within centre and gender
- Blinding: not reported
- Comparability of treatment groups: states preliminary analysis found no significant differences between groups for any of the dependent variables, indicating that randomisation was effective in producing comparable treatment groups. For 30-month follow-up, also states there were no differences among treatment groups, centres or genders in the per cent of participants lost to follow-up
- Method of data analysis: dependent variables were assessed using a repeated measures ANOVA. Factors included in the analysis were gender, centre, treatment group, time and their interactions. Treatment effects due to FP, incentives, the interaction between FP and incentives, and all active treatments versus the control were specifically tested for
- ITT analysis: not reported for 30-month follow-up. Analysis for an 18-month follow-up explored two approaches for dealing with missing data, neither were ITT
- Sample size/power calculation: not reported
- Attrition/dropout: reasons not provided

General comments

- Generalisability: subjects described as relatively well educated, and predominantly white. May not be representative of the obese population in the UK
- Outcome measures: no detailed results at 30 months for other outcomes. States at 30 months there were no significant differences between groups in dietary intake, exercise, or nutrition knowledge. At 18 months data reported on possible mechanisms for observed treatment effects: attendance at treatment sessions; completion of food records; effect of provision of food on percentage of calories from fat and total calorific intake; increases in nutritional knowledge, exercise, perception of barriers. These outcomes were not reported in detail or separately for each study group
- Facilitators/barriers not reported as outcomes: states at 30 months there were no significant differences between groups in perceived barriers
- Intercentre variability: to ensure standardisation across treatment groups and centres interventionists attended a 2-day training session. Identical instructional materials and identical leader guidelines for interventionists were used at each centre. Interventionists conferred by conference call approximately once per week to co-ordinate activities
- Conflict of interests: not reported. All meals in the FP group prepared by Nutrition Inc. but assume no sponsorship of the trial

Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Not reported
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	Not reported
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	Yes – some outcomes reported at 18 months, not reported on at 30 months
9. (i) Did the analysis include an intention to treat analysis?	Not reported
(ii) If so, was this defined?	
10. (i) Did the analysis account for missing data?	Not reported
(ii) If so, were the methods appropriate?	

Logue et al.

Study details	Participants			Outcome measures
Author: Logue *et al.*[72]	Number of participants:			Primary outcome:
Year: 2005	Transtheoretical Model and Chronic Disease Paradigm (TM-CD): 329			Change in body weight
Country: USA	Augmented usual care (AUC): 336			Secondary outcomes (data not extracted):
Study design: RCT	Total randomised: 665			Waist girth; blood lipids; BP; behavioural and cognitive-based estimates of daily energy intake and total energy expenditure; psychosocial assessments including self-efficacy, social support, decisional balance for healthy eating and exercise; general physical and mental health; social desirability; anxiety, depression; binge-eating disorder; stages of change.
Number of centres: 15 primary-care practices	Sample attrition/dropout:			
Funding: study supported by Agency for Healthcare Research and Quality and the National Institute of Diabetes, Digestive, and Kidney Diseases grants and by Nutrition and Exercise grants from the Summa Health System Foundation	*Attrition, n (%) 18 months:* TM-CD: 123 (37); AUC: 155 (46)			
	Attrition, n (%) 24 months: TM-CD: 103 (31); AUC: 127 (38)			
	Attendance at sessions measured: not reported			
	Other measures of adherence: not reported			
	Sample crossovers: none reported			
Recruitment dates: not reported; study conducted July 1998 to December 2002	Inclusion/exclusion criteria for study entry:			Facilitators and barriers: none explicitly assessed
	Inclusion:			Methods of assessing outcomes:
Setting: primary care	Participants of one of the primary-care practices affiliated with the study; had to provide written informed consent; men and women, 40–69 years of age; elevated BMI (> 27 kg/m^2) or elevated waist-to-hip ratio (> 0.95 for men or > 0.8 for women)			Weight measured using a standardised calibrated scale
Length of follow-up: 18 and 24 months after randomisation	*Exclusion:*			*Subgroup analyses:* none
	No access to a telephone; difficulty understanding eight-grade spoken or written English; pregnancy, lactation, or < 6 months post partum; use of a wheelchair for mobility; high-risk participants with severe heart or lung disease			
	Characteristics of participants:			
	Risk factors noted: none			
		TM-CD (*n* = 329)	AUC (*n* = 336)	95% CI of difference
	Gender (M : F) (%):	97 : 232 (29 : 71)[a]	110 : 226 (33 : 67)	–3.8 to 10 (for number of men)
	Age group (years), *n* (%)			
	40–49:	139 (42)	129 (38)	–11 to 3.6
	50–59:	138 (42)	141 (42)	–7.5 to 7.5
	60–69:	52 (16)	66 (20)	–2.0 to 9.6
	Weight (kg), mean ± SD	Not reported	Not reported	Not reported
	Total number of minutes exercised	Not reported	Not reported	Not reported
	Energy expenditure	Not reported	Not reported	Not reported
	BMI kg/m^2, *n* (%)			
	25–29.9	59 (18)	73 (22)	–2.3 to 9.8
	30–34.9	119 (36)[a]	107 (32)	–12 to 2.9
	35–39.9	69 (21)	82 (24)	–2.9 to 9.8
	40.0 +	79 (24)	74 (22)	–8.4 to 4.4
	% weight lost before starting	Not reported	Not reported	Not reported
	Duration of overweight/obesity	Not reported	Not reported	Not reported
	Previous weight loss attempts *n* (%)	306 (93)[a]	303 (90)[a]	–7.0 to 1.4

	Previous commercial weight loss programmes, *n* (%)	147 (45)[a]	155 (46)[a]	–6.1 to 9.0
	Physician said to lose weight, *n* (%)	246 (75)[a]	262 (78)[a]	–3.3 to 9.7
	Ethnicity: *n* (%) African American	88 (27)[a]	87 (26)[a]	–7.5 to 5.8
	Socioeconomic position	Not reported	Not reported	Not reported
	Prior/current psychotropic medicine, *n* (%)	85 (26)	79 (24)	–8.9 to 4.2
	Hypertension, *n* (%)	138 (42)[a]	151 (45)[a]	–4.5 to 11
	Elevated blood cholesterol, *n* (%)	107 (33)[a]	115 (34)[a]	–5.5 to 8.9
	Diabetes, *n* (%)	41 (12)[a]	51 (15)[a]	–2.5 to 8.0
Intervention details				
1. TM-CD **(*n* = 329)**	Aim or goal: not explicitly reported *Diet:* *Type of diet:* based on either the United States Department of Agriculture (USDA) Food Guide Pyramid (*Dietary Guidelines for Americans*) or a standard prescription to reduce calories, increase fruit and vegetables, and reduce fat *Frequency and length of each session and total number sessions:* 10 minutes of in-person counselling (not stated whether group or individual) once every 6 months and mean of 15 minutes telephone counselling every month *Level of supervision:* no further details reported *Calories:* not reported (consult the materials referred to above) *Proportions of diet:* not reported (references given; see above) *Monitoring:* participants were asked to provide dietary data every 6 months and other information as reported below for behaviour modification *Exercise:* *Mode:* not reported whether individual or group contact *Type:* included a standard prescription to increase activity and exercise but no details provided *Frequency and length of each session and total number sessions:* as reported above for diet *Delivered:* by registered dietician (RD) and weight loss advisor (WLA). The RD prepared written exercise prescriptions based on the information from dietary recalls. The WLA provided phone counselling *Level of supervision:* no further details reported *Monitoring:* participants were asked to provide exercise data every 6 months and other information as reported below for behaviour modification *Behaviour modification:* *Mode:* not reported, however, assume from description of telephone calls that is individual *Type:* behavioural techniques based on TM-CD were taught consistent with Prochaska's description of the relationship between the processes of change and the stages of change (SOC) for increasing five target behaviours (exercise, usual activity, dietary portion control, dietary fat control, fruit and vegetable intake) *Content:* participants were mailed stage- and behaviour-matched workbooks that corresponded to their most recent SOC profile as identified by monitoring. Content of WLA telephone contacts not reported			
2. AUC: **(*n* = 336)**	Aim or goal: not explicitly reported *Diet:* *Type of diet:* based on either the USDA Food Guide Pyramid (*Dietary Guidelines for Americans*) or a Soul Food Guide Pyramid. Included a standard prescription to reduce calories, increase fruit and vegetables, and reduce fat *Frequency and length of each session and total number sessions:* 10 minutes of counselling once every 6 months *Level of supervision:* no further details reported *Calories:* not reported (references given) *Proportions of diet:* not reported (references given) Noted that participants were advised to discuss their lipid and BP values with their primary care physician, but not stated whether or how the results of such discussions influenced the diet *Monitoring:* participants were asked to provide anthropometric and dietary data every 6 months *Exercise:* *Mode:* not reported whether individual or group contact *Type:* not reported *Frequency and length of each session and total number sessions:* as reported above for diet *Delivered:* by a registered dietitian who prepared written exercise prescriptions based on the information from the exercise recalls *Level of supervision:* no further details reported *Monitoring:* participants were asked to provide exercise data every 6 months *Behaviour modification:* *Mode:* not reported whether individual or group contact *Type:* not reported *Content:* counselling based on 6-monthly review of diet, exercise and anthropometric monitoring, consistent with behavioural self-monitoring principles			

Frequency and length of each session and total number sessions: as reported above for diet *Delivered:* by a RD and a WLA trained to apply the processes of change that corresponded to a participant's SOC profile. The RD prepared written dietary prescriptions based on the information from dietary recalls. The primary-care physicians were expected to counsel participants on obesity issues but only when issues were raised by participants or at infrequent (one to three times/year) chronic disease visits (diabetes check-ups). Overall, physicians had little involvement (6% of participants) in dietary, exercise or weight issues *Monitoring:* formal evaluation for anxiety, depression and binge eating disorder every 6 months. A SOC assessment for five behaviours was completed every 2 months (references cited). Self-monitoring by participants was recommended but self-monitoring records were not reviewed by the physician or the WLA *Ongoing support:* Upon request, the WLA mailed participants with public domain handouts and other materials (menu suggestions, mall walking impacts, descriptions of local walking trails) Other details: *Financial incentives:* participants were paid US$25 for completing each postbaseline assessment (6, 12, 18 and 24 months) *Training/supervision of trainers:* a part-time pharmaceutical representative was trained to provide academic detailing to physicians on the use of the SOC profiles, the processes of change, and how to use a SOC flip chart when counselling participants in the examination room. The project psychologist (KS) monitored implementation of the WLA telephone protocol and periodically debriefed the WLAs and advised WLAs how to interact with problematic participants	*Frequency and length of each session and total number sessions:* as reported above for diet *Delivered:* as reported above for exercise *Monitoring:* as reported for diet and exercise. (No evaluation was carried out for anxiety, depression and binge eating disorder as it was considered unethical to do this without informing the primary care physicians) *Ongoing support:* None reported *Other details* *Financial incentives:* participants were paid US$25 for completing each postbaseline assessment (6, 12, 18 and 24 months)

a Calculated by reviewer; slight discrepancy with reported value.

Results

Outcomes	1. TM-CD: $n=226$ unless stated	2. AUC: $n=209$ unless stated	Difference (TM-CD – AUC) 95% CI, p-value
Mean (SE), 95% CI weight change (kg) from baseline to 24 months[a]	–0.39 (0.38), –1.1 to 0.4 For adjusted difference[b] $n=271$	–0.16 (0.42), –1.0 to 0.7 For adjusted difference[b] $n=266$	Unadjusted difference 0.23 kg –1.4 to 0.9, $p=0.50$ (NS) Adjusted difference[c] 0.22 kg (CI and p-value not reported) Adjusted difference[b] 0.21 kg (CI and p-value not reported)
Facilitators	None explicitly reported	None explicitly reported	
Barriers	None explicitly reported	None explicitly reported	

AUC, augmented usual care; NS, not statistically significant; TM–CD, Transtheoretical Model and Chronic Disease paradigm.

a Chart weights were substituted for measured weights where the latter were missing. Seventy per cent of participants had a measured weight at 18 and 24 months. Pearson correlation coefficients between measured and chart weights averaged 0.99 (over repeated measurements). At month 18 there were significantly more weight measurements available for TM-CD (85%) than AUC (78%) ($\chi^2=5.6$; p-value not reported). At month 24 weight data (measurement or chart) were equally available from both treatment groups.

b After substituting baseline weight (i.e. no weight change) for final weight for the 12% of participants with missing final weight data.

c After adjustment for baseline weight and other (unspecified) covariates.

Methodological comments/notes

- Allocation to treatment groups: participants were randomised by opening an envelope with a set of ordered tickets indicating Transtheoretical Model and Chronic Disease (TM-CD) paradigm or 'Traditional Care'. The order of randomisation tickets was prepared using permuted blocks of 10 by the Office of Biostatistics. A separate randomisation sequence was used for each primary-care practice
- Blinding: reported that participants and research staff at each practice were blind to the assignment of participants while obtaining baseline measures, because assignment envelopes were not opened until the end of the visit
- Comparability of treatment groups: no major differences in baseline characteristics noted (the 95% CI for all reported baseline variables included zero)
- Method of data analysis: the primary hypothesis test focused on the final weight change from baseline to month 24 (or month 18 if the month 24 value was missing). Analysis was based on linear models and linear mixed (repeated measures) models
- ITT analysis: stated yes. Analysis included all randomised participants using linear models and linear mixed (repeated measures) models that included baseline variables, unstructured covariance matrices, and a missing at random (MAR) assumption. Sensitivity analysis considered the 12% of participants who had missing 18- or 24-month data, using baseline weight as a substitute
- Sample size/power calculation: clearly reported for both primary (weight loss) and secondary outcomes. Power 0.9 to detect a difference of 4.5 kg (about 5% weight loss difference) between TM-CD and AUC with $\alpha = 0.05$ and assuming 20% attrition
- Attrition/dropout: reasons for attrition reported (primarily because participants declined further participation when an effort was made to schedule a follow-up appointment) but not separated for the intervention groups. Attrition was defined imprecisely as participants who did not have 'a measured weight and other information'

General comments

- Generalisability: stated that the original design called for equal numbers of male and female participants and African American participants to be in proportion to their local and national representation (12%) but supplemental funds secured in the second year of the trial allowed African American enrolment to double. Results indicate approximately 27% African American, 25% were on or had received psychotropic medicine, and the majority (≥90%) had made previous weight loss attempts. Participants were recruited when they inquired about the study after either talking to their physician or reading study brochures, posters, or letters that were mailed to potential participants identified by primary care physicians. Participants also responded to waiting room brochures and posters, general newspaper articles (no details given) and announcements at churches with African American congregations, which may affect generalisability. Also, participants were paid US$25 for completing each postbaseline assessment
- Outcome measures: psychosocial assessments including self-efficacy, social support, decisional balance for healthy eating and exercise, general physical and mental health, and social desirability were stated as secondary outcomes but no quantitative or narrative results were provided for these. Other intermediate outcomes (no quantitative data reported) were: waist girth at 24 months [difference between interventions stated not statistically significant (NS); $p = 0.57$]; energy intake (difference stated NS; $p = 0.69$); blood lipids at 24 months (difference stated NS; no p-value reported); and BP at 24 months (difference stated NS; no p-value reported). The mean change in reported exercise minutes per week (time period not reported – assumed over 0–24 months) was 31.5 ± 12 additional minutes per week in TM-CD across all measurements compared with augmented usual care (AUC) (variance measure not stated; difference $p = 0.008$)
- Facilitators/barriers not reported as outcomes: none reported
- Intercentre variability: not reported
- Conflict of interests: none reported

Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Yes
2. Was the allocation adequately concealed?	Unclear
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Unclear
6. Was the participant blinded?	Unclear
7. (i) Were there any unexpected imbalances in dropouts between groups?	(No
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	Yes
9. (i) Did the analysis include an intention to treat analysis?	Yes
(ii) If so, was this defined?	Yes
10. (i) Did the analysis account for missing data?	Yes
(ii) If so, were the methods appropriate?	Yes

Simkin-Silverman et al.

Study details	Participants	Outcome measures
Author: Simkin-Silverman *et al.*[73,100,105,107] Year: 1998 Country: USA Study design: RCT Number of centres: one Funding: National Heart, Lung and Blood Institute Recruitment dates: August 1992 to March 1994 Setting: clinic (unclear whether university clinic) Length of follow-up: 54 months	Number of participants: 535 randomised. Lifestyle intervention (LI) $n=260$, control (C) $n=275$. Only results for the subgroups classified as overweight or obese at baseline are reported here (LI $n=117$; C $n=131$) Sample attrition/dropout: 509 attended 54-month visit and were analysed. Fourteen participants missing from the LI, and 12 from the C (reasons given) Attendance at sessions measured: yes Other measures of adherence: yes Sample crossovers: not reported Inclusion/exclusion criteria for study entry: aged 44–50 years, < 3 months amenorrhea in 6 months prior to initial interview; not taking hormone replacement therapy; no surgically induced menopause (hysterectomy or bilateral oophorectomy); diastolic BP < 95 mmHg; BMI between 20 and 34 kg/m^2; fasting glucose < 140 mg/dl; not taking any lipid-lowering agents, insulin, thyroid, antihypertensive, psychotropic medications; not treated for cancer in the past 5 years; not having participated in a weight reduction programme within the past 4 months Characteristics of participants: Any risk factors noted: none, other than baseline values for high- and low-density lipoprotein cholesterol, triglycerides, BP, menopausal status during follow-up Gender (M:F), *n* (%): 100% female Age (years), mean (SD): LI = 47 years (SD = 2); C = 47 (SD = 2) Mean BMI, kg/m^2: LI = 25 (SD = 3); C = 25 (SD = 3) 53.6% (287/535) were normal weight (BMI ≤ 24.9 kg/m^2) (LI = 143; C = 144) 35.5% (190/535) were overweight (BMI = 25–29.9 kg/m^2) (LI = 95; C = 95) 10.8% (58/535) were obese (BMI ≥ 30 kg/m^2). (LI = 22; C = 36) Weight lb, mean (SD): LI 148.0 (21.3); C 147.6 (21.9) Weight kg, mean (calculated by reviewer): LI 67.1; C 67.0 % weight lost before starting: not reported Duration of overweight/obesity: not reported Previous weight loss attempts: not reported Physical activity level (kcal/wk): LI = 1248 (SD = 1064); C = 1412 (SD = 1386) Ethnicity: white LI = 92.1%; C = 91.8% Socioeconomic position: educated beyond high school (LI = 83.2%; C = 86.2%), employed for wages (LI = 86.2%; C = 86.1%)	Primary outcomes: weight, body fat distribution, and body composition. Measured in terms of BMI, waist-to-hip ratio and changes in fat-free mass (FFM) (Note: not consistently reported which outcomes were primary) Secondary outcomes: Physical activity, nutrient intake Lipids, BP, glucose levels, cigarette smoking, alcohol intake, menopausal status (not data extracted) Facilitators and barriers: not reported Methods of assessing outcomes: Weight measured with balanced beam scale Height measured by a stationary vertical height board

Intervention details

1. Intervention 1 (*n* = 260): LI (Women's Healthy Lifestyle Project)

Aim or goal: to prevent naturally occurring weight gain and sustain baseline lipid profiles during the perimenopausal to postmenopausal transition. Two phases – phase 1 (weeks 1–20) focus on modest weight loss, described as the intensive phase. Phase 2 (months 6–54) continued focus on weight loss, but also then weight stabilisation and maintenance

Phase 1 included 10 weekly group meetings followed by biweekly meetings for the remaining 10 weeks (in total there were 15 group meetings with approximately 20 women per group). Phase 2 – following the initial 5 months group meetings occurred at months 6, 7, 8, 10, 12 and 14. Participants attended refresher programmes on nutrition, weight control and physical activity between months 14 and 54 (no detail on frequency of these sessions)

Diet:

Details, type of diet: reduced fat and calorie diet (also lipid-lowering dietary strategies). Weight loss goals were tailored to baseline BMI. Women with BMI of 25 to 26 kg/m^2 were given 10 lb and women with a BMI or ≥ 27 kg/m^2 were given 15 lb weight loss goals. Women with normal weight (BMI ≤ 24 kg/m^2) were asked to lose 5 lb

Calories: participants were given a 1300–1500 kcal meal plan (for first month). As participants met their weight goal their caloric intake was gradually increased until weight stabilised

Proportions of diet: lowering of dietary fat to 25% of daily calories, saturated fat to 7%, and dietary cholesterol to 100 mg/day (for first month)

Monitoring: self-monitoring daily using 7-day pocket diaries for 6 months

Exercise:

Mode: group meetings

Type: recommended activities: walking, aerobic dance, cycling, swimming, strength training

Frequency and length of each session and total number sessions: phase 1 (10 weekly group meetings followed by 10 biweekly meetings). At the third week participants instructed to increase physical activity in step-wise manner to expend 1000 kcal per week. Women already active but expending < 1500 kcal per week were encouraged to gradually increase activity to 1500 kcal. Women already expending 1500 kcal encouraged to maintain this level. During phase 2 there were refresher meetings which covered physical activity, among other things

Delivered: behavioural psychologists and nutritionists

Level of supervision: appears that participants supervised themselves largely, but there were regular group meetings in phase 1 and in phase 2 there was regular mail and telephone contact

Monitoring: self-monitoring on a daily basis for first 6 months

Behaviour modification:

Mode: group (approximately 20 women per group)

Type: mentions that it is an empirically-based cognitive behavioural approach to weight control, citing two references, one of which is the NIH Clinical Guidelines on obesity in adults, the other being a chapter in a handbook of obesity

Content: included the following: stimulus control, goal-setting, self-monitoring, modelling, problem solving, assertiveness training, relapse prevention, and cognitive and motivational techniques. For instance, participants were taught to identify cues in their environment to promote healthy eating and activity. They were instructed on how to set realistic goals and extensive time was spent on problem solving within the group. The coping strategies taught were based on the relapse prevention model

Frequency and length of each session and total number sessions: not explicit whether each of the weekly/biweekly sessions included behavioural approaches, but presume that most of the psychological techniques were taught during phase 1. Additional behavioural skills, support and motivation was provided in phase 2, where sessions focused on adherence, emotions and eating

Delivered: behavioural psychologists and nutritionists

Ongoing support:

After month 14 (in phase 2) participants were offered 6-week refresher programmes, specifically to help with maintenance of behaviour change

Mode: presume group

Type: individual or small group consultation was provided to those who experienced a rise in weight gain during phase 2. Mail and telephone contact (newsletter, self-monitoring diaries) also used

Frequency and length of each session and total number sessions: not stated

Other details:

Incentives and lotteries were used periodically for healthy lifestyle prizes to enhance attendance at group programmes and to encourage return of self-monitoring diaries

Other features of the intervention included: cooking demonstrations, and low-fat taste panels

Calcium supplementation (1200 mg/day) was given to offset any decreases in calcium during weight loss

2. Intervention 2 (*n* = 275):

Assessment only control group (received a health education pamphlet on reducing cardiovascular risk factors and for those who were smokers, advice to quit)

Results

Outcomes			
Subset of participants overweight at baseline (BMI = 25–29.9 kg/m²)	**LI (*n* = 95)**	**C (*n* = 95)**	***p*-value between groups**
Weight change, mean kg (SD) % of initial weight lost 18 months	–3.5 (5.8) –4.6[a]	0.1 (4.0) 0.07	$p < 0.001$
Weight change, mean kg (SD) % of initial weight lost 30 months	–2.7 (5.4) –3.5	0.3 (5.1) 0.41	$p < 0.001$
Weight change, mean kg (SD) % of initial weight lost 42 months	–1.4 (5.7) –1.7	1.3 (5.5) 1.9	$p < 0.001$
Weight change, mean kg (SD) % of initial weight lost 54 months	0.1 (6.1) 0.31	1.5 (5.2) 2.2	Not significant
Subset of participants obese at baseline (BMI ≥ 30 kg/m²)	**LI (*n* = 22)**	**C (*n* = 36)**	***p*-value between groups**
Weight change, mean kg (SD) % of initial weight lost 18 months	–6.6 (8.4) –7.7	–0.5 (4.5) –0.36	$p < 0.01$
Weight change, mean kg (SD) % of initial weight lost 30 months	–4.3 (6.7) –5.0	2.9 (5.4) 3.5	$p < 0.01$
Weight change, mean kg (SD) % of initial weight lost 42 months	–2.0 (6.4) –2.3	1.9 (5.7) 2.5	$p < 0.05$
Weight change, mean kg (SD) % of initial weight lost 54 months	–0.2 (6.9) –0.17	3.1 (7.7) 3.7	Not significant
Percentage of participants at or below baseline weight at 54 months – (subset overweight at baseline)	57.3% (51/89)	Not reported	$p = 0.352$[b]
Percentage of participants at or below baseline weight at 54 months – (subset obese at baseline)	40% (8/20)	Not reported	
Facilitators	Not reported	Not reported	Not reported
Barriers	Not reported	Not reported	Not reported

a Percentages are per cent of initial weight lost.
b For the comparison between baseline weight status (normal vs overweight vs obese for the LI group only).
Only results for participants classified as obese or overweight at baseline were extracted. Results for those classified as normal weight at baseline, and results for the whole sample irrespective of baseline weight classification have not been extracted.
Outcomes at 6 months reported, but not extracted.

Methodological comments/notes

- Allocation to treatment groups: states randomised. Actual method of randomisation not explicitly reported except that the sequence was prepared by the project's statistician prior to recruitment. Randomisation was done either in person at the Health Studies Clinic or by telephone to study personnel to ensure the participant was fully informed of the study design and to answer any questions prior to revealing the group assignment. Group assignments were concealed in envelopes labelled by study identification number, and the sequence remained confidential to study personnel until revealed to the participant during randomisation
- Blinding: outcome assessors were reported to be blinded to group assignment
- Comparability of treatment groups: the authors report that groups did not differ at baseline on primary dependent measures, nor were there any differences in dietary intake and physical activity (with the exception of alcohol use), or socio demographic data
- Method of data analysis: outcomes reported at 6, 18, 30, 42 and 54 months. Independent-sample *t*-tests using change scores from baseline were used to compare intervention and control groups on continuous methods. Chi-square analysis used to compare the percentage of LI and C participants who were at or below baseline weight at 54 months. Analysis of covariance (ANCOVA) used to examine physical activity, dietary adherence and weight change at 54 months. A probability value of 0.05 determined statistical significance for all tests
- ITT analysis: reports an ITT analysis and defines it as being an analysis that uses all available data from participants regardless of degree of intervention contact or adherence. Data from earlier assessments for the 26 non-attendees at the 54-month visit were included, but no data were carried forward to estimate the missing final assessment. It is not clear whether a true ITT analysis was conducted
- Sample size/power calculation: based on a series of power analyses (two-tailed comparisons with an alpha level of 0.05), taking into consideration the primary outcomes of the trial (low-density lipoprotein cholesterol and weight) and an estimated 10% loss to follow-up. A sample of 250 in each group allowed for sufficient power of 90% or greater to test both primary and subgroup comparisons between the study groups. Mentions that the sample size calculation took into account various planned subgroup analyses by menopausal status, but no discussion of the potential limitations of the subgroup outcomes based on baseline classification of normal, overweight or obese (e.g. that they may be underpowered)
- Attrition/dropout: reasons provided for both intervention and control group

General comments

- Generalisability: results applicable mainly to perimenopausal women not being treated for hypertension, or not taking lipid-lowering medication, thyroid medication, psychotropic medication or insulin. Only just under half of those randomised were classified as overweight or obese at baseline (although weight loss goals were tailored to baseline BMI classification)
- Outcome measures: a number of additional outcomes were reported, but were not data extracted. Attendance at follow-up assessments described as 'consistently excellent' (averaging 90%, with 95% at final assessment). Reports adherence to the physical activity and dietary goals
- Facilitators/barriers not reported as outcomes: reports that intervention participants who were low adherers gained more weight (mean adjusted weight gain = 1.5 kg) than intervention participants who were high adherers (mean adjusted weight loss = 2.0 kg)
- Intercentre variability: not applicable. Appears to be only one centre ('Health Studies Clinic')
- Conflict of interests: none reported

Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Yes
2. Was the allocation adequately concealed?	Yes
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Yes
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	No
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis?	Yes
(ii) If so, was this defined?	Yes
10. (i) Did the analysis account for missing data?	No
(ii) If so, were the methods appropriate?	

Skender et al.

Study details	Participants	Outcome measures
Author: Skender *et al.*[79] (Baseline population characteristics reported by Foreyt *et al.*[108]) Year: 1996 Country: USA Study design: RCT Number of centres: not reported Funding: study supported in part by research grant DK30921 from the National Institutes of Health, Bethesda, MD Recruitment dates: not reported Setting: not reported. Participants were recruited from an urban area of Houston, TX Length of follow-up: 2 years after randomisation (1 year after end of treatment)	Number of participants: Diet and exercise (D + E): $n = 42$ Exercise only (E only): $n = 43$ Diet only (D only): $n = 42$ Waiting list control group (no data reported for these): $n = 38$ Total randomised: $n = 165$ Sample attrition/dropout: Numbers reported but not reasons *Completed 1-year treatment:* $n = 86/127$ (68%) *Completed 2-year follow-up:* Statistically significant differences between groups (overall $p = 0.03$; difference between diet and exercise groups $p = 0.014$) D + E: 21 (50%) D only: 15 (35.7%) E only: 25 (58%) Attendance at sessions measured: not reported Other measures of adherence: yes Sample crossovers: none reported Inclusion/exclusion criteria for study entry: men and women aged 25–45 years; volunteers recruited through (unspecified) media announcements; at least 14 kg overweight (Metropolitan Insurance height-weight tables); not engaged in regular exercise. No exclusion criteria specified Characteristics of participants: *Risk factors noted:* none Gender, M : F (%): 1. D + E: baseline: 21 : 21 (50 : 50) $n = 42$; 2-year follow-up: 10 : 11 (48 : 52) $n = 21$ 2. D only: baseline: 22 : 20 (52 : 48) $n = 42$; 2-year follow-up: 9 : 6 (60 : 40) $n = 15$ 3. E only: baseline: 23 : 20 (53 : 47) $n = 43$; 2-year follow-up: 13 : 12 (52 : 48) $n = 25$ *Baseline characteristics* *Reported by Foreyt* et al.[108] *for 86 participants who completed treatment* Weight (kg), mean ± SD: 1. (D + E): 97.60 ± 25.48 ($n = 27$); 2. (D only): 97.65 ± 21.96 ($n = 29$); 3. (E only): 93.92 ± 20.83 ($n = 30$) (stated NS in text) *Reported by Skender* et al.[79] *for 61 participants who completed 2-year follow-up (not reported for all randomised participants):* Weight (kg), mean ± SD: 1. (D + E): 100.1 ± 27.4 ($n = 21$); 2. (D only): 98.5 ± 25.9 ($n = 15$); 3. (E only): 93.7 ± 21.1 ($n = 25$) ($p = 0.66$; NS) *Baseline characteristics for all participants not reported. Foreyt* et al.[108] *reported only for unspecified cohorts of the population (sample sizes variable but unexplained; data not extracted):* % body fat, mean ± SD: reported for unspecified cohort only (D + E: $n = 24$; D: $n = 22$; E: $n = 27$) Waist circumference (cm), mean ± SD: reported for unspecified cohort only (D + E: $n = 24$; D: $n = 23$; E: $n = 27$) Total number of minutes exercised: reported for unspecified cohort only (D + E: $n = 15$; D: $n = 18$; E: $n = 17$) Energy expenditure: reported for unspecified cohort only (D + E: $n = 15$; D: $n = 17$; E: $n = 16$) Age: not reported BMI, kg/m^2: not reported % weight lost before starting: not reported Duration of overweight/obesity: not reported Previous weight loss attempts: not reported Physical activity level: not reported Ethnicity: not reported Socioeconomic position: not reported	Primary outcomes: (Reported, but not stated explicitly that this was a primary outcome): changes in body weight Secondary outcomes: (Reported, but not stated explicitly that these were secondary outcomes; not data extracted): attitudes to diet and exercise; adherence to diet and exercise; physical activity (1 year); % body fat (1 year); cardiorespiratory fitness (1 year) Facilitators and barriers: none explicitly assessed Methods of assessing outcomes: Weight measured using a balance beam scale *Subgroup analyses:* none. Note that attrition was reported separately by gender

Intervention details

1. D+E

(*n* = 42)

Aim or goal: not explicitly reported

Diet:

Type of diet: participants were instructed to plan their daily meals and snacks from the foods recommended in the HYHEP, a nutritionally adequate, well-balanced low-cholesterol diet (reference cited). A table listing the calorie content of popular foods was provided. Instructors advised participants to adjust their caloric intake so that weight loss would not exceed 1 kg/week. Class instructors reviewed the food records weekly and returned them to participants at the next class

Frequency and length of each session and total number sessions: 12 weekly group instructional sessions followed by three biweekly sessions then eight monthly maintenance sessions (total 1 year). (Note discrepancy in text.) The group sessions were 60 minutes long, delivered as reported below for exercise

Calories: not reported

Proportions of diet: to provide 30% of calories as fat, 50% as carbohydrate, and 20% as protein, based on HYHEP

Monitoring: daily food intake was monitored by participants recording the food eaten and calorie content of each portion in food diaries and (separately?) completing a self-monitoring questionnaire about diet (no details reported)

Exercise:

Mode: groups of approximately 15 participants

Type: lecture and discussion focused on the physical and psychological benefits of exercise. Proper methods of walking were taught on an indoor track during two supervised sessions. The walking regimen was adapted from a very gradual plan designed for the treatment of depression (reference cited) to maximize adherence. Participants were instructed to self-regulate the intensity of brisk walking based on heart rate, breathing difficulty, and perceived effort. They were instructed to exercise at a level that felt 'vigorous' but never 'strenuous'

Frequency and length of each session and total number sessions: as reported above for diet. The duration of beginning exercise sessions was as short as 5 minutes. The goal was three to five sessions per week of 45 minutes or more per session

Delivered: by registered dietitians who were trained and experienced in behaviour modification (exercise qualifications and competencies not reported)

Level of supervision: supervision only of intervention groups reported

Monitoring: self-monitoring questionnaire which included an hedonic five-point rating scale for exercise (no further details provided)

Behaviour modification:

Mode: groups of approximately 15 participants

Type: followed the principles outlined in the LEARN programme for weight control (reference cited)

Content: both diet behaviour modification and exercise behaviour modification involved the teaching or use of self-monitoring contracts to reward behaviour change (contingency contracting), stress management, stimulus control, goal-setting and maintenance techniques (references cited)

Frequency and length of each session and total number sessions: as reported above for diet

Delivered: as reported above for exercise

Ongoing support:

None reported other than 'maintenance' sessions noted above

Other details

Financial deposits: at the start of the study participants deposited US$100 in an account which was refunded in increments according to the number of sessions attended

Financial incentives: participants were offered US$35 for fulfilling the 2-year follow-up requirements

2. E only

(*n* = 43)

Aim or goal: not explicitly reported

Diet:

Type of diet: participants were asked to maintain their current eating habits and nutrition was not discussed

Frequency and length of each session and total number sessions: not reported (participants continued their current eating habits)

Calories: not reported

Proportions of diet: not reported (participants continued their current eating habits)

Monitoring: none reported (participants continued their current eating habits)

Exercise:

Mode: as reported for D + E

Type: as reported for D + E

Frequency and length of each session and total number sessions: as reported for D + E

Delivered: as reported for D + E

Level of supervision: as reported for D + E

Monitoring: as reported for D + E

Behaviour modification:

Mode: as reported for D + E

Type: as reported for D + E

Content: as reported for D + E

Frequency and length of each session and total number sessions: as reported for D + E

Delivered: as reported for D + E

Ongoing support:

None reported

Other details

Financial deposits and incentives: as reported for D + E

3. D only

(*n* = 42)

Aim or goal: to produce 1kg/week loss of weight

Diet:

Type of diet: as reported for D + E

Frequency and length of each session and total number sessions: as reported for D + E

Calories: not reported

Proportions of diet: as reported for D + E

Monitoring: as reported for D + E

Exercise:

Mode: as reported for D + E

Type: normal physical activity only: participants were asked to maintain their relatively sedentary lifestyles and not to begin any new exercise programme

Frequency and length of each session and total number sessions: no exercise

Delivered: as reported for D + E

Level of supervision: as reported for D + E

Monitoring: none reported (participants continued their current physical activity)

Behaviour modification:

Mode: as reported for D + E

Type: as reported for D + E

Content: as reported for D + E

Frequency and length of each session and total number sessions: as reported for D + E

Delivered: as reported for D + E

Ongoing support:

None reported

Other details

Financial deposits and incentives: as reported for D + E

Results

Outcomes	D + E ($n = 21$)	D only ($n = 15$)	E only ($n = 25$)	p-value
Mean ± SD weight change (kg) from baseline (0–2 years)[b,c]	–2.2 ± 6.7	0.9 ± 7.7	–2.7 ± 9.2	$p = 0.36$ (NS)[a]
Number (%)[d] of participants with weight gain (> 4.5 kg)	3 (14%) (Variance not reported)	4 (27%) (Variance not reported)	1 (4%) (Variance not reported)	Not reported
Number (%)[d] of participants with no weight change (within ± 4.5 kg)	10 (48%) (Variance not reported)	9 (60%) (Variance not reported)	18 (72%) (Variance not reported)	Not reported
Number (%) of participants with clinical success (weight loss > 4.5 kg)	8 (38%) (Variance not reported)	2 (13%) (Variance not reported)	6 (24%) (Variance not reported)	$p = 0.36$ (NS)[e]
Facilitators	None reported	None reported	None reported	
Barriers	None reported	None reported	None reported	

D, diet only; D + E, diet and exercise; E, exercise only.
a ANOVA.
b Calculated from baseline weight for those attending follow-up at 24 months only.
c Gender had no significant influence on the relationship between treatment group and change in body weight over time.
d Calculated by reviewer; the percentage is of those participants who completed 2-year follow-up.
e Fisher's Exact test.
All results are presented for follow-up at 2 years after enrolment ($n = 61$).
Reported that mean weight change from end of treatment to follow-up (1–2 years) differed significantly between the intervention groups ($p = 0.005$; ANOVA), but no means or variances were provided. (Stated descriptively that marked weight gain occurred in D + E and D only groups, but not in the E only group.)

Methodological comments/notes

- Allocation to treatment groups: stated only that participants were assigned randomly to treatment group by a table of random numbers. No other details of treatment allocation were reported
- Blinding: not reported
- Comparability of treatment groups: not reported for all randomised participants. Baseline comparability was only reported for initial weight of those participants who completed follow-up. Baseline comparability of some other variables was reported but for unknown cohorts of the population (the reported sample sizes do not correspond to any defined populations)
- Method of data analysis: Mantel–Haenszel χ^2 tests were used to compare gender and attrition across the intervention groups. ANOVA was used to examine differences between the interventions in weight changes over time
- ITT analysis: not reported
- Sample size/power calculation: not reported. Relatively small sample size
- Attrition/dropout: numbers reported but not reasons

General comments

- Generalisability: participants had answered a newspaper advertisement, paid US$100 initially to enrol, and were offered US$35 for fulfilling the follow-up requirement. This may have had an impact on those taking part. The authors note (in the abstract) that the large outcome variability and 'unequal difficulty' of the regimens across groups limits the generalisability of the findings
- Outcome measures: unclear how missing data were accounted for (all outcome data excluded attrition). Participants' self-reported adherence to diet and exercise (no details provided) was recorded in diet and exercise questionnaires, but results were incompletely and inconsistently reported: 1. Diet and exercise (D + E): three participants (14.3%) reported adhering 'often' to dietary recommendations (adherence to exercise not reported); 2. Diet (D) only: one participant (6.7%) reported adhering 'often' to dietary recommendations; 3. Exercise (E) only: 11 participants (44%) reported 'exercising often during the year after treatment'
- Facilitators/barriers not reported as outcomes: none reported
- Intercentre variability: not reported, number of centres unclear
- Conflict of interests: none reported

Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Yes
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Unclear
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	Yes
(ii) If so, were they explained or adjusted for?	No
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis?	Not reported
(ii) If so, was this defined?	
10. (i) Did the analysis account for missing data?	No
(ii) If so, were the methods appropriate?	

Stevens et al. *and Whelton* et al.

Study details	Participants	Outcome measures
Author: Stevens *et al.*[74] and Whelton *et al.*[109] Linked to He *et al.*[110] (one participating centre only. Outcome data not extracted) Year: 1993 Country: USA Study design: RCT Number of centres: six (although 10 for entire TOHP study) Funding: National Heart, Lung and Blood institute Recruitment dates: September 1987 to October 1988 Setting: not explicitly stated, appears to be hospital clinics Length of follow-up: 18 months	Number of participants: total $n=564$, weight loss intervention $n=308$, usual-care control $n=256$ [as part of a bigger study looking at non-pharmacological interventions to lower BP. See also Whelton *et al.*[111] which compares three active treatments (combined) with controls so is therefore not relevant] Sample attrition/dropout: only adherence/attendance reported. Unclear how many participants may have dropped out completely Attendance at sessions measured: yes Other measures of adherence: no Sample crossovers: not applicable Inclusion/exclusion criteria for study entry: aged between 30 and 54 years, between approximately 115% and 165% of desirable body weight, BMI of 26.1–36.1 kg/m^2 for men, 24.3–36.1 kg/m^2 for women, average BP (DBP) of 80–89 mmHg. Exclusion criteria: history of cardiovascular disease, diabetes mellitus, gastrointestinal tract disease, chronic renal failure, malignant neoplasm, current pregnancy or intent to become pregnant during the study, recent history of psychiatric disorders, or unwillingness to accept randomisation into any study group Characteristics of participants: overall (data also reported separately for men and women in each group) Any risk factors noted: yes, but for high BP (all high-normal BP) Gender (M:F), *n* (%): weight loss 224:84 (72.7:27.3); control 161:95 (62.9:37.1) (*n*'s and % calculated by reviewer) Age (years), mean (SD): weight loss: 43.1 ± 6.0; control 42.4 ± 6.2 BMI kg/m^2 mean (SD): weight loss: 29.5 ± 2.9; control 29.5 ± 2.8 Weight kg mean (SD): weight loss: 90.2 ± 13.3; control 89.3 ± 13.0 % weight lost before starting: not reported Duration of overweight/obesity: not reported Previous weight loss attempts: not reported Physical activity level, vigorous exercise (resulting in perspiration) times/week mean (SD): weight loss: 2.0 ± 2.2; control 2.1 ± 2.3 Ethnicity %: weight loss: white 81.8, black 16.6; control: white 76.6, black 21.1 Socioeconomic position: not reported If a mixed group of participants with pre-existing medical condition report *n* (%)'s with the condition: not applicable Baseline information reported but not data extracted on % college graduates, % employed full-time, % married, health status [systolic BP (SBP), DBP, heart rate, height, cigarette smoking, alcohol intake, urinary sodium excretion), and energy intake (overall, and % energy from fat, % energy from saturated fat)	Primary outcomes: weight loss Secondary outcomes: change in BP (SBP and DBP). Attendance (not data extracted) Facilitators and barriers: not reported Methods of assessing outcomes: Weights were taken without shoes but including light, indoor clothing. Weights recorded for all participants during official clinic visits 3, 6, 12, and 18 months after study entry. Weights also recorded throughout the weight loss intervention Methods of BP assessment not data extracted Any self-reported outcomes? Yes – food diaries and exercise recorded (outcomes not reported) Any subgroup analysis: weight loss by gender reported, and within gender by white ethnicity

Intervention details: This study was part of phase 1 of the TOHP study. The comparison is one of three LIs that were tested in people with high to normal BP to study the efficacy and safety of non-pharmacologic therapy for the prevention of hypertension

Weight loss intervention ($n=308$)

Aim or goal: to achieve a weight loss of at least 4.5 kg during the first 6 months of intervention and to maintain this weight loss throughout the remaining 12 months of trial

Study is not described as a weight maintenance study. However there were two phases. Firstly an intensive phase of an individual counselling session followed by 14 weekly group meetings (for the intensive phase it is generally unclear from study description what aspects of the intervention were provided during the individual sessions, and which in the weekly group meetings). After the intensive phase participants asked to attend monthly meetings for the duration of follow-up (18 months). This phase is described as 'Extended Intervention' and details are noted under 'Ongoing support' below

Usual-care control ($n=256$)

No description provided

Diet:

Details, type of diet: focus on reducing total energy consumption by reducing fat, sugar and alcohol intake. Nutrition topics discussed included guidelines for healthy eating, reducing energy intake, identifying sources of dietary fat and methods for reducing fat intake, recipe modification, restaurant eating, social eating, menu planning, label reading, and shopping strategies. The importance of nutritional balance was discussed at group meetings and incorporated into comments on the food records. Goal of achieving gradual weight loss not to exceed 0.9 kg per week. After reaching goal weight, participants adjusted their energy intake gradually to maintain the new weight level

Calories: average energy intake not to fall below 1200 kcal, no upper limit stated

Proportions of diet: not explicitly stated. Counting energy intake from fat and the percentage of daily energy intake from fat suggested as an optional method for focussing on major sources of energy intake

Monitoring: participants encouraged to make series of small progressive steps to reduce energy intake. To help this, participants expected to keep food diaries for the first 14 weeks of the intervention, recording food intake for 3 of 7 days initially, increasing to 5 or more days per week by the fourth week of intervention. Entries included food description, estimate of amount eaten, and estimate of its energy value. Participants also asked to maintain graph of weight change from baseline

Exercise:

Mode: individual

Type: principally walking. Participants were given general exercise guidelines including warm-up and cool-down exercises, and appropriate application of such exercising as walking, cycling, circuit training, and selected recreational activities. Participants encouraged to become more aware of their normal daily routines and to incorporate more physical activities, such as using stairs rather than elevators, to enhance daily energy expenditure

Frequency and length of each session and total number sessions: initially to walk at least 3 days per week for a minimum of 20 minutes per session. As the intervention progressed exercise goal was 4–5 days per week with between 30 and 45 minutes of exercise per session, at an intensity of 40% to 55% of heart rate reserve (heart rate reserve had been determined empirically before intervention start)

Delivered: mainly self-directed

Level of supervision: mainly unsupervised, except for exercise demonstrations presented during meetings. Several meetings included supervised exercise periods in which the group leaders helped participants adjust their intensity of exercise to be consistent with protocol guidelines

Monitoring: participants asked to record daily exercise time as a bar graph, superimposed on the weight graph

Behaviour modification:

Mode: group 7–20 participants (plus occasional friends or family members there to provide support). At some point during each intervention session, the group was divided into smaller discussion groups for intensive review of each person's progress and plans for the next week

Type: behavioural self-management techniques (two references provided). Relapse prevention was also addressed (reference provided)

Content: strategies included setting reasonable short-term goals, formulating specific plans of action to achieve these goals, developing reinforcement and social support for each major element of the plan, keeping records to assess progress (monitoring of diet and exercise as noted above), and regularly evaluating and modifying action plans by using these records. During the smaller discussion groups, participants displayed graphs and discussed self-management efforts for the past week. Leaders facilitated discussion so that individuals worked on problem solving and developing specific and detailed goals and action plans for the next week. Relapse prevention included: introducing the concept of high-risk situations; identifying high-risk situations in which relapse was likely to occur; developing alternative coping strategies; teaching participants strategies for minimising the occurrence of high-risk situations. Walking opportunities were often made available

Frequency and length of each session and total number sessions: 14 weekly meetings, each of 90 minutes

Delivered: by a registered dietitian and a psychologist or exercise physiologist

Ongoing support:

After the intensive phase, intervention leaders attempted to make at least one intervention contact per month for the remainder of the trial. The type and exact number of contacts varied monthly according to individual needs

Mode: attendance options included any one or combination of the following: (1) monthly extended intervention group sessions, (2) group weigh-in sessions, (3) individual weigh-in sessions, and (4) individual counselling sessions

Type: extended follow-up groups were formed by combining several initial intervention groups. The format of the extended intervention meetings was similar to that of the initial intervention meetings. They featured formal presentations and group discussions on selected nutrition, exercise, and behavioural change topics as well as time for general discussion and problem solving, and for demonstrations/participation in exercise opportunities. A series of extended intervention session outlines were developed on the basis of the perceived needs of the participants. Each centre could adapt the sequence and content of session to meet the ethnic and situational needs of the participants

Frequency and length of each session and total number sessions: monthly meetings, length and number not explicitly stated

Diet and Exercise: during the extended intervention phase, subjects were encouraged to continue monitoring their weight and exercise. If a graph was not maintained an individual monitoring system of some type, such as recording the information on a calendar on in an appointment book, was encouraged

Other details:

If a meeting was missed an intervention leader scheduled a make-up visit as soon as possible. When participants were unable or unwilling to attend make-up visits, attempts were made to maintain contact through telephone calls and mailings

For the extended intervention frequent conference calls helped timely sharing and review of meeting experiences. All sessions were evaluated for effectiveness and archived for easy access

Attendance (at extended intervention meetings) was encouraged by the addition of occasional special events such as cooking demonstrations and guest speakers

A brief, informal meeting with a weigh-in was also offered between the monthly-extended sessions for those who missed the scheduled intervention meetings or who desired more frequent contact. Current weight and amount of exercise since last contact was obtained and individual strategies were discussed with participants during these weigh-ins. Walking opportunities were often made available in conjunction with the weigh-ins

Interventionists collaborated in the preparation of a detailed, session by session protocol and tested its feasibility at each centre with volunteer pilot subjects. This pilot was used to prepare the final version of the protocol. Ongoing quality control activities included biweekly conference calls, two all-centre staff training meetings, and a site visit to each centre

Results

Outcomes	Weight loss ($n=308$)	Control ($n=256$)	p-value, 95% CI
Weight loss at 18 months, mean kg	Men 4.7, women 1.6	Men unchanged (no value provided), women +0.2	$p<0.001$.
Difference in weight loss at 18 months between intervention and control groups, mean ± SEM[a]	Overall: 3.9 ± 0.4		
	Men: 4.7 ± 0.5		$p<0.01$
	Women: 1.8 ± 0.8		$p<0.01$
Success at 18 months[b]	Men 45%, women 26%	Men 12%, women 18%	
Success at more than 24 or 30 months?	Phase II study included separately		
Facilitators	Not reported		
Barriers	Not reported		
Other intermediate outcomes	Not reported		

SEM, standard error of mean.

a Data from this analysis restricted to whites not extracted.

b Success defined as having met weight loss goal of 4.5 kg. Numbers not calculated as value of denominator not clear.

States that the average treatment effect remained highly significant when weight loss was expressed as a percentage change from baseline weight, or as the change in BMI but no data provided. The difference between women and men in percentage changes from baseline weight and change in BMI remained statistically significant although at a diminished level of significance ($0.05>p>0.001$ for both measures at each follow-up).

Treatment effect on weight was more strongly modified by baseline weight than by sex. Paper provides data on estimated difference in weight loss for those less than, and more than the median weight (not data extracted). Differences in intervention effect were also examined by race (not data extracted).

Changes in measures of BP associated with changes in weight not data extracted.

Methodological comments/notes

- Allocation to treatment groups: once eligibility for the trial was confirmed, participants in the high-weight stratum (who were those eligible for the weight loss intervention of interest here) were randomised to all TOHP treatment groups and controls. Each participating clinic notified the co-ordinating centre by telephone and obtained a randomisation assignment (no details of randomisation schedule). Clinics were also provided with sealed envelopes containing randomisation assignments for use when telephone contact with the co-ordinating centre was not possible (not stated if these were used). Once the assignment was communicated to the participant, he or she was considered officially randomised. Randomisation was to more than the two groups relevant to this review
- Blinding: the Whelton and colleagues[109] paper (p. 298) notes that a small sample of randomly selected high-weight participants from other LI arms had the same baseline assessments as those assigned to the weight loss intervention to maintain observer blinding. Baseline assessments obtained by blinded observers. He and colleagues[110] report that for one centre data collectors were also blinded at follow-ups, however, Sattersfield and colleagues[112] provide conflicting information stating that the lifestyle arm of the trial had an open design (while supplement interventions were double-blinded and placebo-controlled with data collectors for BP measurements blinded to treatment)
- Comparability of treatment groups: baseline similarity overall and by gender was examined. There were no significant differences between the two groups except that the intervention group had slightly larger proportion of men (72.7% vs 62.9%, $p=0.02$). There was a higher proportion of black participants among women than among men in both groups
- Method of data analysis: statistical tests for differences in means or proportions included student's two-sample *t*-test (for means) and the chi-squared test of association (for proportions). Mean differences in weight change from baseline between intervention and control groups were assessed overall and for men and women separately with a *t*-test at each follow-up visit. Linear regression analysis was used to adjust for age, race, baseline BP and gender (when appropriate). However, because results did not change the unadjusted results are presented. A difference in treatment effect by gender was tested in a regression model with a gender-by-treatment interaction term. Data collectors were trained centrally, were required to pass certification examinations and periodic recertification evaluations
- ITT analysis: not reported (and therefore not defined). Appears unlikely that analysis is ITT
- Sample size/power calculation: power of 85% to detect a diastolic BP (DBP) effect of 2 mmHg in the complete study sample. For the weight reduction part of the trial there was a power of 96% to detect a DBP effect of 2 mmHg, and 93% power to detect a change of 3 mmHg in systolic BP (SBP). No further details are provided, and no comment made regarding power for detecting weight reduction, also unclear whether powered for subgroups
- Attrition/dropout: attendance reported but unclear how many participants dropped out completely and reasons for dropout not provided

General comments

- Generalisability: not generalisable to older people due to inclusion criterion of age 30–54 years. Not generalisable to those with BMI > 36 kg/m^2. Typical participants were well-educated, middle-aged, white males with a full time job. Participants were volunteers that may affect generalisability
- Outcome measures: the main focus of the trial is BP status. No further outcomes to weight loss, diet or exercise apparent
- Facilitators/barriers not reported as outcomes: not reported
- Intercentre variability: no comments found relating to this. Note that interventionists were all involved in the protocol preparation and piloting of this. Biweekly conference calls, two all-centre staff training meetings and a site visit ensured quality control
- Conflict of interests: no statement of conflicts of interest found

Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Not reported
2. Was the allocation adequately concealed?	Yes
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Unclear
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	Not reported
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis?	Not reported
(ii) If so, was this defined?	
10. (i) Did the analysis account for missing data?	Not reported
(ii) If so, were the methods appropriate?	

Stevens et al. *and TOHP collaborative research group*

Study details	Participants	Outcome measures
Author: Stevens *et al.*[70] and TOHP collaborative research group[113] Data also reported in studies[114–118] Year: 2001 Country: USA Study design: RCT Number of centres: nine Funding: numerous grants from National Heart, Lung and Blood Institute Recruitment dates: December 1990 to March 1992 Setting: clinics Length of follow-up: minimum of 36 months; additional data at 42 ($n=1458$, 61%) and 48 ($n=464$, 19%) months depending on randomisation date	Number of participants: $n=1191$ Weight loss (WL) group, $n=595$ Usual-care (UC) group, $n=596$ Part of an RCT of four groups: weight loss only, sodium reduction only, weight loss and sodium reduction, usual-care controls ($n=2382$) Sample attrition/dropout: at 18 months 50 were not included in the analysis in the WL group and 45 in the UC group; at 36 months these rates were 48 and 42, respectively Attendance at sessions measured: yes, although rates could differ depending on delay before first group session Other measures of adherence: yes Sample crossovers: none reported Inclusion/exclusion criteria for study entry: overweight adults with non-medicated DBP of 83–89 mmHg and SBP < 140 mmHg, aged 30–54 years, BMI of 26.1–37.4 kg/m^2 for men and 24.4–37.4 kg/m^2 for women (approximately 110%–165% of ideal weight based on 1983 Metropolitan life tables) Exclusion criteria: current hypertension or treatment with medications that might affect BP, clinical or laboratory evidence of cardiovascular disease, diabetes mellitus, renal insufficiency [serum creatinine concentration ≥ 150 µmol/l (≥ 1.7 mg/dl) for men and ≥ 132 µmol/l (≥ 1.5 mg/dl) for women] or other serious illness, current or planned pregnancy, non-fasting serum glucose concentration of ≥ 200 mg/dl, alcohol intake of ≥ 21 drinks per week, residing more than 50 miles from the centre, evidence of unwillingness to adhere to the trial intervention or data collection procedures Characteristics of participants: Any risk factors noted: all participants had high–normal BP Gender (M : F), *n* (%): WL 375 : 220 (63.0 : 37.0); UC 407 : 189 (68.3 : 31.7) Age (years), mean (SD): WL 43.4 (6.1); UC 43.2 (6.1) BMI kg/m^2, mean (SD), M : F: WL 31.0 (2.9) : 31.0 (3.6); UC 31.0 (2.9) : 30.8 (3.5) Weight, kg, mean (SD), M : F: WL 98.9 (12.3) : 84.1 (11.9); UC 98.54 (11.7) : 82.9 (10.9) Overall weight kg, mean (SE): WL 93.4 (14.1); UC 93.6 (13.5) Vigorous exercise, times per week: WL 2.0 (4.0); UC 1.8 (1.9) Ethnicity % white : black: WL 78 : 17.8; UC 79.5 : 17.3	Primary outcomes: BP (not extracted), weight loss Secondary outcomes: dietary intake, physical activity, medication use – not extracted Facilitators and barriers: none Methods of assessing outcomes: Weight measured to the nearest 0.2 kg (0.5 lb) by using a calibrated balance beam scale; participants wore indoor clothing without shoes Subgroup analyses by gender and ethnicity (not extracted)

Intervention details	
WL	**UC**
(*n* = 595)	**(*n* = 596)**
Aim or goal: to lose at least 4.5 kg (10 lb) during the first 6 months of the intervention and to maintain the weight loss for the remainder of the trial. The intervention has a pre-intensive phase (while clinics accrued enough participants for the group intervention), an intensive phase, a transitional phase and then an extended phase. The transitional phase was designed to prevent relapse and to ease transition from weekly to less frequent contacts. The goal of the final extended phase was to maintain participants' behaviour changes	No details reported
Diet:	
Details, type of diet: focus on reducing caloric intake but weight loss of > 0.9 kg (2 lb) per week was discouraged	
Calories: suggested that men not consume < 1500 kcal/day and women ⩽ 1200 kcal/day but with experience participants determined the caloric intake that produced moderate weight loss for them	
Proportions of diet: states decreasing consumption of excess fat, sugar and alcohol	
Monitoring: self-monitoring with daily food diaries, known as 'scorekeepers'. Asked to record intake for at least 6 days a week during the intensive phase, after this time the frequency was individualised. Progress also monitored at group meetings and by frequent measurement of weight	
Exercise:	
Mode: group discussion of goals but individual exercise	
Type: primarily brisk walking, states moderate intensity exercise of approximately 40%–55% of heart rate reserve	
Frequency and length of each session and total number sessions: to gradually increase activity from 10–15 minutes at least 3 days per week to 30–45 minutes per day, 4–5 days per week at an intensity of 40%–55% of heart rate reserve	
Delivered: group discussion of exercise by dietitians and health educators, otherwise exercise was undertaken individually (four of the 14 sessions were specifically designated for engaging in physical activity)	
Level of supervision: discussed at group interventions, otherwise assume self-supervised	
Monitoring: graphs of physical activity per day used and recorded activity in the 'scorekeepers'. Progress reviewed at the group meetings	
Behaviour modification:	
Mode: individual counselling session until groups could be formed (at least one) and some group meetings or by telephone during the 'preintensive' phase, followed by group sessions thereafter. Groups of 11–34 participants	
Type: states based on behaviour change principles, but no further details	
Content: focus on self-directed behaviour change (behavioural self-management), nutrition education, information on physical activity, and social support for making and maintaining behaviour changes. Specifically included self-monitoring, short-term goal-setting, developing specific action plans to achieve objectives, developing alternative strategies for situations which trigger problem eating	
Frequency and length of each session and total number sessions: monthly contact (pre-intensive phase) weekly for 14 weeks (intensive phase) then six biweekly meetings and then monthly meetings for additional 3–4 months (although one study publication suggests for 18 months) (transitional phase)	
Delivered: led by dietitians and health educators (and some psychologists) who were centrally trained and had experience of conducting weight loss interventions	
Ongoing support:	
In the extended phase of the study participants were given options to keep them informed, including individual counselling sessions, special refresher group sessions (mini-modules) and biweekly meetings	
Mode: could be group/individual/telephone/postcards/faxes	
Type: refreshing or redelivering the intervention content, especially for those who had not lost weight initially or relapsed. Modules included a wide range of topics and activities that were determined by a combination of participant and interventionist interest, as well as by centre and local area resources, season of the year and current events	
Frequency and length of each session and total number sessions: biweekly contacts for three to six sessions in each mini-module, offered six times a year (participants expected to attend at least three)	
Other details:	
Family members were invited to group meetings when the participant felt it helpful	

Results

Outcomes	WL group ($n=595$)	UC group ($n=596$)	Difference (SE), 95% CI, p-value
Weight change from baseline at 18 months, kg (SD), 95% CI, n	–2.0 (5.8), –2.5 to –1.5, $n=545$	0.7 (4.2), 0.4 to 1.6, $n=551$	–2.7 (0.3), –3.3 to –2.1, $p<0.001$
Weight change from baseline at 36 months, kg (SD), 95% CI, n	–0.2 (5.9), –0.7 to 0.3, $n=547$	1.8 (5.3), 1.3 to 2.2, $n=554$	–2.0 (0.2), –2.6 to –1.3, $p<0.001$
Facilitators	Not reported	Not reported	
Barriers	Not reported	Not reported	
Other intermediate outcomes	None	None	

Methodological comments/notes

- Allocation to treatment groups: states participants were randomly assigned with equal probability to one of four groups. Those undertaking the assignment were blind to the intervention assignment, performed by telephone contact with the TOHP co-ordinating centre (in 77% of participants, as only open during normal working hours) or by opening a sealed, opaque envelope. Randomisation was stratified by clinic to provide an even distribution to the four groups at each site
- Blinding: clinic staff who were blinded to study group assignment assessed outcomes (questionnaires to data collectors at the end indicated 31.6% guessed correctly which intervention group a participant was in, which was more than expected by chance, 25%)
- Comparability of treatment groups: states baseline characteristics compared by t-tests and chi-square tests and groups were comparable (p-values reported for the comparison of the four treatment groups)
- Method of data analysis: two sample t-tests were used to compare changes in weight from baseline overall, by gender, ethnicity and by gender and ethnicity
- ITT analysis: not reported
- Sample size/power calculation: sample size (for primary outcome of BP) was expected to provide greater than 80% power to detect a treatment-related difference in DBP between the varying groups in the factorial design of the overall study. Not strictly powered for the weight outcome. Attrition/dropout: states weight data collected every 6 months, with special efforts to achieve high follow-up rates at 18 and 36 months. Numbers analysed reported but no reasons (except the few who died)

General comments

- Generalisability: not generalisable to older people due to inclusion criterion of age 30–54 years. Study also undertaken in those described as 'moderately overweight' therefore excludes people with BMI > 37 kg/m^2, also only applies to those with high-normal DBP. Candidates were canvassed from mass mailing, community screening, media advertising, and other sources and thus were volunteers to the study that may reduce the generalisability of the study. Some centres had higher proportions eligible after screening than others
- Outcome measures: 6-month outcome data reported for weight loss (not extracted here)
- Facilitators/barriers not reported as outcomes: none
- Intercentre variability: not reported, states quality control procedures including periodic retraining and monthly reviews were put in place
- Conflict of interests: none reported

Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Yes
2. Was the allocation adequately concealed?	Yes
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Yes
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	No
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis?	No
(ii) If so, was this defined?	
10. (i) Did the analysis account for missing data?	Not reported
(ii) If so, were the methods appropriate?	

Tate et al.

Study details	Participants	Outcome measures
Author: Tate *et al.*[77] (Linked to Jeffery *et al.*[119] and Raynor *et al.*[120]) Year: 2007 Country: USA Study design: RCT (two arms) Number of centres: not reported (recruitment was from two centres) Funding: National Institutes of Health grants HL41330 and HL41332 Recruitment dates: not reported Setting: not reported but recruitment by public advertisement Length of follow-up: 30 months	Number of participants: Standard behavioural treatment (SBT) $n=93$ High physical activity (HPA) treatment group $n=109$ Total number randomised: $N=202$ Sample attrition/dropout: *HPA retention:* 94% at 6 months, 79% at 12 months, 80% at 18 months, 77% (84/109) at 30 months *SBT retention:* 90% at 6 months, 82% at 12 months, 87% at 18 months, 79% (74/93) at 30 months Total number of drop outs at 30 months: $n=44$ Attendance at sessions measured: not reported Other measures of adherence: none reported Sample crossovers: none Inclusion/exclusion criteria for study entry: age 25–50 years; overweight of 14–32 kg according to actuarial norms; free from serious concurrent medical or psychological problems thought to interfere with treatment Characteristics of participants: most demographic and baseline data not reported separately for each group. States there were no significant differences between treatment groups for age, gender, % of college graduates, white ethnicity, and mean BMI *Any risk factors noted:* no Gender (M:F), *n* (%): 85:117 (42%:58%) *(n*:n *calculated by reviewer)* Age (years), mean (SD): 42.2 (6.4) BMI kg/m^2, *n* (%): mean (SD): BMI 31.7 (2.6) kg/m^2, range 26–44 Weight kg, mean: approximately 90.5 for both interventions (data extracted from graph by reviewer) % weight lost before starting: not reported Duration of overweight/obesity: not reported Previous weight loss attempts: not reported Physical activity level (assessed by self-report with Paffenbarger Physical Activity Questionnaire): baseline weekly energy expenditure (kcal/week), mean (SD): HPA 1278.0 (1369), $n=109$. SBT 1286.0 (1258.0), $n=93$ Ethnicity: 80% white Socioeconomic position: not reported Pre-existing medical conditions: not reported	Primary outcomes: change in body weight Secondary outcomes: physical activity (energy expenditure); Dietary intake (energy intake kcal/day; protein g/day; fat g/day; carbohydrate g/day); Adverse effects of exercise programme – not extracted Facilitators and barriers: none reported Methods of assessing outcomes: Body weight: measured in clinic using a calibrated scale while the subject wore light street clothes and no shoes Height (used for BMI calculation): wall-mounted stadiometer *Subgroup analyses:* Tate *et al.* paper[77] reports weight changes for subgroups of consistently high exercises versus all others

Intervention details

SBT group

(*n* = 93)

Aim or goal: encourage increasing physical activity to reach standard 1000 kcal physical activity/week prescription during a behavioural weight loss programme

Diet:

Type of diet: calorie restriction, low fat

Frequency and length of each session and number of sessions: not reported explicitly for diet; probably as reported below for behaviour modification as this included nutritionists

Calories: goal to reduce daily energy intake to 1000–1500 kcal depending on initial body weight (no further details provided)

Proportions of diet: consume < 20% of energy as fat

Monitoring: participants asked to keep complete diet records daily for the first 6 months and for 1 week/month thereafter during the 18-month intervention phase

Exercise:

Mode: not stated but appears to be individual

Type: not stated, but goal was to build up from energy expenditure of 250 kcal/week, increasing by 250 kcal/week, to energy expenditure of 1000 kcal/week (roughly equivalent to walking for 30 minutes/day)

Frequency and length of each session and total number sessions: not stated, but goal was to initiate a regular physical activity programme

Delivered: not stated, but appears to be no set class, instead self-directed by participant

Level of supervision: not stated, but appears to be unsupervised

Monitoring: participants were asked to keep complete physical activity records daily for the first 6 months and for 1 week/month thereafter during the 18-month intervention phase

Behaviour modification:

Mode: small groups, e.g. 10–20 participants

Type: no theoretical basis or definition of behaviour modification component reported

Content: didactic presentations of material needed to develop obesity management skills, group discussions, and problem solving. Session content adapted from prior research (referenced by Jeffery *et al.*[119]) included diet, physical activity, stimulus control, problem solving, goal-setting, social support, motivation, and relapse prevention topics

Frequency and length of each session and total number sessions: weekly meetings for first 6 months, biweekly from 6 to 12 months, then monthly from 12 to 18 months. No treatment contact after the 18-month programme until participants were re-contacted at 30 months for the final assessment

Delivered: led by trained interventionists (nutritionists, exercise physiologists, or psychologists) with expertise in both content area (i.e. physical activity and nutrition) and behavioural therapy

Other details:

Participants were not encouraged to recruit friends or family members

Financial incentives: none

HPA group

(*n* = 109)

Aim or goal: encourage increasing physical activity to reach 2500 kcal physical activity/week during a behavioural weight loss programme

Study reports a weight management (weight loss) intervention (duration of intervention 18 months) with participants followed up for a further year after the end of the intervention (to determine how well weight loss maintained, but no intervention in this period)

Diet: identical goals as the SBT group

Exercise:

Mode: not explicitly stated but appears to be a mix of individual and group (with support partners, *n* = 1–3; see 'Other' details below)

Type: not stated, but goal was to build up to an energy expenditure of 2500 kcal/week by the end of the first 6 months of the intervention (roughly equivalent to walking < 75 minutes/day)

Frequency and length of each session and number of sessions: not reported explicitly for diet; probably as reported below for behaviour modification as this included exercise physiologists

Appears also to be participant determined

Delivered: by exercise coaches (also referred to as exercise physiologists) skilled in exercise science and prescription

Level of supervision: the exercise coaches met with small groups of study participants before or after each group session. They reviewed exercise progress with each participant individually and provided encouragement, support, and problem-solving strategies for participants who were having difficulty reaching their physical activity goals

Monitoring: same as the SBT group

Behaviour modification: identical to that of the SBT group

Ongoing support:

Other than contact as described above during the intervention, there was no contact between the end of the intervention at 18 months and the final follow-up at 30 months

Other details:

Participants were strongly encouraged to recruit friends or family members to participate in the study with them due to prior research suggesting benefits of social support for exercise and maintenance of weight loss. Participants were encouraged to recruit one to three partners, overall 54% of this group recruited one or more support partners. Entry criteria for support partners were wider than for trial participants but they went through the same screening, received the same intervention and participated in same outcome assessments

Financial incentives: incentives of US$3 for each week that participants achieved or exceed the energy expenditure goal of 2500 kcal/week during the last 6 months of active intervention (months 12–18). Participants were paid US$50 for completing the 30-month assessment

Results

Outcomes:	1. HPA	2. SBT	*p*-value
Weight loss kg, baseline to 18 months	6.7 ± 8.1 (*n* = 87) (variance estimate not defined)[a]	4.1 ± 8.3 (*n* = 80) (variance estimate not defined)[a]	*p* = 0.04
Weight loss kg, baseline to 30 months (unclear whether this is an ITT analysis)	2.86 8.6 (*n* = 84) (variance estimate not defined)	0.9 ± 8.9 (*n* = 74) (variance estimate not defined)	States no significant difference, *p* = 0.16
Weight loss % of initial body weight, baseline to 30 months (unclear whether this is an ITT analysis)	3 (variance estimate not reported)	1 (variance estimate not reported)	States no significant difference, *p*-value not reported
Weight regain from 18 to 30 months, kg (unclear whether this is an ITT analysis)	5.9 5.9 (*n* not reported) (variance estimate not defined)	5.3 ± 7.0 (*n* not reported) (variance estimate not defined)	States no significant difference, *p*-value not reported
Success at 30 months (ITT, assuming no weight loss for missing data)	Total weight loss ≥ 5% achieved by 26% Total weight loss ≥ 10% achieved by 12%		States no significant difference, *p*-value not reported
Facilitators	Not reported	Not reported	Not reported
Barriers	Not reported	Not reported	Not reported

a The standard error of the mean (SEM) shown in Figure 2 of Jeffery and colleagues[119] has bars which are much narrower than the variance estimates reported here, suggesting these are not SEM.

Taking all participants (both interventions together), mean (± SD) weight loss (kg) 0–30 months was significantly greater ($p = 0.04$) in men (4.2 ± 7.1) than in women (0.29 ± 9.5).

Post hoc analyses were conducted by Tate and colleagues.[77] in a selected 'high-adherence' exercise group but have not been data extracted. These analyses were conducted to explore whether those reporting high levels of activity at all follow-ups were protected against weight regain.

Raynor and colleagues[120] reported on 122 of the 202 participants who had complete data, including complete dietary data but changes in foods eaten and weight were not reported by study group and have not been data extracted.

Methodological comments/notes

- Allocation to treatment groups: randomisation and allocation procedures not described
- Blinding: not reported
- Comparability of treatment groups: stated there were no significant differences between treatment groups for age, gender, % of college graduates, white ethnicity, and mean BMI but data not reported separately for each group and no *p*-value(s) provided.[119] Examination of the baseline characteristics of study completers ($n=168$) and study dropouts ($n=34$) at 18 months found no significant difference in body weight, gender, exercise level, energy intake or percentage of energy from fat.[119] Examination of the baseline characteristics of study completers ($n=158$) and study dropouts ($n=44$) at 30 months found no significant difference in body weight, BMI, gender, energy intake or energy expenditure[77]
- Method of data analysis: continuous dependent variables (weight, total energy expenditure, and total energy intake) were analysed by using general linear modelling procedures for repeated measurements. Energy expenditure was not normally distributed, and the data were log transformed before analysis. Between-group comparisons of baseline characteristics, weight change or change in calories (exercise or diet) at specific end points were analysed by using ANOVA. Analyses of exercise subgroups controlled for baseline weight and gender
- ITT analysis: reported but not defined. For ITT analyses, participants for whom data were missing at any time point were assumed not to have lost any weight, and an approach of carrying the baseline forward was used
- Sample size/power calculation: not reported
- Attrition/dropout: reasons not provided. Stated that dropouts and completers did not differ in BMI, gender, energy expenditure and energy intake (other variables not examined). Jeffery and colleagues[119] reported an interaction for weight loss at 6 months between intervention and attrition. In HPA, subjects with complete data (for 18 months) had higher mean 6-month weight losses than those with incomplete data (i.e. those who did not complete 18 months) ($p<0.02$). In SBT the pattern was reversed ($p=0.10$). They stated that this strongly suggests that the assumption in their ANOVA analysis that the loss to follow-up is unbiased may not be correct. However they believed that the repeated measures ANOVA is likely to be biased toward the null hypothesis, i.e. in favour of no difference between the study groups. No test for an interaction beyond 6 months was reported

General comments

- Generalisability: uncertain, but 80% white ethnicity and 43% college graduates so may not be representative of the overweight and obese population in the UK. Free from serious concurrent medical or psychological problems. Recruitment was by public advertisement and participants received monetary incentives. This may have had an impact on those taking part
- Outcome measures: reported as mean ± unspecified variance estimate; effect size and statistical significance not reported for most outcomes. Additional measures reported but not data extracted: energy intake (kcal/day); protein (g/day); fat (g/day); carbohydrate (g/day); energy expenditure (kcal/week). Adverse effects of exercise programme (at 18 months only[119])
- Facilitators/barriers not reported as outcomes: none, but note that discussion in Tate and colleagues[77] stated that failure to maintain higher levels of physical activity 1 year after treatment ended was the likely reason for the failure of the HPA group to achieve greater long-term weight loss than the SBT group. Discussion in Jeffery and colleagues[119] suggests that injuries may undermine the ability of participants to stick with an exercise programme over time (and the injury rate was consistently greater in the HPA treatment group than in the SBT group for the 18 months of this study)
- Intercentre variability: not mentioned. Number of centres not explicitly stated (seem to be only two)
- Conflict of interests: stated that none of the authors had a financial or personal conflict of interest

Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Not reported
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	Unclear
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis?	Yes
(ii) If so, was this defined?	No
10. (i) Did the analysis account for missing data?	Yes
(ii) If so, were the methods appropriate?	Unclear

Wadden et al.

Study details	Participants	Outcome measures
Author: Wadden *et al.*[69,121] Years: 1986, 1988 Country: USA Study design: RCT Number of centres: not reported Funding: researchers supported by three grants from: National Institute of Mental Health; National Institute of Child Health and Human Development; MacArthur Foundation's Network on Health Promoting and Disease Preventing Behaviors Recruitment dates: not reported Setting: not reported; VLCD intervention aimed to simulate physician's outpatient practice Length of follow-up: 3 years	Number of participants: Standard behaviour therapy (SBT) [referred in publication as Behavioural Therapy (BT)]: $n=18$ Combined treatment (VLCD + SBT): $n=23$ Very-low-calorie diet (VLCD): $n=18$ Total: $N=59$ Sample attrition/dropout: Not reported separately by intervention but stated that attrition was spread evenly across the interventions *At end of treatment (4 or 6 months):* overall 15.3% (nine participants) *At 1-year follow-up:* overall 18.6% (11 participants) *At 3-year follow-up:* overall 23.7% (14 participants) Attendance at sessions measured: not reported Other measures of adherence: none reported Sample crossovers: none reported Inclusion/exclusion criteria for study entry: *Inclusion:* written approval from participant's physician; responders to newspaper advertisements; at least 25 kg overweight (based on height-weight tables of Metropolitan Insurance Company) *Exclusion:* recent cardiac abnormality including myocardial infarction; history of cerebrovascular, kidney, or liver disease; cancer; type I diabetes; severe psychiatric illness	Primary outcomes: (reported, but not stated explicitly that these were primary outcomes): weight loss; percentage of participants maintaining weight loss at 1 and 3 years' follow-up Secondary outcomes: (reported, but not stated explicitly that these were secondary outcomes; not data extracted): depression; psychological and physical consequences of regaining weight (not validated); BP Facilitators and barriers: none reported Methods of assessing outcomes: Weight measured using a balance beam scale *Subgroup analyses:* Interventions each stratified into three groups based on degree overweight Post hoc comparison of participants who after 1-year follow-up did ($n=19$) or did not ($n=26$) receive additional therapy from external weight loss programmes

Characteristics of participants:

Risk factors noted: 14 participants (23.7%) were taking antihypertensive treatment

Reported only for 50 participants who completed treatment (VLCD = 15; SBT = 16; VLCD + SBT = 19):

Gender (M:F), *n* (%):	VLCD: 2:13 (13:87)	SBT: 3:13 (19:81)	VLCD + SBT: 2:17 (11:89)
Age (years), mean ± SD:	VLCD: 44.3 ± 8.7	SBT: 44.3 ± 8.6	VLCD + SBT: 43.6 ± 7.8
Height (cm), mean ± SD:	VLCD: 162.1 ± 7.0	SBT: 166.5 ± 10.3	VLCD + SBT: 165.6 ± 7.3
Weight (kg), mean ± SD:	VLCD: 106.4 ± 18.4	SBT: 112.2 ± 21.5	VLCD + SBT: 108.0 ± 21.5
Degree overweight (%), mean ± SD:	VLCD: 85.4 ± 27.4	SBT: 91.8 ± 32.2	VLCD + SBT: 90.7 ± 37.4
BMI, kg/m^2, *n* (%):	Not reported	Not reported	Not reported
% weight lost before starting:	Not reported	Not reported	Not reported
Duration of overweight/obesity:	Not reported	Not reported	Not reported
Previous weight loss attempts:	Not reported	Not reported	Not reported
Physical activity level:	Not reported	Not reported	Not reported
Ethnicity:	Not reported	Not reported	Not reported
Socioeconomic position:	Not reported	Not reported	Not reported

Intervention details

Three *weight loss* interventions of duration 4 months (VLCD), 6 months (SBT) or 6 months (SBT + VLCD), each with follow-up at 1 year (reported in Wadden *et al.*[121]). *Weight loss or maintenance* then assessed after 3 years (reported in Wadden *et al.*[69]). During years 1–3, some participants (19%) received additional weight therapy from unspecified external sources while the remainder (81%) did not receive any additional weight therapy

Intervention details

SBT

(*n* = 18)

Aim or goal: not reported

Diet:

Type of diet: 6-month duration, 1000–1200 kcal/day balanced diet of participants' choosing

Frequency and length of each session and total number sessions: weekly 90-minute sessions of groups of 4–7 participants led by two doctoral-level clinical psychologists, following procedures described in detailed treatment manuals which differed for each intervention (no details reported)

Calories:

Months 1–6: 1000–1200 kcal/day

Proportions of diet: months 1–6: chosen by participants. No further details reported

Monitoring: none reported

Exercise:

Mode: three groups of 4–7 people

Type: involved walking and using stairs. No other details reported

Frequency and length of each session and total number sessions: as reported above for diet

Delivered: by two doctoral-level clinical psychologists

Level of supervision: not reported (assumed as for VLCD)

Monitoring: none reported

Behaviour modification:

Mode: three groups of 4–7 people

Type: training in skills needed for weight loss maintenance

Content: traditional behavioural methods of weight control taught (based on cited references). Included: recording eating behaviour; controlling stimuli associated with eating; slowing rate of consumption; modifying self-defeating thoughts and emotions associated with dieting; social support; and reinforcing changes in behaviour

Frequency and length of each session and total number sessions: as reported for diet

Delivered: by two doctoral-level clinical psychologists

Ongoing support:

Scheduled follow-up meetings (no other details reported)

Type: group

VLCD + SBT

(*n* = 23)

Aim or goal: not reported

Diet:

Type of diet: 6-month duration including a 2-month VLCD comprising a protein-sparing modified fast (months 1–4 same as VLCD; months 5–6 same as SBT):

Month 1: 1000–1200 kcal/day balanced diet of participants' choosing

Months 2–3: VLCD comprising a protein-sparing modified fast

Month 4: return to conventional food

Months 5–6: 1000–1200 kcal/day balanced diet of participants' choosing

Frequency and length of each session and total number sessions: same as SBT

Calories: months 1–4 same as VLCD; months 5–6 same as SBT:

Month 1: 1000–1200 kcal/day

Months 2–3: 400–500 kcal/day

Month 4: return to 1000–1200 kcal/day (managed refeeding)

Months 5–6: 1000–1200 kcal/day

Proportions of diet:

Month 1: 'balanced calorie diet' (no details reported)

Months 2–3: VLCD comprising meat, fish, fowl, plus daily supplements of 3 g each of potassium and sodium chloride and 800 mg of calcium

Month 4: conventional food, with introduction of (in order) fruits and vegetables, breads and cereals, and fats

Months 5–6: chosen by participants

Monitoring: not reported (assumed the same as VLCD)

Exercise:

Mode: three groups of 4–7 people

Type: involved walking and using stairs. No other details reported

Frequency and length of each session and total number sessions: as reported for diet

Delivered: by the same people as SBT

Level of supervision: not reported (assumed as for VLCD)

Monitoring: none reported

Behaviour modification:

Mode: as reported for SBT

Type: as reported for SBT

Content: as reported for SBT

Frequency and length of each session and total number sessions: as reported for SBT

Delivered: as reported for SBT

VLCD

(*n* = 18)

Aim or goal: to simulate treatment as delivered in a physician's outpatient practice (no quantitative goal specified)

Diet:

Type of diet: 4-month duration including a 2-month VLCD comprising a protein-sparing modified fast

Months 1–4: same as VLCD + SBT

Frequency and length of each session and total number sessions: same as SBT

Calories:

Months 1–4: same as VLCD + SBT

Proportions of diet:

Months 1–4: same as VLCD + SBT

Monitoring: participants were encouraged to record their food intake

Exercise:

Mode: three groups of 4–7 people

Type: no formal instruction in modifying exercise habits

Frequency and length of each session and total number sessions: as reported for diet

Delivered: by the same people as SBT

Level of supervision: supervision only of discussion groups

Monitoring: participants were encouraged to record their exercise

Behaviour modification:

No behaviour modification. At weekly group meetings participants discussed their reactions to the diet but received no formal instruction in modifying their eating and exercise habits

Ongoing support:

Scheduled follow-up meetings (no other details reported)

Mode: group; size not reported

Type: group

Frequency and length of each session and total number sessions: six scheduled follow-up meetings at 1, 2, 3, 6, 9, and 12 months post-treatment (no other details reported)

Other details:

As reported for SBT

Frequency and length of each session and total number sessions: 11 scheduled follow-up meetings: fortnightly for 2 months post-treatment, then monthly for 4 months then at 2-month intervals for 6 months (no other details reported) Other details: Subjects paid US$10 per visit plus US$40 which was refunded at the 1-year follow-up	*Ongoing support:* Scheduled follow-up meetings (no other details reported) *Mode:* group; size not reported *Type:* group *Frequency and length of each session and total number sessions:* as reported for SBT Other details: As reported for SBT

Results

Outcomes	VLCD + SBT ($n=16$)	VLCD ($n=15$)	SBT ($n=14$)	*p*-value, 95% CI
Mean ± SD weight loss (kg)				
(a) uncorrected analysis[a]	(a) 6.53 ± 9.50	(a) 3.76 ± 8.85	(a) 4.76 ± 6.56	Stated NS; no *p*-values reported
(b) corrected analysis[a]	(b) 5.11 ± 8.28	(b) 2.20 ± 8.50	(b) 3.54 ± 6.26	
	(variance not reported)	(Variance not reported)	(Variance not reported)	
Mean proportion (%) of participants who equalled or exceeded their pre-treatment weight (stated that the % are approximate)	38	47	43	Stated NS; no *p*-values reported
	(Variance not reported)	(Variance not reported)	(Variance not reported)	
(based on corrected analysis[a])				
Mean proportion (%) of participants who maintained weight loss within 2 kg of their end-of-treatment weight	19	13	7	Not reported
	(Variance not reported)	(Variance not reported)	(Variance not reported)	
(based on corrected analysis[a])				
Mean proportion (%) of participants who maintained weight loss:				
(a) 5 kg or greater	(a) 44	(a) 33	(a) 29	Stated NS; no *p*-values reported
(b) 10 kg or greater	(b) 31	(b) 27	(c) 7	
(based on corrected analysis[a])	(Variance not reported)	(Variance not reported)	(Variance not reported)	
Stated that the percentages are approximate				
Facilitators	None reported	None reported	None reported	
Barriers	None reported	None reported	None reported	

NS, not statistically significant.

a Some participants in each intervention group received additional external therapy 1–3 years after the end of treatment (VLCD: $n=8$; SBT: $n=5$; VLCD + SBT: $n=6$).

All results are presented for follow-up at 3 years after end of treatment.

These participants lost on average 3.42 kg during additional therapy before participating in the 3-year follow-up. The *uncorrected analysis* includes these participants but does not take into account the effect of additional therapy on their weight. The *corrected analysis* includes these participants but accounts for the effect of additional therapy by subtracting their self-reported weight at the time they received additional therapy from their pre-treatment weight.

Methodological comments/notes

- Allocation to treatment groups: participants were stratified into three blocks according to degree overweight. No other details of randomisation and treatment allocation were reported
- Blinding: not reported
- Comparability of treatment groups: few details were provided. Stated only that according to ANOVA there were no statistically significant pre-intervention differences ($p > 0.10$) between groups in age, height, weight, percentage overweight or depression
- Method of data analysis: both ANOVA and ANCOVA were conducted to test for differences between interventions. In the ANCOVA, initial values for weight, BP, and depression were the covariates. The authors stated that as both methods yielded similar results only those of ANOVA were reported (unless otherwise noted in the paper)
- ITT analysis: not reported
- Sample size/power calculation: not reported. Small sample size
- Attrition/dropout: reasons for overall attrition reported (reasons not reported separately by intervention)

General comments

- Generalisability: the study population was dominated by women but included some men. Participants had answered a newspaper advertisement and paid US$10 per visit. This may have had an impact on those taking part
- Outcome measures: depression scores reported separately by intervention for 3-year follow-up (data not extracted)
- Facilitators/barriers not reported as outcomes: none reported
- Intercentre variability: not reported, number of centres unclear
- Conflict of interests: none reported

Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Not reported
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Unclear[a]
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	No
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis?	Not reported
(ii) If so, was this defined?	
10. (i) Did the analysis account for missing data?	No
(ii) If so, were the methods appropriate?	

a Only reported for those completing treatment.

Weinstock et al.

Study details	Participants	Outcome measures
Author: Weinstock *et al.*[78,122] Year: 1998 Country: USA Study design: RCT Number of centres: two Funding: National Institute of Mental Health/National Institutes of Health Recruitment dates: not stated Setting: university (Syracuse and Pennsylvania) Length of follow-up: 96 weeks	Number of participants: 128 women randomised to four groups[a]: Intervention 1: diet plus aerobic training (DA) ($n=31$) Intervention 2: diet alone (D) ($n=29$) Intervention 3: diet plus strength training (DS) ($n=31$) Intervention 4: diet plus combined strength and aerobic training (DSA) ($n=29$) Sample attrition/dropout: At week 48, 29 participants had discontinued treatment. Numbers discontinuing in each study group not given, though it is reported that there were no differences in attrition between interventions At week 96 it is stated that 22 participants returned for follow-up visit, though this is based on a subgroup analysis of a total of 45 women in intervention groups 2, 3 and 4 Attendance at sessions measured: yes Other measures of adherence: adherence to diet was measured at weeks 5, 9, 13 and 17 based on weekly diet diaries Sample crossovers: none Inclusion/exclusion criteria for study entry: women only; overweight (BMI 39.5 ± 0.9 kg/m^2). Excluded if bulimia nervosa; significant depression; major psychiatric disturbance (but not binge eating disorder); recent myocardial infarction; cerebrovascular, kidney, or liver disease; cancer; type I diabetes; pregnancy; use of medications known to affect weight and energy expenditure Characteristics of participants: Any risk factors noted: none Gender (M:F) – all female Age (years): mean (SD): DSA: 42.8 (8.3); DS: 40.0 (9.1); DA: 40.8 (7.9); D: 41.0 (8.8) BMI kg/m^2: mean (SD): DSA: 35.3 (4.4); DS: 36.5 (6.0); DA: 37.3 (5.1); D: 36.4 (5.5) Weight kg, mean (SD): DSA: 92.4 (14.8); DS: 96.8 (14.2); DA: 98.7 (12.5); D: 96.3 (8.8) Age of onset of overweight/obesity, years (SD): DSA: 20.9 (11.3); DS: 20.0 (10.6); DA: 20.1 (9.5); D: 19.5 (8.8) Ethnicity: $n=99$: Caucasian, 28 African American, one Hispanic Baseline data on weight (kg), height, fat, % fat, fat free mass (FFM) and REE not data extracted	Primary outcomes: body composition, in terms of fat-free mass (FFM) and REE (as mentioned in study hypothesis) Secondary outcomes: weight, appetite, mood, insulin resistance, glucose tolerance, BP Facilitators and barriers: none Methods of assessing outcomes: weight measured using a balance-beam scale. Only weight outcomes are extracted here

Intervention details

Aim or goal: preservation of FFM and REE at weeks 24 and 48, resulting in superior maintenance of weight loss at week 48 (for participants taking part in the three exercise conditions compared with those who received diet alone). Women who received strength training, whether alone or in combination with aerobic activity, were expected to achieve best maintenance of FFM

1. DA

Diet:

Details, type of diet: meal replacement plus dinner entrée (weeks 2–17), refeeding (weeks 17–26), self-selected diet (weeks 22–48)

Calories: 900–925 kcal/day (weeks 2–17). Increasing to 1250 kcal/day (weeks 18–20); 1500 kcal/day (weeks 22–48)

Proportions of diet:

150 kcal, 15 g protein, 11.2 g carbohydrate, 5 g fat (per serving of the liquid meal replacement four times per day, weeks 2–17)

280–300 kcal, 20 g protein, 35–40 g carbohydrate, 7 g fat (per dinner entrée, weeks 2–17)

12–15% calories from protein, 55–60% from carbohydrate, and 15–30% from fat (weeks 22–48)

2. D

Diet:

As intervention DA

Exercise:

None. Participants agreed not to engage during the study in any programme of regular activity that resembled the aerobic or strength training conditions (but they were allowed to maintain lifestyle activities such as occasionally playing tennis, bowling or lunchtime walks). This was recorded in their activity logs

Behaviour modification:

As DA except there was no discussion of adherence

3. DS

Diet:

As intervention DA

Exercise:

Mode: participants exercised with members of their behavioural treatment groups (up to week 28)

Type: strength training, using gym equipment such as the bench press, latissimus pull down, shoulder press (targeting large muscle groups). Exercises were performed with a resistance that allowed them to do ≥ 10 repetitions but not > 14

4. DSA

Diet:

As intervention DA

Exercise:

Mode: participants exercised with members of their behavioural treatment groups (up to week 28)

Type: 60% strength training, 40% aerobic activity. Women in the Syracuse cohort did step aerobics, women in the Pennsylvania cohort did treadmill walking and stationary bicycling (due to space constraints)

Monitoring: participants kept weekly diet diaries. As part of the behavioural treatment component it is stated that participants were instructed in traditional behavioural methods that included recording food intake (amounts, calories, etc.). The refeeding protocol was supervised by a registered dietitian who coled group sessions from weeks 17–26 *Exercise:* *Mode:* participants exercised with members of their behavioural treatment groups (up to week 28) *Type:* step aerobics *Frequency and length of each session and total number sessions:* Three sessions per week (non-consecutive days) for first 28 weeks, two per week during weeks 29–48. 12 minutes at week 1, additional 2 minutes to routine each week, by week 14 performed 40 minutes of stepping During weeks 29–48 they were assisted in developing at home exercise to replace the third exercise session deleted from their supervised training *Delivered:* graduate students in exercise physiology who followed structured protocols *Level of supervision:* all sessions were supervised (no further detail given) *Monitoring:* Borg Rating of perceived Exertion Scale (to assess intensity of exercise). The aim was to exercise at moderate intensity *Behaviour modification:* *Mode:* group sessions (7–10 members each) *Type:* described as cognitive behavioural weight loss programme, based on the OPTIFAST programme *Content:* practicing skills to maintain weight loss (first 28 weeks only). Participants were given manuals summarising materials for the first 28 weeks, and weeks 29–48 *Frequency and length of each session and total number sessions:* 28 weekly 90 minute sessions, followed by biweekly maintenance programme sessions (weeks 29–48) *Delivered:* by clinical psychologists and groups co-led by a dietitian (weeks 17–26) In addition the exercisers took approximately 5–10 minutes each week to discuss adherence to their exercise programme *Ongoing support:* Participants attended group sessions once every 3 months in the year following treatment. Between weeks 48–96 the women were encouraged to continue exercising unsupervised	*Ongoing support:* Mentions only that participants attended group sessions once every 3 months in the year following treatment	*Frequency and length of each session and total number sessions:* Three sessions per week (non-consecutive days) for first 28 weeks, two per week during weeks 29–48. Initial workouts lasted approx. 20 minutes, weeks 3–14 an extra set of exercises were added, participants eventually did two sets of each exercise at each session. By end of week 14 (until week 48) weight training lasted approx. 40 minutes per session. Resistance increased whenever participants were able to perform >14 repetitions for two consecutive sets During weeks 29–48 they were assisted in developing a personal programme of strength training to replace the third session deleted from the supervised practice (e.g. joining a health club) *Delivered:* graduate students in exercise physiology who followed structured protocols *Level of supervision:* all sessions were supervised (no further detail given) *Monitoring:* not reported *Behaviour modification:* As DA *Ongoing support:* Participants attended group sessions once every 3 months in the year following treatment. Between weeks 48–96 the women were encouraged to continue exercising unsupervised	*Frequency and length of each session and total number sessions:* three sessions per week (non-consecutive days) for first 28 weeks, two per week during weeks 29–48. Women in this intervention progressed through the sequence of training on approximately the same schedule as those in interventions 2 and 3 *Delivered:* graduate students in exercise physiology who followed structured protocols *Level of supervision:* all sessions were supervised (no further detail given) *Monitoring:* Borg Rating of perceived Exertion Scale (to assess intensity of exercise) *Behaviour modification:* AS DA except there was no discussion of adherence *Ongoing support:* Mentions only that participants attended group sessions once every 3 months in the year following treatment

a Number randomised to each intervention not reported. Figures in parentheses are the number of women per group for whom baseline data are given, which sums to 120. The eight women who dropped out because of medical conditions or who became pregnant were not included in the presentation of baseline data (but other dropouts were, see 'Sample attrition/dropout').

Results

Outcomes	D/DS/SA (groups 2, 3 and 4) combined	*p*-value, 95% CI
Maintenance of weight loss at week 96[a], mean (SE) kg	87.6 (2.8) kg. A 9.9 kg net weight loss from baseline	Reports no significant differences between the diet and exercise groups at week 96
Weight regain (weeks 44 to 96)[a]	76% of participants gained weight, and 14 (64%) of 22 gained more than 5 kg	
BMI kg/m^2, mean (SE)	Dropped to 32.7 (1.2) from 36.4 (1.4) at baseline (loss of 3.7)	

D, diet alone (D); DS, diet plus strength training; DSA, diet plus combined strength and aerobic training.

a Results pertain to 22 women attending week 96 follow-up from a subgroup of 45 women assigned to interventions 2, 3 and 4 (i.e. diet alone, diet plus strength training, and diet plus aerobic training, respectively) but not intervention 1 (diet plus combined strength and aerobic training). The subgroup comprises women enrolled in the first of two cohorts recruited to the study. This first cohort was treated at Syracuse University and originally included 68 women. It is presumed that exclusion of intervention 1 resulted in 45 women remaining in the analysis (Note: no reason is given for the exclusion of intervention 1 from the analysis of results at 96 weeks). Results are not given by intervention group, only for the cohort as a whole. Caution is advised in the interpretation of these results (see below under 'Sample size/power calculation').

Methodological comments/notes

- Allocation to treatment groups: random, no further information given
- Blinding: no information given
- Comparability of treatment groups: authors state that the intervention groups did not differ significantly on measures of age, weight, fat, BMI, fat-free mass (FFM), REE, appetite or mood at baseline based on ANOVA
- Method of data analysis: changes in the principal measures assessed using ANCOVA, with initial values as covariates. Series of one-way univariate tests were used at each time period to maximize the available sample size. The Duncan test was used to determine specific differences among groups
- ITT analysis: ITT analysis not presented. Mentions that dropouts were retained in the analyses until the time of their attrition
- Sample size/power calculation: not reported. Note that week 96 results, as presented above, should be treated with caution as they are based on a subgroup of randomised participants (only women from the first of two cohorts treated and omitting one of the randomised intervention groups altogether). At week 96 only 22 of the 45 women in this subgroup were available for outcome measurement and the results are likely to be underpowered. Therefore, it is not possible to draw meaningful conclusions drawn from the data for changes in weight
- Attrition/dropout: reasons given for dropouts up to week 48. No reasons given for those dropping out between week 48 and 96

General comments

- Generalisability: based on limited detail given the results are applicable mainly to Caucasian middle-aged obese women
- Outcome measures: no detail given on intermediate outcomes such as diet or exercise
- Facilitators/barriers not reported as outcomes: none
- Intercentre variability: preliminary ANOVA showed no significant difference between the two treatment cohorts in baseline measures of age, weight, fat, BMI, FFM, REE, appetite or mood. There were no treatment × cohort interactions hence the decision to collapse the two cohorts in the analysis
- Conflict of interests: none reported

Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Not reported
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	No
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis?	No
(ii) If so, was this defined?	
10. (i) Did the analysis account for missing data?	No
(ii) If so, were the methods appropriate?	