UNIVERSITY OF OXFORD

How components of behavioural weight management programmes affect weight change

Review 1b

Hartmann-Boyce J, Johns D, Aveyard P, Onakpoya I, Jebb SA, Phillips D, Ogden J, Summerbell C, Perera R

3/28/2013

Declarations of interest: Paul Aveyard is an author of one included study (Jolly 2011) and Susan Jebb is an author of one included study (Jebb 2011). Paul Aveyard and Susan Jebb are currently involved in another two trials, one of which has treatment courses donated by Weight Watchers and the other which involves treatment courses donated by Slimming World and Rosemary Conley. Paul Aveyard and Susan Jebb have been out for meals courtesy of Weight Watchers and Nestle (owners of Jenny Craig). Susan Jebb writes for a magazine published by Rosemary Conley Enterprises and receives a fee.

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Executive summary

Introduction

This review builds upon Review 1a, assessing the effects of multicomponent behavioural weight management programmes (BWMPs) in overweight and obese adults which may be applicable in the UK. At 12 to 18 months, the meta-analysis showed BWMPs led to a statistically significant reduction in weight when compared to control interventions. Though the vast majority of studies induced more weight loss in the intervention than in the control arm, the size of the effect varied substantially between studies (from a mean difference in weight change of -8.3 kg to +4.1 kg). In Review 1a, we identified preliminary evidence to explain this variation by considering various components that differed between programmes, such as length, intensity, and delivery mode. Review 1b builds upon the evidence in Review 1a in three important ways: first, it examines how components of a programme affect the weight lost, second it uses metaregression (indirect) to assess associations between intervention components and weight change at 12 months, and third it provides evidence from within study (direct) comparisons. Direct evidence is preferable to indirect evidence, but is often not available.

Methods

A protocol for Review 1a was agreed with NICE before starting work. After the protocol had been finalised, it was agreed that Review 1 would be delivered in three phases: Review 1a, Review 1b, and Review 1c. Review 1b draws on the same pool of studies as Review 1a but uses meta-regression and direct comparisons to analyse the effectiveness of components of BWMPs and considers these in relation to current NICE best practice principles. Review 1c examines issues relating to weight loss maintenance. Unlike 1a, Review 1b includes data from studies without a no or minimal intervention control arm.

We coded interventions based on their characteristics and also applied a behavioural taxonomy to each intervention to assess whether the behavioural change techniques used were associated with the outcome. Behavioural change techniques were placed in groups to aid analysis. The outcome of interest was mean difference in weight change at 12 to 18 months, using a baseline observation carried forward (BOCF) approach. For direct comparisons, we report mean difference and use meta-analysis where appropriate. For indirect comparisons, we used univariate meta-regression as well as a forward stepwise approach to test associations between intervention characteristics and outcome, and refer to subgroup analyses conducted in Review 1a where relevant. Where direct evidence was available (within study comparisons), we placed more emphasis on this in our interpretation than we did on indirect comparisons, but report both.

Results

Included studies

This review includes 43 studies, 30 of which are included in Review 1a. The included studies represented a total 17,001 participants. Twenty-six studies were conducted in the USA, three were conducted in the UK, two each were conducted in the Netherlands and Sweden, and one each were

conducted in Australia, Belgium, Brazil, Canada, Finland, Japan, New Zealand, Portugal, and Switzerland. The final study was multi-centre and was conducted in the UK, Germany, and Australia. The majority of participants were female (68%) with the average study consisting of 70% females. The average age of study participants was 48 years, ranging from 32 to 70 years. Only 22 of the 43 included studies reported any data on ethnicity – of those that did, the mean percentage minority group was 25% (median 18%), ranging from 0 to 100%. In the 40 studies which reported mean baseline BMI, the average was 33 kg/m^2 (the median was also 33 kg/m^2), ranging from 27 to 40 kg/m^2.

The 43 included studies represent 73 intervention arms and 30 control arms in total. Twenty-five studies compared one BWMP to another. Many interventions were similar in the behavioural change techniques they employed, and the following behavioural change techniques were present in the majority of interventions: goal setting and review of goals (behaviour and outcome); action planning; barrier identification and/or problem solving; graded tasks; self-monitoring of behaviour; feedback on performance; instruction on how to perform behaviour; and planning social support and/or social change. The majority of studies were judged as ++ (high) for internal validity (study quality). Just under half were judged as high (++) for external validity.

Relationship between programme components and outcomes

Direct comparisons

Direct comparisons found that programmes which involved diet and exercise were more effective than those which involved diet only or exercise only. Seven studies compared a multicomponent BWMP (for our purposes defined as involving both diet and exercise components) with a diet only arm. In the six studies for which we could calculate BOCF outcomes, pooled results showed that mean weight loss at 12 months was significantly higher in programmes which involved diet and exercise than in those which involved diet alone (mean difference -1.79 kg, 95% CI -2.86 to -0.72, I^2 = 30%). In the five studies that randomised participants to diet and exercise versus exercise alone, pooled results showed significantly greater weight loss at 12 months in programmes that combined diet and exercise than in those that involved exercise only (mean difference -6.33 kg, 95% CI -7.30 to -5.37, I^2 = 9%).

Three studies randomised participants to in-person versus remote contact. Pooled results did not detect a significant effect (mean difference -0.17 kg, 95% CI -1.23 to 0.89) and were highly heterogeneous (I^2= 65%). Two studies that randomised participants to supervised exercise versus recommended exercise only had effect sizes pointing in opposite directions, and the pooled mean difference was not statistically significant (mean difference 1.22, 95% CI -0.88 to +3.32, I^2 = 68%). There were six studies in which participants were randomised to BWMPs offering more or less frequent contact over a set length of time; pooled results detected no significant difference in mean weight loss at 12 months, with a difference of -0.23 kg (95% CI -0.57 to +0.12, I^2 = 25%).

Results from meta-regression

In a multivariate (adjusted) model considering programme characteristics, the presence of set energy prescriptions and contact with a dietitian were significantly associated with greater weight loss. The presence of a set energy prescription was associated with an additional -3.3 kg of weight loss at 12 to 18 months (95% CI -4.6 to -2.0, $p < 0.001$) and contact with a dietitian was associated with an additional -1.5 kg of weight loss (95% CI -2.9 to -0.2, $p = 0.027$). This included any

programmes where at least some contact was provided from a dietitian, and includes programmes in which a dietitian was not the primary therapist.

In a multivariate (adjusted) model looking only at behavioural change techniques, a group of techniques classed under the 'comparison of behaviour' heading were found to be significantly associated with a greater mean difference in weight loss, but this association was no longer significant when controlling for presence of set energy prescriptions and involvement of a dietitian.

No other programme characteristics or behavioural change techniques were found to be significantly associated with weight loss outcome.

Results as they apply to current NICE best practice principles

Some, but not all, existing NICE best practice principles are supported by findings from this review. Judgements are summarised below:

Statement	Supported?	Notes
Help people assess their weight and decide on a realistic healthy target weight (people should usually aim to lose 5 to 10% of their original weight)	**Neutral**	Assessment of weight is an integral part of weight loss programmes and hence evidence from our analysis cannot be applied to this part of the principle. All reported percentage weight loss targets fell within NICE's specified range (5 to 10% of baseline weight). Meta-regression did not detect a significant association of setting target weights with weight change at 12 months (though the estimate suggested greater weight loss when this technique was employed).
Aim for a maximum weekly weight loss of 0.5 to 1 kg	**Neutral**	Findings from this review do not suggest that a target of 0.5 to 1kg week is more or less preferable than a target of > 1 kg week. Only one of our included studies involved a weekly weight loss target above this range, and none had a target > 2 kg/week.
Focus on long-term lifestyle changes rather than a short-term, quick-fix approach	**Supported**	Longer programmes (especially above 6 months) were associated with greater weight loss at 12 months. No studies compared a longer BWMP with a shorter BWMP or a BWMP of 6 months or less. Greater weight loss was seen in intervention arms where repeated contacts were received than in control arms where advice was given on a one off basis. As discussed below, interventions that involved both diet and exercise were shown to induce greater weight loss than interventions that involved diet or exercise only, regardless of intervention length.
Be multicomponent, addressing both diet and activity, and offering a variety of approaches	**Supported**	Direct comparisons between BWMPs involving diet and exercise and those involving either diet or exercise, but not both, found that programmes that combined the two led to significantly more weight loss at 12 months.
Use a balanced, healthy-eating approach	**Supported in part**	No studies compared diets where macronutrient proportions were specified to diets where the macronutrient proportions were not specified. Data showed that multicomponent interventions that involved diets with recommended macronutrient proportions were associated with greater weight loss than programmes that had no diet component. We did not find studies that tested interventions which recommended diets that were explicitly unhealthy or unbalanced, nor did we find studies that directly compared diets with recommended macronutrient proportions to diets without recommended macronutrient proportions.
Recommend regular physical activity (particularly activities that can be part of daily life, such as brisk walking and gardening) and offering practical, safe advice about being more active	**Supported in part**	Meta-analysis found that interventions incorporating physical activity led to more weight loss at 12 months than those that focussed on diet only. Meta-regression did not detect a significant association between weight loss at 12 months and whether or not the recommended physical activity was deemed easy to incorporate into daily life (defined as not requiring a specific setting or site to perform).

Statement	Supported?	Notes
Include some behaviour change techniques, such as keeping a diary and advice on how to cope with 'lapses' and 'high-risk' situations	**Supported in part**	A univariate meta-regression found that the technique of modelling/demonstrating behaviour was associated with significantly greater weight loss at 12 months, but this was no longer significant in a model adjusting for set energy targets and involvement of a dietitian. A significant association was found between self-belief techniques and *increased* weight at 12 months, but this association was no longer significant when adjusting for 'comparison of behaviour' techniques. There was no significant association between weight loss and any other behavioural technique groupings, but the following groupings were not far from significance: goals and planning, shaping knowledge, antecedents, and feedback and monitoring. In a meta-regression controlling for 'comparison of behaviour' techniques, none of the techniques specified in the current principle (relapse prevention/coping planning and self-monitoring of behaviour/outcome) were significantly associated with weight loss at 12 months.
Recommend and/or provide ongoing support	**Supported**	Evidence from Review 1a demonstrated that programmes with ongoing support were more effective than one or two episodes of advice (control arms). Though a univariate model detected a significant association between programme length and weight loss, this association was no longer significant in a multivariate model. Meta-regression did not detect a significant effect of offering less frequent sessions after a more intensive period of intervention.

Conclusions

Behavioural weight loss programmes can be effective and vary greatly in their effectiveness. Programmes that incorporate both physical activity and dietary interventions are more effective than addressing only one of these alone. Interventions that set energy prescriptions and that are delivered by a team that includes a dietitian may be more effective. However, the key ingredients that differentiate more effective from less effective interventions remain largely unclear. This reflects a paucity of primary data and inadequate descriptions of some of the components of interventions.

Summary of evidence statements

Conclusions from evidence statements are summarised below (full evidence statements can be seen in 'Evidence statements'). All evidence was directly applicable to the UK and comes from randomized controlled trials, though in the case of meta-regression, should be interpreted as observational data (i.e. indirect comparisons). Unless stated otherwise, data is for weight loss at 12 to 18 months.

- Strong evidence from a meta-analysis indicates that BWMPs that involve both diet and exercise can lead to greater weight loss over a 12 to 18 month period than those that involve diet only or exercise only. (Evidence statement 1.11)
- There was weak evidence from direct comparisons to suggest that there is no difference in weight loss at 12 to 18 months between programmes delivered by in-person contact and those delivered by remote contact only. (Evidence statement 1.12)
- There was moderate evidence to suggest that interventions that involved contact with a dietitian (or the equivalent of a dietitian in countries where 'dietitian' is not a registered term) were associated with greater weight loss than those which did not involve dietitian

contact. This variable was not significant in a single variable meta-regression, but was significant when adjusted for presence or absence of a set energy prescription. (Evidence statement 1.13)

- There is inconsistent evidence as to whether programmes which involve supervised exercise lead to greater weight loss than those that recommend exercise only. (Evidence statement 1.14)
- There is strong evidence from meta-regression that programmes which specify a daily energy intake are associated with greater weight loss than those that do not prescribe an energy intake. This association persisted and remained largely unchanged when adjusting for the involvement of a dietitian. (Evidence statement 1.15)
- There is weak evidence from meta-regression that weight loss at 12 months is not associated with programme length. Univariate results suggested that each additional month of programme up to 12 months was associated with an additional 0.3 kg weight loss. This result was, however, no longer significant when adjusted for set energy prescriptions and dietitian involvement. (Evidence statement 1.16)
- There moderate evidence that weight loss at 12 to 18 months is not associated with the number of intervention sessions offered (up to 12 months). Pooled results from direct comparisons where participants were randomised to more sessions or fewer sessions favoured the provision of more sessions but were not statistically significant. (Evidence statement 1.17)
- There was strong evidence that the following behavioural techniques are used in most BWMPs: goal setting and review of goals (behaviour and outcome); action planning; barrier identification and/or problem solving; graded tasks; self-monitoring of behaviour; feedback on performance; instruction on how to perform behaviour; and planning social support and/or social change. There was no evidence that greater use of any particular groups of these techniques is associated with greater weight loss. (Evidence statement 1.18)

Commonly used terms and abbreviations

Adjusted: An adjusted statistic (for example, an adjusted coefficient) means that the result being presented has been adjusted for other factors. So, for example, if we were looking at the association between programme length and weight loss, we might adjust for the effect of number of sessions, which is linked with, but not the same as, programme length. An adjusted statistic in this case would show the association of programme length *regardless of* the number of sessions, whereas an unadjusted result would not take into account any other variables.

BMI – Body Mass Index: A simple index of weight-for-height that is commonly used to classify underweight, overweight and obesity in adults. It is defined as the weight in kilograms divided by the square of the height in metres (kg/m^2)

BOCF - Baseline observation carried forward: a method to handle missing data from treatment discontinuation, where people with missing data at follow-up are assumed to weigh the same amount as they did at the start of the study (for detailed explanation, see Appendix 1).

BWMPs - Multicomponent behavioural weight management programmes: To be considered a multicomponent BWMP, a programme must include diet, physical activity, and behavioural therapy components (for example, counselling sessions).

Coefficient: a number multiplied with a variable in an algebraic equation. For the purposes of this review, the coefficient describes the association of a given variable (for example, length of intervention in months) and weight loss, so if in this case the coefficient was -0.5 kg, this would suggest that each additional month of a programme is associated with an additional -0.5 kg difference in weight change between intervention and control arms.

CI - Confidence Interval: A measure of the uncertainty around the main finding of a statistical analysis. It provides an estimated range of values within which the population parameter lies for a set percentage of certainty.

Control: A participant in the arm that acts as a comparator for one or more experimental interventions. Controls may receive placebo, no treatment, standard treatment, or an active intervention. (For control classifications see the Methods section.)

Completer: An individual who provides, in the context of this report, weight-loss data at the follow-up examination being assessed.

External validity: The extent to which results provide a correct basis for generalisations to other circumstances.

Follow-up: The observation over a period of time of study/trial participants to measure outcomes under investigation

Heterogeneity: The quality of diversity, or differences, within a set of data.

Intention-to-treat: A strategy for analysing data from a randomised controlled trial. All participants are included in the arm to which they were allocated, whether or not they received (or completed) the intervention given to that arm. Intention-to-treat analysis prevents bias caused by the loss of participants, which may disrupt the baseline equivalence established by randomisation and which may reflect non-adherence to the protocol.

Kcal – kilocalories (Calories)

Metaregression: A tool used in meta-analysis to examine the impact of study moderators (e.g. length of intervention, type of behavioural change techniques) on study effect size (i.e. mean difference in weight loss at 12 to 18 months).

Multivariate: For the purposes of this review, a multivariate model is one in which multiple components are considered (i.e. results are adjusted).

p-value: This represents the probability of obtaining a result (in the case of meta-regression, a coefficient) at least as extreme as the one that was actually observed. It is a measure of statistical significance, and for the purposes of this review, a result is considered statistically significant when the p value is less than 0.05.

Quality: A notion of the methodological strength of a study, indicating the extent of bias prevention (judgement criteria outlined in Methods section)

Randomisation: The process of randomly allocating participants into one of the arms of a controlled trial. There are two components to randomisation: the generation of a random sequence, and its implementation, ideally in a way so that those entering participants into a study are not aware of the sequence.

RCT - Randomised Control Trial: An experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants. It is considered the Gold standard experimental design for clinical studies.

Statistically significant: A result that is unlikely to have happened by chance. The usual threshold for this judgement is a result would occur by chance with a probability of less than 0.05 (5%).

Sub-group analysis: An analysis in which the intervention effect is evaluated in a defined subset of the participants in a trial.

Systematic review: A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies

Univariate: For the purposes of this review, a univariate model is one in which only one component is considered (i.e. results are unadjusted).

VLED/VLCD – very low energy diet/very low calorie diet: Diets which generally contain approximately 800 calories a day or less.

Introduction

This review builds upon Review 1a, and both reviews assess the effects of multicomponent behavioural weight management programmes (BWMPs) in overweight and obese adults which may be applicable in the UK. To be considered a multicomponent BWMP, the components of the programme had to include diet, physical activity, and behavioural therapy (for example, counselling sessions). The scope included commercial weight loss programmes and non-commercial programmes, such as those delivered in primary care settings (for example, in GP practices).

Review 1a and 1b build upon an existing review published in 2011 (Loveman 2011[1]) and the methods used closely follow those used by Loveman et al, with the main difference being that we included studies with 12 month follow-up or longer, whereas Loveman required a follow-up of at least 18 months. We ran systematic searches of ten electronic databases and also screened reference lists and considered references submitted to NICE in a call for evidence. We found 34 studies that met our inclusion criteria. We included a further nine studies from the original Loveman review (43 total). Of these, 30 involved a comparison between a multicomponent BWMP and a control, and were examined Review (1a). The other 13 studies are included in Review 1b. Review 1b builds upon evidence in Review 1a in three important ways: first, it examines how the behavioural change programme affects the weight lost, second it uses metaregression (indirect) to assess associations between intervention components and weight change at 12 months, and third it provides evidence from within study (direct) comparisons.

Summary of findings from Review 1a

Review 1a included 30 studies, testing 44 interventions versus control, and included 14,169 participants in total. Results from 29 of the 30 studies (representing 40 out of 44 intervention arms) could be combined in a meta-analysis; we were not able to include the remaining study in our meta-analysis because of insufficient data. At 12 to 18 months, the meta-analysis showed a statistically significant effect of BWMPs on weight loss when compared to control (mean difference -2.58 kg, with 95% confidence intervals (CI) -2.76 to -2.40). This effect was found to continue over time (in the four studies with results at 36 months, the mean difference was -2.21 kg, 95% CI -2.66 to -1.75). Though the vast majority of studies induced more weight loss in the intervention than in the control arm, the size of the effect varied substantially between studies. We sought to explain this variation by considering various components that differed between programmes, such as length, intensity, and face-to-face contact alone. We produced preliminary evidence that such differences were important, but we extend that analysis in this review.

[1] Loveman E, Frampton GK, Shepher J, Picot J, Cooper K, Bryant J, et al. The clinical effectiveness and cost-effectiveness of long-term weight management schemes for adults: a systematic review. *Health Technology Assessment* 2011;15(2).

Direct versus indirect evidence

It is important to understand the difference between direct and indirect evidence. Ideally, all evidence would come from direct comparisons, i.e. studies that randomise participants to the intervention and its natural comparator. For example, if we are interested in whether supervised exercise leads to more weight loss than recommending exercise only, we would want to consider direct comparisons from studies with two arms that were exactly the same, except one had supervised exercise and other only recommended exercise.

In reality, we are interested in how several components affect the success of weight loss programmes, but there are few studies that look at these individual components. In the absence of direct evidence, therefore, we also use indirect evidence to look for associations between components (such as supervised exercise) and outcome (e.g. weight loss at 12 months). Indirect comparisons can be made through subgroup analyses, as in Review 1a, where we compare the effect sizes between different groups of studies, each of which compares an intervention with a control. In this review, we use meta-regression, which is similar, but allows us to control for the effect of other differences between studies. Although these data are derived from randomised controlled trials (RCTs), it is important to interpret these data as observational data only. Differences in weight change between subgroups of studies may represent differences attributable to the characteristic in question, but there are other possible causes. We use meta-regression to try to control for differences, but we can only adjust for characteristics of the participants or the programmes which have been measured and reported. There are likely to be other differences too, which cannot be controlled for in the analysis. It could be that these differences explain the apparent difference in effectiveness.

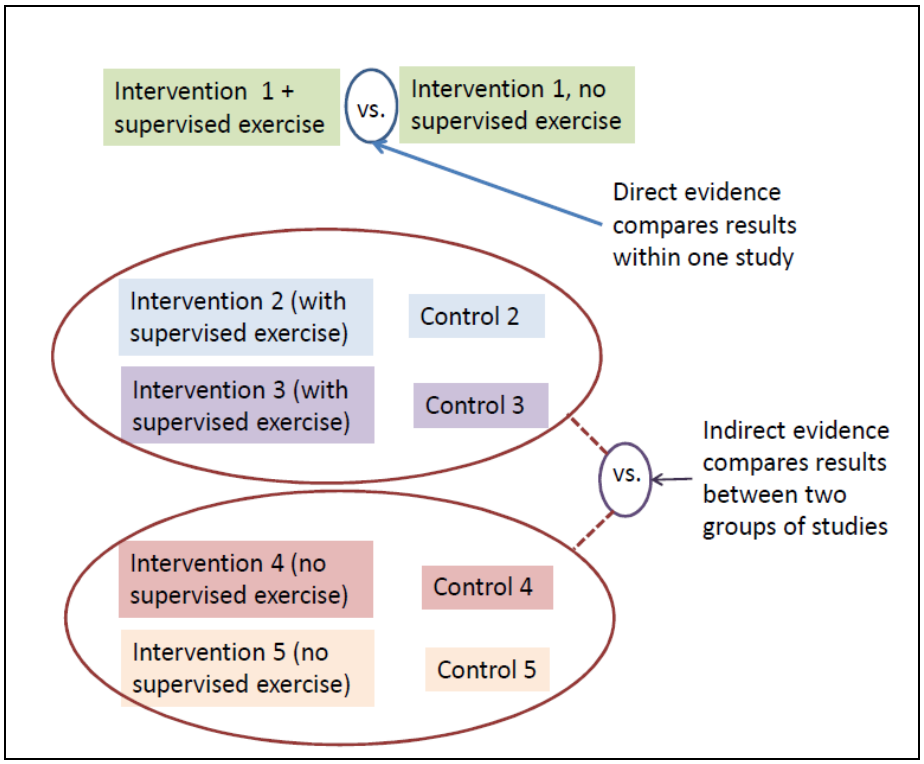
In Review 1b, we separate results into direct versus indirect evidence. Direct evidence is preferable, but sparser.

Understanding why direct comparisons are preferable to indirect comparisons

Studies can vary on a whole host of factors. In particular, some studies will have different intensities or types of interventions and will be conducted in different settings or populations. This can influence the outcome. This isn't an issue for direct evidence, where (assuming randomisation has been successful) both arms have an equal chance of losing weight at the outset, so we can be confident that greater weight loss in the intervention arm is actually due to the intervention itself. When we use indirect evidence, however, we can't be as sure that the differences we see are due to the component we are interested in. Take, for example, the supervised versus recommended exercise comparison. If we have a study that tests an intervention that lasts 12 months, with both arms receiving the exact same intervention, except one receives supervised exercise and the other has recommended exercise only, we can be fairly confident that the difference in weight loss between the two arms reflects the presence or absence of supervised exercise. If, however, we are comparing results from two separate studies, one of which (study 1) compares a 10 month intervention with supervised exercise to control and the other of which (study 2) compares a four month intervention with recommended exercise only to control, if the weight loss at 12 months is greater in study 1 than in study 2, we can't necessarily assume this is due to the supervised exercise.

It could be due to programme length, or the population, or a huge number of other factors. Figure 1 displays the difference between direct and indirect evidence graphically.

Figure 1 Direct versus indirect evidence



Methods

A protocol for Review 1 was agreed with NICE before starting work (Appendix 1). After the protocol had been finalised, it was agreed that Review 1 would be delivered in three phases: Review 1a, Review 1b and Review 1c. Review 1a has been written and presented to the PDG, and assesses the effectiveness of multicomponent BWMPs. Review 1b draws on the same pool of studies as Review 1a but considers the effectiveness of components of BWMPs. Review 1c considers weight loss maintenance after programme end. Unlike 1a, Review 1b includes data from studies without a control arm.

This document covers those aspects of Review 1b that relate to the effectiveness of components of BWMPs. Full methods are detailed in Review 1a and in appendices 1 (Review 1 protocol, before the review was split into two components) and 2 (Review 1b protocol). Aspects key to the understanding of Review 1b are described here. See Review 1a for information on inclusion criteria, searching, screening, and the data extraction process.

Questions covered by Review 1b

Whereas Review 1a considers the effectiveness of multicomponent BWMPs, Review 1b considers the effects of specific elements or aspects of BWMPs, addressing the below questions.

How do components of behavioural weight loss programmes affect the outcome?

This question is assessed via meta-analysis and meta-regression of included studies from Review 1a. Unless noted otherwise, outcome is BOCF weight change at 12 months (or closest point to 12 months within 10-18 months). Components explored through narrative description and subgroup analyses in Review 1a include:

1. Whether the programme is delivered in groups or individually
2. The length of the programme
3. Whether the aim was weight loss or diabetes prevention
4. Whether the programme was delivered remotely, for example by Internet, or face-to-face
5. Supervised versus recommended exercise programme
6. Energy prescription target or no target
7. Frequency of contact with participants
8. Person delivering intervention

Review 1b complements the above subgroup analyses by discussing direct comparisons relating to the above features and using metaregression to evaluate the effects of individual components. It also expands upon the list of components evaluated in Review 1a, assessing:

9. Behavioural change techniques

10. Weight loss targets
11. Type of exercise (ease of incorporating into daily life)
12. Provision of ongoing support

We used random effects meta-regression to test the effect of the variables below, using a forward stepwise approach to fit a model with multiple components (where $p < 0.05$ considered as significant):

- Behavioural taxonomy groupings (see below)
- Group versus individual delivery
- Length of intervention (up to 12 months) in months
- Whether the intervention involved face-to-face contact or not
- Number of sessions offered in the first 12 months of a programme
- Frequency of contact (defined as number of weeks between contacts in most intensive phase)
- Whether the programme involved supervised exercise or recommended exercise only
- Whether or not the exercise required a specific setting or equipment to perform
- Whether or not the intervention involved contact with a dietitian (or equivalent in countries where 'dietitian' is not a registered term)
- Whether or not weight loss goals were set

Where variables were measured on a continuous scale of a range greater than 3, we also displayed fitted models using a graph, where the x axis was the variable (for example, number of months of programme) and the y axis was the mean difference in weight loss. The graph then fits a model representing the association between weight loss and that variable.[2] Results are reported as kilograms (kg) weight change calculated using baseline observation carried forward (BOCF), with p values and/or 95% confidence intervals (CIs) as appropriate.

Is there evidence to support the best practice principles that NICE proposed in its 2006 guidance?

The current best practice principles are taken from existing NICE guidance on obesity, CG43:

> Primary care organisations and local authorities should recommend to patients, or consider endorsing, self-help, commercial and community weight management programmes only if they follow best practice by:
>
> - helping people assess their weight and decide on a realistic healthy target weight (people should usually aim to lose 5–10% of their original weight)
> - aiming for a maximum weekly weight loss of 0.5–1 kg
> - focusing on long-term lifestyle changes rather than a short-term, quick-fix approach
> - being multicomponent, addressing both diet and activity, and offering a variety of approaches
> - using a balanced, healthy-eating approach
> - recommending regular physical activity (particularly activities that can be part of daily life, such as brisk walking and gardening) and offering practical, safe advice about being more active
> - including some behaviour change techniques, such as keeping a diary and advice on how to cope with 'lapses' and 'high-risk' situations
> - recommending and/or providing ongoing support.

[2] See Harbord and Higgins 2008 for methods and codes used

We used evidence from the studies included in Review 1a and 1b to evaluate these principles as they apply to BWMPs. Within the results section, each principle is identified as 'supported' or 'supported in part' (findings from this review support all or some of the principle), 'refuted' (findings from this review contradict the principle), and 'neutral' (evidence from this review neither supports nor refutes the principle as it is written/no evidence identified).

Random versus fixed-effect models for meta-regression

In both Reviews 1a and 1b the data to examine the effectiveness of these elements largely comes from between study comparisons. That is to say, it assesses differences between studies of programmes that set an energy prescription, for example, compared to a control group, and other studies with programmes that do not set an energy prescription compared to a control group. Although setting an energy prescription may explain the difference in effect between the weight change in the programmes, there are many other potential causes of the difference. Each study is likely to have recruited a different population who may be inherently more likely to lose weight. In addition, the programmes will differ in many other ways other than setting or not setting an energy prescription and it is impossible to account for all those differences in the analysis.

In Review 1a we used fixed effect meta-analysis to examine the impact of programmes and the subgroup analyses. In this report, we used random effects models. A fixed effect model assumes that the impacts of all programmes are estimates of a single underlying effect. It assumes that variation of results is simply due to the play of chance and that if all studies were infinitely large then the weight lost in every programme would be exactly the same. Review 1a showed evidence that this assumption is untenable, which is why we use random effects models in 1b. A random effects model assumes that studies vary in the size of the true effect and models this uncertainty. Random effects models almost always give answers that are less precise than the equivalent fixed effect model, but in this case we think that they are a more appropriate reflection of the variability in likely response.

Intervention and control classifications

As in Review 1a, we grouped studies by the nature of the comparison, including the nature of the control group. The groupings are described below. We classified comparisons 1 through 4 as 'control', including them in Review 1a. Studies which only investigated 6 versus 5 or 6 versus 6 are not addressed in Review 1a and are covered in Review 1b along with those studies included in Review 1a. The coding we used for weight loss interventions was:

1. No intervention at all or leaflet/s only[3]
2. Discussion/advice/counselling in one-off session +/-leaflet
3. Seeing someone more than once for discussion of something other than weight loss.
4. Seeing someone more than once for weight management, person untrained +/- leaflets
5. Behavioural weight loss programme comprising one of either diet or physical activity plus behavioural programme. 5 also includes seeing a health professional with special training on

[3] Note that leaflets included static websites, i.e. information and advice only, not interactive weight loss programmes, which come under 5 or 6).

more than one occasion, such as a dietitian, who, because of their training will naturally create a weight loss programme with (in this case) dietary and behavioural elements (unless explicitly stated that they did not create a weight loss programme, in which case coded as 4). 5 also included seeing a professional with no basic training in weight loss management but who has received bespoke training to run a behavioural weight loss programme which involves at least two consultations.

6. Behavioural weight loss programme comprising diet and physical activity plus behavioural programme. 6 also includes seeing a professional has no basic training in weight loss management but has received bespoke training to run a behavioural weight loss programme which involves at least two consultations.

Behavioural taxonomy: coding, groupings, and scores

Behavioural change techniques were assessed through the use of a pre-defined taxonomy, included as an element of the data extraction process. We used the 40-item refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours (the CALORE taxonomy) as defined by Michie et al.[4] Each study was assessed against a checklist, with a yes/unclear/no option for the reviewer to indicate if the intervention included that technique. Items were coded as U where the technique was not explicitly stated but reviewers agreed it was implied. The description was obtained through the study report and through protocols and additional information from authors or published online, where available, and hence it should be noted that the application of the taxonomy is limited by the depth of description available. Taxonomies for each study were completed independently by two reviewers with disagreements resolved by consensus or by a third reviewer where necessary.

Due to the relatively large number of taxonomy items and the relatively small number of included studies, we clustered taxonomy items into groupings of techniques to aid meta-regression. These were mapped from an article currently in press, written by the same authors who developed the behavioural taxonomy[5]. Techniques are listed in Table 1 along with their number on the taxonomy checklist and are arranged by grouping. One taxonomy element, use of follow-up prompts (27), is not included in the list below and was instead assessed as an individual component.

All study arms that involved a multicomponent BWMP were assigned a numerical score for each grouping based on the number of yes, no, and unclear answers against the items listed in that group (where yes = 1, unclear = 0.5, and no = 0).

[4] Susan Michie, Stefanie Ashford, Falko F. Sniehotta, Stephan U. Dombrowski, Alex Bishop & David P. French (2011): A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALO-RE taxonomy, Psychology & Health, 26:11, 1479-1498

[5] REFERENCE MICHIE UNPUBLISHED PAPER

Table 1 Index to groupings of taxonomy items

Technique group	Taxonomy item
Goals and planning	05- Goal setting (behaviour) 06- Goal setting (outcome) 07- Action planning 08- Barrier identification/problem solving 10- Prompt review of behavioural goals 11- Prompt review of outcome goals 20- Provide information on where and when to perform the behaviour 25- Agree behavioural contract 35- Relapse prevention/coping planning
Reward and threat	12- Prompt rewards contingent on effort or progress towards behaviour 13- Provide rewards contingent on successful behaviour 14- Shaping 32- Fear arousal 40- Stimulate anticipation of future rewards
Regulation	36- Stress management/emotional control training 38- Time management
Antecedents	24- Environmental restructuring
Identity	30- Prompt identification as role model/position advocate
Self-belief	18- Prompting focus on past success 33- Prompt self talk
Covert learning	34- Prompt use of imagery
Feedback and monitoring	16- Prompt self-monitoring of behaviour 17- Prompt self-monitoring of behavioural outcome 19- Provide feedback on performance
Social support	29- Plan social support/social change 37- Motivational interviewing 39- General communication skills training
Shaping knowledge	21- Provide instruction on how to perform the behaviour
Natural consequences	01- Provide information on consequences of behaviour in general 02- Provide information on consequences of behaviour to the individual 31- Prompt anticipated regret
Comparison of behaviour	03- Provide information about others' approval 04- Provide normative information about others' behaviour 22- Model/Demonstrate the behaviour 28- Facilitate social comparison
Associations	23- Teach to use prompts/cues
Repetition and substitution	09- Set graded tasks 15- Prompting generalisation of a target behaviour 26- Prompt practice

Results

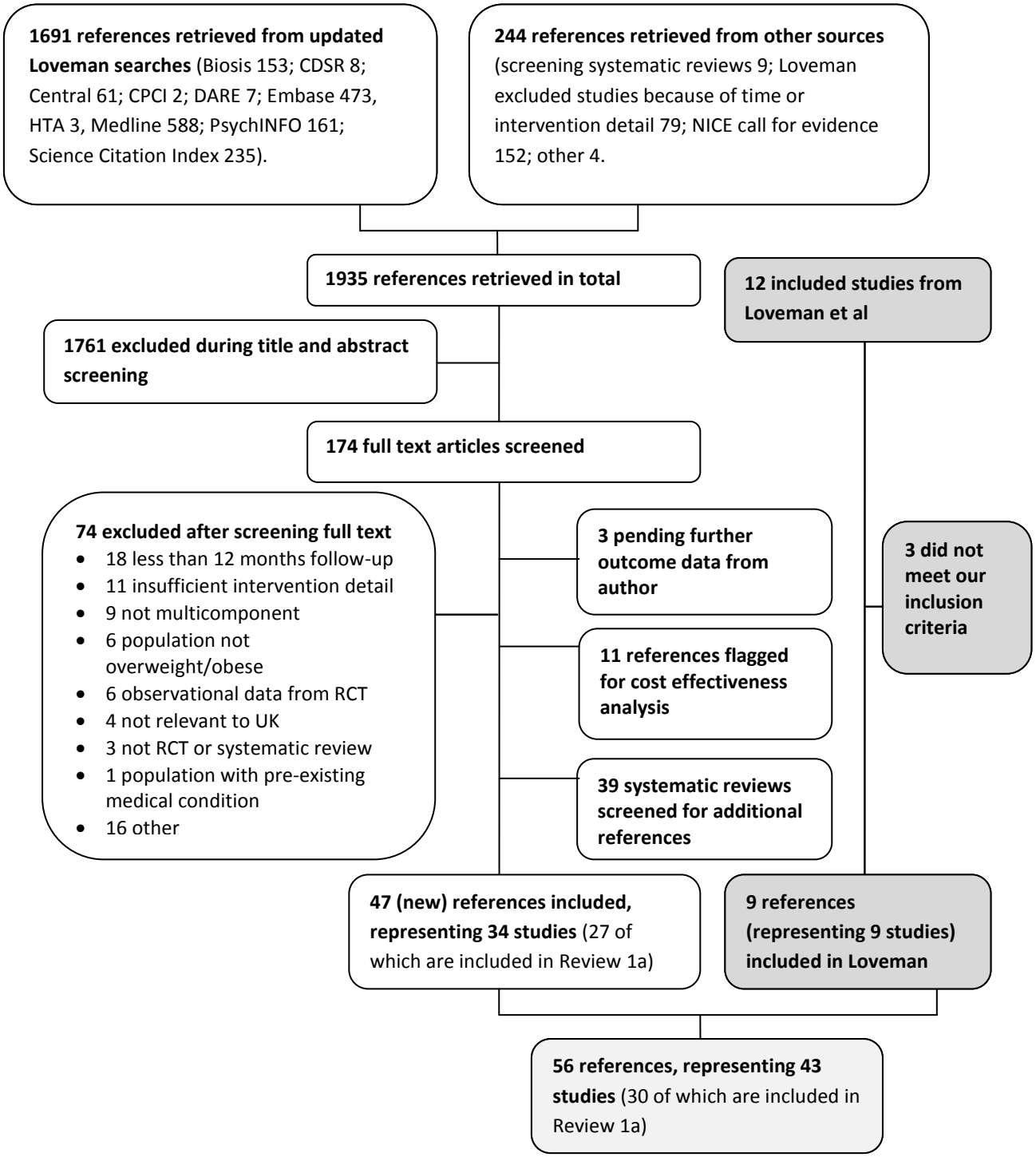
This report is intended to be read in tandem with Review 1a, and hence results reported here relate to those elements specific to Review 1b or not covered fully in Review 1a. Readers should therefore refer to Review 1a for further detail, especially for characteristics of the 30 studies which compare an intervention with a control.

Search results

Results of the search are summarized in Review 1a (Methods section, page 22) and figure 2 shows a diagram of study flow. Our search retrieved 1935 references in total. Full text was retrieved and screened for 174 references. Of these, 74 were excluded (see Review 1a, appendix 4), 53 represented systematic reviews, cost effectiveness analyses, or had requests for more data pending with authors, and the remaining 47 represented 34 included studies. In addition to the studies retrieved through our searches, we also re-evaluated (and re-extracted where relevant) the 12 studies included in Loveman et al. Of these, three did not meet our inclusion criteria: two were tests of very specific aspects of an intervention, rather than of the efficacy of a behavioural weight management programme or broader component itself (Burke LE 2007;Tate DF 2007), and one did not meet our criteria for the population being overweight or obese (Simkin-Silverman LR 1998).[6]

[6] 50% of participants had a BMI <24 kg/m^2

Figure 2 Diagram of study flow[7]



[7] The three references pending further outcome data are: McConnon, A., et al. 2007. The internet for weight control in an obese sample: results of randomised controlled trial. BMC Health Services Research, 7, 206; Moore, H. et al. 2003. Improving management of obesity in primary care: cluster randomised trial. BMJ, 327, 1085; and Truby, H., et al. 2006. Randomised controlled trial of four commercial weight loss programmes in the UK: initial findings from the BBC 'diet trials.' BMJ, 332, 1309–14.

Characteristics of included studies

The 25 studies (representing 68 interventions) comparing one BWMP to another (6 vs 5 and 6 vs 6) and are summarized in table 2. A table of the thirty studies (representing 44 interventions) comparing BWMP (6) to control (1-4) can be found in Review 1a (table 1, page 33). Evidence tables for all 43 studies (those used in direct comparisons and those used in indirect comparisons) can be found in appendix 3.

Population

Twenty-six studies were conducted in the USA. Three were conducted in the UK (Jolly et al. 2011;Nanchahal et al. 2011;Penn et al. 2009), two each were conducted in the Netherlands and Sweden, and one each were conducted in Australia, Belgium, Brazil, Canada, Finland, Japan, New Zealand, and Portugal. The final study was multi-centre and was conducted in the UK, Germany, and Australia (Jebb et al. 2011).

The included studies represented a total of just over 17,000 participants. The average number of participants per study was approximately 400, with a median of 261, ranging from 45 to over 2,100. The majority of participants were female (68%) with the average study consisting of 70% females. Seven studies recruited women only and two recruited men only. The average age of study participants was 48, ranging from 32 to 70. Two studies recruited only older adults (one in people 60 or older and one in people 65 or older). Only 22 of the 43 included studies reported any data on ethnicity – of those that did, the mean percentage minority group was 25% (median 18%), ranging from 0 to 100%. One study recruited only African-Americans (Fitzgibbon et al. 2010). Socioeconomic data were not reported in a standardized fashion, though when reported the most common variable was years of education. Where available, this information is recorded in the evidence tables for each study.[8]

The mean BMI across the 40 studies in which it was reported was 33 kg/m^2 (the median was also 33 kg/m^2), ranging from 27 (Saito 2011, which was conducted in Japan) to 40 kg/m^2 (Fitzgibbon 2012). Nineteen of the 43 included studies had a maximum BMI as an inclusion criteria; this ranged from 35 to 55 kg/m^2 (average 40 kg/m^2). The other included studies had no maximum cut off for baseline BMI. In all but two of the studies, overweight or obesity was an inclusion criterion. In two diabetes prevention studies, participants were not required to be overweight or obese, but reported data indicated that greater than 80% of participants in each study arm were overweight or obese (Dale et al. 2009;Eriksson et al. 2009). Four studies required that participants were at increased risk of cardiovascular disease or had multiple risk factors for metabolic syndrome (Appel et al. 2011;Eriksson, Franks, & Eliasson 2009;Seligman et al. 2011;Wadden et al. 2011), two studies required that baseline blood pressure be in the elevated but normal range(Stevens 1993;Stevens 2001), and eight required some measure of elevated risk for developing type 2 diabetes beyond overweight/obesity(Dale 2009; Diabetes Prevention Program Research Group 2009;Lindström J and

[8] Note, review 1a did not find any evidence to suggest that one BWMP suits one demographic group more than another.

Finnish Diabetes Prevention Study Group 2013;Mensink M 2003;Penn 2009;Saito et al. 2011;Tate 2011;Vermunt et al. 2011).

Interventions

The 43 included studies represent 73 intervention arms (5 or 6) and 30 control (1-4) arms in total. Evidence tables provide more detail on each included intervention (appendix 3).

The average intervention lasted 17 months, ranging from 3 to 36 months (median 18 months). Three interventions involved very low energy diets (VLEDs; two arms from Wadden TA 1988; one from Weinstock RS 1998) and in eight the physical activity component required either specific equipment or a specific setting. The majority of interventions were delivered by multiple types of therapist (type = background/qualifications). Of those interventions delivered by only one type of therapist, one was delivered by a dietitian only (Skender ML 1996), eight were delivered by a health professional without specific weight loss training, six were delivered by psychologists, and ten were delivered by trained lay people. In seven, the background of the therapist was not reported. In total, 35 interventions involved dietitians, 19 involved physical therapists or exercise specialists, 24 involved psychologists, 17 involved other health professionals, and 15 involved lay people.

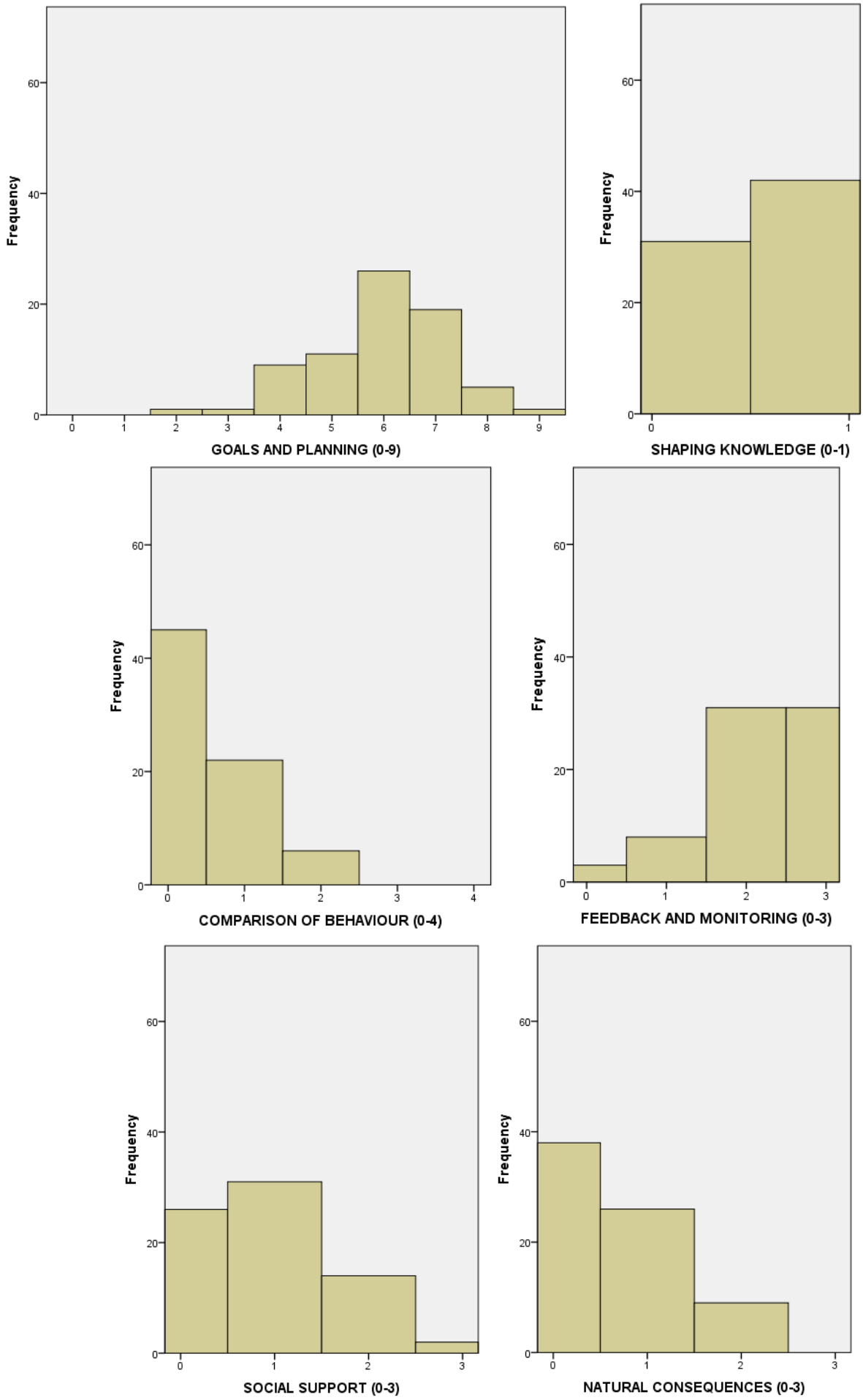
Of the 19 interventions for which authors reported a theoretical orientation, eight were based on social cognitive theory, eight were based on the transtheoretical model, and six involved motivational interviewing. One each involved cognitive behavioural theory and self-determination theory. Twenty-seven interventions set a target for weekly weight loss (ranging from 0.3 to 1.5 kg/week) and 30 set targets for longer term weight loss (targets ranging from 2 to 10% of baseline weight, 4.5 to 6.4 kg or 5% waist circumference; time within which to reach target ranging from three to 24 months). Thirty-seven interventions involved at least some element of flexible scheduling, and in 34 contact frequency or intensity declined over the course of the intervention.

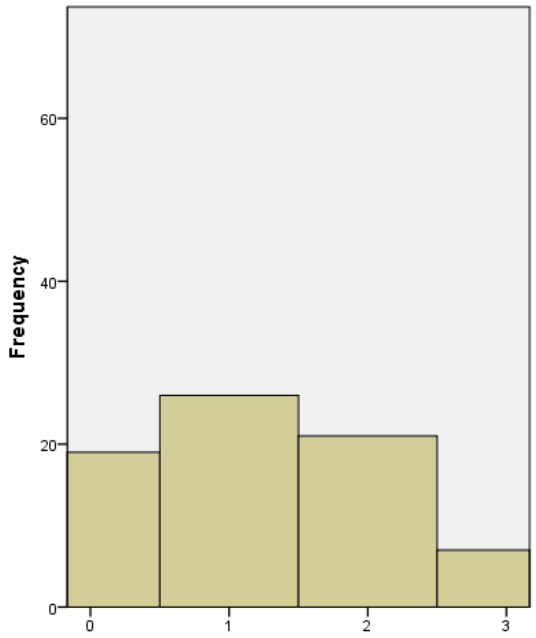
Behavioural techniques

Full details on how each intervention was marked against the behavioural technique taxonomy can be found in appendix 4. The following behavioural change techniques were present in the majority of interventions: goal setting and review of goals (behaviour and outcome); action planning; barrier identification and/or problem solving; graded tasks; self-monitoring of behaviour; feedback on performance; instruction on how to perform behaviour; and planning social support and/or social change.

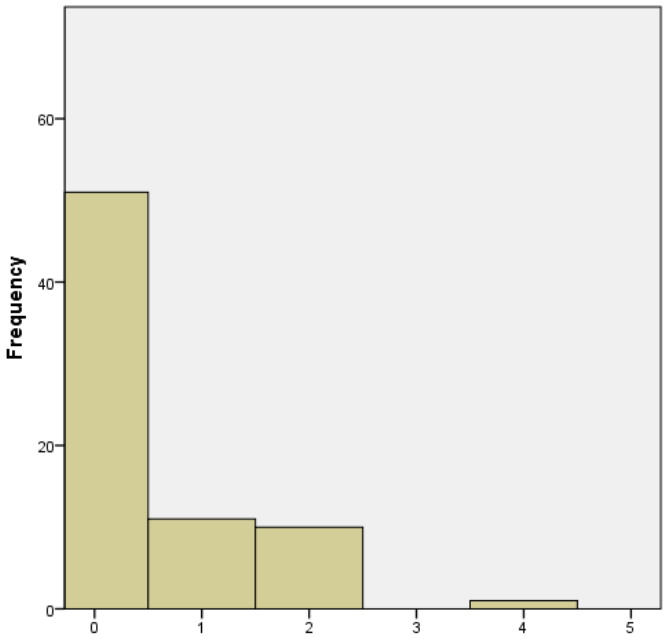
Individual techniques were gathered into larger groupings to aid with analysis (see 'Methods' section), with the score within each grouping representing the number of techniques in that group that the intervention was reported to use (for example, there were nine techniques that fell under the 'goals and planning' grouping and a study that employed four of these techniques would be scored as '4' within this area). Figure 3 shows the distribution of interventions (y axis shows frequency, or number of interventions) across the scores (x axis) within each grouping. As demonstrated in this figure, scores within each grouping were relatively similar between interventions: most scored highly in 'goals and planning' and 'feedback and monitoring', and lower in other categories, though higher goals and planning scores were not necessarily correlated with higher feedback and monitoring scores.

Figure 3 Histograms of BCT grouping scores of included studies

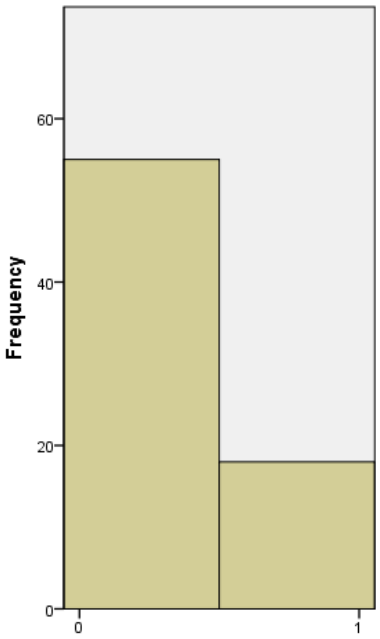




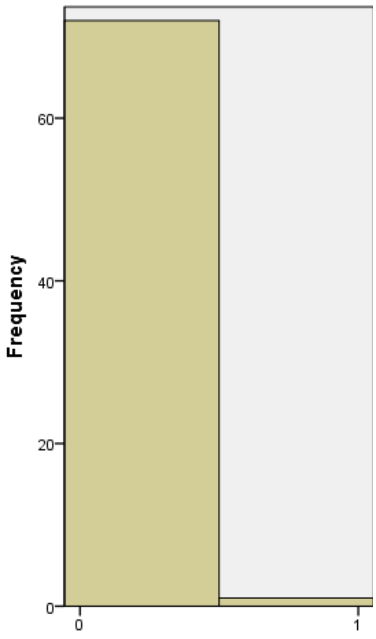
REPETITION AND SUBSTITUTION (0-3)



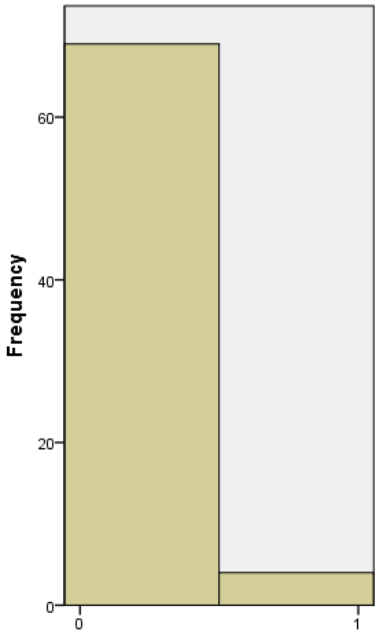
REWARD AND THREAT (0-5)



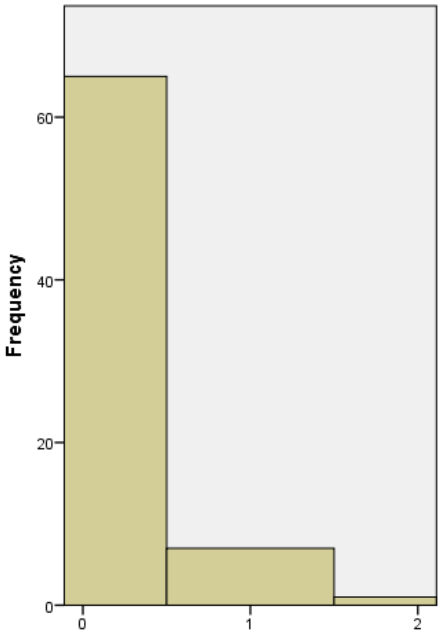
ANTECEDENTS (0-1)



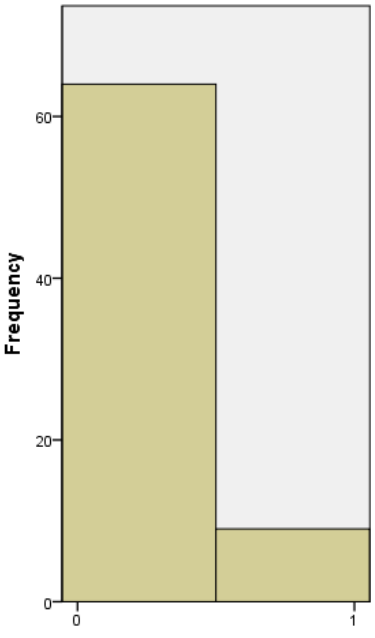
IDENTITY (0-1)



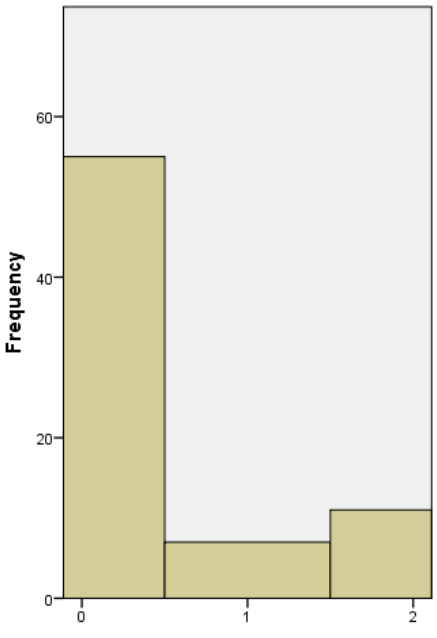
COVERT LEARNING (0-1)



SELF BELIEF (0-2)



ASSOCIATIONS (0-1)



REGULATION (0-2)

Comparisons

Thirty of the 43 included studies compared a BWMP with a control and were included in Review 1a (6 versus 1, 2, 3 or 4).

Twelve studies involved a comparison between a BWMP (involving both diet and exercise) and a diet or exercise-only programme (seven had diet-only comparators, five had exercise-only comparators, 6 versus 5). Twenty studies involved direct comparisons between BWMPs (6 versus 6). Six studies compared BWMPs differing in contact frequency, six compared BWMPs differing in delivery mode, and four involved comparisons based on who delivered the intervention. Eleven studies provided data comparing BWMPs based on other characteristics. Some of these comparisons are not relevant to our review questions (for example, different types of diet, different types of exercise), and hence are not reported in the main text. Full detail can be found in the evidence tables in appendix 3.

Outcomes

All included studies reported some measure of weight change. Fourteen of the 43 included studies reported a follow-up period longer than end of intervention. Ten of the 43 included studies reported any information on adverse events.[9] No new studies in Review 1b reported cost effectiveness analyses (the three studies that did are covered in Review 1a). Two studies that were not included in Review 1a but that were included in Review 1b provided data on cost per participant (Jakicic 2012 and Saito 2011).

Quality and external validity

The majority of studies were judged as ++ (high) for internal validity (study quality). Just under half were judged as high (++) for external validity. Reasons for study downgrading are detailed in the evidence tables (appendix 3).

Twenty-five studies were judged to be of high quality: all or most quality checklist criteria were fulfilled and conclusions were judged unlikely to alter. Sixteen studies were awarded only one +, most commonly because randomisation and/or allocation procedures were not described or were judged to not be sufficiently robust; in these cases, conclusions were still judged unlikely to alter. Two studies were rated as -, with few or no criteria fulfilled and conclusions judged likely to alter. One was downgraded as the randomisation process was not defined, groups were not similar at study outset, and an imbalance in dropouts between arms was not accounted for (Munsch S 2003). This was a relatively small study, however, and its inclusion is unlikely to affect the overall quality of the evidence base. The second study had a larger sample size and was downgraded as randomisation procedures were not described and follow up was less than 50% at 12 months (Hersey et al. 2012). Quality checklist results are reported for each study in appendix 5.

Twenty-two studies were rated as ++ on external validity, the extent to which the findings of the study were judged to be generalisable to the population in question. The remaining 21 studies were

[9] This represents one further study (Saito 2011) in addition to the nine included in Review 1a. No serious adverse events were reported in this additional study; no further information was provided.

rated as + for external validity, with the most common reason for downgrading being that the majority of participants initially screened were not enrolled.

Table 2 Characteristics of studies involving a comparison between multicomponent BWMPs (diet and exercise) or BWMPs with diet or exercise only

Study ID and details	Participants	Validity scores	Outcomes	Comparisons
Appel 2011 Aim: Weight loss Country: USA	N: 415 Mean baseline BMI: In person contact arm 36.8 (5.2); remote contact arm 36.0 (4.7); control 36.8 (5.1) Additional inclusion criteria: One or more CVD risk factors	Internal validity: ++ External validity: +	Intervention length: 24 months Longest follow-up: 24 months ***Data reported:*** Weight: Yes BMI: Yes Waist: No	Control group: Yes Other comparisons: Remote versus in person support
Bertz 2012 Aim: Weight loss Country: Sweden	N: 68 Mean baseline BMI: Diet only 30.0 (2.6); exercise only 30.4 (3.1); diet and exercise 29.2 (2.2); control 30.2 (3.4) Additional inclusion criteria: women 8-12 weeks post partum	Internal validity: ++ External validity: ++	Intervention length: 3 months Longest follow-up: 12 months ***Data reported:*** Weight: Yes BMI: Yes Waist: No	Control group: Yes Other comparisons: Multicomponent versus diet only versus exercise only
Dale 2008 Aim: Diabetes prevention Country: New Zealand	N: 79 Mean baseline BMI: modest intervention 33.9 (4.4); intensive intervention 32.5 (5.2); control 36.5 (4.3) Additional inclusion criteria: Impaired insulin sensitivity. Overweight/ obese not an inclusion criteria.	Internal validity: + External validity: +	Intervention length: 4 months Longest follow-up: 24 months ***Data reported:*** Weight: Yes BMI: Yes Waist: Yes	Control group: Yes Other comparisons: More intense energy and PA instructions versus less intense
Dubbert 1984 Aim: Weight loss Country: USA	N: 62 Mean baseline BMI: NR Additional inclusion criteria: Married/living with spouse who is willing to come to 8 sessions	Internal validity: ++ External validity: +	Intervention length: 4 months Longest follow-up: 34 months ***Data reported:*** Weight: Yes BMI: No Waist: No	Control group: No Other comparisons: All four arms multicomponent, varied by couple vs individual and distal vs proximal goals
Foster-Schubert 2012 Aim: Weight loss Country: USA	N: 439 Mean baseline BMI: diet and exercise 31.0 (4.3); diet only 31.0 (3.9); exercise only 30.7 (3.7); control 30.7 (3.9) Additional inclusion criteria: post menopausal women	Internal validity: ++ External validity: +	Intervention length: 12 months Longest follow-up: 12 months ***Data reported:*** Weight: Yes BMI: Yes Waist: Yes	Control group: Yes Other comparisons: Multicomponent versus diet only versus exercise only
Gold 2007 Aim: Weight loss Country: USA	N: 122 Mean baseline BMI: VTrim arm 32.3 (3.9); eDiets.com arm 32.5 (4.2) Additional inclusion criteria: Owner of (relatively) new computer	Internal validity: + External validity: +	Intervention length: 12 months Longest follow-up: 12 months ***Data reported:*** Weight: Yes BMI: No Waist: No	Control group: No Other comparisons: one weight loss website vs another weight loss website

Study ID and details	Participants	Validity scores	Outcomes	Comparisons
Hersey 2012 Aim: Weight loss Country: USA	N: 1755 Mean baseline BMI: 33.6 (across all arms, data not available per arm) Additional inclusion criteria: n/a	Internal validity: + External validity: ++	Intervention length: 18 months Longest follow-up: 18 months ***Data reported:*** Weight: Yes BMI: No Waist: No	Control group: Yes Other comparisons: telephone and email support set frequency vs web support no set frequency
Jakicic 2012 Aim: Weight loss Country: USA	N: 363 Mean baseline BMI: Intervention 33 (4); Control 33. (4) Additional inclusion criteria: n/a	Internal validity: + External validity: ++	Intervention length: 18 months Longest follow-up: 18 months ***Data reported:*** Weight: Yes BMI: Yes Waist: Yes	Control group: No Other comparisons: BWMP following stepped approach tailored to individual stage of weight loss, compared to a set approach
Jeffery 1995 Aim: Weight loss Country: USA	N: 202 Mean baseline BMI: 31 (across all groups, no SD provided) Additional inclusion criteria: n/a	Internal validity: + External validity: +	Intervention length: 18 months Longest follow-up: 30 months ***Data reported:*** Weight: Yes BMI: Yes Waist: No	Control group: Yes Other comparisons: All arms multicomponent, comparing effects of incentives and free meals
Jeffery 1998 Aim: Weight loss Country: USA	N: 196 Mean baseline BMI: 31.4 (across all groups; SD approx 2) Additional inclusion criteria: n/a	Internal validity: + External validity: +	Intervention length: 18 months Longest follow-up: 18 months ***Data reported:*** Weight: Yes BMI: No Waist: No	Control group: No Other comparisons: All arms multicomponent, comparing effects of supervised exercise, trainers, and incentives
Jolly 2011 Aim: Weight loss Country: UK	N: 640 Mean baseline BMI: 34 (across all groups; SD approx 4) Additional inclusion criteria: n/a	Internal validity: + External validity: ++	Intervention length: 3 months Longest follow-up: 12 months ***Data reported:*** Weight: Yes BMI: Yes Waist: No	Control group: Yes Other comparisons: 3 commercial weight loss programmes versus NHS based weight loss programme vs GP care vs pharmacist care
Kumanyika 2012 Aim: Weight loss Country: USA	N: 261 Mean baseline BMI: basic 37.3 (6.4); basic plus 37.2 (6.5) Additional inclusion criteria: n/a	Internal validity: ++ External validity: ++	Intervention length: 12 months Longest follow-up: 12 months ***Data reported:*** Weight: Yes BMI: No Waist: No	Control group: No Other comparisons: All arms multicomponent, more frequent contact involving healthcare assistants and GPs versus less frequent GP only contact
Logue 2005 Aim: Weight loss Country: USA	N: 665 Mean baseline BMI: NR (23% BMI 40 or higher) Additional inclusion criteria: n/a	Internal validity: ++ External validity: ++	Intervention length: 24 months Longest follow-up: 24 months ***Data reported:*** Weight: Yes BMI: No Waist: No	Control group: No Other comparisons: All arms multicomponent, one enhanced with stage of change methodology and phone calls from Weight Loss Advisor

Study ID and details	Participants	Validity scores	Outcomes	Comparisons
Micco 2007 Aim: Weight loss Country: USA	N: 123 Mean baseline BMI: VTrim 32.3 (3.9); VTrim + personal contact 31.0 (4.1) Additional inclusion criteria: Owner of (relatively) new computer	Internal validity: + External validity: +	Intervention length: 12 months Longest follow-up: 12 months ***Data reported:*** Weight: Yes BMI: No Waist: No	Control group: No Other comparisons: internet only vs internet and in-person support
Munsch 2003 Aim: Weight loss Country: Switzerland	N: 122 Mean baseline BMI: GP 36.2 (6.5); clinic 38.5 (7.5); control 32.6 (1.8) Additional inclusion criteria: n/a	Internal validity: - External validity: ++	Intervention length: 4 months Longest follow-up: 12 months ***Data reported:*** Weight: Yes BMI: Yes Waist: No	Control group: Yes Other comparisons: delivered in GP practice by GP versus delivered in clinic by clinic tutor
Rejeski 2011 Aim: Increased mobility Country: USA	N: 288 Mean baseline BMI: intervention 33.1 (4.1); exercise only 32.8 (3.9); control 32.6 (3.5) Additional inclusion criteria: older adults with evidence of CVD or metabolic syndrome and self-reported mobility limitation	Internal validity: + External validity: +	Intervention length: 18 months Longest follow-up: 18 months ***Data reported:*** Weight: Yes BMI: No Waist: No	Control group: Yes Other comparisons: multicomponent versus exercise only
Rock 2010 Aim: Weight loss Country: USA	N: 442 Mean baseline BMI: centre based 33.8 (3.6); telephone based 33.8 (3.3); control 34.0 (3.2) Additional inclusion criteria: women only	Internal validity: ++ External validity: ++	Intervention length: 24 months Longest follow-up: 24 months ***Data reported:*** Weight: Yes BMI: No Waist: No	Control group: Yes Other comparisons: In person & remote vs remote contact only
Saito 2011 Aim: Diabetes prevention Country: Japan	N: 641 Mean baseline BMI: intensive intervention 26.9 (2.6); less intensive intervention 27.1 (2.6) Additional inclusion criteria: elevated fasting glucose but not full type 2 diabetes	Internal validity: ++ External validity: +	Intervention length: 36 months Longest follow-up: 36 months ***Data reported:*** Weight: Yes BMI: Yes Waist: Yes	Control group: No Other comparisons: Different number of contacts within same set period of time
Seligman 2011 Aim: Weight loss Country: Brazil	N: 76 Mean baseline BMI: supervised low carb 35.2 (2.5); low carb not supervised 34.4 (3.0); low fat not supervised 34.7 (3.0) Additional inclusion criteria: 3 metabolic sydrome criteria	Internal validity: ++ External validity: +	Intervention length: 3 months Longest follow-up: 12 months ***Data reported:*** Weight: Yes BMI: No Waist: Yes	Control group: No Other comparisons: Supervised versus recommended exercise, low carb versus low fat diet
Skender 1996 Aim: Weight loss Country: USA	N: 127 Mean baseline BMI: NR Additional inclusion criteria: n/a	Internal validity: + External validity: +	Intervention length: 12 months Longest follow-up: 24 months ***Data reported:*** Weight: Yes BMI: No Waist: Yes	Control group: No Other comparisons: Multicomponent versus diet only versus exercise only

Study ID and details	Participants	Validity scores	Outcomes	Comparisons
Tate 2003 Aim: Weight loss Country: USA	N: 92 Mean baseline BMI: basic 32.5 (3.8); basic + 33.7 (3.7) Additional inclusion criteria: One or more risk factors for type 2 diabetes	Internal validity: ++ External validity: +	Intervention length: 12 months Longest follow-up: 12 months ***Data reported:*** Weight: Yes BMI: Yes Waist: Yes	Control group: No Other comparisons: Internet vs internet with internet counselling
Villareal 2011 Aim: Weight loss & improved physical function Country: USA	N: 107 Mean baseline BMI: diet and exercise 37.2 (5.4); diet only 37.2 (4.5); exercise only 36.9 (5.4); control 37.3 (4.7) Additional inclusion criteria: aged 65 years or older; mild to moderate frailty	Internal validity: ++ External validity: ++	Intervention length: 12 months Longest follow-up: 12 months ***Data reported:*** Weight: Yes BMI: No Waist: No	Control group: Yes Other comparisons: Multicomponent versus diet only versus exercise only
Vissers 2010 Aim: Weight loss Country: Belgium	N: 79 Mean baseline BMI: vibration 3.19)4.7); fitness 33.1 (3.4); diet only 32.9 (3.1); control 30.8 (3.4) Additional inclusion criteria: n/a	Internal validity: + External validity: ++	Intervention length: 12 months Longest follow-up: 12 months ***Data reported:*** Weight: Yes BMI: Yes Waist: No	Control group: Yes Other comparisons: Fitness versus vibration and multicomponent versus diet
Wadden 1988 Aim: Weight loss Country: USA	N: 59 Mean baseline BMI: NR Additional inclusion criteria: n/a	Internal validity: + External validity: +	Intervention length: 18 months Longest follow-up: 36 months ***Data reported:*** Weight: Yes BMI: No Waist: No	Control group: No Other comparisons: VLED & exercise versus diet & exercise versus diet only
Weinstock 1998 Aim: Weight loss Country: USA	N: 45 Mean baseline BMI: diet and aeorobic 36.4 (1.1); diet and resistance 36.2 (1.9); control 35.2 (1.4) Additional inclusion criteria: Female only	Internal validity: - External validity: +	Intervention length: 23 months Longest follow-up: 23 months ***Data reported:*** Weight: Yes BMI: Yes Waist: No	Control group: No Other comparisons: diet & strength versus diet & aerobic versus diet only

Effects and associations of programme components with mean difference in weight change at 12 months

Studies that involved direct comparisons between items of interest (where these were not heavily confounded) are reported below. We used random effects meta-regression to further explore the effects of individual programme components on weight loss at 12 to 18 months. Where relevant, we also summarise findings from indirect comparisons (subgroup analyses) in Review 1a.

Multicomponent programmes (diet and exercise) compared with diet or exercise-only programmes

Multicomponent BWMP compared with diet-only (direct comparisons)

Seven studies compared a multicomponent BWMP (for our purposes defined as involving both diet and exercise components) with a diet only arm (Bertz 2012, Foster-Schubert 2012, Skender 1996,

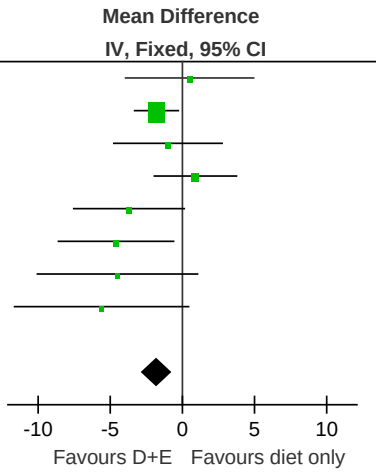
Villareal 2007, Vissers 2010, Wadden 1998, Weinstock 1998). In the six studies for which we could calculate BOCF outcomes, pooled results showed that mean weight loss at 12 months was significantly higher in programmes which involved diet and exercise than in those which involved diet alone (mean difference -1.79 kg, 95% CI -2.86 to -0.72, figure 4). Statistical heterogeneity was low (I^2 = 30%). One further study could not be included in the meta-analysis due to limited data (Weinstock RS 1998). This study compared weight loss in three arms: diet and strength training; diet and resistance training; and diet only. At 10 months, complete case mean weight loss in the diet and strength training and diet and resistance training arms (-14.1 kg and -13 kg, respectively) were greater than that in the diet only arm (-12 kg), following the same trend as findings from the meta-analysis.

Figure 4 Mean difference in weight loss between BWMPs involving both diet and exercise and programmes involving diet only

	BWMP (D+E)			diet only				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Bertz 2012	-7.3	6.3	16	-7.8	6.7	17	5.8%	0.50 [-3.94, 4.94]
Foster-Schubert 2012	-8.9	5.5	117	-7.1	6.3	118	50.1%	-1.80 [-3.31, -0.29]
Skender 1996	-5.7	10.1	42	-4.7	7.2	42	8.1%	-1.00 [-4.75, 2.75]
Villareal 2011	-7.7	4.5	28	-8.6	6	26	14.1%	0.90 [-1.95, 3.75]
Vissers 2010 (fitness)	-6.3	6.4	20	-2.6	4.2	10	7.8%	-3.70 [-7.53, 0.13]
Vissers 2010 (vibration)	-7.2	6.9	20	-2.6	4.2	10	7.2%	-4.60 [-8.59, -0.61]
Wadden 1988 (no VLED)	-8.4	7	18	-3.9	6.9	9	3.7%	-4.50 [-10.05, 1.05]
Wadden 1988 (VLED)	-9.5	9.8	23	-3.9	6.9	9	3.1%	-5.60 [-11.63, 0.43]
Total (95% CI)			**284**			**241**	**100.0%**	**-1.79 [-2.86, -0.72]**

Heterogeneity: Chi² = 9.94, df = 7 (P = 0.19); I² = 30%

Test for overall effect: Z = 3.28 (P = 0.001)



Comparator arms with diet-only programmes of six months or less

In consultation with NICE colleagues, we agreed that the data could be used to test one of the current NICE best practice principles: namely, that programmes should "focus on long-term lifestyle changes rather than a short-term, quick-fix approach." As agreed with NICE, we confined the analysis to studies that compared a BWMP to a diet-only programme lasting six months or less (this cut off was decided based on results from subgroup analysis in Review 1a). Two studies met this criterion. In Bertz 2012, all interventions lasted 12 weeks. There was no significant difference between the diet and exercise arm and the diet only arm at 12 months; confidence intervals were wide due to a small sample size (see figure 4). A second study, Wadden 1988, compared the efficacy of a very low energy diet (VLED) to a behaviour therapy programme + VLED and a behaviour therapy programme with a reduced calorie diet (not a VLED). The VLED only arm had an intensive phase of four months, with five follow-up meetings in the year following the intensive phase. The arm receiving both the VLED and behaviour therapy met 12 times over the year following the intervention and received behavioural counselling and exercise advice throughout. Though again results were not statistically significant (small sample sizes), at 12 months the arm that received behavioural therapy and more contact lost more weight than those that participated in the VLED only (mean weight loss: behaviour therapy + VLED -9.5 kg (9.8); VLED only -3.9 kg (6.9)). This trend persisted at 36 months (mean weight loss: behaviour therapy + VLED -3.8 kg (7.4); VLED only -1.8 kg (7.8)) and was consistent with the trend seen in the behavioural therapy + reduced calorie diet arm.

BWMP compared with exercise only (direct comparisons)

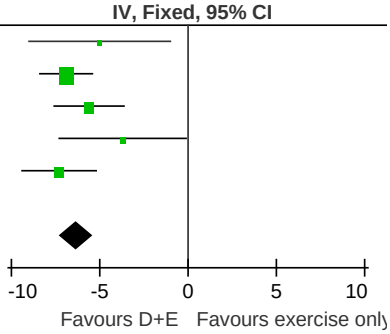
Five studies randomised participants to diet and exercise versus exercise alone (Bertz 2012, Foster-Schubert 2012, Rejeski 2011, Skender 1996, Villareal 2011). Pooled results from these five studies showed significantly greater weight loss at 12 months in programmes that combined diet and exercise than in those that involved exercise only (mean difference -6.33 kg, 95% CI -7.30 to -5.37, figure 5).[10] Statistical heterogeneity was low (I^2 = 9%). All of the BWMPs that were compared with exercise-only programmes had hypo-energetic (reduced calorie)diets that specified a low fat diet (with recommended macronutrient proportions).

Figure 5 Mean difference in weight loss between BWMPs involving both diet and exercise and programmes involving exercise only

	BWMP (D+E)			exercise only				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Bertz 2012	-7.3	6.3	16	-2.3	5.5	18	5.8%	-5.00 [-9.00, -1.00]
Foster-Schubert 2012	-8.9	5.5	117	-2	6.1	117	41.9%	-6.90 [-8.39, -5.41]
Rejeski 2011	-6.3	7.7	98	-0.7	6.3	97	23.8%	-5.60 [-7.57, -3.63]
Skender 1996	-5.7	10.1	42	-2	6.3	43	7.2%	-3.70 [-7.29, -0.11]
Villareal 2011	-7.7	4.5	28	-0.4	3.3	26	21.2%	-7.30 [-9.39, -5.21]
Total (95% CI)			**301**			**301**	**100.0%**	**-6.33 [-7.30, -5.37]**

Heterogeneity: Chi² = 4.40, df = 4 (P = 0.35); I² = 9%

Test for overall effect: Z = 12.88 (P < 0.00001)



Weight loss curves

In addition to the above forest plots, we also drew weight loss curves for interventions involving diet only, interventions involving exercise only, and arms from these studies that involved both diet and exercise. Only those studies that report weight at more than one follow-up point are included in the weight curves and the limited number of studies hampers our ability to draw conclusions. As is to be expected, arms that involved both diet and exercise showed a similar shape to the interventions examined in Review 1a, with an initial weight-loss phase followed by a period of weight regain (figure 6x). Participants in diet-only arms (figure 7) appeared to lose weight initially in a pattern similar to the diet and exercise combined arms, but some diet only groups had greater immediate weight regain. Participants in exercise only arms did not regain weight during the follow-up provided but produced only modest weight-loss (figure 8).

[10] SD not available

Figure 6 Weight change over time in arms that involved both diet and exercise (and that were compared with diet-only or exercise-only)

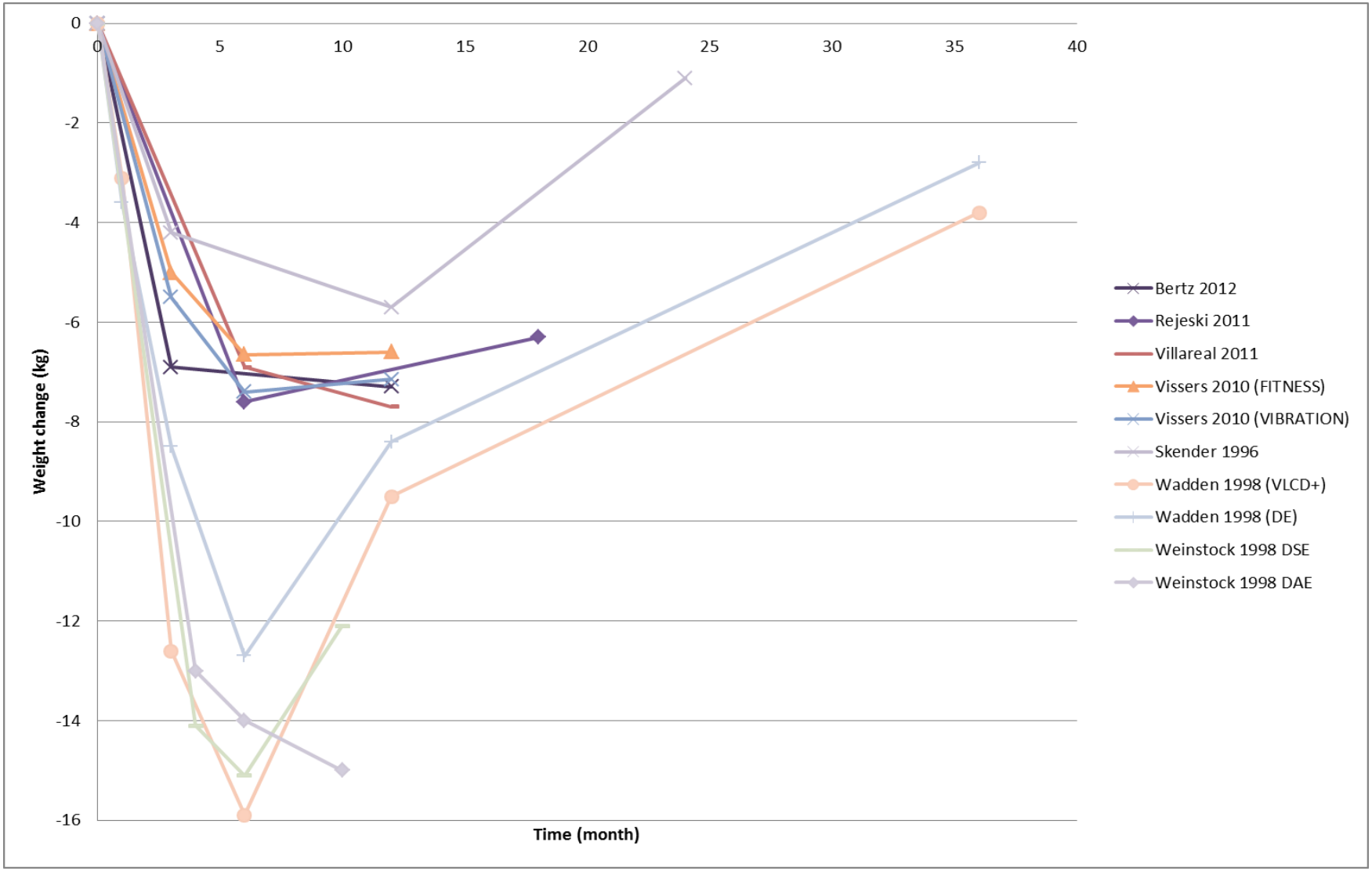


Figure 7 Weight change over time in arms that involved diet only

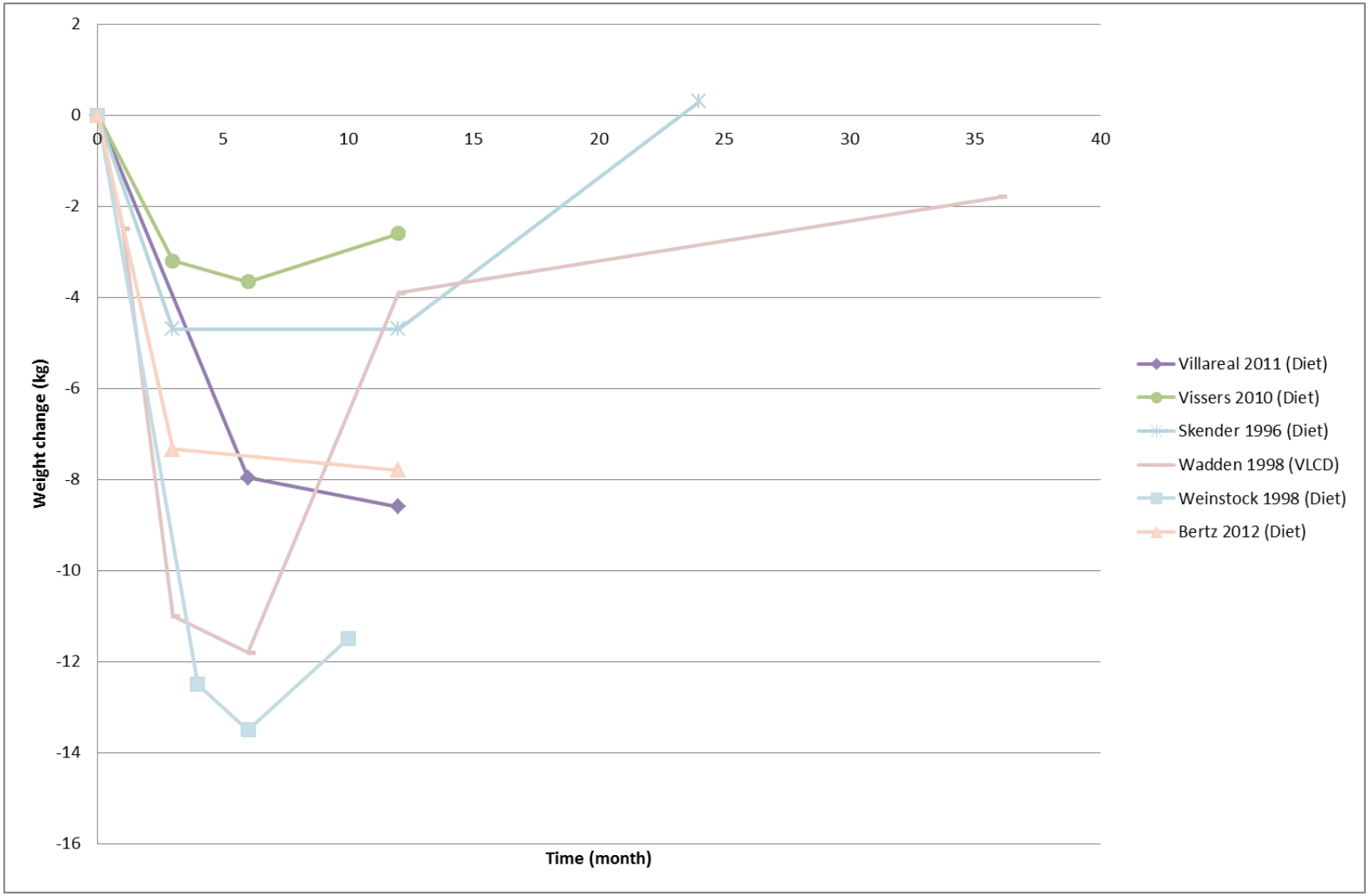
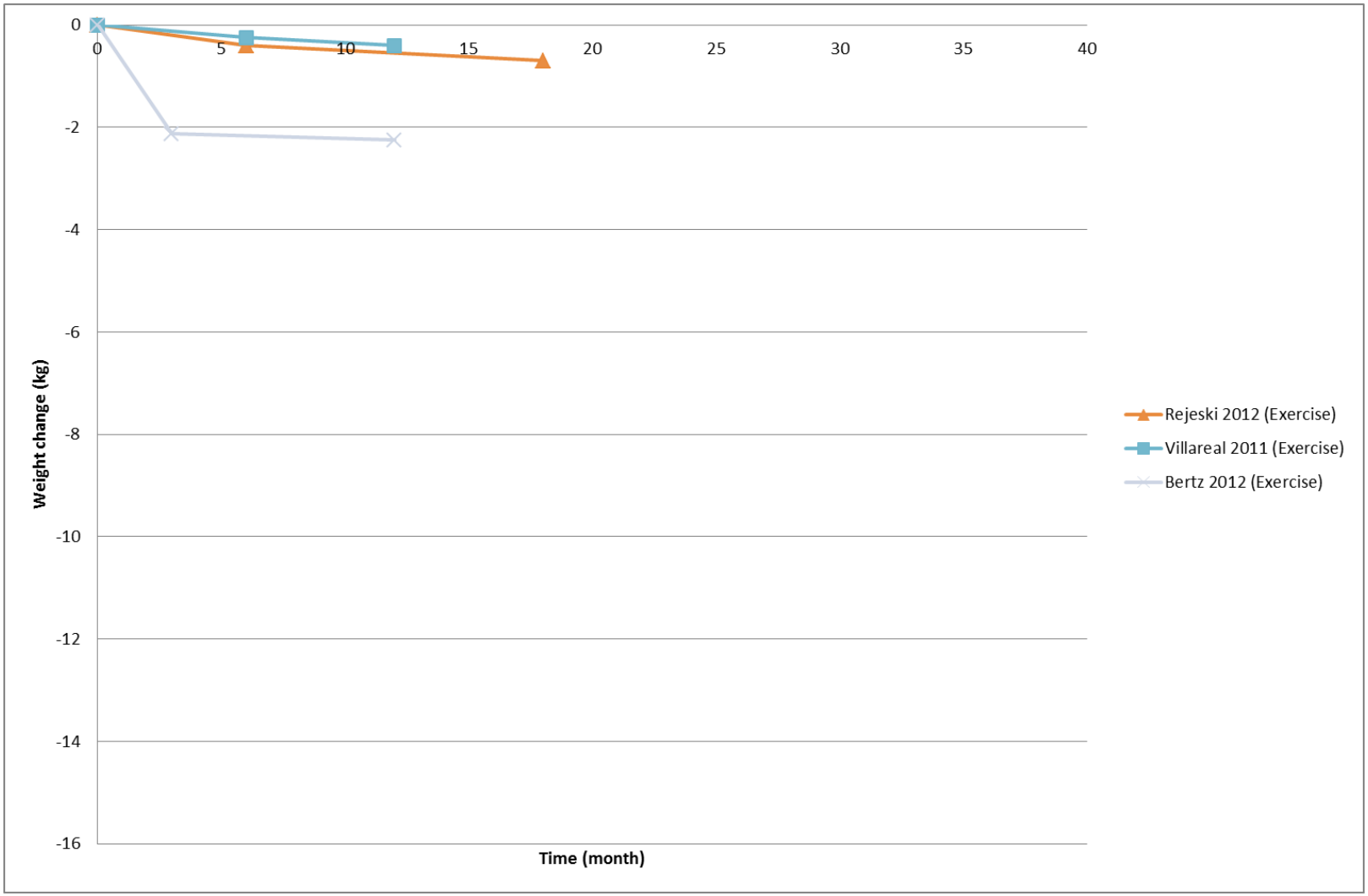


Figure 8 Weight change over time in arms that involved exercise-only



Programme delivery

Group versus individual

Direct comparisons

No studies provided direct comparisons of group versus individual delivery (or combinations of the two).

Indirect comparisons

Subgroup analysis in Review 1a found that combined group and individual programmes were associated with greater weight loss at 12 months than were programmes delivered in group or individual settings only, but levels of statistical heterogeneity were high in each group. Random effects meta-regression did not detect a significant association of group, individual or combined group and individual delivery on mean difference in weight loss at 12 months (combined group and individual: coefficient -0.4 kg, 95% CI -1.6 to +2.7, p = 0.678; group only: coefficient -0.04, 95% CI -1.9 to +2.0, p = 0.966; individual only: coefficient +0.4, 95% CI -1.6 to +2.3, p = 0.706).

Programme delivery mode (remote versus in person)

Direct comparisons

Three trials randomised participants to in-person versus remote contact. Appel 2011 evaluated the effect of adding in-person sessions to an intervention delivered via the phone and web, whereas Micco 2007 and Rock 2010 evaluated programmes with one arm receiving only remote contact and the other arm involving some in-person contact (same number of total sessions across arms). As shown in figure 9, pooled results did not detect a significant effect (mean difference -0.17 kg, 95% CI -1.23 to 0.89) and were highly heterogeneous (I^2= 65%).

Indirect comparisons

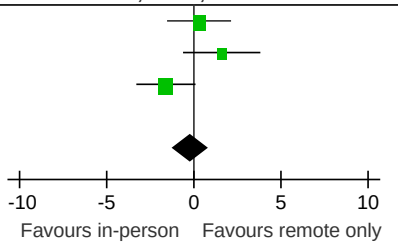
The pooled result from the direct comparison was consistent with the indirect evidence. In a subgroup analysis from Review 1a, interventions involving face-to-face contact were associated with significantly more weight loss than those with remote contact only (-2.93 kg, 95% CI -3.13 to -2.72, compared to -1.11 kg, 95% CI -1.53 to -0.69), but there was high heterogeneity within both groups (I^2 ≥ 90%). Random effects meta-regression did not detect a significant association of in-person versus remote delivery with weight loss at 12 months (for programmes involving face-to-face contact, coefficient -0.6 kg, 95% CI -3.2 to +2.1, p = 0.656).

Figure 9 Meta-analysis of studies comparing programmes with some in-person contact to those delivered via remote contact only (direct comparisons)

	In-person (+/- remote)			Remote contact only				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Appel 2011	-4.8	7.6	138	-5.1	7.6	139	35.0%	0.30 [-1.49, 2.09]
Micco 2007	-3.5	5.1	63	-5.1	7.1	62	23.8%	1.60 [-0.57, 3.77]
Rock 2010	-10.1	7.3	167	-8.5	8	164	41.2%	-1.60 [-3.25, 0.05]
Total (95% CI)			**368**			**365**	**100.0%**	**-0.17 [-1.23, 0.89]**

Heterogeneity: Chi² = 5.70, df = 2 (P = 0.06); I² = 65%

Test for overall effect: Z = 0.32 (P = 0.75)



Professional background of therapist

Direct comparisons

Jolly 2011 and Munsch 2003 included comparisons that varied only on person delivering the programme. Two arms of Jolly 2011 compared weekly sessions delivered by a GP and weekly sessions delivered by a pharmacist, where the content and schedule of the sessions was the same. There was no significant difference in weight loss between groups at 12 months (GP versus pharmacist, mean difference -0.10, 95% CI -1.69 to +1.49). Two arms in Munsch 2003 compared the same intervention, one delivered by a general practitioner (in a general practice setting) and one delivered by a 'clinic tutor' (in a clinic setting, no further information provided). GPs and clinic tutors both received training in the intervention over the course of two four-hour sessions. Again, differences in weight loss were not statistically significant between the two arms at 12 months. The point estimate favoured the GP arm (GP versus clinic, mean difference -2.70 kg, 95% CI -5.54 to +0.14).

Indirect comparisons

Interventions varied greatly in terms of the background of the therapist, and many interventions were delivered by more than one professional (e.g. dietitian, exercise trainer, psychologist), making any indirect analysis difficult. Of those delivering the interventions, dietitians were the only group whose core role would have involved weight loss counselling. Therefore, using meta-regression, we tested if the involvement of a dietitian (or someone with the equivalent professional qualification in countries where 'dietitian' is not a registered term) was associated with mean weight loss at 12 to 18 months; the association was not statistically significant when unadjusted (coefficient -1.0 kg, 95% CI -2.8 to +0.8, p = 0.255), but when adjusting for the presence or absence of set energy prescriptions, a significant association emerged (coefficient -1.5 kg, 95% CI -2.9 to -0.1, p = 0.035, see 'Multivariate model' for more discussion).

Programme elements

Supervised versus recommended exercise

Direct comparisons

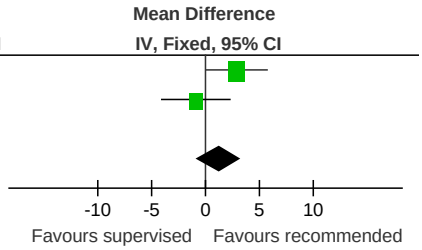
Two studies randomised participants to BWMPs that incorporated supervised exercise versus recommending exercise only. Results were conflicting. Jeffery 1998 compared a BWMP with recommended physical activity to the same BWMP with the same physical activity goal, but with three supervised walking sessions a week. At 18 months, participants in the group without supervised exercise lost significantly more weight than those in the group with supervised exercise (supervised versus recommended mean difference +2.90 kg, 95% CI +0.09 to +5.71). The authors speculate this may have been due to the development of increased self-motivation in the arm without supervised exercise. Seligman 2011 evaluated the effect of supervised sessions three times a week compared to the same programme with home-based, recommended exercise only. In this study, participants in the arm with supervised exercise lost more weight at 12 months, but the difference was not statistically significant (supervised versus recommended mean difference -0.90 kg, 95% CI -4.06 to +2.26). As shown in figure 10, pooled results were also not statistically significant (mean difference 1.22, 95% CI -0.88 to +3.32) and heterogeneity was high (I^2 = 68%).

Figure 10 Mean difference in weight loss at 12 to 18 months, supervised exercise versus recommended exercise only

Study or Subgroup	Supervised exercise Mean	SD	Total	Recommended exercise only Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Jeffery 1998	-3	6.7	41	-5.9	6.2	40	55.8%	2.90 [0.09, 5.71]
Seligman 2011	-7.3	6.1	26	-6.4	5.4	25	44.2%	-0.90 [-4.06, 2.26]
Total (95% CI)			**67**			**65**	**100.0%**	**1.22 [-0.88, 3.32]**

Heterogeneity: Chi² = 3.10, df = 1 (P = 0.08); I² = 68%

Test for overall effect: Z = 1.14 (P = 0.25)



Indirect comparisons

Within the supervised exercise category, programmes ranged from those with most exercise being recommended to those with all exercise being supervised. A subgroup analysis in Review 1a found that weight loss was greater in programmes involving supervised exercise than in those that only recommended exercise (-4.08 kg, 95% CI -4.39 to -3.78, compared with -1.71 kg, 95% CI -1.94 to -1.47), but within group heterogeneity was very high (I^2 > 85%). Random effects meta-regression on this variable did not detect a significant association (coefficient -1.7 for supervised exercise, 95% CI -3.5 to 0, p = 0.055).

Physical activity: easy versus difficult to implement recommendations

To test current NICE best practice principles, we divided interventions into those in which the exercise involved a specific setting or specific equipment (difficult to implement), and those that did not require any specific setting or equipment (easy to implement).

Direct comparisons

There were no direct comparisons addressing this question.[11]

Indirect comparisons

We used meta-regression to test the association of easy versus difficult to implement physical activity with weight change at 12 months, defining difficult as requiring specific equipment or settings to perform the activity. Again, meta-regression did not detect a significant association of this variable with weight loss at 12 to 18 months, but the evidence suggested that programmes incorporating specific equipment or requiring special settings for physical activity may be more effective (coefficient -0.8 kg, 95% CI -3.4 to +1.9, p = 0.562). This was not evaluated in Review 1a.

Energy intake prescription (set energy prescription)

Direct comparisons

No studies reported direct comparisons of programmes with set energy prescriptions compared to the same programme without set energy prescriptions.

[11] Note, comparisons of supervised versus unsupervised exercise do not answer this question unless the type of exercise itself differs between arms, and no studies of this type existed.

Indirect comparisons

Univariate meta-regression detected a significant association of set energy prescriptions and greater weight loss (coefficient -3.3 kg, 95% CI -4.7 to -1.9, $p < 0.001$). In a multivariate model (see 'Multivariate regression model'), this association persisted and remained largely unchanged when adjusting for the involvement of a dietitian.

These findings are consistent with a subgroup analysis on this variable in Review 1a, which found that interventions that involved a set energy prescription led to significantly greater weight loss at 12 months than those that did not include a set energy prescription (set goal -3.76 kg, 95% CI -4.06 to -3.46; no set goal -1.88 kg, 95% CI -2.11 to -1.64). However, here again heterogeneity was very high within subgroups ($I^2 > 85\%$).

Programme intensity

Length

Direct comparisons

No studies provided direct comparisons based on programme length.

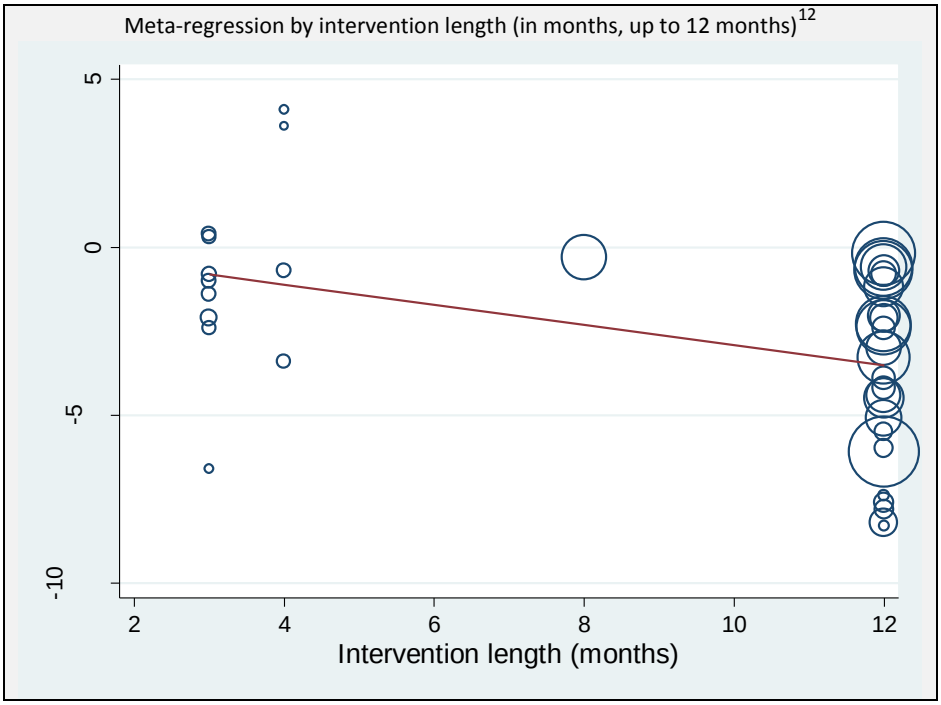
Indirect comparisons

Using meta-regression, we evaluated the association of programme length in months (on a continuous scale) with weight loss at 12 months. Though some programmes lasted longer than 12 months, 12 was the maximum length in this analysis as we were using outcome data at 12 months. Figure 11 displays a graph of the fitted model, showing a trend towards greater weight loss as programme length increased (coefficient -0.3, 95% CI -0.5 to -0.1, $p = 0.009$; note this does not control for number of sessions). Each circle in this graph represents a comparison between intervention and control, and the size of the circle represents the standard error of the mean difference in weight loss (bigger circles mean there is more variation in the result or that the result is less precise).

Intervention length still had a significant effect on mean difference in weight change at 12 months when adjusted for number of sessions. Adjusted results suggest that for each additional month of a programme, participants lost an additional 0.2 kg of weight at 12 months (95% CI -0.4 to -0.01, $p = 0.040$). However, results were no longer statistically significant in the multivariate model that adjusted for involvement of a dietitian and presence of a set energy prescription (see 'Multivariate regression model').

Results from the meta-regression are consistent with subgroup analysis conducted as part of Review 1a, which found that weight loss at one year was higher in interventions lasting longer than six months than in those lasting four to six months and those lasting up to three months.

Figure 11 Graph of fitted model, intervention length



Contact frequency

Direct comparisons

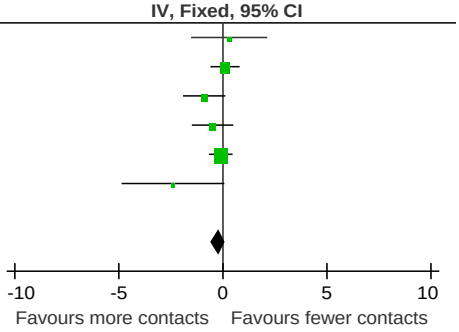
There were six studies in which participants were randomised to BWMPs offering more or less frequent contact over a set length of time (Appel 2011, Hersey 2012, Kumanyika 2012, Logue 2005, Saito 2011, Tate 2003). As seen in Figure 12, there was no significant difference in mean weight loss at 12 months, with a difference of -0.23 kg (95% CI -0.57 to +0.12, I^2 = 25%). It is important to note that these interventions varied on other components besides contact frequency, and that all arms met our definition of BWMP and hence involved repeated contact with someone trained in weight management.

Figure 12 Direct comparisons between study arms involving more versus less contact over a set period of time

	More contacts			Fewer contacts				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Fixed, 95% CI**
Appel 2011	-4.8	7.6	138	-5.1	7.6	139	3.7%	0.30 [-1.49, 2.09]
Hersey 2012	-1.8	5.7	578	-1.9	5.8	579	26.8%	0.10 [-0.56, 0.76]
Kumanyika 2012	-1.3	4.6	124	-0.4	3.3	137	12.3%	-0.90 [-1.88, 0.08]
Logue 2005	-1.3	6.4	329	-0.8	6.2	336	12.8%	-0.50 [-1.46, 0.46]
Saito 2011	-2.4	3.2	300	-2.3	3.5	321	42.4%	-0.10 [-0.63, 0.43]
Tate 2003	-4.4	6.2	46	-2	5.7	46	2.0%	-2.40 [-4.83, 0.03]
Total (95% CI)			**1515**			**1558**	**100.0%**	**-0.23 [-0.57, 0.12]**

Heterogeneity: Chi² = 6.68, df = 5 (P = 0.25); I² = 25%

Test for overall effect: Z = 1.30 (P = 0.20)

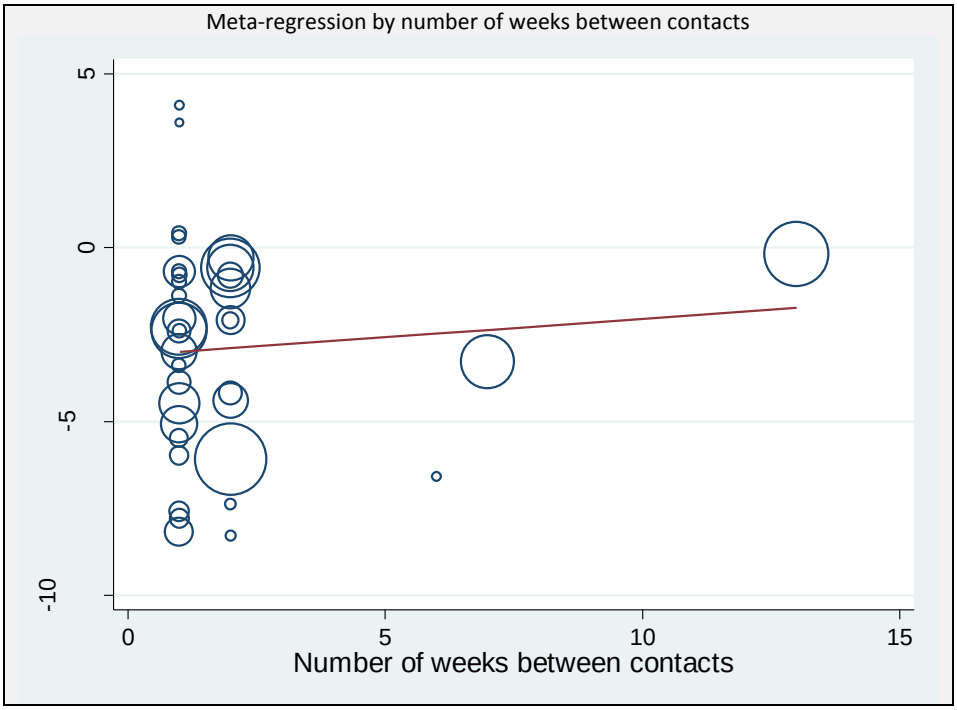


[12] Size of circle represents SE

Indirect comparisons

Meta-regression did not detect any significant association of contact frequency on weight loss at 12 months (coefficient 0.1 kg per additional week between contacts, 95% CI -0.3 to +0.5, p = 0.603). We classified studies by number of weeks between contacts (weekly =1, fortnightly = 2, and so on), and figure 13 shows this model graphically. As seen in figure 13, the vast majority of interventions had contact at least weekly or fortnightly, limiting our ability to draw conclusions. Review 1a included a subgroup analysis based on contact frequency. In the meta-analysis, confidence intervals overlapped for groups of studies with weekly contact, contact at least fortnightly, and contact at least once every two months. Interventions which involved contact at least monthly or contact less than every two months had point estimates that were significantly less effective, but this represented only four studies in total, and is likely to be due to chance given the non-linear nature of the results.

Figure 13 Graph of fitted model, weeks between contacts



Number of sessions of therapy

Direct comparisons

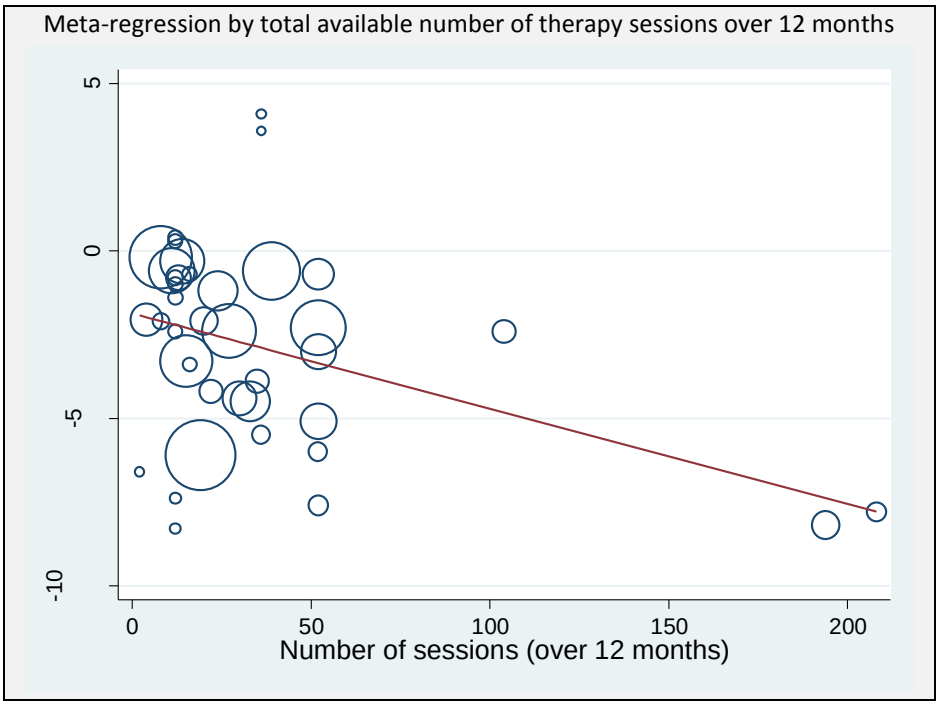
The studies in figure 12 above also serve as direct comparisons between more and fewer sessions of therapy, but number of sessions within each arm varied considerably.

Indirect comparisons

In contrast to the non-significant findings from direct comparisons, a significant association was found between number of sessions and weight loss at 12 months, with each additional session associated with an addition 0.03 kg weight loss in a univariate model (95% CI -0.04 to -0.01, p = 0.004). Figure 14 displays a fitted model, showing a trend towards greater weight loss as the number of sessions increased. The association remained significant when adjusting for presence of a set energy prescription, but was no longer significant when also adjusting for involvement of a

dietitian (see 'Multivariate regression model'). Review 1a did not explore the effect of number of sessions.

Figure 14 Graph of fitted model, number of sessions of therapy



Provision of decreasing intensity of support

Direct comparisons

No studies randomised participants to a programme that ended abruptly or provided reducing intensity support.

Indirect comparisons

Meta-regression investigating the provision of follow-up support (defined as a decrease in contact frequency or intensity after a set period of time, CALORE code 27) found no significant association with weight loss at 12 months. When adjusting for the number of sessions and length of intervention, the evidence suggested a small but not significant effect of decreasing intensity support (coefficient -1.4 kg, 95% CI -3.0 to +0.2, p = 0.092). This variable was not examined in Review 1a.

Theoretical orientation

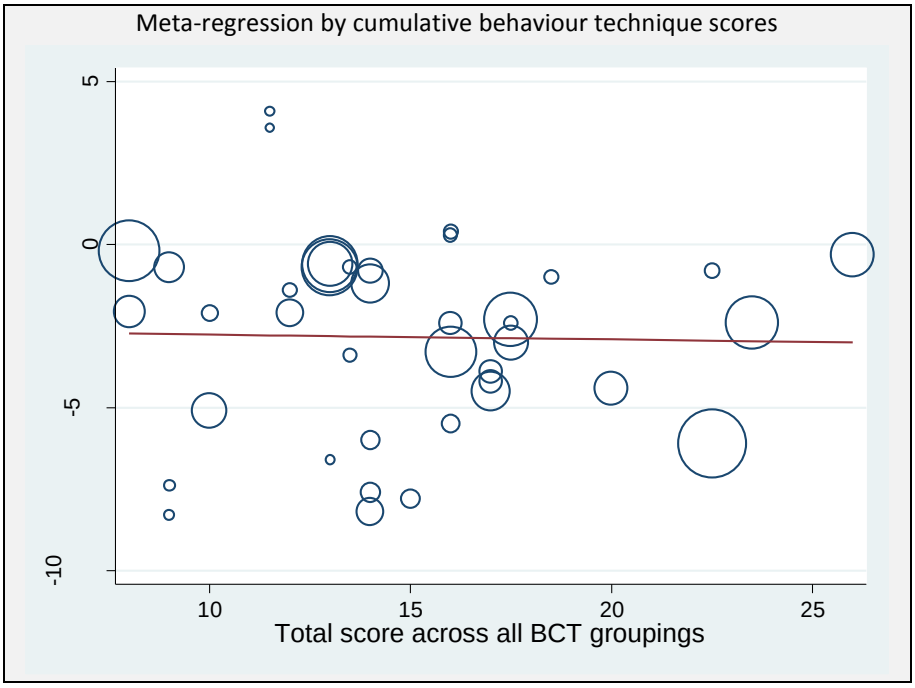
No studies provided direct comparisons based on theoretical orientation (i.e. the model used to explain behaviour or personality).

Most studies did not report that they had a particular theoretical orientation. Furthermore, there appeared to be no relation between the theoretical orientation and the behavioural change techniques used in the intervention, which would normally be expected, suggesting this was not an important variable. We therefore did not evaluate the effect of theoretical orientation on outcome as this would likely be a measure of reporting rather than of the intervention delivered.

Associations of behavioural techniques and weight loss

We used meta-regression to test the associations of the 14 behavioural technique groupings with weight loss at 12 months. Cumulative scores (scores from all groupings combined) did not have a significant effect on mean difference in weight loss (p = 0.890, see figure 15), suggesting that the overall presence, absence, or reporting of techniques did not impact weight change. Taxonomy scores for individual techniques can be found in Appendix 4.

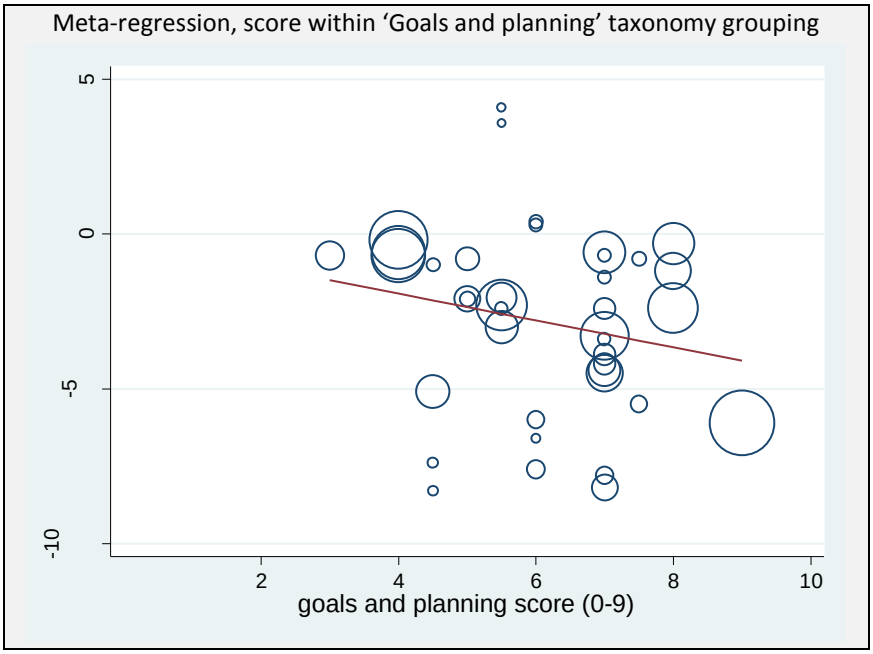
Figure 15 Graph of fitted model, metaregression of cumulative scores across all BCTs



Goals and planning

Meta-regression testing the effect of goals and planning techniques did not show a significant association with weight loss (coefficient -0.4 kg, 95% CI -1.1 to + 0.2, p = 0.179). As displayed in Figure 16, the trend was towards increased weight loss as the number of goals and planning techniques increased.

Figure 16 Graph of fitted model, score within Goals and planning taxonomy grouping



Weight loss goals

For each study, we extracted weight loss goals both weekly and in the long term. However, of those studies which reported goals, targets were homogenous and the vast majority fit within current NICE best practice guidelines (0.5 to 1kg/week and/or 5 to 10% of baseline weight in the longer term). None had long term weight loss targets higher than the range specified by NICE and only one had a weekly weight loss target higher than that specified by NICE (Jolly 2011 RC arm 1.5kg/week at intervention start). In none of the studies did the weight change data provided suggest participants were losing more than 1kg/week on average (though studies did not report weight weekly, so exact figures for weekly weight loss are not available).

The main programmes that aim for rapid weight loss (e.g. > 2kg/week) are very low energy diets (VLEDs). However, the effectiveness of setting high weight loss goals in VLED programmes is confounded with providing meals, which is a universal feature of VLEDs. Few of our included studies involved meal replacement independent of VLEDs, so we were unable to assess the effectiveness of higher weight loss goals net of the effect of meal replacement. To further complicate matters, neither of the included studies that involved VLEDs had a control arm.

Behavioural goals

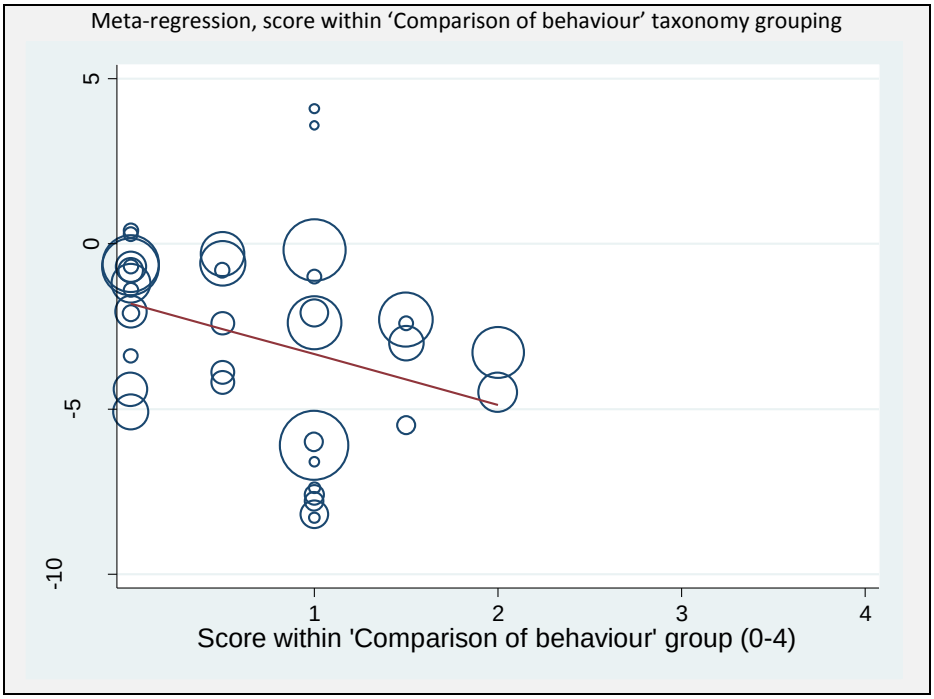
One study presented direct comparisons based on behavioural goals. Dubbert 1984 evaluated the effect of having a spouse accompany a participant to a weight loss programme and of proximal (daily) versus distal (weekly) energy and physical activity goals (Dubbert PM 1984). Due to limitations with the data reported, it was not possible to calculate BOCF weight change or mean differences. At 10 months, in the two arms with individual attendance, participants with proximal goals lost more weight than those with distal goals (complete case mean weight loss proximal: -9.3 kg, distal -5.9 kg). However, in the two arms where partners attended, participants assigned distal goals lost more

weight than those assigned proximal goals (complete case mean weight loss: proximal -5.4 kg, distal -6.9 kg). Sample sizes were very small and numbers followed-up were not provided, making it difficult to draw any conclusions from the data presented.

Comparison of behaviour

Comparison of behaviour means providing information about others' approval of a person's behaviour or social norm behaviour, as well as modelling. It was scored from 0 to a maximum of 4 (i.e. the intervention employed no techniques in this grouping through to the intervention employed all four techniques in this grouping), though the interventions in this review scored a maximum of 2. Comparison of behaviour was the only behavioural technique grouping that was associated with a significant positive effect on weight loss at 12 months in a univariate model; each additional technique was associated with an additional 1.5 kg weight loss, 95% CI -2.9 to -0.1, $p = 0.032$). Figure 17 displays a fitted model.

Figure 17 Graph of fitted model, score within Comparison of behaviour taxonomy grouping



The coefficients given above presume that each technique within this grouping has the same association with weight loss. To investigate this, we ran an exploratory meta-regression on the four techniques that fell under this grouping. Only two of these techniques were associated with increased weight loss ('model/demonstrate behaviour' and 'facilitate social comparison'), but the result for 'facilitating social comparison' was not statistically significant (coefficient -1.0 kg, 95% CI -4.8 to +2.8, p = 0.583). Modelling or demonstrating behaviour, however, was significantly associated with weight loss when controlling for the other three techniques. Use of this technique was associated with a 2.7 kg increase in weight loss at 12 months (95% CI -4.5 to -0.8 kg, p = 0.005). As modelling or demonstrating behaviour could be correlated with provision of supervised exercise, we also ran a meta-regression controlling for this variable. The association of modelling/demonstrating behaviour remained statistically significant (coefficient -2.1 kg, 95% CI -3.9 to -0.3, p = 0.024).

Self-belief

Self-belief means reminding users of past success or prompting self-talk[13] and scored on a scale of 0 to 2. Most intervention programmes included no self-belief behavioural change techniques. The greater use of self-belief techniques was associated with lower effectiveness (coefficient +2.1 kg, 95% CI +0.1 to +4.1, p = 0.040). An exploratory meta-regression of the individual techniques within this grouping ('prompting focus on past success' and 'prompting self-talk') did not detect a significant association of either individual technique with weight loss (p > 0.05), though coefficients suggested that use of either technique was associated with lower weight loss at 12 months.

[13] A technique that involves encouraging a person to talk to themselves (aloud or silently) before and during planned behaviours to encourage, support and maintain action.

Other behavioural taxonomy groupings

No significant associations were detected via meta-regression for any of the other behavioural taxonomy groupings. Table 3 displays results for each variable as per a forward stepwise meta-regression controlling for 'comparison of behaviour' techniques.

Table 3 Coefficients and p-values for taxonomy groupings in a metaregression controlling for 'Comparison of behaviour' score

Grouping	Coefficient	95% CI	P value
Shaping knowledge	-1.2 kg	-3.2 to +0.9	0.254
Repetition and substitution	-0.7 kg	-1.6 to +0.3	0.191
Antecedents	-0.7 kg	-3.3 to +1.9	0.585
Feedback and monitoring	-0.2 kg	-1.3 to +0.8	0.644
Social support	+0.1 kg	-1.0 to +1.2	0.815
Covert learning	+0.5 kg	-3.2 to +4.2	0.797
Reward and threat	+0.7 kg	-0.2 to +1.6	0.103
Regulation	+0.7 kg	-0.3 to +1.8	0.160
Associations	+1.0 kg	01.3 to +3.2	0.386
Natural consequences	+1.1 kg	-0.2 to +2.3	0.092
Identity	+1.8 kg	-4.0 to +7.6	0.530

Individual techniques in NICE's current best practice principles

NICE's current best practice principles specify three behavioural techniques in particular: relapse prevention/coping planning (planning for lapses and high risk situations); prompting self-monitoring of behaviour; and prompting self-monitoring of outcome (keeping a diary). A separate meta-regression controlling for 'comparison of behaviour' did not detect a significant effect on weight loss at 12 months from any of these techniques ($p > 0.05$), though in all cases the estimates suggested that the use of each technique was associated with greater weight loss.

The other behavioural technique which is implied in NICE's current best practice principles is setting a weight loss target (setting an outcome goal). In a meta-regression controlling for 'comparison of behaviour' this technique also did not significantly affect weight at 12 months ($p = 0.442$), though again the estimate suggested increased weight loss when the technique was used.

Multivariate regression modelling

As well as the above single variable meta-regressions, we also fit a multivariate model using a forward stepwise procedure. We first tested the association of each variable on its own in univariate models (as reported above) and then ran each variable again, controlling for the effect of the most significant variable. We did this until all variables with significant associations ($p < 0.05$) had been tested. We ran this separately for behavioural technique groupings and intervention characteristics, and then ran both together.

Intervention characteristics

In the univariate model, the inclusion of a set energy prescription was the single most significant association. Length of intervention, number of sessions, and involvement of a dietitian were all significantly associated with weight loss at 12 months when adjusting for the presence or absence of a set energy prescription (see table 4 below) when added to the model one at a time.

Table 4 Coefficients of characteristics when adjusted for presence or absence of set energy prescription

Characteristic	Coefficient	95% CI	p value
Involvement of dietitian	-1.5 kg	-2.9 to -0.1	0.035
Length of intervention	-0.2 kg	-0.4 to – 0.02	0.034
Number of sessions	-0.02 kg	-0.03 to -0.001	0.042

Following the forward stepwise approach, we then ran the characteristics again, this time adjusting for both set energy prescription and the involvement of a dietitian. When adjusting for these two variables, no other significant associations were found between any intervention characteristic and weight loss at 12 months (including length and number of sessions).

Behavioural technique groupings

Only two behavioural techniques demonstrated significant associations in single variable regressions: 'comparison of behaviour' and 'self-belief'. In adjusted models, no significant associations between behavioural technique groupings and weight loss were detected.

When 'comparison of behaviour' and 'self-belief' were combined in a multivariate meta-regression, neither association was statistically significant on its own, but coefficients were similar to single variable models. The coefficient for self-belief was +1.8 kg (95% CI -0.1 to +3.8, p = 0.067) and the coefficient for 'comparison of behaviour' was -1.35 kg (95% CI -2.7 to 0, p = 0.051).

Combined model

Finally, we ran a model that used only variables that were significantly associated with weight loss in adjusted models, namely: energy prescription and involvement of a dietitian. The association with weight loss remained significant for both variables (see table 5).

Table 5 Coefficients in the combined model

Characteristic	Coefficient	95% CI	p value
Set energy prescription	-3.3 kg	-4.6 to -2.0	< 0.001
Involvement of a dietitian	-1.5 kg	-2.9 to -0.1	0.035

Cost data

A separate piece of work has been commissioned by NICE to address cost effectiveness models for weight loss interventions. Five of the included studies in Review 1a provided data on cost per participant, and three of these provided further cost effectiveness analyses (see Review 1a, table 4). Two additional studies in Review 1b provided information on cost per participant, this is recorded in table 6 below. In both cases, the difference in costs between intervention arms is likely due to an increased number of contacts. No studies unique to Review 1b reported cost effectiveness analyses.

Table 6 Cost data from Review 1b studies[14]

Study ID	Cost data
Jakicic 2012	*Cost per participant:* Intervention 1 (contact frequency dependent on individual, minimum 18 sessions over 18 months): 358 USD Intervention 2 (45 sessions over 18 months): 494 USD *Cost to participant:* Intervention 1: 427 USD Intervention 2: 863 USD *Cost to society:* Intervention 1: 785 USD Intervention 2: 1357 USD
Saito 2011	*Cost per participant:* Intervention 1 (approx.. 10 sessions): 800 USD Intervention 2 (3 sessions): 650 USD

Evaluating current NICE best practice statements

Table 7 NICE best practice principles, and relevant evidence from this review

Statement	Supported?	Notes
Help people assess their weight and decide on a realistic healthy target weight (people should usually aim to lose 5 to 10% of their original weight)	**Neutral**	Assessment of weight is an integral part of weight loss programmes and hence evidence from our analysis cannot be applied to this part of the principle. All reported percentage weight loss targets fell within NICE's specified range (5 to 10% of baseline weight). Meta-regression did not detect a significant association of setting target weights with weight change at 12 months (though the estimate suggested greater weight loss when this technique was employed).
Aim for a maximum weekly weight loss of 0.5 to 1 kg	**Neutral**	Findings from this review do not suggest that a target of 0.5 to 1kg week is more or less preferable than a target of > 1 kg week. Only one of our included studies involved a weekly weight loss target above this range, and none had a target > 2 kg/week.
Focus on long-term lifestyle changes rather than a short-term, quick-fix approach	**Supported**	Longer programmes (especially above 6 months) were associated with greater weight loss at 12 months. No studies compared a longer BWMP with a shorter BWMP or a BWMP of 6 months or less. Greater weight loss was seen in intervention arms where repeated contacts were received than in control arms where advice was given on a one off basis. As discussed below, interventions that involved both diet and exercise were shown to induce greater weight loss than interventions that involved diet or exercise only, regardless of intervention length.
Be multicomponent, addressing both diet and activity, and offering a variety of approaches	**Supported**	Direct comparisons between BWMPs involving diet and exercise and those involving either diet or exercise, but not both, found that programmes that combined the two led to significantly more weight loss at 12 months.

[14] Note, this table only includes those studies *unique* to review 1b. Review 1a includes cost data from studies that compared interventions with a control group.

Use a balanced, healthy-eating approach	**Supported in part**	No studies compared diets where macronutrient proportions were specified to diets where the macronutrient proportions were not specified. Data showed that multicomponent interventions that involved diets with recommended macronutrient proportions were associated with greater weight loss than programmes that had no diet component. We did not find studies that tested interventions which recommended diets that were explicitly unhealthy or unbalanced, nor did we find studies that directly compared diets with recommended macronutrient proportions to diets without recommended macronutrient proportions.
Recommend regular physical activity (particularly activities that can be part of daily life, such as brisk walking and gardening) and offering practical, safe advice about being more active	**Supported in part**	Meta-analysis found that interventions incorporating physical activity led to more weight loss at 12 months than those that focussed on diet only. Meta-regression did not detect a significant association between weight loss at 12 months and whether or not the recommended physical activity was deemed easy to incorporate into daily life (defined as not requiring a specific setting or site to perform).
Include some behaviour change techniques, such as keeping a diary and advice on how to cope with 'lapses' and 'high-risk' situations	**Supported in part**	A univariate meta-regression found that the technique of modelling/demonstrating behaviour was associated with significantly greater weight loss at 12 months, but this was no longer significant in a model adjusting for set energy targets and involvement of a dietitian. A significant association was found between self-belief techniques and *increased* weight at 12 months, but this association was no longer significant when adjusting for 'comparison of behaviour' techniques. There was no significant association between weight loss and any other behavioural technique groupings, but the following groupings were not far from significance: goals and planning, shaping knowledge, antecedents, and feedback and monitoring. In a meta-regression controlling for 'comparison of behaviour' techniques, none of the techniques specified in the current principle (relapse prevention/coping planning and self-monitoring of behaviour/outcome) were significantly associated with weight loss at 12 months.
Recommend and/or provide ongoing support	**Supported**	Evidence from Review 1a demonstrated that programmes with ongoing support were more effective than one or two episodes of advice (control arms). Though a univariate model detected a significant association between programme length and weight loss, this association was no longer significant in a multivariate model. Meta-regression did not detect a significant effect of offering less frequent sessions after a more intensive period of intervention.

Evidence statements

Notes:

- The evidence statements below draw on both direct (within study comparisons) and indirect evidence (subgroup analyses and meta-regression). In indirect comparisons, factors other than the characteristic of question may be influencing the results. The data from indirect analyses are therefore effectively observational data and subject to confounding in the way that observational data are. Better data on the effectiveness of setting dietary goals versus not setting them, for example, would come from trials that directly randomised people to programmes that differed only in the setting of a dietary goal.
- Unless stated otherwise, mean differences and coefficients given are for weight loss at 12 to 18 months. All data are from randomised controlled trials. Quality scores for individual studies are represented as ++, +, or -.

Evidence statement 1.11 Weight loss in programmes involving diet and exercise versus diet-only or exercise-only programmes

Strong evidence from a meta-analysis indicates that BWMPs that involve both diet and exercise can lead to greater weight loss over a 12 to 18 month period than those that involve diet only or exercise only. Pooled results showed that mean weight loss at 12 to 18 months was significantly higher in programmes which involved diet and exercise than in those which involved diet alone (mean difference -1.79 kg, 95% CI -2.86 to -0.72, I^2 = 30%) or in those which involved exercise alone (mean difference -6.33 kg, 95% CI -7.30 to -5.37, I^2 = 9%). Data in the diet-only comparison comes from six randomised controlled trials involving 535 participants: four were conducted in the USA (two ++ [1], two +[2]), one was conducted in Sweden[3] (++), and one was conducted in Belgium[4] (+). Data in the exercise-only comparison comes from five randomised controlled trials involving 602 participants: four studies were conducted in the USA (two ++ [1], two +[5]) and one was conducted in Sweden (++).[3]

[1] Foster-Schubert 2012, Villareal 2011
[2] Skender 1996, Wadden 1988
[3] Bertz 2012
[4] Vissers 2010
[5] Rejeski 2011, Skender 1996

Evidence statement 1.12 Weight loss by in-person versus remote contact

There was weak evidence from direct comparisons to suggest that there is no difference in weight loss at 12 to 18 months between programmes delivered by in-person contact versus those delivered by remote contact only. Of three studies that provided direct comparisons on this variable, none detected a significant effect. Pooled results also did not detect a significant effect (mean difference -0.17 kg, 95% CI -1.23 to -0.89) but were highly heterogeneous (I^2 = 65%).The three RCTs represented 624 participants and all three were conducted in the USA (two ++[1], one +[2]).

[1] Appel 2011, Rock 2010
[2] Micco 2007

Evidence statement 1.13 Weight loss by professional background of therapist

There was moderate evidence to suggest that interventions that involved contact with a dietitian* were associated with greater weight loss than those which did not involve dietitian contact. This variable was not significant in a single variable meta-regression, but was significant when adjusted for presence or absence of a set energy prescription (coefficient -1.5 kg, 95% CI -2.9 to -0.1). Fifteen randomised controlled trials tested interventions which involved dietitian contact were included in this comparison: six were conducted in the USA (all ++)[1], two were conducted in Sweden (both ++)[2], two were conducted in the Netherlands (+)[3], and one each were conducted in Belgium (+)[4], Finland (++)[5], New Zealand (+)[6], Portugal (+)[7], and the UK (+)[8]. These were compared with 14 randomised controlled trials which involved interventions with no dietitian contact: eight were conducted in the USA (six ++[9], two +[10]), two were conducted in the UK (one +[11], one ++[12]), one was a multicentre study conducted in the UK, Germany and Australia (+)[13], and one each were conducted in Australia (++)[14], Canada (++)[15], and Switzerland (-)[16].

[1] Diabetes Prevention Programme 2006, Foster-Schubert 2012, Patrick 2011, Stevens 1993, Stevens 2001, Villareal 2011
[2] Bertz 2012, Eriksson 2009
[3] Mensink 2003, Vermunt 2011
[4] Vissers 2010
[5] Lindstrom 2003
[6] Dale 2008
[7] Silva 2010
[8] Penn 2009
[9] Appel 2011, Fitzgibbon 2010, Heshka 2006, Kuller 2012, Rock 2010, Wadden 2011
[10] Hersey 2012, Rejeski 2011
[11] Jolly 2011
[12] Nanchahal 2011
[13] Jebb 2011
[14] Morgan 2011
[15] Ross 2012
[16] Munsch 2003

*'Dietitian' is a protected term within the UK and US. The above statement refers to registered dietitians and, in the case of Lindstrom 2003, to the Finnish equivalent.

Evidence statement 1.14 Weight loss by supervised versus recommended exercise

There is inconsistent evidence as to whether programmes which involve supervised exercise lead to greater weight loss than those that recommend exercise only. Two randomised controlled trials provided direct comparisons between supervised and recommended exercise. One study, conducted in the USA (+)[1], found that at 18 months, participants in the group without supervised exercise lost significantly more weight than those in the group with supervised exercise (supervised versus recommended mean difference +2.90 kg, 95% CI +0.09 to +5.71). In contrast, in the second study, conducted in Brazil (++)[2], participants in the arm with supervised exercise lost more weight at 12 months, but the difference was not statistically significant (supervised versus recommended mean difference -0.90 kg, 95% CI -4.06 to +2.26). Subgroup analysis suggested that supervised exercise led

to greater weight loss, but results were highly heterogeneous. Meta-regression did not detect a significant association.

[1] Jeffrey 1998
[2] Seligman 2011

Evidence statement 1.15 Weight loss by energy intake prescription

There is strong evidence that programmes which specify a daily energy intake are associated with greater weight loss than those that do not prescribe an energy intake. Meta-regression detected a significant association of set energy prescriptions and greater weight loss at 12 to 18 months (coefficient -3.3 kg, 95% CI -4.7 to -1.9, $p < 0.001$). This association persisted and remained largely unchanged when adjusting for the involvement of a dietitian. These findings are consistent with a subgroup analysis on this variable. These analyses included 13 RCTs with no set daily energy intake in the following countries, three USA (two ++[1], one +[2]), three UK (one ++[3], two +[4]), two Netherlands (two +)[5], one Sweden (++)[6], one New Zealand (+)[7], one Finland (++)[8], one Switzerland (-)[9], one Canada (++)[10]; and 16 studies with set daily energy intake in the following countries, 10 USA studies (9 ++[11], one +[12]), one Sweden (++)[13], one multi-country (+)[14], one UK (+)[15], one Australia (++)[16], one Portugal (++)[17], and one Belgium (+)[18].

[1] Diabetes Prevention Programme 2006, Patrick 2011
[2] Hersey 2012
[3] Jolly 2011
[4] Nanchahal 2011, Penn 2009
[5] Mensink 2003, Vermunt 2011
[6] Eriksson 2009
[7] Dale 2008
[8] Lindstrom 2003
[9] Munsch 2003
[10] Ross 2012
[11] Appel 2011, Fitzgibbon 2010, Foster-Schubert 2012, Kuller 2012, Rock 2010, Stevens 1993, Stevens 2001, Villareal 2011, Wadden 2011
[12] Rejeski 2011
[13] Bertz 2012
[14] Jebb 2011
[15] Jolly 2011
[16] Morgan 2011
[17] Silva 2011
[18] Vissers 2010

Evidence statement 1.16 Weight loss by programme length

There is weak evidence from meta-regression that weight loss at 12 months is not associated with programme length. Univariate results suggested that each additional month of programme up to 12 months was associated with an addition 0.3 kg weight loss (95% CI -0.5 to -0.1, $p = 0.009$). This result was, however, no longer significant when adjusted for set energy prescriptions and dietitian involvement. Results are therefore inconsistent with a subgroup analysis that found greater weight

loss in programmes lasting longer than six months. The analyses of programme length included three RCTs with programmes lasting up to three months in the following countries, one Sweden (++)[1], one UK (+)[2], one Australia (++)[3]; two studies with programmes lasting four to six months in New Zealand (+)[4] and Switzerland (-)[5]; 24 studies with programmes lasting longer than 6 months in the following countries, 14 US studies (12 ++[6], two +[7]), two UK (one ++[8], one +[9]), two Netherlands (two +)[10], one Sweden (++)[11], one Canadian (++)[12], one Finland (++)[13], one Portugal (++)[14], one Belgium (+)[15] and one multi-country (UK, Germany, Australia) study (+)[16].

[1] Bertz 2012
[2] Jolly 2011
[3] Morgan 2011
[4] Dale 2008
[5] Munsch 2003
[6] Appel 2011, Diabetes Prevention Programme 2006, Fitzgibbon 2010, Foster-Schubert 2012, Heshka 2006, Kuller 2012, Rock 2010, Stevens 1992, Stevens 2001, Villareal 2011, Wadden 2011
[7] Hersey 2012, Rejeski 2011
[8] Nanchahal 2011
[9] Penn 2009
[10] Mensink 2003, Vermunt 2011
[11] Eriksson 2009
[12] Ross 2012
[13] Lindstrom 2003
[14] Silva 2011
[15] Vissers 2010
[16] Jebb 2011

Evidence statement 1.17 Weight loss by number of sessions

There moderate evidence that weight loss at 12 to 18 months is not associated with the number of intervention sessions offered (up to 12 months). Pooled results from direct comparisons where participants were randomised to more sessions or fewer sessions favoured the provision of more sessions but were not statistically significant (mean difference -0.23 kg, 95% CI -0.57 to +0.12, I^2 = 25%). In a meta-regression, a significant association was found between number of sessions and weight loss at 12 months, with each additional session associated with an addition 0.03 kg weight loss in a single variable model (95% CI -0.04 to -0.01, p = 0.004). The association remained significant when adjusting for presence of a set energy prescription, but was no longer significant when also adjusting for involvement of a dietitian. Direct comparisons come from six RCTs, five of which were conducted in the USA (four ++[1], one +[2]) and one of which was conducted in Japan (+)[3].

[1] Appel 2011, Kumanyika 2012, Logue 2005, Tate 2003
[2] Hersey 2012
[3] Saito 2011

Evidence statement 1.18 Association of behavioural change techniques with weight loss

There was strong evidence that the following behavioural change techniques are used in most BWMPs: goal setting and review of goals (behaviour and outcome); action planning; barrier

identification and/or problem solving; graded tasks; self-monitoring of behaviour; feedback on performance; instruction on how to perform behaviour; and planning social support and/or social change. There was no evidence that greater use of any particular groups of these techniques are associated with greater weight loss. Findings are from 29 RCTs.[1]

[1] Appel 2011, Bertz 2012, Dale 2008, Diabetes Prevention Programme 2006, Eriksson 2009, Fitzgibbon 2010, Foster-Schubert 2012, Hersey 2012, Heshka 2006, Jebb 2011, Jolly 2011, Kuller 2012, Lindstrom 2003, Mensink 2003, Morgan 2011, Munsch 2003, Nanchahal 2011, Penn 2009, Rejeski 2011, Rock 2010, Ross 2012, Silva 2011, Stevens 1992, Stevens 2001, Villareal 2011, Wadden 2011, Vermunt 2011, Vissers 2010

Discussion

Summary of findings

Evidence from direct comparisons shows that programmes that involve both diet and exercise lead to greater weight loss than those which involve only diet or only exercise. Indirect comparison shows that the only programme characteristics independently associated with greater effectiveness are setting energy prescriptions and involvement of a dietitian in programme delivery. Groups of behavioural techniques were not associated with improved effectiveness independently of these characteristics.

Interpretation of the data on programme delivery

There was strong evidence that incorporating physical activity and dietary interventions together was more effective than either alone. The trials were of high quality and there is good reason to think therefore that this is causal. The data on the association with dietitian delivery and energy prescriptions are harder to interpret. They come from cross-study comparisons and as such there are several competing explanations for the associations. It is possible that differences in the propensity of participants in one trial differed from those in another and that differences in the association could be due to this. Alternatively, these interventions differed in numerous other ways than simply the contrast we investigated in the meta-regression. These characteristics may have been associated with greater or lesser effectiveness. This means that the associations we found are subject to potential confounding. This could create spurious associations or mask true differences in effectiveness. Thus meta-regression results must be interpreted cautiously.

Interpretation of the data on behavioural techniques

This review is unique in its attempt to examine whether the content of the behavioural programme is associated with greater weight loss. We used the taxonomy of behavioural change techniques to code interventions and then grouped these. We aimed to assess whether greater use of a range of behavioural techniques within each group was associated with more effective programmes. However, the most striking result from this analysis was the homogeneity of techniques used across the interventions. Most interventions used the following techniques: goal setting and review of goals (behaviour and outcome); action planning; barrier identification and/or problem solving; graded tasks; self-monitoring of behaviour; feedback on performance; instruction on how to perform behaviour; and planning social support and/or social change. This may have limited our ability to assess the importance of some types of techniques: for example, only two of the 43 interventions included in the meta-regression involved three or fewer goal setting techniques. In our meta-regression, only one type of technique was associated with greater weight loss at 12 months: comparison of behaviour. Even then, the association was not independent of how the programme was delivered. There was another key factor limiting our ability to detect a difference in effectiveness between programmes with different behavioural techniques. We had to assume that the 'dose' of technique in each group was proportional to the number of techniques used. In truth,

techniques within a particular group may have been used rarely and simply counting the number reported by authors may not truly reflect the emphasis placed on particular techniques in the intervention.

Findings as they apply to NICE best practice principles

Some, but not all, existing NICE best practice principles are supported by findings from this review. This review did not find evidence to either support or refute current principles regarding target weights: all interventions which set long-term targets fell within the range currently specified by NICE, and the vast majority of interventions which set weekly targets also fell within the range specified by NICE. We are aware of one review of VLEDs (in which weekly weight loss targets are likely to be higher); findings from this external review did not suggest that weight regain was a particular problem when programmes advocated weekly weight loss targets above 1 kg, and the review did not find any studies where serious adverse events were considered attributable to study treatment (Mulholland 2012). The principle that BWMPs should include both diet and exercise was strongly supported by direct evidence. Meta-regression did not detect a significant association between weight loss at 12 months and whether or not the recommended physical activity was deemed easy to incorporate into daily life. Longer programmes and those that combined both diet and exercise were associated with greater weight loss; this can be interpreted as supporting the statement that BWMPs should 'focus on long-term lifestyle changes rather than a short-term, quick fix approach', but our ability to test this principle was limited by the wording of the principle itself. The principle that interventions 'use a balanced, healthy eating approach' was also difficult to test, as we did not find any studies that tested interventions which recommended diets that were explicitly unhealthy or unbalanced. The vast majority of interventions used dietary programmes in line with current UK healthy eating guidelines.

Conclusions

Behavioural weight loss programmes can be effective and vary greatly in their effectiveness. Programmes that incorporate both physical activity and dietary interventions are more effective than addressing only one of these alone. Interventions that set energy prescriptions and that are delivered by a team that includes a dietitian may be more effective. However, the key ingredients that differentiate more effective from less effective interventions remain largely unknown.

Appendices

Appendix 1. Review protocol: Managing overweight and obese adults: update review (covering Review 1a and Review 1b)[15]

NICE Reference	CPHE-URWMS-EV03-2012
Long title	The clinical effectiveness of long-term weight management schemes for adults: a systematic review
Project lead	Paul Aveyard (paul.aveyard@phc.ox.ac.uk)
Project manager	Jamie Hartmann-Boyce (Jamie.hartmann-boyce@phc.ox.ac.uk)
CPHE Technical Lead	Adrienne Cullum
CPHE Associate Director	Jane Huntley

Review team

This project will be conducted by a team of researchers from different institutions. The team members, and their roles on the review, will be:

Paul Aveyard, Professor of Behavioural Medicine, Department of Primary Care Health Sciences, University of Oxford	Lead systematic reviewer. Making key methodological choices within the systematic review. Chair meetings of the review team. Overall responsibility for delivery to NICE, ensuring report meets agreed protocol, discussing and agreeing with NICE any divergences from protocol. Writing and editing drafts and final report. Acting as third reviewer in cases of controversy.
Jamie Hartmann-Boyce, Research Associate, Department of Primary Care Health Sciences, University of Oxford	Systematic reviewer. Project managing the delivery of the various parts of the project. Working with NICE on search methods. Screening, appraisal and data extraction of included studies. Writing and editing drafts and final report.
David Johns, Investigator Scientist, MRC Human Nutrition Research	Systematic reviewer. Screening, appraisal and data extraction of included studies. Writing and editing

[15] The protocol is recorded here exactly as it was agreed with NICE. Since the protocol was signed off, NICE and the review team agreed to split Review 1 into two parts, as described in the introduction and methods section of this review.

	drafts and final report.
Rafael Perera, Director Statistics Group, Department of Primary Health Care Sciences, University of Oxford	Statistics advice.
Igho Onakpoya, Researcher in Pharmacovigilance, Department of Primary Health Care Sciences, University of Oxford	Systematic reviewer. Assisting with data extraction.

Note: The search will be run by Daniel Tuvey at NICE, with input from Jamie Hartmann-Boyce.

Advisory team

In addition to the core project team, we have a team of advisors who the core team will call upon the on matters relating directly to their areas of expertise, as identified below.

Carolyn Summerbell, Professor of Human Nutrition and Principal of John Snow College, Durham University	Advice on matters relating to systematic review methodology
Jane Ogden, Professor in Health Psychology, Department of Psychology, University of Surrey	Guidance on psychological theories and patients views and perceptions regarding weight loss programmes
Susan Jebb, Head of Department, Diet and Population Health, MRC Human Nutrition Research	Advice in relation to dietary prescriptions
Dawn Phillips, Public Health Portfolio Lead for Adult Obesity and Physical Activity, County Durham	Guidance on clinical aspects
Igho Onakpoya, Researcher in Pharmacovigilance, Department of Primary Care Health Sciences, University of Oxford	Advice on systematic review methodology

Key deliverables and dates

Deliverable	**Date**	**Comments back from NICE CPHE by:**
1st Draft review protocol	19 October 2012	26 October 2012
Revised review protocol	30 October 2012	2 November 2012
Signing-off of review protocol	7 November 2012	
Signing-off of search strategy	5 November 2012	
Interim progress meeting/ teleconference (1) –	21 November	

Interim progress meeting/ teleconference (2) –	19 December 2012	
Draft report submitted to NICE	18 January 2013	25 January 2013
Amended report submitted to NICE	11 February 2013	
Slides for PDG meeting submitted to NICE	19 February 2013	
Review presented to PDG	26 February 2013	
Final review submitted	13 March 2013	

Context

This Review Protocol is for Review 1, with the first draft submitted by the agreed delivery date of 18 January 2013, and the final review to be submitted by 13 March 2013. A separate but related evidence review (Review 2) is covered in a separate protocol. As this is an update of an existing review (Loveman et al 2011[16]), the scope is unlikely to change beyond what is agreed here.

Purpose of this document

This document describes the aims, scope and intended methods of the update review which will be produced to support the development of NICE Public Health Guidance on lifestyle weight management programmes for overweight and obese adults.

Unless otherwise stated in this Review Protocol, this review, and its report will be conducted according to the rigorous methods described in the Cochrane Handbook, the York Centre for Reviews and Dissemination Handbook, and the 2nd Edition of the *Methods for the development of NICE public health guidance* (2009). As this is an update review it will follow as closely as possible the scope and format of the original review (Loveman 2011) to enable direct comparison between the two, and the use of the two reviews in conjunction with one another. Where there is a discrepancy between Loveman's reporting methods and those suggested by the above listed handbooks, CPHE will be consulted.

Clarification of scope

This review aims to inform readers about the relative importance of the components included in multi-component lifestyle interventions for the treatment of obesity. This review will therefore cover only those interventions that include both a diet and exercise component, and will exclude referral to individual clinicians, management of associated conditions, surgery, and pharmacological treatments. The review will be restricted to interventions that are judged to be feasible for implementation in the UK.

For the remainder of the document, multi-component lifestyle weight management programs (LWMPs) will be defined as those which focus on reducing energy intake, increasing physical activity and changing behaviour. These may include weight management programmes, courses or clubs:

- specifically designed for adults who are obese or overweight
- that accept adults through self-referral or referral from a health practitioner

[16] Loveman E, Frampton GK, Shepher J, Picot J, Cooper K, Bryant J, et al. The clinical effectiveness and cost-effectiveness of long-term weight management schemes for adults: a systematic review. *Health Technology Assessment* 2011;15(2).

- provided by the public, private or voluntary sector
- based in the community, workplaces, primary care or online.

Review questions

The primary question in this review is similar to that of Loveman 2011, though this update will not focus on cost-effectiveness. The primary question is therefore:

- How effective and cost-effective are multi-component lifestyle weight management programmes for adults?

We will also attempt to answer secondary questions relating to these programmes. Should data be available, we will attempt to answer:

- How does effectiveness vary for different population groups (for example, men, black and minority ethnic or low-income groups)?
- How does effectiveness and cost effectiveness vary based on the components of the individual programmes (including behavioural or psychological components)?
- Are there any adverse or unintended effects associated with the use of LWMPs?

Factors which influence the effectiveness, implementation or sustainability of initiatives may be either positive ('facilitators') or negative ('barriers'), and will also be explored when assessing the included studies. However, detailed questions about key components of LWMPs, their implementation, user experience, and facilitators and barriers (overall and for specific population groups) will be addressed separately in review 2. Review 1 will focus only on the effectiveness of the LWMPs.

Outcomes

We will extract and report data on the following outcomes:

- Quantitative changes in anthropometric measures – weight, BMI, waist circumference, etc
- Intermediate measures of diet and physical activity
- Process measures such as participant satisfaction with weight management services, adherence to the intervention and attendance at sessions
- Economic outcomes (narrative only)
- Adverse effects

Inclusion criteria

For the clinical effectiveness review, we propose to follow similar criteria for including and excluding studies as used in the Loveman 2011 report, with two key changes: we will not include LWMPs that involve medications for obesity of any type, unless their use is not part of the LWMP and is comparable in both intervention and control groups; and we will include studies with 12 month follow-up or longer (Loveman required a minimum of 18 months follow-up, we will examine those studies excluded from Loveman on the basis of too short a follow-up period.. The revised inclusion criteria are listed below.

Population

- Adults (≥ 18 years) classified as overweight or obese, i.e. people with a BMI of ≥ 25 kg/m2 and ≥ 30 kg/m2, respectively.
- Studies in children, pregnant women, and people with eating disorders were not included, nor were studies specifically in people with a pre-existing medical condition such as diabetes, heart failure, uncontrolled hypertension or angina.

Intervention

- Structured, sustained multi-component weight management programmes (i.e. the intervention had to be a combination of diet and physical activity with a behaviour change strategy to influence lifestyle).
- Components of the programme had to be clearly specified (i.e. details provided of the diet, behavioural definition, and exercise components; see below).
- Programmes that included a long-term follow-up of more than 12 months.
- The programme was delivered by the health sector, in the community or commercially.
- Multi-component programmes that involved the use of any surgery or medication, over-the-counter or otherwise, are excluded.
- Interventions incorporating other lifestyle changes such as efforts at smoking cessation or reduction of alcohol intake were not included.

Comparators

- Normal practice (as defined by the study).
- Single-component weight management strategies.
- Other structured multi-component weight management programmes.

Outcomes

- Studies were required to include a measure of weight loss.

Types of studies

- RCTs only.
- Studies published as abstracts or conference presentations were only included if sufficient details were presented to allow an appraisal of the methodology and the assessment of results to be undertaken.
- Case series, case studies, cohort studies, narrative reviews, feasibility studies, editorials and opinions were not included.
- Systematic reviews were used as a source of references.

Location

- Undertaken in any setting (i.e. community, commercial, primary care, online).
- Studies conducted in OECD countries will be considered for inclusion.[17] In the instance that a study has been conducted in an OECD country but the reviewers and advisory panel judge that

[17] The original scope specified studies in the UK only. The extension to OECD countries has been agreed with NICE with the understanding that the completion of the review by stated dates is the key priority, and that the revised scope can be limited to UK only countries if the schedule so requires.

the intervention would not be feasible for implementation in the UK, the reviewers will consult with CPHE regarding its inclusion.

- Studies conducted in non OECD countries will be excluded.

Cost effectiveness

As per Loveman 2011, references identified by the search strategy for the systematic review of cost-effectiveness will be considered for inclusion only if:

- They report both health service costs and effectiveness of multicomponent adult weight management programmes

OR

- Present a systematic review of such evaluations

Unlike Loveman, initially, only UK cost effectiveness studies will be included in the search, but if this results in too few studies being included, we will consult NICE to agree on a wider search being undertaken (likely all English language OECD countries).

Specification of components of intervention

Loveman et al required that, in order for a study to be included, at least two items under each of the below components (diet, exercise, and behaviour modification) had to be specified.

Diet

- type of diet
- calories
- proportion of diet (e.g. proportion of diet made up of fats, protein, carbohydrate)
- monitoring

Exercise

- mode
- type
- frequency/length sessions
- delivered by
- level of supervision
- monitoring

Behaviour modification

- mode
- type
- content
- frequency/length sessions
- delivered by.

Where studies are multicomponent but the study report does not meet the above criteria, we will follow the below approach:

- If the study identifies that the intervention is a defined weight loss programme (commercial or otherwise), we will search online for details of the weight loss programme and use these to classify the study components. Where insufficient details are available online, we will contact the programme directly, specifying that a response will be needed by 10 December 2012.

- If the study is not of an identifiable and defined weight loss programme, we will email study authors with a template email asking them to provide any details they have on the above elements, specifying that a response will be needed by 10 December 2012.
- Where authors do not respond by the deadline specified, provide insufficient information, or where we cannot find a current e-mail address, the study will be excluded, with the reason for exclusion clearly identified (for example, "unclear detail on physical activity component").

Search methods

This is an update of an existing review and as such the existing search strategy as published in Loveman 2011 will be used. The literature search will be run by NICE with input from one reviewer (Jamie Hartmann-Boyce). Searches will be fully documented and references will be stored in a Reference Manager database.

The detailed search strategy will be agreed separately between reviewers and the CPHE's information specialist (see schedule). Any adaptations to the Loveman 2011 strategy will be confirmed with NICE and are likely to be related to increasing the specificity of the search, given the time constraints involved.

Study selection at search stage

- Studies indexed since date of last Loveman search (December 2009)
- Studies conducted in OECD countries.

In addition to running the updated searches specified above, we are aware that Loveman has excluded some diabetes prevention studies which meet the above inclusion criteria (ie lifestyle interventions for overweight and obese adults, pre-existing clinical condition not a prerequisite for study enrollment). After discussion with NICE, we have agreed to include these studies. These have not been explicitly excluded from Loveman so there is no means of gathering a quick list of these studies. Instead, to ensure we have not missed major trials in this area published prior to the period of our updated search, we will use published reviews of diabetes prevention trials to identify relevant studies.

Study selection process

Assessment for inclusion will be undertaken initially at title and/or abstract level (to identify potential papers/reports for inclusion) by a single reviewer (and a sample checked by a second reviewer), and then by examination of full papers. A third reviewer will be used to help adjudicate inclusion decisions in cases of disagreement. Where the research methods used or type of initiative evaluated are not clear from the abstract, assessment will be based upon a reading of the full paper.

Quality assessment and data extraction

For the review of clinical effectiveness, we will critically appraise the literature for inclusion using a checklist based on the York CRD approach and as described in the CPHE manual.[18] However, we will modify this slightly for behavioural intervention trials and will not evaluate included studies on the basis of blinding. We will present the appraisal in tables and summarise the findings in text as described in the CPHE manual.

Data extraction will be conducted using a pre-specified data extraction form, which will be piloted by two reviewers before its use. Data extraction and quality assessment will be done independently by

two reviewers, who will then compare data extraction forms. Any discrepancies will be resolved by discussion or, where needed, by referral to a third reviewer.

If deemed to be helpful for the write-up, we will reference data extracted as part of the Loveman 2011 review, but in narrative elements of the write-up we will use the data extracted by the Loveman et al rather than re-extracting these data ourselves (full, completed data extraction forms are published in the appendices of Loveman). If we conduct meta-analyses or meta-regression (see next section), we will re-extract key outcomes from the included studies in Loveman to ensure we are using the same approach to data across all studies included in the analysis.

For the review of cost-effectiveness, we will critically appraise the literature using Lovemans' *Critical appraisal checklist of economic evaluation* (table 23, page 53). Elements of this table refer to applicability to the UK; if as discussed above we do not include cost-effectiveness literature from outside the UK, we will remove these items from the checklist. All other items will remain the same.

Data synthesis and presentation, including evidence statements

We will synthesise the data in narrative form, as Loveman et al did. However, we will consider whether meta-analysis and meta-regression could be undertaken and use the baseline observation carried forward approach with standard errors calculated as described recently.[18] This is likely to be an exploratory technique rather than a definitive guide to a single underlying effect size, and such analyses will only be conducted if appropriate data is available and if time allows.

If data and time allow, we will run a meta-regression on variables of LWMPs. Meta-regression will allow us to explore whether outcomes are associated with the various characteristics of the interventions and this will prove especially useful when it comes to giving guidance on Review 2 questions. Regardless of whether a meta-regression is performed, we will categorise studies based on the following elements (taken from Jolly et al[19]):

- Professional background of therapies
- Training of therapist
- Assessment of therapist's competence
- Fidelity checking of intervention
- Group or individual
- Duration of sessions, frequency, programme length and setting
- Content of sessions
- Weight loss goal
- Relative emphasis on diet and exercise
- Intervention theoretical background
- Predominant behavioural change techniques used

[18] Kaiser KA, Affuso O, Beasley TM, Allison DB. Getting carried away: a note showing baseline observation carried forward (BOCF) results can be calculated from published complete-cases results. Int J Obes 2012; 36(6):886-889.

[19] Jolly K, Lewis A, Beach J, Denley J, Adab P, Deeks JJ et al. Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: Lighten Up randomised controlled trial. BMJ 2011; 343.

Behavioural change techniques will be assessed through the use of a pre-defined taxonomy, included as an element of the data extraction process. Each study will be assessed against a checklist of the taxonomy, with a dichotomous yes/no option for the reviewer to indicate if the intervention included that behavioural element. The description will be obtained through the study report, and hence it should be noted that the application of the taxonomy will be limited by the depth of description provided in the report. We will use the 40-item refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours (the CALORE taxonomy) as defined by Michie et al.[20]

Where possible, we will draw weight curves for each study, mapping weight change during intervention and weight change after intervention end and seek to summarise these as appropriate.

We will group studies by the nature of the comparison, including the nature of the control group. We will note whether the control group received an active treatment that might be expected to lower weight gain or not and try to account for this in the analysis. We will also describe the nature of the intervention e.g. the energy prescription/deficit given, the intensity of the physical activity prescription, the length of the programme, and any ongoing support offered. If possible, we will calculate the energy expenditure prescription in METs so that it will be possible to compare energy restriction with increased energy burning.

Data synthesis and presentation, including evidence statements, will be conducted according to the procedures outlined in the 2nd Edition of *Methods for development of NICE public health guidance 2009* where appropriate.

Key choices in how to synthesise the included evidence, or in how to develop evidence statements for this review, will be discussed with the relevant analysts at CPHE.

[20] Susan Michie, Stefanie Ashford, Falko F. Sniehotta, Stephan U. Dombrowski, Alex Bishop & David P. French (2011): A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALO-RE taxonomy,
Psychology & Health, 26:11, 1479-1498

Appendix 2. Protocol for Review 1.5: managing overweight and obese adults, evidence review

NICE Reference	CPHE-URWMS-EV03-2012
Long title	The clinical effectiveness of long-term weight management schemes for adults: a systematic review
Project lead	Paul Aveyard (paul.aveyard@phc.ox.ac.uk)
Project manager	Jamie Hartmann-Boyce (Jamie.hartmann-boyce@phc.ox.ac.uk)
CPHE Technical Lead	Adrienne Cullum
CPHE Associate Director	Jane Huntley

Review team

This project will be conducted by a team of researchers from two different institutions. The team members, and their roles on the review, will be:

Paul Aveyard, Professor of Behavioural Medicine, Department of Primary Care Health Sciences, University of Oxford	Lead systematic reviewer. Making key methodological choices within the systematic review. Chair meetings of the review team. Overall responsibility for delivery to NICE, ensuring report meets agreed protocol, discussing and agreeing with NICE any divergences from protocol. Writing and editing drafts and final report. Acting as third reviewer in cases of controversy.
Jamie Hartmann-Boyce, Research Associate, Department of Primary Care Health Sciences, University of Oxford	Systematic reviewer. Project managing the delivery of the various parts of the project. Working with NICE on search methods. Screening, appraisal and data extraction of included studies. Writing and editing drafts and final report.
David Johns, Investigator Scientist, MRC Human Nutrition Research	Systematic reviewer. Screening, appraisal and data extraction of included studies. Writing and editing drafts and final report.
Rafael Perera, Director Statistics Group, Department of Primary Health Care Sciences, University of Oxford	Statistics advice.

Advisory team

In addition to the core project team, we have a team of advisors who the core team will call upon for matters relating directly to their areas of expertise, as identified below.

Carolyn Summerbell, Professor of Human Nutrition and Principal of John Snow College, Durham University	Advice on matters relating to systematic review methodology
Jane Ogden, Professor in Health Psychology, Department of Psychology, University of Surrey	Guidance on psychological theories and patients views and perceptions regarding weight loss programmes
Susan Jebb, Head of Diet and Population Health, MRC Human Nutrition Research	Advice in relation to dietary prescriptions and weight management
Dawn Phillips, Public Health Portfolio Lead for Adult Obesity and Physical Activity, County Durham	Guidance on clinical aspects
Amanda Lewis, NIHR SPCR Research Fellow, Department of Primary Care Health Sciences, University of Oxford	Guidance on research into weight management in primary care
Igho Onakpoya, Researcher in Pharmacovigilance, Department of Primary Care Health Sciences, University of Oxford	Systematic reviewer. Data extraction of included studies.

Key deliverables and dates

Deliverable	Date	Comments back from NICE CPHE by:
1st Draft review protocol	15/2/13	
Revised review protocol	25/2/13	25/2/13
Signing-off of review protocol	27/2/13	
Signing-off of search strategy	n/a	
Interim progress teleconference–	6th March 20th March 4th April	
Draft report submitted to NICE ("drip feeding approach" as per Review 1a)	7 March 2013 – 21 March	14 March (on components submitted 7 March)
Amended report submitted to NICE	28 March	
Slides for PDG meeting submitted to NICE	11 April	
Review presented to PDG	16 April	
Final review submitted	30 April	

Context

This Review Protocol is for Review 1b. Review 1a, which will be presented in final form on 11.2.13 in response to fulfilment of the tender for the Update Review, commissioned by NICE. There were substantial overlaps between the two reviews. In agreement with NICE, we agreed to defer some analyses for a separate review, this is Review 1b, which also incorporates some questions from the Evidence Review tender.

Purpose of this document

This document describes the aims, scope and methods of Review 1b, which will be produced to support the development of NICE Public Health Guidance on lifestyle weight management programmes for overweight and obese adults.

Unless otherwise stated in this Review Protocol, this review, and its report will be conducted according to the rigorous methods described in the Cochrane Handbook, the York Centre for Reviews and Dissemination Handbook, and the 2nd Edition of the *Methods for the development of NICE public health guidance* (2009).

Clarification of scope

The aim of this review is to examine

1. How components of behavioural weight loss programmes affect the outcome. (This is question 2 of the Evidence Review tender)
2. What happens to the difference in weight between people treated on a behavioural weight loss programme and a control group in the longer term (once the intervention has ended)? How quickly does weight increase after the end of the programme and do the characteristics of the programme affect the rate of increase in weight? (These questions are not specified in the tender but the review team think that they are important and useful).

3. What interventions can maintain weight loss after the end of a behavioural weight loss programme? (This is question 4 of the Evidence Review tender).
4. Is there evidence to support the best practice principles that NICE proposed in its 2006 guidance? (This is question 1 of the Evidence Review).

How components of behavioural weight loss programmes affect the outcome

This is phrased in the tender as "What are the most effective and cost effective behavioural or psychological components of a lifestyle weight management programme for adults – and who might best deliver them?"

The data to answer this question will come from Review 1a and a review of a further group of trials that were uncovered during the search for studies for Review 1a. The trials in Review 1a were defined as behavioural weight loss programmes that incorporated dietary and physical activity interventions versus a control group. The control interventions were rarely no intervention at all, but we included the following as unlikely to be providing much active treatment

1. No intervention at all or leaflet/s only[21]
2. Discussion/advice/counselling in one-off session +/-leaflet
3. Seeing someone more than once for discussion of something other than weight loss.
4. Seeing someone more than once for weight management, person untrained +/- leaflets

A fifth group of studies includes those that have a behavioural weight management programme that incorporates only physical activity or diet but not both, and a sixth group of studies includes behavioural programmes with both diet and physical activity components. In this review, we will appraise such papers as were found and catalogued in Review 1a and incorporate those arms of trials excluded from Review 1a that have interventions of this type.

In Review 1a we reviewed the effectiveness of 44 different interventions and we split the interventions versus control comparisons using subgroup analyses. We considered the following questions:

13. Whether the programme is delivered in groups or individually
14. The length of the programme
15. Whether the aim was weight loss or diabetes prevention
16. Whether the programme was delivered remotely, for example by Internet, or face-to-face
17. Supervised versus recommended exercise programme
18. Energy prescription target or no target
19. Frequency of contact with participants

[21] Note that leaflets included static websites, i.e. information and advice only, not interactive weight loss programmes, which come under 5 or 6).

In addition, in Review 1b, we will consider an eighth question

20. Are the behavioural change techniques used associated with improved effectiveness

The one element that requires explanation in this list is the behavioural change techniques. These are elements of the behavioural programme that can be used to encourage behaviour change. At the simplest, this can include advice giving. The taxonomy has been developed to allow researchers to describe behavioural counselling in standardised ways that allow comparison across studies.(Abraham & Michie 2008;Michie et al. 2011)

As described in Review 1a, we extracted data on the behaviour change techniques (BCTs) used to try to motivate and support individuals to change their behaviour. We said "Behavioural change techniques will be assessed through the use of a pre-defined taxonomy, included as an element of the data extraction process. Each study will be assessed against a checklist of the taxonomy, with a yes/unclear/no option for the reviewer to indicate if the intervention included that behavioural element. The description will be obtained through the study report, and hence it should be noted that the application of the taxonomy will be limited by the depth of description provided in the report. We will use the 40-item refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours (the CALORE taxonomy) as defined by Michie et al.[22]" Items were coded as U where the technique was not explicitly stated but reviewers agreed it was implied. Michie and colleagues have grouped these 40 BCTs together using a grouping system (Table 1), which is essential for meaningful meta-analysis or meta-regression. We will give each BCT within each category a score: 0 if it is not used, 0.5 if the description was unclear, and 1 if the technique is clearly used. We will total these within categories as a measure of the emphasis of a particular intervention on BCTs of that type. One item on the CALORE taxonomy (27 – use of follow-up prompts) was not assigned to a BCT category and will be assessed independently.

[22] Susan Michie, Stefanie Ashford, Falko F. Sniehotta, Stephan U. Dombrowski, Alex Bishop & David P. French (2011): A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALO-RE taxonomy,
Psychology & Health, 26:11, 1479-1498

Table 1 BCTs from the CALORE taxonomy grouped as proposed by Michie and colleagues

Technique group	Taxonomy item
Goals and planning	05- Goal setting (behaviour) 06- Goal setting (outcome) 07- Action planning 08- Barrier identification/problem solving 10- Prompt review of behavioural goals 11- Prompt review of outcome goals 20- Provide information on where and when to perform the behaviour 25- Agree behavioural contract 35- Relapse prevention/coping planning
Reward and threat	12- Prompt rewards contingent on effort or progress towards behaviour 13- Provide rewards contingent on successful behaviour 14- Shaping 32- Fear arousal 40- Stimulate anticipation of future rewards
Regulation	36- Stress management/emotional control training 38- Time management
Antecedents	24- Environmental restructuring
Identity	30- Prompt identification as role model/position advocate
Self-belief	18- Prompting focus on past success 33- Prompt self talk
Covert learning	34- Prompt use of imagery
Feedback and monitoring	16- Prompt self-monitoring of behaviour 17- Prompt self-monitoring of behavioural outcome 19- Provide feedback on performance
Social support	29- Plan social support/social change 37- Motivational interviewing 39- General communication skills training
Shaping knowledge	21- Provide instruction on how to perform the behaviour
Natural consequences	01- Provide information on consequences of behaviour in general 02- Provide information on consequences of behaviour to the individual 31- Prompt anticipated regret
Comparison of behaviour	03- Provide information about others' approval 04- Provide normative information about others' behaviour 22- Model/Demonstrate the behaviour 28- Facilitate social comparison
Associations	23- Teach to use prompts/cues
Repetition and substitution	09- Set graded tasks 15- Prompting generalisation of a target behaviour 26- Prompt practice

Whereas in Review 1a we used subgroup analysis to investigate differences in effectiveness, in Review 1b we will use meta-regression. Meta-regression is more powerful because it affords us the ability to examine the effects of interventions characterised in one way while accounting for other differences between programmes. However, with 40 intervention-control comparisons, it is possible to include a maximum of four predictors to avoid over-fitting the model. Therefore there is limited scope to address all differences between

programmes. Where data exist, we will use within trial data to examine some of these questions and use the totality of evidence to draw conclusions.

What happens to the difference in weight between people treated on a behavioural weight loss programme and a control group in the longer term?

This questions relates to the maintenance of weight loss achieved by behavioural weight loss programmes. The review team will report data from Review 1a that includes:

- A trajectory of weight change for all studies.
- A meta-regression to examine whether the weight trajectory after programme end depends upon the characteristics discussed above ('How components of behavioural weight loss programmes affect the outcome'). For this analysis, we will ignore the initial weight loss and will look at how weight changes that occur after the end of the programme vary among the programme types.
- A meta-analysis where possible of within study data of trials that randomised participants to longer or shorter behavioural weight loss programmes
- A meta-regression of between study data of trials that compared behavioural weight loss programmes to control and where the length of the programme varied between studies

What interventions can maintain weight loss after the end of a behavioural weight loss programme?

To answer this question we will conduct a review of reviews with the below inclusion criteria.

Inclusion criteria

Population

- Adults (≥ 18 years) initially classified as overweight or obese prior to starting a weight loss programme, i.e. people with a BMI of ≥ 25 kg/m2 and ≥ 30 kg/m2, respectively. Enrolment in a weight loss maintenance intervention implies that people who have lost weight are enrolled. We propose no restrictions on how much weight loss has been achieved prior to enrolment in a weight loss maintenance trial.
- Reviews of trials in children, pregnant women, and people with eating disorders will not be included, nor studies specifically in people with a pre-existing medical condition such as diabetes, heart failure, uncontrolled hypertension or angina.

Intervention

Any intervention aimed at maintenance of weight loss that is not pharmacotherapy or surgery

Control

Usual care or other control condition

Types of studies

A weight loss maintenance study enrols participants who have already lost weight by means other than surgery.

Reviews of randomised controlled trials, whether systematic or unsystematic, will be included. We will not include reviews of observational studies that compare the characteristics of weight loss maintainers to those who regain weight.

Location

- Undertaken in any setting
- Studies in any country will be included, though we anticipate that reviews are likely to include overwhelmingly studies conducted in OECD countries.

Search methods

The aim is to be systematic but not comprehensive and thus the searches will concentrate on specificity over sensitivity. We have already established that there are no specific MeSH terms for weight loss maintenance. Therefore our search strategy for Review 1a, which included systematic reviews, will have located such reviews. We will therefore rerun our searches for Review 1a but remove the date restriction. We will use text word searches for relevant terms, such as 'maintenance' and 'review', to find reviews of weight loss maintenance in the thousands of papers retrieved during the search for Review 1a. In addition, we will include other reviews on the topic that are referenced in the reviews that we find as a result of this search.

Study selection process

Assessment for inclusion will be undertaken initially at title and/or abstract level (to identify potential reviews for inclusion) by a single reviewer and then by examination of full papers. A second reviewer will be used to help adjudicate inclusion decisions. Where the abstract is unclear, assessment will be based upon a reading of the full paper.

Quality assessment

One reviewer will appraise reviews using the methods for appraisal of reviews described in CPHE manual. We will produce a table relating to each review and assess its quality.

Data synthesis and presentation, including evidence statements

We will extract data on the strength of evidence for particular interventions in each review and also the applicability of the evidence to the target population. We will synthesise this narratively across reviews to examine a range of interventions that affect weight loss maintenance. It is important to note that this review will exclude behavioural weight loss programmes unless such programmes have enrolled participants who have already lost weight. Randomised trials of longer versus shorter weight loss programmes are included in Review 1a.

Is there evidence to support the best practice principles that NICE proposed in its 2006 guidance?

The current best practice principles are taken from existing NICE guidance on obesity, CG43:

The best practice principles identified in NICE guidance on management of obesity are:

Primary care organisations and local authorities should recommend to patients, or consider endorsing, self-help, commercial and community weight management programmes only if they follow best practice [4] by:

- helping people assess their weight and decide on a realistic healthy target weight (people should usually aim to lose 5–10% of their original weight)
- aiming for a maximum weekly weight loss of 0.5–1 kg
- focusing on long-term lifestyle changes rather than a short-term, quick-fix approach
- being multicomponent, addressing both diet and activity, and offering a variety of approaches
- using a balanced, healthy-eating approach
- recommending regular physical activity (particularly activities that can be part of daily life, such as brisk walking and gardening) and offering practical, safe advice about being more active
- including some behaviour change techniques, such as keeping a diary and advice on how to cope with 'lapses' and 'high-risk' situations
- recommending and/or providing ongoing support.

The data to address the question of whether these principles are evidence based will be derived from the data in Review 1a, for which there is a detailed protocol. If there are no data available in the review that are relevant, we will perform a bespoke search and, depending on the data available, may also refer to other published guidelines.

Principles: helping people assess their weight and decide on a realistic healthy target weight (people should usually aim to lose 5–10% of their original weight) and aiming for a maximum weekly weight loss of 0.5–1 kg/week

For each study in Review 1a we extract whether or not a target was set and what that target was. We will use meta-regression to examine whether studies that set targets and the weight loss target is associated with greater weight loss. However, there are several caveats. First, the nature of behavioural weight loss programmes under study is that they tend not to have very extreme goals so that there may be little variation between studies. Second, there are many dimensions on which programmes might vary and it is impossible statistically to control for all such variations and many variations will not be recorded.

The main programmes that do aim for rapid weight loss are very low calorie diets (VLCDs). However, the effectiveness of setting high weight loss goals in VLCD programmes is confounded with providing meals, which is a universal feature of VLCDs. Meal replacement was a feature of only a few of the included studies in Review 1a, so assessing the effectiveness of extreme weight loss goals net of the effect of meal replacement is challenging as there are too few behavioural weight management interventions that aimed for moderate weight loss and yet which provided meals, in the way that VLCD programmes do.

We found two programmes that incorporated VLCDs in Review 1a. These were Wadden (1988), which includes very few participants, and Weinstock (1998), which also includes few participants and has no usable outcome data presented in the paper. However, for work outside the NICE review, we have systematically searched for reviews of VLCDs, which yielded a recent systematic review (Mulholland 2012). We will examine the reviews to assess whether there is evidence that the rapid weight loss typically induced by VLCDs results in weight regain. This will be a narrative synthesis .

Principle: focusing on long-term lifestyle changes rather than a short-term, quick-fix approach

We will use data from Review 1a, considering those studies that compare lifestyle weight management programmes with a diet only comparator that lasts for less than 6 months. A 6 month cut off was chosen because subgroup analysis from Review 1a suggested that studies less than 6 months were not as effective as those last 6+ months.

Principle: being multicomponent, addressing both diet and activity, and offering a variety of approaches

Review 1a examines the effectiveness of multicomponent lifestyle programmes compared with no intervention. As outlined above, in Review 1b, we will examine trials of the effectiveness of diet and physical activity interventions compared with diet only and physical activity only weight loss programmes. Meta-analysis will be used to compare programmes that include both physical activity and dietary behaviour change to programmes that include only one of those elements.

Principle: using a balanced, healthy-eating approach

We will use data from Review 1a, looking specifically at studies which compare BWMPs with comparator arms where no dietary advice has been given.

Principle: recommending regular physical activity (particularly activities that can be part of daily life, such as brisk walking and gardening) and offering practical, safe advice about being more active

In Review 1b we will characterise interventions by the type of physical activity that they promote. We will classify the activities in the programme as easy to incorporate or specific exercise activities and use meta-regression to examine whether there is evidence that programmes that include this kind of activity are more effective than programmes that include other forms of activity.

Principle: including some behaviour change techniques, such as keeping a diary and advice on how to cope with 'lapses' and 'high-risk' situations

By definition, all multicomponent behavioural weight management programmes include behavioural change techniques. The key question is which techniques are associated with greater effectiveness. We are investigating these as described above.

Principle: recommending and/or providing ongoing support.

The contrast with offering ongoing support is to offer one-off advice on how to lose weight. In Review 1a we investigated whether programmes in which participants were randomised to advice, usually a single session of advice by an untrained advisor, or to a programme of ongoing support. There was convincing evidence that programmes with ongoing support were more effective than one or two episodes of advice.

In addition, the trials in Review 1a randomised participants to BWMP or control, but the BWMPs varied in length trials of programmes compared long programmes to control, while others compared short programmes to control. We will use meta-regression on the studies in Review 1b to examine whether there is data that support the notion that longer support is more effective than shorter support. We will also use meta-analysis and meta-regression to compare the effectiveness of programmes in which contact frequency or intensity declined over time (for example, initially in person sessions but then phone sessions, or initially weekly declining to monthly to trials where the

intervention was of consistent intensity and ended abruptly. These data will be derived from taxonomy item 27 – use of follow-up prompts).

References

Abraham, C. & Michie, S. 2008, "A Taxonomy of Behavior Change Techniques Used in Interventions", *Health Psychology*, vol. 27, no. 3, pp. 379-387.

Michie, S., Ashford, S., Sniehotta, F. F., Dombrowski, S. U., Bishop, A., & French, D. P. 2011, "A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALO-RE taxonomy", *Psychology & Health*, vol. 26, no. 11, pp. 1479-1498.

Appendix 3. Evidence tables

Unless otherwise specified, all values given are as mean (SD). Weight and weight change values are given in kg, all BMIs are kg/m^2, and all waist circumference measurements are cm.

Control group coding based on following scale (also reported in methods):

1. No intervention at all or leaflet/s only[23]
2. Discussion/advice/counselling in one-off session +/-leaflet
3. Seeing someone more than once for discussion of something other than weight loss.
4. Seeing someone more than once for weight management, person untrained +/- leaflets
5. Behavioural weight loss programme comprising one of either diet or physical activity plus behavioural programme. 5 also includes seeing a health professional with special training on more than one occasion, such as a dietitian, who, because of their training will naturally create a weight loss programme with (in this case) dietary and behavioural elements (unless explicitly stated that they did not create a weight loss programme, in which case coded as 4). 5 also included seeing a professional with no basic training in weight loss management but who has received bespoke training to run a behavioural weight loss programme which involves at least two consultations.
6. Behavioural weight loss programme comprising diet and physical activity plus behavioural programme. 6 also includes seeing a professional has no basic training in weight loss management but has received bespoke training to run a behavioural weight loss programme which involves at least two consultations.

Internal validity (study quality) scores

Studies were rated ++ if all or most of checklist criteria were fulfilled and conclusions were judged very unlikely to alter; + if some criteria were fulfilled and conclusions were unlikely to alter; and - if few or no criteria were fulfilled and conclusions were likely or very likely to alter.

External validity

As for internal validity, studies were rated ++, + or –. This was based on:

- If the participants were representative of the general population of people who are overweight (in part through assessing the number of those screened who were enrolled, where this information was provided)
- If the intervention required no extraordinary efforts to implement broadly in the UK

[23] Note that leaflets included static websites, i.e. information and advice only, not interactive weight loss programmes, which come under 5 or 6).

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Appel et al **Year:** 2011 **Citation:** Appel, L.J., Clark, J.M., Yeh, H.C., Wang, N.Y., Coughlin, J.W., Daumit, G., et al. 2011. Comparative effectiveness of weight-loss interventions in clinical practice. *New England Journal of Medicine*, 365, (21) 1959-1968. **Aim of study:** Weight loss **Study design:** RCT **Quality score:** ++ **External validity score:** + (requirement of computer literacy and regular access to computer)	**Source population/s:** USA; *Across whole study:* 64% F, mean age 54 years, 44% minority population, 59% college graduate. *For each arm* (mean, SD): baseline weight (kg): in-person directed (IPD) 105.0 (20.7), call centre directed (CCD) 102.1 (13.9), control 104.4 (18.6); baseline BMI: IPD 36.8 (5.2), CCD 36.0 (4.7), control 36.8 (5.1); baseline weight circumference (cm): IPD 118 (14), CCD 118 (13), control 118 (14). **Eligible population:** Recruited through primary care practices – physician referral, brochures and targeted mailings **Selected population:** Obese (BMI ≥ 30), at least 21 years old, one or more cardiovascular risk factors (hypertension, hypercholesterolemia, diabetes mellitus). Regular access to a computer, basic computer skills. **Excluded population/s:** Recently lost 5% or more of body weight, taking medications that affect weight. 43% of those screened were enrolled. **Setting:** Telephone, web and face-to-face intervention. Setting for counselling not specified.	**Method of allocation**: Web based randomisation and allocation **Intervention (1) description**: *In-person directed (IPD)*: • Reduced energy diet (DASH) (calorie intake dependent on weight, 1200-2200 kcal/day) • Recommended moderate intensity physical activity, 180 minutes/week, >10 minutes/session • Group and individual delivery, phone, web, in-person • Delivered by weight loss coaches trained before intervention and quarterly thereafter • 61 sessions of 20-90 minutes over 24 months • PCPs play supportive role **Intervention (2) description**: *Call centre directed (CCD):* As per intervention 1, except: • 33 sessions of 20 minutes over 24 months • Delivered via phone and web only • Individual counselling via weight loss coaches and HealthWays call centre **Control description:** (2) Usual care: Met with weight loss coach at randomisation. Received brochures and list of recommended web sites promoting weight loss. **Sample sizes (baseline):** Total n = 415 In person = 138 Call centre = 139 Control = 138 **At 12 months** Total n = 355 In person = 123 Call centre = 124 Control = 108 **At 24 months** Total n = 401 In person = 133 Call centre = 139 Control = 129 **Baseline comparisons**: Groups similar at study outset	**Published data only** **Outcome calculation method:** When necessary, reviewers calculated SD from SE provided **Follow up periods:** 6, 12 and 24 months	**BOCF weight change**: 12m IPD -4.8 (7.6), CCD -5.1 (7.6), control -0.9 (4.6). At 24m, IPD -4.9 (9.1), CCD -4.5 (8.3), control -0.8 (7.7). **Complete case weight change:** 12m IPD -5.4 (7.8), CCD -5.7 (7.8), control -1.1 (5.2). At 24m, IPD -5.1 (9.2), CCD -4.5 (8.3), control -0.8 (8.0). **Secondary outcomes:** waist circumference at 12m NR, complete case change in BMI (mean, SD) at 12m: IPD -1.8 (2.2), CCD -1.9 (2.2), control -0.4 (2.1) *Adverse effects:* One AE in IPD arm possibly related to study treatment – assault whilst exercising resulting in musculoskeletal injuries. No difference in total number of hospitalizations between arms (18 IPD, 15 CCD, 15 control). **Attrition details:** 86% followed up at 12m, IPD 89%, CCD 89%, control 78%. Reasons for attrition NR.	**Source of funding:** National Heart, Lung and Blood institute, Baltimore Diabetes research and Training Center, National Center for Research Resources **Other notes:** See also: Jerome, G. J., Yeh, H-C., Dalcin, A., Reynolds, J., Gauvey-Kern, M. E., Charleston, J., Durkin, N., and Appel, L. J. 2009. Treatment of obesity in primary care practice: The Practice based Opportunities for Weight Reduction (POWER) trial at Johns Hopkins. *Obesity and Weight Management*, 5, (5) 216-221.

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Bertz et al **Year:** 2012 **Citation:** Bertz, F.f.b.g.s., Brekke, H.K., Ellegard, L., Rasmussen, K.M., Wennergren, M., & Winkvist, A. 2012. Diet and exercise weight-loss trial in lactating overweight and obese women. *American Journal of Clinical Nutrition*, 96, (4) 698-705 **Aim of study:** Weight loss **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** Sweden *Across whole study:* 100% female, mean age 32, ethnicity NR, 74% >3 years education post high school *For each arm* (mean, SD): baseline weight (kg): Diet (D) 85.4 (10.0), Exercise (E) 88.3 (11.7), D+E 83.8 (7.3), Control 85.5 (10.3); baseline BMI: D 30.0 (2.6), E 30.4 (3.1), D+E 29.2 (2.2), Control 30.2 (3.4); baseline weight circumference NR. **Eligible population:** Recruited via antenatal clinics, of 76 women screened 5 (7%) excluded and 3 (4%) withdrew prior to randomisation **Selected population:** Self-reported pre-pregnancy BMI 25-35, 8-12wk post partum at study entry, non-smoking, singleton term delivery, intention to breastfeed for 6m, no illness in mother or infant, 20% of infant energy intake as complementary foods, birth weight of infant .2500 g, **Excluded population/s:** Not explicitly stated, but serious illness or anything that ruled out physical activity implied **Setting:** Face-to-face in research clinic and at participant's homes, plus text messaging	**Method of allocation**: Random number table, allocation method not reported but described as 'concealed' **Intervention description**: • Energy restriction (deficit of 500 kcal/day) • Brisk walking (moderate intensity), supervised twice, and recommended 4 days a week, with length of each session incremental to 45 mins • Individual in person sessions • Delivered by dietitians and registered physical therapists • 2 sessions (2.5 hours at baseline, 2 hours at 6 weeks) • Participants instructed to text in weight and number of walks to study staff weekly over 12 weeks **Diet only control:** As per intervention, but shorter sessions (1.5 hours at baseline, 1 hour at 6 weeks), no physical activity instruction or contact with physical therapist, not instructed to text in number of walks **Exercise only control:** As per intervention, but only 2 sessions (1.5 hours at baseline, 1 hour at 6 weeks), no energy restriction or contact with dietitian, not instructed to text in weight **No intervention control:** Usual care (1) **Sample sizes (baseline):** Total n = 68 Intervention n = 16 Diet only = 17 Exercise only = 18 Usual care control n= 17 **12 months:** Total n = 57 Intervention n = 16 Diet only = 13 Exercise only = 15 Usual care control n= 13 **Baseline comparisons**: Groups similar at study outset	**Published or unpublished** Published data only **Outcome calculation method** Standard methods for calculation used **Follow up periods:** 12 weeks and 12 months	**BOCF weight change**: At 12m intervention (D+E): -7.3 (6.3); D only -7.8 (6.7); E only -2.3 (5.5); Usual care control -0.7 (5.7) **Complete case weight change:** At 12m intervention (D+E) -7.3 (6.3); D only -10.2 (5.7); E only -2.7 (5.9); Usual care control -0.9 (6.6) **Secondary outcomes:** Complete case change in BMI (mean, SD): Intervention (D+E): --2.6 (2.2); D only -3.6 (2.0); E only -0.9 (2.0); Usual care control -0.3 (2.4). Waist circumference NR *Adverse effects:* Effects on breastfeeding and infant weight reported. At 1 year, significant main effect of D on introducing non breastfeeding (p=.030). In no cases did women give up breastfeeding involuntarily. No differences in infant weight. **Attrition details:** 92% followed up at 12 months, intervention 100%, D 76%, E 83%, control 76%. 4 missing (6%); 2 medical reasons (3%).	**Source of funding:** Swedish Research Council, Swedish Council for Working Life and Social Research

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Dale et al **Year:** 2008 **Citation:** Dale, K.S., Mann, J.I., McAuley, K.A., Williams, S.M., & Farmer, V.L. 2009. Sustainability of lifestyle changes following an intensive lifestyle intervention in insulin resistant adults: Follow-up at 2-years. Asia Pacific Journal of Clinical Nutrition, 18, (1) 114-120 **Aim of study:** Diabetes prevention (increase insulin sensitivity) **Study design:** RCT **Quality score:** +* **External validity score:** +**	**Source population/s:** New Zealand *Across whole study:* 67% female, mean age 46, 0% ethnic minority, SES data NR *For each arm*: baseline weight modest intervention (MI) 95.1 (12.2), intensive intervention (II) 91.1 (16.2), control 102.8 (15.4); baseline BMI MI 33.9 (4.4), II 32.5 (5.2), control 36.5 (4.3); baseline weight circumference MI 106.1 (9.8), II 100.9 (12.1), control 113.7 (9.7) **Eligible population:** Local advertisements **Selected population:** Being overweight/obese not an inclusion criteria (but baseline figures suggest vast majority would have fell into this category). 25 to 70 years old, able and willing to take part in dietary and exercise program, fasting glucose <6.1mmol/l, insulin sensitivity index <4.2 G mU^{-1} $*l^{-1}$ **Excluded population/s:** Diabetes or major medical condition, psychiatric illness, drug or alcohol dependence, on warfarin or oral steroids, on meds for <6m, likely to alter meds during intervention period 440 responded to advertisements, 79 enrolled (18%) **Setting:** In person, setting not specified. Phone discussion if missed face-to-face check in.	**Method of allocation**: NR **Intervention 1 description**: Intensive arm (II) • Macronutrient balance with some energy restriction, diets individually prescribed to lead to gradual and sustained weight reduction • Recommended and supervised physical activity, 30 minutes 5 days a week (at least 1x week supervised), at 80-90% of age predicted maximum heart rate • Mainly individual, some group exercise sessions, mostly in person but with phone catch ups if session missed • Delivered by dietitians, exercise consultants and researchers • 36 sessions over 4 months (18 diet, 18 exercise), length not specified • Free gym passes and some food provided **Intervention 2 description:** Modest arm (MI) • As per intervention 1, but macronutrient proportions of diet differ (more energy from fat allowed) and no specified heart rate targets for physical activity **Control description:** (4) usual care – at 8 and 12 months, "some advice" regarding lifestyle changes **Sample sizes (baseline):** Total n = 79 II n = 25 MI n = 31 Control n = 23 **At 12 months:** Total n = 70 MI+II n = 50 (not broken down, assumed MI 27, II 23) Control n= 20 **At 24 months:** Total n = 63 MI+II n = 43 (not broken down, assumed MI 23, II 20) Control n= 20 **Baseline comparisons**: At baseline, higher BMI, weight and waist circumference in control group.	**Published data only** **Outcome calculation method** Reviewers calculated weight change from weight data given at each time point. Reviewers interpreted results reported in paper (table 1) as complete case data, though unclear from information reported. Number of participants followed up in each intervention group not clear at 12 or 24 months, only combined n for two intervention groups available. Reviewers assumed equal loss to follow-up between intervention arms. BMI and waist circumference data only available for control and combined intervention, baseline data only represents those with 2 year follow-up **Follow up periods:** 4, 8, 12 and 24 months	**BOCF weight change**: 12 months MI -2.0 (6.6), II -2.5 (7.5), control -6.1 (6.0). At 24 months, MI -2.2 (5.7), II -2.1 (6.9), control -3.7 (5.5). **Complete case weight change (presumed):** 12 months MI -2.3 (7.0), II -2.7 (7.8), control -7.0 (5.9). At 24 months, MI -3.0 (6.5), II -2.6 (7.7), control -4.3 (5.7). **Secondary outcomes:** At 24 months, complete case change in waist circumference MI+II -1 (5.7), control -2 (3.3); complete case BMI change MI+II -0.7 (2.2), control -0.8 (1.9). *Adverse effects:* NR **Attrition details:** 87% followed up at 12 months (87% MI, 92% II, 87% control). Reasons for attrition NR.	**Source of funding:** Health Research Council, Otago University, Otago Diabetes Research Trust, NZ **Other notes:** *Quality score downgraded because randomisation and allocation procedures not described **External validity score downgraded as, of those who initially responded to advertisements, 18% enrolled *See also:* McAuley, K.A. et al. 2002. Intensive lifestyle changes are necessary to improve insulin sensitivity. Diabetes Care, 25, (3) 445-452.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Diabetes Prevention Program Research Group (DPP) **Year:** 2002 **Citation:** Diabetes Prevention Program Research Group. 2002. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. NEJM, 346, (6) 393-403. **Aim of study:** Diabetes prevention **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** USA; *Across whole study:* Female: 68% Age: 51y Ethnicity: 54% White Education: Some college and above: 74% Family income: Median $35-50,000 /y *For each arm* (mean, SD): Weight (kg) Intervention: 94.1 (20.8) Control: 94.3 (20.2) BMI (kg/m^2) Intervention: 33.9 (6.8) Control: 34.2 (6.7) Waist circumference (cm) Intervention: 105.1 (14.8) Control: 105.2 (14.3) **Eligible population:** Participants recruited by a variety of methods including mass media, mail and telephone contacts. Also by work site and other screenings **Selected population:** 1) Age ≥25y 2) BMI ≥ 24kg/m2 (≥22kg/m2 in Asians) 3) Fasting plasma glucose concentration 5.3 to 6.9 mmol/l 4) OGTT : 7.8 to 11.0 mmol/l **Excluded population/s:** Participants with diabetes, and those taking medicines known to alter glucose tolerance. Recent MI or presence of illnesses that could seriously reduce their life expectancy or their ability to participate. **Setting:** In person	**Method of allocation**: Randomisation and allocation methods **Intervention description**: • Lifestyle • Reduction in dietary fat intake to <25% of energy • Energy goal is added, if weight loss does not occur with fat restriction only – 1200 kcal/ day (33g fat) if initial weight 120-170lbs, – 1500 kcal/day (42g fat) if initial weight 175-215lbs, – 1800 kcal/day (50g fat) if initial weight 220-245lbs and – 2000 kcal/day (55g fat) if initial weight >250lbs. • Minimum 3 physical activity sessions weekly • Total of 150 minutes of moderate intensity exercise (e.g. brisk walking) per week with target to burn 700kcal/week • Voluntary activity sessions were organised in the community twice a week e.g. group walks, group aerobic classes • Individual sessions in person and by telephone • Delivered by lifestyle coaches who were dietitans or others with masters degree in exercise physiology, behavioural psychology or health education. • All lifestyle coaches received 2 day national training sessions and ongoing support • 16 core sessions lasting 30-60 minutes delivered in 24 weeks then unspecified but a minmimum of one session of 15-45 minutes every two months. • After 4 years, participants were invited to take part in DPPOS, an observational follow up study. In this phase all	**Published or unpublished** 12 month data from U.S. Preventive Services Task Force as only displayed graphically in published data. **Outcome calculation method** Complete case data not available. Authors report ITT analysis. Reviewers used ITT values to compute BOCF, in place of complete case data. Reviewers calculated SDs from the ITT SEs given using baseline n. **Follow up periods:** 0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9 and 10	**BOCF weight change**: 12 months Intervention: -6.5 (6.6) Control: -0.4 (6.4) **ITT weight change:** 12 months Intervention: -6.8 (6.6) Control: -0.4 (6.6) 4 years *(Standard errors not available)*: Intervention: -3.5 (NR) Control: -0.2 (NR) **Secondary outcomes:** Waist circumference: NR BMI: NR *Adverse effects:* at 3 years Gastrointestinal symptoms (events/100 person years) Intervention: 12.9 Control: 30.7 Musculoskeletal symptoms (events/100 person years) Intervention: 24.1 Control:21.1 No deaths or hospitalisation due to the intervention **Attrition details:** **12 months** Total: 95% follow up **4 years** Total: 98% follow up	**Source of funding:** National Institute of Diabetes and Digestive Kidney Disease (NIDDK) **Other notes:** **DPPOS:** After 4 years, participants were invited to take part in DPPOS, an observational follow up study. In this phase all participants had the option to complete the 16 core DPP sessions and/or booster sessions. **Economic data** **Intervention:** 10-year study cost of $4,601 or $3,023 if completed as groups and not individual sessions 10-year cost outside of DPP : $24,563 Health system: Cost per QALY over placebo = $6,651 (undiscounted) if completed all as a group intervention then becomes cost-saving Societal perspective: Cost per QALY over placebo = $11,274 if completed as a group then cost saving **Control:** 10-year cost of study cost $769 10-year cost outside of

		participants had the option to complete the 16 core DPP sessions and/or booster sessions – no scheduling or time scale reported. **Control description:** Usual care (4). This was a placebo control group with written lifestyle advice provided at baseline and alongside an annual individual session. **Sample sizes (baseline):** Total n = 3234 Intervention n = 1079 Control n= 1082 (Group with metformin n = 1073) **At 12 months (or closest point):** Total n = 3074 Intervention n = 1027 Control n= 1029 (Group with metformin n = 1018) **At longest 4 years:** Total n = 3182 Intervention n = 1066 Control n=1059 (Group with metformin = 1057) Groups similar at study outset			DPP : $27,463 **Additional references:** Report: Screening for the Management of Obesity in adults U.S. Preventive Services Task Force.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Dubbert et al **Year:** 1984 **Citation:** Dubbert PM, W. G. Goal-setting and spouse involvement in the treatment of obesity. Behaviour Research & Therapy 22[3], 227-42. 1984. **Aim of study:** Weight-loss **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** USA *Across whole study:* Female 71%; Age NR; SES or Education: NR *For each arm* (mean, SD): Weight: NR; BMI: NR; Waist circumference: NR **Eligible population:** Recruited from respondents to a newspaper article and public service announcements on local radio stations describing the availability of a new weight reduction programme **Selected population:** 1) Married and currently living with spouse 2) 15lbs+ overweight and not more than 100% overweight 3) No medical problems other than obesity 4) No medication affecting appetite or weight 5) Spouse willing to attend 8 sessions incl 4 groups sessions 6) Physicians approval 7) Married 57% of those screened were excluded or withdrew before randomisation **Excluded population/s:** Significant cardiovascular disease; insulin dependent DM, pregnancy or intention to be pregnant in next 2years, physical impairment, plan to move from area, participating in another research study, clinically judged unsuitable for participation or adherence	**Method of allocation**: Stratified randomisation procedure **Intervention 1 description**: Individual Proximal • 19 week intervention • From week 5: Prescribed a calorie intake goal of 1215kcal/d for females and 1525kcal/day for males • Recommended exercise 5 days a week for 30mins. Caloric-expenditure goals began at 145 kcal/day above their initial baseline then increased by 25kcal each week (equivalent to an extra 10 min walking). Expenditure goals were not advanced unless had met previous targets. • Weeks 1-4: Weekly education consisting of a 2 hour lecture and small group discussions. • Week 5-7: Began weekly face-to-face individual sessions (15-20min) with advanced clinical psychology graduate student who received supervision throughout the programme. • Weeks 7 onwards: Meetings continued every other week. **Intervention 2 description**: Couples Proximal • As Intervention 1 but encouraged to attend with partner from weeks 5 onwards. **Intervention 3 description**: Individual Distal • As Intervention 1 but diet goals presented as weekly not daily targets i.e. calorie prescription of 8500kcal/week for females and 10675kcal/week for males • Similarly for exercise, same levels as Intervention 1 but flexibility of arranging activities to meet a weekly goal emphasised instead of daily expenditure. **Intervention 4 description**: Couples Distal • As Intervention 3 but encouraged to attend with partner from weeks 5 onwards. **Sample sizes:** Total n = 62 NR by interventions **10 months** Total = 47 NR by interventions	**Published data only** **Outcome calculation method:** No calculation possible as n not reported by intervention group and SD/SE also not reported **Follow up periods:** 4, 7 and 10 months. Data from 16 months and 34 months displayed graphically (Fig 2) but does not match data in Table 1.	**Complete case weight change (kg)** *(Not possible to calculate BOCF)*: **10 months** Intervention 1: -9.3 (NR) Intervention 2: -5.4 (NR) Intervention 3: -5.9 (NR) Intervention 4: -6.9 (NR) **Secondary outcomes:** **Waist circumference change:** NR **BMI Change:** NR **Adverse effects:** NR **Attrition details:** **10 months:** Total: 76% FU	**Source of funding:** Based on dissertation at 'The State University of New Jersey' *External validity score downgraded as 57% of those screened were excluded or withdrew prior to randomisation

	Setting: In person	**Baseline comparisons**: Groups similar at study outset			
Study details	**Population and setting**	**Intervention and comparators**	**Outcomes and methods of analysis**	**Results**	**Notes**
Authors: Eriksson et al **Year:** 2009 **Citation:** Eriksson, M.K., Franks, P.W., & Eliasson, M. 2009. A 3-Year Randomised Trial of Lifestyle Intervention for Cardiovascular Risk Reduction in the Primary Care Setting: The Swedish Bjorknas Study. Plos One, 4, (4) e5195 **Aim of study:** cardiovascular disease prevention **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** Sweden *Across whole study:* percentage female: 57%, weighted mean age:54 years, ethnicity NR but likely to be all ethnic Swedish, SES data NR *For each arm* (mean, SD): baseline weight: Intervention 87.0 (16.4)kg and Control 84.5 (19.8), baseline BMI: Intervention 30.1 (5.3) Control 29.4 (5.1), baseline waist circumference Intervention: 104 (13) Control 100 (16) **Eligible population:** computerised search and mailed invitation **Selected population:** aged 18–65 years with a clinically documented diagnosis of hypertension, dyslipidemia, type 2 diabetes, obesity or any combinations thereof were identified from computerised case records. (ie obesity not entrance criteria, but ~90% obese at study entry) **Excluded population/s:** coronary heart disease, stroke, transient ischemic attack, severe hypertension, dementia or severe psychiatric morbidity 82% of those screened were enrolled **Setting:** in person primary care and sports facilities	**Method of allocation**: independent statistician generated the allocation sequence and randomisation numbers were kept in sealed, opaque envelopes. **Intervention (1) description**: • Reduced energy low fat diet, no target calories • Recommended and supervised daily physical activity, supervised 3 times per week. Supervised exercise lasted for 45 minutes increasing to 1 hour. • Group in-person • Delivered by physiotherapist or assistant and dietitian • 8 sessions with a dietitian who dealt only with diet and 45 sessions with a physiotherapist who dealt with diet and exercise over 3 years (53 total). • Focus on exercise over diet **Control description:** (2) One off education session by doctor, physiotherapist, and dietitian **Sample sizes (baseline):** Total n =151 Intervention n =75 Control n=76 **At 12 months (or closest point):** Total n =123 Intervention n =60 Control n=63	**Published data only** **Outcome calculation method:** standard **Follow up periods:** 12 months. 6 months and 36 months reported but data not extractable	**BOCF weight change**: At 12m, intervention -1.2 (2.6)kg Control, -0.6 (2.7) kg **Complete case weight change:** At 12m, intervention -1.5 (2.8), control: -0.7 (2.9) **Secondary outcomes:** At 12m, complete case change in waist circumference: Intervention -2.0 (2.8) Control: -0.2 (2.5) BMI: Intervention: -0.5 (1.0) Control: -0.2 (1.1) *Adverse effects:* no AEs attributed to intervention in either arm **Attrition details:** Total n =123 (81%) Intervention n =60 (80%) Control n=63 (83%) Reasons for loss: Intervention: 3 (4%) unavoidable; 12 (16%) missing; 0 medical. Control: Intervention: 3 (4%) unavoidable; 10 (13%) missing; 0 medical.	**Source of funding:** Swedish local health board **Other notes:** Data on 6 months and 36 months are available but incompletely reported making use in a meta-analysis difficult *See also:*Eriksson K. M., Westborg, C-J., Eliasson, M. C. E. 2006. A randomised trial of lifestyle intervention in primary healthcare for the modification of cardiovascular risk factors: The Bjorknas study. Scandinavian Journal of Public Health, 34, 453-461.

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Fitzgibbon et al **Year:** 2010 **Citation:** Fitzgibbon, M.L., Stolley, M.R., Schiffer, L., Sharp, L.K., Singh, V., & Dyer, A. 2010. Obesity reduction black intervention trial (ORBIT): 18-month results. Obesity, 18, (12) 2317-2325 **Aim of study:** Weight loss in African American women **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** USA; *Across whole study:* All female, mean age 46, 100% minority group (all self-identified African American), 44% college graduate. *For each arm* (mean, SD): baseline weight (kg) intervention 103.9 (15.7), control 105.9 (17.4); baseline BMI intervention 38.7 (5.5), control 39.8 (5.8), weight circumference NR. **Eligible population:** University staff and students, recruited via mass e-mail and face-to-face recruitment within 2 mile radius of campus **Selected population:** Self-identified African American women aged 30-65, BMI 30-50, able to participate in 30 minutes of physical activity and attend classes at scheduled times. **Excluded population/s:** Pregnant, nursing, or planning a pregnancy, planning to move during course of study, consumes more than 2 alcoholic drinks/day on daily basis, treated for cancer in last 5 years (except for skin cancer other than melanoma), unable to exercise because of medical condition, taking weight loss medications prescribed by doctor or currently participating in weight loss program. 31% of those screened were enrolled **Setting:** face-to-face on university campus and telephone	**Method of allocation**: Centralized randomisation and allocation, generated by program written by data analyst **Intervention description**: • Reduced energy and reduced fat diet (reduction based on individual, formula not provided) • Recommended and supervised moderate to high intensity physical activity, incremental to 30-40 minutes 3-4x week, plus goal of >10,000 steps/day. • Group and individual, in person and phone • Delivered by trained interventionists (details NR) and black peer mentors • 134 sessions of 60-90 minutes over 18 months • Intervention elements designed to take into account barriers specific to population (African-American women) **Control description:** (3) General health intervention – regular newsletters covering general health information, phone call from staff member every month relating to newsletter information **Sample sizes (baseline):** Total n = 213 Intervention n = 107 Control n= 106 **At 18 months:** Total n = 190 Intervention n = 93 Control n= 97 **Baseline comparisons**: Groups similar at study outset besides percentage of calories from alcohol, which authors state is "almost certainly not biologically meaningful"	**Published information only** **Outcome calculation method** Standard methods used **Follow up periods:** 6 and 18 months. Change data also provided from 6 to 18 months.	**BOCF weight change**: at 18 months: intervention -1.96 (6.95), control 0.46 (5.41) **Complete case weight change:** at 18 months: intervention -2.26 (7.42), control 0.51 (5.69) **Secondary outcomes:** waist circumference NR, complete case change in BMI at 18 months intervention -0.86 (2.79), control 0.22 (2.07) *Adverse effects:* NR **Attrition details:** 89% followed up at 18 months, 87% intervention, 92% control. 1 unavoidable (dead); 15% missing; 2% medical.	**Source of funding:** National Cancer Institute **Other notes:** External validity score downgraded as only 31% of those screened were subsequently enrolled *For protocol, see*: Fitzgibbon, M. L., Stolley, M., Schiffer, L., Sharp, L., Singh, V., Van Horn L., Dyer, A. 2008. Obesity reduction black intervention trial (ORBIT): Design and baseline characteristics. Journal of Women's Health, 17, (7), 1099-1110. *For 6m results, see*: Stolley, M.R., Fitzgibbon, M.L., Schiffer, L., Sharp, L.K., Singh, V., Horn, L., & Dyer, A. 2009. Obesity reduction black intervention trial (ORBIT): six-month results. Obesity, 17, (1) 100-106

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Foster-Schubert et al **Year:** 2012 **Citation:** Foster-Schubert, K.E., Alfano, C.M., Duggan, C.R., Xiao, L.R., Campbell, K.L., Kong, A., Bain, C.E., Wang, C.Y., Blackburn, G.L., & McTiernan, A. 2012. Effect of Diet and Exercise, Alone or Combined, on Weight and Body Composition in Overweight-to-Obese Postmenopausal Women. Obesity, 20, (8) 1628-1638 **Aim of study:** Weight loss in post-menopausal women **Study design:** RCT, factorial design **Quality score:** ++ **External validity score:** + (limited population)	**Source population/s:** USA; *Across whole study:* 100% female, mean age 58, 15% minority groups, 66% college graduate *For each arm* (mean, SD): baseline weight (kg) diet and exercise (D+E) 82.5 (10.8), diet only (D) 84.0 (11.8), exercise only (E) 83.7 (12.3), usual care 84.2 (12.5); baseline BMI D+E 31.0 (4.3), D 31.0 (3.9), E 30.7 (3.7), usual care 30.7 (3.9); baseline weight circumference (cm) D+E 93.7 (9.9), D 94.6 (10.2), E 95.1 (10.1), usual care 94.3 (11.3) **Eligible population:** Targeted mass mailing campaigns, media publicity and community outreach in greater Seattle, WA area. **Selected population:** Females aged 50-75, BMI ≥25, or ≥23 for Asian-American women, exercising <100 min/week at moderate intensity or greater, post menopausal, able to attend sessions, normal exercise tolerance test **Excluded population/s:** Diagnosed diabetes, use of hormone replacement therapy within prior 3 months, history of breast cancer or other serious medical conditions, alcohol intake in excess of 2 drinks/day, current smoker, contraindication to participating in diet/exercise program, current or planned participation in other weight loss program, use of weight loss medications. 6% of those screened were randomised. **Setting:** Face-to-face, phone and e-mail. "Study facility," location NR.	**Method of allocation**: Computer generated randomisation list, central computerised allocation. **Intervention description (D+E)**: • Reduced energy and low fat (1200-2000 kcal/day based on baseline weight) • Recommended and supervised moderate to high intensity physical activity, 45 minutes 5 days/wk • Group and individual, in person, via phone, and via email • Dietitian with training in behaviour modification and exercise physiologist • 194 sessions, length not specified, over 12 months (156 supervised exercise + minimum of 38 diet) **Control descriptions:** Three control arms: • Usual care (1): no contact. • Diet only (D) (5): diet elements as above • Exercise only (E) (5): exercise elements as above **Sample sizes (baseline):** Total n = 439 Intervention (D+E) n = 117 D n = 118 E n = 117 Usual care n = 87 **At 12 months:** Total n = 399 Intervention (D+E) n = 108 D n = 105 E n = 106 Usual care n = 80 **Baseline comparisons**: Groups similar at study outset	**Published data only** **Outcome calculation method** Complete case data not available, all data presented as BOCF and not as change data. Reviewers calculated BOCF change data using baseline values and BOCF mean weight, BMI, and waist circumference provided by authors at 12m follow-up. **Follow up periods:** 12 months	**BOCF weight change**: At 12m D+E -8.9 (5.5), D -7.1 (6.3), E -2.0 (6.1), usual care -0.7 (4.6) **Complete case weight change:** NR **Secondary outcomes:** Complete case change in waist circumference and BMI NR. At 12m, BOCF BMI change D+E -7 (5.5), D -2.6 (2.2), E -0.8 (1.8), usual care -0.2 (1.5); waist circumference change (cm) D+E -7.0 (5.5), D -4.4 (5.5), E -2.0 (4.9), usual care 1.4 (4.3) *Adverse effects:* NR **Attrition details:** 91% followed up at 12m overall: 92% D+E, 89% D only, 91% E only, 92% usual care. 2 unavoidable losses (<1%); 8% missing; 1% medical reason.	**Source of funding:** National Cancer Institute and National Center for Research Resources **Other notes:** External validity downgraded on basis of high percentage excluded from source population (6% of those screened were randomised) *See also:* Imayama, I., et al. 2011. Dietary weight loss and exercise interventions effects on quality of life in overweight/obese postmenopausal women: a randomised controlled trial. International Journal of Behavioral Nutrition & Physical Activity, 8, 118 Imayama, I., et al. 2012. Effects of a caloric restriction weight loss diet and exercise on inflammatory biomarkers in overweight/obese postmenopausal women: a randomised controlled trial. Cancer Research, 72, (9) 2314-2326 Mason, C., et al. 2011. Dietary weight loss and exercise effects on insulin resistance in postmenopausal women. American Journal of Preventive Medicine, 41, (4) 366-375

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Gold et al **Year:** 2007 **Citation:** Gold, B. C., Burke, S., Pintauro, S., Buzzell, P., and Harvey-Berino, J. 2007. Weight loss on the web: a pilot study comparing a structured behavioural intervention to a commercial program. Obesity, 15, (1) 155-164. **Aim of study:** Weight loss **Study design:** RCT **Quality score:** +* **External validity score:** +*	**Source population/s:** USA; *Across whole study:* 82% female, mean age 48, 2% minority groups, 96% had at least some college education *For each arm*: baseline weight intervention 1: 92.0 (15.7), intervention 2: 90.2 (14.1); baseline BMI intervention 1: 32.3 (3.9), intervention 2: 32.5 (4.2), baseline weight circumference NR **Eligible population:** Recruited through newspaper advertisements **Selected population:** Age over 18 years, BMI >25 and < 39.9 kg/m2, and regular access to a computer (not more than 3 years old with CD-ROM drive, Internet connection, at least 64 Megabytes of RAM, 350 MHz processor speed, and Windows 98 or higher as a computer operating system) **Excluded population/s:** Planned to move from the area or get pregnant within next 12m, history of major medical or psychiatric problems, smoker or been non smoker for less than one year, took meds known to affect weight, unable to participate in mild to moderate exercise program, unable to attend weekly meetings. 20% screened were enrolled **Setting:** Web	**Method of allocation**: Randomisation and allocation methods NR **Intervention 1 description**: • VTrim • Reduced energy diet, deficit of 1000 kcal/day (calculated based on baseline weight in lbs x 12, minus 1000) • Recommended aerobic activity, particularly walking, intensity NR, to increase energy expenditure to 1000 kcal/week. • Individual contact, online only • Qualifications of person delivering therapy NR • 39 sessions (weekly and then biweekly) over 12 months, session length NR **Intervention 2 description:** • eDiets.com • Reduced calorie diet, deficit of 1000 kcal/day (calculated based on estimated metabolic rate x exercise activity factor) • Recommended exercise, participant to choose type based on preference and abilities • Online weight loss programme • Delivered by professional (qualification NR) and peer mentors • No set sessions – all hour-chat rooms, online meetings, mentor option, access over 12 months **Control description:** No control arm **Sample sizes (baseline):** Total n = 124 Intervention 1 = 62 Intervention 2 = 62 **At 12 months (or closest point):** Total n = 88 Intervention 1 = 40 Intervention 2 = 48 Groups similar at study outset	**Published data only** (including information from www.vtrimeonline.com) **Outcome calculation method** BOCF as reported by authors used **Follow up periods:** 6 and 12 months	**BOCF weight change**: At 12 months, intervention 1: -5.1 (7.1); intervention 2: -3.4 (5.8) **Complete case weight change:** At 12 months, intervention 1: -5.1 (7.1); intervention 2: -3.4 (5.8) **Secondary outcomes:** Change in waist circumference and change in BMI NR *Adverse effects:* NR **Attrition details:** 71% followed up at 12m; 65% intervention 1, 77% intervention 2. 2% unavoidable; 25% missing; 2% medical.	**Source of funding:** Department of Agriculture Hatch Funds *Quality score downgraded as randomisation and allocation methods not described **External validity score downgraded due to small percentage enrolled from those screened; computer required to meet a number of specifications

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Hersey et al **Year:** 2012 **Citation:** Hersey, J.C., Khavjou, O., Strange, L.B., Atkinson, R.L., Blair, S.N., Campbell, S., Hobbs, C.L., Kelly, B., Fitzgerald, T.M., Kish-Doto, J., Koch, M.A., Munoz, B., Peele, E., Stockdale, J., Augustine, C., Mitchell, G., Arday, D., Kugler, J., Dorn, P., Ellzy, J., Julian, R., Grissom, J., & Britt, M. 2012. The efficacy and cost-effectiveness of a community weight management intervention: a randomised controlled trial of the health weight management demonstration. Preventive Medicine, 54, (1) 42-49 **Aim of study:** Weight loss **Study design:** **Quality score:** -* **External validity score:** ++	**Source population/s:** USA; *Across whole study:* Female: 74% Age: 40y Non-White: 16.4 Education: NR SES: NR BMI (kg) *(not reported for each arm)* : 33.6 *For each arm* (mean, SD): Weight (kg) Intervention1: 100.6 (18.8) Intervention2: 101.1 (19.1) Control: 99.9 (17.7) Waist circumference: NR **Eligible population:** Population approached for recruitment/recruitment methods **Selected population:** Participants were recruited through direct mail (80.5%) and community outreach (19.5%). Participants were non active duty personnel beneficiaries. **Excluded population/s:** Participants who were pregnant, had eating disorders or active cancer 10% of participants eligible were excluded before randomisation **Setting:** Telephone and Web	**Method of allocation**: NR **Intervention 1 description**: • RCT2 • No specific type of diet, but general advice encouraged reduction in calories, saturated fats, and reduction of salty, sugared rich but low nutrient density snacks ("junk foods") and increases in consumption of F&V's, low-fat proteins, low-fat dairy, and whole grains • An increase in moderate and vigorous physical activity was recommended • Individual internet intervention • Computerised weekly feedback on diet and exercise • Frequency was dependent on participants providing diet and exercise records **Intervention 2 description:** • RCT3 • Same diet and physical activity recommendations as Intervention (1) • Individual intervention • Delivered by health lifestyle coaches with at least an undergraduate degree and who had 2 weeks training with a psychologist • Alternating Telephone and Email support (15-20minutes) every 2 weeks for 18 months (39 sessions) **Control description:** Usual care (2): provided with a booklet about encouraging exercise and weight loss and also access to the basic (non-interactive) internet component. (Study label: RCT1)	**Published or unpublished** Published data with an additional description of the intervention from the author **Outcome calculation method** Standard **Follow up periods:** 6, 12 and 15-18 months	**BOCF weight change**: 12 months Intervention 1: -1.9 (5.8) Intervention2: -1.8 (5.9) Control: -1.2 (4.2) 15-18 months: Intervention 1: -1.0 (4.9) Intervention2: -1.5 (5.6) Control: -1.0 (4.0) **Complete case weight change:** 12 months Intervention 1: -6.0 (8.9) Intervention 2: -5.4 (9.3) Control: : -1.2 (4.2) 15-18 months Intervention 1: -3.5 (8.8) Intervention2: -5.2 (9.4) Control: -3.8 (7.3) **Secondary outcomes:** Waist circumference: NR BMI: NR **Attrition details:** 12 months: Total : 31% follow up Intervention 1: 32% follow up Intervention 2: 33% follow up Control: 28% follow up	**Source of funding:** Department of Defence **Other notes:** *Quality score downgraded as randomisation procedures not described and follow up <50% at 12 months **Economic data** Cost per participant Intervention 1: $160 Intervention 2: $390 Control: $145 Cost per 1% weight-loss Intervention1: $40 Intervention2:$70 Control: $30

		Sample sizes (baseline): Total n = 1755 Intervention1 n = 579 Intervention2 n = 578 Control n= 598 **At 12 months (or closest point):** Total n = 542 Intervention 1 n = 186 Intervention2 n = 188 Control n= 168 **At longest follow-up (as per results column):** **15-18 months** Total n = 486 Intervention 1 = 163 Intervention 2 = 168 Control n= 155 **Baseline comparisons** Groups similar at study outset		15-18 months: Total: 28% follow up Intervention 1: 28% follow up Intervention 2: 29% follow up Control: 26% follow up Reasons 12 months Medical: 3% Unavoidable: 5% 15-18 months Medical: 3% Unavoidable: 6%	

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Heshka et al. **Year:** 2003 **Citation:** Heshka, S., Anderson, J.W., Atkinson, R.L., Greenway, F.L., Hill, J.O., Phinney, S.D., Kolotkin, R.L., Miller-Kovach, K., Pi-Sunyer, F.X. 2003. Weight loss with self-help compared with a structured commercial program: a randomised trial. JAMA, 289, (14) 1792-1798 **Aim of study:** Weight loss **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** USA; *Across whole study:* Female: 82% Age: 45y Ethnicity: NR SES or Education: NR *For each arm*: Weight (kg) Intervention: 94.2 (13.1) Control: 93.1 (14.4) BMI (kg/m^2) Intervention: 33.8 (3.4) Control: 33.6 (3.7) Waist circumference (cm) Intervention: 101 (12) Control: 99 (12) **Eligible population:** Recruited by existing clinic records or by advertising a long-term non-medication weight loss study for moderately overweight persons **Selected population:** 1) Age 18-65 2) BMI 27-40 **Excluded population/s:** Fasting glucose >140 mg/dL (7.8 mmol/L) Triglycerides > 1000 mg/dL (11.3 mmol/L) Liver function test results more than 2 times the upper normal limit Serum creatinine >1.4 mg/dL (124 umol/L) Also, those using systemic or inhaled corticosteroids or lithium; having history of alcohol abuse within past year; history or presence of significant psychiatric disorder or other condition that would interfere with participation Those who had initiated new drug therapy in past 30 days, were already	**Method of allocation**: Random number table with randomisation envelope prepared by data co-ordinator **Intervention description**: • Commercial programme: Weight watchers • Free vouchers for Weight watchers • Energy restricted balanced diet using a points system • The ProPoints plan is a programme designed to deliver an individual energy deficit that leads to a healthy and sustainable rate of weight loss of up to 2lbs a week. • Minimum physical activity recommendation is 30 minutes of moderate intensity aerobic activity on 5 or more days a week with 2+ resistance exercise sessions a week. For weight loss and weight maintenance, the aim was to earn 2-4 ProPoints and 4-6 ProPoints, respectively. This equates to 1hr daily. • In person, group sessions with additional web, mobile and paper based resources • Delivered by trained peers who receive on-going training and assessment. • Weekly sessions of 60 minutes for 24 months. **Control description:** Usual care (4). Participants had a 20minute consultation with a dietitian and received publically available information. The dietitian provided basic information and did not use	**Published or unpublished** Published information supplemented by the provision of raw data and author information on the programme details. **Outcome calculation method** Data presented as LOCF but BOCF and complete case weight change was calculated from raw data by the reviewers. **Follow up periods:** 3, 6, 12, 18 and 24 months	**BOCF weight change**: 12 months Intervention: -4.1 (6.5) Control: -1.1 (5.4) 24 months Intervention: -2.1 (6.1) Control: 0.0 (6.1) **Complete case weight change:** 12 months Intervention: -4.9 (6.8) Control: -1.3 (5.9) 24 months Intervention: -3.0 (7.1) Control: -0.1 (7.1) **Secondary outcomes:** LOCF waist circumference change *(Complete case data NR)* 12 months Intervention: -4.9 (10.6), Control: -1.9 (10.4). 24 months Intervention: -2.6 (8.6) Control: -0.2 (8.8) LOCF BMI change *(Complete case data NR)* 12 months Intervention: -1.9 (2.7) Control: -0.6 (2.6) 24 months Intervention: -1.2 (2.4) Control: -0.1 (2.5) *Adverse effects:* NR **Attrition details:** 80% followed up at 12 months, no difference between arms. Reasons for attrition NR. At 24 months, authors report 2 excluded because of lymphoma, group assignment unclear, and 2 excluded from intervention for using WL meds. No other reasons provided.	**Source of funding:** Weight Watchers International **Other notes:** Vouchers were $9 per session

	participating in WL program or who tool prescription weight loss or investigational medications within 90 days of randomisation were excluded **Setting:** In person at non-clinical community centres	their training to personalise or help set individual goals. **Sample sizes (baseline):** Total n = 433 Intervention n = 221 Control n= 212 **At 12 months:** Total n = 346 Intervention n = 176 Control n= 170 **At 24 months:** Total n = 309 Intervention n = 150 Control n= 159 Groups similar at study outset			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Jakicic et al. **Year:** 2012 **Citation:** Jakicic JM, Tate DF, Lang W, et al. Effect of a Stepped-Care Intervention Approach on Weight Loss in Adults: A Randomised Clinical Trial. *JAMA.* 2012;307(24):2617-2626. doi:10.1001/jama.2012.6866. **Aim of study:** Weight loss **Study design:** **Quality score:** ++ **External validity score:** + *79% of those screened were ineligible, or lost/withdrew before randomisation*	**Source population/s:** USA *Across whole study:* Female 83%; Ethnicity 33% minority; Age 42 (9); University level 59% *For each arm* (mean, SD): **Weight** Intervention: 92.7 (13.6) Control: 93.1 (13.8) **BMI** Intervention: 33 (4) Control: 33 (4) **Waist circumference** Intervention: 107 (105-108) Control: 107 (106-109) **Eligible population:** Overweight adults recruited via TV and newspaper adverts **Selected population:** 1) BMI>25 and <40 2) 18-55 years 79% of those screened were ineligible, or lost/withdrew before randomisation **Excluded population/s:** Cardiovascular disease; metabolic disease that would affect weight; medical condition that would contraindicate diet or exercise; medication that would influence heart rate during exercise; having lost >4.5kg in the last 6 months; >20 mins/day of exercise on at least 3 days/week; pregnancy within 6 months or pregnancy planned. **Setting:** In person and telephone	**Method of allocation**: Computer-generated assignment with variable block sizes **Intervention (1) description**: • STEP • Low fat and calorie • Recommended moderate to vigorous activity progressing to 300min/week over 18months • Group sessions progressing to telephone and Group and finally to Group, telephone and individual face-to-face sessions. • Minimum 18 sessions over 18 months but variable for each individual • Stepwise progression of contact based upon weight-loss **Control description:** Active control with 45 group sessions over 18 months following same diet and activity advice as Intervention 1. **Sample sizes:** Total n = 363 Intervention n = 198 Control n = 165 **18 months** Total n = 260 Intervention n = 139 Control n = 121 **Baseline comparisons** Groups similar at study outset	**Published data only** **Primary outcomes:** Complete case data not available. Authors report ITT analysis using linear mixed models with multiple covariates to impute missing values. Reviewers used ITT values to compute BOCF, in place of complete case data. Reviewers calculated SDs from the ITT SEs . In some cases reviewers could not calculate SDs as n not known, provided as CIs in 'results' **Follow up periods:** 3,6,9,12 and 18 months: BOCF can only be calculated at 18 months as number followed up not reported for other time-points.	**BOCF weight change**: **18 months** Intervention: -4.3 (6.0) Control: -5.6 (6.2) **Multiple Imputation weight change** (Complete cases not available): **12 months** Intervention: -7.5 (CI -8.5,-6.5) Control: -9.1 (CI -10.2, -8.1) **18 months** Intervention: -6.2 (6.3) Control: -7.6 (6.2) **Secondary outcomes:** **Waist circumference Change** Intervention: -9.6 (CI -10.8, -8.3) Control: -10.4 (CI -11.9, -9) **BMI change** Intervention: -2.7 (CI -3, -2.3) Control: -3.2 (CI -3.6, -2.9) **18 months** **Waist circumference Change** Intervention: -9.2 (7.2) Control: -10.0 (8.1) **BMI change** Intervention: -2.21 (2.2) Control: -2.67 (2.2) **Attrition details:** **18 month** **Intervention** Unavoidable: 2% Missing: 25% Medical: 3% **Control** Unavoidable: 2% Missing: 19%	**Source of funding:** National Institutes of Health and National Heart, Lung and Blood institute

				Medical: 5%	
Study details	**Population and setting**	**Intervention and comparators**	**Outcomes and methods of analysis**	**Results**	**Notes**
Authors: Jebb et al **Year:** 2011 **Citation:** Jebb, S.A., Ahern, A.L., Olson, A.D., Aston, L.M., Holzapfel, C., Stoll, J., Amann-Gassner, U., Simpson, A.E., Fuller, N.R., Pearson, S., Lau, N.S., Mander, A.P., Hauner, H., & Caterson, I.D. 2011. Primary care referral to a commercial provider for weight loss treatment versus standard care: a randomised controlled trial. Lancet, 378, (9801) 1485-1492 **Aim of study:** Weight loss **Study design:** **Quality score:** + (<50% follow up at 12m)	**Source population/s:** United Kingdom, Germany and Australia *Across whole study:* Female 87%; Age: 47y; Ethnicity and SES data: NR Baseline weight: intervention 86.9 (11.6), control: 86.5 (11.5) BMI: intervention 31.5 (2.6), control 31.3 (2.6) Waist circumference (cm): intervention 100 (9.2), control: 99.9 (9.3) **Eligible population:** Obese adults recruited from primary care practices **Selected population:** 1) $\geq$ 18 years 2) BMI 27-35 kg/m^2 3) One risk factor for obesity related disease **Excluded population/s:** Weight loss of 5kg or more in last 3 months; history of clinically disordered eating; orthopaedic limitations; untreated thyroid disease; medication that effects weight-loss; GI disorders, previous surgery for WL, major surgery in previous 3m, HbA1C 9% or more, heart problems in previous 3m, uncontrolled hypertension, new rx for chronic disorder in previous 3m or change in dose in previous 1m,	**Method of allocation**: Computer generated randomisation and allocation **Intervention (1) description**: • Weight Watchers • Energy restricted balanced diet using a points system • The ProPoints plan is a programme designed to deliver an individual energy deficit that leads to a healthy and sustainable rate of weight loss of up to 2lbs a week. • Minimum physical activity recommendation is 30 minutes of moderate intensity aerobic activity on 5 or more days a week with 2+ resistance exercise sessions a week. For weight loss and weight maintenance, the aim was to earn 2-4 ProPoints and 4-6 ProPoints, respectively. This equates to 1hr daily. • In person, group sessions with additional web, mobile and paper based resources • Delivered by trained peers who receive on-going training and assessment. • Weekly sessions of 60 minutes for 12 months. **Control description:** Nurse practitioner (4) **Sample sizes:** Total n = 772 Intervention n = 377 Control n= 395 **At 12 months** Total n = 444	**Published data only** **Outcome calculation methods** BOCF reported in paper. Reviewer calculated SD from SE given where possible. **Follow up periods:** 2, 4, 6, 9 and 12 months	**BOCF weight change**: At 12m intervention -4.06 (6.02), control -1.77 (3.78) **Complete case weight change** At 12m intervention -6.65 (0.43) Control: -3.26 (0.33) **Secondary outcomes:** BOCF Waist circumference (SE) 12 months Intervention: -4.05 (0.35) Control: -2.34 (0.26) *Adverse effects*: No adverse events attributable to trial participation **Attrition details:** **12 months** Total: 58% Follow up **Intervention:** Total: 61% follow up Medical: 3% Missing: 34% Unavoidable: 2% **Control:** Total: 54% follow up Medical: 2% Missing: 41% Unavoidable: 3%	**Source of funding:** Weight Watchers International (through grant to UK MRC) **Cost effectiveness summary:** In the UK, the cost per kilogram of weight loss was GBP 55 for the intervention and 92 GBP for the control group. Cost in other countries also available. See Fuller, N. R. et al. 2012. A within-trial cost-effectiveness analysis of primary care referral to a commercial provider for weight loss treatment, relative to standard care- an international randomised contolled trial. International Journal of Obesity. 1-7. *See also:* Eberhard, M. I. et al. 2011. Greater improvements in diet quality in participants randomised to a commercial weight loss programme compared with standard care delivered in GP practices. Proceedings of the Nutrition Scoeity, 70, (OCE4) E252.

External validity score: ++	history or presence of cancer **Setting:** In person	Intervention n= 230 Control n = 214 Groups similar at study outset			

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Jeffery and Wing **Year:** 1995 **Citation:** Jeffery, R.W., and Wing, R. W. 1995. Long-term effects of interventions for weight loss using food provision and monetary incentives. Journal of Consulting and Clinical Psychology, 63, (5) 793-796. **Aim of study:** weight loss **Study design:** RCT **Quality score:** +* **External validity score:** +**	**Source population/s:** USA *Across whole study:* 50% female, mean age 37, 8% ethnic minority, 50% college education. *For each arm*: Baseline weight: intervention 1 89.4, intervention 2 88.1, intervention 3 92.3, intervention 4 91.1, control 88.2. Baseline BMI: intervention 1 30.9, intervention 2 30.8, intervention 3 31.1, intervention 4 31.1, control 31.1 . Baseline weight circumference NR **Eligible population:** Newspaper and radio advertisements and mailed invitations in two US cities **Selected population:** 14-32 kg above insurance industry standards for height and weight (Metropolitan Life Insurance Company, 1983), 25-45 years old, non-smokers, moderate drinkers or non-drinkers, not on any special diet, not taking prescription medications, free of serious medical problems **Excluded population/s:** NR Percentage screened who were enrolled NR **Setting:** In person	**Method of allocation**: NR **Intervention 1 description**: • Standard behavioural therapy (SBT) • Reduced energy diet, 1000 or 1500 kcal/day based on initial body weight • Recommended moderate intensity physical activity (walking or biking) 5 days a week, weekly goal of building up to burning 1000 kcal/week via exercise. • Group in-person • Led by trained interventionists with advanced degrees in nutrition or behavioural sciences • 33 sessions over 18 months, length not specified **Intervention 2 description:** SBT + food. As per SBT above, plus provided with food each week for 18 months (premeasured and prepackaged dinners and breakfasts for 5 days/week) **Intervention 3 description:** SBT + incentives. As per SBT above, plus incentive program – each participant could earn financial rewards up to $25/week for achieving and maintaining weight loss **Intervention 4 description:** SBT + incentives + food. As per interventions 2 and 3. **Control description:** (1) no intervention **Sample sizes (baseline):** Total n = 202 Intervention 1 n = 40 Intervention 2 n = 40 Intervention 3 n = 41 Intervention 4 n = 41 Control n= 40 **At 12 months:** Total n = 176. Breakdown by group NR **At 30 months:** Total at least 153, breakdown by group NR Groups similar at study outset	**Published data only** **Outcome calculation method** Limited data available, study not included in meta analysis or weight curves. SDs not available except for at 30 months. Weight change data extrapolated from graph. BOCF calculations not available as number followed-up at each time point not provided by arm. Unclear if 30 month data is complete case, ITT, or other. BMI change calculated based on mean BMIs given. At 12 months, BMI data reported in control group not consistent with weight change data reported. **Follow up periods:** 6, 12, 18, 30 months	**BOCF weight change**: Unable to calculate **Complete case weight change:** At 12 months: intervention 1 -4.5, intervention 2 -9.0, intervention 3 -5.5, intervention 4 -9.0, control -0.2 At 30 months (unclear if data is complete case): intervention 1 -1.4 (7.2), intervention 2 -2.2 (6.6), intervention 3 -1.6 (5.5), intervention 4 -1.6 (6.3), control +0.6 (5.3) **Secondary outcomes:** Complete case BMI change at 12 months: intervention 1 -1.95, intervention 2 -3.20, intervention 3 -1.85, intervention 4 -2.97, control -0.5 Waist circumference NR *Adverse effects:* NR **Attrition details:** 87% completed 12 month follow-up, no differences between treatment groups	**Source of funding:** National Heart, Lung and Blood Institute **Other notes:** Loveman 2011 included study. *Quality score downgraded as no information on randomisation or allocation provided **External validity score downgraded as unclear percentage screen who enrolled and no numbers on who was followed up within groups See also Jeffrew, R.W., Wing, R.R., et al. 1993. Strengthening behavioural interventions for weight loss: a randomised trial of food provision and monetary incentives

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Jeffery et al **Year:** 1998 **Citation:** Jeffery, R.W., Wing, R., Thorson, C., Burton, L.R. 1998. Use of personal trainers and financial incentives to increase exercise in a behavioural weight loss program. Journal of Consulting and Clinical Psychiatry, 66, (5) 777-783. **Aim of study:** Weight loss **Study design:** RCT **Quality score:** +* **External validity score:** +**	**Source population/s:** USA *Across whole study:* 83% female, mean age 41, 20% ethnic minority, 77% college education or higher. *For each arm*: Baseline weight: (1) SBT 85.6 (10.8); (2) supervised exercise 87.1 (10.2); (3) trainer 84.7 (10.4); (4) incentive 87.7 (10.3); (5) trainer & incentive 85.7 (10.2). Baseline BMI: (1) SBT 31.4 (1.9); (2) supervised exercise 31.5 (1.9); (3) trainer 31.4 (1.9); (4) incentive 31.5 (2.4); (5) trainer & incentive 30.6 (2.4). Baseline waist circumference NR. **Eligible population:** Recruited via media advertisements in two urban communities **Selected population:** 14 to 32 kg overweight according to 1983 insurance standards, 25 to 55 years old, free of serious disease, able to walk for exercise **Excluded population/s:** Exclusion criteria NR Percentage screened who were enrolled NR **Setting:** In-person (and telephone in some arms) setting NR	**Method of allocation**: Randomisation and allocation methods NR **Intervention (1) description**: • Standard behavioural therapy (SBT) • Low-fat, calorie restricted diet (1000 kcal/day if baseline weight <91kg, 1500 kcal/day if 91kg+, restrict fat intake to 20% of kcal) • Recommended moderate intensity physical activity (walking and bicycling) incremental to 1000kcal/week expenditure • Group in person • Delivered by "trained interventionists" with advanced degrees in nutrition or behavioural sciences • 36 sessions over 18 months (weekly for 24 weeks, monthly thereafter) **Intervention (2) description:** • Supervised exercise • As per SBT (intervention 1) except supervised walking 3 times a week, gradually increasing to 2.5 miles/session (same goal of 1000kcal weekly expenditure) **Intervention (3) description:** • Trainer • As per supervised exercise (intervention 2) except for addition of personal trainer who walked with participants, made reminder phone calls before each session, and scheduled make-up sessions when needed **Intervention (4) description:** • Incentive • As per supervised exercise (intervention 2) except for addition of financial incentive based on number of walks attended each month. Rewards increase over time. **Intervention (5) description:** • Incentive • As per trainer (intervention 3) except for addition of financial incentive based on number of walks attended each month. Rewards increase over time. **No control arm**	**Published data only** **Outcome calculation method** Reviewers calculated SD from SE provided. N followed up in each group unclear at 6 and 18 months; authors provide only overall percentages and state that the percentage followed up did not differ between groups. Reviewers used overall percentages provided to calculate N in each group at follow-up. **Follow up periods:** 6 and 18 months.	**BOCF weight change**: At 18 months: (1) SBT -5.9 (6.2); (2) supervised exercise -3.0 (6.7); (3) trainer -2.3 (5.7); (4) incentive -3.5 (6.0); (5) trainer and incentive -4.0 (6.4). **Complete case weight change:** At 18 months: (1) SBT -7.6 (6.1); (2) supervised exercise -3.8 (7.4); (3) trainer -2.9 (6.3); (4) incentive -4.5 (6.5); (5) trainer and incentive -5.1 (6.9) **Secondary outcomes:** Change in BMI and change in waist circumference NR *Adverse effects:* NR **Attrition details:** 78% followed up at 18 months, details not broken down by group, reasons for attrition NR	**Source of funding:** National Heart, Lung and Blood Institute **Other notes:** *Quality score downgraded as methods of randomisation and allocation concealment NR **External validity score downgraded as percentage screened who were enrolled NR ***N followed up in each group not provided, calculated from percentages provided

		Sample sizes (baseline): Total n = 196 Intervention 1 n = 40 Intervention 2 n = 41 Intervention 3 n = 42 Intervention 4 n = 37 Intervention 5 n = 36 **At 18 months:** Total n = 171*** Intervention 1 n = 35 Intervention 2 n = 36 Intervention 3 n = 37 Intervention 4 n = 32 Intervention 5 n = 31 Groups similar at study outset			

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Jolly et al **Year:** 2011 **Citation:** Jolly, K., Daley, A., Adab, P., Lewis, A., Denley, J., Beach, J., & Aveyard, P. 2010. A randomised controlled trial to compare a range of commercial or primary care led weight reduction programmes with a minimal intervention control for weight loss in obesity: the Lighten Up trial. Bmc Public Health, 10, 439 **Aim of study:** weight loss **Study design:** 8 arm RCT (choice arm excluded from review) **Quality score:** + **External validity score:** ++	**Source population/s:** UK Percentage female: 71%, Mean age: 49 years, Percentage in all minority groups: 6%, SES: IMD score- participants more deprived than country average Baseline weight: Weight Watchers: 93 (14) Slimming World: 94 (13) Rosemary Conley: 94 (14) Size Down: 95 (18) GP: 92 (15) Pharmacist: 93 (14) Control: 93 (15) Baseline BMI Weight Watchers: 34.0 (3.9) Slimming World: 33.8 (3.8) Rosemary Conley: 33.4 (3.5) Size Down: 33.8 (3.9) GP: 33.1 (3.5) Pharmacist: 33.4 (3.5) Control: 33.9 (4.4) Baseline weight circumference: NR **Eligible population:** Practices wrote to patients >18 with a raised BMI (dependent upon ethnic group and comorbidities) and invited them to join the study. **Selected population:** Everyone who responded who did not have a comorbidity **Excluded population/s:** Unable to understand English, pregnant, so ill that weight loss inappropriate e.g. terminal	**Method of allocation**: Sequence prepared by statistician using block randomisation and concealment through envelopes **Intervention 1 description**: • Weight Watchers (WW) • Low fat diet, set based upon height and weight but aiming for 500Kcal deficit • Recommended physical activity, no specific target • Group in-person • Delivered by lay person who successfully lost weight with WW and then trained • 12 weekly hour long sessions **Intervention 2 description:** • Slimming World (SW) • Low fat low energy density diet, includes free foods, eaten without restriction, and allowances for other types of food. No energy restriction as such • Recommended physical activity, building to 10x15 minutes of moderate activity or 5x30 minutes weekly • Group in-person • Delivered by lay person who successfully lost weight with SW and then trained • 12 weekly hour long sessions **Intervention 3 description:** • Rosemary Conley (RC) • Reduced energy low fat diet, low GI diet with energy goals of week 1&2: 1200kcal, Week 3&4: 1400kcal, Week 5 onwards: personal energy allowance based on age, gender and current weight • Recommended physical activity and one 45-minute dance-based exercise session per week • Group in-person • Delivered by lay person who successfully lost weight with RC and then trained • 12 weekly hour long sessions **Intervention 4 description:** • Size Down (NHS group-based weight loss programme)	**Published or unpublished** Published only **Outcome calculation method** Standard **Follow up periods:** 3 and 12 months	**BOCF weight change**: 12 months WW -3.5 (6.9) SW -1.9 (5.1) RC -2.1 (6.4) SD -2.5 (5.9) GP -0.8 (5.1) Pharmacist -0.7 (4.5) Control -1.1 (5.1) **Complete case weight change:** 12 months WW -4.4 (7.7) SW -3.1 (6.4) RC -3.3 (7.8) SD -3.7 (7.0) GP -1.3 (6.4) Control -1.7 (6.6) **Secondary outcomes:** Waist circumference: NR Change in BMI WW -1.8 (3.2) SW -1.4 (2.6) RC -1.3 (4.2) SD -1.2 (2.7) GP -0.7 (2.4) Pharmacist -0.7 (2.6) Control -0.8 (2.6) Adverse effects: NR though all participants had the opportunity to given feedback. **Attrition details:** Reasons for loss to follow up not reported	**Source of funding:** Local health service **Other notes:** Lost a + on quality because >20% difference between arms in loss to follow up at 12m

	illness Percentage screened who were enrolled NR **Setting:** In person programmes delivered in community settings, pharmacies, or GP surgeries depending on programme.	• Reduced energy low fat diet based on Eatwell plate aiming to lose about 0.15kg/week • Recommended physical activity, no specific target • Group in-person • Lay people taken NVQ Level 3- 25 hours of training from dietitians plus assessment to pass • 8 sessions of 2 hours over 12 wks **Intervention 5 description:** • GP and pharmacist based care differed only in the background of the therapist • Reduced energy low fat diet based on Eatwell plate aiming to lose about 0.5-1kg/week • Recommended physical activity incremental to 30 mins of moderate activity/week 3-6 METS • Individual in-person • GP mainly given by nurses. GPs, nurses and pharmacists all had 2-day training to deliver course • 12 sessions of approx 20 mins over 12 weeks **Control description:** (1) Offered 12 free entries to local sports centre **Sample sizes (baseline):** Total n = 100 for all groups except GP and pharmacist, which was 70 each **At 12 months (or closest point):** Total n = 430 (67%); WW n =78 (78%); SW n=62 (62%); RC n=68 (68%); SD n=66 (66%); GP n=46 (66%) Pharmacist n=40 (57%); Control n=70 (70%) Groups similar at study outset.			

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Kuller et al **Year:** 2012 **Citation:** Kuller, L.H., Pettee Gabriel, K.K., Kinzel, L.S., Underwood, D.A., Conroy, M.B., Chang, Y., Mackey, R.H., Edmundowicz, D., Tyrrell, K.S., Buhari, A.M., & Kriska, A.M. 2012. The Women on the Move Through Activity and Nutrition (WOMAN) study: final 48-month results. Obesity, 20, (3) 636-643 **Aim of study:** Modify lipoproteins, weight loss and exercise in postmenopausal women (originally designed to slow progression of subclinical atherosclerosis among women on hormone therapy) **Study design:** RCT **Quality score:** ++ **External validity**	**Source population/s:** USA *Across whole study:* 100% female, mean age 57, 12% minority group, 80% had 0-4 years college, 79% employed for wages *For each arm*: baseline weight (kg) intervention 105.5 (11.1), control 106.3 (11.4); baseline BMI intervention 30.6 (3.8), control 30.9 (3.8); baseline weight circumference NR **Eligible population:** Direct mailings to selected zip codes **Selected population:** Postmenopausal women, 52-62 years old, BMI 35-39.9, waist circumference >80cm, BP <140/90, LDL cholesterol 100-1600mg%, Beck Depression Inventory score <20, successful completion of 400 meter corridor walk test. Originally also required to be on hormone therapy for at least 2 years. **Excluded population/s:** History of CVD, diagnosis of psychotic disorder, use of cholesterol-lowering medication, diagnosis of diabetes or use of diabetes medication. 52% of those screened were randomised.	**Method of allocation**: Randomisation sequence designed by independent statistician, allocation via sealed, numbered envelopes opened sequentially **Intervention description**: • Energy and fat reduction (1300 kcal/day if baseline weight < 175 lb, if >175 lb 1500 kcal/day) • Recommended moderate intensity physical activity incremental to 240 minutes/week. • Group face-to-face • Delivered by qualified nutritionists, behavioural psychologists, and exercise physiologists • 64 sessions over 36 months, length not specified • Intervention was originally intended to last 48 months but study was cut short **Control description:** Health education group (3): met 6x in year one and 'several times' over following years to discuss women's health **Sample sizes (baseline):** Total n = 508 Intervention n = 253 Control n= 255 **At 18 months:** Total n = 421 Intervention n = 208 Control n= 213 **At 48 months:** Total n = 446	**Published data only** **Outcome calculation method** Standard methods used **Follow up periods:** 6, 18, 30, 48 months	**BOCF weight change**: at 18m intervention -6.4 (7.1), control -1.3 (5.1); at 48m intervention -2.9 (6.7), control -0.2 (5.3) **Complete case weight change:** at 18m intervention -7.8 (7.1), control -1.6 (5.5); at 48m intervention -3.4 (7.2), control -0.2 (5.6) **Secondary outcomes:** Complete case change in waist circumference and BMI NR *Adverse effects:* NR **Attrition details:** 83% followed up at 18m overall: 82% intervention, 84% control. Reasons for attrition NR.	**Source of funding:** National Heart, Lung and Blood Institute **Other notes:** This was originally a trial exclusively in women with HRT. However, when risks discovered, turned into study in general population. *See also:* *Design:* Kuller, L. H., et al. 2007. The clinical trial of Women On the Move through Activity and Nutrition (WOMAN) study. Contemporary Clinical Trials 28, 370-381. *For results at 18m:* Kuller, L. H., et al. 2006. Lifestyle intervention and coronary heart disease risk factor changes over 18 months in postmenopausal women: the Women On the Move through Activity and Nutrition (WOMAN Study) clinical trial. Journal of Women's Health, 15, (8) 962-974. *Other outcomes:* Gabriel, K.K., et al. 2011. The impact of weight and fat mass loss and increased physical activity on physical function in overweight, postmenopausal women: results from the Women on the Move Through Activity

score: ++	**Setting:** face-to-face, location not specified	Intervention n = 216 Control n= 230 Groups similar at study outset			and Nutrition study. Menopause, 18, (7) 759-765

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Kumanyika et al **Year:** 2012 **Citation:** Kumanyika SK;Fassbender JE;Sarwer DB. One-year results of the Think Health! study of weight management in primary care practices. Obesity 2012:20:1249-1257 **Aim of study:** weight loss, **Study design:** **Quality score:** ++ **External validity score:** ++	**Source population/s:** country; USA *Across whole study:* percentage female 85%, weighted mean age 47 years, percentage in all minority groups 82%, SES data 69% >12y education *For each arm* (mean, SD): baseline weight (kg) Basic 102 (21) Basic plus 101 (19), baseline BMI Basic 37.3 (6.4) Basic plus 37.2 (6.5), baseline weight circumference (cm) Basic 111cm, Basic plus 112 **Eligible population:** Primary care population probably recruited through list searches though not quite clear. **Selected population:** 18-70 years BMI 27-55, weighing less than 182kg **Excluded population/s:** Unable to climb 1 flight of stairs, pregnant or lactating, wt loss of >5kg in last 3 months, on medication that causes weight gain, major psychiatric disorders, active treatment for cancer, unstable major disease, MI LVF stroke. People at high risk of CVD were eligible 75% of people who remained interested were enrolled **Setting:** Mode of delivery: in person primary care.	**Method of allocation**: Permuted block randomisation, method of implementation not described **Intervention (1) description**: Basic Plus • Based on DPP • Reduced calorie low fat diet • Type of physical activity: recommended moderate intensity 5 days/week 30 minutes/day • Mode of delivery: individual, in person with extensive self-help materials • Qualifications of person delivering therapy: GP and lifestyle coach (practice assistant) • Number of sessions 4 with GP 13 with lifestyle coach, 10-15 minutes per session with both GP and coach, programme lasting 12 months • Any other key information unique to the intervention **Intervention 2 description:** Basic (Grade 6 intervention) • Based on DPP • Reduced calorie low fat diet • Type of physical activity: recommended moderate intensity 5 days/week 30 minutes/day • Mode of delivery: individual, in person with extensive self-help materials • Qualifications of person delivering therapy: GP • Number of sessions 3 with GP over 12 months • Any other key information unique to the intervention **Control**: no control group **Sample sizes (baseline):** Total n = 261 Basic n = 137 Basic Plus n=124 **At 12 months (or closest point):** Total n = 187 Basic n =98 Basic Plus n=89 **Baseline comparisons**: groups similar at study outset	**Published or unpublished:** Published only but data also taken from protocol paper: Contemp Clin Trials. 2011; 32: 215–224. doi:10.1016/j.cct.2010.11.002 **Outcome calculation method:** standard **Follow up periods:** None	**BOCF weight change**: Basic: -0.40 (3.31) Basic Plus: -1.27 (4.58) **Complete case weight change:** Basic: -0.62 (4.1) Basic Plus: -1.61 (5.1) **Secondary outcomes:** Complete case change in waist circumference: NR Complete case change in BMI: NR Adverse effects: NR **Attrition details:** Overall percentage followed up at 12m: 72%, Basic 72% Basic Plus 72% Percentages lost in three categories: NR	**Source of funding:** Pennsylvania Department of Health, though various other public sources

Study details	**Population and setting**	**Intervention and comparators**	**Outcomes and methods of analysis**	**Results**	**Notes**
Authors: Lindstrom et al **Year:** 2003 **Citation:** Lindstrom, J., et al. Finnish Diabetes prevention Study Group. 2003. The Finnish Diabetes Prevention Study (DPS): Lifestyle intervention and 3-year results on diet and physical activity. Diabetes Care, 26, 3230-3236. **Aim of study:** Diabetes prevention **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** Finland *Across whole study:* Female 67%, mean age 55, Ethnicity NR, SES: years of education 0-9 : 40%, 10-12 : 27%, >=13 : 33% *For each arm* (mean, SD): Weight Intervention: 86.7kg (14.0) Control: 85.5kg (14.4) BMI Intervention: 31.4 (4.5) Control: 31.1 (4.5) Weight circumference Intervention: 102.0 (11.0) Control: 100.5 (10.9) **Eligible population:** High-risk groups such as first-degree relatives of type 2 diabetes patients **Selected population:** 1) Age 40–64y 2) BMI >25 kg/m2 3) Impaired glucose tolerance **Excluded population/s:** Diabetes, unlikely to survive 6 years due to disease, psychological or physical characteristics that mean that intervention or study follow up impractical. Percentage screened but not	**Method of randomisation and allocation concealment** A randomisation list was used. The nurses scheduling visits were blinded to randomisation. Study staff were not blinded. **Intervention description**: • Lifestyle Intervention • Low fat diet (<30% kcal from fat) • Recommended moderate intensity exercise every day for 30 minutes • Individual with voluntary group sessions • Delivered by dietitian/nutritionist and physician • 7 compulsory sessions in year one then every 3 months indefinitely. Plus voluntary sessions. **Control description:** Usual Care (2) – General information about lifestyle was provided at baseline in an individual or group session lasting 30-60minutes. Written material was also provided at baseline. **Sample sizes:** Total n = 522 Intervention n = 265 Control n = 257 **12 months** Total n = 506	**Published or unpublished** Published **Outcome calculation method** Standard **Follow up periods:** 1y, 3y	**BOCF weight change** **12 months** Intervention: -4.3 (5.0) Control: -1.0 (3.7) **3 years** Intervention: -3.5 (5.6) Control: -0.7 (4.8) **Complete case weight change** **12 months** Intervention: -4.5 (5.0) Control: -1.0 (3.7) **3 years** Intervention: -3.5 (5.1) Control: -0.9 (5.4) **Secondary outcomes:** **12 months** *Waist circumference change* Intervention: - 4 (5) Control - 1 (5) *BMI change* Intervention: -1.6 (1.8) Control: - 0.4 (1.3) Adverse events NR **Attrition details:** **12 months** 97% followed-up overall. Intervention = 97% follow up Control n = 97% follow up Reasons for attrition:	**Source of funding:** Finish academy, ministry of education; Novo nordisk foundation; Yrjo Jahnsson Foundation; Juho Vainio Foundation; and Finish diabetes research foundation **Other notes:** The study was prematurely terminated in March 2000 by an independent end point committee, since the incidence of diabetes in the intervention group was highly significantly lower than in the control group *See also:* Tuomilehto J, Lindström J, Eriksson JG, Valle TT, Hämäläinen H, Ilanne-Parikka P, Keinänen-Kiukaanniemi S, Laakso M, Louheranta A, Rastas M, Salminen V, Uusitupa M: Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. N Engl J

	enrolled: NR **Setting:** In person & phone	Intervention n = 256 Control n = 250 **3 years** Total n = 434 Intervention n = 231 Control n = 203 Groups similar at study outset		NR	Med344:1343–1350, 2001

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Logue et al **Year:** 2005 **Citation:** Logue E, Sutton K, Jarjoura D, Smucker W, Baughman K, Capers C: Transtheoretical model-chronic disease care for obesity in primary care: a randomised trial. *Obesity research* 2005, 13:917-927 **Aim of**	**Source population/s:** USA *Across whole study:* Female 69%; Age 53y; Ethnicity 28% African American; SES data NR *For each arm*: Weight: NR BMI (%) Intervention 1: 25 to 29.9: 22 30 to 34.5: 32 35 to 39.0: 24 40.0+: 22 Intervention 2: 25 to 29.9: 18 30 to 34.5: 37 35 to 39.0: 21 40.0+: 24 Waist circumference NR **Eligible population:** 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 **Selected population:** Age 40-69y; BMI	**Method of allocation**: The (NEOUCOM) Office of Biostatistics prepared the ordered randomisation tickets using permuted blocks of 10. A separate randomisation sequence was used for each primary care practice site. **Intervention 1 description**: Augmented usual care • 24 month intervention • Calorie restriction by reduced fat, eating more fruits & vegetables and smaller portions. • Recommended increase in usual everyday physical activity. • Individual diet and exercise plan provided by a dietitian with training in exercise physiology • Had assessment and met dietitan every 6 months for 10 minutes • Advised to discuss lipid and BP values with primary care physician **Intervention 2 description**: TM-CD: Transtheoretical model and some elements of chronic disease • As Intervention 1, but in addition: • Weight Loss advisors (WLA) trained to apply processes of change that corresponded to the patient's Stages of change profile. • Monthly telephone calls with WLA (followed telephone protocol) • Sent written material matching their most recent Stages of Change profile • Additional material on local walks and menu suggestions available on request **Sample sizes:** Total n = 665	**Published data and information from the author** **Outcome calculation method** At 12 months, authors report ITT analysis with multiple covariates to impute missing values. This data was obtained from the author and used to compute BOCF, in place of complete case data. Reviewers calculated SDs from the ITT SEs BOCF was reported by authors at 24 months **Follow up periods:** 6, 12, 18 and 24 months	**BOCF weight change**: **12 months** Intervention 1 : -0.79 (5.5) Intervention 2: -1.28 (5.7) **24 months** Intervention 1 : -0.13 (6.0) Intervention 2: -0.32 (5.7) **Secondary outcomes:** Waist circumference change: NR BMI Change: NR *Adverse events:* NR **Attrition details:** **12 months:** Intervention 1 Total: 85.4% FU Intervention 2	**Source of funding:** Agency for Healthcare Research and Quality and the National Institute of Diabetes, Digestive, and Kidney Diseases Grants and by consecutive Nutrition and Exercise Studies grants (1998 to 2002) from the Summa Health System Foundation

study: Weight loss **Study design:** RCT **Quality score:** ++ **External validity score:** ++	>27; or Waist:Hip >0.95 for men and >0.8 for women **Excluded population/s:** Those with no access to a telephone; difficulty understanding eighth-grade level spoken or written English; pregnancy; lactation; <6 months postpartum; or use of a wheel chair for mobility. Primary care physicians excluded high-risk patients with severe heart or lung disease. **Setting:** Face-to Face and telephone	Intervention 1 n = 336 Intervention 2 n = 329 12 months Total n = 579 Intervention 1 n = 287 Intervention 2 n = 292 24 months Total n = 537 Intervention 1 n = 266 Intervention 2 n = 271 **Baseline characteristics:** Groups were similar at study outset		Total: 88.8% FU **24 months:** Intervention 1 Total: 79.2% FU Intervention 2 Total: 82.4% FU	

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Mensink et al. **Year:** 2003 **Citation:** Mensink M., Blaak E. E., Corpeleijn, E., Saris W. H., de Bruin T. W., Feskens, E. J. 2003. Lifestyle interventions according to general recommendations improves glucose tolerance. Obesity Research, 11, (12) 1588-1596 **Aim of study:** Improved glucose tolerance in subjects with high risk for developing type 2 diabetes **Study design:** RCT **Quality score:** +* **External validity score:** ++	**Source population/s:** Netherlands. *Across whole study:* 43% female, mean age 57, ethnicity and SES data NR *For each arm*: baseline weight intervention 86 (14.1), control 83.7 (11.5), baseline BMI intervention 29.8 (3.7), control 29.3 (3.1), baseline weight circumference intervention 102.4 (11.1), control 102.3 (8.4) ** **Eligible population:** Selected from existing cohort in Maastricht area **Selected population:** Aged >40, family history of diabetes or BMI ≥25, mean 2 hour glucose concentration of two OGTTs between 7.8 and 12.5, with fasting glucose concentration <7.8 mM **Excluded population/s:** Previously diagnosed diabetes (other than gestational), medication known to interfere with glucose tolerance, participation in regular vigorous	**Method of allocation**: Randomisation and allocation methods **Intervention (1) description**: • Fat and carbohydrate restriction based on Dutch Nutrition Council guidelines. If participants did not lose 5-7% weight by year 2, given 'mild' energy restriction diet. • Recommended and supervised, moderate intensity physical activity for 30 minutes 5 days a week • Individual in person counselling, supervised exercise in group form • Trained dietitian and exercise trainers • 8 behavioural sessions over 2 years, length not specified. 208 supervised physical activity sessions of 30 minutes each over 2 years. **Control description:** Oral and written information (2): at baseline, oral and written information on diet, weight loss, and physical activity. **Sample sizes (baseline):** Total n = 114 Intervention n = 55 Control n = 59 **At 12 months:**	**Published information only** **Outcome calculation method** Reviewer calculated SD from SE provided **Follow up periods:** 12 and 24 months	**BOCF weight change**: 12 months intervention -2.25 (3.51), control -0.2 (3.1); 24 months intervention -1.8 (3.9), control -0.1 (3.2) **Complete case weight change:** 12 months intervention -3.1 (3.8), control -0.2 (3.5); 24 months intervention -2.4 (4.4), control -0.1 (3.5) **Secondary outcomes:** At 12 months, complete case change in waist circumference (cm) intervention -3.8 (3.8), control -1.2 (4.2), at 24 months intervention -1.9 (4.4), control -0.6 (4.2). Complete case change in BMI at 12 months intervention -1.1 (1.3), control -0.1 (1.4); at 24 months intervention -0.8 (1.3), control 0.00 (1.4)	**Source of funding:** Diabetes Research Foundation and Netherlands Organization for Scientific Research **Other notes:** *Quality score downgraded by one as allocation methods unclear, unlikely to affect results but it is a possibility **Being overweight/ obese was not an inclusion criteria, but included as 93% intervention and 91% control BMI >25. *See also:* Mensink, M., et al. 2003. Study on lifestyle-intervention and impaired glucose tolerance Maastricht (SLIM): design and screening results. Diabetes Research and

	exercise or intensive weight reduction programme in year prior to study start, any chronic disease that 'hampered participation' in lifestyle intervention, improbability of 5-yr survival Percentage screened who were enrolled NR **Setting:** face-to-face, setting NR	Total n = 88 Intervention n = 40 Control n = 48 **At 24 months:** Total n = 88 Intervention n = 40 Control n = 48 **Baseline comparisons**: Groups similar at study outset		*Adverse effects:* Authors state no serious adverse effects were observed. No other details reported. **Attrition details:** 77% followed up at 12 months overall: 73% intervention, 81% control. 18% missing; 4% medical.	Clinical Practice, 61, (1) 49-58
Study details	**Population and setting**	**Method of allocation to intervention/control**	**Outcomes and methods of analysis**	**Results**	**Notes**
Authors: Micco et al **Year:** 2007 **Citation:** **Aim of study:** Micco, N., Gold, B., Buzzell, P., Leonard, H., Pintauro, S., Harvey-Berino, J. 2007. Minimal in-person support as an adjunct to internet obesity treatment. Annals of Behavioral Medicine, 33, (1) 49-56. **Study design:** RCT **Quality score:** +* **External validity score:** +**	**Source population/s:** USA; *Across whole study:* 83% female, mean age 47, 1% minority group, 93% at least some college. *For each arm*: baseline weight intervention 1: 92.0 (15.7), intervention 2: 86.1 (12.8), baseline BMI intervention 1: 32.3 (3.9), intervention 2: 31.0 (4.1), baseline weight circumference NR **Eligible population:** Local newspaper advertisements. Directed to online application interface and then those eligible phones for further screening **Selected population:** 18 years or older, BMI 25 to 39.9, computer (with at least 64 MB RAM; CD drive, 350 MHz processor, 33 kbps connection speed) **Excluded population/s:** History of major medical or psychiatric conditions, recent changes in medications known to affect weight, smoking or having quit in	**Method of allocation**: Randomisation and allocation methods NR **Intervention 1 description**: • VTrim • Energy restriction, 1200-2100 kcal day based on baseline body weight (baseline weight in lb x 12 – 1000 kcal) • Recommended walking or stationery biking, 5 days a week, gradual to 1,000 kcal/week • Online only, delivered in group • Delivered by registered dietitian and masters level graduate student • 39 sessions over 12 months (weekly for first 6m, then biweekly), session length NR **Intervention 2 description:** • VTrim plus personal contact • Exactly as per above, but each month one of the scheduled sessions took place in person (group) **Control description:** no control arm **Sample sizes (baseline):** Total n = 123 Intervention 1 n = 62 Intervention 2 n = 63 **At 12 months:**	**Published data only** plus information from www.vtrimonline.com **Outcome calculation method** Standard methods used **Follow up periods:** 6 and 12 months	**BOCF weight change**: At 12 months intervention 1: -5.1 (7.1), intervention: 2 -3.5 (5.1) **Complete case weight change:** At 12 months intervention 1: -8.1 (7.5), intervention: 2 -5.6 (5.5) **Secondary outcomes:** Change in waist circumference and BMI NR *Adverse effects:* NR **Attrition details:** 63% followed up at 12m , 63% intervention 1, 62% intervention 2. Reasons for attrition NR	**Source of funding:** USDA Hatch Act funds and National Institute of Diabetes and Digestive and Kidney Diseases *quality score downgraded as randomisation and allocation methods NR **external validity score downgraded as required computer meeting a number of specifications

	last year, current planned or recent pregnancy, medical condition prohibiting exercise, schedule that would prohibit or restrict attendance at designated weekly meeting Percentage screened who were enrolled NR **Setting:** Online and in person, setting for in person meetings NR	Total n = 77 Intervention 1 n = 39 Intervention 2 n = 38 **Baseline comparison:** BMI and weight higher in internet only group			
Study details	**Population and setting**	**Intervention and comparators**	**Outcomes and methods of analysis**	**Results**	**Notes**
Authors: Morgan et al. **Year:** 2011 **Citation:** Morgan, P.J., Lubans, D.R., Collins, C.E., Warren, J.M., & Callister, R. 2011. 12-month outcomes and process evaluation of the SHED-IT RCT: an internet-based weight loss program targeting men. Obesity, 19, (1) 142-151 **Aim of study:** Weight loss in men **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** Australia *Across whole study:* 0% female, mean age 36, ethnicity NR, 52% in high or highest SES bracket (7-10 on scale of 1-10) *For each arm*: baseline weight (kg) intervention 99.1 (12.2), control 99.2 (13.7); baseline BMI intervention 30.6 (2.7), control 30.5 (3.0), baseline weight circumference (cm) intervention 102.8 (6.8), control 103.4 (8.3) **Eligible population:** university staff and students recruited through university notice boards and website **Selected population:** male university staff and students, BMI 25-37, aged 18-60 years **Excluded population/s:** history of major medical problems (eg heart disease) in past 5 years, diabetes, orthopaedic, or joint problems that would be a barrier to physical activity, recent weight loss of ≥4.5 kg, taking medications that might	**Method of allocation**: Computer-based random allocation sequence, randomisation completed by research assistant not involved in project and allocation sequence was 'concealed.' **Intervention description**: • Reduced energy diet, deficit of at least 480 kcal/day less than personal daily energy expenditure (calculated using Harris Benedict equation and personalized activity factor) • Recommended moderate to high intensity physical activity for 30 minutes a day • 1 session face-to-face group, remaining contacts individual e-mail • Male researcher, training not specified • 8 sessions over 3 months. First session 75 minutes, all other contacts e-mail-based. • Free access to Calorie King website **Control description:** Information session (2): identical information session to that in intervention, without online component description, plus program booklet **Sample sizes (baseline):**	**Published and unpublished data** Further detail on intervention components provided via email from author **Outcome calculation method** Authors report ITT analysis only, including all randomised participants (using linear mixed models, results adjusted for effects of significant covariates). Reviewers used ITT in place of complete case data to calculate BOCF using standard methods. Reviewers calculated SDs from 95% CIs provided, using t values to derive denominators due to small sample sizes. **Follow up periods:** 3, 6 and 12 months	**BOCF weight change**: (kg) at 12 months intervention -4.1 (5.4), control -2.0 (4.3) ***ITT analysis (not complete case) weight change:*** (kg) at 12 months intervention -5.3 (5.6), control -3.1 (5.0) **Secondary outcomes:** *ITT analysis (not complete case)* change in waist circumference (cm) intervention -5.8 (5.3), control -3.8 (4.8); change in BMI intervention -1.7 (1.7), control -0.9 (1.6) *Adverse effects:* NR **Attrition details:** 71% followed up at 12m overall: 76% intervention, 65% control. 3% unavoidable, 26% missing.	**Source of funding:** University of Newcastle Strategic Pilot grant and The Men's Health Golf Day **Other notes:** Additional intervention detail provided by authors. *External validity score downgraded due to requirement of access to a computer with e-mail and internet facilities. 48% of those screened were enrolled. *See also:* Morgan, P.J., et al. 2010. The SHED-IT community trial study protocol: a randomised controlled trial of weight loss programs for overweight and obese men. Bmc Public Health, 10, 701

	affect body weight. Access to a computer with email and Internet facilities. 48% screened subsequently enrolled **Setting:** group and online, setting for group session NR	Total n = 65 Intervention n = 34 Control n = 31 **At 12 months:** Total n = 46 Intervention n = 26 Control n = 20 **Baseline comparisons**: Groups similar at study outset			Morgan, P.J., et al. 2009. The SHED-IT randomised controlled trial: evaluation of an Internet-based weight-loss program for men. Obesity, 17, (11) 2025-2032

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Munsch et al **Year:** 2003 **Citation:** Munsch S, Biedert E et al. Evaluation of a lifestyle change programme for the treatment of obesity in general practice. *Swiss Med Wkly* 2003;133: 148-154. **Aim of study:** Weight loss **Study design:** **Quality score:** -* **External validity score:** ++	**Source population/s:** Switzerland *Across whole study:* Female: 75% Age: 46y Ethnicity: NR SES/Education: NR *For each arm* (mean, SD): Weight (kg) Intervention 1: 96.8 (17.1) Intervention 2: 106.8 (26.1) Control: 86.3 (6.4) BMI (kg/m^2) Intervention 1: 36.2 (6.5) Intervention 2: 38.5 (7.5) Control: 32.6 (1.8) Waist circumference (cm): NR **Eligible population:** Patients were recruited from a clinical centre, GP practices and via a newspaper advert **Selected population:** 1) BMI >30kg/m^2 2) GP physical exam **Excluded population/s:** Severe mental disorders, insulin-dependent diabetes,	**Method of allocation**: NR **Intervention (1) description**: • GP BASEL • Balanced diet with fat intake target of 20g per day. • 15 mins of exercise daily with examples swimming, walking and incorporation into daily life. • Group • Delivered by a General Practitioner who was trained by a psychologist and dietitian in two 4 hour sessions. • 16 weekly sessions of 90 minutes over 16 weeks **Intervention 2 description:** • Clinic BASEL • Balanced diet with fat intake target of 20g per day. • 15 mins of exercise daily with examples swimming, walking and incorporation into daily life. • Group • Delivered by a clinic tutor who was trained by a psychologist and dietitian in two 4 hour sessions. • 16 weekly sessions of 90 minutes for **Control description:** Usual care (4): received non-specific comments about general measures to lose weight from GP. Authors write "No specific technique, tools or written material was used." **Sample sizes (baseline):** Total n = 122 Intervention 1 n = 53 Intervention2 n= 52	**Published or unpublished** Published data was supplemented with intervention details provided by the authors **Outcome calculation method** Complete cases converted to BOCF **Follow up periods:** 16 weeks and 12 months	**BOCF weight change (kg)**: 12 months Intervention 1: -3.6 (7.9) Intervention2: -0.9 (6.9) Control : -0.2 (2.7) **Complete case weight change:** Intervention 1: -4.7 (8.7) Intervention 2: -2.9 (12.5) Control: -0.4 (4.0) **Secondary outcomes: 12 months** **BMI change:** Intervention1: -1.8 (3.3) Intervention 2: -0.9 (3.6) Control: -0.2 (1.2) **Waist circumference:**	**Source of funding:** Unrestricted grant from Knoll AG, Liestal, Switzerland **Other notes:** *Quality score downgraded as randomisation process not defined; Groups were not similar at outset; and imbalance in dropouts between arms not accounted for. Quality of life variables available

	hypothyroidism, terminal diseases **Setting:** In person at GP or health clinic	Control n= 17 **At 12 months:** Total n = 65 Intervention 1 n = 41 Intervention 2 n = 16 Control n= 8 **Baseline comparisons**: Groups similar at study outset		NR *Adverse effects:* NR **Attrition details:** No breakdown	

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Nanchahal et al **Year:** 2012 **Citation:** Nanchahal K, Power T, Holdsworth E, et al. A pragmatic randomised controlled trial in primary care of the Camden weight loss (CAMWEL) programme. BMJ Open 2012;2:e000793 **Aim of study:** Weight-loss **Study design:** **Quality score:** ++ **External validity score:** ++	**Source population/s:** UK *Across whole study:* Female: 72%; Age: 49y Minority: 29%; Education: 12% had no qualification *For each arm* (mean, SD): Weight: Intervention 91 (18); Control 94 (18) BMI: Intervention 33.0 (5.4); Control: 33.9 (5.6) Waist circumference: Intervention 106 (13); Control 108 (13) **Eligible population:** Population recruited by letter (and some text messages) from GP and personal referral from GP in consultations **Selected population:** Age 18 years and above, BMI >25 kg/m^2, attending a participating practice and willing to attend visits with a CAMWEL advisor over 12 months. **Excluded population/s:** Pregnancy or lactation, diagnosis of renal failure, use of a pacemaker, recent diagnosis of cancer or participation in another weight management	**Method of allocation**: Computer generated randomisation **Intervention description**: • Calorie reduced diet based on the Eatwell plate. energy prescription set to achieve 1kg/week weight-loss. • Recommended exercise focussing on walking with exercise diaries provided. • Individual, in person delivery • Delivered by health trainers who are lay people trained in behaviour change counselling. • The advisors received initial training over 2 days and further meetings with the research team every 3 to 4 months. • 14, 30 minute sessions in total over 36 weeks. Sessions were every fortnight for the first 12 weeks, every 3 weeks for 12 weeks and finally monthly for the next 12 weeks **Control description:** Usual care (1) group who received a British Health Foundation booklet at baseline **Sample sizes (baseline):** Total n = 381 Intervention n = 191	**Published or unpublished** Published data only **Outcome calculation method** Standard BOCF calculation **Follow up periods:** 6,12 months	**BOCF weight change**: Intervention: -1.3 (4.3) Control: -1.0 (4.5) **Complete case weight change:** Intervention:-2.4 (5.6 Control: -1.3 (5.1) **Secondary outcomes:** Waist circumference (cm) Intervention: -3.37 (8) Control: -1.49 (6) BMI (kg/m^2) Intervention: -0.8 (2.0) Control: -0.5 (1.9) *Adverse effects:* NR **Attrition details:** Total: Intervention Unavoidable 3% Missing 42% Medical 1% Control Unavoidable 1%	**Source of funding:** Camden PCT

	study. **Setting:** In person at primary care centre	Control n= 190 **At 12 months:** Total n = 117 Intervention n = 103 Control n= 114 Groups similar at study outset		Avoidable 39%	

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Patrick **Year:** 2011 **Citation:** Patrick, K., Calfas, K.J., Norman, G.J., Rosenberg, D., Zabinski, M.F., Sallis, J.F., Rock, C.L., & Dillon, L.W. 2011. Outcomes of a 12-month web-based intervention for overweight and obese men. Annals of Behavioral Medicine, 42, (3) 391-401 **Aim of study:** Weight Loss **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** USA *Across whole study:* 0% female Age 44y 29% minority group SES data: College graduate and above 63.1% *For each arm* (mean, SD): Weight (kg) Intervention: 104.7 (15.3) Control: 104.6 (15.3) BMI (kg/m^2) Intervention: 34.2 (4.2) Control: 34.3 (4.0) Waist circumference (cm) Intervention: 113.7 (11) Control: 112.9 (11.1) **Eligible population:** Printed advertisements to local newspapers, radio advertisements and a TV news story featuring our study, and flyers **Selected population:** 1) Age 25-55y 2) BMI $\geq$25kg/m^2 **Excluded population/s:** NR **Setting:** Web based	**Method of allocation**: Fixed allocation and randomisation by computer **Intervention (1) description**: • Balanced diet with emphasis on increasing fruit and vegetable intake (5-9 servings); 3+ servings of whole grains; and <20g saturated fat. • Recommendation of 10,000 steps on 5 days per week and strength training on 2 days per week. • Group based web sessions with option of individual email support • Delivered by a dietitian, exercise trainer and psychologist • Weekly sessions for 12 months (52 sessions) **Control description:** (1) Access to alternate website with general health information, authors state not likely to lead to changes in diet or physical activity **Sample sizes (baseline):** Total n = 441 Intervention n = 224 Control n= 217 **At 12 months:** Total n = 309 Intervention n = 154 Control n= 155 **Baseline comparisons**: Difference in age with control group younger (44.9 (7.8) v 42.8 (8.0)). No other differences.	**Published data only** **Outcome calculation method** Authors report BOCF calculations only. Complete case data not available **Follow up periods:** 12 months	**BOCF weight change**: 12 months Intervention: -0.9 (7.7) Control: -0.2 (5.7) *Complete case weight change data NR.* **Secondary outcomes:** 12 months, *BOCF only, complete case data NR.* BOCF BMI change Intervention = -0.4 (2.1) Control = -0.1 (1.5) BOCF waist circumference change Intervention = -1.6 (5.6) Control = -1.3 (4.3) **Adverse events :** NR **Attrition details:** **12 months** 70% Follow up total, 69% intervention, 71% control. Reasons for attrition: intervention Unavoidable: 2% Missing: 30%; control Unavoidable: 1% Missing: 29%	**Source of funding:** NIH/NCI **Other notes:** *External validity score downgraded as only 44% of those contacted enrolled in the study

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Penn et al **Year:** 2009 **Citation:** Penn, L., White, M., Oldroyd, J., Walker, M., Alberti, K.G., & Mathers, J.C. 2009. Prevention of type 2 diabetes in adults with impaired glucose tolerance: the European Diabetes Prevention RCT in Newcastle upon Tyne, UK. Bmc Public Health, 9, 342 **Aim of study:** diabetes prevention, **Study design:** 2-arm RCT **Quality score:** +* **External validity score:** ++	**Source population/s:** UK percentage female: 60% mean age: 57 years percentage in all minority groups: NR SES: Manual workers 48% Baseline weight: Intervention:93 (16) Control: 91 (13) Baseline BMI Intervention: 34.1 (5.5) Control 33.5 (4.6) Baseline waist circumference Intervention: 105 (11) Control: 104 (9) **Eligible population:** Population approached for recruitment/recruitment methods: GPs wrote to people over 40 years with a BMI>25 and this population were tested twice for impaired glucose tolerance **Selected population:** Inclusion criteria: IGT, >40 years, BMI>25 **Excluded population/s:** illness that would make PA impossible, on a special diet for medical reasons 96% of all volunteers who met inclusion criteria were enrolled but many people were not screened for IGT **Setting:** Mode of delivery: in person, in hospital intervention.	**Method of allocation**: Randomisation stratified by age, sex, and 2-hour plasma glucose level. Allocation concealment not described though likely **Intervention description**: • Low fat weight loss diet, no specific target • Recommended accumulation of 30 minutes of PA moderate intensity 3-6 METS/day • Mainly individual with few group cook and eat sessions. • Delivered by dietitian and physiotherapist • 30 minutes/session with physio and dietitian combined. Seen baseline, 2 weeks, then monthly until 3 months then every 3 months i.e. 8x30 mins to 12 months and 20 sessions total • Based on motivational interviewing **Control description:** (2) single session of advice from dietitian and physio (we assume) and leaflets **Sample sizes (baseline):** Total n =102 Intervention n=51 Control n=51 **At 12 months (or closest point):** Total n =82 (80%) Intervention n = 39 (76%) Control n= 43 (84%) **At longest follow-up (as per results column):** 48 months (60 months also reported but follow up incomplete) Total n = 56 (55%) Intervention n = 28 (55%) Control n= 28 (55%)	**Published and unpublished data** Authors sent unpublished data on weight **Outcome calculation method** Standard from completer data **Follow up periods:** 12, 24, 36, 48 and 60 months. Very small numbers followed up in time for 60 month follow-up (as dependent on time of study enrolment), hence data at 48 months used as longest follow-up.	**BOCF weight change**: At 12 months Intervention: -2.0 (4.1) Control: +0.1 (3.1) At 48 months Intervention: -1.3 (4.6) Control: -1.0 (4.7) **Complete case weight change:** At 12 months Intervention: -2.4 (4.4) Control: 0.1 (3.5) At 48 months Intervention: -2.3 (6.1) Control: - 1.8 (6.3) **Secondary outcomes:** Waist circumference: NR Change in BMI: NR Adverse effects: NR **Attrition details:** At 12 months Intervention: unavoidable 2 (4%), avoidable 9 (18%), medical 0 Control unavoidable 4 (8%), avoidable 4 (8%), medical 0 At 48 months Intervention: unavoidable 5 (10%), avoidable 20 (40%), medical 5 (10%) Control unavoidable 5 (12%), avoidable 17 (24%), medical 7 (14%)	**Source of funding:** Wellcome Trust (medical charity) **Other notes:** *Downgraded because no clear evidence of allocation concealment Unpublished data from authors contributes to this.

		Groups similar at study outset			
Study details	**Population and setting**	**Intervention and comparators**	**Outcomes and methods of analysis**	**Results**	**Notes**
Authors: Rejeski et al. **Year:** 2011 **Citation:** Rejeski, W.J., Brubaker, P.H., Goff, D.C., Jr., Bearon, L.B., McClelland, J.W., Perri, M.G., & Ambrosius, W.T. 2011. Translating weight loss and physical activity programs into the community to preserve mobility in older, obese adults in poor cardiovascular health. Archives of Internal Medicine, 171, (10) 880-886 **Aim of study:** Determine effects of physical activity and weight loss intervention on mobility in overweight or obese adults	**Source population/s:** USA *Across whole study:* 67% female, mean age 67, 15% minority group, 50% had at least 4 years of college education *For each arm*: baseline weight intervention 92.8 (16.1), physical activity only (PA) 91.7 (13.1), control 91.2 (15.1); baseline BMI intervention 33.1 (4.1), PA 32.8 (3.9), control 32.6 (3.5); baseline weight circumference NR **Eligible population:** Newspaper advertisements and direct mailings in local area **Selected population:** Ambulatory, community-dwelling, older adults 60-79 years old. Less than 60 mins/wk moderate PA. BMI >28 and <40. Evidence of cardiovascular disease or diagnosis of the metabolic syndrome. Self-reported mobility limitation. **Excluded population/s:** Bipolar or schizophrenia, unstable angina, symptomatic congestive heart failure, exercise induced complex ventricular arrhythmias, resting BP >160/100, diagnosis of systemic diseases that preclude safely participating in	**Method of allocation**: Randomisation and allocation methods NR, permuted block randomisation used. **Intervention (1) description**: • Reduced energy diet (1200-1500 kcal/day if baseline weight <113.4kg, 1500-1800 kcal/day if ≥113.4 kg) • Recommended and supervised, moderate intensity physical activity, at least 5 days/week, 30-45 minutes per session. • Group and individual, in person and via telephone • "Professional interventionists" (degree in health sciences, trained by study investigators) and Cooperative Extension Agents (Family and Consumer Science educators, field faculty from university, degrees in home economics and/or nutrition education) • 48 sessions of 10-90 minutes over 18 months • Months 1-6 most intensive, months 7-18 'maintenance' but weight loss continued unless BMI <20 **Control description:** Two control arms: 1. Physical activity only (PA) (5): as above, but no Cooperative Extension Agents, no diet component 2. Successful aging education control arm (3): 18 sessions over 18 months covering general topics related to aging and health. Physical activity and nutrition for aging addressed, but not focus. **Sample sizes (baseline):**	**Published data only** **Outcome calculation method** Authors do not provide weight change data, reviewer calculated based on complete case compared with baseline, but not a true cohort due to dropouts. N in each arm unclear for weight at follow-up points, reviewer used N of those who completed 400 metre walk test. BOCF calculated from these figures. **Follow up periods:** 6, 12 and 18 months, though weight data not provided at 12 months.	**BOCF weight change**: at 18 months intervention -6.3 (7.7), PA -0.7 (6.3), control -0.8 (7.2) **Complete case weight change:** at 18 months intervention -7.1 (7.8), PA -0.8 (6.9), control -0.9 (7.7) **Secondary outcomes:** Complete case change in waist circumference and BMI NR *Adverse effects:* Serious adverse effects possibly or definitely related to study treatment: intervention 6, PA 3, control 0. More AEs in total in intervention and PA arms than in control (35, 34 and 18, respectively). **Attrition details:** 86% followed up at 18 months (for walk test) overall: 96% intervention, 86% physical activity, 90% control. 1% unavoidable; 11% missing; 1% medical (unable to complete walk test).	**Source of funding:** National Heart, Lung and Blood Institute; National Institutes for Aging; General Clinical Research Center **Other notes:** *Quality score downgraded as randomisation and allocation concealment methods not detailed, and as authors measured, but did not report, weight at 12 months ** External validity score downgraded as less than half of those screened were enrolled (44%), suggesting limited external validity of selected population

Study design: RCT **Quality score:** +* **External validity score:** +**	intervention, fasting blood glucose >140mg/dl, type 1 DM, type 2 DM with insulin therapy, active treatment for cancer, clinically significant visual or hearing impairment, dementia, delirium, impaired cognitive function, participation in another medical intervention study, more than 21 alcoholic drinks/wk, inability to walk unassisted, inability to speak or read English. 44% of those screened were enrolled. **Setting:** face-to-face and phone, setting for face-to-face not specified	Total n = 288 Intervention n = 98 Physical activity n = 97 Control n= 93 **At 18 months:** Total n = 261 Intervention n = 94 Physical activity n = 83 Control n= 84 **Baseline comparisons**: Groups similar at study outset			

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Rock et al. **Year:** 2010 **Citation:** Rock, C.L., Flatt, S.W., Sherwood, N.E., Karanja, N., Pakiz, B., & Thomson, C.A. 2010. Effect of a free prepared meal and incentivized weight loss program on weight loss and weight loss maintenance in obese and overweight women: a randomised controlled trial. JAMA, 304, (16) 1803-1810 **Aim of study:** Weight loss **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** USA *Across whole study:* 100% female, mean age 44, 26% minority group, 45% college graduate or higher *For each arm*: baseline weight (kg) centre-based (CB) 92.2, telephone-based (TB) 92.9 (11.8), control 91.0 (10.5); baseline BMI CB 33.8 (3.6), TB 33.8 (3.3), control 34.0 (3.2); baseline weight circumference (cm) CB 108.9 (8.9), TB 108.5 (10.1), control 108.3 (9.1) **Eligible population:** List serves and flyers distributed at universities and health maintenance organization (HMO) **Selected population:** Women 18 years or older, BMI 25-40, minimum 15kg over ideal weight as defined by 1983 Metropolitan Life Insurance Tables **Excluded population/s:** Pregnant or breastfeeding or planning to become pregnant in next 2 years, eating disorders, food allergies or intolerances, current active involvement in another diet intervention study or organized weight loss program, history or	**Method of allocation**: Randomisation sequence generated by study statistician, centralized web-based allocation **Intervention 1 description (CB)**: • Jenny Craig, centre-based • Low fat and reduced energy (1200-2000 kcal/day, aiming for deficit of 500-1000 kcal/day). Includes free, pre-packaged meals. • Recommended physical activity, intensity not specified, 5 or more days a week for 30 minutes a session. CDs and DVDs provided for physical activity support • Individual, in person, with follow-up via phone, email, and website message board • Delivered by trained lay person (certified Jenny Craig Trainer) • 104 sessions ("brief," length NR), plus follow-up by phone, email, and message board (frequency NR), over 24 months **Intervention 2 description (TB):** • Jenny Craig, telephone-based • As per CB, but no in person interaction – telephone, email and website message board only **Control description:** Repeated weight loss contact (4): consultation with research staff dietetics professional plus written information at baseline and 6 months, plus monthly check-ins by email or phone.	**Published data only** Data from website used for additional information on intervention (see See www.jennycraig.com/ how-it-works/science-weight-loss/) **Outcome calculation method** Reviewer calculated SD from 95% CI given for anthropometric data. Authors report ITT analysis using BOCF but slight discrepancies (SD only) with reviewers BOCF calculations based on complete case data. Reviewers BOCF calculations presented here. **Follow up periods:** 6, 12 and 24 months	**BOCF weight change**: at 12 months CB -10.1 (7.3), TB -8.5 (8.0), control -2.5 (6.2); at 24 months CB -7.4 (8.4), TB -6.3 (9.3), control -1.9 (7.2) **Complete case weight change:** at 12 months CB -10.6 (7.1), TB -8.9 (8.0), control -2.7 (6.4); at 24 months CB -8.2 (8.5), TB -6.7 (9.5), control -2.1 (7.5) **Secondary outcomes:** Complete case change in waist circumference and BMI NR *Adverse effects:* NR **Attrition details:** 94% followed up at 12 months overall: 95% CB, 96% TB, 91% control. Over course of study (not broken down by follow-up point) at 24 months: 0% unavoidable; 5% missing; 2% medical.	**Source of funding:** Jenny Craig Inc **Other notes:** Additional information on intervention extracted from Jenny Craig website.

	presence of significant psychiatric disorder or any other condition that would interfere with participation 78% of those screened were enrolled **Setting:** CB face-to-face, phone, email, website. TB phone, email, website. Setting "conveniently located" centres, further details NR.	**Sample sizes (baseline):** Total n = 442 CB n = 167 (originally 169, 2 excluded post randomisation) TB n = 164 Control n = 111 (originally 113, 2 excluded post randomisation) **At 12 months:** Total n = 417 CB n = 159 TB n = 157 Control n = 101 **At 24 months:** Total n = 442 CB n = 151 TB n = 153 Control n = 103 **Baseline comparisons**: Groups similar at study outset			

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Ross et al **Year:** 2012 **Citation:** Ross, R., Lam, M., Blair, S.N., Church, T.S., Godwin, M., Hotz, S.B., Johnson, A., Katzmarzyk, P.T., Levesque, L., & MacDonald, S. 2012. Trial of prevention and reduction of obesity through active living in clinical settings: a randomised controlled trial. Archives of Internal Medicine, 172, (5) 414-424 **Aim of study:** Weight loss **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** Canada *Across whole study:* Female 71% Age 52 Ethnicity and SES data NR *For each arm*: Weight Intervention: 91 (14) Control: 89 (14) BMI Intervention: 32.6 (4.1) Control: 32.0 (4.2) Waist circumference Intervention: 107 (11) Control: 106 (11) **Eligible population:** Population approached for recruitment/recruitment methods **Selected population:** 1) Age 25-75y 2) BMI 25-39.9 3) Waist circumference >102cm in men or >88cm in women 4) Sedentary (planned activity for purpose of health <=1d/wk); 5) Weight stable (w/in 2kg) for 6m before study start **Excluded population/s:** Significant cardiovascular disease; insulin dependent DM, pregnancy or intention to be pregnant in next 2years, physical impairment, plan to move from area, participating	**Method of allocation**: Computer generated randomisation **Intervention description**: • Mediterranean diet – increase in whole grains, fruits, veg, legumes, nuts, seeds, health fats and low fat dairy products • Recommended moderate exercise for 45-60min daily • Individual, in person sessions • Delivered by Health educators with a degree in kinesiology and training in behavioural counselling. • 33 sessions over a 24 month intervention. Eight sessions in the first 6 weeks. Every fortnight until 6 months then monthly till 24 months. **Control description:** (2) usual care – general advice from physicians on merits of physical activity as strategy for obesity reduction **Sample sizes:** Total n = 490 Intervention n = 249 Control n= 241 **12 months** Total n = 415 Intervention n = 207 Control n = 208 **24 months** Total n = 396 Intervention n = 190 Control n = 206 Groups similar at study outset	**Published data only** **Outcome calculation method** Complete case data not available. Authors report ITT analysis using linear mixed models with multiple covariates to impute missing values. Reviewers used ITT values to compute BOCF, in place of complete case data. Reviewers calculated SDs from the ITT SEs given using baseline n. **Follow up periods:** All follow up periods	**BOCF weight change**: 12 months Intervention: -2.0 (4.4) Control: -0.8 (5.8) 24 months Intervention: -0.9 (5.5) Control: -0.5 (5.7) **Multiple imputation weight change** *(Complete case not available)***:** **12 months** Intervention: -2.4 (4.7) Control: -0.9 (6.2) **24 months** Intervention: -1.2 (6.3) Control: -0.6 (6.2) **Secondary outcomes:** **12 months** *(Using multiple imputation data, complete case not available)***:** Waist circumference change Intervention: -2.5 (6.3), Control: -0.9 (6.2) BMI Change Intervention: -0.84 (2.1), Control: -0.27 (2.0) *Adverse events:* Intervention:300 musculoskeletal injuries during exercise Control: 311 musculoskeletal injuries during exercise No differences in other	**Source of funding:** Canadian Institute of Health *See also:* Ross, R., Blair, S.N., Godwin, M., Hotz, S., Katzmarzyk, P.T., Lam, M., Lévesque, L., & MacDonald, S. 2009. Prevention and Reduction of Obesity through Active Living (PROACTIVE): rationale, design and methods. British Journal of Sports Medicine, 43, (1) 57-63

	in another research study, clinically judged unsuitable for participation or adherence 19% of those screened were excluded or withdrew before randomisation **Setting:** In person			non-study related adverse events reported. **Attrition details:** 12 months 84% followed up overall, Intervention 83%, control 86% **Reasons for attrition at 24 months** Intervention Missing: 28% Medical: 3% Unavoidable: 0.5% Control Missing: 14% Medical: 2% Unavoidable: 1%	

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Saito et al **Year:** 2011 **Citation:** Saito, T., Watanabe, M., Nishida, J., Izumi, T., Omura, M., Takagi, T., Fukunaga, R., Bandai, Y., Tajima, N., Nakamura, Y., Ito, M., & Zensharen Study for Prevention of Lifestyle Diseases Group 2011. Lifestyle modification and prevention of type 2 diabetes in overweight Japanese with impaired fasting glucose levels: a randomised controlled trial. Archives of Internal Medicine, 171, (15) 1352-1360 **Aim of study:** Diabetes prevention **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** Japan *Across whole study:* 29% female, mean age 49, 0% minority group, SES data NR. *For each arm*: baseline weight intervention 1: 74.1 (10.4), intervention 2: 74.8 (10.7); baseline BMI intervention 1: 26.9 (2.6), intervention 2: 27.1 (2.6); baseline weight circumference NR **Eligible population:** Patients attending basic statutory health checkups at participating study centres **Selected population:** 30-60 years old, fasting plasma glucose 100-125 mg/dl, BMI at least 24.0, 75g OGTT after overnight fasting 2hr plasma glucose less than 200 mg/dl **Excluded population/s:** Diagnosed diabetes or receiving treatment for diabetes, history of ischemic heart disease, stroke, chronic hepatitis, liver cirrhosis, chronic pancreatitis, chronic nephritis, pituitary disease, thyroid disease, adrenal gland disease, mental illness, gastrectomy, or advanced malignant tumour, receiving corticosteroid or thyroid hormone medication, being judged by responsible physician of local study centre as unfit to participate (other serious disease) Percentage screened who were enrolled NR **Setting:** In-person, in clinic	**Method of allocation**: Randomisation via computer generated list, central allocation via telephone **Intervention 1 description**: • Reduced energy intake achieved through low fat diet (20-25% fat, 55-60% carbohydrates) • Recommended moderate physical activity (walking) daily, gradual to 10,000 steps a week • Individual in person • Delivered by nurses, dietitians, physical therapists, and physicians • Between 9 and 11 sessions over 3 years (at baseline, 1, 3, and 6 months and then every 6 months, plus 2 optional visits), session length NR **Intervention 2 description:** As per intervention 1, but only four sessions at 12 month intervals **Control description:** no control arm **Sample sizes (baseline):** Total n = 641 Intervention 1 n = 311 Intervention 2 n = 330 **At 12 months:** Total n = 621 Intervention 1 n = 300 Intervention 2 n = 321 **At 36 months:** Total n = 498 Intervention 1 n = 245 Intervention 2 n = 253 Groups similar at study outset	**Published and unpublished data** (authors provided weight data at 24 and 36 months via email) **Outcome calculation method** Standard methods used **Follow up periods:** 12, 24, 36 months	**BOCF weight change**: At 12 months intervention 1: -2.4 (3.2), intervention 2: -1.1 (3.2). At 36 months intervention 1: -2.3 (3.5), intervention 2: -1.3 (3.2) **Complete case weight change:** At 12 months intervention 1: -2.5 (3.2), intervention 2: -1.1 (3.2). At 36 months intervention 1: -3.0 (3.9), intervention 2: -1.7 (3.6) **Secondary outcomes:** Complete case change in waist circumference at 12 months intervention 1: -3.1 (4.3), intervention 2: -1.3 (4.7); complete case change in BMI intervention 1: -0.9 (1.2), intervention 2: -0.4 (1.2) *Adverse effects:* Authors report no serious adverse events recorded. **Attrition details:** 97% followed up at 12 months, same in both arms. Over 36 months, 2% lost for unavoidable reasons; 9% missing; 2% medical.	**Source of funding:** All Japan Federation of Social Insurance Associations *External validity score downgraded as percentage screened who enrolled NR

Study details	**Population and setting**	**Method of allocation to intervention/control**	**Outcomes and methods of analysis**	**Results**	**Notes**
Authors: Seligman BGS;Polanczyk CA;Santos ASB;Foppa M;Junges M;Bonzanini L;Nicolaidis G;Camey S;Lopes AL;Sehl P;Duncan BB;Clausell N; **Year:** 2011 **Citation:** Metabolism-Clinical and Experimental 60:1736-1740 **Aim of study:** To examine the effect of three different weight loss and exercise programmes on endothelial function **Study design:** **Quality score:** ++ **External validity score:** +	**Source population/s:** Country: Brazil Percentage female: 43%; Mean age 43; Ethnicity NR; SES NR **Baseline weight (kg),** Low carb + supervised: 97 (11.0) Low carb + pedometer: 99 (10.5) Low fat + advice: 96 (13) **Baseline BMI,** Low carb + supervised: 35.2 (2.5) Low carb + pedometer: 34.4 (3.0) Low fat + advice: 34.7 (3.0) **Baseline waist circumference (cm)** Low carb + supervised: 107 (12) Low carb + pedometer: 106 (7) Low fat + advice: 105 (7) **Eligible population:** Metabolic syndrome **Selected population**: BMI>=30 and <40 3 metabolic syndrome criteria, waist>=95cm **Exclusion criteria:** Abnormal treadmill test, pregnancy, lactation, chronic diseases, renal failure creatinine > 133mmol/l, corticosteroid treatment, appetite suppressant use	**Method of allocation**: Randomisation using computer sequence, centrally concealed allocation. **Intervention (1) description**: Low carbohydrate supervised exercise programme • Unrestricted portions but high protein low carbohydrate • Vigorous supervised exercise 3 times weekly progressing from 60% of the individual attainable heart rate peak to 40 minutes per session at 75% to 80% of HRpeak with 1 hour of daily walking on the other days • Mode of delivery: One-to-one • Delivered by physicians and medical students plus exercise trainers for supervised sessions • 15 minutes individual counselling 2 weekly for 7 occasions plus seen every 3 months **Intervention (2) description**: Low carbohydrate home based pedometer walking programme • Unrestricted portions but high protein low carbohydrate • Recommended 10,000 steps daily • Mode of delivery: One-to-one • Delivered by physicians and medical students • 15 minutes individual counselling 2 weekly for 7 occasions plus seen every 3 months **Intervention (3) description**: High carbohydrate low fat diet with recommended physical activity • Calorie restricted to about 2100 Kcal/day • Recommended 1 hour walking daily • Mode of delivery: One-to-one • Delivered by physicians and medical students • 15 minutes individual counselling 2 weekly for 7 occasions plus seen every 3 months	**Published or unpublished** Data on 12 months weight loss and additional outcome data provided by the authors **Outcome calculation method** Standard but calculated from weight supplied at each follow up not just weight loss **Follow up periods:** Additional follow-ups 3 months 6 months	**BOCF weight change**: Low carbohydrate supervised exercise programme -7.3 (6.1) Low carbohydrate home based pedometer walking programme -6.4 (5.4) High carbohydrate low fat diet with recommended physical activity -9.7 (6.8) **Complete case weight change:** Low carbohydrate supervised exercise programme -9.0 (5.5) Low carbohydrate home based pedometer walking programme -7.0 (5.2) High carbohydrate low fat diet with recommended physical activity -11.0 (6.1) **Secondary outcomes:** Change in waist circumference: Low carbohydrate supervised exercise programme -14 (7) Low carbohydrate home based pedometer walking programme -1 (3) High carbohydrate low fat diet with recommended physical activity -14 (4)	**Source of funding:** Brazilian research council and hospital **Other notes:** Lost + on external validity because 84% of potential participants excluded. Data on 12 months weight loss and additional outcome data provided by the authors

	Percentage screened who were enrolled: 16% **Setting:** in person delivery hospital based programme	**Control description:** No control group **Sample sizes (baseline):** Total n = 76 Low carbohydrate supervised exercise programme = 26 Low carbohydrate home based pedometer walking programme = 25 High carbohydrate low fat diet with recommended physical activity = 25 **At 12 months (or closest point):** Total n = 65 (86%) Low carbohydrate supervised exercise programme = 21 (81%) Low carbohydrate home based pedometer walking programme = 22 (92%) High carbohydrate low fat diet with recommended physical activity = 22 (88%) **Baseline comparisons**: Groups similar at study outset		Change in BMI NR Adverse effects: NR **Attrition details:** All losses in avoidable category Follow up: Low carbohydrate supervised exercise programme = 21 (81%) Low carbohydrate home based pedometer walking programme = 22 (92%) High carbohydrate low fat diet with recommended physical activity = 22 (88%)	

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Silva et al. **Year:** 2010 **Citation:** Silva, M.N., Vieira, P.N., Coutinho, S.R., Minderico, C.S., Matos, M.G., Sardinha, L.B., & Teixeira, P.J. 2010. Using self-determination theory to promote physical activity and weight control: a randomised controlled trial in women. Journal of Behavioral Medicine, 33, (2) 110-122 **Aim of study:** Weight loss **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** Portugal *Across whole study:* 100% female, mean age 38, ethnicity NR, 67% had education beyond high school *For each arm*: baseline weight (kg) intervention 82.1 (11.9), control 81.5 (12.1); baseline BMI intervention 31.7 (4.24), control 31.3 (4.0); baseline weight circumference NR **Eligible population:** Respondents to newspapers, flyers and TV advertisements **Selected population:** Premenopausal women, 25-50 years old, not pregnant, BMI 25-40, willing to attend weekly meetings for 1 year and be tested regularly, willing not to participate in any other weight loss programme during first year of study **Excluded population/s:** "Major illnesses," taking meds that affect weight (or having done so in past year) 25% of those screened were enrolled	**Method of allocation**: Random number generator used, allocation concealment methods NR. **Intervention (1) description**: • Reduced energy diet (reduction of daily caloric intake 300-400 kcal/day) • Recommended and supervised physical activity, intensity NR, daily, length NR • Group in-person • Dietitians, nutritionists, psychologists, exercise physiologists, all PhD or MS level • 30 sessions of 120 minutes over 12 months **Control description:** General health education programme (3): 29 face-to-face sessions in thematic courses, including healthy nutrition, but weight loss not focus **Sample sizes (baseline):** Total n = 239 Intervention n = 123 Control n = 116 **At 12 months:** Total n = 201 Intervention n = 112 Control n = 89 **Baseline comparisons**: Groups similar at study outset	**Published and unpublished data** Complete case weight data at 4 and 12 months provided by author via e-mail **Outcome calculation method** 19 participants who were enrolled were subsequently excluded from all analyses for violating study protocol; authors report that participants had a similar age and BMI to those of the whole same. Otherwise, standard methods used. **Follow up periods:** 4 and 12 months available, plus percentage weight loss at 3 years.	**BOCF weight change**: at 12 months intervention -5.49 (5.13), control -1.07 (3.69) **Complete case weight change:** at 12 months intervention -6.03 (5.06), control -1.4 (4.2) **Secondary outcomes:** Complete case change in waist circumference and BMI NR *Adverse effects:* NR **Attrition details:** 84% followed up at 12m overall: 91% intervention, 77% control. 12% missing, 1% unavoidable (note, numbers reported in paper do not quite add up).	**Source of funding:** Portuguese Science and Technology Foundation, Calouste Gulbenkian Foundation, The Oeiras City Council, Nestlé Portugal, and IBESA Portugal **Other notes:** Additional weight data provided by author via e-mail *External validity downgraded as 25% of those screened enrolled, suggests population may not be representative of source population. *See also:* Silva, M. N., et al. 2008. A randomised controlled trial to evaluate self-determination theory for exercise adherence and weight control: rationale and intervention description. BMC Public Health, 8, 234. Silva, M. N., et al. 2011. Exercise autonomous motivation predicts 3-yr weight loss in women. Medicine & Science in Sports and Exercise, 43, (4) 728-737. Teixeira, P.J., et al. 2010. Mediators of weight loss and weight loss maintenance in middle-aged women. [References]. Obesity, 18, (4) 725-735

	Setting: Face-to-face, setting NR				
Study details	**Population and setting**	**Method of allocation to intervention/control**	**Outcomes and methods of analysis**	**Results**	**Notes**
Authors: Skender et al **Year:** 1996 **Citation:** Skender, M.L., Goodrick, G.K., Del Junco, D.J., Reeves, R.S., Darnell, L., Gotto, A.M., Foreyt, J.P. 1996. Comparison of 2-year weight loss trends in behavioural treatments of obesity: diet, exercise and combination interventions. Journal of the American Dietetic Association, 96, (4) 342-346. **Aim of study:** Weight loss **Study design:** RCT **Quality score:** +* **External validity score:** +**	**Source population/s:** USA *Across whole study:* 49% female, age NR, ethnicity NR, SES data NR. *For each arm* (mean, SD): baseline weight intervention 97.6 (25.5), diet only 93.9 (20.8), exercise only 97.7 (22.0); baseline BMI NR; baseline weight circumference intervention 108.9 (16.0), diet only 107.3 (16.7), exercise only 106.0 (13.7). **Eligible population:** Media announcements in Houston, TX. **Selected population:** 25-45 years old, at least 14kg overweight, not currently engaged in regular exercise **Excluded population/s:** Exclusion criteria NR Percentage screened who were enrolled NR **Setting:** Face-to-face, setting NR	**Method of allocation**: Randomisation via random numbers table, allocation procedure NR. **Intervention description**: • "Controlled energy intake" diet, calories NR, 30% fat, 50% carbohydrate, 20% protein, using Help Your Heart Eating Plan. • Recommended and supervised brisk walking ("vigorous" but not "strenuous"), gradual to 45 minutes or more 3 to 5 times a week. • Group in person • Registered dietitians • 18 sessions of 60 minutes over 12 months (weekly for first 12 weeks, then declining in frequency) **Control description:** (5) diet-only: as per above, but only received dietary elements. Same number of sessions and schedule. (5) exercise-only: as per above, but only received exercise elements. Same number of sessions and schedule. **Sample sizes (baseline):** Total n = 127 Intervention n = 42 Diet only n = 42 Exercise only n = 43 **At 12 months (or closest point):** Total n = 86 Intervention n = 27 Diet only n = 29 Exercise only n = 30 **At 24 months:** Total n = 61	**Published data only** **Outcome calculation method** Change in waist circumference calculated from mean values at follow-up compared to mean values at baseline **Follow up periods:** 3, 12, 24 months	**BOCF weight change**: At 12 months intervention -5.7 (10.1), diet only -4.7 (7.2), exercise only -2.0 (6.3). At 24 months, intervention -1.1 (4.8), diet only +0.3 (4.5), exercise only -1.6 (7.1) **Complete case weight change:** At 12 months intervention -8.9 (11.5), diet only -6.8 (7.8), exercise only -2.9 (7.4). At 24 months, intervention -2.2 (6.7), diet only +0.9 (7.7), exercise only -2.7 (9.2) **Secondary outcomes:** Complete case change in waist circumference at 12 months intervention -10.1 (8.3), diet only -10.7 (8.2), exercise only -5.1 (7.3). BMI change NR *Adverse effects:* NR **Attrition details:** 67% followed up at 12 months: 64% intervention, 69% diet only, 70% exercise only. Reasons for attrition NR.	**Source of funding:** National Institutes of Health **Other notes:** *Quality score downgraded as allocation method NR **External validity score downgraded as percentage screened who were enrolled NR See also: Foreyt, J.P., Goodrick, G.K., Reeves, R.S., Raynaud, A.S., Darnell, L., Brown, A.H., Gotto, A.M. 1993. Response of free-living adults to behavioural treatment of obesity: attrition and compliance to exercise. Behavior Therapy, 24, 659-669.

		Intervention n = 21 Diet only n = 15 Exercise only n =25 Groups similar at study outset.			

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Stevens et al. **Year:** 1993 **Citation:** Stevens, V. J., Corrigan, S. A., Obarzanek, E., Bernauer, E., Cook, N. R., Hebert, P., Mattfeldt-Beman, M., Oberman, A., Sugars, C., Dalcin, A. T., Whelton, P. K. 1993. Weight loss intervention in Phase 1 of the trials of hypertension prevention. Archives of Internal Medicine, 153, 849-858 **Aim of study:** Lowering diastolic blood pressure in those whose blood pressure was initially in the high normal range **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** USA *Across whole study:* 79% female, mean age 43, 21% ethnic minority, 47% college graduates, 91% full time employed *For each arm*: baseline weight (kg) intervention 90.2 (13.3), control 89.3 (13.0); baseline BMI intervention 29.5 (2.9), control 29.5 (2.8); waist circumference NR **Eligible population:** NR **Selected population:** 30-54 years old, BMI 26.1-36.1 for men, 24.3-36.1 for women, diastolic blood pressure 80-89 mmHg (average over 3 visits 1 to 3 wks apart), compliance (ability to complete and return 24 hour urine collection and food frequency questionnaire) **Excluded population/s:** History of cardiovascular disease, diabetes mellitus, gastrointestinal disease, chronic renal failure, malignant neoplasm, current pregnancy	**Method of allocation**: Sequence generation NR. Centralized allocation by telephone; if not possible, sealed opaque envelopes. **Intervention description**: • Reduced energy diet calculated individually with goal of achieving weight loss not to exceed 0.9 kg/wk, not to fall below 1200 kcal/day • Recommended and supervised moderate intensity physical activity at 40-55% heart rate reserve, incremental to 4-5 days/ week, 30-45 minutes/session • Group and individual, in-person but with phone and e-mail if in-person appointment missed • Registered dietitian, exercise physiologist, psychologist • 45 sessions (90 minutes group, individual length NR) over 18 months • Occasionally friends and family invited to group sessions. Participants offered informal weigh ins between sessions, in addition to 45 scheduled. **Control description:** Usual care (1): details NR **Sample sizes (baseline):** Total n = 564	**Published data only** **Outcome calculation method** Limited weight data presented (means for men and women separately but no combined means and no SDs reported). Means and SDs given calculated by reviewers, assuming that the p value at 12 and 18 m was the same as that calculated at the first follow-up visit ($7*10^{-21}$). Control values extrapolated from graph. N at follow-up derived from blood pressure results tables. **Follow up periods:** 6, 12, 18 months	**BOCF weight change**: at 12 months intervention -4.5 (6.3), control 0 (5.6); at 18 months intervention -3.7 (5.0), control 0 (4.3); at 18 months intervention -3.7 (5.0), control 0 (4.3) **Complete case weight change:** at 12 months intervention -4.8 (6.4), control 0 (5.8); at 18 months intervention -3.85 (5.0), control 0 (4.5) ; at 18 months intervention -3.7 (5.0), control 0 (4.3); at 18 months intervention -3.85 (5.0), control 0 (4.5) **Secondary outcomes:** Complete case change in waist circumference and BMI NR *Adverse effects:* NR **Attrition details:** 93% followed up at 12	**Source of funding:** National Heart, Lung and Blood Institute **Other notes:** Included study from Loveman 2010. This is a subset of data (2 arms reported here, out of 10 arms total in the study). Other arms not relevant to weight loss and not valid comparators. *Downgraded as number screened enrolled not reported. *See also:* Satterfield, S., et al. Trials of Hypertension Prevention: Phase 1 design. Annals of Epidemiology, 1, (5) 455-471 The Trials of Hypertension Prevention Collaborative

	or intent to become pregnant during study, recent history of psychiatric disorders, unwillingness to accept randomisation into any study group, serious physical handicap, current alcohol intake >21 drinks/wk, current use of meds that could interfere with study intervention (diuretics, beta-blockers, anticoagulants), serum cholesterol >=260 mg/dL, serum creatinine >=1.7mg/dL for men or 1.5mg/dL for women, casual serum glucose >=200 mg/dL, unexplained hyperkalemia, hypercalcemia. Percentage screened who were enrolled NR **Setting:** Face-to-face at 'clinical centres', phone and email if face-to-face not possible	Intervention n = 308 Control n = 256 **At 12 months (those who completed blood pressure test):** Total n = 524 Intervention n = 287 Control n = 237 **At 18 months (those who completed blood pressure test):** Total n = 531 Intervention n = 295 Control n = 236 **Baseline comparisons**: More men in intervention group (72.7% versus 62.9%), no other significant between-group differences.		months overall: 93% intervention, 93% control. Reasons for attrition NR.	Research Group. The effects of nonpharmacologic interventions on blood pressure of persons with high normal levels: Results of the Trials of Hypertension Prevention, Phase I. JAMA, 267, (9) 1213-1220

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Stevens et al **Year:** 2001 **Citation:** Stevens, V.J., Obarzanek, E., Cook, N. R., Lee, I-M., Appel, L. J., West, D. S., et al. Trials of Hypertension Prevention (TOHP) Collaborative Research Group. 2001. Long-term weight loss and changes in blood pressure: Results of the trials of hypertension prevention, phase II. Annals of Internal Medicine, 134, (1) 1-11 **Aim of study:** Test efficacy of lifestyle interventions for reducing blood pressure over 3-4 years **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** USA *Across whole study:* 34% female, mean age 43, 21% minority group, 51% college graduate *For each arm*: baseline weight (kg) intervention 91.5 (12.1), control 90.7 (11.3), baseline BMI intervention 31.0 (3.3), control 30.9 (3.2), baseline waist circumference NR **Eligible population:** NR, varied by recruiting centre **Selected population:** Age 30 to 54 years, BMI 26.1-37.4 for men and 24.4 -37.4 women. Diastolic blood pressure 83-89, systolic blood pressure <140, compliance (completion and return of 24 hour and 8 hour urine collections and 3 day food record) **Excluded population/s:** Hypertension, current (w/in past 2 months) use of antihypertensives, history of cardiovascular disease, diabetes mellitus, malignancy (other than nonmelanoma skin cancer) during past 5 years, other serious life-threatening conditions that require medication, renal deficiency, current alcohol intake > 21 drinks/week, current pregnancy or intent to become pregnant.	**Method of allocation**: Method of sequence generation NR. Centralized allocation via telephone to central randomising centre or via sealed opaque envelopes. **Intervention description**: • Reduced energy diet (individually determined to produce moderate weight loss no more than 2lbs/week, men not to consume ≤1500 kcal/day, women not ≤1200 kcal/day) • Recommended and supervised moderate intensity physical activity at 40-55% heart rate reserve, incremental to 4-5 days/ week, 30-45 minutes/session • Group and individual, primarily in person but some contact via phone, fax, and post • Registered dietitians, psychologists, MA level counsellors • 41-47 structured sessions total (90 minutes in first phase, then length NR) over 36 months, plus participant initiated contacts • Occasionally friends and family invited to group sessions. Participants waited 1- 4 months between randomisation and first group meeting, contacted monthly by interventionist during this time **Control description:** Usual care (1): details NR **Sample sizes (baseline):** Total n = 1191 Intervention n = 595	**Published or unpublished** Published data only **Outcome calculation method** Baseline weight and BMI reported by gender, reviewers computed averages to derive combined mean and SD at baseline. Follow-up results reported with 95% CI, reviewer calculated SD. **Follow up periods:** 6, 12, 18 and 36 months. 12 month weight data not reported except in graph.	**BOCF weight change**: at 18 months intervention -1.8 (5.8), control 0.6 (6.9); at 36 months intervention -0.2 (5.8), control 1.7 (5.2). **Complete case weight change:** at 18 months intervention -2.0 (6.0), control 0.7 (7.2); at 36 months intervention -0.2 (6.0), control 1.8 (5.4) **Secondary outcomes:** Complete case change in waist circumference and BMI NR *Adverse effects:* NR **Attrition details:** 92% followed up at 18 months overall: 92% intervention, 92% control. Reasons for attrition NR.	**Source of funding:** National Heart, Lung, and Blood Institute, National Institutes of Health **Other notes:** Included study from Loveman 2011. Four armed study, two arms not reported here (reduced sodium and reduced sodium + weight loss). *External validity score downgraded due to representativeness of population – only 13% of screened population were randomised *See also*: Hebert, P.R., Bolt, R.J., Borhani, N.O., Cook, N.R., Cohen, J.D, Cutler, J.A., Hollis, J.F., et al. Trials of Hypertension Prevention (TOHP) Collaborative Research Group. 1995. Design of a multcentre trial to evaluate long-term life-style intervention in adults with high-normal blood pressure levels: Trials of hypertension prevention (Phase II). Annals of Epidemiology, 5,

	13% of those screened were enrolled (in study overall, including all 4 arms) **Setting:** Mostly in-person, plus participant initiated via phone, mail, and fax. Setting NR.	Control n= 596 **At 18 months:** Total n = 1096 Intervention n = 545 Control n = 551 **At 36 months:** Total n = 1101 Intervention n = 547 Control n = 554 **Baseline comparisons**: Groups similar at study outset			(2) 130-139 Hollis J.F., Satterfield S., Smith F., Fouad M., Allender P.S., Borhani N., et al. Recruitment for phase II of the Trials of Hypertension Prevention. Effective strategies and predictors of randomisation. Trials of Hypertension Prevention (TOHP) Collaborative Research Group. Annals of Epidemiology, 5, 140-8.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Tate et al **Year:** 2003 **Citation:** Tate DF, J. R. S. N. W. R. Long-term weight losses associated with prescription of higher physical activity goals. Are higher levels of physical activity protective against weight regain? 4. American Journal of Clinical Nutrition 85, 954-9. 2007. **Aim of study:** Weight loss **Study design:** RCT **Quality score:** ++ **External validity score:** +*	**Source population/s:** USA *Across whole study:* Female 90%; Age 49; Ethnicity 11% minority group; 50% with college degree and above *For each arm*: Weight Intervention1: 86 (14) Intervention2: 89 (13) BMI Intervention1: 32.5 (3.8) Intervention2: 33.7 (3.7) Waist circumference Intervention: 108 (12) Control: 111 (12) **Eligible population:** Recruited through newspaper advertisements and were drawn from a waiting list at a research centre **Selected population:** BMI 27-40; One or more risk factors for type 2 diabetes **Excluded population/s:** Participants with major health or psychiatric diseases, pregnancy, or recent weight loss of 4.5 kg or more were excluded 39% of those screened were randomised (63% of those excluded had too few risk factors) **Setting:** Internet	**Method of allocation**: Computer generated random numbers **Intervention 1 description**: • Name: Basic internet • Calorie intake of 1200-1500kcal/d • <20% of total energy intake from fat • Recommended weekly energy expenditure exercise of 1000kcal/week (Equivalent to walking 10miles/week) • 12 month Individual, internet based intervention (with message boards) • Weekly tip and link to resources • Weekly reminder to submit his/her weight **Intervention 2 description**: • Name: Basic internet + e-counselling • Same diet and physical activity guidance as Intervention 1 • Same 12 month individual internet based intervention as Intervention 1 In addition: • Submitted daily diet diaries for one month and then daily or weekly (their choice) thereafter. • Received feedback emails from Counsellor with a master's or doctoral degree in health education, nutrition or psychology. Counsellors also answered any participant questions. • 64 contacts with counsellor with 5/week in the first month and then weekly for 11 months. **Sample sizes:** Total n = 92 Intervention 1 n = 46 Intervention 2 n = 46 **12 months** Total n = 415 Intervention 1 n = 38 Intervention 2 n = 39	**Published data only** **Outcome calculation method** BOCF reported by authors **Follow up periods:** 6, 12 months	**BOCF weight change**: 12 months Intervention 1 : -2.0 (5.7) Intervention 2: -4.4 (6.2) **Secondary outcomes:** **12 months** *(BOCF as reported)*: Waist circumference change Intervention 1 : -4.4 (5.7) Intervention 2: -7.2 (7.5) BMI Change Intervention 1 : -0.8 (2.1) Intervention 2: -1.6 (2.2) *Adverse events:* NR **Attrition details:** 12 months Intervention 1: Medical: 2% Missing: 15% Intervention 2: Medical: 2% Missing: 13%	**Source of funding:** Clinical Research Award from American Diabetes Association *External validity score downgraded as only 39% of those screened were randomised)

		Baseline characteristics: Groups were similar at study outset			

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Vermunt et al **Year:** 2011 **Citation:** Vermunt, P.W., Milder, I.E., Wielaard, F., de Vries, J.H., van Oers, H.A., & Westert, G.P. 2011. Lifestyle counseling for type 2 diabetes risk reduction in Dutch primary care: results of the APHRODITE study after 0.5 and 1.5 years. Diabetes Care, 34, (9) 1919-1925 **Aim of study:** Diabetes prevention **Study design:** 2 arm RCT **Quality score:** +* **External validity score:** ++	**Source population/s:** Netherlands Percentage female ~60% Mean age: 58 years Percentage in all minority groups: NR SES data: 50% of low education Baseline weight (kg), Intervention: 89 Control: 88 Baseline BMI, Intervention: 29.0 (4.4) Control: 28.5 (4.1) Baseline waist circumference (cm) Intervention: 100 (12) Control: 99 (11) **Eligible population:** Primary care random sample of patients fitting criteria written to and asked to complete FINDRISC score for predicting diabetes. Invited for OGT and then entered into study if risk score >=13 (out of 26 and not having frank diabetes **Selected population:** Inclusion criteria. FINDRISC>13 **Excluded population/s:** Known diabetes, terminal disease or physical or mental disabilities making active participation in the	**Method of allocation**: Alternate allocation, non-random though list randomly ordered **Intervention description**: • Name of programme: Aphrodite • Low fat, reduced energy, high fibre diet aiming for 5% weight loss • Recommended 30 mins of moderate-high (3-6 METS) intensity physical activity for 5 days per week • Individual in-person • Nurse practitioner was main therapist had 5 evening sessions of training, also saw dietitian and GP who had 2 hours of training as well as physiotherapist • 17 sessions over 3 years, length not specified (7 with nurse, 4 with dietitian, 5 with GP, 1 with physiotherapist) **Control description:** (2) Single session of advice from GP about health benefits of healthy diet and exercise **Sample sizes (baseline):** Total n = 925 Intervention n = Calculated number at baseline is 479 but baseline data on 393 presented Control n= Calculated number at baseline is 444 but baseline data on 371 is presented **At 18 months (closest point to 12 months):** Total n = 764 (83%) Intervention n = 393 (82%) Control n= 371 (84%) **At longest follow-up (as per results column):**	**Published or unpublished** Published **Outcome calculation method** Based on change in BMI. This study did not report weight loss only BMI change but not mean height. We therefore assumed the males and females were the mean height of the Dutch population. Mean baseline weights are calculated on this basis. 18% of participants were of healthy weight but were excluded from the analysis of weight loss. **Follow up periods:** 6 and 18 months	**BOCF weight change:** (18 months) Intervention: -0.5 (4.7) Control: -0.3 (4.9) **Complete case weight change:** (18 months) Intervention: -0.6 (5.2) Control: -0.3 (4.9) **Secondary outcomes:** Waist circumference: Intervention: -0.4 (6.5) Control: +0.3 (5.6) Change in BMI: Intervention: -0.2 (1.7) Control: -0.1 (1.6) Adverse effects*:* *NR*. **Attrition details:** Overall percentage followed up at 12m: 83% Intervention loss to follow up: Avoidable: 10% Unavoidable:0% Medical:7% Control loss to follow up: Avoidable:8%	**Source of funding:** Netherlands R&D government funding **Other notes:** *Quality score downgraded because allocation to intervention and control was alternate and known to GP prior to enrolment. If alternate allocation was used it is impossible to have this much imbalance in number in each arm, suggesting biased allocation.

	study impossible. **Percentage screened who were enrolled** 96% of all eligible volunteers **Setting:** In person primary care	N/A **Baseline comparisons**: Groups pretty similar but significant difference in baseline weight adds to suspicion of biased allocation		Unavoidable:0% Medical:7%	

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Villareal **Year:** 2011 **Citation:** Villareal, D.T., Chode, S., Parimi, N., Sinacore, D.R., Hilton, T., Armamento-Villareal, R., Napoli, N., Qualls, C., & Shah, K. 2011. Weight loss, exercise, or both and physical function in obese older adults. New England Journal of Medicine, 364, (13) 1218-1229 **Aim of study:** Weight-loss and improvement in physical function **Study design:** RCT **Quality score:** ++ **External validity score:** ++	**Source population/s:** USA *Across whole study:* Female: 63% Age: 70y Ethnicity: NR College degree and above: 70% *For each arm* (mean, SD): Weight (kg) Intervention: 99.1 (16.8) Control 1: 104.1 (15.3) Control 2: 99.2 (17.4) Control 3: 101 (16.3) BMI (kg/m^2) Intervention 37.2 (5.4) Control 1: 37.2 (4.5) Control 2: 36.9 (5.4) Control 3: 17.3 (4.7) Waist circumference: NR **Eligible population:** Media advertisements **Selected population:** 1) Age 65 years or older 2) BMI 30 or more 3) Sedentary lifestyle 4) Stable body weight for 12 months	**Method of allocation**: Random permutations procedure. **Intervention description**: • Diet and Exercise • Energy restriction of 500-750kcal per day (determined by REE x 1.7) • Supervised activity sessions (3/wk) of 90 mins including moderate to high intensity exercise (gradual increase to 70-80% of peak HR) • Both exercise and diet were delivered in, in person group sessions. • Delivered by a dietitian and physical therapist • 208 sessions over 12 months, length not specified. (Weekly sessions with a dietitian over 1y and 3 exercise sessions a week for a 1y). • Participants aimed to lose 10% of their baseline weight by 6 months and maintain during the next 6 months. **Control 1**: (5) (diet) Participants completed only the diet portion of Intervention 1. **Control 2:** (5) (exercise) Participants completed only the exercise portion of Intervention 1. **Control 3:** (4) Usual care Participants were provided general information about	**Published or unpublished** Published **Outcome calculation method** Authors report LOCF analysis only, including all randomised participants. Reviewers used LOCF in place of complete case data. Reviewers calculated BOCF based on LOCF data provided, therefore some margin of error possible. **Follow up periods:** 6 and 12 months	**BOCF weight change** 12 months Intervention: -7.7 (4.5) Control 1: -8.6 (6.0) Control 2: -0.4 (3.3) Control 3: 0.1 (3.1) **LOCF weight change**: 12 months Intervention: -8.6 (3.8) Control 1: -9.7 (5.4) Control 2: -0.5 (3.6) Control 3: 0.1 (3.5) **Secondary outcomes:** Waist circumference and BMI change NR. *Adverse effects:* One participant in the intervention group fell during exercise training **Attrition details:** **12 months** **Total:** 87% follow up. **Intervention** Missing: 3.5% Medical: 7% **Control 1** Missing: 12% **Control 2**	**Source of funding:** National Institutes of Health

	5) Stable medications for 6 months 6) Mild to moderate frailty **Excluded population/s:** Persons who had severe cardiopulmonary disease; musculoskeletal or neuromuscular impairments that preclude exercise; visual, hearing, or cognitive impairments; or a history of cancer, as well as persons who were receiving drugs that affect bone health and metabolism or who were current smokers. 54% of those screened were excluded **Setting:** In person	a healthy diet during monthly visits with the staff. **Sample sizes (baseline):** Total n = 107 Intervention n = 28 Control 1 n= 26 Control 2 n =26 Control 3 n = 27 **At 12 months:** Total n = 93 (87%) Intervention n = 25 Control 1 n= 23 Control 2 n = 22 Control 3 n = 22 **Baseline comparisons**: Groups similar at study outset		Missing: 12% Medical: 4% **Control 3** Missing: 3.7% Medical: 11%	

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Vissers **Year:** 2010 **Citation:** Vissers, D., Verrijken, A., Mertens, I., Van, G.C., Van de Sompel, A., Truijen, S., & Van, G.L. 2010. Effect of long-term whole body vibration training on visceral adipose tissue: a preliminary report. Obesity Facts, 3, (2) 93-100 **Aim of study:** Weight loss **Study design:** RCT **Quality score:** +* **External validity score:** ++	**Source population/s:** Belgium *Across whole study:* Gender: NR; Age: 45y Education: NR; SES: NR *For each arm* (mean, SD): Weight Control: 88.6 (15.9) Diet: 92.1 (11.1) Fitness: 94.5 (11.7) Vibration: 95.2 (17.8) BMI Control: 30.8 (3.4) Diet: 32.9 (3.1) Fitness: 33.1 (3.4) Vibration: 31.9 (4.7) Waist circumference Control: 99.7 (11.1) Diet: 102.3 (7.9) Fitness: 103.5 (9.4) Vibration: 100.0 (13.5) **Eligible population:** Obese adults approached via media advertising and outpatient clinic **Selected population:** NR **Excluded population/s:** Diabetes, pregnancy, treatment with tricyclic antidepressants, joint replacement orthopaedic surgery, use of weight loss drugs, endocrine conditions causing weight change, BMI >40 kg/m2, weight loss > 5% of body weight within 6 weeks prior to start of the study. **Setting:** In person	**Method of allocation**: Unclear **Intervention (1) description:** Fitness • Hypocaloric diet calculated on an individual level using: (RMRx1.3) – 600kcal/d • Aerobic interval training + general muscle strengthening exercise • Individual, in person sessions • Dietitian & Physiotherapist • 12 sessions over 12 months as: 0-3 months: every fortnight; 3-6 months: 1x month; 6-12 months: 3 more visits • In addition exercise sessions: 0-3 Months: 2 supervised and one home/week; 3-6 months: 1 supervised session and 2 home/week; 6-12 months: advised to maintain an active lifestyle **Intervention (2) description:** Vibration • Diet as per intervention 1 • Whole body vibration – exercises chosen to train all major muscle groups with machine frequency increasing from 30 to 35 and finally 40Hz. • Individual, in person sessions • Dietitian & Physiotherapist • 12 sessions over 12 months, schedule as intervention 1 • In addition exercise sessions: 0-3 Months: Static exercises on whole body vibration platform; 3-6 months: Dynamic exercises; 6-12 months: advised to maintain an active lifestyle **Control (1) description:** Single component (5). Diet (as per diet component of intervention 1, without fitness and exercise elements) **Control (2) description:** No contact (1) **Sample sizes:** Total n = 79 Intervention 1 n = 20 Intervention 2 n = 18 Control 1 n= 20 Control 2 n= 21 **12 months** Total n = 61 Intervention 1 n = 19 Intervention 2 n = 13	**Published data only** **Outcome calculation method:** standard **Follow up periods:** 3, 6, 12 months	**BOCF weight change**: 12 months Intervention 1: -6.3 (6.4) Intervention 2: -7.2 (6.9) Control 1:-2.6 (4.2) Control 2: 1.1 (3.4) **Complete case weight change:** 12 months Intervention 1: -6.6 (6.4) Intervention 2: -9.9 (6.2) Control 1: -4.3 (4.8) Control 2: 1.3 (3.7) **Secondary outcomes:** 12 months complete case BMI change: Intervention 1: -2.3 (2.1) Intervention 2: -3.4 (2.0) Control 1: -1.5 (1.7) Control 2: 0.4 (1.4) 12 months complete case waist circumference change: Intervention 1: -6.9 (7.4) Intervention 2: -9.5 (6.3) Control 1: -3.5 (3.8) Control 2: 0.5 (4.0) **Attrition details:** **12 months** Total: 77.2% Follow up **Intervention 1:** Medical 5% **Intervention 2:** Missing 22%; Medical 6% **Control 1:** Missing 35%; Medical 5% **Control 2:** Unavoidable 10%; Missing 5%; Medical	**Source of funding:** Doctorate grant, University College of Antwerp **Other notes:** *Quality score downgraded by one as randomisation and allocation procedures NR

		Baseline comparisons: Groups similar at study outset. Some differences in VO2 max with higher values in Intervention 2.		5%	

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Wadden et al **Year:** 1988 **Citation:** Wadden, T. A., Stunkard, A.J., Liebschutz, J. 1988. Three-year follow-up of the treatment of obesity by very low calorie diet, behaviour therapy, and their combination. Journal of Consulting and Clinical Psychology, 56, (6) 925-928. **Aim of study:** This will be a very brief description – eg weight loss, diabetes prevention, improved mobility, etc **Study design:** RCT **Quality score:** +* **External validity score:** +*	**Source population/s:** USA *Across whole study:* 86% female, mean age 44, ethnicity NR, SES data NR *For each arm*: baseline weight (kg) intervention 1: 108.0 (21.5), intervention 2: 112.2 (21.5), control: 106.4 (18.4), baseline BMI and baseline weight circumference NR **Eligible population:** Recruited via local newspaper advertisements **Selected population:** Adults at least 25kg overweight as determined by height weight tables of Metropolitan Life Insurance Company (1959) **Excluded population/s:** Recent MI or evidence of cardiovascular abnormalities, history of cerebrovascular, kidney, or liver disease, cancer, Type 1 diabetes, severe psychiatric illness Percentage screened who were enrolled NR **Setting:** in-person, setting NR	**Method of allocation**: Randomisation and allocation methods NR **Intervention 1 description**: "Combined" arm • Energy restricted diet, including very low energy component. Month 1 1000-1200 kcal/day, months 2 and 3 400-500 kcal/day, month 4 "refeeding," months 5 and 6 1000-1200 kcal/day • Recommended moderate physical activity (walking and using stairs), frequency NR • Group face-to-face sessions • Delivered by doctoral level clinical psychologists • 37 sessions of 90 minutes each over 18 months (weekly for first 6 months, then declining in frequency) **Intervention 2 description:** "Behavioural therapy" arm. As per intervention 1 except for diet: 1000-1200 kcal/day for entire study period (no very low energy component) **Control description:** (5) diet only. Very low energy diet (as per intervention 1), delivered over 4 months. **Sample sizes (baseline):** Total n = 59 Intervention 1 n = 23 Intervention 2 n =18 Control n = 18 **At 12 months:** Total n = 48 Intervention 1 n = 17 Intervention 2 n = 16 Control n = 15 **At 36 months:**	**Published data only** **Outcome calculation method** Standard methods used **Follow up periods:** 1, 3, 4-6, 12 and 36 months	**BOCF weight change**: At 12 months intervention 1: -9.5 (9.8), intervention 2: -8.4 (7.0), control: -3.9 (6.9). At 36 months, intervention 1: -3.8 (7.4), intervention 2: -2.8 (5.7), control -1.8 (7.8). **Complete case weight change:** At 12 months intervention 1: -12.9 (9.3), intervention 2: -9.5 (6.7), control: -4.7 (7.3). At 36 months, intervention 1: -5.1 (8.3), intervention 2: -3.5 (6.3), control -2.2 (8.5). **Secondary outcomes:** Waist circumference and BMI NR *Adverse effects:* NR **Attrition details:** 81% followed up at 12 months, 74% intervention 1, 89% intervention 2, 83% control. At 12 months, 12% unavoidable attrition,	**Source of funding:** National Institute of Mental Health, National Institute of Child Health and Human Development, MacArthur Foundation **Other notes:** *Quality score downgraded as method of randomisation and allocation NR **External validity score downgraded as percentage screened who were enrolled NR *** One additional participant is missing at 36 months but group not clear, hence complete case N at 36 months is actually 45. For shorter term results, see also Wadden, T.A. and Stunkard, A.J. 1986. Controlled trial of very low calorie diet, behaviour therapy, and their combination in the treatment of obesity. Journal of Consulting and Clinical Psychology, 54, (4) 482-488.

		Total n = 46*** Intervention 1 n = 17 Intervention 2 n = 14 Control n = 15 Groups similar at study outset.		7% medical.	

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Wadden **Year:** 2011 **Citation:** Wadden, T. A., Volger, S., Sarwer, D. B., Vetter, M. L., Tsai, A. G., Berkowitz, R. I., Kumanyika, S., Schmitz, K. H., Diewald, L. K., Barg, R., Chittams, J., Moore, R. H. 2011. A two-year randomised trial of obesity treatment in primary care practice. NEJM, 365, 1969-79. **Aim of study:** Weight loss **Study design:** **Quality score:** ++ **External validity score:** +	**Source population/s:** USA *Across whole study:* Female: 80% Age: 52y Ethnicity NR Education: 39% University or higher *For each arm:* Weight Intervention: 106 (17) Control: 111 (20) BMI Intervention: 38.5 (4.6) Control: 39.0 (4.8) Waist circumference Intervention: 117.1 (11.9) Control: 119.8 (13.9) **Eligible population:** Referral from Primary Care Provider and self-referral through clinic ads **Selected population:** 1) Age: 21y+ 2) BMI 30-50 3) Weight <400lbs 4) 2+ criteria for metabolic syndrome **Excluded population/s:** - Medical condition that may hinder weight measurement - Prior or planned bariatric surgery - Blood pressure > 160/100 - Chronic use of medications that affect body weight - Unintentional weight loss in last 6 months (≥ 5% of body weight) - Intentional weight loss in last	**Method of allocation**: Computerised randomisation and allocation **Intervention description**: • Brief lifestyle intervention • Energy restriction: If weight <113.4, 1200-1500 kcal/day; and If 113.4kg or more, 1500-1800 per day • Recommended moderate intensity physical activity for minimum 30 minutes, 6 days/week • Individual in person and some telephone conversations • Delivered by a lifestyle coach • 25 (plus 8 visits with PCPs as per control) sessions over 24 months **Control description:** (4) GP care - same goals as intervention, and given pedometer, calorie counting book and handouts. Quarterly PCP visits during 24m to address coexisting illnesses. At each visit, PCP spent 5-7min reviewing weight change and discussing info in handouts. **Sample sizes:** Total n = 261 Intervention n = 131 Control n= 130 **12 months** Total n = 221 Intervention n = 109 Control n = 112 **24 months** Total n = 222 Intervention n = 112 Control n = 110 Groups similar at study outset	**Published data only** **Method of analysis:** Complete case data not available. Authors report ITT analysis using linear mixed models with multiple covariates to impute missing values. Reviewers used ITT values to compute BOCF, in place of complete case data. Reviewers calculated SDs from the ITT SEs given using baseline n. **Follow up periods:** 6, 12, 18, 24 months	**BOCF weight change**: 12 months Intervention: -2.8 (6.4) Control: -2.0 (6.4) 24 months Intervention: -2.4 (7.4) Control: -1.5 (7.4) **Multiple imputation weight change:** *(Complete case data NR)* 12 months Intervention: -3.4 (6.9) Control: -2.3 (6.8) 24 months Intervention: -2.9 (8.0) Control: -1.7 (8.0) **Secondary outcomes:** 12 months, multiple imputation *(Complete case data NR)* BMI Change Intervention: -1.3 (2.3) Control: -0.8 (2.3) 24 months Intervention: -0.9 (2.3) Control: -0.6 (2.3) Waist circumference NR *Adverse events:* NR **Attrition details:** 85% followed up at 12m overall, 83% intervention, 86% control At 24 months, reasons for attrition: Missing Intervention 28%, Control	**Source of funding:** National Heart Lung and Blood Institute **Other notes:** *External validity score downgraded as 60% excluded from 1196 that were screened Third study arm not included as included option to use drugs

	6 months (≥ 5% of body weight) - Pregnant or nursing within past 6 months - Plans to relocate from the area within 2 years - Another member of household is a study participant or staff in the trial - Consumes > 14 alcoholic drinks per week - Current use of illicit substances - Psychiatric hospitalization in last year - Psychiatric condition likely to impair adherence to treatment (e.g., schizophrenia) 60.2% of those screened were excluded before randomisation **Setting:** In person and telephone			31%; medical Intervention 0.8%	

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Weinstock et al **Year:** 1998 **Citation:** Weinstock RS, D. H. W. T. Diet and exercise in the treatment of obesity: effects of 3 interventions on insulin resistance. Archives of Internal Medicine 158[22], 2477-83. 1998. **Aim of study:** Weight loss **Study design:** RCT **Quality score:** - * **External validity score:** +	**Source population/s:** USA *Across whole study:* Female 100% Age 43 Ethnicity NR SES and Education data NR *For each arm*: Weight (kg) Intervention 1: 97.1 (3.3) Intervention 2: 99.0 (4.3) Control: 94.5 (3.8) BMI Intervention 1: 36.4 (1.1) Intervention 2: 36.2 (1.9) Control: 35.2 (1.4) Waist circumference NR **Eligible population:** Drawn from the first cohort of a larger study of diet and exercise **Selected population:** NR **Excluded population/s:** Bulimia nervosa; depression; other major psychological disturbance. Also based upon a medical exam for contraindications e.g. recent MI, history of kidney or liver disease, cancer, diabetes, pregnancy or the use of medication known to affect weight or energy expenditure **Setting:** Face-to Face	**Method of allocation**: NR **Intervention 1 description**: • Name: Diet and Aerobic exercise • 23 month intervention • Calorie restricted liquid replacement diet – *Week 1:* Usual – *Week 2-17:* Prescribed diet of 925kcal/d (4 liquid replacements and dinner entrée and salad) – *Week 18-22:* Decreased liquid diet and increased consumption of conventional foods (W18: 1053kcal/d; W19: 1150kcal/d; W20:1250kcal/d) – *Week 22 on:* Self-selected diet of 1500kcal/d with 12-15% energy from protein; 55-60% from CHO and 25-30% from fat. • Recommended exercise and step aerobics classes – 12 minutes exercise adding 2 minutes each week so by week 14 was 40 minutes of step class – 10cm step then those comfortable moved to 15-20cm step at week 5 – *Week 1 -28:* 3 supervised sessions/week – *Week 29-48:* 2 supervised sessions/week – *Week 48 on:* unsupervised – Assisted in creating their own aerobic plan from 29 onwards to replace missing supervised sessions • 42, 90 minute group sessions with a Clinical psychologist – *1-28 weeks:* weekly – *29-48 weeks:* biweekly group sessions – *48 weeks on:* once every 3 months **Intervention 2 description**: • Name: Diet and Resistance • 23 month intervention • Same dietary approach as Intervention 1 • Recommended exercise plus resistance exercise • Frequency of training: – *Week 1 -28:* 3 supervised sessions/week – *Week 29-48:* 2 supervised sessions/week	**Published data only** **Outcome calculation method** Authors report combined results for the 22 participants who were followed up at 23 months. Weight by group for complete cases for 0-10 months is displayed in a bar chart and has been estimated by the reviewer. SD for weight change or BOCF could not be calculated as no value of n was reported. **Follow up periods:** 12 weeks, 24 weeks, 10 months and 23 months	**Complete case weight change kg** *(not possible to calculate BOCF or SD):* **10 months** Intervention 1 : -14.1 Intervention 2: -13 Control: 12.5 **23 months** Combined: -9.3 **Secondary outcomes:** Waist circumference change: NR **BMI Change (not possible to calculate BOCF or SD)** **10 months:** Intervention 1: -3.7 Intervention 2: -5.2 Control: - 3.7 **23 months** Combined: -3.2 *Adverse events:* NR **Attrition details:** **23 months:** Total: 48% FU Intervention 1 Total: 50% FU Intervention 2 Total: 38% FU Control Total: 60% FU	**Source of funding:** SUNY Health Science Centre, NY; National Institute of Mental Health, Bethesda MD; and Department of Veterans Affairs *Quality score downgraded as randomisation NR; ITT not reported clearly; 49% FU

		– *Week 48 on:* unsupervised • Initials sessions lasted 20 minutes plus warm up and cool down increasing to 40 minutes by week 14. • Content of training – *Week 1:* familiarised with equip – *Week 2:* One set each on a number of exercise targeting major muscle groups – Exercise was performed with weight that allowed them to do 10-14 repetitions. – *Week 3-14:* extra set for each exercise added – *Week 14 on:* resistance increased if able to complete 14 reps. – *Week 29-48:* Given help creating own resistance workouts to replace 3rd session. • Initials sessions lasted 20 minutes plus warm up and cool down increasing to 40 minutes by week 14. • 42, 90 minute group sessions with a Clinical psychologist – *1-28 weeks:* weekly – *29-48 weeks:* biweekly group sessions – *48 weeks on:* once every 3 months **Control description**: (5) Diet only control with the same dietary intervention as described in Intervention 1. **Sample sizes:** Total n =45 Intervention 1 n =14 Intervention 2 n = 16 Control n = 15 10 months Total n = 36 23 months Total n = 22 Intervention 1 n =7 Intervention 2 n = 6 Control n = 9 Groups were similar at study outset			

Appendix 4. Behavioural taxonomy codes for each study arm

	Appel 2011 CCD	Appel 2011 IPD	Bertz 2012	Dale 2008 modest	Dale 2008 intense	DPP	Dubbert 1984 (P and D) individual	Dubbert 1984 (P and D) couples	Eriksson 2009
01- Provide information on consequences of behaviour in general	U	U	Y	N	N	N	N	N	y
02- Provide information on consequences of behaviour to the individual	N	N	N	N	N	Y	N	N	n
03- Provide information about others' approval	N	N	N	N	N	N	N	N	n
04- Provide normative information about others' behaviour	N	N	N	N	N	N	N	N	n
05- Goal setting (behaviour)	Y	Y	Y	Y	Y	Y	Y	Y	y
06- Goal setting (outcome)	Y	Y	Y	U	U	Y	Y	Y	y
07- Action planning	Y	Y	Y	Y	Y	Y	Y	Y	y
08- Barrier identification/problem solving	Y	Y	Y	N	N	Y	Y	Y	y
09- Set graded tasks	N	N	Y	N	N	U	Y	Y	y
10- Prompt review of behavioural goals	Y	Y	Y	Y	Y	Y	Y	Y	y
11- Prompt review of outcome goals	Y	Y	Y	Y	Y	Y	Y	Y	n
12- Prompt rewards contingent on effort or progress towards behaviour	N	N	N	U	U	U	N	N	n
13- Provide rewards contingent on successful behaviour	N	N	N	N	N	Y	N	N	n
14- Shaping	N	N	N	N	N	N	N	N	n
15- Prompting generalisation of a target behaviour	U	U	N	U	U	Y	N	N	n
16- Prompt self-monitoring of behaviour	Y	Y	Y	Y	Y	Y	Y	Y	n
17- Prompt self-monitoring of behavioural outcome	Y	Y	Y	Y	Y	Y	Y	Y	n
18- Prompting focus on past success	N	N	N	U	U	U	N	N	n
19- Provide feedback on performance	Y	Y	Y	U	U	Y	Y	Y	u
20- Provide information on where and when to perform the behaviour	N	N	N	Y	Y	Y	N	N	y
21- Provide instruction on how to perform the behaviour	Y	Y	Y	Y	Y	N	Y	Y	y
22- Model/Demonstrate the behaviour	N	N	Y	Y	Y	Y	N	N	u
23- Teach to use prompts/cues	N	N	N	N	N	N	N	N	n
24- Environmental restructuring	U	U	N	N	N	Y	Y	Y	n
25- Agree behavioural contract	N	N	N	N	N	Y	N	N	n
26- Prompt practice	N	N	N	N	N	Y	Y	Y	n
27- Use of follow-up prompts	Y	Y	N	N	N	Y	Y	Y	n
28- Facilitate social comparison	U	U	N	N	N	N	N	Y	n
29- Plan social support/social change	Y	Y	N	N	N	Y	Y	Y	y
30- Prompt identification as role model/position advocate	N	N	N	N	N	N	N	N	n
31- Prompt anticipated regret	N	N	N	N	N	N	Y	Y	n
32- Fear arousal	N	N	N	N	N	N	N	N	n
33- Prompt self talk	N	N	N	N	N	N	N	N	n
34- Prompt use of imagery	N	N	N	N	N	N	Y	Y	n
35- Relapse prevention/coping planning	Y	Y	N	N	N	Y	N	N	y
36- Stress management/emotional control training	Y	Y	N	N	N	N	N	N	y
37- Motivational interviewing	Y	Y	N	N	N	Y	N	N	n
38- Time management	Y	Y	N	N	N	N	N	N	n
39- General communication skills training	N	N	N	N	N	N	N	N	n
40- Stimulate anticipation of future rewards	N	N	N	N	N	Y	N	N	n

	Fitzgibbon 2010	Foster-Schubert 2012	Gold 2007 Vtrim	Gold 2007 eDiets	Hersey 2012 (2)	Hersey 2012 (3)	Heshka 2006	Jakicic 2012 STEP	Jakicic 2012 SBW1	Jebb 2011	Jeffrey 1995 SBT	Jeffrey 1995 SBT+food	Jeffrey 1995 SBT+incentives	Jeffrey 1995 SBT+food+incentives
01- Provide information on consequences of behaviour in general	Y	N	Y	N	Y	Y	Y	N	N	Y	N	N	N	N
02- Provide information on consequences of behaviour to the individual	N	N	N	N	N	N	N	N	N	N	N	N	N	N
03- Provide information about others' approval	N	N	N	N	N	N	N	N	N	N	N	N	N	N
04- Provide normative information about others' behaviour	N	N	N	N	N	N	U	N	N	U	N	N	N	N
05- Goal setting (behaviour)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
06- Goal setting (outcome)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
07- Action planning	Y	Y	Y	Y	N	N	U	Y	Y	U	Y	Y	Y	Y
08- Barrier identification/problem solving	Y	Y	Y	N	Y	Y	U	Y	Y	U	Y	Y	Y	Y
09- Set graded tasks	N	Y	Y	N	N	N	N	Y	Y	N	Y	Y	Y	Y
10- Prompt review of behavioural goals	Y	Y	Y	Y	Y	Y	U	Y	Y	U	Y	Y	Y	Y
11- Prompt review of outcome goals	Y	Y	U	Y	N	N	Y	Y	Y	Y	Y	Y	Y	Y
12- Prompt rewards contingent on effort or progress towards behaviour	N	N	N	N	N	N	U	N	N	U	N	N	N	N
13- Provide rewards contingent on successful behaviour	N	N	N	N	Y	Y	Y	N	N	Y	N	N	Y	Y
14- Shaping	N	N	N	N	N	N	N	N	N	N	N	N	N	N
15- Prompting generalisation of a target behaviour	Y	N	U	N	N	N	Y	N	N	Y	N	N	N	N
16- Prompt self-monitoring of behaviour	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
17- Prompt self-monitoring of behavioural outcome	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	N	N	N	N
18- Prompting focus on past success	N	N	N	N	N	N	N	N	N	N	N	N	N	N
19- Provide feedback on performance	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
20- Provide information on where and when to perform the behaviour	N	N	Y	N	N	N	Y	N	N	Y	N	N	N	N
21- Provide instruction on how to perform the behaviour	U	Y	Y	N	N	N	U	N	N	U	N	N	N	N
22- Model/Demonstrate the behaviour	U	Y	N	N	N	N	Y	N	N	Y	N	N	N	N
23- Teach to use prompts/cues	N	N	N	N	N	N	Y	N	N	Y	N	N	N	N
24- Environmental restructuring	Y	N	N	N	N	N	N	N	N	N	Y	Y	Y	Y
25- Agree behavioural contract	N	N	N	N	N	N	N	N	N	N	N	N	N	N
26- Prompt practice	N	Y	U	N	N	N	N	N	N	N	N	N	N	N
27- Use of follow-up prompts	Y	Y	N	N	Y	Y	N	N	N	N	Y	Y	Y	Y
28- Facilitate social comparison	N	N	N	Y	N	N	N	N	N	N	N	N	N	N
29- Plan social support/social change	Y	N	U	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y
30- Prompt identification as role model/position advocate	N	N	N	N	N	N	N	N	N	N	N	N	N	N
31- Prompt anticipated regret	N	N	N	N	N	N	N	N	N	N	N	N	N	N
32- Fear arousal	N	N	N	N	N	N	N	N	N	N	N	N	N	N
33- Prompt self talk	N	N	N	N	N	N	N	N	N	N	Y	Y	Y	Y
34- Prompt use of imagery	N	N	N	N	N	N	N	N	N	N	N	N	N	N
35- Relapse prevention/coping planning	Y	Y	U	N	N	N	N	N	N	N	Y	Y	Y	Y
36- Stress management/emotional control training	N	N	U	N	Y	Y	N	N	N	N	N	N	N	N
37- Motivational interviewing	Y	N	U	N	Y	Y	N	N	N	N	N	N	N	N
38- Time management	N	N	N	N	Y	Y	Y	N	N	Y	N	N	N	N
39- General communication skills training	N	N	U	U	N	N	N	N	N	N	N	N	N	N
40- Stimulate anticipation of future rewards	N	N	N	N	N	N	U	N	N	U	N	N	N	N

Jeffrey 1998 SBT
Jeffrey 1998 supervised
Jeffrey 1998 trainer
Jeffrey 1998 incentive
Jeffrey 1998 trainer and incentive
Jolly 2011 SD
Jolly 2011 GP
Jolly 2011 Pharm
Jolly 2011 WW
Jolly 2011 SW
Jolly 2011 RC
Kuller 2012
Kumanyika 2012 basic
Kumanyika 2012 Basic +

	Logue 2005 TM-CD	Logue 2005 AUC	Lindstrom 2003	Mensink 2003	Micco 2007 internet only	Micco 2007 internet and person	Morgan 2011	Munsch 2003 clinic	Munsch 2003 GP	Nanchahal 2011	Patrick 2011	Penn 2009	Rejeski 2011	Rock 2010 CB	Rock 2010 TB	Ross 2012	Saito 2011 (1) more frequent	Saito 2011 (2) less frequent
01- Provide information on consequences of behaviour in general	N	N	N	N	N	y	y	y	Y	Y	y	U	y	Y				
02- Provide information on consequences of behaviour to the individual	N	N	N	N	N	n	n	n	N	Y	n	U	n	N				
03- Provide information about others' approval	N	N	N	N	N	n	n	n	N	U	n	N	n	N				
04- Provide normative information about others' behaviour	N	N	N	N	N	n	n	n	U	N	n	N	n	N				
05- Goal setting (behaviour)	Y	Y	Y	Y	Y	y	y	y	Y	Y	y	Y	y	Y				
06- Goal setting (outcome)	U	U	U	U	U	y	y	y	Y	Y	y	Y	y	Y				
07- Action planning	Y	Y	Y	Y	Y	n	n	n	U	Y	n	U	y	Y				
08- Barrier identification/problem solving	Y	Y	Y	Y	Y	y	y	y	U	Y	u	Y	u	U				
09- Set graded tasks	Y	Y	Y	Y	Y	y	y	y	N	Y	y	Y	y	Y				
10- Prompt review of behavioural goals	Y	Y	Y	Y	Y	y	y	y	U	Y	u	N	y	Y				
11- Prompt review of outcome goals	Y	Y	Y	Y	Y	y	y	y	Y	Y	y	N	y	Y				
12- Prompt rewards contingent on effort or progress towards behaviour	N	N	N	N	N	n	y	y	U	Y	u	N	y	Y				
13- Provide rewards contingent on successful behaviour	N	N	N	Y	Y	n	y	y	Y	Y	y	N	n	N				
14- Shaping	N	N	N	N	N	n	n	n	N	Y	n	N	n	n				
15- Prompting generalisation of a target behaviour	N	N	N	N	N	n	n	n	Y	U	y	N	U	U				
16- Prompt self-monitoring of behaviour	Y	Y	Y	Y	Y	y	y	y	Y	U	y	Y	Y	Y				
17- Prompt self-monitoring of behavioural outcome	N	N	N	N	N	n	y	y	Y	Y	u	N	U	U				
18- Prompting focus on past success	N	N	N	N	N	n	n	n	N	Y	U	N	N	N				
19- Provide feedback on performance	Y	Y	Y	Y	Y	y	y	y	Y	N	U	U	Y	Y				
20- Provide information on where and when to perform the behaviour	N	N	N	N	N	y	n	n	Y	Y	N	N	U	U				
21- Provide instruction on how to perform the behaviour	N	Y	Y	Y	Y	y	n	n	U	N	Y	N	U	U				
22- Model/Demonstrate the behaviour	N	Y	Y	Y	Y	n	n	n	Y	N	Y	N	N	N				
23- Teach to use prompts/cues	N	N	N	N	N	n	n	n	Y	N	Y	N	N	N				
24- Environmental restructuring	Y	Y	Y	Y	Y	n	n	n	N	N	U	N	U	U				
25- Agree behavioural contract	N	N	N	N	N	n	n	n	N	N	N	N	N	N				
26- Prompt practice	N	N	N	N	N	n	n	n	N	Y	Y	N	Y	Y				
27- Use of follow-up prompts	Y	Y	Y	Y	Y	y	n	n	N	N	N	N	N	N				
28- Facilitate social comparison	N	N	N	N	N	n	n	n	N	N	N	N	N	N				
29- Plan social support/social change	Y	Y	Y	Y	Y	n	n	n	Y	Y	Y	Y	N	N				
30- Prompt identification as role model/position advocate	N	N	N	N	N	n	n	n	N	Y	N	N	N	N				
31- Prompt anticipated regret	N	N	N	N	N	n	n	n	N	N	N	N	U	U				
32- Fear arousal	N	N	N	N	N	n	n	n	N	N	N	N	N	N				
33- Prompt self talk	U	U	U	U	U	n	n	n	N	N	N	N	N	N				
34- Prompt use of imagery	U	U	U	U	U	n	n	n	N	N	N	N	N	N				
35- Relapse prevention/coping planning	Y	Y	Y	Y	Y	y	y	y	N	U	U	Y	N	N				
36- Stress management/emotional control training	N	N	N	N	N	n	y	y	N	Y	U	N	Y	Y				
37- Motivational interviewing	N	N	N	N	N	n	y	y	N	Y	N	Y	N	N				
38- Time management	N	N	N	N	N	n	y	y	Y	N	N	N	U	U				
39- General communication skills training	N	N	N	N	N	n	n	n	N	N	N	N	N	N				
40- Stimulate anticipation of future rewards	N	N	N	N	N	n	n	n	U	U	Y	N	N	N				

01- Provide information on consequences of behaviour in general	N	N	Y	N	Y	Y	N	Y	Y	N	N	y	N	N	N	U	U	U
02- Provide information on consequences of behaviour to the individual	N	N	U	N	N	N	N	Y	Y	Y	N	n	Y	N	N	N	N	N
03- Provide information about others' approval	N	N	N	N	N	N	N	N	N	N	N	n	N	N	N	N	N	N
04- Provide normative information about others' behaviour	N	N	N	N	N	N	N	N	N	N	N	n	N	N	N	N	N	N
05- Goal setting (behaviour)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	y	Y	Y	Y	Y	Y	Y
06- Goal setting (outcome)	Y	Y	Y	Y	Y	Y	U	Y	Y	Y	N	y	Y	Y	Y	Y	Y	Y
07- Action planning	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	n	Y	Y	Y	Y	Y	Y
08- Barrier identification/problem solving	U	U	Y	N	Y	Y	U	Y	Y	Y	N	n	Y	Y	Y	Y	N	N
09- Set graded tasks	Y	Y	U	N	Y	Y	N	Y	Y	Y	Y	y	N	Y	Y	N	N	N
10- Prompt review of behavioural goals	Y	N	Y	Y	Y	Y	Y	N	N	Y	Y	y	Y	U	U	Y	U	U
11- Prompt review of outcome goals	Y	N	Y	U	U	U	Y	Y	Y	Y	N	Y	Y	U	U	Y	U	U
12- Prompt rewards contingent on effort or progress towards behaviour	N	N	N	N	N	N	N	N	N	N	N	n	N	N	N	N	N	N
13- Provide rewards contingent on successful behaviour	U	N	N	N	N	N	N	N	N	N	N	n	N	N	N	N	N	N
14- Shaping	N	N	N	N	N	N	N	N	N	N	N	n	N	N	N	N	N	N
15- Prompting generalisation of a target behaviour	N	N	N	N	U	U	N	Y	Y	Y	N	n	N	N	N	N	N	N
16- Prompt self-monitoring of behaviour	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
17- Prompt self-monitoring of behavioural outcome	Y	N	Y	N	N	N	Y	N	N	N	N	n	N	U	U	U	Y	Y
18- Prompting focus on past success	N	N	N	N	N	N	N	N	N	Y	Y	n	N	N	N	N	N	N
19- Provide feedback on performance	U	N	Y	U	Y	Y	Y	N	N	Y	Y	y	Y	Y	Y	Y	Y	Y
20- Provide information on where and when to perform the behaviour	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	y	U	N	N	Y	Y	Y
21- Provide instruction on how to perform the behaviour	N	N	Y	Y	Y	Y	Y	N	N	Y	N	y	Y	Y	Y	Y	Y	Y
22- Model/Demonstrate the behaviour	N	N	Y	N	N	N	N	N	N	U	N	y	Y	Y	Y	N	N	N
23- Teach to use prompts/cues	N	N	N	N	N	N	N	U	U	Y	N	n	Y	U	U	N	N	N
24- Environmental restructuring	N	N	N	N	N	N	N	N	N	Y	N	n	N	U	U	N	N	N
25- Agree behavioural contract	N	N	N	N	N	N	N	N	N	N	N	n	N	N	N	N	N	N
26- Prompt practice	Y	N	Y	N	U	U	N	N	N	Y	Y	n	N	U	U	N	N	N
27- Use of follow-up prompts	N	N	N	N	N	N	Y	N	N	Y	N	Y	Y	U	U	N	N	N
28- Facilitate social comparison	N	N	Y	N	N	N	N	N	N	N	N	n	U	N	N	N	N	N
29- Plan social support/social change	N	N	N	N	U	U	Y	Y	Y	Y	Y	n	Y	N	N	Y	N	N
30- Prompt identification as role model/position advocate	N	N	N	N	N	N	N	N	N	N	N	n	N	N	N	N	N	N
31- Prompt anticipated regret	U	N	N	N	N	N	N	N	N	Y	N	n	N	N	N	N	N	N
32- Fear arousal	N	N	N	N	N	N	N	N	N	N	N	n	N	N	N	N	N	N
33- Prompt self talk	N	N	N	N	N	N	N	N	N	Y	N	n	N	N	N	N	N	N
34- Prompt use of imagery	N	N	N	N	N	N	N	N	N	U	N	n	Y	N	N	N	N	N
35- Relapse prevention/coping planning	N	N	N	N	U	U	N	Y	Y	Y	N	n	Y	Y	Y	Y	N	N
36- Stress management/emotional control training	N	N	N	N	U	U	N	N	N	Y	N	n	N	N	N	N	N	N
37- Motivational interviewing	N	N	N	N	U	U	N	N	N	Y	N	y	N	Y	Y	Y	N	N
38- Time management	N	N	N	N	N	N	N	N	N	Y	N	n	N	N	N	N	N	N
39- General communication skills training	N	N	N	N	U	U	N	N	N	Y	N	n	N	N	N	N	N	N
40- Stimulate anticipation of future rewards	N	N	N	N	N	N	N	N	N	N	N	n	N	N	N	N	N	N

	Seligman 2011 Low carb supervised	Seligman 2011 Low carb recommended	Seligman 2011 low fat recommended	Silva 2010	Skender 1996	Stevens 1993	Stevens 2001	Tate 2003 Internet	Tate 2003 Internet +	Vermunt 2011	Villareal 2011	Vissers 2010 fitness	Vissers 2010 vibration	Wadden 1988 Combined	Wadden 1988 behav only	Wadden 2011	Weinstock 1998
01- Provide information on consequences of behaviour in general	Y	Y	Y	Y	N	U	U	N	N	y	N	N	N	Y	Y	N	N

02- Provide information on consequences of behaviour to the individual	n	n	n	Y	N	N	N	N	N	y	N	N	N	N	N	N	N
03- Provide information about others' approval	n	n	n	N	N	U	N	N	N	y	N	N	N	N	N	N	N
04- Provide normative information about others' behaviour	n	n	n	N	N	N	N	N	N	n	N	N	N	N	N	N	N
05- Goal setting (behaviour)	y	y	y	Y	Y	Y	Y	Y	Y	y	Y	Y	Y	Y	Y	Y	Y
06- Goal setting (outcome)	y	y	y	Y	Y	Y	Y	U	U	y	Y	U	U	N	N	N	U
07- Action planning	n	n	n	Y	Y	Y	Y	Y	Y	n	Y	Y	Y	Y	Y	N	Y
08- Barrier identification/problem solving	y	y	y	Y	N	Y	Y	U	U	n	Y	N	N	N	N	Y	N
09- Set graded tasks	n	n	n	N	Y	Y	Y	Y	Y	n	Y	N	N	N	N	Y	Y
10- Prompt review of behavioural goals	y	y	y	Y	Y	Y	Y	Y	Y	y	Y	Y	Y	U	U	Y	Y
11- Prompt review of outcome goals	y	y	y	Y	N	Y	Y	Y	Y	y	Y	Y	Y	N	N	N	Y
12- Prompt rewards contingent on effort or progress towards behaviour	n	n	n	Y	N	N	Y	N	U	n	N	N	N	N	N	N	U
13- Provide rewards contingent on successful behaviour	n	n	n	N	N	N	Y	N	N	n	N	N	N	Y	Y	N	U
14- Shaping	n	n	n	N	N	N	N	N	N	n	N	N	N	N	N	N	U
15- Prompting generalisation of a target behaviour	n	n	n	N	N	N	N	Y	Y	n	Y	Y	Y	N	N	N	Y
16- Prompt self-monitoring of behaviour	y	y	y	Y	Y	Y	Y	Y	Y	n	Y	U	U	Y	Y	Y	N
17- Prompt self-monitoring of behavioural outcome	y	y	y	Y	N	Y	Y	Y	Y	n	Y	U	U	N	N	Y	N
18- Prompting focus on past success	n	n	n	N	N	N	N	N	N	n	N	N	N	N	N	N	N
19- Provide feedback on performance	y	y	y	Y	Y	Y	Y	N	Y	n	Y	N	N	N	N	Y	Y
20- Provide information on where and when to perform the behaviour	n	n	n	N	N	N	Y	N	N	n	Y	N	N	N	N	Y	Y
21- Provide instruction on how to perform the behaviour	y	n	n	Y	Y	Y	Y	Y	Y	n	Y	Y	Y	N	N	Y	Y
22- Model/Demonstrate the behaviour	n	n	n	N	U	Y	Y	N	N	n	Y	Y	Y	N	N	N	Y
23- Teach to use prompts/cues	n	n	n	N	N	N	N	N	N	n	N	N	N	N	N	Y	Y
24- Environmental restructuring	n	n	n	N	Y	U	Y	N	N	n	N	N	N	Y	Y	N	N
25- Agree behavioural contract	n	n	n	N	Y	N	N	N	N	n	N	N	N	N	N	N	N
26- Prompt practice	n	n	n	Y	N	Y	Y	Y	Y	n	Y	U	U	N	N	N	Y
27- Use of follow-up prompts	y	y	y	N	Y	Y	Y	N	Y	n	N	Y	Y	Y	Y	N	N
28- Facilitate social comparison	n	n	n	N	N	U	N	N	N	n	N	N	N	N	N	N	N
29- Plan social support/social change	N	N	N	Y	N	Y	Y	N	N	n	N	N	N	Y	Y	Y	N
30- Prompt identification as role model/position advocate	n	n	n	N	N	N	N	N	N	n	N	N	N	N	N	N	N
31- Prompt anticipated regret	n	n	n	N	N	N	N	N	N	n	N	N	N	N	N	N	N
32- Fear arousal	n	n	n	N	N	N	N	N	N	n	N	N	N	N	N	N	N
33- Prompt self talk	n	n	n	N	N	N	N	N	N	n	N	N	N	U	U	Y	N
34- Prompt use of imagery	n	n	n	N	N	N	Y	N	N	N	N	N	N	N	N	N	N
35- Relapse prevention/coping planning	n	n	n	Y	Y	Y	Y	N	N	N	N	N	N	Y	N	Y	U
36- Stress management/emotional control training	n	n	n	Y	Y	N	Y	N	N	N	N	N	N	N	N	Y	N
37- Motivational interviewing	n	n	n	Y	N	N	Y	N	N	Y	N	N	N	N	N	N	N
38- Time management	n	n	n	Y	N	N	Y	N	N	N	N	N	N	N	N	N	N
39- General communication skills training	n	n	n	Y	N	N	N	N	N	N	N	N	N	N	N	N	N
40- Stimulate anticipation of future rewards	n	n	n	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Appendix 5. Summary of funding source and judgements from quality checklists

Green cells indicate a positive judgement and red cells indicate a negative judgement. Reasons for negative judgements are recorded in comments. Criteria regarding intention to treat analyses and treatment of missing data are not reported here as these would not affect the quality of the findings in our review (because we used the same methods for each study).

Study ID	Commercial funding	Internal validity	External validity	Was the method used to generate random allocations adequate?	Was the allocation adequately concealed?	Were the groups similar at the outset of the study in terms of prognostic factors?	Were there any unexpected imbalances in dropouts between groups?	If so, were they explained or adjusted for?	Is there any evidence to suggest that the authors measured more outcomes than they reported?	Comments
Appel 2011	N	++	+	Y	Y	Y	N	n/a	N	
Bertz 2012	N	++	++	Y	U	Y	Y	Y	N	
Dale 2008	N	+	+	U	U	N	N	n/a	N	Higher BMI, weight and waist circumference in control group
DPP 2006	N	++	++	Y	Y	Y	N	n/a	N	
Dubbert 1984	N	++	+	U	U	Y	N	n/a	N	
Eriksson 2009	N	++	++	Y	Y	N	N	n/a	Y	BMI slightly higher in intervention group but unlikely to affect results. 6 and 36m weight measured but not reported
Fitzgibbon 2010	N	++	+	Y	Y	Y	N	n/a	N	
Foster-Schubert 2012	N	++	+	Y	Y	Y	N	n/a	N	
Gold 2007	N	+	+	U	U	Y	N	n/a	Y	61 participants randomised to arm unrelated to this study. Authors do not report results broken down into separate group for diet and PA adherence, as no statistically sig difference
Hersey 2012	N	+	++	U	U	Y	N	n/a	N	
Heshka 2006	Y	++	++	Y	Y	Y	N	n/a	N	
Jakicic 2012	N	+	++	Y	Y	Y	N	n/a	N	
Jebb 2011	Y	+	++	Y	Y	Y	N	n/a	N	
Jeffery 1995	N	+	+	U	U	U	U	U	N	
Jeffery 1998	N	+	+	U	U	Y	N	n/a	Y	Diet outcomes and perceived barriers not reported at later follow-up points, though they were measured
Jolly 2011	N	+	++	Y	Y	Y	N	n/a	N	Differences in rates of starting intervention and attendance, but this are inherent in the programme and not unexpected.

Study ID	Commercial funding	Internal validity	External validity	Was the method used to generate random allocations adequate?	Was the allocation adequately concealed?	Were the groups similar at the outset of the study in terms of prognostic factors?	Were there any unexpected imbalances in dropouts between groups?	If so, were they explained or adjusted for?	Is there any evidence to suggest that the authors measured more outcomes than they reported?	Comments
										Differences in rates of follow up.
Kuller 2012	N	++	++	Y	Y	Y	N	n/a	N	
Kumanyika 2012	N	++	++	Y	U	Y	N	n/a	N	
Lindstrom 2003	Y	++	++	Y	Y	Y	N	n/a	N	
Logue 2005	Y	++	++	Y	Y	Y	Y	N	N	drop out in augmented usual care group
Mensink 2003	N	+	++	Y	N	Y	N	n/a	N	
Micco 2007	N	+	+	U	U	N	N	n/a	N	BMI and weight higher in internet only group
Morgan 2011	N	++	+	y	Y	Y	N	n/a	N	
Munsch 2003	N	-	++	N	N	N	Y	N	N	Those recruited from GP randomised within two GP groups. Those recruited in clinic stayed in clinic. Those recruited via newspaper unclear. BMI higher in clinic intervention than GP control. Dropout at end of treatment slightly higher in clinic BASEL group but much higher in this group by follow up.
Nanchahal 2011	N	++	++	Y	Y	Y	N	n/a	Y	Psychological variables measured but not reported
Patrick 2011	N	++	+	Y	Y	Y	N	n/a	N	
Penn 2009	N	+	++	Y	U	Y	N	n/a	Y	Authors measured waist circumference and weight annually and did not report it as the differences were not significant
Rejeski 2011	N	+	+	U	U	Y	N	n/a	Y	Authors do not report weight at 12 months although the article suggests this would have been measured.
Rock 2010	N	++	++	Y	Y	Y	N	n/a	N	
Ross 2012	N	++	++	Y	U	Y	N	n/a	N	Allocation method not specified but conducted by data manager
Saito 2011	N	++	+	Y	Y	Y	N	n/a	Y	Weight change measured at 12, 24 and 36m but only reported at 12m; however authors provided
Seligman 2011	N	++	+	Y	Y	Y	N	n/a	N	
Silva 2010	Y	++	+	Y	N	Y	N	n/a	Y	Data on BMI and weight change missing at some follow-up points
Skender 1996	N	+	+	Y	U	Y	N	n/a	N	

Study ID	Commercial funding	Internal validity	External validity	Was the method used to generate random allocations adequate?	Was the allocation adequately concealed?	Were the groups similar at the outset of the study in terms of prognostic factors?	Were there any unexpected imbalances in dropouts between groups?	If so, were they explained or adjusted for?	Is there any evidence to suggest that the authors measured more outcomes than they reported?	Comments
Stevens 1993	N	++	+	U	Y	Y	N	n/a	N	
Stevens 2001	N	++	+	U	Y	Y	N	n/a	Y	BMI not included at 6,18,36 months
Tate 2003	N	++	+	Y	U	Y	N	n/a	N	
Vermunt 2011	N	+	++	N	N	Y	N	n/a	Y	Weight data missing at a number of time points
Villareal 2011	Y	++	++	Y	U	Y	N	n/a	N	
Vissers 2010	Y	+	++	U	U	Y	Y	N	N	Uneven dropouts between arms
Wadden 1988	N	+	+	U	U	Y	N	n/a	N	
Wadden 2011	N	++	+	Y	Y	Y	N	n/a	N	
Weinstock 1998	N	-	+	U	N	Y	U	n/a	N	Dropouts not reported

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