# Weight regain after behavioural weight management programmes

#### Review 1c

Johns D, Hartmann-Boyce J, Aveyard P, Onakpoya I, Jebb S, Phillips D, Ogden J, Summerbell C,
Perera R
03/04/2013

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.

## Contents

Contents
Executive summary4
Introduction4
Methods
Results
Conclusions
Commonly used terms and abbreviations
Introduction9
Clarification of scope
Review Questions
Methods1
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?1
Behavioural taxonomy: coding, groupings, and scores1
Data synthesis and presentation, including evidence statements13
Quantitative data synthesis
Multivariate regression modelling14
What interventions can maintain weight loss after the end of a behavioural weight loss
programme?1
Inclusion and exclusion criteria1
Search methods for identification of studies1
Study selection process
Quality assessment10
Data extraction, data synthesis and presentation, including evidence statements1

Results	18
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?	18
Studies included in the analysis	18
Population	18
Interventions	18
Quality and external validity	19
Effects of programme components on rate of weight-regain during low contact	ct follow-up
	22
Rate of weight regain	22
Weight loss at programme end	22
Programme delivery	22
Programme elements	22
Programme intensity (Active intervention phase)	23
Number of sessions of therapy	23
Multivariate regression modelling	23
Intervention characteristics	23
Associations of behavioural techniques and weight loss	23
Weight regain curves	24
What interventions can maintain weight loss after the end of a behavioural weight	eight loss
programme?	26
Results of the search	26
Quality of included reviews	27
Summary of findings	27
Turk et al. 2009	27
Catenacci and Wyatt 2007	29

Evidence statements31
Notes:31
Evidence statement 1.26 Applicability of available data
Evidence statement 1.27 Rate of weight regain after Multicomponent behavioural
weight management programmes31
Evidence statement 1.28 Effect of Multicomponent behavioural weight management
programme characteristics on the rate of weight regain after programme end32
Evidence statement 1.29 Effect of ease of activity during a behavioural weight
management programme on the rate of weight regain after programme end32
Evidence statement 1.30 Effective weight-loss maintenance interventions33
Discussion34
Appendices36
Appendix 1. Evidence tables36
Appendix 2. Summary of judgements from quality checklists52
Appendix 3. Behavioural taxonomy codes for each study arm54
Appendix 4. Search methods (Review of reviews of weight-loss maintenance
interventions)56
Appendix 5: Excluded studies (Review of reviews)74
Appendix 6: Evidence tables (Systematic reviews)75
Appendix 7: Summary of judgements from quality checklists (Systematic reviews)78
References

### **Executive summary**

#### Introduction

This review builds upon Review 1a and Review 1b by assessing the rate of weight regain after a multicomponent behavioural weight management programme (BWMP). At 12 to 18 months, the meta-analysis in Review 1a showed a statistically significant effect of BWMPs on mean weight loss when compared to control. Similarly, BWMPs had a statistically significant effect on mean weight loss at 36 months follow up.

In Review 1a and 1b, we sought to explain the variation in weight-loss by various components that differed between programmes, such as length, intensity, and face-to-face contact. These reviews used both direct (within study) and indirect (between study) comparisons. Review 1c examined only studies with follow up data after programme end and considered the effect of programme characteristics on the rate of weight regain during follow-up. It also included a review of systematic reviews examining the effectiveness of weight-loss maintenance strategies and programmes. Weight loss maintenance interventions are interventions used by people who have already lost weight in order to prevent regaining it.

#### **Methods**

A protocol for Review 1 was agreed with NICE before starting work. After the protocol had been finalised, it was agreed that Review 1 would be delivered as: Review 1a, Review 1b, and Review 1c. Review 1c drew on the same pool of studies as Review 1a but considered the effect of components of BWMPs on weight maintenance. As such, included studies were limited to those with follow-up data after programme end.

We coded interventions based on their characteristics and also applied a behavioural taxonomy to each intervention to describe the intervention in standard terms. The behavioural change techniques were grouped to aid analysis. The outcome of interest was the rate of weight regain during follow-up. All weights were reported using a baseline observation carried forward (BOCF) approach. We used univariate meta-regression to test associations between intervention characteristics and outcome.

To examine reviews of weight maintenance, we ran systematic searches of ten electronic databases and also screened reference lists and considered references submitted to NICE in a call for evidence. One reviewer screened titles and abstracts using an inclusion criteria checklist that had been agreed before screening. Two reviewers independently assessed full text articles and extracted data from included studies. Any disagreements were resolved by discussion or consulting a third reviewer. Results were presented narratively.

#### Results

#### Weight regain

#### **Included studies**

Of the 30 studies included in review 1a, this review includes 11 studies with follow-up data after programme end. Three studies were conducted in the UK, two in the USA and one each in Sweden,

New Zealand, Australia, Switzerland, Finland and Belgium. The included studies represented a total of 4,874 participants. The majority of participants were female (72%) with the average study consisting of 68% females. Only 5 of the 11 included studies reported any data on ethnicity – of those that did, the mean percentage minority group was 19%, ranging from 0 to 46%.

The 11 included studies represent 19 interventions. The average active intervention phase (as defined by reviewer as more than one visit every other month) was 6 months, ranging from 3 to 36 months (median 4 months). The average length of total follow-up was 25 months, ranging from 12 to 120 months (median 12 months). The average length of follow-up after programme end was 18 months (median 9). Six of the studies were judged as ++ (high) for internal validity (study quality). All eleven were judged as high (++) for external validity.

#### Relationship between programme components and outcomes

The average rate of weight regain for participants in BWMPs was calculated (0.047kg/month; 95 Cl% 0.0294 to 0.066). This implies that the intervention group gain approximately half a kilogram per year more than those in the control group. The coefficients below represent an increase or decrease in this rate.

In univariate models considering the characteristics of programmes during their active phase, programmes incorporating specific equipment or requiring special settings for physical activity (0.19 kg/month, 95% CI -0.048 to -0.3; p = 0.01) were associated with a significant increase in the rate of weight regain after the programme had ended. Of the 19 interventions (from 11 studies), only three BWMPs (two from one study) used specific equipment or required a special setting for physical activity. Requiring special equipment or setting for physical activity remained significant in multivariate models with other programme characteristics.

#### Reviews of weight-loss maintenance interventions

We screened 610 references in total only two of which reviewed weight-loss maintenance trials i.e. where participants are randomised after weight-loss to an intervention. These reviews presented 42 studies with 4 studies being presented in both reviews. The review by Turk *et al* (2009) was of medium (+) quality and a review by Catenacci and Wyatt 2007 was of low (-) quality having not provided sufficient details on screening or formally assessed scientific quality or publication bias.

Both reviews were narrative and neither review combined study results statistically. Both reviews concluded that physical activity (and adherence to it) is an important part of a weight maintenance intervention. Neither study provided an insight into the best way to improve adherence to physical activity. In addition, Turk *et al* 2007 considered the significant effect of a number of other interventions on improved weight maintenance including the use of green tea, increased protein intake, contact frequency and problem solving.

#### **Conclusions**

People who follow a weight loss programme lose more weight during the programme than people who try to lose weight without support, with a difference of -3.3 kg at 12-18 months from baseline (Review 1a). However the active intervention period for most programmes is shorter than this and it is apparent that after the end of the programme the population mean weight slowly increases. The average rate of weight regain, based predominantly on studies with follow up periods of up to 1y is 0.56kg/y. This is consistent with evidence from 1 study with longer follow up. Weight regain is unrelated

to initial weight loss. Indeed few characteristics of the preceding programme are related to the rate of weight regain.

#### **Summary of evidence statements**

Please see the final agreed evidence statements for this guideline which are contained in a separate document on the NICE website. The final statements reflect conclusions drawn from reviews 1a, 1b, 1c and 2 (as appropriate)

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).

- There is strong evidence that following a multicomponent behavioural weight management programme and during low contact follow-up (once every two months or less), weight regain is 0.047kg/month higher than in a control group (Evidence statement 1.20).
- There is moderate evidence that the amount of weight-lost at the end of the active intervention (contact greater than once every two months), supervised exercise during the active intervention phase and behavioural technique score were not associated with rate of weight regain (Evidence statement 1.21).
- There is weak evidence that type of contact (group, individual or combination of both), number of contacts, frequency of contacts, set energy prescription and the professional background of the therapist during the active intervention phase was not associated with rate of weight regain (Evidence statement 1.21).
- There is moderate evidence that requiring specific equipment or settings to perform activity (0.19kg/month, 95% CI: 0.048 to 0.33; p = 0.01) during the active intervention is associated with faster weight regain after the programme end (Evidence statement 1.22).
- There is a lack of high quality reviews on the effectiveness of weight-loss maintenance interventions. There is weak evidence that after weight-loss, the use of a low-fat diet, caffeine supplementation, an increased protein intake, and increased contact frequency and problem solving as part of a weight maintenance programme can be effective in reducing weight regain (Evidence statement 1.23).

# 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 Review 1a; 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

#### **Clarification of scope**

This report is a natural continuation of Review 1a and Review 1b in that it considers long-term weight change and the effectiveness of weight-loss maintenance interventions.

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 of 44 intervention arms) could be combined in a meta-analysis in Review 1a. At 12 to 18 months, the meta-analysis showed a statistically significant effect of behavioural weight management programmes (BWMPs) on weight loss when compared to control (mean difference -2.58 kg, with 95% confidence intervals (CI) -2.76 to -2.40), though with very great differences between studies.. Review 1a has also demonstrated that BWMPs may be effective over extended periods with studies at 36 month follow up (4 studies) having a mean difference of -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 various components that differed between programmes, such as length, intensity, and face-to-face contact alone.

Review 1b included 44 studies, testing 73 intervention arms and 30 control arms. It included more than 17,000 participants in total. Twenty-five studies compared one BWMP to another. Direct comparisons found that programmes which involved diet and exercise were more effective than those which involved diet only or exercise only. Similarly direct comparison found in person contact was more effective than remote contact. Meta regression showed 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). However, the key ingredients that differentiate more effective from less effective interventions remain largely unknown.

Review 1c examines the rate of weight regain in studies where follow-up data were available and used meta regression (indirect) to assess the effect of intervention components on the rate of weight regain; and secondly, it appraises and summarise systematic and non-systematic reviews that have examined the effectiveness of weight-loss maintenance interventions. A weight loss maintenance intervention is defined as an intervention that starts after a weight loss programme and enrols only people who have been successful in losing weight.

#### **Review Questions**

This report, Review 1c, addresses effectiveness of interventions to promote weight-loss maintenance.

To do this it seeks to answer the following questions:

- 1. What happens to the difference in weight between people treated on a behavioural weight loss programme and a control group in the longer term?
- 2. 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?
- 3. What interventions can maintain weight loss after the end of a behavioural weight loss programme?

To answer the above questions, this report focuses on two types of studies. Firstly, those which compare BWMPs with a control group and secondly, reviews which have examined the effectiveness of specific weight-loss maintenance interventions

#### Methods

The protocol was agreed with NICE prior to commencing work. This review draws on the same pool of studies as review 1a and considers weight maintenance after programme end (defined as a contact frequency of less than or equal to once every two months). Secondly, it considers published reviews of weight-loss maintenance interventions and the effectiveness of the strategies used. Aspects key to the understanding the weight maintenance aspects of review 1b are described here.

# 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?

This question considers studies which compare multi-component behavioural interventions (BWMPs) with a control group. These studies have been previously identified in review 1a and include studies which with a comparison group coded 1-4:

- 1. No intervention at all or leaflet/s only<sup>1</sup>
- 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

Studies from Review 1a were reassessed and an active intervention phase redefined as the period where contact was greater than one contact every two months. Studies that provided data at one or more time-point after this active phase were included.

#### 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<sup>2</sup>. 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.

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

<sup>&</sup>lt;sup>1</sup> Note that leaflets included static websites, i.e. information and advice only, not interactive weight loss programmes, which come under 5 or 6).

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<sup>3</sup>. 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).

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				

.

<sup>&</sup>lt;sup>3</sup> REFERENCE MICHIE UNPUBLISHED PAPER

#### Data synthesis and presentation, including evidence statements

We presented evidence tables summarising key features of each included study, and narratively summarised the characteristics of the studies overall in review 1a.

#### Quantitative data synthesis

Weight change was measured as kilograms (kg) from programme start (baseline) and was calculated using baseline observation carried forward (BOCF).

Effect size and standard errors were obtained at the end of intervention and end of follow-up and the difference calculated. This difference was then divided by the length of follow-up. We then took the difference between the intervention and the control group and calculated the standard error for this difference. Thus our final figure gives the rate of change of the effect size i.e. the difference in rate of weight change between the intervention group and the control group in (kg/month).

A weight change graph for comparison groups rated 1-4 are displayed in Review 1a (Figure 6, p43 and; Figure 19, p57-58). They showed that participants in control groups tended to lose a little weight or stay steady during the 'weight loss programme time' and remain fairly steady after that. These data can help ease the interpretation of the coefficients, which otherwise might seem convoluted and difficult to understand. If, as demonstrated in Review 1a, there is almost no weight change in the control group then we may interpret this coefficient as the rate of change in weight in the intervention group. More strictly, the coefficient is the difference in weight change between the intervention and control groups. For ease of reading, we have referred to the coefficient as the rate of change in the intervention group. Awe positive coefficient indicates that participants in the intervention group regain weight, a negative coefficient that they lose weight, and zero as weight is steady.

The initial model was an empty model, which includes only the constant term from the regression equation, which estimated the average weight of regain in participants who had finished the programmes in the review. We then included the amount of weight loss in the preceding programme. This examined whether the amount of weight lost was associated with more rapid weight regain. Thereafter, we examined the effects of BWMP characteristics on the rate weight regain. We used a random effects model to account for the differences in populations, length of follow up, and prior programme characteristics which could not be modelled explicitly. The variables used were:

- Individual 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 at least weekly, every two weeks, monthly, every two months, and less than every two months)

- Whether the programme involved supervised exercise or recommended exercise only
- Whether or not the exercise required a specific setting or equipment to perform
- Whether the intervention was delivered by a dietitian, a person with detailed training in supporting weight loss, or a person with another background and only a little training in weight loss
- Whether or not weight loss goals were set.

#### **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.

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

We examined this with a review of reviews.

#### Inclusion and exclusion criteria

#### **Population**

- Adults ( $\geq$  18 years) initially classified as overweight or obese prior to starting a weight loss programme, i.e. people with a BMI of  $\geq$  25 kg/m<sup>2</sup> and  $\geq$  30 kg/m<sup>2</sup>, respectively.
- Enrolment in a weight loss maintenance intervention implies that people who have lost weight were enrolled. *No restriction was placed on how much weight loss was achieved prior to enrolment in a weight loss maintenance trial.*
- Reviews of trials in children, pregnant women, and people with eating disorders were not 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 but excluding pharmacotherapy or surgery

#### **Types of studies**

A weight loss maintenance study was defined as one which enrolled and randomised participants who had already lost weight by means other than surgery.

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

#### Location

- Undertaken in any setting
- Reviews that included studies undertaken in any country were included, though we anticipated that reviews would include overwhelmingly studies conducted in OECD countries.

#### Search methods for identification of studies

#### **Database searches**

As in review 1a, we searched BIOSIS, the Cochrane Database of Systematic Reviews, CENTRAL, the Conference Proceedings Citation Index, the Database of Abstracts of Reviews and Effects (DARE), Embase, the Health Technology Assessment database, Medline, PsychInfo, and Science Citation Index for references relating to weight loss programmes.

The literature search was run on 1<sup>st</sup> March, 2013 by NICE with input from one reviewer. Full search strategies can be found in Appendix 4. In brief, we adapted the search strategy defined in review 1a by including text word searches for terms relevant to weight maintenance. These included 'review' and the following terms within 4 words of weight: Maintenance; Maintain\*; Regain\*; Gain\*; Relapse\*; Sustain\*. We included reviews published from the year 2000.

#### **Study selection process**

Assessment for inclusion was initially undertaken at title and/or abstract level (to identify potential papers/reports for inclusion) by a single reviewer (and a sample of over 10% checked by a second reviewer), and then by examination of full papers. A third reviewer helped adjudicate inclusion decisions in cases of disagreement. Where the research methods used or type of initiative evaluated were not clear from the abstract, assessment was based upon a reading of the full paper, conducted by two reviewers.

#### **Quality assessment**

We critically appraised the literature for inclusion using a checklist based on the 'assessment of multiple systematic reviews'  $(AMSTAR)^4$ . A method of categorising the AMSTAR scores has been used by the Cochrane tobacco group in  $Oxford^5$ . Each review is graded ++, + or – based on the following criteria:

- 1. Was an 'a priori' design provided?
- 2. Was there duplicate study selection and data extraction?
- 3. Was a comprehensive literature search performed?
- 4. Were published and unpublished studies eligible, irrespective of language of publication?
- 5. Was a list of studies (included and excluded) provided?
- 6. Were the characteristics of the included studies provided?
- 7. Was the scientific quality of the included studies assessed and documented?
- 8. Was the scientific quality of the included studies used appropriately in formulating conclusions?
- 9. Were the methods used to combine the findings of studies appropriate?
- 10. Was the likelihood of publication bias assessed?
- 11. Was the conflict of interest stated?

Each criterion is rated as 'Yes' (definitely done), 'No' (definitely not done), 'Can't answer' (status unclear) or 'Not applicable'. A 'Yes' rating is taken to indicate adequate quality. We have graded the included reviews as being of ++ (scoring 8-11), + (scoring 4-7), or - (scoring 0-3). Scores were adjusted for the number of criteria deemed 'Not applicable' by using a percentage system. We have not excluded reviews on the basis of AMSTAR rankings.

<sup>&</sup>lt;sup>4</sup> Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C, Porter AC, Tugwell P, Moher D, Bouter LM. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Med Res Methodol. 2007 Feb 15;7:10.

<sup>&</sup>lt;sup>5</sup> Cochrane tobacco group. Pharmacological interventions for smoking cessation: an overview and network meta-analysis; 27th Feb 2013. Oxford

## Data extraction, data synthesis and presentation, including evidence statements

Data extraction was conducted using a pre-defined evidence table. Data extraction and quality assessment were done by one reviewer and independently checked by a second reviewer. Any discrepancies were resolved by discussion or, where needed, by referral to a third reviewer.

We presented evidence tables summarising key features of each included review. The characteristics, results and conclusions of these reviews are narratively summarised.

#### Results

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?

#### Studies included in the analysis

Results of the search are summarized in Review 1a (Methods section, page 22). In total, 30 studies included a comparison of a behavioural weight management program versus a control (defined as no contact through to seeing someone with no training in weight management more than once, but excluding conditions where a health professional with relevant training was seen on one or more occasion or behavioural interventions with diet or exercise were delivered). Of these, eleven studies representing 19 interventions provided sufficient follow-up data after the active intervention phase (defined as contact greater than once every two months) to be included. These studies are summarised in Table 2.

#### **Population**

Three studies were conducted in the UK (Penn, 2009; Jolly, 2011; Nanchahal, 2011), two in the USA and one each in Sweden, New Zealand, Australia, Switzerland, Finland and Belgium.

The eleven included studies represented a total of 4,874 participants. The average number of participants per study was approximately 430, ranging from 65 to over 2,100. The majority of participants were female (72%) with the average study consisting of 68% females. Two studies recruited women only (Bertz, 2012; Kuller, 2012) and one study recruited men only (Morgan, 2011). Only 5 of the 11 included studies reported any data on ethnicity – of those that did, the mean percentage minority group was 19%, ranging from 0 to 46%. 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.

Four studies required some measure of elevated risk for developing type 2 diabetes beyond overweight/obesity (family history, elevated fasting glucose, impaired glucose tolerance, etc.)(Penn, 2009; Diabetes Prevention Program Research, 2009; Dale, 2009; Lindström, 2003).

#### **Interventions**

The 11 included studies represented 19 intervention arms. Evidence tables provide more detail on each included intervention (Appendix 1). The average intervention (as defined by the study) lasted 9 months, ranging from 3 to 36 months (median 4 months). The average active intervention phase (as defined by reviewer as more than one visit every other month) was 6 months, ranging from 3 to 36 months (median 4 months). The average length of total follow-up was 25 months, ranging from 12

to 120 months (median 12 months). The average length of follow-up after programme end was 18 months (median 9).

In total, seven interventions involved dietitians (Bertz, 2012;Dale, 2009;Diabetes Prevention Program Research, 2009;Lindström, 2003;Penn, 2009;Vissers, 2010), five involved health professionals (Jolly, 2011;Lindström, 2003;Munsch, 2003) without specific weight loss training, two involved psychologists (Munsch, 2003;Kuller, 2012), and five involved trained lay people (Nanchahal, 2011;Jolly, 2011). Sixteen interventions set a target for weekly weight loss (ranging from 0.9 to 1.5 kg/week) and 11 set targets for longer term weight loss (targets ranging from 2 to 10% of baseline weight, or 6.4kg; time within which to reach target ranging from three to 6 months). In seven interventions contact frequency or intensity declined over the course of the intervention.

#### **Quality and external validity**

Six studies were judged to be of high quality: all or most quality checklist criteria were fulfilled and conclusions were judged unlikely to alter. Four studies were awarded only one + (Vissers, 2010;Penn, 2009;Jolly, 2011;Dale, 2009), 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. One study was rated as - (Munsch, 2003), with few or no criteria fulfilled and conclusions judged likely to alter. Reasons for study downgrading are detailed in the evidence tables (Appendix 1).

Eleven 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.

**Table 2. Overview of included studies** 

Study ID and aim	Population and setting	Quality and validity scores	Intervention	Outcomes
Bertz 2012 Aim: Weight loss	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	Quality score: ++ External validity score: ++	Individual Delivered by: dietitians and physical therapists Mode of delivery: in-person Number of sessions: 2 Active intervention: 3 months Session length: 135 mins	Longest follow-up: 12 months Change reported: Weight: Yes BMI: Yes Waist circumference: No
Dale 2008 Aim: diabetes prevention	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.	Quality score: + External validity score: +	Group and individual Delivered by: dietitians, exercise consultants and researchers Mode of delivery: phone and in-person Number of sessions: 36 Active intervention: 4 months Session length: NR	Longest follow-up: 24 months Change reported: Weight: Yes BMI: Yes Waist circumference: Yes
DPP Aim: diabetes prevention	Total n: 2161 Mean baseline BMI: Intervention: 33.9 (6.8); Control: 34.2 (6.7) Additional inclusion criteria: Impaired glucose tolerance required	Quality score: ++ External validity score: ++	Group and individual  Delivered by: dietitians, plus people with MA in exercise physiology, behavioural psychology or health education  Mode of delivery: phone and in-person Number of sessions: NR Active Intervention: 3 months Session length: 40 mins	Longest follow-up: 48 months (plus extrapolated data at 10 years) Change reported: Weight: Yes BMI: No Waist circumference: No
Kuller 2012 (WOMAN study) Aim: slow subclinical athleroscler osis in women on HRT	Total n: 508 Mean baseline BMI: Intervention 30.6 (3.8); Control 30.9 (3.8); Additional inclusion criteria: post menopausal women	Quality score: ++ External validity score: ++	Group  Delivered by: nutritionists, psychologists, exercise physiologists  Mode of delivery: in-person Number of sessions: 64 Active intervention: 36 months Session length: NR	Longest follow-up: 48 months Change reported: Weight: Yes BMI: No Waist circumference: No
Jolly 2011 (Lighten Up) Aim: weight loss	N: 640 Mean baseline BMI: 34 (across all groups; SD approx 4) Additional inclusion criteria: n/a	Quality score: + External validity score: ++	Differs by intevention arm, see evidence table Delivered by: Differs by intevention arm, see evidence table Mode of delivery: in-person Number of sessions: 12 Active intervention: 3 months Session length: 60 mins	Longest follow-up: 12 months Change reported: Weight: Yes BMI: Yes Waist circumference: No
Lindstrom 2003 (Finnish DPS) Aim: diabetes prevention	Total n: 522 Mean baseline BMI: Intervention: 31.4 (4.5) Control: 31.1 (4.5) Additional inclusion criteria:People at high risk for type 2 diabetes	Quality score: ++ External validity score: ++	Group and individual Delivered by: dietitian, nutritionist, physician Mode of delivery: phone and in-person Number of sessions: 15 Active intervention: 12 months Session length: NR	Longest follow-up: 36 months Change reported: Weight: Yes BMI: Yes Waist circumference: Yes

Study ID and aim	Population and setting	Quality and validity scores	Intervention	Outcomes
Morgan 2011 (SHED-IT trial) Aim: Weight loss	Total n: 65 Mean baseline BMI: Intervention 30.6 (2.7); Control 30.5 (3.0) male university staff and students	Quality score: ++ External validity score: +	Group and individual Delivered by: researcher Mode of delivery: in-person and web Number of sessions: 8 Active intervention: 3 months Session length: NR	Longest follow-up: 12 months Change reported: Weight: Yes BMI: Yes Waist circumference: Yes
Munsch 2003 Aim: Weight loss	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	Quality score: - External validity score: ++	Group Delivered by: GP trained by psychologist and dietitian Mode of delivery: in-person Number of sessions: 16 Active intervention: 4 months Session length: 90 mins	Longest follow-up: 12 months Change reported: Weight: Yes BMI: Yes Waist circumference: No
Nanchahal 2012 (CAMWEL) Aim: Weight loss	Total n: <i>381</i> Mean baseline BMI: Intervention33.0 (5.4); Control 33.9 (5.6)	Quality score: ++ External validity score: ++	Individual  Delivered by: Health trainers, who are lay people trained by the NHS in behaviour change counselling Mode of delivery: in-person Number of sessions: 14 Active intervention: 8 months Session length: 30 mins	Longest follow-up: 12 months Change reported: Weight: Yes BMI: Yes Waist circumference: Yes
Penn 2009 Aim: diabetes prevention	Total n: 102 Baseline BMI: Intervention: 34.1 (5.5) Control 33.5 (4.6) Additional inclusion criteria: Non diabetic subjects with impaired glucose tolerance	Quality score: + External validity score: ++	Group and individual  Delivered by: dietitian and physiotherapist  Mode of delivery: in-person Number of sessions: 20  Active intervention: 12 months  Session length: 30 mins	Longest follow-up: 60 months Change reported: Weight: Yes BMI: No Waist circumference: No
Vissers 2010 Aim: weight loss	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)	Quality score: + External validity score: ++	Individual Delivered by: dietitian and physiotherapist Mode of delivery: in-person Number of sessions: 12 Active intervention: 6 months Session length: NR	Longest follow-up: 12 months Change reported: Weight: Yes BMI: Yes Waist circumference: No

## Effects of programme components on rate of weight-regain during low contact follow-up

#### Rate of weight regain

The average rate of weight regain for all studies was calculated (0.047kg/month; 95 CI% 0.029 to 0.066). This implies that the intervention group gain approximately half a kilogram per year more than those in the control group. The coefficients below represent an increase or decrease in this rate.

#### Weight loss at programme end

We first ran a meta-regression to consider the effect of the amount of weight lost at the end of the intervention in comparison to a control, on the rate of weight regain and found no significant association (Coefficient -0.0001kg/month; 95% CI -0.009 to 0.008, p = 0.978).

#### **Programme delivery**

#### Group versus individual

Random effects meta-regression did not detect a significant association of group, individual or combined group and individual delivery on the rate of weight regain (combined group and individual: coefficient 0.004 kg/month, 95% CI -0.065 to +0.07, p = 0.913; group only: -0.0095, 95% CI -0.088 to 0.069, p = 0.801; individual only: -0.029, 95% CI -0.17 to 0.11, p = 0.669).

#### **Professional background of therapist**

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 and psychologist), making detailed analysis impossible. Of those delivering the interventions, dietitians were the only group whose core role would have involved weight loss counselling. Therefore, using metaregression, we tested if the involvement of a dietitian in the prior BWMP was associated with the rate of weight regain after the programme. The association was not statistically significant (0.04 kg/month, 95% CI -0.05 to 0.12, p = 0.401)

#### **Programme elements**

#### Physical activity: easy versus difficult to implement recommendations

We used univariate meta-regression to test the association of easy versus difficult to implement physical activity with weight regain in relation to a control group, defining difficult as requiring specific equipment or settings to perform the activity. Three BWMPs from two studies fell within this category (Dale, 2009; Vissers, 2010). There was evidence that having followed a weight loss programme that incorporates specific equipment or requiring special settings for physical activity were associated with greater weight regain (0.19kg/month, 95% CI: 0.048 to 0.33; p = 0.01).

#### Supervised versus recommended exercise

A prior weight loss programme that incorporated supervised exercise rather than behavioural counselling to increase exercise was not associated with greater or lesser weight regain. The coefficient was 0.006 for supervised exercise, 95% CI -0.018 to 0.015, p = 0.12.

#### **Energy intake prescription (set energy prescription)**

Seven programmes set energy prescription. Univariate meta-regression did not detect any significant association of set energy prescription during the programme and weight-regain after the programme (0.024 kg/month, 95% CI -0.06 - 0.11, p = 0.504).

#### **Programme intensity (Active intervention phase)**

#### **Contact frequency**

Meta-regression did not detect any significant association of contact frequency during the preceding BWMP on the rate of weight regain after the programme (0.012 kg/month per additional week between contacts, 95% CI -0.008 to 0.0322, p = 0.227). We classified studies by number of weeks between contacts (weekly =1, fortnightly = 2, and monthly = 4).

#### **Number of sessions of therapy**

Meta regression detected no significant associations between the number of sessions of therapy (continuous) during the BWMP on the rate of weight regain after the programme in comparison to a control (0.028; 95% CI -0.067 to 0.051, p = 0.05).

#### 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 ease to which physical activity could be completed was the only characteristics significantly associated with the rate of weight regain. We therefore ran each variable again, controlling for the effect of the need for physical activity equipment. The need for physical activity equipment remained significantly associated with greater weight regain in all models. No other significant associations were found.

#### Associations of behavioural techniques and weight loss

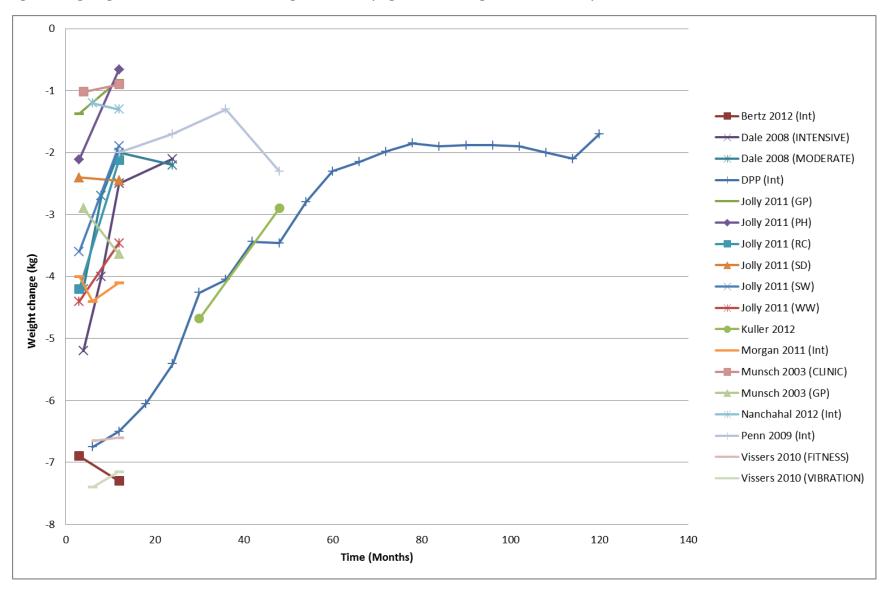
We used meta-regression to test the associations of the 14 behavioural technique groupings with the rate of weight regain. Cumulative scores (scores from all groupings combined) did not have a significant effect on the rate of weight regain (-0.00027kg/month; 95% CI -0.0056 to 0.0051, p = 0.916) suggesting that the overall presence, absence, or reporting of techniques did not impact the rate of weight regain. Univariate meta-regression models were run for each behavioural technique separately but none were found to have a significant effect on the rate of weight regain. Taxonomy scores for individual techniques can be found in Appendix 3.

#### Weight regain curves

In addition to the above analysis, we drew weight-regain curves for BWMP intervention arms with post intervention follow-up data. As can be seen from Figure 4, participants in the majority of studies regained weight once the active intervention had come to an end. However, some studies see some small continued weight loss in the short term.

The variation in the rate of weight regain can also be seen in this figure. Studies with more than two follow-up data points show the complexity of weight regain over a prolonged period.

Figure 2. Weight regain in BWMP interventions following the end of the programme but during low contact follow-up

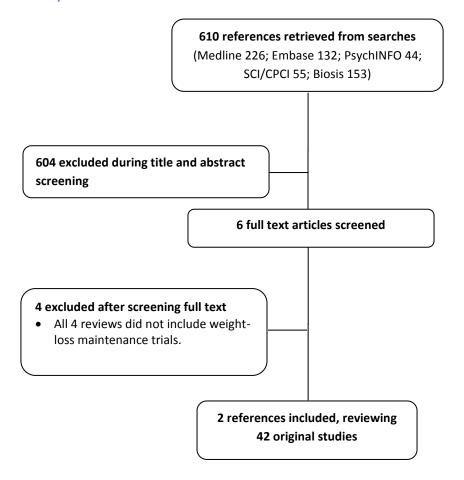


## What interventions can maintain weight loss after the end of a behavioural weight loss programme?

#### Results of the search

A flow chart detailing the search and screening process can be found in Figure 2. Our search retrieved 610 references in total. 604 references were excluded during title and abstract screening. Full text was retrieved and screened for 6 reviews. Four of these six were excluded after full text screening and two included in the review. The reason for excluding the four studies at full-text stage was that they did not review studies of weight-loss maintenance interventions (Appendix 5). The majority of these excluded reviews looked at studies whose primary intention was weight-loss but had an extended follow-up period. These reviews are similar in design to Review 1a, 1b and the first part of Review 1c and so were not the focus of this review. We defined a weight-loss maintenance study as one which enrols and randomises participants who have already lost weight by means other than surgery. By definition all studies included in Reviews 1a, 1b or the first part of 1c are excluded in these reviews.

Figure 3. Diagram of study flow



#### Quality of included reviews

One review was rated + (Turk, 2009) and the second review - (Catenacci, 2007). Neither review had an a priori plan or provided screening methods in sufficient detail. The scientific quality of included studies was also not assessed formally by either review. Similarly, no formal consideration was given to publication bias. Reasons for study downgrading are given in evidence tables (Appendix 7).

#### **Summary of findings**

In total, the two reviews represented the findings of 42 studies. Four studies were reviewed by both authors. However, the reviews report different aspects of these studies such as follow-up and adherence to physical activity. Both reviews conclude that physical activity (and adherence to it) is an important part of a weight maintenance intervention. Turk *et al.* also found evidence that caffeine; protein intake; contact frequency; problem solving; and some alternative therapies may also have beneficial effects on weight maintenance. Further details are summarised below and reported in Appendix 6.

#### Turk et al. 2009

#### **Inclusion criteria**

The search was conducted between the dates 1984 to 2007. The criteria for inclusion in the review were:

- 1) A randomized clinical trial of a weight-loss maintenance intervention after an initial weight loss;
- 2) Adult population (18 years of age, 1 trial > 17 years old); and
- 3) English language.

The authors state that to isolate the specific effect on weight-maintenance, only trials of a true experimental design and those which, in agreement with our definition, randomly assigned participants to an intervention for maintenance were included. Weight-loss trials with a maintenance phase that did not randomly assign participants to the maintenance intervention were excluded.

#### **Interventions**

Turk et al. found 42 studies that met their inclusion criteria. These studies were organised according to the type of intervention. Six categories of studies were found 1) Internet (4 studies), 2) maintenance strategies after a very-low-calorie diet (19 studies), 3) pharmacotherapy (7 studies), 4) behaviour therapy (10 studies), 5) physical activity (1 study), and 6) alternative therapies (1 study).

Pharmacotherapy is beyond the scope of this work and as such, the results of the seven studies in category three and seven studies in category two (VLCD followed by medications in maintenance) are not summarised in this report.

#### **Outcomes**

The principal outcome of interest in this review was weight change (continued loss, maintenance, or regain). The authors also calculated effect sizes in order to determine the magnitude of the treatment effect for each study.

#### Internal and external validity of included studies

The review does not provide a score for either internal or external validity of the studies included. See Section: Limitations, for some additional information on the quality of studies included.

#### **Effects of interventions**

Excluding pharmacology and alternative therapies, the review found 14 studies with beneficial effects on weight-loss maintenance.

These studies suggested that promising methods for reducing weight regain include inclusion of caffeine (a green-tea mix) (one study), added dietary protein (two studies), consuming fewer calories from fat (one study), adherence to physical activity (two studies), continued therapist contact (6 studies) and problem solving (one study).

The efficacy of a green-tea mix was found only within participants consuming lower baseline levels of caffeine, the authors' therefore suggested these results should be interpreted with caution.

Increased protein intake resulted in less weight regain in two studies testing the effect of 30 g/day and 42.8 g/day of added protein. In both studies, the actual consumption of protein was 18% of calories in the protein groups compared to 15% of calories from protein in the control groups.

Two RCTs of weight-loss maintenance explored the role of physical activity after a VLCD; one in women and one in men. Although neither study found a difference between groups in weight regain at the completion of the trial, adherence to the exercise prescription was negatively correlated with weight gain. Both studies offered counselling to follow a low-fat diet. The review did not offer any insight into how to best include physical activity in a maintenance programme to increase adherence.

Ten studies in the review investigated different behavioural strategies and six of these showed that maintaining contact with participants reduced weight regain and one found problem-solving therapy to be significantly better at promoting weight maintenance than no contact or relapse prevention training.

In addition to the above results, the authors' present mixed results on the effectiveness of internet-based programmes in comparison to in-person group programmes. Two studies found no difference in weight-loss maintenance between the groups and two found an internet based programme to be less effective in prolonging weight-loss or preventing weight regain than in-person group treatment.

The review reported statistics on its whole study set (including pharmacological and alternative therapies). Therefore the below figures have been calculated using the review's table of studies to include just those within scope. Of these studies, 34% had fewer than 100 participants. This supports the authors' statement that some studies may have been underpowered to detect a difference in treatment effect. Effect sizes ranged from very small (0.01) to medium-large effect (0.39). This is lower than the figures reported in the review when pharmacological and alternative therapies are included.

#### Authors' conclusions (omitting those on pharmacological and alternative therapies)

The authors concluded: The reviewed studies found that weight-loss maintenance treatment with dietary modification, supplementing caffeine or protein, following a lower-fat diet, adherence to

physical activity, continued participant contact and problem-solving therapy were effective in reducing weight regain after weight-loss treatment. Additional studies are needed to confirm and expand upon these findings.

The review does not provide insight into methods of improving adherence to physical activity.

#### Limitations as stated by the review's authors (from all studies)

The authors' report that the results are limited by the methodological limitations of the reported studies, e.g., small sample size, participant attrition, short treatment duration, and sample characteristics that limit generalisability, (e.g., mostly women, mostly White). Many trials were limited by a lack of male and minority groups. Few studies reported on the ethnicity of participants, and all but one included predominantly white individuals.

The authors' report that ten of the reviewed trials had attrition rates of more than 35% with a variety of intention to treat methods used to account for this.

#### Catenacci and Wyatt 2007

#### **Inclusion criteria**

The search was conducted for studies published between 1997 and 2006. Relevant articles published prior to 1997 were identified from the 1998 Obesity Education Initiative Expert Panel clinical guidelines.

The criteria for inclusion in the review were:

- A randomised control trial evaluating the role of physical activity alone or in combination with diet in short-term weight loss (<1 year) or weight-loss maintenance (follow up ≥1 year after weight reduction);
- 2) An intervention of ≥4 months; and
- 3) English language.

The above inclusion criteria lead to a review that is broader than our current scope but the review presents a table of studies meeting our inclusion criteria. The results of these weight maintenance studies alone shall be presented.

#### **Interventions**

Catenacci and Wyatt found 41 studies that met their inclusion criteria. However, of these only 4 studies evaluated the impact of a physical activity intervention during the weight-loss maintenance phase.

These four studies compared physical activity interventions with a sedentary control group after initial weight reduction. The studies are reported to have begun with a 12-26 week weight-loss intervention (two involving VLCDs and two others) after which individuals were randomly assigned either an exercise intervention or diet only control intervention for a 26-40 week weight-maintenance period. In most of these studies, the individuals in both arms were given advice to continue some degree of dietary modification

One study is reported in men only, one in women only and two in both men and women. For the latter two studies, no breakdown in the percentage of men and women is reported. The proportion of ethnic minorities in the studies is not reported or commented on in the review.

#### Outcomes

The principal outcome of interest in this review was weight change (continued loss, maintenance, or regain).

#### Internal and external validity of included studies

The review does not provide a score for either internal or external validity of the studies included.

#### **Effects of interventions**

The table of studies presented in the review shows mixed results with one study reporting significantly less weight regain in the exercise and diet group after 3 years in comparison to diet only. This study, in women only, reported significant findings in an arm with moderate physical activity (walking 2-3 hours per week) but did not see a reduction in weight regain in a more intensive walking group (4-6 hour per week) in comparison to a diet only control group. This suggests a more moderate physical activity prescription may be more acceptable. A second study did not find significant differences in weight regain between a behavioural intervention and either resistance or anaerobic exercise but reported both exercise groups favoured weight maintenance in comparison to a control group. One study found the addition of exercise led to significantly greater weight regain at 18 months.

#### **Authors' conclusions**

The authors concluded that RCTs that have investigated the role of physical activity in weight-loss maintenance have reported mixed findings. As the review also included a broader range of study types, they also conclude that studies in which activity is measured by observation or retrospective analysis illustrate a strong relationship between physical activity and success in weight-loss maintenance.

They highlight that few RCTs truly address the role of activity in weight-loss maintenance by providing a long term, sustained activity intervention and there is a need for well designed, prospective, randomised trials to assess such regimens.

#### Limitations as stated by the review's authors

The authors' conclusions are limited by the degree of adherence in individual RCTs and the range of methods used to promote physical activity. The review does not report on the adherence of participants to physical activity or if this information is available in the four studies relevant to this report.

#### **Evidence statements**

Please see the final agreed evidence statements for this guideline which are contained in a separate document on the NICE website. The final statements reflect conclusions drawn from reviews 1a, 1b, 1c and 2 (as appropriate)

#### **Notes:**

• We have determined evidence strength in univariate models by considering the width of the confidence intervals. The strength of non-significant findings was downgraded if the confidence interval included 0.02kg/month (half the average weights regain).

#### Evidence statement 1.19 Applicability of available data

There is a large body of evidence on BWMPs that was judged to be of high quality and applicable to the UK. Eleven RCTs provide follow up data for weight after an active intervention (contact greater than once every two months). Of the 11 RCTs identified, 11 were judged to be applicable to the UK population and to be of high external validity. Of the RCTs identified, three were from the UK (one  $++^{1}$ , two  $+^{2}$ ), two USA (two  $++^{3}$ ) and one each from Australia ( $++^{4}$ ), Belgium ( $+^{5}$ ), Finland ( $++^{6}$ ), New Zealand ( $+^{7}$ ), Sweden( $++^{8}$ ) and Switzerland( $-^{9}$ ).

```
<sup>1</sup> Jolly 2011
```

## Evidence statement 1.20 Rate of weight regain after Multicomponent behavioural weight management programmes.

There is strong evidence that following a multicomponent behavioural weight management programme and during low contact follow-up (once every two months or less), weight regain is 0.047kg/month higher than in a control group. Meta-regression of programme characteristics on the rate of weight regain included eleven RCTs in the following countries, three UK (one ++<sup>1</sup>, two +<sup>2</sup>), two USA (two ++<sup>3</sup>) and one each from Australia (++<sup>4</sup>), Belgium (+<sup>5</sup>), Finland (++<sup>6</sup>), New Zealand (+<sup>7</sup>), Sweden (++<sup>8</sup>) and Switzerland (-<sup>9</sup>).

<sup>&</sup>lt;sup>2</sup> Nanchahal 2011, Penn 2009

<sup>&</sup>lt;sup>3</sup> DPP, Kuller 2012

<sup>&</sup>lt;sup>4</sup>Morgan 2011

<sup>&</sup>lt;sup>5</sup>Vissers 2010

<sup>&</sup>lt;sup>6</sup> Lindstrom 2003

<sup>&</sup>lt;sup>7</sup> Dale 2008

<sup>&</sup>lt;sup>8</sup>Bertz 2012

<sup>&</sup>lt;sup>9</sup> Munsch 2003

<sup>&</sup>lt;sup>1</sup> Jolly 2011

<sup>&</sup>lt;sup>2</sup> Nanchahal 2011, Penn 2009

<sup>&</sup>lt;sup>3</sup> DPP, Kuller 2012

<sup>&</sup>lt;sup>4</sup>Morgan 2011

<sup>&</sup>lt;sup>5</sup>Vissers 2010

<sup>&</sup>lt;sup>6</sup> Lindstrom 2003

## Evidence statement 1.21 Effect of Multicomponent behavioural weight management programme characteristics on the rate of weight regain after programme end.

There is moderate evidence that the amount of weight-lost at the end of the active intervention (contact greater than once every two months), supervised exercise during the active intervention phase and behavioural technique score were not associated with rate of weight regain. There is weak evidence that type of contact (group, individual or combination of both), number of contacts, frequency of contacts, set energy prescription and the professional background of the therapist during the active intervention phase was not associated with rate of weight regain. Meta-regression of programme characteristics on the rate of weight regain included eleven RCTs in the following countries, three UK (one  $++^1$ , two  $+^2$ ), two USA (two  $++^3$ ) and one each from Australia ( $++^4$ ), Belgium ( $+^5$ ), Finland ( $++^6$ ), New Zealand ( $+^7$ ), Sweden ( $++^8$ ) and Switzerland ( $-^9$ ).

# Evidence statement 1.22 Effect of ease of activity during a behavioural weight management programme on the rate of weight regain after programme end.

There is moderate evidence that requiring specific equipment or settings to perform activity (0.19kg/month, 95% CI: 0.048 to 0.33; p = 0.01) during the active intervention is associated with faster weight regain after the programme end. Meta-regression included eleven RCTs in the following countries, three UK (one ++¹, two +²), two USA (two ++³) and one each from Australia (++⁴), Belgium (+⁵), Finland (++⁶), New Zealand (+७), Sweden (++⁶) and Switzerland (-⁶). Of these, three interventions required specific equipment or settings to perform activity during the active intervention; these were from two studies: one in New Zealand (+७) and one in Belgium (+⁵).

<sup>&</sup>lt;sup>7</sup> Dale 2008

<sup>&</sup>lt;sup>8</sup>Bertz 2012

<sup>&</sup>lt;sup>9</sup> Munsch 2003

<sup>&</sup>lt;sup>1</sup> Jolly 2011

<sup>&</sup>lt;sup>2</sup> Nanchahal 2011, Penn 2009

<sup>&</sup>lt;sup>3</sup> DPP, Kuller 2012

<sup>&</sup>lt;sup>4</sup>Morgan 2011

<sup>&</sup>lt;sup>5</sup>Vissers 2010

<sup>&</sup>lt;sup>6</sup> Lindstrom 2003

<sup>&</sup>lt;sup>7</sup> Dale 2008

<sup>&</sup>lt;sup>8</sup> Bertz 2012

<sup>&</sup>lt;sup>9</sup> Munsch 2003

<sup>&</sup>lt;sup>1</sup> Jolly 2011

<sup>&</sup>lt;sup>2</sup> Nanchahal 2011, Penn 2009

<sup>&</sup>lt;sup>3</sup> DPP, Kuller 2012

<sup>&</sup>lt;sup>4</sup>Morgan 2011

<sup>&</sup>lt;sup>5</sup>Vissers 2010

<sup>&</sup>lt;sup>6</sup> Lindstrom 2003

#### **Evidence statement 1.23 Effective weight-loss maintenance interventions.**

There is a lack of high quality reviews on the effectiveness of weight-loss maintenance interventions. There is weak evidence that after weight-loss, the use of a low-fat diet, an increased protein intake, and increased contact frequency and problem solving as part of a weight maintenance programme can be effective in reducing weight regain. There is weak evidence that weight-loss maintenance programmes containing diet and exercise are more effective than those containing diet alone. An increased protein intake, low fat diets, increased contact frequency and problem solving is reviewed in one systematic review conducted in the USA (+¹) representing the findings of 42 studies. Physical activity is reviewed in two systematic reviews conducted in USA (one +¹, one -²) representing 42 studies of which four were present in both reviews.

<sup>&</sup>lt;sup>7</sup> Dale 2008

<sup>&</sup>lt;sup>8</sup> Bertz 2012

<sup>&</sup>lt;sup>9</sup> Munsch 2003

<sup>&</sup>lt;sup>1</sup> Turk 2009

<sup>&</sup>lt;sup>2</sup>Catenacci and Wyatt 2007

#### Discussion

Findings in this review extend those from review 1a and review 1b, by exploring the effects of characteristics of BWMPs on the rate of weight regain after programme end. In addition, it summarises the limited evidence on interventions that begin after weight-loss to improve weight-loss maintenance.

Review 1b found that in person contact, set energy prescriptions and inclusion of a dietitian during a BWMP were more effective for weight-loss. None of these programme characteristics were associated with changes in the rate of weight regain after programme end. How might the data included in Review 1c's meta-analysis be interpreted? Even though the data derive from RCTs, they are essentially observational. We investigated differences between programmes defined by the presence or absence of one characteristic, but of course programmes differed in many ways other than the particular one under investigation. In addition, by comparing programmes, we are comparing very different populations who may differ in their propensity to gain weight after stopping a weight loss programme. These differences could have obscured important differences between programme effects on subsequent weight regain or have led to spurious associations with use of special equipment for physical activity.

These results may have important practical implications. First, it is clear from the data that weight regain is common and the data should encourage further efforts at preventing it.

Second, only one programme characteristic was associated with increased rate of weight regain. This result implies that incorporating exercise opportunities that are sustainable offers a better opportunity for long-term weight-loss than including an exercise programme that relies on specialist equipment or locations. There is little evidence that anything else about the programme that induced weight loss affects the rate of weight regain after the programme has finished. This means that programmes might aim for maximum initial weight loss as weight regain appears inevitable. It also implies that weight loss at the end of a programme is the key statistic to monitor programme effectiveness in a non-research setting where collection of long-term follow-up data is difficult to achieve.

Although these findings may seem pessimistic, they should not be over interpreted. The data presented is limited by the short period of post-programme follow-up in the majority of studies. The rate of weight regain presented may therefore apply to the immediate post-programme period only. Furthermore, as the majority of studies present just two data points, weight regain in these studies is assumed to be linear. Only one trial in the review, the Diabetes Prevention Programme (DPP), had longer post-programme follow-up; it suggested weight regain is not linear and may decline with time. Furthermore, it shows no evidence that during the 10 year follow-up that weight in the intervention group ever reached that of the control group. There were insufficient data to examine whether this finding is unique to DPP although a study published too late to meet our search criteria shows a similar result in the Finnish Diabetes Study.

The second part of Review 1c considered the effectiveness of interventions that take place after weight-loss with the specific aim of reducing weight-regain. Such trials were few and we found only

two relevant systematic reviews of these trials. Also, these reviews did not formally assess the quality of studies or provide detailed methodology. Our conclusions are therefore limited.

However, the two included reviews considered overlapping evidence for the use of physical activity in weight maintenance interventions. As in review 1b where both diet and exercise led to greater weight loss than those which involve only diet or only exercise, weight maintenance strategies that include exercise and diet as opposed to diet alone are believed to be more effective in reducing weight regain. However, this association is obviously heavily influenced by the participants' levels of adherence and neither review sheds light on to how best to improve adherence.

#### **Conclusions**

People who follow a weight loss programme lose more weight during the programme than people who try to lose weight without support, with a difference of -3.3 kg at 12-18 months from baseline (Review 1a). However the active intervention period for most programmes is shorter than this and it is apparent that after the end of the programme the population mean weight slowly increases. The average rate of weight regain, based predominantly on studies with follow up periods of up to 1y is 0.56kg/y. This is consistent with evidence from 1 study with longer follow up. Weight regain is unrelated to initial weight loss. Indeed, few characteristics of the preceding programme are related to the rate of weight regain.

# **Appendices**

### **Appendix 1. 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<sup>2</sup>, 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<sup>6</sup>
- 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.

<sup>&</sup>lt;sup>6</sup> 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: 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 randomization  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	<ul> <li>Method of allocation: Random number table, allocation method not reported but described as 'concealed' Intervention description:</li> <li>Energy restriction (deficit of 500 kcal/day)</li> <li>Brisk walking (moderate intensity), supervised twice, and recommended 4 days a week, with length of each session incremental to 45 mins</li> <li>Individual in person sessions</li> <li>Delivered by dietitians and registered physical therapists</li> <li>2 sessions (2.5 hours at baseline, 2 hours at 6 weeks)</li> <li>Participants instructed to text in weight and number of walks to study staff weekly over 12 weeks</li> <li>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</li> <li>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</li> <li>No intervention control: Usual care (1)</li> <li>Sample sizes (baseline):</li> <li>Total n = 68</li> <li>Intervention n = 16</li> <li>Diet only = 17</li> <li>Exercise only = 18</li> <li>Usual care control n= 17</li> <li>12 months:</li> <li>Total n = 57</li> <li>Intervention n = 16</li> <li>Diet only = 13</li> <li>Exercise only = 15</li> <li>Usual care control n= 13</li> <li>Baseline comparisons: Groups similar at study outset</li> </ul>	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	Results	Notes
			methods of analysis		
Authors: Dale et	Source population/s: New Zealand	Method of allocation: NR	Published data only	BOCF weight	Source of
al	Across whole study:	Intervention 1 description: Intensive arm (II)	Outcome calculation	change:	funding: Health
Year: 2008	67% female, mean age 46, 0% ethnic	<ul> <li>Macronutrient balance with some energy restriction,</li> </ul>	method	12 months MI -2.0	Research
Citation: Dale,	minority, SES data NR	diets individually prescribed to lead to gradual and	Reviewers calculated	(6.6), II -2.5 (7.5),	Council, Otago
K.S., Mann, J.I.,	For each arm:	sustained weight reduction	weight change from	control -6.1 (6.0). At	University,
McAuley, K.A.,	baseline weight modest intervention	<ul> <li>Recommended and supervised physical activity, 30</li> </ul>	weight data given at	24 months, MI -2.2	Otago Diabetes
Williams, S.M., &	(MI) 95.1 (12.2), intensive	minutes 5 days a week (at least 1x week supervised), at	each time point.	(5.7), II -2.1 (6.9),	Research Trust,
Farmer, V.L.	intervention (II) 91.1 (16.2), control	80-90% of age predicted maximum heart rate	Reviewers interpreted	control -3.7 (5.5).	NZ
2009.	102.8 (15.4); baseline BMI MI 33.9	Mainly individual, some group exercise sessions, mostly	results reported in	Complete case	Other notes:
Sustainability of	(4.4), II 32.5 (5.2), control 36.5 (4.3);	in person but with phone catch ups if session missed	paper (table 1) as	weight change	*Quality score
lifestyle changes	baseline weight circumference MI	Delivered by dietitians, exercise consultants and	complete case data,	(presumed):	downgraded
following an	106.1 (9.8), II 100.9 (12.1), control	researchers	though unclear from	12 months MI -2.3	because
intensive lifestyle	113.7 (9.7)	• 36 sessions over 4 months (18 diet, 18 exercise), length	information reported.	(7.0), II -2.7 (7.8),	randomization
intervention in	Eligible population: Local	not specified	Number of participants	control -7.0 (5.9). At	and allocation
insulin resistant	advertisements	Free gym passes and some food provided	followed up in each	24 months, MI -3.0	procedures not
adults: Follow-up	Selected population: Being	Intervention 2 description: Modest arm (MI)	intervention group not	(6.5), II -2.6 (7.7),	described
at 2-years. Asia	overweight/obese not an inclusion	As per intervention 1, but macronutrient proportions of	clear at 12 or 24	control	**External
Pacific Journal of	criteria (but baseline figures suggest	diet differ (more energy from fat allowed) and no	months, only combined	-4.3 (5.7).	validity score
Clinical Nutrition,	vast majority would have fell into this	specified heart rate targets for physical activity	n for two intervention	Secondary	downgraded as,
18, (1) 114-120	category). 25 to 70 years old, able	Control description: (4) usual care – at 8 and 12 months,	groups available.	outcomes:	of those who
Aim of study:	and willing to take part in dietary and	"some advice" regarding lifestyle changes	Reviewers assumed	At 24 months,	initially
Diabetes	exercise program, fasting glucose	Sample sizes (baseline):	equal loss to follow-up	complete case	responded to
prevention	<6.1mmol/l, insulin sensitivity index	Total n = 79	between intervention	change in waist	advertisements,
(increase insulin	<4.2 G mU <sup>-1</sup> *I <sup>-1</sup>	II n = 25	arms.	circumference MI+II	18% enrolled
sensitivity)	Excluded population/s: Diabetes or	MI n = 31	BMI and waist	-1 (5.7), control -2	
Study design:	major medical condition, psychiatric	Control n = 23	circumference data	(3.3); complete case	See also:
RCT	illness, drug or alcohol dependence,	At 12 months:	only available for	BMI change MI+II -	McAuley, K.A. et
Quality score: +*	on warfarin or oral steroids, on meds	Total n = 70	control and combined	0.7 (2.2), control -	al. 2002.
External validity	for <6m, likely to alter meds during	MI+II n = 50 (not broken down, assumed MI 27, II 23)	intervention, baseline	0.8 (1.9).	Intensive
score: +**	intervention period	Control n= 20	data only represents	Adverse effects: NR	lifestyle changes
	440 responded to advertisements,	At 24 months:	those with 2 year	Attrition details:	are necessary to
	79 enrolled (18%)	Total n = 63	follow-up	87% followed up at	improve insulin
	Setting: In person, setting not	MI+II n = 43 (not broken down, assumed MI 23, II 20)	Follow up periods: 4, 8,	12 months (87% MI,	sensitivity.
	specified. Phone discussion if	Control n= 20	12 and 24 months	92% II, 87%	Diabetes Care,
	missed face-to-face check in.	Baseline comparisons: At baseline, higher BMI, weight and		control). Reasons	25, (3) 445-452.
		waist circumference in control group.		for attrition NR.	
				1	

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

Study details	Population and setting	Method of allocation to	Outcomes and	Results	Notes
		intervention/control	methods of analysis		
		take part in DPPOS, an observational			\$769
		follow up study. In this phase all			10-year cost outside of
		participants had the option to complete			DPP: \$27,463
		the 16 core DPP sessions and/or booster			
		sessions – no scheduling or time scale			Additional references:
		reported.			Report: Screening for the
		Control description: Usual care (4). This was			Management of Obesity
		a placebo control group with written lifestyle			in adults U.S. Preventive
		advice provided at baseline and alongside an			Services Task Force.
		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			

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	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	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	Source of funding: Local health service  Other notes: Lost a + on quality because >20% difference between arms in loss to follow up at 12m
	Excluded population/s: Unable	with RC and then trained		up not reported	

to understand English,	• 12 weekly hour long sessions		
pregnant, so ill that weight loss	Intervention 4 description:		
inappropriate e.g. terminal	Size Down (NHS group-based weight loss programme)		
illness	Reduced energy low fat diet based on Eatwell plate		
Percentage screened who	aiming to lose about 0.15kg/week		
were enrolled NR	Recommended physical activity, no specific target		
Setting: In person	• Group in-person		
programmes delivered in	Lay people taken NVQ Level 3- 25 hours of training from		
community settings,	dietitians plus assessment to pass		
pharmacies, or GP surgeries	8 sessions of 2 hours over 12 wks		
depending on programme.	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 P	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
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 score: ++	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 randomized.  Setting: face-to-face, location not specified	Method of allocation: Randomization 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  Intervention n = 216  Control n= 230	Published data only Outcome calculation method Standard methods used Follow up periods: 6, 18, 30, 48 months	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 and Nutrition study. Menopause, 18, (7) 759-765

[BLANK PAGE: UNABLE TO DELETE PAGE]

Study details	Population and setting	Intervention and comparators	Outcomes and	Results	Notes
			methods of analysis		
Authors: Lindstrom et	Source population/s: Finland	Method of randomization and allocation	Published or	BOCF weight change	Source of funding:
al	Across whole study:	concealment	unpublished	12 months	Finish academy, ministry
Year: 2003	Female 67%, mean age 55,	A randomization list was used. The nurses	Published	Intervention: -4.3 (5.0)	of education; Novo
Citation: Lindstrom, J.,	Ethnicity NR, SES: years of	scheduling visits were blinded to	Outcome calculation	Control: -1.0 (3.7)	nordisk foundation; Yrjo
et al. Finnish Diabetes	education 0-9 : 40%, 10-12 :	randomisation. Study staff were not	method	3 years	Jahnsson Foundation;
prevention Study	27%, >=13 : 33%	blinded.	Standard	Intervention: -3.5 (5.6)	Juho Vainio Foundation;
Group. 2003. The	For each arm (mean, SD):		Follow up periods: 1y,	Control: -0.7 (4.8)	and Finish diabetes
Finnish Diabetes	Weight	Intervention description:	3y		research foundation
Prevention Study	Intervention: 86.7kg (14.0)	Lifestyle Intervention		Complete case weight	Other notes:
(DPS): Lifestyle	Control: 85.5kg (14.4)	• Low fat diet (<30% kcal from fat)		change	The study was
intervention and 3-year	BMI	Recommended moderate intensity		12 months	prematurely terminated
results on diet and	Intervention: 31.4 (4.5)	exercise every day for 30 minutes		Intervention: -4.5 (5.0)	in March 2000 by an
physical activity.	Control: 31.1 (4.5)	Individual with voluntary group sessions		Control: -1.0 (3.7)	independent end point
Diabetes Care, 26,	Weight circumference	Delivered by dietitian/nutritionist and		3 years	committee, since the
3230-3236.	Intervention: 102.0 (11.0)	physician		Intervention: -3.5 (5.1)	incidence of diabetes in
Aim of study: Diabetes	Control: 100.5 (10.9)	• 7 compulsory sessions in year one then		Control: -0.9 (5.4)	the intervention group
prevention	Eligible population: High-risk	every 3 months indefinitely. Plus		Secondary outcomes:	was highly significantly
Study design: RCT	groups such as first-degree	voluntary sessions.		12 months	lower than in the control
Quality score: ++	relatives of type 2 diabetes	Control description:		Waist circumference	group
External validity score:	patients	Usual Care (2) – General information about		change	
++	Selected population:	lifestyle was provided at baseline in an		Intervention: - 4 (5)	See also: Tuomilehto J,
	1) Age 40–64y	individual or group session lasting 30-		Control - 1 (5)	Lindström J, Eriksson JG,
	2) BMI >25 kg/m2	60minutes. Written material was also		BMI change	Valle TT, Hämäläinen H,
	3) Impaired glucose tolerance	provided at baseline.		Intervention: -1.6 (1.8)	Ilanne-Parikka P,
	Excluded population/s:	provided accounts.		Control: - 0.4 (1.3)	Keinänen-Kiukaanniemi S,
	Diabetes, unlikely to survive 6	Sample sizes:			Laakso M, Louheranta A,
	years due to disease,	Total n = 522		Adverse events	Rastas M, Salminen V,
	psychological or physical	Intervention n = 265		NR	Uusitupa M: Prevention of
	characteristics that mean that	Control n = 257			type 2 diabetes mellitus
	intervention or study follow up	12 months		Attrition details:	by changes in lifestyle
	impractical.	Total n = 506		12 months	among subjects with
		Intervention n = 256		97% followed-up overall.	impaired glucose
	Percentage screened but not	Control n = 250		Intervention = 97% follow	tolerance. N Engl J
	enrolled: NR	3 years		up	Med344:1343–1350, 2001
		Total n = 434		Control n = 97% follow up	
	Setting: In person & phone	Intervention n = 231		Reasons for attrition:	
		Control n = 203		NR	
		Groups similar at study outset			
		Groups similar at study outset	l		

Study details	Population and setting	Intervention and comparators	Outcomes and methods	Results	Notes
			of analysis		
Authors: Morgan	Source population/s: Australia	Method of allocation: Computer-based	Published and	BOCF weight change:	Source of funding:
et al.	Across whole study:	random allocation sequence,	unpublished data	(kg) at 12 months	University of Newcastle
Year: 2011	0% female, mean age 36, ethnicity	randomization completed by research	Further detail on	intervention -4.1 (5.4),	Strategic Pilot grant and
Citation: Morgan,	NR, 52% in high or highest SES	assistant not involved in project and	intervention components	control -2.0 (4.3)	The Men's Health Golf
P.J., Lubans, D.R.,	bracket (7-10 on scale of 1-10)	allocation sequence was 'concealed.'	provided via email from	ITT analysis (not	Day
Collins, C.E.,	For each arm:	Intervention description:	author	complete case) weight	Other notes:
Warren, J.M., &	baseline weight (kg) intervention	<ul> <li>Reduced energy diet, deficit of at least</li> </ul>	Outcome calculation	change: (kg) at 12	Additional intervention
Callister, R. 2011.	99.1 (12.2), control 99.2 (13.7);	480 kcal/day less than personal daily	method	months intervention	detail provided by
12-month	baseline BMI intervention 30.6	energy expenditure (calculated using	Authors report ITT	-5.3 (5.6), control -3.1	authors.
outcomes and	(2.7), control 30.5 (3.0), baseline	Harris Benedict equation and	analysis only, including all	(5.0)	*External validity score
process evaluation	weight circumference (cm)	personalized activity factor)	randomized participants	Secondary outcomes:	downgraded due to
of the SHED-IT RCT:	intervention 102.8 (6.8), control	Recommended moderate to high	(using linear mixed	ITT analysis (not complete	requirement of access to
an internet-based	103.4 (8.3)	intensity physical activity for 30	models, results adjusted	case) change in waist	a computer with e-mail
weight loss	Eligible population: university staff	minutes a day	for effects of significant	circumference (cm)	and internet facilities.
program targeting	and students recruited through	• 1 session face-to-face group,	covariates). Reviewers	intervention -5.8 (5.3),	48% of those screened
men. Obesity, 19,	university notice boards and	remaining contacts individual e-mail	used ITT in place of	control -3.8 (4.8); change	were enrolled.
(1) 142-151	website	Male researcher, training not specified	complete case data to	in BMI intervention -1.7	
Aim of study:	Selected population: male	8 sessions over 3 months. First session	calculate BOCF using	(1.7), control -0.9 (1.6)	See also:
Weight loss in men	university staff and students, BMI	75 minutes, all other contacts e-mail-	standard methods.	Adverse effects: NR	Morgan, P.J., et al. 2010.
Study design: RCT	25-37, aged 18-60 years	based.	Reviewers calculated SDs	Attrition details:	The SHED-IT community
Quality score: ++	Excluded population/s: history of	Free access to Calorie King website	from 95% CIs provided,	71% followed up at 12m	trial study protocol: a
External validity	major medical problems (eg heart	Control description: Information session	using t values to derive	overall: 76% intervention,	randomised controlled
score: +*	disease) in past 5 years, diabetes,	(2): identical information session to that	denominators due to	65% control. 3%	trial of weight loss
	orthopaedic, or joint problems that	in intervention, without online	small sample sizes.	unavoidable, 26%	programs for overweight
	would be a barrier to physical	component description, plus program	Follow up periods: 3, 6	missing.	and obese men. Bmc
	activity, recent weight loss of ≥4.5	booklet	and 12 months		Public Health, 10, 701
	kg, taking medications that might	Sample sizes (baseline):			
	affect body weight.	Total n = 65			Morgan, P.J., et al. 2009.
	Access to a computer with email	Intervention n = 34			The SHED-IT randomized
	and Internet facilities.	Control n = 31			controlled trial:
	48% screened subsequently	At 12 months:			evaluation of an Internet-
	enrolled	Total n = 46			based weight-loss
	Setting: group and online,	Intervention n = 26			program for men. Obesity,
	setting for group session NR	Control n = 20			17, (11) 2025-2032
		Baseline comparisons: Groups similar at			
		study outset			

Study details	Population and setting	Intervention and comparators	Outcomes and	Results	Notes
			methods of analysis		
Authors:	Source population/s:	Method of allocation: NR	Published or	BOCF weight change	Source of funding:
Munsch et al	Switzerland	Intervention (1) description:	unpublished	(kg):	Unrestricted grant
Year: 2003	Across whole study:	• GP BASEL	Published data was	12 months	from Knoll AG,
Citation:	Female: 75%	Balanced diet with fat intake target of 20g per day.	supplemented with	Intervention 1: -3.6	Liestal,
Munsch S,	Age: 46y	• 15 mins of exercise daily with examples swimming, walking and	intervention details	(7.9)	Switzerland
Biedert E et al.	Ethnicity: NR	incorporation into daily life.	provided by the	Intervention2: -0.9	Other notes:
Evaluation of a	SES/Education: NR	• Group	authors	(6.9)	*Quality score
lifestyle change	For each arm (mean, SD):	Delivered by a General Practitioner who was trained by a		Control : -0.2 (2.7)	downgraded as
programme for	Weight (kg)	psychologist and dietitian in two 4 hour sessions.	Outcome calculation		randomisation
the treatment	Intervention 1: 96.8 (17.1)	• 16 weekly sessions of 90 minutes over 16 weeks	method	Complete case	process not
of obesity in	Intervention 2: 106.8 (26.1)	Intervention 2 description:	Complete cases	weight change:	defined; Groups
general	Control: 86.3 (6.4)	Clinic BASEL	converted to BOCF	Intervention 1: -4.7	were not similar
practice. Swiss	BMI (kg/m²)	Balanced diet with fat intake target of 20g per day.		(8.7)	at outset; and
Med	Intervention 1: 36.2 (6.5)	15 mins of exercise daily with examples swimming, walking and	Follow up periods: 16	Intervention 2: -2.9	imbalance in
Wkly 2003;133:	Intervention 2: 38.5 (7.5)	incorporation into daily life.	weeks and 12 months	(12.5)	dropouts between
148-154.	Control: 32.6 (1.8)	Group		Control: -0.4 (4.0)	arms not
Aim of study:	Waist circumference (cm): NR	•			accounted for.
Weight loss	Eligible population:	Delivered by a clinic tutor who was trained by a psychologist  and distribution in the A bour associates.		Secondary outcomes:	
Study design:	Patients were recruited from	and dietitian in two 4 hour sessions.		12 months	Quality of life
Quality score: -	a clinical centre, GP practices	• 16 weekly sessions of 90 minutes for		BMI change:	variables available
*	and via a newspaper advert	Control description: Usual care (4): received non-specific		Intervention1: -1.8	
External	Selected population:	comments about general measures to lose weight from GP.		(3.3)	
validity score:	1) BMI >30kg/m <sup>2</sup>	Authors write "No specific technique, tools or written material was used."		Intervention 2: -0.9	
++	2) GP physical exam			(3.6)	
	Excluded population/s:	Sample sizes (baseline):		Control: -0.2 (1.2)	
	Severe mental disorders,	Total n = 122			
	insulin-dependent diabetes,	Intervention 1 n = 53		Waist circumference:	
	hypothyroidism, terminal	Intervention2 n= 52		NR	
	diseases	Control n= 17			
	Setting: In person at GP or	At 12 months:		Adverse effects:	
	health clinic	Total n = 65		NR	
		Intervention 1 n = 41			
		Intervention 2 n = 16		Attrition details:	
		Control n= 8		No breakdown	
		Baseline comparisons: Groups similar at study outset			

Study details	Population and setting	Method of allocation to	Outcomes and methods	Results	Notes
		intervention/control	of analysis		
Authors:	Source population/s: UK	Method of allocation: Computer	Published or unpublished	BOCF weight change:	Source of funding:
Nanchahal et al	Across whole study:	generated randomisation Intervention	Published data only	Intervention: -1.3 (4.3)	Camden PCT
Year: 2012	Female: 72%; Age: 49y	description:	Outcome calculation	Control: -1.0 (4.5)	
Citation:	Minority: 29%; Education: 12% had	<ul> <li>Calorie reduced diet based on the</li> </ul>	method	Complete case weight	
Nanchahal K,	no qualification	Eatwell plate. Calorie goal set to	Standard BOCF	change:	
Power T,	For each arm (mean, SD):	achieve 1kg/week weight-loss.	calculation	Intervention:-2.4 (5.6	
Holdsworth E, et al.	Weight: Intervention 91 (18);	<ul> <li>Recommended exercise focussing on</li> </ul>	Follow up periods: 6,12	Control: -1.3 (5.1)	
A pragmatic	Control 94 (18)	walking with exercise diaries provided.	months	Secondary outcomes:	
randomised	BMI: Intervention 33.0 (5.4);	<ul> <li>Individual, in person delivery</li> </ul>		Waist circumference (cm)	
controlled trial in	Control: 33.9 (5.6)	Delivered by health trainers who are		Intervention: -3.37 (8)	
primary care of the Camden weight	Waist circumference: Intervention 106 (13); Control 108 (13)	lay people trained in behaviour change counselling.		Control: -1.49 (6)	
loss (CAMWEL)	Eligible population: Population	The advisors received initial training		BMI (kg/m <sup>2</sup> )	
programme. BMJ	recruited by letter (and some text	over 2 days and further meetings with		Intervention: -0.8 (2.0)	
Open	messages) from GP and personal	the research team every 3 to 4		Control: -0.5 (1.9)	
2012;2:e000793	referral from GP in consultations	months.			
Aim of study:	Selected population:	• 14, 30 minute sessions in total over 36		Adverse effects: NR	
Weight-loss	Age 18 years and above, BMI >25	weeks. Sessions were every fortnight			
Study design:	kg/m <sup>2</sup> , attending a participating	for the first 12 weeks, every 3 weeks		Attrition details:	
Quality score: ++	practice and willing to attend visits	for 12 weeks and finally monthly for		Total:	
External validity	with a CAMWEL advisor over 12	the next 12 weeks		Intervention	
score: ++	months.	Control description: Usual care (1) group		Unavoidable 3%	
	Excluded population/s:	who received a British Health Foundation		Missing 42%	
	Pregnancy or lactation,	booklet at baseline		Medical 1%	
	diagnosis of renal failure, use of	Sample sizes (baseline):			
	a pacemaker, recent diagnosis	Total n = 381		Control	
	of cancer or participation in	Intervention n = 191		Unavoidable 1%	
	another weight management	Control n= 190		Avoidable 39%	
	study.	At 12 months:			
	Setting: In person at primary	Total n = 117			
	care centre	Intervention n = 103			
		Control n= 114			
		Groups similar at study outset			

Study details	Population and setting	Intervention and comparators	Outcomes and methods of analysis	Results	Notes
Authors: Penn et al Year: 2009	Source population/s: UK percentage female: 60% mean age: 57 years	Method of allocation: Randomization stratified by age, sex, and 2-hour plasma glucose level. Allocation concealment not described though	Published and unpublished data Authors sent	BOCF weight change: At 12 months Intervention: - 2.0 (4.1)	Source of funding: Wellcome Trust (medical charity)
-		, , ,	•	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%), avoidable 5 (10%), Control unavoidable 5 (10%) Control unavoidable 5 (12%), avoidable 17 (24%), medical 7	
	hospital intervention.	Control n= 28 (55%) Groups similar at study outset		(14%)	

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

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

### Appendix 2. Summary of 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	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
Bertz 2012	Υ	U	Υ	Υ	Υ	N	
Dale 2008	U	U	N	N	n/a	N	Higher BMI, weight and waist circumference in control group
DPP	Υ	Υ	Υ	N	n/a	N	
Jolly 2011	Υ	Υ	Υ	N	n/a	N	Differences in rates of starting intervention and attendance, but this is inherent in the programme and not unexpected (therefore does not need to be adjusted for).  Differences in rates of follow up.
Kuller 2012	Υ	Υ	Υ	N	n/a	N	
Lindstrom 2003	Y	Υ	Y	N	n/a	N	
Morgan 2011	Y	Y	Y	N	n/a	N	
Munsch 2003	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.
13232005					-		Psychological variables
Nanchahal 2011	Υ	Υ	Υ	N	n/a	Υ	measured but not reported

Penn 2009	Y	U	Υ	N	n/a	Υ	Authors measured waist circumference and weight annually and did not report it as the differences were not significant
Vissers 2010	U	U	Υ	Υ	N	N	Uneven dropouts between arms

### Appendix 3. Behavioural taxonomy codes for each study arm

Appendix 3. Benavioural taxonomy codes	101	Cati	Stu	ду	aı	111		
	Bertz 2012	Dale 2008 modest	Dale 2008 intense	DPP	Jolly 2011 SD	olly 2011 GP	Jolly 2011 Pharm	Jolly 2011 WW
01- Provide information on consequences of behaviour in general	Υ	N	N	N	У	У	У	Υ
02- Provide information on consequences of behaviour to the individual	N	N	N	Υ	n	n	n	N
03- Provide information about others' approval	N	N	N	N	n	n	n	N
04- Provide normative information about others' behaviour	N	N	N	N	n	n	n	U
05- Goal setting (behaviour) 06- Goal setting (outcome)	Y	Y	Y U	Y	У	У	У	Y
07- Action planning	Y	Y		Y	y n	y n	y n	U
08- Barrier identification/problem solving	Y	N	N	Y	У	У	у	U
09- Set graded tasks	Y	N	N	U	У	у	у	N
10- Prompt review of behavioural goals	Υ	Υ	Υ	Υ	У	у	у	U
11- Prompt review of outcome goals	Υ	Υ	Υ	Υ	У	у	у	Υ
12- Prompt rewards contingent on effort or progress towards	N	U	U	U	n	У	У	U
behaviour								
13- Provide rewards contingent on successful behaviour	N	N	N	Υ	n	У	У	Υ
14- Shaping	N	N	N	N	n	n	n	N
15- Prompting generalisation of a target behaviour	N	U	U	Υ	n	n	n	Υ
16- Prompt self-monitoring of behaviour	Υ	Υ	Υ	Υ	У	У	У	Υ
17- Prompt self-monitoring of behavioural outcome	Υ	Y	Υ	Υ	n	У	У	Υ
18- Prompting focus on past success	N	U	U	U	n	n	n	N
19- Provide feedback on performance	Υ	U	U	Υ	У	У	У	Υ
20- Provide information on where and when to perform the behaviour	N	Y	Υ	Υ	У	n	n	Υ
21- Provide instruction on how to perform the behaviour	Υ	Y	Υ	N		n	n	U
22- Model/Demonstrate the behaviour	Y	Y	<u>т</u> Ү	Y	y n	n	n	Y
		-						
23- Teach to use prompts/cues	N	N	N	N	n	n	n	Υ
24- Environmental restructuring	N	N	N	Υ	n	n	n	N
25- Agree behavioural contract	N	N	N	Υ	n	n	n	N
26- Prompt practice	Ν	N	N	Υ	n	n	n	N
27- Use of follow-up prompts	N	N	N	Υ	У	n	n	Ν
28- Facilitate social comparison	N	N	N	Ν	n	n	n	N
29- Plan social support/social change	N	N	N	Υ	n	n	n	Υ
30- Prompt identification as role model/position advocate	N	N	N	N	n	n	n	N
31- Prompt anticipated regret	N	N	N	N	n	n	n	N
32- Fear arousal	N	N	N	N	n	n	n	N
33- Prompt self talk	N	N	N	N	n	n	n	N
34- Prompt use of imagery	N	N	N	N	n	n	n	N
35- Relapse prevention/coping planning	N	N	N	Υ	У	У	у	N
36- Stress management/emotional control training	N	N	N	N	n	У	У	N
37- Motivational interviewing	N	N	N	Υ	n	У	у	N
38- Time management	N	N	N	N	n	У	у	Υ
39- General communication skills training	N	N	N	N	n	n	n	N
40- Stimulate anticipation of future rewards	N	N	N	Υ	n	n	n	U
<u> </u>							ш	ш

	olly 2011 SW	Jolly 2011 RC	Kuller 2012	Lindstrom 2003	Morgan 2011	Munsch 2003 clinic	Munsch 2003 GP	Nanchahal 2011	Penn 2009	Vissers 2010 fitness	Vissers 2010 vibration
	llol	llol	Kul	Li	ĭ	Σ	Σ	Nai	Per	Vis	Vis
01- Provide information on consequences of behaviour in	Υ	У	U	Υ	N	Υ	Υ	Ν	У	Ν	N
general	\ \ \					.,	.,	.,			
02- Provide information on consequences of behaviour to the individual	Υ	n	U	U	N	Υ	Υ	Υ	n	N	N
03- Provide information about others' approval	U	n	N	N	N	N	N	N	n	N	Ν
04- Provide normative information about others' behaviour	N	n	N	N	N	N	N	N	n	N	N
05- Goal setting (behaviour)	Υ	У	Υ	Υ	Υ	Υ	Υ	Υ	У	Υ	Υ
06- Goal setting (outcome)	Υ	у	Υ	Υ	U	Υ	Υ	Υ	у	U	U
07- Action planning	Υ	n	U	Υ	Υ	Υ	Υ	Υ	n	Υ	Υ
08- Barrier identification/problem solving	Y	u	Υ	Υ	U	Υ	Υ	Y	n	N	N
09- Set graded tasks	Υ	У	Υ	U	N	Υ	Υ	Υ	У	N	N
10- Prompt review of behavioural goals	Υ	u	N	Υ	Υ	N	N	Υ	у	Υ	Υ
11- Prompt review of outcome goals	Υ	У	N	Υ	Υ	Υ	Υ	Υ	Y	Υ	Υ
12- Prompt rewards contingent on effort or progress	Υ	u	N	N	N	N	N	N	n	N	N
towards behaviour	ļ.,					ļ.,	ļ.,				
13- Provide rewards contingent on successful behaviour	Υ	У	N	N	N	N	N	N	n	N	N
14- Shaping	Y	n	N	N	N	N	N	N	n	N	N
15- Prompting generalisation of a target behaviour	U	У	N	N	N	Υ	Υ	Υ	n	Υ	Υ
16- Prompt self-monitoring of behaviour	U	У	Y	Υ	Υ	Y	Y	Y	Υ	U	U
17- Prompt self-monitoring of behavioural outcome	Y	u	N	Y	Y	N	N	N	n	U	U
18- Prompting focus on past success 19- Provide feedback on performance	Y N	U	N U	N Y	N Y	N	N N	Y	n	N	N N
20- Provide information on where and when to perform the	Y	N	N	Υ	N	Y	Y	Y	У	IN	IN
behaviour	'	IN	IN	<b>'</b>	IN	ļ '	ļ '	l '	У	N	Ν
21- Provide instruction on how to perform the behaviour	N	Υ	N	Υ	Υ	N	N	Υ	У	Υ	Υ
22- Model/Demonstrate the behaviour	N	Υ	N	Υ	N	N	N	U	У	Υ	Υ
23- Teach to use prompts/cues	N	Υ	N	N	N	U	U	Υ	n	N	N
24- Environmental restructuring	N	U	N	N	N	N	N	Υ	n	N	N
25- Agree behavioural contract	N	N	N	N	N	N	N	N	n	N	N
26- Prompt practice	Υ	Υ	N	Υ	N	N	N	Υ	n	U	U
27- Use of follow-up prompts	N	N	N	N	Υ	N	N	Υ	Υ	Υ	Υ
28- Facilitate social comparison	N	N	N	Υ	N	N	N	N	n	N	N
29- Plan social support/social change	Υ	Υ	Υ	N	Υ	Υ	Υ	Υ	n	N	N
30- Prompt identification as role model/position advocate	Υ	N	N	N	N	N	N	N	n	N	N
31- Prompt anticipated regret	N	N	Ν	N	N	N	N	Υ	n	Ν	Ν
32- Fear arousal	N	N	N	N	N	N	N	N	n	N	Ν
33- Prompt self talk	N	N	N	N	N	N	N	Υ	n	N	Ν
34- Prompt use of imagery	N	N	N	N	N	N	N	U	n	N	N
35- Relapse prevention/coping planning	U	U	Υ	N	N	Υ	Υ	Υ	n	N	N
36- Stress management/emotional control training	Y	U	N	N	N	N	N	Υ	n	N	N
37- Motivational interviewing	Υ	N	Υ	N	N	N	N	Υ	У	N	N
38- Time management	N	N	N	N	N	N	N	Υ	n	N	N
39- General communication skills training	N	N	N	N	N	N	N	Υ	n	N	N
40- Stimulate anticipation of future rewards	U	Υ	N	N	N	N	N	N	n	N	N

# Appendix 4. Search methods (Review of reviews of weight-loss maintenance interventions)

### **Database: Medline** Strategy used: Obesity/ or Obesity, Morbid/ or Obesity, Abdominal/ exp weight gain/ Overweight/ (overweight or over weight or overeat\* or over eat\* or overfeed\* or over feed\*).ti,ab. (weight adj1 gain\*).ti,ab. obes\*.ti,ab. or/1-6 (modific\* or therap\* or intervention\* or strateg\* or program\* or management or scheme\* or group\* or pathway\*).ti,ab. (weight adj1 los\*).ti,ab. (weight adj1 reduc\*).ti,ab. exp weight loss/ 8 and (9 or 10 or 11) Obesity/dh, pc, th Obesity, Morbid/pc, dh, th 8 and (13 or 14)

16	Diet Therapy/	9191
17	Diet, Fat-Restricted/	2535
18	Diet, Reducing/	8926
19	Dietetics/ed, mt	1429
20	(diet or diets or dieting).ti,ab.	209843
21	(low calorie or hypocaloric or calorie control*).ti,ab.	3096
22	(health* adj1 eating).ti,ab.	2488
23	(diet* adj2 (modific* or therapy or intervention* or strateg* or program* or management or scheme*)).ti,ab.	14437
24	(nutrition adj2 (modific* or therapy or intervention* or strateg* or program* or management or scheme*)).ti,ab.	5310
25	(Weight Watchers or weightwatchers).ti,ab.	67
26	(slimming world or slimmingworld).ti,ab.	6
27	(lighterlife or "lighter life").ti,ab.	1
28	or/16-27	233754
29	8 and 28	113120
30	exp exercise/	99128
31	exercise therapy/	23408
32	(exercise and (therapy or therapies or activity or activities or class* or program* or group* or session* or scheme*)).ti,ab.	82025
33	(Gym and (trainer* or therap* or activit* or class* or program* or group* or session* or scheme* or club*)).ti,ab.	266

34	(walk* or step* or jog* or run*).ti,ab.	504602
35	(aerobic* or physical therap* or physical activit*).ti,ab.	102905
36	(fitness adj (class or regime* or program* or group* or session* or scheme*)).ti,ab.	638
37	(reduc* adj2 sedentary behavio?r).ti,ab.	77
38	(dance and (therap* or activit* or class* or program* or group* or session* or scheme*)).ti,ab.	930
39	personal trainer*.ti,ab.	48
40	(gym or gyms or gymnasium*).ti,ab.	793
41	or/30-40	704689
42	8 and (30 or 31 or 34 or 35)	275976
43	32 or 33 or 36 or 37 or 38 or 39 or 40 or 42	324543
44	cognitive therapy/	13650
45	Counseling/	26136
46	behavior therapy/	22458
47	cognitive therapy/	13650
48	behavio?ral intervention*.ti,ab.	4069
49	(change* adj2 lifestyle*).ti,ab.	4699
50	(changing adj2 lifestyle*).ti,ab.	238
51	(lifestyle adj2 modif*).ti,ab.	3195
52	Hypnosis/	7937
53	Counseling/	26136

54	(counseling or counselling).ti,ab.	51052
55	or/44-54	115022
56	(weight adj4 (maintenance or maintain* or regain* or gain* or relapse* or sustain*)).tw.	47765
57	Meta-Analysis.pt.	37359
58	Meta-Analysis as Topic/	12419
59	Review.pt.	1744901
60	exp Review Literature as Topic/	6549
61	(metaanaly\$ or metanaly\$ or (meta adj2 analy\$)).tw.	44678
62	(review\$ or overview\$).ti.	239776
63	(systematic\$ adj4 (review\$ or overview\$)).tw.	40269
64	((quantitative\$ or qualitative\$) adj4 (review\$ or overview\$)).tw.	3109
65	((studies or trial\$) adj1 (review\$ or overview\$)).tw.	6447
66	(integrat\$ adj2 (research or review\$ or literature)).tw.	3095
67	(pool\$ adj1 (analy\$ or data)).tw.	7605
68	(handsearch\$ or (hand adj2 search\$)).tw.	4360
69	(manual\$ adj2 search\$).tw.	2434
70	or/57-69	1881498
71	animals/ not humans/	3673440
72	70 not 71	1753790
73	12 or 15	40522

74	7 and 72 and 73 and 56	1417
75	7 and 28 and 72 and 56	1168
76	7 and 29 and 72 and 56	877
77	7 and 41 and 72 and 56	1010
78	7 and 43 and 72 and 56	836
79	7 and 55 and 72 and 56	495
80	75 or 77 or 79	1849
81	76 or 78 or 79	1472
82	75 and 77 and 79	169
83	75 and 77	501
84	75 and 79	239
85	77 and 79	253
86	83 or 84 or 85	655
87	76 and 78	434
88	76 and 79	230
89	78 and 79	238
90	87 or 88 or 89	570
91	82 or 86 or 90	655
92	Anti-Obesity Agents/	2813
93	(sibutramine or orlistat or rimonabant).ti,ab,nm.	3817

94	exp Bariatric Surgery/	12484
95	exp obesity/su	9092
96	92 or 93 or 94 or 95	20184
97	91 not 96	528
98	limit 97 to (english language and humans)	490
99	limit 98 to ("all infant (birth to 23 months)" or "all child (0 to 18 years)" or "newborn infant (birth to 1 month)" or "infant (1 to 23 months)" or "preschool child (2 to 5 years)" or "child (6 to 12 years)")	90
100	98 not 99	400
101	(editorial or comment or letter).pt.	1157514
102	100 not 101	400
103	limit 102 to ed=20000101-20091207	220
104	limit 102 to ed=20121101-20130214	6
105	103 or 104	226

### Notes:

This was a re-working of a search originally carried out in November 2012. An additional weight maintenance set has been included and the RCT filter has been replaced with a systematic review filter. A date limit has been applied so that the search does not cover the period of the November search (May 2009 – November 2012).

### **Database: Medline in Process**

Strategy used:

Same strategy as used for Medline

### Database: Embase

Strategy used:

1	morbid obesity/ or abdominal obesity/ or diabetic obesity/ or metabolic syndrome X/	52864
2	weight gain/	56656
3	(overweight or over weight or overeat* or over eat* or overfeed* or over feed*).ti,ab.	47853
4	(weight adj1 gain*).ti,ab.	52330
5	obes*.ti,ab.	206450
6	or/1-5	314124
7	(modific* or therap* or intervention* or strateg* or program* or management or scheme* or group* or pathway*).ti,ab.	6985312
8	(weight adj1 los*).ti,ab.	70213
9	(weight adj1 reduc*).ti,ab.	12043
10	weight reduction/	81604
11	7 and (8 or 9 or 10)	58889
12	obesity/dm, pc, th	22444
13	Obesity, Morbid/dm, pc, th	767

14	7 and (12 or 13)	12629
15	Diet Therapy/	43412
16	low calory diet/	6994
17	low fat diet/	6031
18	diet restriction/	54661
19	caloric restriction/	11028
20	Dietetics/ or Dietetics Education/	4739
21	(diet or diets or dieting).ti,ab.	274968
22	(low calorie or hypocaloric or calorie control*).ti,ab.	4312
23	(health* adj1 eating).ti,ab.	3499
24	(diet* adj2 (modific* or therapy or intervention* or strateg* or program* or management or scheme*)).ti,ab.	20130
25	(nutrition adj2 (modific* or therapy or intervention* or strateg* or program* or management or scheme*)).ti,ab.	6882
26	Weight Watchers.ti,ab.	111
27	slimming world.ti,ab.	22
28	lighterlife.ti,ab.	34
29	or/15-28	374424
30	7 and 29	183939
31	exp exercise/	191580
32	exp kinesiotherapy/	43866

33	(exercise and (therapy or therapies or activity or activities or class* or program* or group* or session* or scheme*)).ti,ab.	114397
34	(Gym and (trainer* or therap* or activit* or class* or program* or group* or session* or scheme* or club*)).ti,ab.	479
35	(walk* or step* or jog* or run*).ti,ab.	692304
36	(aerobic* or physical therap* or physical activit*).ti,ab.	141405
37	(fitness adj (class or regime* or program* or group* or session* or scheme*)).ti,ab.	862
38	(reduc* adj2 sedentary behavio?r).ti,ab.	116
39	(dance and (therap* or activit* or class* or program* or group* or session* or scheme*)).ti,ab.	1593
40	personal trainer*.ti,ab.	77
41	(gym or gyms).ti,ab.	1236
42	or/31-41	1019153
43	7 and (31 or 32 or 35 or 36)	419818
44	33 or 34 or 37 or 38 or 39 or 40 or 41 or 43	470658
45	cognitive therapy/	29507
46	Counseling/ or nutritional counseling/ or patient counseling/ or patient guidance/	66254
47	behavior therapy/	36221
48	cognitive behavio?r* therapy.ti,ab.	9345
49	behavio?ral intervention*.ti,ab.	5740
50	(change* adj2 lifestyle*).ti,ab.	7204
51	(changing adj2 lifestyle*).ti,ab.	365

52	(lifestyle adj2 modif*).ti,ab.	5025
53	Hypnosis/	13921
54	hypnosis.ti,ab.	7734
55	(counseling or counselling).ti,ab.	70526
56	or/45-55	185378
57	11 or 14	65635
58	Antiobesity Agent/	2979
59	(sibutramine or orlistat or rimonabant).mp.	9793
60	exp bariatric surgery/	13185
61	exp obesity/su	11377
62	or/58-61	28905
63	(weight adj4 (maintenance or maintain* or regain* or gain* or relapse* or sustain*)).tw.	64347
64	"systematic review"/	57569
65	meta analysis/	69050
66	"review"/	1969462
67	(metaanaly\$ or metanaly\$ or (meta adj2 analy\$)).tw.	65822
68	(review\$ or overview\$).ti.	320281
69	(systematic\$ adj4 (review\$ or overview\$)).tw.	57884
70	((quantitative\$ or qualitative\$) adj4 (review\$ or overview\$)).tw.	4127
71	((studies or trial\$) adj1 (review\$ or overview\$)).tw.	8529

72	(integrat\$ adj2 (research or review\$ or literature)).tw.	3980
73	(pool\$ adj1 (analy\$ or data)).tw.	
74	(handsearch\$ or (hand adj2 search\$)).tw.	5731
75	(manual\$ adj2 search\$).tw.	3265
76	or/64-75	2219252
77	nonhuman/ not human/	3230367
78	76 not 77	2109546
79	6 and 78 and 57 and 63	1713
80	6 and 29 and 78 and 63	1580
81	6 and 30 and 78 and 63	1221
82	6 and 42 and 78 and 63	1230
83	6 and 44 and 78 and 63	1021
84	6 and 56 and 78 and 63	652
85	80 and 82 and 84	243
86	80 and 82	717
87	80 and 84	342
88	82 and 84	332
89	86 or 87 or 88	905
90	81 and 83	617
91	81 and 84	322

92	83 and 84	312
93	90 or 91 or 92	
94	85 or 89 or 93	905
95	94 not 62	639
96	limit 95 to (human and english language)	550
97	limit 96 to embase	402
98	(editorial or letter or conference*).pt.	2919600
99	97 not 98	386
100	limit 99 to (infant <to one="" year=""> or child <unspecified age=""> or preschool child &lt;1 to 6 years&gt; or school child &lt;7 to 12 years&gt; or adolescent &lt;13 to 17 years&gt;)</unspecified></to>	21
101	99 not 100	365
102	limit 101 to dd=20000101-20090509	186
103	limit 101 to dd=20121109-20130221	6
104	102 or 103	192

### Notes:

This was a re-working of a search originally carried out in November 2012. An additional weight maintenance set has been included and the RCT filter has been replaced with a systematic review filter. A date limit has been applied so that the search does not cover the period of the November search (May 2009 – November 2012).

### **Database: CDSR and DARE**

Strategy used:

- #1 (obes\* or overweight or "over weight" or weight gain) and (diet\* and exercis\* and behav\* and (maintenance or maintain\*)):ti,ab,kw (Word variations have been searched) 99
- #2 (surg\* or sibutramine or orlistat or rimonabant):ti,ab,kw (Word variations have been searched) 76374

#3 #1 not #2 93

### **Database: PsychINFO**

Strategy used:

1	(obes* or overweight or "over weight" or "over eat*" or "weight gain").ti,ab.	27527
2	Obesity/	13571
3	Overweight/	2193
4	2 or 3	14271
5	1 or 4	28208
6	(diet or diets or dieting).ti,ab.	17511
7	(low calorie or hypocaloric or calorie control*).ti,ab.	373
8	(nutrition adj2 (modific* or therapy or intervention* or strateg* or program* or management or scheme*)).ti,ab.	1142
9	(slim* adj1 (world or organisation or organization or group or club)).ti,ab.	10
10	Diets/	8186
11	or/6-10	20954

12	(exercise and (therapy or therapies or activity or activities or class* or program* or group* or session* or scheme*)).ti,ab.	17356	
13	(Gym and (trainer* or therap* or activit* or class* or program* or group* or session* or scheme* or club*)).ti,ab.	203	
14	(walk* or step* or jog* or run*).ti,ab.	107540	
15	(aerobic* or physical therap* or physical activit*).ti,ab.	19402	
16	(fitness adj (class or regime* or program* or group* or session* or scheme*)).ti,ab.	322	
17	(reduc* adj2 sedentary behavio?r).ti,ab.	40	
18	(dance and (therap* or activit* or class* or program* or group* or session* or scheme*)).ti,ab.	2228	
19	personal trainer*.ti,ab.	24	
20	(gym or gyms or gymnasium*).ti,ab.	715	
21	Exercise/	13146	
22	Aerobic Exercise/	1017	
23	Physical Activity/	7988	
24	physical fitness/	2812	
25	or/12-24	143229	
26	Behavior/	19607	
27	Behavior Change/	8749	
28	Behavior Modification/	9848	
29	Behavior Therapy/	12014	
30	Biofeedback Training/	2474	

31	Classroom Behavior Modification/	2394
32	Contingency Management/ 1674	
33	"Fading (Conditioning)"/	174
34	Omission Training/	32
35	Overcorrection/	50
36	Self Management/	3994
37	Time Out/	243
38	Aversion Therapy/	552
39	Exposure Therapy/	1308
40	Implosive Therapy/	411
41	Reciprocal Inhibition Therapy/	91
42	"Response Cost"/	75
43	Systematic Desensitization Therapy/	1740
44	Behaviorism/	3088
45	Counseling/	17935
46	Cognitive Therapy/	11278
47	Hypnosis/	6459
48	behavio?ral intervention*.ti,ab.	5911
49	(change* adj2 lifestyle*).ti,ab.	1504
50	(changing adj2 lifestyle*).ti,ab.	109

51	(lifestyle adj2 modif*).ti,ab.	446
52	(counseling or counselling).ti,ab.	60409
53	((behaviour or behavior) adj2 (change* or therap* or modif*)).tw.	33508
54	hypnosis.ti,ab.	9888
55	or/26-54	168050
56	(weight adj4 (maintenance or maintain* or regain* or gain* or relapse* or sustain*)).tw.	9039
57	meta analysis.sh.	3258
58	meta-anal*.tw.	16029
59	metaanal*.tw.	345
60	meta analysis.id.	3377
61	(systematic* and (review* or overview)).tw.	19345
62	(critical* and apprais*).tw.	2528
63	(critical* and review*).tw.	27841
64	or/57-63	60594
65	literature review.sh.	21903
66	literature review.id.	19250
67	65 or 66	22442
68	64 or 67	80497
69	5 and 11 and 56 and 68	26
70	5 and 25 and 56 and 68	32

71	5 and 55 and 56 and 68	39
72	69 or 70 or 71	71
73	limit 72 to (human and english language and yr="2000 -Current")	53

Notes:

This was a re-working of a search originally carried out in November 2012. An additional weight maintenance set has been included and the RCT filter has been replaced with a systematic review filter. However, the structure of the strategy has been altered (additional search terms included and a re-working of the Boolean logic) to expand the coverage of the search. As a result a date limit has not been applied since there may be records for the original search period that have not been screened.

Database: Science Citation Index via Web of Science (searched 06 November 2012)			
Strateg	gy used:		
# 18	<u>77</u>	#17 AND #16 AND #15 Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=2000-01-01 - 2013-03-05	
# 17	<u>61,846</u>	TS=(weight NEAR/4 (maintenance or maintain* or regain* or gain* or relapse* or sustain*)) Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years	
# 16	924,506	TS=(review* or overview* or pool* or meta*) Databases=SSCI, CPCI-S Timespan=All Years	
# 15	<u>1,116</u>	#14 or #12 or #9 or #13 Databases=SSCI, CPCI-S Timespan=All Years	
# 14	<u>246</u>	#10 and #1 Databases=SSCI, CPCI-S Timespan=All Years	
# 13	<u>1,116</u>	#12 or #10 or #9 Databases=SSCI, CPCI-S Timespan=All Years	
# 12	<u>220</u>	#11 and #1 Databases=SSCI, CPCI-S Timespan=All Years	
# 11	<u>278</u>	TS=(((weight reduc*) SAME (diet and exercise and behav*)))  Databases=SSCI, CPCI-S Timespan=All Years	
# 10	<u>315</u>	TS=(((weight management or weight maintenance) SAME (diet and exercise and behav*)))  Databases=SSCI, CPCI-S Timespan=All Years	
# 9	<u>1,047</u>	#8 OR #6 Databases=SSCI, CPCI-S Timespan=All Years	
# 8	<u>837</u>	#7 AND #1 Databases=SSCI, CPCI-S Timespan=All Years	
#7	<u>1,963</u>	TS=((diet* and exercis* and behav*)) Databases=SSCI, CPCI-S Timespan=All Years	
# 6	<u>786</u>	#5 AND #1 Databases=SSCI, CPCI-S Timespan=All Years	

# 5	<u>1,646</u>	#4 AND #3 AND #2 Databases=SSCI, CPCI-S Timespan=All Years
# 4	<u>43,651</u>	TS=(((exercis* or physical therap*) SAME (scheme* or therapy or therapies or interven* or strateg* or program* or management or maintenance or modif* or reduc*)))  Databases=SSCI, CPCI-S Timespan=All Years
#3	<u>285,150</u>	TS=(((lifestyle or behav*) SAME (scheme* or therapy or therapies or interven* or strateg* or program* or management or maintenance or modif* or reduc*)))  Databases=SSCI, CPCI-S Timespan=All Years
# 2	<u>17,341</u>	TS=(((diet) SAME (scheme* or therapy or therapies or interven* or strateg* or program* or management or maintenance or modif* or reduc*)))  Databases=SSCI, CPCI-S Timespan=All Years
# 1	65,247	TS=((obes* or overweight or "over weight" or weight gain*))  Databases=SSCI, CPCI-S Timespan=All Years

### **Appendix 5: Excluded studies (Review of reviews)**

#### Included studies did not meet the definition of weight maintenance trials

Y. Mulholland, E. Nicokavoura, J. Broom and C. Rolland (2012). Very-low-energy diets and morbidity: a systematic review of longer-term evidence. British Journal of Nutrition, 108, pp 832-851.

Anderson JW, Konz EC, Frederich RC, Wood CL (2001). Long-term weight-loss maintenance: a meta-analysis of US studies. American Journal of Clinical Nutrition; 74(5), pp 579-84.

Mariman EC (2012). Human biology of weight maintenance after weight loss. Journal of Nutrigenetic Nutrigenomics, 5(1):13-25.

Barte, J. C. M., Ter Bogt, N. C. W., Bogers, R. P., Teixeira, P. J., Blissmer, B., Mori, T. A. and Bemelmans, W. J. E. (2010), Maintenance of weight loss after lifestyle interventions for overweight and obesity, a systematic review. Obesity Reviews, 11: 899–906.

## **Appendix 6: Evidence tables (Systematic reviews)**

### **Internal validity (study quality) scores**

Studies were rated ++ if the AMSTAR quality score was between 8-11; + if the score was between 4 and 7; and – if the score was 0-3.

Review Details	Review search parameters	Review population and setting	Intervention/s	Outcomes and method of analysis	Results	Notes
						Limitations identified by
Catenacci, VA and	Databases and websites	Only 4 of the studies	Intervention/s description:	Primary Outcomes:	Primary outcomes: No	author: No limitations of the
Wyatt, HR (2007).	searched: PubMed	identified in the review		Weight change (kg)	sig diff in most of the	review methods reported by
The role of physical		met our criteria.	These studies began		studies. Sig diff in	authors
activity in producing	Other search methods		with a 12–26-week weight-	Secondary outcomes:	subgroup of one RCT	
and maintaining	undertaken (e.g. reference	Included population/s:	loss intervention, after	None	with follow-up 3 yrs; and	Limitations identified by
weight loss. National	checking): Relevant articles		which individuals were		in another study with 1 yr	review team: A conventional
Clinical Practice	published prior to 1997 were	Sex:	randomly assigned		follow-up	review; does not synthesize the
Endocrinology and	identified from the 1998 Obesity	1 men only $(n = 90)$	either an exercise	Follow-up periods:		evidence for the effects of the
Metabolism. 3 (7); pp	Education Initiative Expert Panel	1 female only $(n = 82)$	intervention or control	Unsupervised follow up		interventions; no report on the
518-529	clinical guidelines which	2 mixed studies ( $n = 48$	intervention for a 26–40-	ranged between 6		methodological quality of the
	performed a literature review on	and $n = 91$ ) – no	week weight-maintenance	months to 2 years.		included RCTs.
	this topic using similar search	breakdown provided.	phase, with a subsequent		Secondary outcomes:	
Aim: This article	criteria; manually searched		minimally supervised		NR	Evidence gaps and/or
aims to review the	references in meta-analyses,	Ethnicity: NR	follow-up period.	Methods of		Recommendations for future
published	reviews and position statements	_		analysis: N/A		research: Few RCTs truly
research that	related to this topic.	<b>BMI:</b> >25kg/m <sup>2</sup> before	Control/comparison/s			address the role of activity in
addresses the role of		weight-loss	summary:			weight-loss maintenance by
physical	Years searched: 1997 to 2006				Attrition details: Follow	providing a long term, sustained
activity as a strategy		Other demographics:	All four studies had diet		up ranged from 65% to	activity intervention and there is
in body-weight	Inclusion criteria:	NR	only control groups.		90% in the four included	a need for well designed,
management,	RCTs evaluating the role of				studies	prospective, randomised trials
both when used as a	physical activity alone or in	Excluded population/s:				to assess such regimens.
single intervention	combination with diet in short-	NR				
and when used in	term weight loss (<1 year) or					The impact of exercise on other
combination with	weight-loss maintenance (follow	Setting of included				components of the energy
dietary	up ≥1 year after weight	studies: NR				balance equation, including
restriction.	reduction). The search was					energy intake, RMR, and
	limited to English-language.					spontaneous physical activity
		External validity				during times when exercise is
Review design:		scores: NR				not being undertaken
Narrative						
Quality score: - (NR						Source of funding: NS
for all quality criteria						Source of Immunig. 110
except presence of						
characteristics of						
included studies)						

Turk, MW; Yang, K; Hravank, M; Sereika SM; Ewing, Li; Burke, LE (2009), Dournal of Cardiovascular Nursing, 24(1) pp 58. 30.  Aim: To summarize for clinicians and researchers the efficacy of these interventions.  Aim: To summarize for clinicians and researchers the efficacy of these interventions.  Aim: To summarize for clinicians and researchers the efficacy of these interventions.  Aim: To summarize for clinicians and researchers the efficacy of these interventions.  Aim: To summarize for clinicians and researchers the efficacy of these interventions.  Aim: To summarize for clinicians and researchers the efficacy of these interventions.  Aim: To summarize for clinicians and researchers the efficacy of these interventions.  Aim: To summarize for clinicians and researchers the efficacy of these interventions.  Aim: To summarize for clinicians and researchers the efficacy of these interventions.  Aim: To summarize for clinicians and researchers the efficacy of these interventions.  Aim: To summarize for clinicians and researchers the efficacy of these interventions.  Aim: To summarize for clinicians and researchers the efficacy of these interventions.  Aim: To summarize for clinicians and researchers the efficacy of these interventions.  Aim: To summarize for clinicians and research methods undertaken (e.g. reference tessent studies reported on the efficacy of these interventions.  Aim: To summarize for clinicians and research methods undertaken (e.g. reference tessent studies reported on the efficacy of these interventions.  Aim: To summarize for clinicians and research methods undertaken (e.g. reference tessent studies reported on the efficacy of these interventions.  Aim: To summarize for clinicians and research methods undertaken (e.g. reference tessent studies reported on the efficacy of these interventions.  Aim: To summarize for clinicians and research methods undertaken (e.g. reference tessent studies reported on the efficacy of these interventions.  Aim: To summarize for clinicians and research methods u
than 35%

# Appendix 7: Summary of judgements from quality checklists (Systematic reviews)

11											-		
Study	Was an 'a priori' design provided?	Was there duplicate study selection and data extraction?	Was a comprehensive literature search performed?	Were published and unpublished studies eligible, irrespective of language of publications?	Was a list of studies (included and excluded) provided?	Were the characteristics of the included studies provided?	Was the scientific quality of the included studies assessed and documented?	Was the scientific quality of the included studies used appropriately in formulating conclusions?	Were the methods used to combine the findings of studies appropriate?	Was the likelihood of publication bias assessed?	Was the conflict of interest stated?	QUALITY SCORE	Comments
Turk et al. 2009	N	N	Y	Z	N	Y	Ν	Y	N/A	Z	N	3	The study calculated effect size but did not complete any metaregression and summarised findings narratively only. Despite not assessing quality formally, the authors do consider aspects of scientific quality during the discussion
Catenacci and Wyatt 2007	N	N	N	N	N	Y	N	N	N/A	N	N	1	Poor methods description. This review is intended as an education piece and as such has not provided the expected methodological detail.

# References

Bertz, F., 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)

Catenacci, V.A. & Wyatt, H.R. 2007. The role of physical activity in producing and maintaining weight loss. *Nature Clinical Practice Endocrinology and Metabolism.3 (7) (pp 518-529), 2007.Date of Publication: July 2007.* (7)

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)

Diabetes Prevention Program Research, G., Knowler, W.C., Fowler, S.E., Hamman, R.F., Christophi, C.A., Hoffman, H.J., Brenneman, A.T., Brown-Friday, J.O., Goldberg, R., Venditti, E., & Nathan, D.M. 2009. 10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study.[Erratum appears in Lancet. 2009 Dec 19;374(9707):2054]. *Lancet*, 374, (9702)

Jolly, K., Lewis, A., Beach, J., Denley, J., Adab, P., Deeks, J.J., Daley, A., & Aveyard, P. 2011. Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: lighten Up randomised controlled trial. *Bmj*, 343,

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)

Lindstrom, J., Louheranta, A., Mannelin, M., Rastas, M., Salminen, V., Eriksson, J., Uusitupa, M., & Tuomilehto, J. 2003. The Finnish Diabetes Prevention Study (DPS): Lifestyle intervention and 3-year results on diet and physical activity. *Diabetes Care*, 26, (12)Accessed 1 December 2003.

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)

Munsch, S. Evaluation of a lifestyle change programme for the treatment of obesity in general practice. Biedert E, Keller U. 133. 2003. Ref Type: Generic

Nanchahal, K., Power, T., Holdsworth, E., Hession, M., Sorhaindo, A., Townsend, J., Thorogood, N., Taylor, D., Haslam, D., Kessel, A., & Ebrahim, S. 2011. Weight management in primary care: Results from the camden weight loss (Camwel) randomised controlled trial. *Obesity Reviews.Conference:* 18th European Congress on Obesity, ECO 2011 Istanbul Turkey.Conference Start: 20110525 Conference End: 20110528.Conference Publication: (var.pagings).12 (pp 60), 2011.Date of Publication: May 2011. (var.pagings)

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,

Turk, M.W., Yang, K., Hravnak, M., Sereika, S.M., Ewing, L.J., & Burke, L.E. 2009. Randomized Clinical Trials of Weight Loss Maintenance A Review. *Journal of Cardiovascular Nursing*, 24, (1)

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)