Transtheoretical model for dietary and physical exercise modification in weight loss management for overweight and obese adults (Review)

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[Intervention Review]

Transtheoretical model for dietary and physical exercise modification in weight loss management for overweight and obese adults

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ABSTRACT

Background

Obesity is a global public health threat. The transtheoretical model stages of change (TTM SOC) model has long been considered a useful interventional approach in lifestyle modification programmes, but its effectiveness in producing sustainable weight loss in overweight and obese individuals has been found to vary considerably.

Objectives

To assess the effectiveness of dietary and physical activity interventions based on the transtheoretical model, to produce sustainable weight loss in overweight and obese adults.

Search methods

Studies were obtained from searches of multiple electronic bibliographic databases. Date of last search for *The Cochrane Library was* issue 10, 2010, for MEDLINE Dezember 2010, for EMBASE January 2011 and for PSYCHINFO Januar 2011.

Selection criteria

Trials were included if they fulfilled the following criteria: randomised controlled clinical trials using TTM SOC as a model, theoretical framework or guideline in designing lifestyle modification strategies, mainly dietary and physical exercise versus a comparison intervention of usual care; one of the outcome measures of the study was weight loss; and participants were overweight or obese adults.

Data collection and analysis

Two researchers independently applied the inclusion criteria to the identified studies and assessed risk of bias. Disagreement was resolved by discussion or by intervention of a third party. Descriptive analysis was conducted for the review.

Main results

A total of five studies met the inclusion criteria and a total of 3910 participants were evaluated. The total number of participants randomised to intervention groups was 1834 and 2076 were randomised to control groups. Overall risk of bias was high. The trials varied in length of intervention from six weeks to 24 months, with a median length of nine months. The intervention was found to have limited impact on weight loss (about 2 kg or less). There was no conclusive evidence for sustainable weight loss. However, TTM SOC and a combination of physical activity, diet and other interventions tended to produce significant outcomes (particularly change in physical activity and dietary intake). TTM SOC was used inconsistently as a theoretical framework for intervention in the trials. Death and weight gain are the two adverse events reported by the included trials. None of the trials reported health-related quality of life, morbidity, and costs as outcomes.

Authors' conclusions

TTM SOC and a combination of physical activity, diet and other interventions resulted in minimal weight loss, and there was no conclusive evidence for sustainable weight loss. The impact of TTM SOC as theoretical framework in weight loss management may depend on how it is used as a framework for intervention and in combination with other strategies like diet and physical activities.

PLAIN LANGUAGE SUMMARY

Transtheoretical model for dietary and physical exercise modification in weight loss management for overweight and obese adults

Obesity (body mass index of more than 30 kg/m^2) and overweight (body mass index of 25 to less than 30 kg/m^2) are increasingly important public health issues, and contribute to serious health problems and extensive economic costs worldwide. Body mass index is a common measure used in classifying overweight and obesity in adult populations and individuals, and is conforming to the World Health Organization (WHO) standard. It is defined as the weight in kilograms divided by the square of the height in meters.

Generally, weight loss programmes tend to involve diet and physical activity interventions. The 'Stages of Change' (SOC) model can be used as a framework to plan these interventions in both hospital and community settings. SOC describes the five stages an individual goes through when changing from an unhealthy behaviour to a healthy one. SOC is fundamental to what is known as the 'Transtheoretical Model' (TTM), whereby an individual's readiness to change is assessed. In this review, we assessed the use of the TTM SOC in weight management programmes for overweight and obese adults, in terms of the effects on weight loss and dietary and physical exercise behaviour change.

Five trials were included in the review and 3910 participants were evaluated, with 1834 participants randomly allocated to intervention groups and 2076 to control groups. The trials varied in length of intervention (from 6 weeks to 24 months), with a median length of nine months. The use of TTM SOC resulted in minimal weight loss (about 2 kg or less) and there was no conclusive evidence for sustainable weight loss amongst participants. However, other significant positive outcomes were noted, such as a change in physical activities behaviour and dietary intake. Weight gain was among the adverse events reported.The trials did not report other important outcomes such as health-related quality of life, morbidity and cost. The impact of TTM SOC in weight loss management may depend on how it is used in combination with other strategies and thus further rigorous research is required into this potentially valuable interventional strategy.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Application of the transtheoretical model stages of change (TTM SOC) compared with usual advice on diet, exercise or both for overweight and obesity

Patient or population: adults with overweight and obesity
Settings: hospital and community
Intervention: TTM SOC, diet and physical activity
Comparison: Usual advice on diet, exercise or both

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Usual care	TTM SOC				
Death from any cause	See comment	See comment		3910 (5)		No study aimed to evaluate this outcome.
Morbidity	See comment	See comment		3910 (5)		No study evaluated this outcome.
Health-related quality of life	See comment	See comment		3910 (5)		No study evaluated this outcome.
Adverse events	See comment	See comment		665 (1)	⊕⊕◯◯ **low**[1]	Significant weight gain for both intervention and control groups combined after 12 months
Costs	See comment	See comment		3910 (5)		No study evaluated this outcome.
Weight loss maintenance (measured at 6, 12 and 24 months)	See comment	See comment		2971 (3)	⊕⊕◯◯ **low**[2]	The intervention was found to have limited impact on weight loss (about 2 kg or less) and other outcome measures. There was no

			conclusive evidence for sustainable weight loss

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk Ratio

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Only one study (with high risk of reporting bias and other bias) reported this outcome.
[2] One of the key methodological limitations of the trials was that most had limited intervention and follow-up duration (one year or less) and it was therefore not possible to assess sustainable weight loss amongst participants. Several risk of bias domains were identified.

BACKGROUND

Description of the condition

In this review, overweight and obesity are defined as abnormal or excessive fat accumulation that may impair health. 'Overweight' refers to a body mass index (BMI) equal to or more than 25 to less than 30, and 'obesity' to a BMI equal to or more than 30. BMI is a common measure used in classifying overweight and obesity in adult populations and individuals, and is conforming to the World Health Organization (WHO) standard. It is defined as the weight in kilograms divided by the square of the height in meters. It provides the most useful population-level measure of overweight and obesity for both sexes and for all ages of adults. Nevertheless, it must be considered as a rough guide only because it may not correspond to the same degree of fatness in different individuals. Diabetes, heart disease, hypertension and osteoarthritis are all more common in overweight and obese people (World Health Organization 2011).

Obesity is a major global public health threat due to increasing trends in overweight and obesity among adults and children in many developed and developing countries. In 2008, the WHO projected approximately 1.5 billion adults (age 15 and above) were overweight and at least 500 million adults were obese, and in 2010 at least 43 million children under the age of five years are overweight (World Health Organization 2011). Obesity results in significant impairment of health and longevity. Obesity also increases an individual's risk of illness and reduces their life expectancy (London Health Observatory 2011). Overweight and obesity are major risk factors for serious chronic diseases, such as type 2 diabetes mellitus, cardiovascular disease, hypertension, stroke and some forms of cancer (World Health Organization 2011). Obesity reduces quality-adjusted life expectancy by about three years in males and six years in females (Brønnum-Hansen 2007; Pryke 2008). In the United Kingdom, around 8.7% of deaths are estimated to be a result of excess weight (Banegas 2003), with severely obese individuals on average dying 11 years earlier than non-obese people (London Health Observatory 2011). Furthermore, obesity has huge economic implications for a country from direct treatment costs and from indirect costs (such as sickness absence). For example, in England the disease burden for obesity was estimated at £3.1 to £3.7 billion (approx. 3.6 to 4.4 billion EURO as of August 2009) in 2002 (House of Commons Health Committee 2004) and in the United States, the medical care costs of obesity were approximately $147 billion in 2008 (Centers for Disease Control and Prevention 2011).

Obesity drugs, dietary modification, and physical exercise are common interventions used in the management of obesity among overweight and obese individuals in primary care (or community) and clinical settings. A large systematic review (44 clinical trials) of long-term (more than two years) weight loss studies in obese individuals (19 273 adults with a BMI more than 25 kg/m^2) from 1966 to 2003 investigated dietary and 'lifestyle', drug therapy (orlistat or sibutramine) and surgical (e.g. gastric bypass) methods resulting in modest weight loss, and potentially improving markers of cardiovascular risk factors. Dietary and lifestyle therapy provided less than 5 kg weight loss after 2 to 4 years, drug therapy provided 5 to 10 kg weight loss after 1 to 2 years, and surgical therapy provided 25 to 75 kg weight loss after 2 to 4 years. The limitations of the review were the methodological limitations restricting the applicability of findings to obese patients in other settings (Douketis 2006).There are few systematic reviews conducted showing evidence on the effectiveness of the above interventions for sustainable weight loss at least a year after interventions among obese individuals. There is no clear evidence of effectiveness, especially in producing sustainable weight loss beyond one year after intervention (Douketis 2006; Jain 2005; Nield 2008; Shaw 2006).

A large systematic review of 41 randomised controlled trials (from the United States of America, Netherlands, Canada, Australia and United Kingdom with a total of 3476 participants) assessed exercise as a means of achieving weight loss and demonstrated that exercise had a positive effect on body weight in adults with overweight or obesity. Exercise alone resulted in small weight losses compared with no treatment, however, exercise combined with diet resulted in a greater weight reduction than diet alone (mean difference (MD) -1.0 kg), and increasing exercise intensity increased the magnitude of weight loss (MD - 1.5 kg). The major limitation of the review was lack of long-term trials included in the analyses (Shaw 2006).

A systematic review of 18 randomised controlled trials examined the effects of type and frequency of dietary advice given to all adults (1467 participants who were overweight and had normal weight) with type 2 diabetes mellitus and reported that dietary advice plus exercise was associated with a statistically significant mean decrease in the glycosylated haemoglobin A1c of 0.9% at six months and 0.1% at 12 months. The study found no significant results in relation to weight loss. There were insufficient data for a meta-analysis, so conclusions on the effects of low-fat or other weight reducing diets were limited (Nield 2008).

A systematic clinical literature review found dietary and exercise treatments for obese adults produced moderate weight loss (about 3 kg to 5 kg) compared with no treatment or usual care. Meanwhile, weight loss from drugs used in conjunction with diet or exercise programs also produced 3 kg to 5 kg of weight loss, but the effects did not last after the drug was stopped. The reported weight lost can be statistically significant but it may not be clinically relevant to improve patients' health or quality of life. There was a tendency for weight regain or relapse as shown by most studies with long-term follow up in the review (Jain 2005).

Description of the intervention

Transtheoretical model (TTM) describes the sequential behaviour change in an individual from an unhealthy behaviour to a healthy one. It is a model of intentional change predicting the possible

outcomes during the adaptation process of the 'new' acquired behaviour. TTM has proven successful as an interventional approach in smoking reduction amongst adults (Velicer 1998), but its effectiveness for producing weight reduction in obesity is unclear. Studies have shown that the TTM stages of change model (SOC) can be used to plan dietary interventions, for short term weight loss amongst overweight and obese individuals over a minimum of three months. The effectiveness of TTM for weight loss beyond one year is inconsistent (Curry 1992; Greene 1999; Johnson 2006; Johnson 2008; Laforge 1994; Prochaska 2008b; Vallis 2003; Wee 2005). One study found that the TTM algorithm was insensitive and most individuals failed to meet the behavioural criteria of the model stages (Greene 1994) but other studies did identify stage of change for uptake of low-fat diet in adults (Auld 1997; Lamb 1996; Read 1996; Steptoe 1996).

TTM provides a conceptual explanation of the processes that individuals undergo when modifying a problem behaviour or acquiring a positive behaviour, in this case changing dietary intake and physical activity in order to achieve a sustainable weight loss. The SOC is the main construct of the TTM which illustrates the sequential progress and series of stages that individuals will progress through for a specific behaviour transformation (Velicer 1998). The series of five stages of change are pre-contemplation, contemplation, preparation, action and maintenance which an individual will go through in adopting a healthy behaviour or quitting the unhealthy one (as shown in Appendix 1) (Prochaska 1992; Prochaska 1997; Prochaska 2008a). The model's two main underlying assumptions are firstly that the majority of people are not ready to change their behaviour and will therefore not be helped by traditional action-oriented prevention programs. Secondly that behavioural change is complex and may unfold in a sequence of stages. Individuals typically adapt these different processes of change according to the progress they have made towards changing their behaviour (DiClemente 1985).

For this review, the five SOC need to be clearly included and stated in the intervention, although the framework might not be properly listed as TTM or SOC. The intervention must be delivered by health care professionals or trained lay people at the hospital and community level targeted for overweight and obese adults, such as at community health centres, general practice clinics, community centres and schools. All studies with duration of intervention from 1 to 12 months and above were be included in the review.

Adverse effects of the intervention

The potential main adverse effect of the intervention may include relapse into unhealthy behaviour and weight gain over a specific period of time.

How the intervention might work

The intervention might work by providing information on stage-related strategies that can be applied to individuals' weight loss management programs. The proposed strategies are intended to change both dietary and physical exercise behaviour of participants to achieve sustainable proportion of weight loss among overweight and obese adults. The hypothesis is that the TTM model truly reflects human behaviour in the process of change (DiClemente 1985). The intervention also enables predictions on which strategies are suitable for the individuals at certain stages; therefore weight loss strategies are targeted and tailored to meet the participants' needs.

Dietary strategies based on TTM stages of change might work by meeting individuals' needs according to its predictions; as a result there will be a change in the dietary habits (such as reduction in daily calories and fatty food consumption) which is repeatable (as the behaviour change takes place), leading to sustainable weight loss. Similarly, physical exercise strategies tailored according to the model possibly work by increasing level of exercise and physical activity occurring at continuous and sustainable manner resulting in the targeted outcome. The significance of such an approach is the behaviour change takes place voluntarily and is highly self-driven that may contribute to sustainable desired behaviour change.

A study among overweight or obese adults (1277 participants with a BMI 25 to 39.9) claimed that TMM-based tailored feedback can improve healthy eating, exercise, emotional distress management, and weight of the population. The results showed a significant increase in fruits and vegetables intake and individuals tended to progress to action and maintenance at 24 months (Johnson 2008). However, another review done on TTM application found that it is difficult to apply the model looking at dietary change because most studies demonstrated differences in terms of the aspect of diet being examined, as well as the staging algorithms and dietary assessment methodology (Ni Mhurchu 1997).

TTM is a useful theoretical model in guiding interventions and predicting outcomes in dietary management among adults, as shown in some studies above. The studies with rigorous design have shown statistically significant results that link stages of TTM with the primary measured outcomes, particularly for large sample studies with longer follow up periods. It is potentially plausible applying the TTM model to other settings and may be applicable in measuring other outcomes such as physical exercise modification and weight loss. The two common primary outcomes measured in dietary modification using TTM model as guidelines are reduction in fat consumption and increase in healthy food intake (i.e. increase in fruits and vegetables consumption) (Di Noia 2008; Greene 1994; Johnson 2008; Laforge 1994). There is only one review published to date which reported that it is difficult to apply the model to look at dietary change because most studies differed in terms of the aspect of diet being examined, as well as the staging algorithms and dietary assessment methodology used. Therefore, there were significant differences in methodology which led to variable results and made it difficult to interpret the results of

those studies (Ni Mhurchu 1997). There is a need to do a high-quality systematic review on the application of TTM model in dietary modification and assess the strength of the evidence.

Why it is important to do this review

This review will collate evidence and allow rigorous appraisal on how and to what extent TTM works as a theoretical and pragmatic ('real life tested') framework for lifestyle modification (with diet and physical exercise) resulting in weight loss among the target population. The outcomes of this review will be relevant for patients and practitioners trying to understand strategies and treatment regimes for overweight and obese people at the hospital and primary care (or community) settings. The findings of this review will also be useful for planning and implementing obesity management programs as well as for policy makers.

OBJECTIVES

To assess the effectiveness of dietary and physical activity interventions based on the transtheoretical model (TTM), to produce sustainable weight loss in overweight and obese adults.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled clinical trials.

Types of participants

Adults, aged 18 years and over, who are overweight or obese according to any standard parameters used by the WHO (e.g. body mass index (BMI), waist measurement, waist-to-hip-ratio) and the criteria valid in the country at the time of the start of the trial. Overweight is defined as a BMI 25 to 30, and obesity as a BMI above 30.

Participants with co-morbidities, such as diabetes, heart diseases and hypertension will be included in the review.

Types of interventions

Intervention

Application of the transtheoretical model (TTM) stages of change (SOC) combined with lifestyle modification strategies, mainly dietary and physical exercise, which is tailored to an individual who is overweight or obese.

The studies included must describe the intervention as use of TTM as a model, theoretical framework or guidelines in designing lifestyle modification strategies as stated above. The intervention needs to fulfil the criteria of TTM SOC including pre-contemplation, contemplation, preparation, action, maintenance and termination as described by Prochaska and DiClemente (Prochaska 1992).

Control

Usual advice on diet or advice on physical exercise.

Types of outcome measures

There are two main types of outcome measured and they are as followed:

(1) Change in dietary consumption is defined as:

- a reduction in the daily number of calories;
- a reduction in fatty food intake;
- an increase in daily fruit and vegetable consumption.

(2) Change in physical exercise refers to increase in any form of daily physical activity (in terms of intensity, frequency, duration and types), non-prescribed or prescribed by health professionals.

Primary outcomes

- weight loss (measured at one month, three months or six months after intervention in scale reference use for the trials) maintenance at one to five years and above as mentioned by the study;
- health-related quality of life.

Secondary outcomes

- self-reported change in dietary habit and measured change in dietary habit;
- self-reported uptake in physical activity and measured change in physical activity;
- change in weight loss measures (body mass index, skin folds measurement, waist measurement and waist-to-hip-ratio) at one month, three months and later after intervention;
- adverse events including relapse into unhealthy behaviour and weight gain;
- morbidity;
- death from any cause;
- costs.

Covariates, effect modifiers and confounders

- underlying chronic diseases such as cancer, diabetes, and respiratory disease that may cause weight loss;
- compliance;
- pharmaceutical interventions.

Timing of outcome measurement

At one month, three months, six months, one year and if available two to five years, as stated by each trial.

Search methods for identification of studies

Electronic searches

We used the following sources for the identification of trials:

- *The Cochrane Library* (issue 10, 2010);
- MEDLINE (until December 2010);
- EMBASE (until January 2011);
- PSYCHINFO (until January 2011).

We also searched databases of ongoing trials including current controlled trials (www.controlled-trials.com) and the National Research Register (www.update-software.com/National/nrrframe.html).
For detailed search strategies please see under Appendix 2.
Additional key words of relevance could have been detected during any of the electronic or other searches. If this was the case, we would have modified the electronic search strategies to incorporate these terms. Studies published in any language were included.

Searching other resources

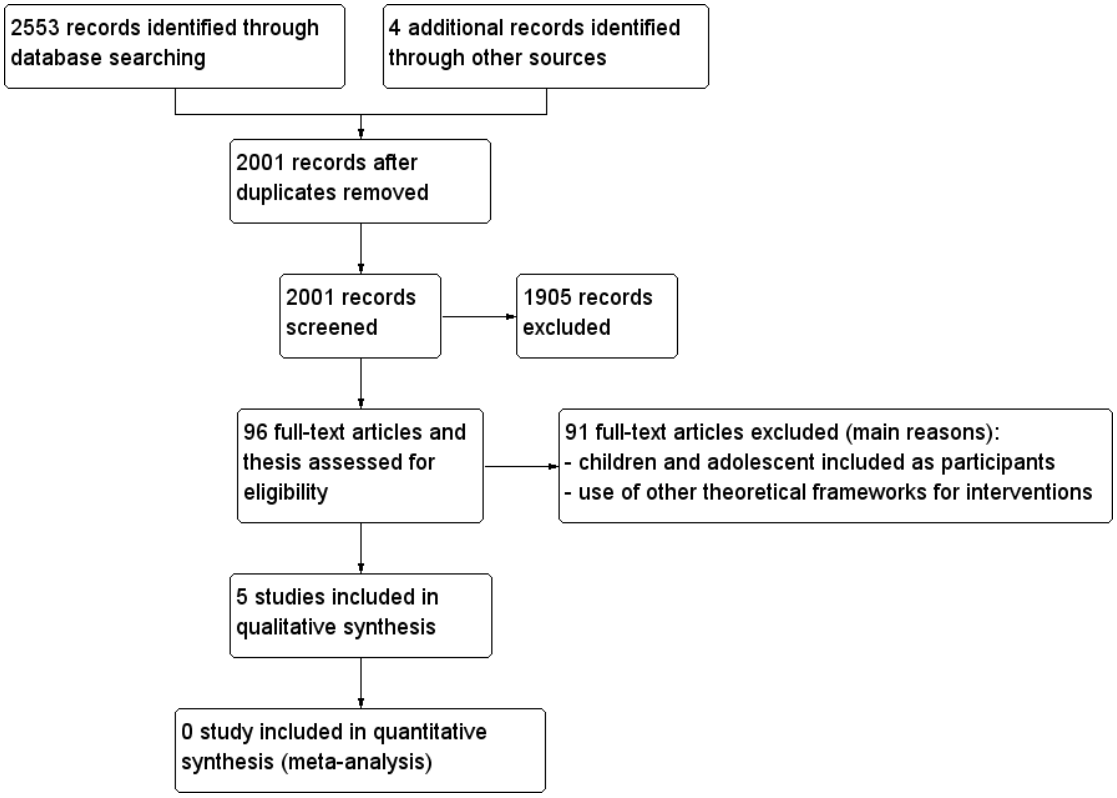
We tried to identify additional studies by searching the reference lists of included trials and (systematic) reviews, meta-analyses and health technology assessment reports noticed.
Potential missing and unpublished studies were sought by contacting experts in the field. We used library resources at Imperial and British Library if potentially relevant articles are cited but not available via databases or web sites.

Data collection and analysis

Selection of studies

To determine the studies to be assessed further, two authors (N.T., C.A.) independently scanned the abstract, title or both sections of every record retrieved. All potentially relevant articles were investigated as full text. Inter-rater agreement for selection of potentially relevant studies was measured using the kappa statistic (Cohen 1960) and the value was 0.82 which showed the strength of agreement between assessors was very good. Differences were marked and if these studies were later on included, we planned to study the influence of the primary choice by means of a sensitivity analysis. Where differences in opinion existed, they were resolved by a third party. If resolving disagreement was not possible, the article was added to those 'awaiting assessment' and authors were be contacted for clarification. An adapted PRISMA (preferred reporting items for systematic reviews and meta-analyses) flow-chart (see Figure 1) of study selection is attached (Liberati 2009).

Figure 1. Study flow diagram.



Data extraction and management

For studies that fulfilled inclusion criteria, two authors (N.T., C. A.) independently abstracted relevant population and intervention characteristics using standard data extraction templates (for details see 'Characteristics of included studies; Table 1; Appendix 3; Appendix 4; Appendix 5; Appendix 6; Appendix 7) with any disagreements to be resolved by discussion, or if required by a third party. We sought any relevant missing information on the trial from the original author(s) of the article, if required.

Assessment of risk of bias in included studies

Two authors (N.T. and C. A.) assessed each trial independently. Possible disagreements were resolved by consensus, or with consultation of a third party in case of disagreement. Inter-rater agreement for key bias indicators (e.g. allocation concealment, incomplete outcome data) was calculated using the kappa statistic (Cohen 1960) and the value was 0.72 which showed the strength of agreement between assessors was good. In cases of disagreement, the rest of the group was consulted and a judgement was made based on consensus.

We assessed risk of bias will using the Cochrane Collaboration's tool (Higgins 2009). We used the following criteria:

- was the allocation sequence adequately generated?
- was the allocation adequately concealed?
- was knowledge of the allocated intervention adequately prevented during the study?
- were incomplete outcome data adequately addressed?
- were reports of the study free of suggestion of selective outcome reporting?
- was the study apparently free of other problems that could put it at a high risk of bias?

We used these criteria for a judgement of high, low or unclear risk of bias for individual bias items as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2009). A 'risk of bias graph' figure and 'risk of bias summary' figure are attached.

We assessed the impact of individual bias domains on study results at endpoint and study levels.

Measures of treatment effect

Dichotomous data were expressed as odds ratio (OR) or risk ratio (RR) with 95% confidence intervals (CI). Continuous were expressed as differences in means (MD) with 95% CI.

Unit of analysis issues

We took into account the level at which randomisation occurred, such as cross-over trials, cluster-randomised trials and multiple observations for the same outcome.

We attempted to assure baseline and follow up weights and heights (or other weights measures used in the trials) from the authors if not reported. For cluster-randomised and cross-over trials, the focus of analysis is on the weight loss value, both absolute and relative as defined by each study. Different units of analysis (for example OR and RR) was planned to be subjected to a sensitivity analysis.

A cluster randomised trial is a trial in which individuals are randomised in groups (i.e. the group is randomised, not the individual). For example, in a TTM study, the patients in one general practice may be randomised as a group to receive either TTM or the control intervention. Reasons for performing cluster randomised trials vary. Sometimes the intervention can only be administered to the group; sometimes the design is simply more convenient or economical. A simple approach to dealing with cluster randomised trials is to assess outcomes only at the level of the group thereby keeping the unit of analysis the same as the unit of randomisation. However, there are limitations to this approach. First, cluster randomised trials are likely to randomise fewer groups. So, we would end up with less data (and hence less statistical power) than a simple trial involving substantially fewer participants analysed as individuals. Second, not all groups were of the same size, and we would give the same weight to clusters of different sizes. An alternative approach is to ignore the groupings and compare all the individuals in intervention groups with all those in control groups. This has been a common approach both to analysing individual cluster randomised trials and to representing them in systematic reviews. But it is problematic because it ignores the fact that individuals within a particular group tend to be more similar to each other than to members of other groups. Such analyses can spuriously overestimate the significance of differences, and should be avoided. Where possible, therefore, we planned to use statistical techniques for appropriate analyses of cluster randomised trials. We can recognize that clusters are made up of individuals and that there may be more individuals in one cluster than in another. The intra-cluster correlation coefficient plays an important role in these techniques (Alderson 2002).

In a cross-over trial, participants are randomised to a sequence of treatments. Analysis of data from cross-over trials should exploit the fact that each patient acts as his or her own control. This gives us data for each patient both when they were in the interventional group and in the control group. We planned to compare these for each patient to assess the effect of TTM within each patient. This is a very efficient approach to analysis, because when making the comparison between treatment and control we do not have to allow for all the variation that occurs between patients, which we have to deal with in a parallel group trial. We will also examine potential sources of bias in cross-over trials. For example, did the patients start the second period in a similar state to how they started the first period? If the characteristics of the participant have changed in some way by the time the second period starts, then the comparison of treatments is not fair, and there will be within patient variation, which needs to be accounted for. Our initial searches have suggested that there will be few if any cross-over trials in the area of TTM and behaviour modification with respect to obesity (Alderson 2002).

Dealing with missing data

We obtained relevant missing data from authors, if feasible and carefully performed evaluation of important numerical data such as screened, randomised patients as well as intention-to-treat (ITT), as-treated and per-protocol (PP) population. We investigated attrition rates, for example drop-outs, losses to follow up and withdrawals and critically appraised issues of missing data and imputation methods (for example, last-observation-carried-forward (LOCF)).

Assessment of heterogeneity

In the event of substantial clinical or methodological or statistical heterogeneity study results were not reported as meta-analytically pooled effect estimates. We identified heterogeneity by visual inspection of the forest plots, by using a standard Chi^2 test and a significance level of $\alpha = 0.1$, in view of the low power of this test. We specifically examined heterogeneity with the I^2 statistic quantifying inconsistency across studies to assess the impact of heterogeneity on the meta-analysis (Higgins 2002; Higgins 2003), where an I^2 statistic of 75% and more indicates a considerable level of inconsistency (Higgins 2009).

When heterogeneity was found, we planned to determine potential reasons for it by examining individual study and subgroup characteristics.

Assessment of reporting biases

We planned to use funnel plots to assess for the potential existence of small study bias. There are a number of explanations for the asymmetry of a funnel plot (Sterne 2001). Therefore, we planned to carefully interpret results (Lau 2006).

Data synthesis

We planned to summarise data statistically if they were available, sufficiently similar and of sufficient quality. We would have performed statistical analyses according to the statistical guidelines

referenced in the newest version of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2009)

Subgroup analysis and investigation of heterogeneity

We had planned to carry out subgroup analyses if one of the primary outcome parameters demonstrated statistically significant differences between intervention groups. In any other case subgroup analyses would have been clearly marked as a hypothesis generating exercise.
We planned the following subgroup analyses:

- overweight and obese groups;
- with co-morbidities and without co-morbidities groups;
- age groups;
- gender.

Sensitivity analysis

We had planned to perform sensitivity analyses in order to explore the influence of the following factors on effect size:

- repeating the analysis excluding unpublished studies;
- repeating the analysis taking account risk of bias, as specified above;
- repeating the analysis excluding very long or large studies to establish how much they dominate the results;
- repeating the analysis excluding studies using the following filters: diagnostic criteria, language of publication, source of funding (industry versus other), country.

We also wanted to test the robustness of the results by repeating the analysis using different measures of effect size (relative risk, odds ratio etc.) and different statistical models (fixed-effect model and random-effects model).

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.
See 'Characteristics of included studies' table and 'Characteristics of excluded studies' table.

Results of the search

The search strategy identified 2557 records. After review of the 2001 titles and available abstracts, 96 potential full text articles and theses were identified for further assessment. A total of five studies met the inclusion criteria of the review after full text review. Please see Figure 1 for the flow chart of the study selection.

Included studies

The details of the studies are described in the table 'Characteristics of included studies'. There were a total of five studies included in the review. Two trials (Johnson 2008; Logue 2005) were of parallel design with one to one randomisation ratios, two trials (Dinger 2007; Steptoe 2001) did not state the randomisation ratio and one trial (Jones 2003) was of factorial design. The transtheoretical model (TTM) stages of change (SOC) was used in a variety of ways in the studies, and dietary modification and exercise were common interventions for weight loss. The trials were published between 2001 and 2007 and the study sample size varied from 56 to 1277 participants. The total number of participants evaluated was 3910 and the duration of included trials ranged from six weeks to 24 months.

Participants and setting

There were a total of 3910 participants in the five trials, 1834 of which were randomised to intervention groups and 2076 to control groups. The total number of participants who had actually completed the trials was 1354 (which consisted of 663 of the intervention and 721 of the control groups) and two trials (Steptoe 2001;Jones 2003) did not report the data (including the proportions for control and intervention groups). Four trials (Dinger 2007; Johnson 2008; Logue 2005; Steptoe 2001) reported the percentages of participants for intervention and control groups finishing each study, and one trial did not (Jones 2003). The participants who completed the studies ranged from 53.5% to 79.2% for the intervention groups and in the control groups from 43% to 82.4%. All participants in the included trials were analysed on the basis of intention to treat (ITT). The overview of included studies' populations is shown in Table 1. The trials were conducted amongst overweight and obese adults participants only. Females were recruited more than males in two trials (Logue 2005; Steptoe 2001), another two trials (Johnson 2008; Jones 2003) recruited more male than female participants, and one trial (Dinger 2007) recruited female participants only. Three trials reported age as a range of values (with included participants between 25 and 75 years), whereas two trials reported age as a mean value. Four trials included both men and women, and one trial included women only. The included trials used a variety of weight entry criteria: most studies used body mass index (BMI) measures only (BMI cut off points and BMI range), whilst one trial used BMI with waist-hip-ratio (WHR). Of the two trials that used BMI cut off points only, one used BMI greater than 30 (Dinger 2007) and the other used BMI greater than 27 (Jones 2003). One trial (Logue 2005) used BMI greater than 25 alongside WHR for men and women. Of the two trials that applied BMI range, one applied the range BMI 25 to 39.9 (Johnson 2008) and one applied the range BMI 25 to 35 (Steptoe 2001). Overall, the studies included participants within the BMI range of 25 to 39.9.

Three trials (Dinger 2007; Johnson 2008; Steptoe 2001) included participants with no co-morbidities and two trials included participants with one or more co-morbidities, such as type 2 diabetes mellitus (Jones 2003), and hypercholesterolaemia (Logue 2005). Three trials reported that included participants were on no medication and the other two trials included participants on a variety of medication, such as psychotropic drugs (Logue 2005), insulin and oral antihyperglycaemic agents (Jones 2003). The majority of participants in the included trials were white or Caucasian, black, Hispanic, Asian and others. Three studies were conducted in the United States of America (Dinger 2007; Johnson 2008; Logue 2005), one in the United Kingdom (Steptoe 2001) and one in Canada (Jones 2003). The included trials' baseline characteristics are stated in Appendix 4

Interventions

The TTM SOC was used in different ways in the trials, as discussed below. Two trials used TTM SOC as an assessment of participants' stage of change and a framework for intervention (Johnson 2008; Logue 2005), whilst two trials used it to assign and assess participant's SOC (Jones 2003; Steptoe 2001). One trial used TTM SOC algorithm to assign participants' SOC for physical activity (Dinger 2007).

In the trials, TTM SOC was used with physical activity or exercise, dietary modification and other interventions. One trial evaluated physical activities (PA) intervention (by using a pedometer and brochure on PA) compared with pedometer only and indicated no weight loss (Dinger 2007). Another trial evaluated dietary modification (by dietary assessment and telephone counselling) plus other interventions (such as information on self-help diabetes care and blood test strips) compared with usual treatment (blood test strips only), and also showed no weight loss (Jones 2003). Similarly, a trial evaluating both diet (via fat intake reduction) and PA counselling sessions (based on number of risk factors) showed no weight loss (Steptoe 2001). Another trial evaluated a combination of PA, diet and other interventions such as stress management strategies (by giving individualized feedback) compared to usual care and showed significant weight loss, particularly at 24 months (Johnson 2008). Finally, a trial involving assessment, advice and 'prescription' of dietary changes and physical activity (alongside anthropometric evaluation) compared to augmented usual care resulted in early weight loss at six months only, but no weight loss at the end of the trial other than decreased waist girth (Logue 2005). The description of interventions for the included trials are shown in Appendix 3

The trials varied in length of intervention (from six weeks to 24 months) and the median length was nine months. Only one trial (Logue 2005) had duration of intervention longer than 12 months, whilst the others were 12 months (Jones 2003), nine months (Johnson 2008), four months (Steptoe 2001) and six weeks (Dinger 2007) respectively. Three trials reported follow up only at the end of intervention (Dinger 2007; Jones 2003; Logue 2005), whilst two trials followed participants up at intervals after intervention (Johnson 2008; Steptoe 2001)

All studies were community-based and the range of settings in which they were conducted included general practices, university campuses and homes. The majority of interventions were delivered by health professionals, including weight loss advisors, dieticians, practice nurses, health educators and counsellors. One trial did not state which personnel conducted the intervention (Johnson 2008).

Outcomes

In this review, the primary outcomes measured are weight loss maintenance (at one year to five years and above) and health-related quality of life. Three trials reported weight loss at 12 months (Jones 2003) and 24 months (Logue 2005; Johnson 2008). The secondary outcomes measured in the included trials are self-reported change in calories intake habit (Jones 2003; Johnson 2008), change in fatty food intake behaviour (Steptoe 2001; Jones 2003), changes in fruits and vegetables consumption (Jones 2003; Johnson 2008), change in physical activity frequency (Steptoe 2001; Dinger 2007; Johnson 2008) and duration (Dinger 2007; Logue 2005), waist girth change (Logue 2005), deaths (Logue 2005; Johnson 2008), progression through SOC (Steptoe 2001; Jones 2003; Dinger 2007; Johnson 2008) and weight gain as an adverse event (Logue 2005).The details of the outcomes are stated in the 'Characteristics of included studies' table and 'Effects of interventions'.

Excluded studies

There were 91 studies excluded in the review and the details are shown in the 'Characteristics of excluded studies' table. The main reasons for excluding those studies were participants included in the studies were either children or adolescents or had a normal body weight (body mass index less or equal to 25); and use of other theoretical frameworks for interventions (such as cognitive behaviour therapy, self-efficacy theory, social action theory and social cognitive theory).

Risk of bias in included studies

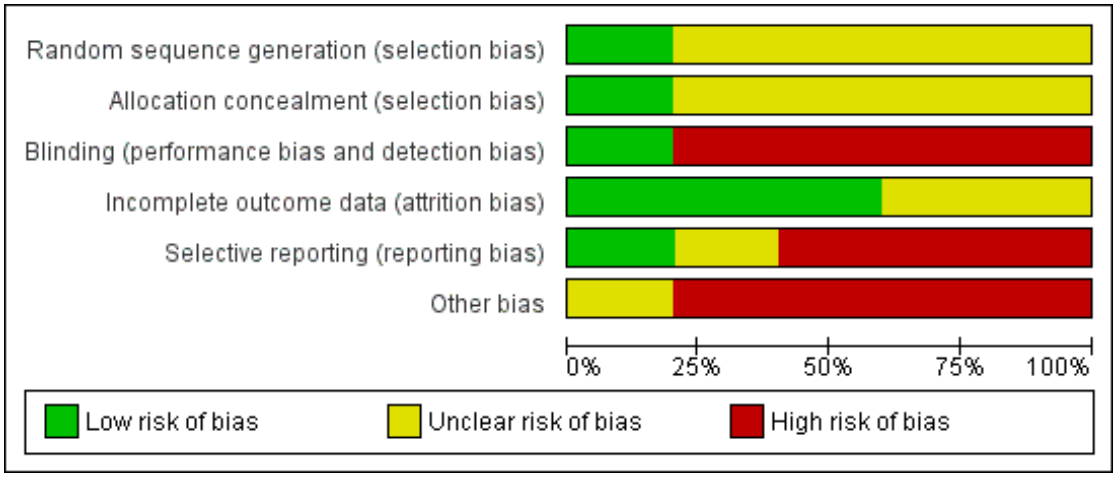
The methodological quality of included studies is described in 'Characteristics of included studies'.

All trials had some methodological weaknesses according to the criteria applied. Just one of the trials reported adequate methods for randomisation, allocation concealment and blinding, and met the reporting outcomes criteria for low risk of bias, whereby the plausible bias within the study was unlikely to seriously alter the results (Logue 2005). Meanwhile, each of the remaining trials had high risk of bias for one or more key domains (Dinger 2007; Jones

2003; Johnson 2008; Steptoe 2001). Therefore, with only one low risk bias trial and four high risk bias trials included in the review, the proportion of information from trials at high risk of bias are sufficient to affect the interpretation of the results across studies. The assessment findings for each domain are explained below, and shown in the 'risk of bias summary' (Figure 2) and 'risk of bias graph' (Figure 3).

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



One trial (20%) reported the method of randomisation (Logue 2005) whilst other trials (80%) stated that participants were randomised and no further explanation was given, thus they were graded 'unclear' for the domain based on the quality criteria (Steptoe 2001; Jones 2003; Dinger 2007; Johnson 2008). The majority of studies were subjected to high risk of bias in their randomisation methods.

Allocation

Only one trial (20%) reported that allocation to groups was concealed (Logue 2005), whilst the rest of the included trials (80%) did not explain how the concealment was done, and were thus graded 'unclear' for the domain based on this criterion (Dinger 2007; Jones 2003; Johnson 2008; Steptoe 2001). Therefore, there was unclear risk of bias in the sampling allocation methods in most of the trials.

Blinding

One trial (20%) explained the blinding methods (Logue 2005), whereas the rest of the included trials (80%) did not explained whether the investigators or the participants were blinded during the study (Dinger 2007; Jones 2003; Johnson 2008; Steptoe 2001). The majority of trials were subjected to high risk of bias (for contamination) due to lack of blinding amongst participants and investigators, however it is not possible to blind them because of the design and nature of the interventions.

Incomplete outcome data

Three trials (60%) addressed the incomplete data for outcomes by reporting exclusions (Dinger 2007) and estimating missing data using multiple imputation (Johnson 2008), whereas one trial explicitly reported the analysis on intention-to-treat (Jones 2003). Two trials (40%) had no adequate information and was graded 'unclear' for the domain (Logue 2005; Steptoe 2001). There was low risk of bias in reporting outcomes data across the included trials.

Selective reporting

One trial (20%) met the quality criteria for outcome reporting, by reporting the pre-specified primary outcomes and all expected outcomes (Steptoe 2001). Meanwhile, one trial (20%) had inadequate information and was graded 'unclear' (Dinger 2007). The majority of trials (60%) had high risk of bias for selective reporting of outcomes (Johnson 2008; Jones 2003; Logue 2005).

Other potential sources of bias

There are other potential sources of bias identified in the included trials for example recall bias in three trials (Johnson 2008; Logue 2005; Steptoe 2001) and commercial source of funding in one trial (Jones 2003).

Effects of interventions

See: **Summary of findings for the main comparison**

Primary outcomes

Weight loss maintenance

TTM SOC application as theoretical framework for dietary, physical activity, monetary rewards and stress management interventions resulted in weight loss in three trials (Jones 2003; Logue 2005; Johnson 2008).

A trial that used TTM SOC with diet and blood testing strips interventions had reported greater weight reduction amongst participants in action stage (individuals are ready to change their behaviour) than in pre-action stage (individuals are not ready to change behaviour) for the intervention (1.4 kg versus 0.7 kg) in the healthy eating group at 12 months. There was a significant weight loss amongst participants in action stage (individuals are ready to change their behaviour) compared to those in pre-action stage (individuals are not ready to change behaviour) for the intervention (1.8 kg versus 0.3 kg, P < 0.01) in both self monitoring blood glucose (SMBG) and healthy eating groups at 12 months. The data for the outcomes measured were not completely reported (such as weight loss values in control groups in healthy eating and both healthy eating and SMBG combined) (Jones 2003). Next, another trial that applied TTM SOC in combination with diet, physical activity and stress management interventions had shown a significant sustainable absolute weight loss in the treatment group; and more than the control group (-2.1 kg, P < 0.05) for both healthy eating and exercise behaviours combined at 24 months. Weight loss of at least 5% of body weight was reported higher amongst participants in the treatment (27.4%) versus control (20.3%) groups with a significant overall effect over time (OR 1.22, 95% CI 10.1 to 1.48, P < 0.05) for healthy eating behaviour at 24 months. Similarly, weight loss of 5% or more was higher in treatment (28.8%) than control (19.4%) groups for exercise behaviour, with increasing differences over time (OR 1.32, 95% CI 0.99 to 1.75, P = 0.05). In both healthy eating and exercise behaviours combined, weight loss of 5% or more was higher amongst participants in treatment (30%) versus control (18.6%) groups at 24 months. The overall group effect for intervention had increased over time (OR 1.35, 95% CI 1.01 to 1.81, P = 0.05,). There were inadequate data given for intervention and control groups pertaining to some of the measured outcomes (for example absolute weight, weight loss of at least 5% and weight loss 5% or more) particularly at 6 and 12 months of the trial (Johnson 2008). TTM SOC used together with diet, physical activity and monetary rewards interventions in a trial reported early (at 6 and 12 months) mean weight loss of 0.5 kg (SE 0.4kg) which was greater in intervention than control groups. The mean weight change was slightly higher in intervention (-0.4 kg (SE 0.4 kg) 95% CI -1.1 to 0.4) versus control groups (-0.2 kg (SE 0.4 kg) 95% CI -1.0 to 0.7) and the weight loss difference was 0.23 kg (95% CI -1 to 0.9, P = 0.50) at 24 months of the trial (Logue 2005).

Meta-analysis for this and the other outcomes was not appropriate primarily because there were different types of outcomes presented (dichotomous and continuous) in the trials. Other reasons were data for intervention and control groups were not completely reported and there were variations in the timing of outcome measurement in the trials. In two trials, weight loss was reported as a dichotomous outcome (Johnson 2008; Jones 2003) and in one trial as continuous outcome (Logue 2005). In the two trials with dichotomous outcomes, the timing of outcome measurement varied; one trial measured weight loss outcome at 12 months (Jones 2003) and the other trial measured it at 6,12 and 24 months (Johnson 2008). In both trials, some data for the outcomes measured in intervention and control groups at 12 months were not reported (such as values for event and no event as well as sample size).

Health-related quality of life

Health-related quality of life is one of the primary outcomes measured in this review but was not reported in all the included trials.

Secondary outcomes

Self-reported change in dietary habit and measured change in dietary habit

TTM SOC combined with diet, physical activity and stress management interventions resulted in significant self reported changes in dietary habit and measures (such as change in daily calorie intake habit, change in daily energy intake and expenditure habits) as reported in three trials (Jones 2003; Logue 2005; Johnson 2008).

Change in daily calories intake habit

A trial using TTM SOC combined with diet and blood testing strips interventions reported lower calories intake from fat amongst participants in the intervention group compared to the control group (35.34% versus 36.1%, P < 0.04) for healthy eating at 12 months (Jones 2003). TTM SOC application in combination with diet, physical activity and stress management interventions in another trial showed more participants progressed to action or maintenance stage in the intervention group versus the control for healthy eating behaviour at 6 (43.9% versus 31.3%), 12 (43.10% versus 35.2%) and 24 months (47.5% versus 34.3%). The overall group effect for all time points was significant (OR 1.61, 95% CI 1.33 to 1.94, P < 0.001). Healthy eating is defined as reducing dietary fat to 30 per cent of calories as well as calorie reduction of 500 calories per day. The term 'progress to action or maintenance stage' refers to individual's readiness to engage in a healthy behaviour (Johnson 2008). TTM SOC combined with diet, physical activity and monetary reward interventions in a trial reported no significant mean change in energy intake per day in the intervention group compare to the control (P = 0.69) at 24 months. There was a significant reduction in the mean energy intake per day for both groups combined (-250kcal/d, P < 0.0001) throughout the 6 to 24 months follow-up. The difference in energy expenditure for intervention group versus the control was not significant (P =

0.31) at 24 months, whereas for both groups combined there was a significant increase in mean energy expenditure per day (~2kcal/kg per day, P = 0.04). The data on energy expenditure at 6, 12 and 18 months were not explicitly reported. The data for the intervention group and the control pertaining to both outcomes (mean energy intake and expenditure) were not given (Logue 2005).

Change in fatty food intake

TTM SOC with diet and physical activity interventions resulted in an increased readiness to reduce fat intake in intervention (67.1%, 95% CI 56.7 to 76.1) compared to control (53.6%, 95% CI 45.8 to 61.3) groups at four months. At 12 months, more participants in the intervention (68.4%, 95% CI 61.1 to 74.8) reduced their fat intake versus control (59.2%, 95% CI 49.2 to 68.6). The strength of association between intervention and the behaviour change was stronger at four months (OR 2.5, 95% CI 1.30 to 3.56) than 12 months (OR 1.26, 95% CI 0.73 to 2.18) (Steptoe 2001). TTM SOC with diet intervention and blood testing strips also showed significant increase among participants taking up healthy eating behaviour (consuming diet with less than 30 percent of fat) in intervention (32.5%) versus control (25.5%) groups (P<0.004) at 12 months (Jones 2003).

Change in fruits and vegetables consumption

Two trials reported significant changes in fruit and vegetable consumption at 6, 12 and 24 months. TTM SOC applied with diet intervention resulted in a significant (P = 0.016) increase in servings of fruit intake per day in intervention (OR 1.89) versus control (OR 1.68) groups; and a significantly (P = 0.011) higher vegetables intake servings for intervention (2.24) compared to control groups (2.06) in the healthy eating intervention at 12 months of the trial. The strength of association between intervention and the outcomes above is stronger for fruit servings intake compared to vegetable servings intake at the end of the trial. There are no data (event, no event and sample size) reported for intervention and control groups of the outcomes measured (Jones 2003). Meanwhile, another trial that used TTM SOC in combination with diet, physical activity and stress management interventions showed greater fruit and vegetable consumption amongst participants in intervention than control groups at 6 (44% versus 31.4%), 12 (45.3% versus 39.6%) and 24 months (48.5% versus 39.0%). Based on the overall group effect, the strength of association between the intervention and outcome was strong at all time points (OR 1.63, 95% CI 1.34 to 1.97, P < 0.0001). There are no data (no event occurred and sample size) reported for intervention and control groups of the outcomes measured (Johnson 2008).

Self-reported uptake in physical activity and measured change in physical activity

There were four trials (Steptoe 2001; Logue 2005; Dinger 2007; Johnson 2008) reporting significant self-reported uptake and measured changes in physical activity using TTM SOC in combination with diet, physical activity, smoking and stress managements interventions at six weeks, 4, 9 and 24 months. The outcomes reported were mainly changes in physical activity frequency (e.g. total steps and per day) and duration (e.g. total minutes and per week), whereas types and intensity were not reported by the given trials.

Change in physical activity frequency

A trial applying TTM SOC combined with diet and physical activity interventions showed increased readiness to exercise amongst participants in intervention group (32.2%, 95% CI 23.7 to 42.0) versus the control (23.9%, 95% CI 17.8 to 31.2) at four months and similarly for intervention group (30.6%, 95% CI 21.8 to 41.2) versus the control (28.9%, 95% CI 24.0 to 34.3) at 12 months. The strength of association between intervention and outcome measured (increase readiness to exercise) was strong at four months (OR 1.89, 95% CI 1.07 to 3.56) as well as at 12 months (OR 1.68, 95% CI 1.08 to 2.61) of the trial. The outcome measured data for intervention and control groups were not fully reported (such as for event, no event and sample size) (Steptoe 2001). TTM SOC in combination of diet, physical activity and stress management interventions in another trial showed an increase in exercise habit amongst participants in intervention compare to control groups at 6 (43% versus 34.6%), 12 (37.7% versus 35.9%) and 24 months (44.9% versus 38.1%). The group effect showed strong association between intervention and outcome measured at baseline and 6 months which were maintained at all time points (OR 1.63, 95% CI 1.34 to 1.97, P < 0.0001). There were incomplete data (the proportions of no event and sample size) stated for intervention and control groups (Johnson 2008). Another trial using TTM SOC in combination with physical activity intervention alone showed a significant increased in the total daily steps from ,419 (SE 2386) in week one to 7984 (SE 2742) in week six (P < 0.001) for both intervention and control groups combined (Dinger 2007).

Change in physical activity duration

TTM SOC used in combination with physical activity intervention only in one trial showed a significant increase in weekly time spent walking (P = 0.002) for both intervention and control groups combined at six weeks (Dinger 2007). In another trial, TTM SOC combined with diet, physical activity and monetary reward interventions resulted in a significant increase in the mean of self-reported exercise minutes per week in intervention versus control groups (P = 0.008) from 6 to 24 months; the mean difference between both groups was 31.5 minutes (SE 12 minutes) (Logue 2005).

Meta-analysis can not be done primarily because of different timing of outcomes measurement and variation in the measurement scales used in each respective trial. The first trial measured outcome at 6 weeks only and used median scores (Dinger 2007). Whilst, the second trial measured the outcome at 6, 12, 18 and 24 months and expressed it as mean values (change in exercise minutes per week) as well as mean difference (Logue 2005).

Change in weight loss measures

TTM SOC combined with diet, physical activity and monetary rewards interventions in a trial reported no significant mean waist girth change in intervention compared to control groups (P = 0.57); however the effects for both groups combined showed a significant decrease in mean waist girth (1.7cm (SE 0.4cm), P = 0.0001) at 24 months (Logue 2005).

Progression through SOC

There were four trials included that reported progression through SOC as an outcome measured in the studies. The term 'progress to action stage' refers to individuals who have changed behaviour within the last 6 months, whereas 'maintenance stage' refers to individuals who have maintained the behaviour change for at least six months. In a trial applying TTM SOC combined with diet and physical activity interventions reported the odds amongst participants moving to action or maintenance stage in the intervention group versus the control for fat reduction behaviour was 2.15 (95% CI 1.30 to 3.56) at 4 months, and 1.26 (95% CI 0.73 to 2.18) at 12 months. For physical activity, the odds amongst participants progressing to action or maintenance stage in intervention group compare to the control at four months was 1.89 (95% CI 1.07 to 3.36), and 1.68 (95% CI 1.08 to 2.61) at 12 months. The data pertaining to intervention and control groups were not completely reported (Steptoe 2001). Another trial using TTM SOC in combination with diet and blood testing strip interventions reported that more participants in intervention group (43.4% for 'pathway to change' plus strips and 27% for treatment as usual plus strips) progressed to action stage in comparison to control group (30.5% for 'pathway to change' alone and 18.4%% for treatment as usual plus strips) at 12 months in self monitoring blood glucose intervention (P < 0.001). Similarly, there was greater proportion of participants moved to action or maintenance in intervention (32.5%) versus control (25.8%) groups for healthy eating behaviour (P < 0.001). The data for the outcomes measured in the intervention group and the control were not completely given (specifically sample size and proportions of no event) (Jones 2003). TTM SOC applied with physical activity intervention only in a trial showed participants moved forward at least one stage (53.6%, P < 0.001), regressed one stage (5.4%) and maintained at their existing stage (41.1%) both in intervention and control groups combined at 6 weeks. The outcome data were not distinctively reported for intervention and control groups (such as date of event and no event as well as sample size) (Dinger 2007). Meanwhile, TTM SOC used in combination with diet, physical activity and stress management interventions in another trial showed that a greater proportions of participants progressed to action or maintenance stage (individual's readiness to engage in healthy behaviour) in the intervention group than the control for healthy eating outcome at 6 (43.9% versus 31.3%), 12 (43.10% versus 35.2%) and 24 months (47.5% versus 34.3%) of the trial. The overall group effect for all time points showed a strong association between the intervention and measured outcome (OR 1.61, 95% CI 1.33 to 1.94, P < 0.001). For exercise outcomes, more participants in the intervention group compared to the control moved to action or maintenance stage at 6 (43% versus 34.6%), 12 (37.7% versus 35.9%) and 24 months (44.9% versus 38.1%). There was a significant group effect at baseline and six months that was maintained at all time points (OR 1.27, 95% CI 1.03 to 1.57, P < 0.05). In the fruit and vegetable outcome, many participants in the intervention group moved to action or maintenance stage in comparison to the control at 6 (44% versus 31.4%), 12 (45.3% versus 39.6%) and 24 months (48.5% versus 39.0%). Based on the overall group effect, the strength of association between the intervention and outcome was strong at all time points (OR 1.63, 95% CI 1.34 to 1.97, P < 0.0001). The data of outcome measured were not adequately reported for intervention and control groups (specifically values for no event and sample size) (Johnson 2008).

Adverse events

Morbidity

Morbidity as an adverse event outcome was not reported by the included trials.

Death from any cause

Death as an adverse event was reported in two included trials; three patients died in one trial (Logue 2005) and there was only one death in the other trial (Johnson 2008) during follow up. The reported deaths were declared not related to the trials.

Weight gain

There was a significant weight gain for both intervention and control groups combined after 12 months in a trial (P < 0.0001), but there were no other data reported on the given outcome measured (Logue 2005).

Costs

None of the included trials reported cost as an outcome.

Reporting bias

In this review, it was not possible to assess reporting bias using funnel plots because there were only five trials included (that might affect the power of the tests to distinguish chance) and furthermore the types of outcomes varied and the estimate effect measures used in each trial differed.

DISCUSSION

Summary of main results

Relatively few trials were identified that met the criteria for the review and most were relatively recent (published in the last 10 years). The trials were heterogeneous, particularly in terms of interventions and outcomes and had small to medium sample sizes, with 3910 participants evaluated in total. They were conducted in community settings, were mainly delivered by health professionals and had short to medium term follow up (one year or less). Body mass index (BMI) was the most common body weight measure used in the trials.

The key finding of the review was that the transtheoretical model (TTM) stages of change (SOC) had limited impact on weight loss and that the weight loss that did occur was not shown to be sustainable. TTM SOC with a combination of physical activities (PA), diet and other interventions (such as feedback reports, anthropometric measurements and counselling) was shown to produce significant effects on other outcome measures, particularly change in PA, change in dietary intake and progression through the SOC process. TTM SOC was used in all studies but investigator's use of the framework varies. The included trials were mainly performed on an intention-to-treat basis. The majority of the trials can be categorised as high-risk bias trials due to inadequate information on methods of randomization, intervention concealment and blinding. Other potential sources of bias were also identified, such recall bias.

Overall completeness and applicability of evidence

Relevance of the evidence

Evidently, TTM SOC is a useful theoretical and pragmatic intervention framework for some aspects of lifestyle modification in overweight and obese individuals. This review demonstrated that TTM SOC and a combination of PA, diet and other interventions resulted in minimal weight loss, and there was no conclusive evidence for sustainable weight loss particularly after 12 months. However, TTM SOC combined with diet, PA and other interventions had a positive impact on fruit and vegetable consumption as well as increased exercise outcomes behaviour that were sustainable over longer periods (12 to 24 months). There were limited association measures between TTM SOC and outcomes reported by the included trials.

The application of TTM was also analysed in the review and an important finding was that TTM SOC was used inconsistently as a theoretical framework for intervention across the included trials, which may impact on outcomes. TTM SOC was used in three different ways (as an assessment tool and framework for intervention; as an assessment and assignment tool only; and in algorithm form to assign participants' SOC for intervention). Trials that used TTM SOC as an assessment and intervention framework, rather than just as a tool to assign and assess stage of change, reported minimal weight loss. Other key characteristics of those trials were longer duration of intervention (9 to 24 months) and follow up (12 to 24 months) as well as using TTM SOC in combination with PA, diet and other interventions. Therefore, the way in which TTM SOC was applied in each trial may have had a critical impact on the outcomes measures.

External validity

In general, the findings of the review are generalizable to overweight and obese adults who are undergoing lifestyle modification programmes for weight loss, specifically programmes which are based on TTM SOC in community settings. However, two trials recruited from selected populations (university students and people with diabetes respectively) which might affect their generalizability to other settings (Dinger 2007; Jones 2003). There were no significant differences in outcome for participants with or without co-morbidities in the included trials. The included trials were conducted in various countries which may increase the generalizability of the findings to other international settings.

Relevance to review's objectives

The included studies contain sufficient information to examine the effectiveness of dietary and physical activity interventions based on TTM SOC for weight loss in overweight and obese adults. However, the review may benefit from studies with longer durations of intervention and follow up to assess the sustainability of the weight loss, particularly beyond two years. The relevant points in the inclusion criteria were investigated and presented in the results, including additional and adverse outcomes, a summary of outcomes and potential bias.

Relevance to current practice

Obesity is one of the world's fastest growing health threats, and commissioning and developing obesity management programmes is a priority for policy makers and health system administrators in

health systems across the world. This review can be used to better inform the planning, implementation and evaluation of such programmes. The review also informs practitioners on existing evidence and expected outcomes (such as weight loss, change in physical activity and dietary intake) when using TTM SOC weight management programmes. Finally, it can also serve to inform and enhance patients' understanding of the effectiveness and limitations of their treatment regimes.

In practice, TTM SOC must be applied with caution because it has a variable impact depending on how it is used and with what other factors (in particular whether it is used in combination with other strategies for example diet and PA; and also the duration of intervention and follow up).

Quality of the evidence

Five small to medium randomised controlled trials (including a total of 3910 participants) were evaluated in this systematic review, using a set of inclusion and exclusion criteria. Meta-analysis was not appropriate because there were different types of outcomes presented in the trials (dichotomous versus continuous) and the data for intervention group as well as control group for each outcome were not completely reported by each trial. There were also variations in the timing of outcome measurement in the included trials.

One of the key methodological limitations of the trials was that most had limited intervention and follow-up duration (one year or less) and it was therefore not possible to assess sustainable weight loss amongst participants. There was also inadequate information on methods of randomization, allocation concealment and blinding reported by most trials, such that they had to be categorised as high-risk bias trials. Other potential sources of bias were identified for example recall bias. The trials were mainly performed on the intention-to-treat basis but there were key bias issues affecting the internal validity of the results as discussed earlier.

Potential biases in the review process

The ways in which potential biases in the review process were minimised included: well defined inclusion and exclusion criteria; independent data extraction by two assessors; use of assessment risk of bias tool (Higgins 2009); and application of effects of intervention tool (to examine and compare outcomes for intervention and control groups). The major limitations were that only a small number of studies met the inclusion criteria and the majority of these had short to medium term intervention and follow up duration (one year and less) which may affect outcome. Also, some trials with dichotomous outcomes that had potential for meta-analysis did not completely reported their data as shown in ' Appendix 7' and the authors were not contactable. It was not possible to assess reporting bias using funnel plots primarily because the types of outcomes and the estimate effect measures used in each trial were different. The above limitations may have introduced bias to the review indirectly.

Agreements and disagreements with other studies or reviews

The key finding that TTM SOC in combination with PA, diet and other interventions had limited impact on weight loss (about 2 kg or less) differs from other studies which reported greater weight loss, although these did not look specifically at TTM SOC as a theoretical framework. A large systematic review of dietary and lifestyle therapy interventions showed weight loss up to 5 kg after 2 to 4 years amongst overweight and obese individuals (Douketis 2006). Meanwhile, a systematic clinical review found moderate weight loss (about 3 to 5 kg) for dietary and exercise interventions amongst obese adults compared with usual care (Jain 2005). Another large systematic review argued that exercise combined with diet resulted in a greater weight reduction than diet alone or PA alone (mean difference (MD) -1.0 kg) (Shaw 2006), which tends to support the findings of this review.

Several studies supported the finding that there was no conclusive evidence for sustainable weight loss particularly after 12 months, and that the effectiveness of TTM SOC for weight loss beyond this time was inconsistent (Curry 1992; Greene 1999; Johnson 2006; Prochaska 2008b; Vallis 2003; Wee 2005).

In this review, TTM SOC combined with diet, PA and other interventions had a positive impact on fruit and vegetable consumption as well as increased exercise outcomes behaviour that were sustainable over long periods (12 to 24 months). However, an earlier review done on TTM SOC application and diet intervention did not find conclusive evidence particularly on dietary change amongst overweight and obese adults. The review argued that most included studies differed in terms of the aspect of diet being examined, staging algorithms and dietary assessment methodology used. Therefore, there were significant variations in results which made it difficult to interpret the results of those studies (Ni Mhurchu 1997). The studies included in the review were not specifically randomised controlled trials and the lack of trials done at that time, as well as a less robust review methodology, may have affected the results.

The review also analysed the use of TTM SOC and supported our findings that it is used inconsistently as a theoretical framework for intervention across included trials. It was used in the three typical ways stated above and should therefore be applied with caution in practice because its impact depends on both the way it is used and other factors. The finding was supported by another study which highlighted the insensitivity of the TTM algorithm, with most individuals failing to meet the behavioural criteria of the model stages (Greene 1994).

AUTHORS' CONCLUSIONS

Implications for practice

The transtheoretical model (TTM) stages of change (SOC) is widely used as an intervention framework in weight management programmes across clinical and community settings. This review provides evidence on the use of the TTM SOC as a theoretical framework for dietary and physical activity interventions in weight loss management for overweight and obese adults. TTM SOC and a combination of physical activities (PA), diet and other interventions (such as feedback reports, anthropometric measurements and counseling) have limited impact on weight loss (about 2 kg or less). There was no conclusive evidence for sustainable weight loss. The impact of TTM SOC as theoretical framework in weight loss management may depend on how it is used as a framework for intervention and in combination with other strategies like diet and PA. Nevertheless, health managers, administrators and practitioners can use evidence from this review to plan, implement and evaluate weight management programmes. For patients, the review may enhance their understanding of the effectiveness and limitations of their treatment regimes. Overall, the review may help to improve knowledge, understanding and practice in tackling the important global health challenge of obesity.

Implications for research

This review applied rigorous and systematic methodology to assess numerous relevant studies and has identified findings that have important implications for future research. Only five RCTs with short to medium duration of intervention and follow-up were included in the review and this may have affected the strength of the evidence. The included trials may have shown different outcomes, particularly on sustainable weight loss, if they had longer durations of intervention (one year and above) and follow-up (beyond two years). Also, some of the trials had small sample sizes and statistical power was therefore inadequate to detect any significant association between intervention and outcome. In addition, the trials were heterogeneous specifically in terms of interventions and outcomes. It is vital that trials report clear, specific definitions for their intervention; and primary and secondary outcome measures to minimize the issue of heterogeneity and enable the conduction of meta-analysis, if appropriate. Some of the trials provided inadequate information on methods of randomisation, allocation concealment and blinding which affected the methodological quality of the studies (particularly the internal validity). Hence, using a protocol in conducting and reporting research may reduce potential biases and enhance the quality of the study.

Future research must focus on well-designed RCTs, preferably with large sample sizes and long durations of intervention and follow-up to evaluate effectiveness of TTM SOC for sustainable weight loss in overweight and obese adults. Trials can examine the application of TTM SOC in three distinct ways (as an assessment tool and framework for intervention; as an assessment and assignment tool only; and in algorithm form to assign participants' SOC for intervention) and then measure its effectiveness. Although TTM SOC in combination with diet and PA had positive effects on weight loss and other outcomes, trials may need to formulate specific and objective outcome measures for diet and PA so that appropriate statistical analysis can be conducted to measure their independent impact on weight loss. Finally, a robust systematic review of non-RCTs to assess the effectiveness of TTM SOC for sustainable weight loss in overweight and obese adults may be of value in the near future.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Dinger 2007

Methods	**PARALLEL RANDOMISED CONTROLLED CLINICAL TRIAL**
Participants	**INCLUSION CRITERIA**: adult (25-54years), female only, Obese (BMI >30), no-co-morbidities & other criteria (not full time college students, <150mins/week of moderate-intensity Physical activities (PA) & <60mins/week of vigorous PA, not pregnant, answered 'no' to PA readiness questionnaire items) **EXCLUSION CRITERIA**: not stated TOTAL N=56, INTERVENTION N=32, CONTROL N= 24 **DIAGNOSTIC CRITERIA**: Height and weight measured at assessment, BMI measured & others (PA Questionnaire, Transtheoretical model (TTM) stages of change (S Questionnaire, Decisional Balance Questionnaire, Self-efficacy Questionnaire) **CO-MORBIDITIES**: not stated **CO-MEDICATIONS**: not stated
Interventions	**NUMBER OF STUDY CENTRES**: 1 **COUNTRY/ LOCATION**: USA **SETTING**: delivered by health care professionals at community and university (via email) **INTERVENTION**: use TTM SOC as algorithm to assign participant's SOC for PA, PA (pedometer, daily log, brochures, weekly email reminders) **CONTROL**: pedometer and weekly email reminders **TREATMENT BEFORE STUDY**: not stated
Outcomes	**OUTCOME(S)** (as stated in the protocol/registered trial documents): **PRIMARY OUTCOME(S)**: no weight loss stated **SECONDARY OUTCOMES**: increased weekly time spent walking (P = 0.002) in both groups; increased in daily steps from 6,419 steps SE 2386 steps (week1) to 7984 steps SE 2742 steps (P < 0.001) in intervention & control groups combined **ADDITIONAL OUTCOMES**: move to one TTM stage (53.6%), regressed one stage (5.4%) and maintained at same stage (41.1%); progression to at least one TTM stage (P < 0.001) for intervention & control groups combined
Notes	Key findings: email delivered, pedometer-based interventions may increase walking and most TTM scores among insufficiently active women

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "Participants were randomly assigned" Comment: No other details given

Dinger 2007 (*Continued*)

Allocation concealment (selection bias)	Unclear risk	Comment: Method of concealment is not described
Blinding (performance bias and detection bias) All outcomes	High risk	Comment: No information is given
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "18 were excluded from analysis because they dropped out (n = 13), had missing data (n = 3), or had extreme values (n = 2). Baseline characteristics did not differ between participants dropped from analysis and those included (P > 0.05, n=56)."
Selective reporting (reporting bias)	Unclear risk	Comment: The study protocol is available but the primary and secondary outcomes are not pre-specified
Other bias	Unclear risk	Comment: No other details given to assess whether an important risk of bias exists

Johnson 2008

Methods	**PARALLEL RANDOMISED CONTROLLED CLINICAL TRIAL**
Participants	**INCLUSION CRITERIA**: adults (18-75 years), male and female, overweight & obese (BMI 25-39.9) **EXCLUSION CRITERIA**: age (under 18 or over 75), BMI below 25 or above 39.9 & other criteria (heart attack in previous three months, angioplasty in previous three months, heart failure, surgery in previous three months, eating disorder, cancer, pregnant or nursing, participation in formal or commercial weight management program, not in a pre-action stage for healthy eating and/or exercise) TOTAL N=1277, INTERVENTION N=628, CONTROL N= 649 **DIAGNOSTIC CRITERIA**: BMI measured and other criteria (SOC for exercise, healthy eating and managing emotional distress) **CO-MORBIDITIES**: not stated **CO-MEDICATIONS**: not stated
Interventions	**NUMBER OF STUDY CENTRES**: nationwide **COUNTRY/ LOCATION**: USA **SETTING**: personnel not stated, home based (using telephone and mail) INTERVENTION: use TTM SOC as assessment and feedback construct for diet (healthy eating - reducing dietary fat to 30% of calories & calories reduction of 500 calories per day), PA (moderate exercise - at least 30 min on 5 days per week) and managing emotional stress without eating (using healthy strategies rather than eating to cope), 4 series of individual reports at baseline, 3, 6, & 9 months) **CONTROL**: usual care (no details stated) **TREATMENT BEFORE STUDY**: not stated

Outcomes	**OUTCOME(S)** (as stated in the protocol/registered trial documents): **PRIMARY OUTCOME(S)**: In healthy eating + exercise groups - self-reported absolute weight loss in intervention group was more than control group (t1614, 2.12kg, P < 0. 05, df 0.17) at 24 months In healthy eating group - weight lost of at least 5% of body weight was higher in intervention (27.4%) versus control (20.3%) (t11119=2.07, P < 0.05, OR 1.22, 95% CI 10.1 to 1.48) at 24 months. In exercise behaviour - weight lost 5% or more was high in intervention (28.8%) than control (19.4%) (t1711=1.96, P = 0.05, OR 1.32, 95% CI 0.99 to 1.75) at 24 months In both healthy eating + exercise behaviours - weight lost 5% or more was higher amongst participants in intervention (30%) versus control (18.6%) groups at 24 months (t1615= 2.05, P < 0.05, OR 1.35, 95% CI 1.01 to 1.81) **SECONDARY OUTCOMES**: In healthy eating behaviour - more participants progressed to action or maintenance stage in intervention group versus control at 6 (43.9% versus 31.3%), 12 (43.10% versus 35.2%) and 24 months (47.5% versus 34.3%). The overall group effect for all time points (t11119=5.02, P < 0.001, OR 1.61, 95% CI 1. 33 to 1.94) In fruit and vegetable consumption behaviour - greater fruit and vegetable consumption amongst participants in intervention group than control group at 6 (44% versus 31.4%) , 12(45.3% versus 39.6%) and 24 months (48.5% versus 39.0%). The overall group effect at all time points (t1856=5.01, P < 0.0001, OR 1.63, 95% CI 1.34 to 1.97) **ADDITIONAL OUTCOMES**: management of emotional distress was higher in intervention group compared with control group at 6 (44% vs. 25.3%), 12 (45% vs. 38.3%) , and 24 months (49.7% vs. 30.3%)
Notes	Key findings: This study demonstrates the ability of TTM-based tailored feedback to improve healthy eating, exercise, managing emotional distress, and weight on a population basis and underscores the potential synergistic effects of multiple behavior interventions

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Overweight or obese adults were randomised to no-treatment control or home-based" Comment: No other details given
Allocation concealment (selection bias)	Unclear risk	Comment: Method of concealment is not described
Blinding (performance bias and detection bias) All outcomes	High risk	Comment: No information on blinding method is given
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Multiple imputation was used to estimate missing data for the 6, 12, and 24 months assessments"

Johnson 2008 (*Continued*)

Selective reporting (reporting bias)	High risk	Comment: The study protocol was not available and some outcomes data were not completely reported
Other bias	High risk	Comment: Self-reported information gathering amongst participants may have subjected the trial to recall bias

Jones 2003

Methods	**FACTORIAL RANDOMISED CONTROLLED CLINICAL TRIAL**
Participants	**INCLUSION CRITERIA**: adult (age not reported), male and female, BMI more than 27 & other criteria (enrolled in healthy eating intervention, in pre-action stage for health - diet more than 30% fat) **EXCLUSION CRITERIA**: not stated & others (on diet therapy alone, if could not respond to English, if required more than usual care, no telephone) TOTAL N=1029, INTERVENTION N=510, CONTROL N= 519 **DIAGNOSTIC CRITERIA**: BMI, Dietary intake using food frequency questionnaire & others (blood glucose meter, SOC algorithms, venous blood sample) **CO-MORBIDITIES**: T1 & T2 diabetes **CO-MEDICATIONS**: insulin or oral antihyperglycaemic
Interventions	**NUMBER OF STUDY CENTRES**: general diabetes population **COUNTRY/ LOCATION**: Southern Ontario, Nova Scotia (Canada) **SETTING**: delivered by investigators and health care professionals (counsellors, family physicians), using mail and telephone call **INTERVENTION**: 1) Pathway to change (PTC): Use of TTM SOC to assign and assess stage of change (staged matched PTC, assess at baseline, 3, 6, 9 & 12 months), self-help manuals for diabetes, monthly newsletters & telephone counselling, staged-based personalized assessment report quarterly, Diet (assessment of intake). 2) PTC + blood test strips **CONTROL**: 1) Usual diabetes treatment (regular family physician visits, diabetes education sessions as prescribed). 2) Usual diabetes treatment + blood test strips **TREATMENT BEFORE STUDY**: non
Outcomes	**OUTCOME(S)** (as stated in the protocol/registered trial documents): **PRIMARY OUTCOME(S)**: in SMBG + healthy eating groups - significant weight loss in action stage (individuals are ready to change their behaviour) versus pre-action stage (individuals are not ready to change behaviour) for PTC (1.78kg vs 0.26kg, P < 0.01) at 12 months. No information given for usual diabetes treatment **SECONDARY OUTCOMES**: In healthy eating group - lower calories from fat for PTC versus usual diabetes treatment (35.34% versus 36.1%, P<0.004) at 12 months; significant increased among participants taking up healthy eating behaviour (consuming diet with less than 30 percent of fat) in group (32.5%) versus C (25.5%) group (P<0.004) at 12 months; significant increased servings of fruit per day for PTC vs usual diabetes treatment (OR 1.89 vs OR 1.68, P<0.01); and higher vegetables servings for PTC vs usual diabetes treatment (OR 2.24 vs OR 2.06, P<0.011)

	ADDITIONAL OUTCOMES: In SMBG - more participants progressed to action stage in intervention groups (PTC + blood test strips= 43.4%, usual diabetes treatment + blood test strips= 27%) vs control groups (PTC= 30.5%, treatment as usual= 18.4%) (P < 0.001) at 12 months In healthy eating behaviour - greater proportion of participants moved to action or maintenance in PTC group (32.5%) vs usual diabetes treatment (25.8%) group (P < 0. 001) at 12 months
Notes	Key findings:PTC intervention is significantly better than TAU in helping individuals move into action stages of critical diabetes self-care behaviour. It also was successful at helping more people engage in SMBG, make healthy low-fat food choices and stop smoking SMBG: self monitoring blood glucose

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote:"Participants were stratified according to whether or not they took insulin or oral agents alone and were then randomised into treatment or strips conditions" Comment: No detail is given on the method
Allocation concealment (selection bias)	Unclear risk	Comment: Method of concealment is not described
Blinding (performance bias and detection bias) All outcomes	High risk	Comment: The study did not give information on blinding method
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Participants who did not complete the entire 12 months of the study did not have different baseline demographic characteristics from those who did complete the study...based on intention-to-treat (ITT) analysis"
Selective reporting (reporting bias)	High risk	Comment: The primary outcome data were not completely reported
Other bias	High risk	Quote: "Successful results of this project may lead to the development of products by LifeScan, which may result in royalties to contributing authors and developers of such products, as well as their employers, the University of Rhode Island" Comment: The commercial source of

		funding of the study may contribute to risk of bias

Logue 2005

Methods	**PARALLEL RANDOMISED CONTROLLED CLINICAL TRIAL**
Participants	**INCLUSION CRITERIA**: adult (40-69 yrs), male and female, BMI> 27, Waist-to-hip ratio >0.95 for men or >0.80 for women **EXCLUSION CRITERIA**: age & BMI not stated & other criteria (no access to a telephone, difficulty understanding eighth-grade level spoken or written English, pregnancy, lactation, <6 months postpartum, use of a wheel chair for mobility, severe heart or lung disease) TOTAL N=665, INTERVENTION N=329, CONTROL N= 336 **DIAGNOSTIC CRITERIA**: BMI, Waist girths and other criteria (blood lipids, BP, Daily energy intake & total energy expenditure, PRIME-MD for depression, anxiety, and binge eating disorder) **CO-MORBIDITIES**: Hypertension, hypercholesterolaemia, osteoarthritis, stomach problems, diabetes **CO-MEDICATIONS**: psychotropic medication
Interventions	**NUMBER OF STUDY CENTRES**:15 primary care practices **COUNTRY/ LOCATION**: Ohio, USA **SETTING**: delivered by weight loss advisor and dietician. Telephone-based **INTERVENTION**: TTM SOC used as framework for intervention and assessment. TM-CD: Psychosocial evaluation (anxiety, depression and binge eating disorder) 6 monthly; SOC assessment for five target behaviours (increased exercise, increased usual activity, increased dietary portion control, decreased dietary fat and increased fruits and vegetables) every 2 months; assessment on anthropometric, dietary & exercise 6 monthly; 10min counselling on diet; prescriptions (dietary & exercise); monetary reward for completing each post baseline assessment **CONTROL**: Augmented usual care; assessment on anthropometric; dietary & exercise 6 monthly; 10min counselling on diet; prescriptions (dietary & exercise); monetary reward for completing each post baseline assessment **TREATMENT BEFORE STUDY**: none
Outcomes	**OUTCOME(S)** (as stated in the protocol/registered trial documents): **PRIMARY OUTCOME(S)**: Early mean weight loss greater in I group 0.5kg (SE=0. 4kg) vs C group at 6 and 12 months; higher mean weight loss in I group (-0.39kg, SE 0.38kg, 95% CI -1.1 to 0.4) vs C group (-0.16kg, SE 0.42kg, 95% CI -1.0 to 0.7) and weight loss difference was 0.23kg (P = 0.50, 95% CI -1.4 to 0.9); weight mean change for I group and C group combined was -0.29kg (95% CI -0.9 to 0.3) at 24 months; no significant mean waist girth change for I group vs C group; decreased in mean waist girth for I group and C group combined (1.7cm SE 0.4 cm, P = 0.0001) at 24 months; weight gain in I and C groups combined was significant (P < 0.0001) after 12 months (adverse event) **SECONDARY OUTCOMES**: no significant mean energy intake per day in I group compared to C group (P = 0.69) at 24 months; a significant reduction in the mean of energy intake per day for I and C groups combined (-250kcal/d, P < 0.0001) throughout

Logue 2005 (*Continued*)

	the 6 to 24 months; mean energy expenditure for I group compared to C group not significant (P = 0.31); energy expenditure mean increased (-2kcal/kg per day, P = 0.04) for I and C groups combined at 24 months; significant increased in the mean of self-reported exercise minutes per week in I versus C groups (P = 0.008) from 6 to 24 months and the mean difference between I and C groups was 31.5 minutes (SE 12 minutes) **ADDITIONAL OUTCOMES**: Mean blood lipid showed no difference. Mean blood pressure showed no difference
Notes	Key findings:A combination of mailed patient materials and monthly telephone calls based on the TTM and some elements of chronic disease care is not powerful enough, relative to augmented usual care, to alter target behaviours among overweight primary care patients in an obesogenic environment

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "The Office of Biostatistics prepared the ordered randomization tickets using permuted blocks of 10"
Allocation concealment (selection bias)	Low risk	Quote: "Participants were randomised by opening an envelope with a set of ordered tickets indicating "TM-CD" or "Traditional" care. A separate randomization sequence was used for each primary care practice site"
Blinding (performance bias and detection bias) All outcomes	Low risk	Quote: "Participants and research staff at each practice were blind to the assignment of patients while obtaining baseline measures, because assignment envelopes were not opened until the end of the visit"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "The majority of missing values occurred because participants declined further participation when an effort was made to schedule a follow-up appointment. 3 patients died during follow-up"
Selective reporting (reporting bias)	High risk	Comment: The study protocol was not available and some outcomes data was not completely reported
Other bias	High risk	Comment: Self-reported information gathering amongst participants may have subjected the trial to recall bias

Steptoe 2001

Methods	**PARALLEL RANDOMISED CONTROLLED CLINICAL TRIAL**
Participants	**INCLUSION CRITERIA**: adult (age not reported), male and female, Obese (BMI 25-35) & other criteria (have risk factors - cigarette smoking more than 1 cigarette per day, high cholesterol (6.5-9.0 mmol/L or combination of high BMI, physical activity <12 episodes in the past 4 weeks of vigorous or moderate exercise lasting 20 minutes) **EXCLUSION CRITERIA**: age & BMI not stated & other criteria (on active medical follow-up, on medication for coronary heart diseases, history of cardiovascular diseases, serious chronic illness, prescribed a special diet or lipid lowering drugs) TOTAL N=883, INTERVENTION N=316, CONTROL N= 567 **DIAGNOSTIC CRITERIA**: BMI not stated and other criteria (smoking - cotinine verified, dietary assessment, physical activity assessment - no. of episodes of activity in the past 4 weeks) **CO-MORBIDITIES**: not stated **CO-MEDICATIONS**: not stated
Interventions	**NUMBER OF STUDY CENTRES**: 20 General practices **COUNTRY/ LOCATION**: United Kingdom **SETTING**: delivered by practice nurse and health educators. GP surgery setting **INTERVENTION**: TTM SOC used as algorithms to assign and assess participant's (reducing dietary fat intake, stop smoking & increase PA). Behavioural lifestyle counselling; baseline assessment of soc; counselling (fat intake reduction, physical activity) based on no. of risk factors (2 given 3 counselling sessions & 1 given 2 counselling sessions) after 4 months and 12 months **CONTROL**: Usual health promotion; education on healthy life style, encouragement and advice **TREATMENT BEFORE STUDY**: none
Outcomes	**OUTCOME(S)** (as stated in the protocol/registered trial documents): **PRIMARY OUTCOME(S)**: not weight loss stated **SECONDARY OUTCOMES**: Increased readiness to reduce fat intake in I (67.1%, 95% CI=56.7,76.1) vs C (53.6%, 95% CI=45.8,61.3) groups at 4 months (OR 2.15, 95% CI 1.30 to 3.56); and at 12 months in I group (68.4%, 95% CI 61.1 to 74.8) vs in C group (59.2%, 95% CI 49.2 to 68.6) (OR 1.26, 95% CI 0.73 to 2.18) Increased readiness to exercise in I group (32.2%, 95% CI 23.7 to 42.0) vs C group (23.9%, 95% CI 17.8 to 31.2) at 4 months (OR 2.5, 95% CI 1.30 to 3.56); and at 12 months in I group (30.6%, 95% CI 21.8 to 41.2) vs C group (28.9%, 95% CI 24.0 to 34.3) (OR 1.68, 95% CI 1.08 to 2.61) **ADDITIONAL OUTCOMES**: For fat reduction behaviour, progression to action or maintenance stage in I group vs C was OR 2.15 (95% CI 1.30 to 3.56) at 4 months, and OR 1.26 (95% CI 0.73 to 2.18) at 12 months. For physical activity, progression to action or maintenance stage in I group vs C group was OR 1.89 (95% CI 1.07 to 3.36) at 4 months, and OR 1.68 (95% CI 1.08 to 2.61) at 12 months. For smoking cessation, progression to action/maintenance stage in I vs C was OR 1.77 (95% CI 0.76 to 4.14) at 4 months, OR 1.49 (95% CI 0.56 to 4.00) at 12 months
Notes	Key findings:Brief behavioural counselling based on advice matched to stages of readiness for change may be valuable in encouraging healthy lifestyles among patients in primary care at raised risk of cardiovascular disease

Steptoe 2001 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "Twenty general practices were randomised to lifestyle counselling by behavioural methods or to causal health promotion" Comment: No other detail is given
Allocation concealment (selection bias)	Unclear risk	Comment: Method of concealment is not described
Blinding (performance bias and detection bias) All outcomes	High risk	Comment: No information on blinding method is given
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: No information is reported on missing data, lost to follow-up or attrition rate
Selective reporting (reporting bias)	Low risk	Comment: All of the study's pre-specified primary outcomes have been reported
Other bias	High risk	Comment: Self reported data collection from participants may introduced recall bias in the trial

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Annunziato 2009	Randomised controlled trial using cognitive behaviour therapy as framework for intervention
Bennett 2010	Randomised controlled trial using self-efficacy theory and obesogenic behavior change principles as framework for intervention
Bibeau 2008	Randomised controlled trial with children as participants included
Blalock 2002	Randomised controlled trial with participants' body mass index (BMI) status not specified
Bonner 1997	Non-randomised experimental design with participants' BMI not stated
Burke 2002	Randomised controlled trial with unspecified theoretical framework for intervention

(*Continued*)

Chin 2002	Randomised controlled trial with participants' BMI less than or equal to 25 and TTM SOC not used as framework for intervention
Coday 2002	Randomised controlled trial using social action theory as framework for intervention
Dallow 2003	Randomised controlled trial using TTM SOC and self-efficacy theory as frameworks for intervention
De Vet 2007	Randomised controlled trial with non-overweight and obese participants included in the study
Demark-Wahnefried 2008	Randomised controlled trial using social cognitive theory as framework for intervention
Digenio 2009	Randomised controlled trial using behaviour treatment strategies as framework for intervention
Donnelly 2008	Randomised controlled trial TTM SOC is not used as framework of intervention
DPPRG 2009	Randomised clinical trial using lifestyle curriculum strategies as framework for intervention
Eriksson 2009	Randomised controlled trial using TTM SOC as framework for intervention with normal weight participants included
Feldman 2000	Randomised controlled trial with participants' BMI status not specified
Fernandez 2009	Randomised controlled trial applying TTM SOC with normal weight participants included
Finckenor 2000	Non-randomised experimental design with non-equivalent control group and participants' BMI status not stated
Folta 2009	Randomised controlled trial using social cognitive theory as framework for intervention and participants with normal weight included
Fox 2009	Randomised controlled trial using social cognitive theory as framework for intervention
Frisch 2009	Randomised controlled trial using telemedicine principles as framework for intervention
Gill 1998	Non-randomised Experimental design using biopsychosocial model as framework for intervention
Glanz 1994	Cross-sectional prospective study.
Greene 1998	Randomised controlled trial with normal weight participants included in the study
Gusi 2008	Randomised controlled trial using no explicit behaviour model or theory as framework for intervention
Hersberger 2006	Prospective evaluation study with no intervention and control group, using diabetes risk assessment and TTM SOC as framework for intervention
Huisman 2009	Randomised controlled trial using self-regulation principles as framework for intervention

(*Continued*)

Hussien 2007	Randomised controlled trial with no theoretical model use as framework for intervention
Irwin 2004	Randomised controlled trial using TTM SOC and self efficacy as theoretical frameworks for intervention and participants with normal weight included
Jeffery 1999	A follow up prospective study design of a randomised controlled trial with participants within normal BMI range
Jeffery and French 1999	Randomised controlled trial with no theoretical model use as framework for intervention
Jimmy 2005	Randomised controlled trial with normal weight participants aged below 18 included in the study
Johnson 2006	Randomised controlled trial with undefined participants' weight categories
Jones 2005	Prospective study using self efficacy and TTM SOC as framework for intervention
Jonsson 2009	Randomised controlled trial using Paleolithic diet principles framework for intervention
Kallings 2009	Randomised controlled trial using social cognitive theory, TTM SOC, motivational interviewing and supportive environment as theoretical frameworks for intervention
Kelly 2005	Cross-sectional study with TTM SOC and decisional balance theory as framework for intervention
Kennedy 2009	Randomised controlled trial using unspecified theoretical framework for intervention
Keranen 2009	Randomised controlled trial using effective counselling principles as theoretical framework for intervention
Kirk 2003	Randomised controlled trial with normal weight participants included in the study
Kris-etherton 2002	Randomised controlled trial using unspecified theoretical framework for intervention
Laforge 1994	Cross-sectional study using TTM SOC as framework for intervention
Latka 2009	Randomised controlled trial using TTM SOC as framework for intervention with normal weight participants included
Lee 1996	Non-randomised prospective experimental study with participants' BMI status not stated
Lee 2009	Randomised controlled trial using counselling principles as frameworks for intervention
Ma 2009	Randomised controlled trial using TTM SOC and Social Cognitive Theory as theoretical frameworks for intervention
Macrodimitris 2005	Descriptive study as part of a larger RCT which only looked at preliminary assessment phase prior to randomisation to intervention groups and participants with normal weight and obese included

(*Continued*)

Mardones 2009	Cross-sectional descriptive study to assess participants' TTM SOC
Martin 2007	Randomised controlled trial using social cognitive theory and TTM SOC
McTiernan 1999	Randomised controlled trial using cognitive-behavioural skills framing and TTM SOC as theoretical frameworks for intervention
Merriam 2009	Randomised controlled trial using social cognitive theory as framework for intervention
Morgan 2009	Randomised controlled trial using social cognitive theory as framework for intervention
Nanchahal 2009	Randomised controlled trial using unspecified theoretical framework for intervention
Oden 2005	Experimental study with underweight and normal weight participants included in the study
Ostbye 2009	Randomised controlled trial using social cognitive theory , stages of readiness and motivation models as frameworks for intervention
Ostendorf 1998	Cross-sectional exploratory descriptive study.
O'Connell 1988	Cross-sectional study with participants' BMI status not specified
Parra 2010	Randomised controlled trial using TTM SOC and SCT as framework for intervention with normal weight participants included
Partick 2009	Randomised controlled trial using behavioural and dietary strategies as framework for intervention
Pekmezi 2009	Randomised controlled trial using TTM SOC and social cognitive theory as framework for intervention
Pettman 2009	Randomised controlled trial using unspecified theoretical framework for intervention
Pinto 2002	Randomised controlled trial using TTM SOC and Social Cognitive Theory as framework for intervention
Pinto 2005	Randomised control trial with normal weight participants included
Prestwich 2010	Randomised controlled trial using Intention behaviour gap theory and theory of goal systems as frameworks for intervention, and normal weight participants included
Prochaska 2008	Randomised controlled trial with normal weight participants included
Provencher 2009	Randomised controlled trial using health-c entered approach as framework for intervention
Retterstol 2009	Randomised cross-over study using dietary strategies as framework for intervention
Rimmer 2009	Randomised controlled trial using unspecified theoretical framework for intervention

(*Continued*)

Robinson 2007	Randomised controlled trial with normal weight participants included
Roesch 2010	Randomised controlled trial using TTM SOC and social cognitive theory as framework for intervention
Ross 2009	Randomised controlled trial using TTM SOC and social cognitive theory as framework for intervention
Sarkin 2001	Cross-sectional study design.
Schelling 2009	Randomised controlled trial using Cognitive behavioural strategies as framework for intervention
Schumann 2006	Randomised controlled trial for smoking cessation.
Siegel 2010	Randomised controlled trial using social cognitive and self-efficacy theories as framework for intervention
Silva 2008	Randomised controlled trial using self-determination theory as framework for intervention
Silva 2010	Randomised controlled trial using self-determination theory as framework for intervention
Smith 2007	Cross-sectional study design.
Sutton 2003	A trial's baseline assessment study.
Vallis 2003	Cross-sectional study comparing patients at entry into an intervention trial
Van der Vee 2002	Randomised controlled trial with normal weight participants included in the study and a duplicate publication
Vazquez 2009	Randomised controlled trial using unspecified theoretical framework for intervention
Verheijden 2004	Randomised controlled trial with normal weight participants included
Veverka 2003	Randomised controlled trial with normal weight participants included in the study
Waddden 2009	Randomised controlled trial using unspecified theoretical framework for intervention
Webber 2010	Randomised controlled trial using self-efficacy theory and motivational interviewing principles as framework for intervention
Wee 2005	Cross-sectional design with normal weight, overweight and obese participants are included
White 2004	Randomised controlled trial using unspecified theoretical framework for intervention and participants included is adolescents
Williamson 2010	Randomised controlled trial using behaviour modification methods as framework for intervention
Wing 2010	Randomised controlled trial using social learning theory as theoretical frameworks for intervention

(*Continued*)

Yassine 2009	Randomised controlled trial using unspecified theoretical framework for intervention

DATA AND ANALYSES

This review has no analyses.

ADDITIONAL TABLES

Table 1. Overview of study populations

Characteristic ▸ Study ID ▾	Intervention(s) & control(s)	[n] screened	[n] randomised	[n] safety	[n] ITT	[n] finishing study	[%] of randomised participants finishing study	Comments
Dinger 2007	I: pedometer + TTM SOC C: pedometer only	I: - C: - T: 74	I: 32 C: 24 T: 56	-	I: 32 C: 24 T: 56	I: 32 C: 24 T: 56	I: 57% C: 43%	drop-outs (n=13), missing data (n=3) and extreme values (n=2)
Johnson 2008	I: SOC + diet, physical activities + stress management C: usual care	I: - C: - Total: 4290	I: 628 C: 649 T: 1277	-	I: 628 C: 649 T: 1277	I: 335 C: 426 T: 761	I:53.7% C:66.7%	losses to follow-up (n=261), no longer eligible (n=24), refused (n=37) and dead (n=1)
Jones 2003	I1: PTC I2: PTC + blood test strips C1: usual diabetes treatment C2: usual diabetes treatment + blood test strips	I: 860 C: 169 Total: 1029	I1: 260 I2: 269 C1: 250 C2: 250 T: 1029	-	I1: 260 I2: 269 C1: 250 C2: 250 T: 1029	-	-	data on drop-outs, losses to follow-up and missing were not reported
Logue 2005	I: TM-CD C: augmented usual care	I: - C: - Total: 665	I: 329 C: 336 T: 665	-	I: 329 C: 336 Total: 665	I: 266 C: 271 T: 537	I: 79.2% C: 82.4%	dead (n=3) with non-study related cause, missing data (12%)

Table 1. Overview of study populations (*Continued*)

								and losses to follow-up were not accounted
Steptoe 2001	I: behavioural lifestyle counselling C: usual health promotion	I: - C: - Total: 883	I: 316 C: 567 Total: 883	-	I: 316 C: 567 Total: 883	-	I: 53.5% C: 61.9%	data on drop-outs, losses to follow-up and missing data were not reported
Total			***I: 1834 C: 2076 Total: 3910***					two trials did not reported no. of participants finishing the study

"-" denotes not reported

C: control; I: intervention; ITT: intention-to-treat; PTC: pathways to change; SOC: stages of change; T: total; TM-CD: transtheoretical model-chronic disease; TTM: transtheoretical model

APPENDICES

Appendix 1. Transtheoretical model (TTM)

Stages of change	Characteristics
Pre-Contemplation	• A person has no intent to change behaviour in the near future (usually measured as the next six months) • Individuals may be not be informed or lack information about the consequences of their behaviour, or have attempted to change their behaviour and failed, therefore are demoralized on their ability to change the behaviour. • These people are often characterized as resistant or unmotivated and tend to avoid information, discussion, or thought with regard to the targeted health behaviour
Contemplation	• Individuals openly state their intent to change within the next six months. • Individuals have increased awareness on the benefits of changing but are still considering the cost involved in changing the behaviour (and are seriously undecided to change and are stucked at this stage for a longer period of time) • They are also known as contemplators or procrastinators and are often not ready for traditional action-

(*Continued*)

	oriented programs
Preparation	• The person intends to take steps to change (and usually occurring within the next months) • Individuals have attempted some important action in the past and most often have a plan of action, for example attending health education classes and talking to the counsellor. • These are the people who should be recruited for action-oriented programs • The individuals have not met the criteria for effective action and can be considered as at the early stirrings of the action stage
Action	• People made overt modifications in their lifestyles within the past six months. • Individuals must meet the criterion agreed by professionals to reduce the risk of a disease. • Action is defined as most explicit behavioural transformation and needs considerable commitment of time and energy (a successful change of addictive behaviour means achieving a specific criterion such as abstinence)
Maintenance	• Individuals work to avoid relapse and are most often less tempted to deteriorate as they increasingly become confident and able to continue their changes. • It was conventionally viewed as a static stage, whereas it is actually a continuation and not merely an absence of change • The main characteristics are stabilizing behaviour change and avoiding relapse

Appendix 2. Search strategies

Search terms
Unless otherwise stated, search terms are free text terms; MeSH = Medical subject heading (MEDLINE medical index term); exp = exploded MeSH; the dollar sign ($) stands for any character(s); the question mark (?) substitutes one or no characters; tw = text word; pt = publication type; sh = MeSH; adj = adjacent
The Cochrane Library
1 MeSH descriptor Obesity explode all trees
2 MeSH descriptor Weight gain explode all trees
3 MeSH descriptor Weight loss explode all trees
4 MeSH descriptor Body mass index explode all trees
5 MeSH descriptor Skinfold thickness explode all trees
6 MeSH descriptor Waist-hip ratio explode all trees
7 MeSH descriptor Abdominal fat explode all trees
8 MeSH descriptor Overweight explode all trees
9 (overweight* in All Text or (overin All Text and weight* in All Text))
10 (fat in All Text and overloadin All Text and syndrom* in All Text)
11 (overeat* in All Text or (overin All Text and eat* in All Text))
12 (overfeed* in All Text or (overin All Text and feed* in All Text))
13 (adipos* in All Text or obes*in All Text)
14 (weight in All Text near/3 cyc*in All Text) or (weight in All Text near/3 reduc*in All Text) or (weight in All Text near/3 los*in All Text) or (weight in All Text near/3 maint*in All Text) or (weight in All Text near/3 decreas*in All Text) or (weight in All Text near/3 watch*in All Text) or (weight in All Text near/3 control*in All Text) or (weight in All Text near/3 gain*in All Text) or (weight in All Text near/3 chang*in All Text))
15 (body in All Text and massin All Text and ind* in All Text) or (waist-hipin All Text and ratio* in All Text))

(*Continued*)

16 (skinfold in All Text and thickness*in All Text)
17 (abdominal in All Text and fat*in All Text)
18 (#1 or #2 or #3or #4 or #5 or #6 or #7or #8 or #9 or #10 or #11or #12 or #13 or #14 or #15or #16 or #17)
19 prochaska in All Text
20 diclemente in All Text
21 ((transtheoretical in All Text near/6 model* in All Text) or (trans in All Text and (theoretical in All Text near/6 model*in All Text)))
22 "stages of chang*" in All Text
23 (behavio?r in All Text and theor*in All Text)
24 ((lifestyl* in All Text near/6 model*in All Text) or (behavio?r in All Text near/6 model*in All Text))
25 "psychological model*" in All Text
26 (diet* in All Text near/6 theor* in All Text)
27 MeSH descriptor Health Promotion explode all trees
28 MeSH descriptor Psychology explode all trees
29 MeSH descriptor Diet explode all trees
30 MeSH descriptor Life Style explode all trees
31 MeSH descriptor Exercise explode all trees
32 (#19 or #20 or #21 or #22 or #23 or #24 or #25 or #26)
33 (#27 or #28 or #29 or #30 or #31 or #32)
34 MeSH descriptor Models, theoretical explode all trees
35 MeSH descriptor Models, psychological explode all trees
36 (#34or #35)
37 (#33and #36)
38 (#32or #37)
39 (#18 and #38)

MEDLINE

1 exp Obesity/
2 exp weight gain/ or exp weight loss/
3 exp body mass index/ or exp skinfold thickness/ or exp waist-hip ratio/
4 exp Abdominal Fat/
5 exp Overweight/
6 (overweight$ or over weight$).tw,ot.
7 fat overload syndrom$.tw,ot.
8 (overeat$ or over eat$).tw,ot.
9 (overfeed$ or over feed$).tw,ot.
10 (adipos$ or obes$).tw,ot.
11 (weight adj3 (cyc$ or reduc$ or los$ or maint$ or decreas$ or watch$ or control$ or gain$ or chang$)).tw,ot.
12 (body mass ind$ or waist-hip ratio$).tw,ot.
13 skinfold thickness$.tw,ot.
14 abdominal fat$.tw,ot.
15 or/1-14
16 Prochaska.ab,ti,ot.
17 Diclemente.ab,ti,ot.
18 ((transtheoretical or trans theoretical) adj6 model$).ab,ti,ot.
19 stages of chang$.ab,ti,ot.
20 behavio?r theor$.ab,ti,ot.
21 ((lifestyle or behavio?r) adj6 model$).ab,ti,ot.
22 psychological model$.ab,ti,ot.

(*Continued*)

23 (diet$ adj6 theor$).ab,ti,ot.
24 exp Health Promotion/mt [Methods]
25 exp Models, Psychological/
26 *Models, theoretical/
27 exp Diet Therapy/is, mt [Instrumentation, Methods]
28 exp Exercise/px [Psychology]
29 *Lifestyle/
30 or/16-29
31 15 and 30
32 randomized controlled trial.pt.
33 controlled clinical trial.pt.
34 randomi?ed.ab.
35 randomly.ab.
36 placebo.ab.
37 drug therapy.fs.
38 trial.ab.
39 groups.ab.
40 or/32-39
41 Meta-analysis.pt.
42 exp Technology Assessment, Biomedical/
43 exp Meta-analysis/
44 exp Meta-analysis as topic/
45 hta.tw,ot.
46 (health technology adj6 assessment$).tw,ot.
47 (meta analy$ or metaanaly$ or meta?analy$).tw,ot.
48 ((review$ or search$) adj10 (literature$ or medical database$ or medline or pubmed or embase or cochrane or cinahl or psycinfo or psyclit or healthstar or biosis or current content$ or systemat$)).tw,ot.
49 or/41-48
50 40 or 49
51 31 and 50
52 limit 51 to "all adult (19 plus years)"

EMBASE

1 exp Obesity/
2 exp weight change/ or exp weight control/ or exp weight gain/ or exp weight reduction/
3 exp body mass/ or exp waist circumference/ or exp waist hip ratio/
4 (obes$ or overweight or over weight).ab,ti.
5 (overeat or over eat or overfeed or over feed or fat overload syndrom$).ab,ti.
6 (weight adj6 (cyc$ or reduc$ or los$ or maint$ or decreas$ or watch$ or control or chang$ or gain)).ab,ti.
7 (body mass ind$ or waist hip ratio or waist circumferenc$).ab,ti.
8 adipos$.ab,ti.
9 exp skinfold thickness/
10 (abdominal fat or skinfold thickness).ab,ti.
11 or/1-10
12 prochaska.ab,ti,ot.
13 Diclemente.ab,ti,ot.
14 ((transtheoretical or trans theoretical) adj6 model$).ab,ti,ot.
15 stage$ of chang$.ab,ti,ot.

(*Continued*)

16 behavio?r theor$.ab,ti,ot.
17 ((lifestyle or behavio?r) adj6 model$).ab,ti,ot.
18 psychological model$.ab,ti,ot.
19 (diet$ adj6 theor$).ab,ti,ot.
20 *Health Promotion/
21 exp Psychological Model/
22 exp Theoretical Model/
23 *Diet Therapy/
24 (exercis$ adj6 psycholog$).ab,ti,ot.
25 exp lifestyle modification/
26 or/12-25
27 11 and 26
28 random$.tw.
29 (crossover$ or cross over$).tw.
30 placebo$.tw.
31 (double adj blind$).tw.
32 (single adj blind$).tw.
33 (assign$ or allocat$ or volunteer$).tw.
34 Crossover Procedure/
35 Double Blind Procedure/
36 Randomized Controlled Trial/
37 Controlled Clinical Trial/
38 Single Blind Procedure/
39 Randomization/
40 or/28-39
41 exp meta analysis/
42 exp Review/
43 (metaanaly$ or meta analy$ or meta?analy$).ab,ti,ot.
44 ((review$ or search$) adj10 (literature$ or medical database$ or medline or pubmed or embase or cochrane or cinahl or psycinfo or psyclit or healthstar or biosis or current content$ or systematic$)).ab,ti,ot.
45 exp Literature/
46 exp Biomedical Technology Assessment/
47 hta.tw,ot.
48 (health technology adj6 assessment$).tw,ot.
49 or/41-48
50 40 or 49
51 27 and 50
52 limit 51 to (adult <18 to 64 years> or aged <65+ years>)

PsycINFO

1 exp Obesity/
2 exp weight gain/ or exp weight loss/
3 exp body mass index/ or exp skinfold thickness/ or exp waist-hip ratio/
4 exp Overweight/
5 (overweight$ or over weight$).tw,ot.
6 fat overload syndrom$.tw,ot.
7 (overeat$ or over eat$).tw,ot.
8 (overfeed$ or over feed$).tw,ot.
9 (adipos$ or obes$).tw,ot.

(*Continued*)

10	(weight adj3 (cyc$ or reduc$ or los$ or maint$ or decreas$ or watch$ or control$ or gain$ or chang$)).tw,ot.
11	(body mass ind$ or waist-hip ratio$).tw,ot.
12	skinfold thickness$.tw,ot.
13	abdominal fat$.tw,ot.
14	or/1-13
15	Prochaska.ab,ti,ot.
16	Diclemente.ab,ti,ot.
17	((transtheoretical or trans theoretical) adj6 model$).ab,ti,ot.
18	stages of chang$.ab,ti,ot.
19	behavio?r theor$.ab,ti,ot.
20	((lifestyle or behavio?r) adj6 model$).ab,ti,ot.
21	psychological model$.ab,ti,ot.
22	(diet$ adj6 theor$).ab,ti,ot.
23	or/15-22
24	14 and 23
25	randomi?ed.ab.
26	randomly.ab.
27	placebo.ab.
28	trial.ab.
29	groups.ab.
30	or/25-29
31	exp Review/
32	exp Meta-analysis/
33	hta.tw,ot.
34	(health technology adj6 assessment$).tw,ot.
35	(meta analy$ or metaanaly$ or meta?analy$).tw,ot.
36	((review$ or search$) adj10 (literature$ or medical database$ or medline or pubmed or embase or cochrane or cinahl or psycinfo or psyclit or healthstar or biosis or current content$ or systemat$)).tw,ot.
37	or/31-36
38	30 or 37
39	24 and 38

Appendix 3. Description of interventions

Study ID ▸ Characteristic ▾	Dinger 2007	Johnson 2008	Jones 2003	Logue 2005	Steptoe 2001
Intervention: Application of TTM:	pedometer +TTM SOC: record daily steps using pedometer, PA brochures (pre-intervention) & email reminders weekly TTM SOC use as	assessment and feedback on fat intake, PA per week & stress management at baseline, 3, 6, & 9 months TTM SOC use as assess-	I1: PTC I2: PTC (diabetes manuals, monthly newsletters, telephone counselling, staged-based personalized assessment report quar-	TM-CD:Psychosocial evaluation every 6 months; SOC assessment for five target behaviours every 2 months; assessment on anthropometric, dietary &	behavioural lifestyle counselling: baseline assessment of SOC; counselling (fat intake reduction, PA) based on no. of risk factors (2 given 3

(*Continued*)

	algorithm for PA to assign participant's SOC	ment and feedback construct for Diet, PA and stress management	terly & dietary intake assessment) + blood testing strips TTM SOC use to assign and assess participants	exercise every 6 months; 10min counselling on diet; dietary & exercise prescriptions; & monetary reward for completing each post baseline assessment TTM SOC use as framework for intervention and to assess participants	counselling sessions & 1 given 2 counselling sessions) after 4 months and 12 months TTM SOC use as algorithms to assign and assess participants
Control: Usual advice on diet, exercise or both	pedometer only: record daily steps using pedometer, email reminders weekly	usual care	C1: usual diabetes treatment (family physician visits, diabetes education) C2: usual diabetes treatment (family physician visits, diabetes education) + blood testing strips	augmented usual care: assessment on anthropometric, dietary & exercise every 6 months;10min counselling on diet; dietary & exercise prescriptions; & monetary reward for completing each post baseline assessment	usual health promotion (education on healthy life style, encouragement and advice)

Footnotes
C: control; I: intervention; PA: physical activities; PTC: pathways to change; SOC: stages of change; TM-CD: transtheoretical model-chronic disease; TTM: transtheoretical model

Appendix 4. Baseline characteristics

Study ID ▸ Characteristic ▾	**Dinger 2007**	**Johnson 2008**	**Jones 2003**	**Logue 2005**	**Steptoe 2001**
Intervention(s) & control(s)	I: pedometer + TTM SOC C: pedometer only	I: SOC + diet, physical activities + stress management C: usual care	I1: PTC I2: PTC + blood test strips C1: usual diabetes treatment C2: usual diabetes treatment + blood test strips	I: TM-CD C: augmented usual care	I: behavioural lifestyle counselling C: usual health promotion

(*Continued*)

Participating population [n]	56	1277	1029	665	883
Country / Location	USA	USA	Canada	USA	UK
Sex [female%]	100	47	48	I: 70 C: 67	I: 54 C: 54
Age [mean years (SD)/range]	41.5 (7.6)	45.4	I1: 55.1 I2: 54.6 C1: 54.6 C2: 54.9	I: 40 to 49 (42%), 50 to 59 (42%), 60 to 69 (16%) C: 40 to 49 (38%), 50 to 59 (42%), 60 to 69 (20%)	I: 48 C: 46
Body mass index [kg/m^2 (SD)]	31.2 (6.6)	30.75	I1: 32.2 I2: 32 C1: 31.6 C2: 31.4	BMI 25-29.9 (20%) BMI 30-34.5 (34%) BMI 35-39.0 (23%) BMI 40.0+ (23%)	25-35
Duration of disease for co-morbidities [mean years (SD)]	-	-	Diabetes: I1: 10.4 I2: 10.1 C1:10.2 C2: 11.2		
Duration of intervention	6 weeks	9 months	12 months	24 months	4 months
Duration of follow-up	at 6 weeks	12 & 24 months	3, 6, 9 & 12 months	6, 12, 18 & 24 months	4 &12 months
Ethnic groups [%]	Caucasian (86%), others (14%)	White, not Hispanic (79.1%), Hispanic (7.0%), Black not Hispanic (6.5%), Asian or other Pacific Islander (0.9%) , American Indian or Alaskan Native (0.9%), others (5.4%), missing (0.3%)	-	African American (55%)	White (96.2%), Black or Indian (1. 7%)

Footnotes
"-" denotes not reported
C: control; I: intervention; PTC: pathways to change; SOC: stages of change; TM-CD: transtheoretical model-chronic disease; TTM: transtheoretical model

Appendix 5. Matrix of study endpoints

Study ID ▸ Characteristic ▾	Dinger 2007	Johnson 2008	Jones 2003	Logue 2005	Steptoe 2001
Intervention(s) & control(s)	I: pedometer + TTM SOC C: pedometer only	I: SOC + diet, physical activities + stress management C: usual care	I1: PTC I2: PTC + blood test strips C1: usual diabetes treatment C2: usual diabetes treatment + blood test strips	I: TM-CD C: augmented usual care	I: behavioural lifestyle counselling C: usual health promotion
Primary[1] endpoint (s):	change in walking steps (frequency & duration), change in TTM scores	healthy eating, exercise, managing emotional stress & fruits and vegetables intake	readiness to change, increases in self-care, improved diabetes control	weight change	readiness to reduce dietary fat, increase physical activities & smoking cessation
Secondary[2] endpoint(s)	-	-	-	-	-
Other[3] endpoint(s)	SOC progression	weight loss, SOC progression (action / maintenance)	weight loss, decreased calories (fat) , increase fruits and vegetables servings, SOC progression	change in energy intake, energy expenditure, self reported exercise, blood pressure & blood lipids	-

Footnotes
"–" *denotes not reported*

[1,2] as stated in the publication; [3] not stated as primary or secondary endpoint(s) in the publication
C: control; I: intervention; PTC: pathways to change; SOC: stages of change; TM-CD: transtheoretical model-chronic disease; TTM: transtheoretical model

Appendix 6. Adverse events

Study ID ▸ Characteristic ▾	Dinger 2007	Johnson 2008	Jones 2003	Logue 2005	Steptoe 2001
Intervention (I): Application of TTM Control (C): Usual	I:pedometer + TTM SOC C: pedometer only	I: SOC + diet, physical activities + stress management C: usual care	I1: PTC I2: PTC + blood test strips C1: usual diabetes	I: TM-CD C: augmented usual care	I: behavioural lifestyle counselling C: usual health promotion

(*Continued*)

advice on diet and/ or exercise			treatment C2: usual diabetes treatment + blood test strips		
Deaths [n/N]	-	I: 0 /628 C: 1/649 Total: 1/1277	-	I: 3/329 C: 0/336 Total: 3/665	-
Adverse events: relapse into unhealthy behaviour and weight gain [%]	-	-	-	-	-
Serious adverse events [%]	-	-	-	-	-
Drop-outs due to adverse events [%]	-	-	-	-	-
Hospitalisation [%]	-	-	-	-	-
Out-patient treatment [%]	-	-	-	-	-
Symptoms [%]	-	-	-	-	-

Footnotes
"-" denotes not reported
C: control; I: intervention; PTC: pathways to change; SOC: stages of change; TM-CD: transtheoretical model-chronic disease; TTM: transtheoretical model

Appendix 7. Primary and secondary outcomes

Study ID ▸ Characteristic ▾	**Dinger 2007**	**Johnson 2008**	**Jones 2003**	**Logue 2005**	**Steptoe 2001**
Intervention (I): application of transtheoretical model Control (C): usual advice on diet, exercise or both	I:pedometer + TTM SOC C: pedometer only	I: SOC + diet, physical activities + stress management C: usual care	I1: PTC I2: PTC + blood test strips C1: usual diabetes treatment C2: usual diabetes treatment + blood test strips	I: TM-CD C: augmented usual care	I: behavioural lifestyle counselling C: usual health promotion

(*Continued*)

Data for primary outcomes of this Cochrane review					
Weight-loss maintenance	-	Absolute weight loss (healthy eating + exercise behaviours) at 24 months: I: - C:- T: - The treatment group weight lost vs control at 24 months: t(1 615), -2.12kg, P < 0.05, df 0.17) At least 5% of body weight for healthy eating behaviour at 24 months: I:27.4% C:20.3% T:- The overall effect over time: t(11119), 2.07kg, P < 0.05, OR 1.22 (95% CI 10.1 to 1.48) Weight lost 5% or more for exercise behaviour at 24 months: I:28.8% C:19.4% T: - The overall effect with increasing differences overtime:t (1711), 1.96kg, P = 0.05, OR 1.32 (95% CI 0.99 to 1.75) Weight lost 5% or more for (healthy eating + exercise behaviours) at	In healthy eating group (at 12 months): I: 1.38kg (action stage) C: - T: - Both SMBG & healthy eating groups (at 12 months): I:1.78kg (action stage) C: - T: - (P < 0.01)	Early mean weight loss (6 and 12 months): I: 0.5kg (SE 0.4) C:- T:- (P < 0.0001) Mean weight loss (at 24 months): I:-0.39kg (SE 0.38kg, 95% CI -1.1 to 0.4) C:-0.16kg (SE 0.42kg, 95% CI -1.0 to 0.7) T: -0.29kg (95% CI -0.9 to 0.3)	-

(*Continued*)

		24 months: I: 30% C:18.6% T: - The overall group effect for intervention had increased overtime t(1615), 2. 05kg, P < 0.05, OR 1.35 (95% CI 1.01 to 1.81)			
Health-related quality of life	-	-	-	-	-
Data for secondary outcomes of this Cochrane review					
Self-reported change in dietary habit and measured change in dietary habit	-	Increased healthy eating behaviour (reduce calories intake per day) at 6 months: I: 43.9% C: 31.3% T: - At 12 months: I: 43.10% C: 35.2% T: - At 24 months: I:47.5% C:34.3% T:5.02, P < 0.001, OR 1.61 (95% CI 1. 33 to1.94) The overall group effect for all time points t(1,1119), 5. 02, P < 0.001, OR 1.61 (95% CI 1.33 to 1.94) Greater fruit and vegetables intake (progression to action/ maintenance) at 6	lower calories intake from fat in healthy eating behaviour at 12 months: I:35.34% C:36.1% T: - (P < 0.004) Higher vegetable intake per day I:2.24 C:2.06 T: - (P < 0.011) Higher Fruit servings intake I:1.89 C:1.68 T: - (P < 0.011)	Decreased in mean energy intake per day at 6 to 24 months: I: - C: - T:-250kcal/d (P < 0.0001) Increased in mean energy expenditure per day at 24 months: I:- C:- T:-2kcal/kg per day (P = 0.04)	Readiness to reduce fat intake (for action/maintenance stage) at 4 months: I:67.1% (95% CI 56.7 to 76.1) C:53.6% (95% CI 45.8 to 61.3) T:OR 2.15 (95% CI 1.30 to 3.56) Readiness to reduce fat intake (for action/maintenance stage) at 12 months: I: 68.4% (95% CI 61.1 to 74.8) C:59.2% (95% CI 49.2 to 68.6) T: OR 1.26 (95% CI 0.73 to 2.18)

(*Continued*)

		months: I: 44% C: 31.4% T: - At 12 months: I: 45.3% C: 39.6% T: - At 24 months: I:48.5% C:39.0% T: - The overall group effect for all time points t(1856), 5. 01, P < 0.0001, OR 1.63 (95% CI 1.34 to1.97)			
Self-reported uptake in physical activity and measured change in physical activity	Increased total daily steps increased at 6 weeks: I: - C: - T: 7984, SE 2742 (P < 0.0001) Increased weekly walking time (minutes) at 6 weeks: I:- C: - T:145 (median), P < 0.001	Increased exercise habit (progression to action/maintenance stage) at 6 months: I:43% C:34.6% T: - Increased exercise habit (progression to action/maintenance stage) at 12 months: I:37.7% C:35.9% T: - Increased exercise habit (progression to action/maintenance stage) at 24 months: I:44.9% C:38.1% T: -	-	Increased in mean self-reported exercise minutes per week (from 6 to 24 months): I:- C:- T:31.5 min (MD), SE 12min (P = 0. 008)	Increased readiness to exercise (for action/maintenance stage) at 4 months: I:32.2% (95% CI 23.7 to 42.0) C:23.9% (95% CI17.8 to 31.2) T:OR 1.89 (95% CI 1.07 to 3.36) Increased readiness to exercise (for action/maintenance stage) at 12 months: I:30.6% (95% CI 21.8 to 41.2) C:28.9% (95% CI 24.0 to 34.3) T:OR 1.68 (95% CI 1.08 to 2.61)
Change in weight loss measures	-	-	-	Decreased in mean waist girth (at 24 months): I:- C: -	-

(*Continued*)

				T: 1.7cm, SE 0.4cm (P = 0.0001)	
Progression through SOC	Moved forward at least one stage at 6 weeks: I:- C:- T:53.6% (P < 0. 001) Maintained existing stage at 6 weeks: I:- C:- T:41.1%	Progressed to action or maintenance stage for healthy eating outcome at 6 months: I: 43.9% C: 31.3% T: - At 12 months: I: 43.10% C: 35.2% T: - At 24 months: I: 47.5% C:34.3% T: - The overall group effect for all time points: t(11119), 5. 05, P < 0.001, OR 1.61, 95% CI 1.33 to1.94 Progressed to action or maintenance stage for exercise outcome at 6 months: I: 43% C: 34.6% T: - At 12 months: I: 37.7% C: 35.9% T: - At 24 months: I: 44.9% C: 38.1% T: - The overall group effect for all time points: t(1711), 2.25, P < 0. 05, OR 1.27, 95% CI 1.03 to 1.57 Progressed to ac-	Progessed to action stage in SMBG at 12 months: I1:30.5% C1:18.4% I2:43.4% C2: 27% T: - (P < 0.001) Progessed to action stage for healthy eating behaviour at 12 months: I1:32.5% C1:25.8% T: - (P < 0.001)	-	Progressed to action or maintenance stage for fat reduction habit at 4 months: I:- C: - T: OR 2.15 (95% CI 1.30 to 3.56) Progressed to action or maintenance stage for fat reduction habit at 12 months: I:- C: - T: OR 1.26 (95% CI 0.73 to 2.18) Progressed to action or maintenance stage at for physical activity at 4 months: I:- C: - T: OR 1.89 (95% CI 1.07 to 3.36) Progressed to action or maintenance stage at for physical activity at 12 months: I:- C: - T: OR 1.68 (95% CI 1.08 to 2.61)

(*Continued*)

		tion or maintenance stage for fruit & vegetable outcome at 6 months: I: 44% C: 31.4% T: - At 12 months: I: 45.3% C: 39.6% T: - At 24 months: I: 48.5% C: 39.0% T: - The overall group effect at all time points: t(1856), 5.01, P < 0.0001, OR 1.63, 95% CI 1.34 to 1.97			
Adverse events	Regressed one stage at 6 weeks: I:- C:- T:5.4%	-	-	Weight gain after 12 months: I: - C:- T: - (P < 0.0001)	-
Morbidity	-	-	-	-	-
Death from any cause	-	I:- C:1 T:1	-	I:3 C:- T:3	-
Costs	-	-	-	-	-

Footnotes
"-" denotes not reported
C: control; I: intervention; PTC: pathways to change; SMBG: self monitoring blood glucose; SOC: stages of change; TM-CD: transtheoretical model-chronic disease; TTM: transtheoretical model

FEEDBACK

Flaws in review call into question the validity of the conclusions drawn, 16 November 2011

Summary

On Wednesday, October 5h, 2011, the Cochrane Collaboration published a narrative review of five studies by Tuah, Amiel, Qureshi, Car, Kaur, and Majeed that claimed to assess the effectiveness of dietary and physical activity interventions based on the Transtheoretical Model of behavior change (TTM) to produce sustainable weight loss in overweight and obese adults. The review included a series of serious flaws that call into question the validity of the conclusions drawn.

(a) First, the authors claimed to be studying the impact of TTM-based intervention on weight loss and reported that the selection criteria included randomized controlled trials using the TTM SOC as a model, theoretical framework, or guideline in designing lifestyle modification strategies, mainly dietary and physical activity versus a comparison intervention of usual care, one of the outcome measures of the study was weight loss, and participants were overweight and obese adults.

(b) These criteria, however, were not systematically applied. Most glaringly, two of the five trials (Dinger et al., 2007 & Steptoe et al., 2001) did not include weight loss as an outcome.

(c) Furthermore those two studies included participants who were not overweight or obese. Jones et al. (2003) included no physical activity intervention and measured weight only as a secondary outcome. That leaves two studies that potentially met the inclusion criteria.

(d) A careful reading of Logue et al. (2005), however, indicates that behavior change targets were not clearly specified in that intervention, which the authors defined as a minimal intervention for obesity. Rather than using public health criteria for reaching action for diet and physical activity, Logue et al. (2005) reported focusing on small, non-specific increases in exercise and eating.

(e) Second, though the stated outcome of the review was to assess the potential for TTM-based interventions to measure sustained weight loss, sustainability of weight loss was not adequately assessed. Of the three studies that measured weight loss, two of the three (Jones et al., 2003 and Logue et al., 2005) measured weight loss only at the end of treatment. No follow-up beyond the end of treatment was included.

(f) Only one of five studies measured weight loss at one year post-intervention (Johnson et al., 2008). When examined carefully, the results of this study demonstrate that in the context of a truly effective, evidence-based TTM individualized intervention, weight loss in the treatment and control groups begins to diverge at 24 months (a full 12 months after treatment ended). In fact, Johnson et al. (2008) reported that among participants in the pre-action stages (i.e., those at risk for diet and/or physical activity), there was a significant and increasing difference over time in the proportion of participants losing at least 5% of their body weight. At the 24 month follow-up, 30% of those in a pre-action stage for both healthy eating and exercise at baseline had lost at least 5% of their body weight in the treatment group versus only 18.6% of the comparison group.

(g) Third, the bar for being defined as TTM-based intervention study was set far too low. The authors note that listing stage names fulfills criteria for using TTM SOC. The only thing common to the included studies, however, is that stages of change (SOC) names appeared in the abstracts. As the authors acknowledge, the TTM was inconsistently applied in everything from one size fits all email reminders (improperly using primarily behavioral processes of change for a sample almost entirely in contemplation at pre-test) in an under-powered 6 week long study with no follow-up in which weight wasn't even measured (Dinger et al., 2007) to stage-matched messages in 2-3 interactions from a nurse with only brief training (Steptoe et al., 2001), to weight loss advisors who adhered to the intervention protocol less than 50% of the time (Logue et al., 2005). Investigators with adequate knowledge of the TTM recognize that it is a comprehensive model of behavior change in which stage of change is one of 14 variables that make up the model.

(h) To date, the best practices for TTM-based interventions employ statistical decision-making to derive evidence-based decision rules about how to best match messages to participants' readiness to change and status on multiple behavior change variables. Conclusions regarding the efficacy and effectiveness of TTM-based interventions should be based on high quality research that applies the model appropriately, just as conclusions about the efficacy of medications are based on well-controlled trials of pharmacologic agents manufactured under the strictest quality controlled procedures. Unfortunately, those standards were not applied here.

(i) The review gave no consideration to the quality of studies included beyond the reporting of potential biases that were often, as the authors admitted, inappropriate for consideration for the trials included. No mention, for example, was made about whether the studies reviewed had adequate statistical power.

(j) Finally, the review included multiple errors and inconsistencies in reporting. A brief, but not exhaustive, list of examples includes: Page 2: Main Results. The overall sample size is technically inaccurate because only 445 of 1029 individuals in Jones et al. (2003), study were overweight or obese and therefore included in the healthy eating condition.

(k) Page 6: The authors state that for a study to be included in the review the intervention had to be delivered by health care professionals or trained lay-people. However, two of five studies do not meet these inclusion criteria. Johnson et al. (2008) applied a computer and mail-based intervention, and Dinger (2007) delivered the intervention through e-mail.
(l) Page 6: The authors state that another review done on TTM application found that it is difficult to apply the model looking at dietary change (Ni Mhurchu, 1997). However, the Ni Mhurchu citation never appears in the reference list, making it difficult for interested readers to evaluate this claim.
(m) Page 7: The authors erroneously report that all interventions included in the study were tailored to individuals who were overweight or obese. Dinger (2007), used a one size fits all intervention that was not tailored. All participants received the same intervention messages through e-mail regardless of their stage of change.
(n) Page 13: Erroneously reported that all participants in the included trials were analyzed based on traditional intention-to-treat (ITT). Johnson et al. (2008) conducted contemporary ITT analyses on data derived from multiple imputation rather than using traditional ITT analyses to address missing data.
(o) Page 13: Erroneously reported that Johnson et al. (2008) showed no weight loss despite the fact that this study reported statistically significant long-term weight loss outcomes. The Johnson et al. (2008) outcomes are correctly reported on page 17.
(p) Page 14 & page 20: Criticized Johnson et al. (2008) for not reporting which study personnel delivered the intervention when Johnson et al. (2008) clearly reported that the intervention was computer-tailored and reports were mailed to participants' homes.
(q) Page 17: Mis-reported Jones outcomes. The authors reported that there was a significant weight loss amongst participants in the action stage (individuals are ready to change their behavior) compared to those in the pre-action stage (individuals are not ready to change behavior) for the intervention in both the self-monitoring of blood glucose (SMBG) and healthy eating groups at 12 months. The definitions of stages provided are incorrect: Being in the action stage does not mean being ready to change. Action is having recently made the change/adopted the new behavior. Preparation, which is a pre-action stage, is defined as being ready to change. Furthermore, to clarify, the authors should have reported that weight loss was significantly greater for those receiving the intervention for SMBG & healthy eating who progressed to action or maintenance for SMBG.
(r) Page 17: The authors mis-reported changes in self-reported dietary intake for Logue et al. (2005), but Logue reports no differences on self-reported energy expenditure or intake.
(s) Page 17: The authors erroneously defined progress to action/maintenance.
(t) Page 22: In the same paragraph, the authors report that this review provides evidence for the efficacy of dietary and physical activity interventions based on the TTM SOC in producing sustainable weight loss in overweight and obese adults. Immediately before stating TTM SOC and a combination of physical activities, diet, and other interventions resulted in minimal weight loss, and there was no conclusive evidence for sustainable weight loss.
(u) In summary, we wholeheartedly and respectfully disagree with the assertion that the included studies contain sufficient information to examine the effectiveness of dietary and physical activity interventions based on the TTM SOC for weight loss in overweight and obese adults. The authors included only one study (Johnson et al., 2008) that provided an adequate test of this question, and erroneously and inconsistently reported the nature and findings of that study throughout the review.
(v) Given that the selection criteria were not applied correctly, sustainability of weight loss cannot be assessed based on a single study, the inappropriately low bar set for defining a TTM-based intervention, and the number of errors in this review, we would suggest that this review be retracted from *The Cochrane Library*.

Reply

(a) Disagree: The assessment about the aim of the study is not accurate ('…studying the impact of TTM-based intervention on weight loss…'). The objective of the review is 'to assess the effectiveness of dietary and physical activity interventions based on the transtheoretical model (TTM), to produce sustainable weight loss in overweight and obese adults'. This review is intended to collate evidence and allow rigorous appraisal on how and to what extent TTM works as a theoretical and pragmatic ('real life tested') framework for lifestyle modification (with diet and physical exercise) resulting in weight loss among the target population. This is clearly stated on 'page 7'.
The assessment on the inclusion criteria is also inaccurate. The 'inclusion' criteria were formulated using 'PICO' based on Cochrane review guidelines and a protocol approved by the Cochrane Review Group (CRG), and are clearly defined in 'page 7'.
(b) Disagree: The comment ('…these criteria, however, were not systematically applied. Most glaringly…') is not an accurate assessment on how the criteria of the review are applied during the data extraction and management of the review. The authors have read and followed the data collection and extraction methods stated in the Cochrane review guidelines. The explanation on systematic application of the criteria are explained in 'page 9' and explicitly shown in 'table 1', 'Characteristics of the included studies', 'appendix 3', 'appendix

4', 'appendix 5', 'appendix 6' and 'appendix 7' of the review. All methods used and the results in the review (including on eligibility and appropriateness of each included study) were discussed among authors and submitted to peer-reviewers through the CRG for approval. The main outcomes measured in the review are 'weight loss', 'changes in diet', 'changes in physical activity', 'health-related quality of life' and others (as clearly stated in 'the criteria of considering studies for this review: types of outcome measures' in p.4).

The authors agreed to include Dinger et al. (2007) because the article met the inclusion criteria, particularly on applying TTM SOC (as explained in p. 298 of the article) and reporting changes in physical activities (PA) as an outcome (stated in p.301 of the article). Although, there is no information on 'weight loss', 'changes in diet' and 'health-related quality of life' other outcomes are reported in the article, and the study's results provide useful information on how TTM works for a short-term study. We also have considered all the limitations of this study including small sample size and potential biases (as stated in the review in p.31).

Similarly, the authors included Steptoe et. al (2001) because the article met the inclusion criteria, in particular on using TTM SOC as intervention (as explained in p.266 of the article) and reporting changes in the readiness for dietary fat intake and PA as its main outcomes. We identified an additional outcome, i.e. progression through SOC for targeted behaviours: dietary fat intake, PA and smoking reported when assessing this study. This was also found in some other included studies. Therefore, we added the 'progression through SOC' as an outcome in our review, although it was not stated in our original protocol. There is no information on 'weight loss', 'health-related quality of life' and other outcomes reported in the article. We have declared any differences found in the final manuscript from the protocol when submitting the review.

(c) Disagree: The comment is an inaccurate assessment of the body mass index (BMI) status of the participants and outcomes for Jones et al. (2003). The article has clearly reported 'BMI >27 kg/m2' in the 'inclusion criteria' for self monitoring blood glucose (SMBG) and health eating interventions (as clearly stated in p.733 of the article). The article did not specifically report the outcomes as primary or secondary. The outcomes stated are shift in SOC for SMBG, healthy eating and smoking, changes in self-care outcomes, changes in health care utilization and impact of self-change (as described in p.734-5 of the article). We have explained issues related to outcomes measured throughout the review (in particular in p.17-21)

(d) Disagree: The comment is not clearly written (either it is referring to the inclusion criteria or results of the review). The comment is an inaccurate assessment of the information we have reported for the study (Logue et al. 2005) in the review (as shown in pg.3, 35 & 36).

The comment as such '…behavior change targets were not clearly specified in that intervention, which the authors defined as a minimal intervention for obesity...' is written in the 'objective' section of the study's abstract (in p. 917 of the article). We have extracted more information on the given point from 'the research methods and procedure' section of the paper, '…the target behaviours were increased exercise, increased usual activity, increased dietary portion control, decreased dietary fat and increased fruits and vegetables…' (p.919).

(e) Disagree: The comment is not an accurate assessment of the outcome measurement and results reported in the review. We have clearly defined the 'timing of outcome measurement: at one month, three months, six months, one year and if available two to five years, as stated by each trial' (p.8). All the studies (Jones et al., 2003 and Logue et al., 2005) met the given criteria.

For Logue et. all (2005), the 'abstract' of the article did not discuss 'follow up', but more information is available in the 'results' section of the article, '.. Figure1 shows the proportion of participants in each study group (AUC or TM-CD) with a measured weight (53.9% to 79.6%) and other information at the four follow-up assessments' (p.920-1). The study delivered the intervention and follow-up at the same time point. Similarly, for Jones (2003), the 'abstract' of the article did not discuss 'follow up', but more information is available in the 'Research design and methods' section of the article (p.733-4) and 'conclusion' (p.736). We have considered this point in the review (p.14). The information is stated in the 'intervention' and 'outcome' sections of the 'Characteristics of included studies' table.

(f) Disagree: Although, the comments reiterated the use of 'superficial judgments' based on information stated in the 'abstract' and 'weight outcomes' section of the article, there is no explanation on methods used in examining the information.

We have sufficiently reported the weight loss outcome in the study (Johnson et al 2008) as described in the paper (p.243) together with the statistical values (which are stated in p.17 of the review). Two assessors used the data extraction templates generated based on Cochrane review guidelines and recommended by the CRG (e.g. appendix 7 'primary & secondary outcomes' table). The templates enable the assessors to identify some missing data for intervention and control groups pertaining to some of the measured outcomes (e.g. absolute weight, weight loss of at least 5% and weight loss of 5% or more) particularly at 6 and 12 months of the trial.

(g) Disagree: We have clearly described TTM SOC in the 'description of intervention' section of the review (p. 5-6) and the characteristics are stated in appendix 1 (p.44) as described by Prochaska and DiClemente (Prochaska 1992).

Two assessors independently read and assessed the entire article based on the given description. Each study is included upon discussion and agreement of both assessors, as stated in the 'extraction and management' section of the review (p.9).

We also took account of important considerations when assessing the included studies, including the fact that the framework might not be properly listed as TTM or SOC in the included studies; limitations in each study; and limited information reported in each article. For example, in Dinger et al. (2007), use of TTM SOC is reported as '… the stage of change questionnaire was used to assess motivational readiness to become regularly physically active. An algorithm was used to categorize participants as contemplators,

preparers, active and maintainers…' (p.298) and more information is given in table 1 'Curriculum outline for COMBO group' (p.299). We made our judgments based on the reported information, retrieving the articles related to the questionnaire used in the study and contacting the authors for additional information. The summary of information about use of TTM SOC in each included study is stated in the 'Characteristics of included studies' table of the review (p.30-8). We are fully aware of the complete components of the TTM as it is investigated in our other ongoing research project. However, for the purpose of this review we only focus on SOC as stated in our approved review protocol.

(h) Agree and disagree: We will consider these points in our future projects on TTM. We found only a few studies that used suitable statistical approaches in measuring stage-matched intervention and outcomes. As stated earlier, this review is intended to collate evidence and allow rigorous appraisal on how and to what extent TTM works as a theoretical and pragmatic ('real life tested') framework for lifestyle modification (with diet and physical exercise) resulting in weight loss among the target population. as clearly stated in 'page 7'. The second comment is not clear. However, we have considered the limitations (e.g. prior exposure, lack of blinding) of using the RCT design for behavioural intervention particularly at community settings when conducting the review (as stated in p.16)

(i) Disagree: The comment is an inaccurate assessment of our results. We assessed 'risk of bias' and the 'quality of included studies' based on guidelines in the '*Cochrane Handbook for Systematic Reviews of Interventions*'. Information on 'statistical power' of included studies was stated in the review (p.22).

(j) Disagree: The comment is not an accurate assessment of the overall sample size. We have explained our methods in considering the sample sizes in 'types of participants' section (p.7), the 'unit of analysis' section of the review (p. 0) and please refer to table 1 'overview of study populations' (p.42), based on the *'Cochrane Handbook for Systematic Reviews of Interventions'*. The inclusion criteria for Jones et al. (2003) indicated that '… Participants were considered as being in a pre-action stage if they performed SMBG fewer than four times per day…and/or of they had a BMI >27 kg/m2..' (p.733). Furthermore, the data analysis methods in the study reported '… participants who did not complete the study were coded as remaining in pre-action for the ITT analyses. The main comparisons were between the proportion of participants in PTC versus TAU, and free strips versus no free strips for the SMBG intervention, across the stages at the end of study….' (p.734).

(k) Disagree: The comment is an inaccurate interpretation of our statements about 'delivery of intervention' in the review (p.6). The method of delivery is useful and additional information we wish to consider when defining the intervention but is not the main reason for including the studies (please refer to 'criteria of considering studies for this review' in p.7). We agreed to include both studies (Johnson et al. 2008 and Dinger 2007) upon carefully considering the description on the methodology of each study and our inclusion criteria. We have reported '… personnel not stated, home based using telephone and email...' (p.29) for Johnson et al. (2008); and '…delivered by health care professionals at community and university via email…' for Dinger (2007) in the 'characteristics of included studies' table of the review (p.28).

(l) Disagree: The reference is listed in pg.31 of the review (under additional references).

(m) Disagree: The comment '… all interventions included in the study were tailored to individuals who were overweight or obese…' is not found in the review (p.7).

The comment is an inaccurate assessment of the result for 'interventions of included studies'. We have discussed our results in the 'interventions' section of the review (p.12) and 'Characteristics of included studies' table (p.28-35) as well as 'Descriptions of interventions' table (p.48). The study by Dinger (2007) did not report adequate information on the intervention in the 'abstract', however there is more information on the study's intervention reported in the 'methods' section of the article (p.298-299).

(n) Disagree: The comment is an inaccurate assessment of our results on 'risk of bias in the included studies' of the review (please refer to p.12-14). For Johnson et al. (2008), we have reported MI approach in the study in the 'characteristics of included studies' table of the review (p.30).

(o) Agree, thank you: This statement contains a typing error. The statement should read as "… Another trial evaluated a combination of PA, diet and other interventions such as stress management strategies (by giving individualized feedback) compared to usual care and showed significant weight loss, particularly at 24 months (Johnson 2008)." This information is correctly reported together with statistical values in various sections throughout the review (e.g. 'Effects of interventions, primary outcomes, weight loss maintenance; 'Characteristics of include studies' table; and 'Appendix 7. Primary and secondary outcomes').

(p) Disagree: The point is similar to question 'k', and has been addressed above.

(q) Disagree: The comment is an inaccurate assessment of our results on the 'secondary outcomes' in the review (p.17). We have described the 'progression through SOC' outcome using the statistical values extracted from the articles of the included studies, including the study by Jones (2003, refer to p.732-35 in the article). The definition of SOC in the review is based on the description given by Prochaska (1992; 1997; 2008a) and is one that is widely used in studies as discussed in the review (p.5, 6 and 43). The point on definition of SOC is similar to question 'h' and has been addressed above.

Please take note of the given references used in the review to define the SOC as stated below (p.27):

Prochaska J.O., DiClemente C.C., Norcross J.C. In search of how people change: Applications to addictive behaviors. American Psychologist. 1992;47(9):1102-14.
Prochaska J.O, Redding C.A, Evers K.E. The transtheoretical model and stages of change. In: K Glanz, F Marcus Lewis, BK Rimer, editors. Health behavior and health education : theory, research, and practice. 2nd ed. San Francisco Jossey-Bass; 1997.
Prochaska J.O., Redding C.A., Evers K.E. The transtheoretical model and stages of change. In: Karen Glanz BKR, and K. Viswanath editor. Health behavior and health education : theory, research, and practice. 4th ed. San Francisco Jossey-Bass; 2008.
(r) Disagree: The comment is an inaccurate assessment of our results on 'self-reported change in dietary habit and measured change in dietary habit' outcome reported in the 'secondary outcomes' section of the review (p.15-16). We have clearly defined the 'change in dietary consumption' outcome as a reduction in the daily number of calories, a reduction in fatty food intake and an increase in daily fruit and vegetable consumption, as stated in 'types of outcome measures' in the review (p.7). For the study by Logue (2005), we have reported as such '… TTM SOC combined with diet, physical activity and monetary reward interventions in a trial reported no significant mean change in energy intake per day in the intervention group compare to control (P = 0.69) at 24 months. There was a significant reduction in the mean change energy intake per day for both groups combined (-250 kcal/d, P < 0.0001) throughout the 6 to 24 months follow-up…' (p.15-16). We also reported that the data on energy expenditure at 6, 12 and 18 months were not explicitly reported. The data for the intervention group and the control pertaining to both outcomes (mean energy intake and expenditure) were not given. We have extracted the data of the given outcome from the article on 'page 922 and 923'. The abstract of the article reported the results simply as 'Repeated measures models under the missing at random assumption yielded non-significant adjusted differences between the AUC and TM-CD groups for weight change, waist circumference, energy intake or expenditure, blood pressure, and blood lipids…' (p.917), but we have examined the results systematically using methods recommended by the Cochrane review guidelines. Please refer to more information shown in the review including 'Characteristics of included studies' table (p.33-34) , matrix of study endpoints (appendix 5, p.51) and the 'primary and secondary outcomes' table (appendix 7, p.52).
(s) Disagree: We have explicitly defined the terms 'progress to action stage' and 'maintenance stage' in the review (p.17) as defined in the study by Steptoe 2001 (p.266). This point was recommended by the CRG during the peer-review process and aimed to provide a clear explanation of the results when reporting the outcome of the study in the review. We think the definitions for the terms given throughout the article are acceptable and similar to our definition of SOC (as mentioned on question 'q' above).
(t) Agree, thank you: The statement in 'Abstract/Main results' should read "The intervention was found to have limited impact on weight loss (about 2 kg or less). There was no conclusive evidence for sustainable weight loss." and the statement in 'Implications for practice' should read "This review provides evidence on the use of the TTM SOC as a theoretical framework for dietary and physical activity interventions in weight loss management for overweight and obese adults. TTM SOC and a combination of physical activities, diet and other interventions (such as feedback reports, anthropometric measurements and counseling) have limited impact on weight loss (about 2 kg or less). There was no conclusive evidence for sustainable weight loss."
(u) Disagree: We have reviewed the current evidence and based our conclusions on this evidence. Future research from new high-quality studies may change our findings but until then, our findings are valid.
(v) Disagree: We think the request is invalid because most of the comments are based on an inaccurate assessment of the review. We have followed an approved protocol in conducting this review which is based on the *'Cochrane Handbook for Systematic Reviews of Interventions'.* The information and results in the review reported are peer-reviewed and approved by the editor of the CRG. We have reviewed the current evidence and based our conclusions on this. Future research from high-quality studies may change our findings but until then, our findings are valid.

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Submitter has modified conflict of interest statement: I am an employee of Pro-Change Behavior Systems, Inc. who licenses evidence-based behavior change programs grounded in the Transtheoretical Model of Behavior Change.
Nik Tuah on behalf of the authors.
Notes: Listing (such as (a), (b) etc.) was introduced by the Feedback Editor to provide better comparability between contributor's comments and authors' replies.

WHAT'S NEW

Last assessed as up-to-date: 1 January 2011.

Date	Event	Description
18 January 2012	Feedback has been incorporated	New feedback received on 16 November 2011, authors replied on 11 and 17 January 2012
18 January 2012	Amended	Abstract, results section; description of studies (interventions); implications for practice

HISTORY

Protocol first published: Issue 4, 2009

Review first published: Issue 10, 2011

CONTRIBUTIONS OF AUTHORS

NIK TUAH: protocol draft, search strategy development, acquirement of trial copies, trial selection, data extraction, data analysis, data interpretation, review draft and update draft.

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JOSIP CAR: protocol draft, search strategy development, data analysis, data interpretation and review draft.

AZEEM MAJEED: protocol draft, search strategy development, trial selection, data extraction, data analysis, data interpretation, review draft and update draft.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Imperial College of London, UK.

Support provided includes library facilities, statistician support, computer supplies and consumables, funds for training and others.

External sources

- Public Service Department, Brunei Goverment, Brunei Darussalam.

Support provided is mainly funding for the project by yearly basis.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

There are few distinctive differences between protocol and review: Firstly, the timing of outcome measurement begins at one month to take account of results from short-term trials that may provide useful analysis about the topic. Secondly, 'progression through SOC' is introduced as a new secondary outcome as it is a commonly reported outcome in the included trials. Thirdly, meta-analysis was not appropriate because there were different outcomes (dichotomous versus continuous) presented in included trials for each outcome measured and some data (for intervention group and control group for each outcome measured) were not completely reported by each trial. Also, the timing of outcome measurement varied in the included trials. The reporting and small study bias was not assessed using funnel plots because there were only a few trials included and furthermore the types of outcomes as well as the estimate effect measures used in each trial were different. Lastly, acknowledgements are added to highlight contributions of individuals throughout the project.

INDEX TERMS

Medical Subject Headings (MeSH)

*Diet, Reducing; *Exercise; *Models, Psychological; *Weight Loss; Health Behavior; Obesity [psychology; *therapy]; Overweight [psychology; therapy]; Randomized Controlled Trials as Topic

MeSH check words

Adult; Humans