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

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[Intervention Review]

Transtheoretical model stages of change 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 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 intervention or physical activity interventions, or both, and other interventions based on the transtheoretical model (TTM) stages of change (SOC) to produce sustainable (one year and longer) weight loss in overweight and obese adults.

Search methods

Studies were obtained from searches of multiple electronic bibliographic databases. We searched *The Cochrane Library*, MEDLINE, EMBASE and PsycINFO. The date of the last search, for all databases, was 17 December 2013.

Selection criteria

Trials were included if they fulfilled the criteria of randomised controlled clinical trials (RCTs) using the TTM SOC as a model, that is a theoretical framework or guideline in designing lifestyle modification strategies, mainly dietary and physical activity interventions, versus a comparison intervention of usual care; one of the outcome measures of the study was weight loss, measured as change in weight or body mass index (BMI); participants were overweight or obese adults only; and the intervention was delivered by healthcare professionals or trained lay people at the hospital and community level, including at home.

Data collection and analysis

Two review authors independently extracted the data, assessed studies for risk of bias and evaluated overall study quality according to GRADE (Grading of Recommendations Assessment, Development and Evaluation). We resolved disagreements by discussion or consultation with a third party. A narrative, descriptive analysis was conducted for the systematic review.

Main results

A total of three studies met the inclusion criteria, allocating 2971 participants to the intervention and control groups. The total number of participants randomised to the intervention groups was 1467, whilst 1504 were randomised to the control groups. The length of intervention was 9, 12 and 24 months in the different trials. The use of TTM SOC in combination with diet or physical activity, or both, and other interventions in the included studies produced inconclusive evidence that TTM SOC interventions led to sustained weight loss (the mean difference between intervention and control groups varied from 2.1 kg to 0.2 kg at 24 months; 2971 participants; 3 trials; low quality evidence). Following application of TTM SOC there were improvements in physical activity and dietary habits, such as increased exercise duration and frequency, reduced dietary fat intake and increased fruit and vegetable consumption (very low quality evidence). Weight gain was reported as an adverse event in one of the included trials. None of the trials reported health-related quality of life, morbidity, or economic costs as outcomes. The small number of studies and their variable methodological quality limit the applicability of the findings to clinical practice. The main limitations include inadequate reporting of outcomes and the methods for allocation, randomisation and blinding; extensive use of self-reported measures to estimate the effects of interventions on a number of outcomes, including weight loss, dietary consumption and physical activity levels; and insufficient assessment of sustainability due to lack of post-intervention assessments.

Authors' conclusions

The evidence to support the use of TTM SOC in weight loss interventions is limited by risk of bias and imprecision, not allowing firm conclusions to be drawn. When combined with diet or physical activity, or both, and other interventions we found very low quality evidence that it might lead to better dietary and physical activity habits. This systematic review highlights the need for well-designed RCTs that apply the principles of the TTM SOC appropriately to produce conclusive evidence about the effect of TTM SOC lifestyle interventions on weight loss and other health outcomes.

PLAIN LANGUAGE SUMMARY

Behaviour changes for dietary and physical exercise modification in overweight and obese adults

Review question

What are the effects of dietary interventions or physical activity interventions, or both, based on the transtheoretical model (TTM) stages of change (SOC) to produce sustainable (one year and longer) weight loss in overweight and obese adults?

Background

Generally, weight loss programmes tend to involve diet and physical activity interventions. The TTM describes a series of five SOC an individual goes through when changing from an unhealthy behaviour to a healthy one. In this review, we assessed the use of the TTM SOC in weight management programmes for overweight and obese adults especially in terms of the effects on weight loss, dietary habits, physical activity and behaviour changes.

Obesity (body mass index of at least 30 kg/m²) and overweight (body mass index of 25 to less than 30 kg/m²) are increasingly being recognised as important public health issues. Together, they contribute to serious health problems and extensive economic costs worldwide. Body mass index (BMI) is a measure of body fat and is defined as the individual's weight in kilograms divided by the square of the height in metres (kg/m²). The BMI should be considered as a rough guide only because it is mainly used for whole populations and may not correspond to the same degree of fatness in different individuals (like for athletes and physically non-active individuals).

Study characteristics

We included three studies in our systematic review. Altogether the studies evaluated 2971 participants, with 1467 participants allocated to the intervention groups and 1504 to the control groups. The studies had a length of intervention of 9, 12 and 24 months.

This plain language summary was current as of December 2013.

Key results

The use of the TTM SOC in combination with diet or physical activity, or both, and other interventions in the included studies provided inconclusive evidence about the impact of such interventions on sustainable weight loss (mean difference in favour of the TTM SOC was between 2.1 kg and 0.2 kg at 24 months). However, other positive effects were noted, such as changes in physical activity and dietary habits that included increased exercise duration and frequency, reduced fat intake and increased fruit and vegetable consumption. The studies did not report other important outcomes such as health-related quality of life, illness (morbidity) and economic costs.

Quality of the evidence

Overall, the quality of the evidence was low or very low. The main limitations included incomplete reporting of outcomes, methodological shortcomings, extensive use of self-reported measures and insufficient assessment of sustainability due to the lack of long-term assessments.

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

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

Population: adults with overweight and obesity
Settings: hospital and community
Intervention: TTM SOC on diet or physical activity, or both
Comparison: usual advice on diet or physical activity, or both

Outcomes	Mean differences (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
Weight loss [kg] a) Follow-up: 12 months b) Follow-up: 24 months	a) 0.7 b1) Objectively measured: -0.2 (-1.0 to 0.9) b2) Self measured: -2.1	2971 (3)	⊕⊕◯◯ **low**[a]	a) TTM SOC subgroup - 1.4 kg, control - 0.7 kg (difference not statistically significant) b1) P = 0.50 b2) P <0.05
Health-related quality of life	See comment	See comment	See comment	No study reported this outcome
Adverse events	See comment	See comment	See comment	No adverse events were reported
Physical activity, self-reported exercise [minutes per week] Follow-up: 24 months	32 (8 to 55)	665 (1)	⊕◯◯◯ **very low**[b]	P = 0.008 (from 6 to 24 months) in favour of TTM SOC
Dietary habits a) Diet with <30% fat [%] Follow-up: 12 months b) Servings of fruit (vegetables) per day [n] Follow-up: 12 months	a) 0.9 b) 0.2 (+ 0.1)	a) 665 (1)	a) ⊕◯◯◯ **very low**[b]	a) TTM SOC 35.2%, control 36.1% (P = 0.004) b) TTM SOC 1.9 (+ 2.2) , control 1.7 (+ 2.1); (P = 0.016, P = 0.011)
Costs	See comment	See comment	See comment	No study evaluated this outcome

*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.

[a] Downgraded by two levels because of imprecise results (confidence interval includes null effect and benefit or harm) and high risk of performance, detection and recall bias

[b] Downgraded by three levels because of few participants and one trial only, high risk of performance, detection and recall bias and indirectness (surrogate outcome parameter)

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 adults, and conforms to the World Health Organization (WHO) standard. It is defined as the weight in kilograms divided by the square of the height in metres. 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.

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. The WHO projected that approximately 1.5 billion adults (age 20 years and above) would be overweight in 2008, 500 million of whom would be obese; while at least 43 million children under the age of five years were overweight or obese in 2010 (World Health Organization 2012). In the United States (US), obesity is reaching alarming rates. According to the most recent (2009 to 2010) estimates of the National Health and Nutrition Examination Survey (NHANES), 78 million US adults aged 20 years and over (35.7%) and 12.5 million US children and adolescents between 2 and 19 years of age (16.9%) are obese (Ogden 2012a), while 33% and 31.8% of adults and children, respectively, are overweight (Ogden 2012b). In the United Kingdom (UK), obesity figures are slightly lower. According to data from the English Health Survey 2009 to 2010, 23% of adults and 15.5% of children are classified as obese, while approximately 38.5% of adults and 14.5% of children (aged between 2 and 15 years) are overweight (NHS Information Centre 2011).

Obesity results in significant impairment of health and longevity. Obesity also increases individuals' 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 2012). Osteoarthritis is also more commonly seen among overweight and obese individuals. Obesity reduces quality-adjusted life expectancy by about three years in males and six years in females (Brønnum-Hansen 2007; Pryke 2008). In the US, adult obesity and overweight were associated with 111,909 and 33,746 excess deaths, respectively, in 2000 (Flegal 2005). In the UK, the number of deaths as a result of excess weight was estimated to be 8.7% of the total number of deaths (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 alone was estimated at GBP 2.7 billion (approximately EUR 3.2 billion, May 2013 conversion rate) in 2007, with a projection to rise to GBP 3.9 billion (approximately EUR 4.6 billion) by 2015, while the NHS expenditure for both obese and overweight individuals was approximately GBP 4.2 billion (approximately EUR 4.9 billion) in 2007 and is expected to rise as high as GBP 6.3 billion (approximately EUR 7.4 billion) by 2015 (Foresight 2007). In the US, the medical care costs of obesity were approximately USD 147 billion (approximately EUR 113 billion, May 2013 conversion rate) in 2008 (Finkelstein 2009).

Description of the intervention

The 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. The 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 (SOC) can be used to plan dietary interventions for short-term weight loss amongst overweight and obese individuals over a minimum of three months (Shaw 2006). The effectiveness of TTM dietary interventions beyond one year is inconsistent (Curry 1992; Greene 1999; Johnson 2006; Johnson 2008; Laforge 1994; Prochaska 2008a; 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 identified stages of change for uptake of low-fat diet in adults (Auld 1997; Lamb 1996; Read 1996; Steptoe 1996).

The TTM provides a conceptual explanation of the processes that individuals go through when modifying a problem behaviour or acquiring a positive behaviour, in this case changing dietary intake or physical activity, or both, in order to achieve a sustainable weight loss. The SOC is the main construct of the TTM and 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 precontemplation, 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 2008b). 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, 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).

Adverse effects of the intervention

The potential main adverse effects of the intervention include relapse into unhealthy behaviour; weight gain over a specific period of time; and economic costs.

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 the dietary and physical activity behaviours of participants to achieve a sustainable proportion of weight loss among overweight and obese adults. The hypothesis is that the TTM 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 the TTM SOC might work by meeting individuals' needs according to the predictions of the TTM; 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 activity strategies tailored according to the model possibly work by increasing the level of exercise and physical activity, occurring in a continuous and sustainable manner, resulting in the targeted outcome. The significance of such an approach is that the behaviour change takes place voluntarily and is highly self-driven, which may contribute to a sustainable desired behaviour change.

A study among overweight or obese adults (1277 participants with a BMI of 25 to 39.9) claimed that TTM-based tailored feedback can improve healthy eating, exercise, emotional distress management, and weight of the study population. The results showed a significant increase in fruit and vegetable intake and individuals tended to progress to action and maintenance at 24 months (Johnson 2008). However, a review done on the TTM application found that it is difficult to apply the model when 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).

The TTM is a useful theoretical model in guiding interventions and predicting outcomes for dietary management among adults, as shown in some of the studies above. The studies with a rigorous design have shown statistically significant results that link stages of the TTM with the primary measured outcomes, particularly for large sample studies with longer follow-up periods. It is potentially plausible to apply the TTM to other settings and it 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 the TTM as the guidelines are reduction in fat consumption and increase in healthy food intake (that is increase in fruit and vegetable consumption) (Di Noia 2008; Greene 1994; Johnson 2008; Laforge 1994).

Why it is important to do this review

Obesity drugs, dietary modification and physical activity 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 overweight and obese individuals (19,273 adults with a BMI of at least 25 kg/m^2) from 1966 to 2003 investigated dietary and 'lifestyle', drug therapy (orlistat or sibutramine) and surgical (for example gastric bypass) methods resulting in modest weight loss, and potentially improving markers of cardiovascular risk factors (Douketis 2005). Dietary and lifestyle therapy provided less than 5 kg weight loss after two to four years, drug therapy provided 5 to 10 kg weight loss

after one to two years, and surgical therapy provided 25 to 75 kg weight loss after two to four years. The review, however, reported methodological limitations in the included studies that restricted the applicability of findings to overweight and obese individuals in other settings (Douketis 2005). There are few systematic reviews and no clear evidence exists of the effectiveness of such interventions in producing sustainable weight loss beyond one year after intervention among overweight and obese individuals (Douketis 2005; Jain 2005; Nield 2007; Shaw 2006).

A large Cochrane systematic review of 41 randomised controlled trials (from the US, Netherlands, Canada, Australia and UK, 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 who were overweight or obese (Shaw 2006). Exercise alone resulted in a small weight loss 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 the lack of long-term trials included in the analyses (Shaw 2006).

Another Cochrane systematic review of 18 randomised controlled trials examined the effects of the type and frequency of dietary advice given to adults with type 2 diabetes mellitus (1467 participants who were either overweight or had normal weight) (Nield 2007). They reported that dietary advice plus exercise was associated with a statistically significant mean decrease in the glycosylated haemoglobin A1c (HbA1c) levels of 0.9% at six months and 0.1% at 12 months. The study found no statistically 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 2007).

A systematic clinical literature review found that dietary and exercise treatments for obese adults produced moderate weight loss (about 3 kg to 5 kg) compared with no treatment or usual care (Jain 2005). Meanwhile, weight loss from drugs used 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 loss can be statistically significant but it may not be clinically sufficient 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).

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

This is an updated version of the original Cochrane systematic review (Tuah 2011). In this update we have carefully reviewed the studies included in the original publication, in response to feedback on their eligibility, and searched for new studies. Inconsistencies in the original review have been resolved to provide an accurate assessment of the use of the TTM SOC as a model, theoretical framework or guideline in designing lifestyle modification interventions in overweight and obese adults.

OBJECTIVES

To assess the effects of dietary interventions or physical activity interventions, or both, and other interventions based on the transtheoretical model (TTM) stages of change (SOC) to produce sustainable (one year and longer) 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, age 18 years and over, who were overweight or obese according to any standard parameters used by the WHO (for example 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 of 25 to 29.9 and obesity as a BMI of at least 30.

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

Types of interventions

Intervention

Application of the transtheoretical model (TTM) stages of change (SOC) combined with lifestyle modification strategies, consisting of dietary intervention or physical activity intervention, or both, which was tailored to an individual who was overweight or obese.

The included studies had to describe the intervention as using the TTM as a model, theoretical framework or guideline in designing lifestyle modification strategies, as stated above. The intervention needed to fulfil the criteria of the TTM SOC including precontemplation, contemplation, preparation, action, and maintenance (Appendix 1) as described by Prochaska and DiClemente (Prochaska 1992). The intervention must be delivered by healthcare professionals or trained lay people and targeted for overweight and obese adults at the hospital or community level, such as at community health centres, general practice clinics, community centres, schools and homes. All studies with an intervention duration from one to 12 months and above were included in the review.

Control

Usual advice on diet or advice on physical activity, or both.

Types of outcome measures

Primary outcomes

- Sustained weight loss (changes in weight or BMI at one to five years and above).
- Short-term weight loss (changes in weight or BMI at less than 12 months).
- Health-related quality of life.

Secondary outcomes

The first two outcomes below comprise the main types of secondary outcomes, although additional secondary outcomes are given.

(1) Change in self-reported or measured dietary consumption, 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 self-reported or measured physical activity, referring to an increase in any form of physical activity (in terms of intensity, frequency, duration and type) that was non-prescribed or prescribed by health professionals.

- Uptake or increase in physical activity.

(3) Change in other weight loss measures (skin fold measurement, waist measurement, and waist-to-hip ratio).

(4) Change in the SOC progression.

Adverse events

There are three main adverse events measured. These include

- Relapse into unhealthy behaviour and weight gain.
- Morbidity.
- Economic costs.

Covariates, effect modifiers and confounders

- Underlying chronic diseases such as cancer, diabetes, and respiratory disease that may cause weight loss.
- Compliance.
- Pharmaceutical interventions.
- Bariatric surgery.

Timing of outcome measurement

At one month, three months, six months, nine months, one year and, if available, beyond one year, as stated by each trial.

Search methods for identification of studies

Electronic searches

We used the following sources, from inception until specified, for the identification of trials:

- *The Cochrane Library* (17 December 2013).
- MEDLINE (17 December 2013).
- EMBASE (17 December 2013).
- PsycINFO (17 December 2013).

We also searched databases of ongoing trials including the *meta*Register of Controlled Trials (www.controlled-trials.com/mrct/).

For detailed search strategies, see Appendix 2.

Additional key words that were of relevance could have been detected during any of the electronic or other searches. If this had been 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.

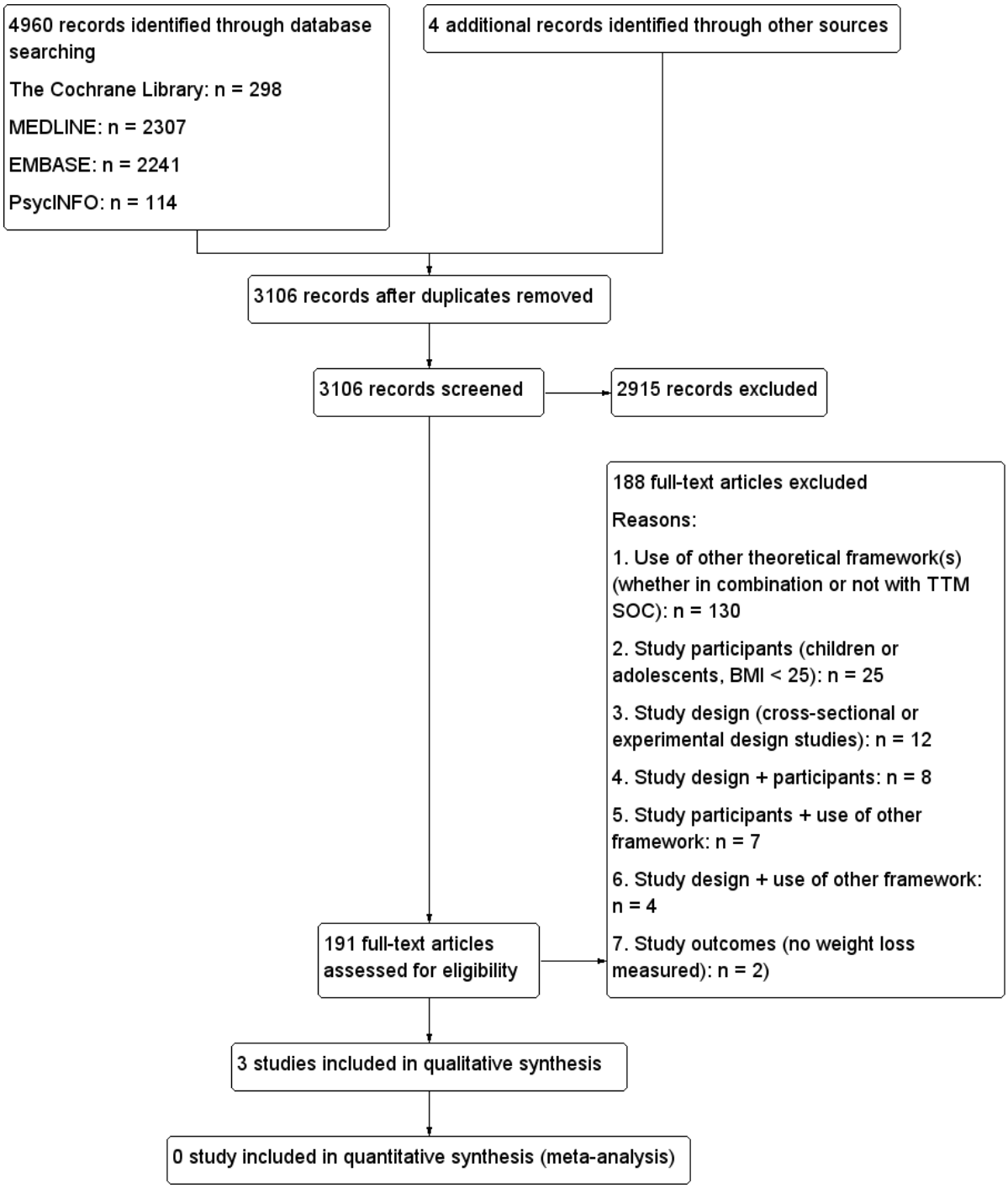
Potential missing and unpublished studies were sought by contacting experts in the field. We used the library resources at Imperial and the British Library if potentially relevant articles were cited but not available via databases or websites.

Data collection and analysis

Selection of studies

To determine the studies to be assessed further, two review authors (NM, LF) independently scanned the abstract, title, or both sections of every record retrieved. All potentially relevant articles were investigated as the full text. Inter-rater agreement for selection of potentially relevant studies was measured using the kappa statistic (Cohen 1960) and the value was 0.81, which showed that the strength of agreement between assessors was very good. Where differences in opinion existed, they were resolved by a third party (LG). If resolving disagreement was not possible, the article was added to those 'awaiting assessment' and study authors were contacted for clarification. An adapted PRISMA (preferred reporting items for systematic reviews and meta-analyses) flow chart of the study selection is presented in Figure 1 (Liberati 2009).

Figure 1. Study flow diagram.



Data extraction and management

For studies that fulfilled the inclusion criteria, two review authors (NM, LF) independently abstracted the 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; Appendix 8) with any disagreements resolved by discussion, or if required by a third party (LG).

We sent an e-mail to all authors of included studies to enquire whether they were willing to answer questions regarding their trials. We present the results of this e-mail survey in Appendix 9. Thereafter, we sought relevant missing information on the trial from the primary author(s) of the article, if required.

Assessment of risk of bias in included studies

Two review authors (NM, LF) assessed each trial independently. We resolved possible disagreements by consensus, or through consultation with a third party (LG). In cases of disagreement, the rest of the authors were consulted and a judgement was made based on consensus.

We assessed the risk of bias using the Cochrane Collaboration's tool (Higgins 2011a; Higgins 2011b). We used the following criteria.

- Random sequence generation (selection bias).
- Allocation concealment (selection bias).
- Blinding, separated for blinding of participants and personnel (performance bias) and blinding of outcome assessment (detection bias).
- Incomplete outcome data (attrition bias).
- Selective reporting (reporting bias).
- Other bias.

We judged the risk of bias criteria as 'low risk', 'high risk' or 'unclear risk' and evaluated individual bias items as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). We present a 'Risk of bias' graph and a 'Risk of bias summary' figure (Figure 2; Figure 3).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

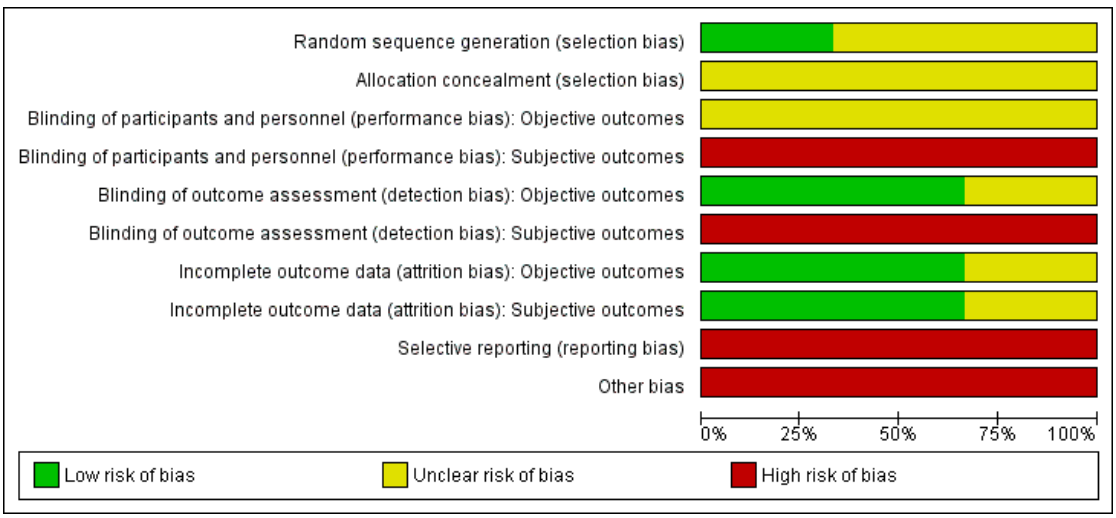
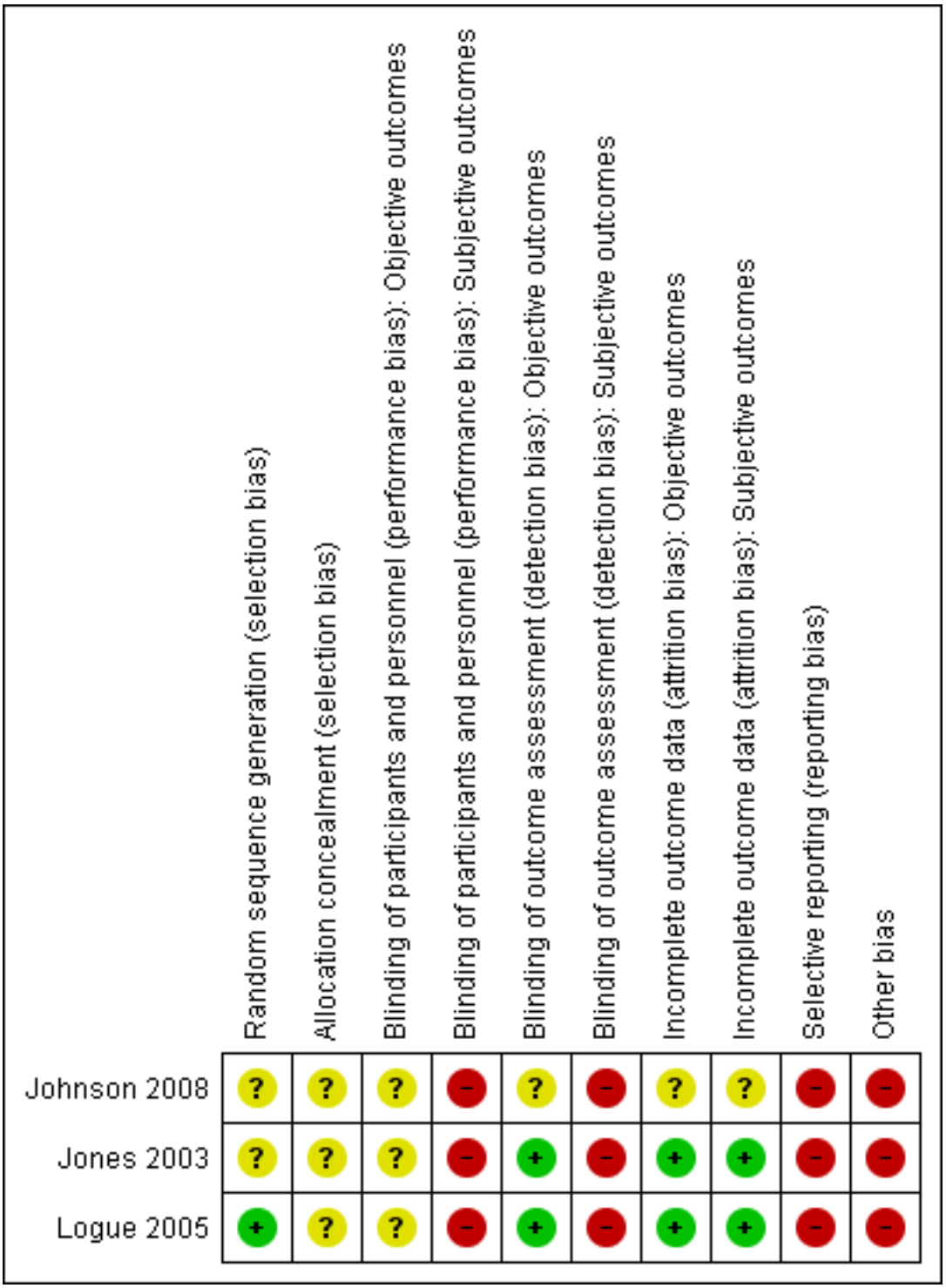


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



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

For performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessors) and attrition bias (incomplete outcome data), we evaluated risk of bias separately for subjective and objective outcomes.

We defined the following outcomes as objective outcomes.

- Sustained weight loss (measured using weight or BMI at one year and above).
- Short-term weight loss (measured using weight or BMI at less than 12 months).
- Measured change in dietary consumption.
- Measured uptake or change in physical activity.
- Change in other weight loss measures (skin fold measurement, waist measurement and waist-to-hip ratio).
- Relapse into unhealthy behaviour and weight gain.
- Morbidity.
- Economic costs.

We defined the following endpoints as subjective outcomes.

- Health-related quality of life.
- Self-reported change in dietary consumption.
- Self-reported uptake or change in physical activity.
- Progression through the SOC.
- Adverse events.

Measures of treatment effect

Dichotomous data were expressed as odds ratios (ORs) or risk ratios (RRs) with 95% confidence intervals (CIs). Continuous data were expressed as differences in means (MDs) with 95% CIs.

Unit of analysis issues

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

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

In a cluster-randomised trial, individuals are randomised in groups (that is the group is randomised, not the person). For example, in a TTM study the patients in one general practice may be randomised as a group to receive either the TTM or usual care. Had cluster-randomised trials been included, we had planned to use appropriate statistical analyses of cluster-randomised trials with the intra-cluster correlation coefficient and design effect playing an important role in these analyses (Campbell 2004). In a cross-over trial, individuals are randomised to a sequence of interventions and each person is his or her own control. Had there been any cross-over trials among the included studies, we would have compared the intervention(s) and control for each patient to assess the effect of the TTM within each patient. Furthermore, we would have examined any potential sources of bias as a result of the cross-over design (for example any carry-over effects that could bias the results). For example, did patients begin the second period (that is the intervention if the first period consisted of the control, or vice versa) in a similar state to how they began the first period, or have the patients' characteristics changed throughout the course of the first period? Analysis of any cross-over trials would have followed guidelines outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). Our initial searches suggested that there would be few if any cross-over trials in the area of the TTM and behaviour modification with respect to obesity.

Dealing with missing data

We contacted the authors to obtain relevant missing data (Appendix 9), if feasible. We carefully performed evaluation of important numerical data, as necessary, with either screened, randomised patients, intention-to-treat (ITT) populations, as-treated or per protocol (PP) populations.

Assessment of heterogeneity

Since substantial clinical and methodological heterogeneity was present across the included trials, study results were not reported as pooled effect estimates from meta-analyses. Had a meta-analysis been appropriate, we would have identified any statistical heterogeneity by visually inspecting the forest plots and using a standard Chi² test with a significance level of $\alpha = 0.1$, in view of the low power of this test. We would have 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% or more would have been considered a considerable level of inconsistency (Higgins 2009).

Furthermore, if a meta-analysis had been conducted and statistical heterogeneity had been found, then we would have attempted to determine potential explanations for this heterogeneity by exploring individual study and subgroup characteristics.

Assessment of reporting biases

We had planned to use funnel plots to assess the potential existence of small study bias, in the case where we could include 10 studies or more investigating a particular outcome. Several explanations

can be offered for the asymmetry of a funnel plot, including true heterogeneity of effect with respect to trial size, poor methodological design (and hence bias of small trials) and publication bias (Sterne 2011).

Data synthesis

We had planned to summarise data statistically if the data were available, sufficiently similar and of sufficient quality (Higgins 2011a). We would have performed analyses according to the statistical guidelines contained in the latest version of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a).

Subgroup analysis and investigation of heterogeneity

In order to avoid a hypothesis-generating situation, we had planned to carry out subgroup analyses only if the primary outcome parameter demonstrated statistically significant differences between the intervention and control groups.
We had planned the following subgroup analyses and to investigate interaction.

- 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.

- Restricting the analysis to published studies.
- Restricting the analysis to take into account risk of bias, as specified in Assessment of risk of bias in included studies.
- Restricting the analysis to very long or large studies to establish how much they dominated the results.
- Restricting the analysis to studies using the following filters: diagnostic criteria, language of publication, source of funding (industry versus other), country.

We had also planned to test the robustness of the results by repeating the analysis using different measures of effect size (RR, OR etc.) and different statistical models (fixed-effect and random-effects models).

RESULTS

Description of studies

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

Results of the search

The original search strategy (from inception to January 2011) identified 2557 records and the updated search (from January 2011 to December 2013) added another 2403 reports. Following initial screening of titles and abstracts, 186 potentially eligible studies (96 and 90 for the original and updated searches, respectively) were identified for full text review. A total of three studies met the inclusion criteria and were included in the updated review. 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'. A total of three studies were included in the review. Two trials (Johnson 2008; Logue 2005) were of parallel design with a one to one randomisation ratio and one trial (Jones 2003) was of factorial design. The transtheoretical model stages of change (TTM SOC) was used as a framework for intervention and assessment in all included studies. Dietary modification and physical activity were common interventions for weight loss. The trials were published between 2003 and 2008, and the study sample size varied from 665 to 1277 participants. Trial durations across the included studies ranged from 9 to 24 months.

Participants and setting

There were a total of 2971 participants across the three trials, 1467 of which were randomised to intervention groups and 1504 to control groups. Two trials (Johnson 2008; Logue 2005) reported the data for participants in the intervention and control groups finishing each study, whilst one trial did not provide this information (Jones 2003). The percentage of participants who completed the studies ranged from 53.7% to 79.2% in the intervention groups and from 66.7% to 82.4% in the control groups. All participants in the three included trials were analysed on the basis of intention to treat (ITT).
An overview of the populations in the included studies is shown in Table 1. The trials were conducted with the participation of overweight and obese adults only. One trial (Logue 2005) included more female participants, whereas two trials (Johnson 2008; Jones 2003) comprised more male than female participants. Two trials reported age as a mean value (Johnson 2008; Jones 2003), whereas one trial (Logue 2005) reported age as a range of values (with included participants ranging between 40 and 69 years). The included trials used a variety of weight entry criteria: two studies used BMI measures only (BMI cut-off points and BMI range) (Johnson 2008; Jones 2003), whilst one trial used BMI with waist-to-hip ratio (WHR) (Logue 2005). Of the two trials that used BMI measures only, one used a BMI cut-off point of 27 kg/m^2 (Jones 2003) while one trial applied a BMI range from 25 to 39.9 (Johnson 2008). Another trial (Logue 2005) used a BMI of at least 25 kg/m^2 alongside WHR for men and women. Overall,

the studies included participants within the BMI range of 25 to 39.9.

One trial (Johnson 2008) did not report whether it included participants with co-morbidities, while two trials included participants with one or more co-morbidities, such as type 2 diabetes mellitus (Jones 2003) and hypercholesterolaemia (Logue 2005). Two trials included participants on a variety of medications, such as psychotropic drugs (Logue 2005) and insulin (Jones 2003), whilst one study provided no information on medications (Johnson 2008). Participants in the included trials were mostly white or Caucasian and African American. Two studies were conducted in the US (Johnson 2008; Logue 2005) and one in Canada (Jones 2003). The baseline characteristics of the included trials are stated in Appendix 5 and Appendix 6.

Interventions

The TTM SOC was used as a framework for intervention and assessment of participants' stages of change in the included studies (Johnson 2008; Jones 2003; Logue 2005) (Appendix 3).

The TTM SOC was used with physical activity or dietary modification, or both, with other interventions. One 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 showed significantly greater weight loss (measured as a direct weight reduction) for those progressing to the action stage compared to those who remained in a pre-action stage (that is contemplation or pre-contemplation) (Jones 2003). Another trial evaluated a combination of physical activity, diet and other interventions such as stress management strategies (by giving individualised feedback) compared to usual care and showed significant sustainable weight loss (measured as a direct weight reduction), particularly at 24 months (Johnson 2008). In addition, a trial involving assessment, advice and 'prescription' of dietary changes and physical activity (alongside anthropometric evaluation) combined with monetary rewards for completing each assessment, compared to augmented usual care, resulted in early weight loss (measured as direct weight reduction) at six months only, but no sustainable weight loss at 12 or 24 months (Logue 2005). The descriptions of interventions for the included trials are shown in Appendix 3.

The trials varied in length of intervention (from 9 to 24 months). One trial (Logue 2005) had an intervention duration of 24 months, another trial lasted for 12 months (Jones 2003), while the length of intervention in one study was nine months (Johnson 2008). Two trials reported final assessments but did not follow up participants after the end of the intervention (Jones 2003; Logue 2005), whilst one trial followed participants at intervals after the intervention (Johnson 2008).

All studies were community-based and were conducted in primary care practices (Logue 2005), health centres (Jones 2003) and homes (Johnson 2008). The majority of interventions were delivered by health professionals, including weight loss advisors, dieticians and counsellors. One trial did not clearly state which personnel delivered the intervention (Johnson 2008).

Outcomes

In our systematic review, the primary outcomes measured were sustained weight loss maintenance (at one to five years and above), short-term weight loss (at 1 to 12 months) (both measured using weight or BMI) and health-related quality of life. One trial reported weight loss at 12 months (Jones 2003) and two trials at 24 months (Logue 2005; Johnson 2008). None of the included studies measured or reported health-related quality of life. The secondary outcomes that were measured were self-reported changes in calorie or energy intake or expenditure (Jones 2003; Johnson 2008; Logue 2005), fruit and vegetable consumption (Johnson 2008; Jones 2003), physical activity frequency (Johnson 2008) and duration (Logue 2005), as well as measured change in waist circumference (Logue 2005) and progression through the SOC (Johnson 2008; Jones 2003). Weight gain was reported as an adverse event in one study (Logue 2005). No other adverse intervention effects were reported. Details of the outcomes are stated in the 'Characteristics of included studies' table and 'Effects of interventions' section of this review.

Excluded studies

In total, there were 183 excluded studies in this review: 93 in the original review and 90 in the updated review. The details of those studies are shown in the 'Characteristics of excluded studies' table. The main reasons for excluding these studies were that other theoretical frameworks, such as cognitive behaviour therapy, self-efficacy theory, social action theory and social cognitive theory, were used in designing the intervention (whether in combination with the TTM SOC or not); study participants were children or adolescents or had a normal body weight (BMI less than 25); or the study design did not meet the criteria for a randomised controlled trial. For instance, one study was excluded as it employed a non-random method (that is alternate allocation) to allocate participants to the intervention and control groups (Vermunt 2011).

Risk of bias in included studies

The risk of bias of the included studies is described in ' Characteristics of included studies'.

All trials had some methodological weaknesses according to the criteria applied. No trial reported adequate methods for randomisation and allocation. None of the included studies reported methods for blinding participants and personnel. Two studies used an intention-to-treat (ITT) analysis to deal with missing objective data (Jones 2003; Logue 2005) while one study used subjective

outcome measures only (ITT was used for missing weight values in a subsample of participants who provided objective data) (Johnson 2008). All studies reported adequate imputation techniques for subjective outcomes. However, they were subjected to reporting bias as they inadequately reported weight loss and other outcome data (Johnson 2008; Jones 2003; Logue 2005). The assessment for each domain is explained below and shown in the 'Risk of bias' graph (Figure 2) and 'Risk of bias' summary (Figure 3).

Allocation

Random sequence generation (selection bias)

One trial reported the method of randomisation (Logue 2005) and was therefore categorised as 'low risk' for selection bias. The other trials stated that participants were randomised and no further explanation was given (Johnson 2008; Jones 2003). These studies were graded 'unclear' with regards to selection bias (Johnson 2008; Jones 2003).

Allocation concealment (selection bias)

One trial reported that allocation to the groups was concealed (Logue 2005) but it was unclear whether concealment was done appropriately. The other two studies did not describe allocation concealment (Johnson 2008; Jones 2003).

Blinding

Blinding (performance bias): objective and subjective outcomes

One trial reported that participants and staff were blinded while obtaining baseline measures; however, it was unclear whether they were blinded during the study (Logue 2005). The rest of the included trials did not explain whether investigators or participants, or both, were blinded during the study (Johnson 2008; Jones 2003). All included trials were considered 'unclear' in terms of blinding for objective outcomes. For subjective outcomes there was a high risk of performance bias in all trials.

Blinding (detection bias): objective outcomes

One study did not use any objective measures (that is weight loss was self-reported) (Johnson 2008), therefore it was classified as 'unclear' with regards to this domain (Johnson 2008). The rest of the included trials did not provide adequate information on blinding during assessment (Jones 2003; Logue 2005). However, it was unlikely that the objective outcomes (that is weight loss measures) were affected by unblinded outcome assessors and therefore these studies were designated 'low risk' for detection bias (Jones 2003; Logue 2005).

Blinding (detection bias): subjective outcomes

The included studies did not explain whether outcome assessors (that is participants in this case) were blinded during assessment (Johnson 2008; Jones 2003; Logue 2005). They were thus considered 'high risk' in terms of detection bias.

Incomplete outcome data

Incomplete outcome data (attrition bias): objective outcomes

Two trials addressed incomplete data for objective outcomes by incorporating imputation techniques (Jones 2003; Logue 2005). One trial did not employ any objective measures and was categorised as 'unclear risk' in terms of attrition bias (Johnson 2008).

Incomplete outcome data (attrition bias): subjective outcomes

The included trials addressed the incomplete data for subjective outcomes by incorporating imputation techniques (Johnson 2008; Jones 2003; Logue 2005). However, one trial had high attrition rates (in total, only 54% in the intervention group and 67% in the control group finished the trial) and was characterised 'unclear risk' with regards to this domain (Johnson 2008). The other two trials were categorised 'low risk' in terms of attrition bias (Jones 2003; Logue 2005).

Selective reporting

Although the study protocols were not available, it appears that the included studies reported all expected outcomes (that is weight loss, diet and physical activity outcomes, SOC progression). However, the included trials did not provide complete weight loss data (that is short-term weight loss, at least 5% weight loss, weight loss at 12 months, energy intake and expenditure) and were thus subjected to a 'high risk' of reporting bias (Johnson 2008; Jones 2003; Logue 2005).

Other potential sources of bias

All trials used valid measures (Johnson 2008; Jones 2003; Logue 2005). However, they also used self-reported instruments to measure subjective outcomes (that is self-reported changes in weight, physical activity, dietary intake and SOC), which has subjected these trials to risk for recall bias. One study performed objective

measures of weight, physical activity and food intake in a subsample of participants (n = 202/1277) to try to protect against recall bias (Johnson 2008).

Effects of interventions

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

For details on primary and secondary outcome measures see Appendix 8. All reported outcomes refer to the comparison of the application of the TTM SOC with 'usual' care.

Meta-analysis for sustained or short-term weight loss, as well as other outcomes, was not appropriate, primarily because of the clinical and methodological heterogeneity across the study interventions. In particular, interventions varied in content, frequency and intention (see Characteristics of included studies). There were also variations in the timing of the outcome measurement and the types of outcomes presented (dichotomous versus continuous, objective versus self-reported) in the included trials. Last but not least, the included studies were methodologically weak with regards to reporting bias and thus meta-analysis could be misleading, if feasible at all.

Primary outcomes

Weight loss

The application of the TTM SOC as a theoretical framework for dietary or physical activity interventions, or both, as well as combined with monetary rewards or stress management interventions, resulted in statistically significant, sustainable (one year and longer) weight loss in one trial (Johnson 2008) while one trial indicated non-significant sustainable weight loss (Logue 2005). Another trial reported significant weight loss for participants in the intervention group in the action stage compared to those in a pre-action stage at 12 months, but no comparison was reported between the intervention and control groups (Jones 2003). None of the trials reported short-term weight loss results (less than 12 months), although short-term weight change was measured in two studies (Johnson 2008; Logue 2005). All trials used a direct measure of weight (kg) as the outcome measure (Johnson 2008; Jones 2003; Logue 2005). Two studies reported objective weight loss outcomes measured at a diabetes centre (Jones 2003) and primary care physician offices using calibrated weight scales (Logue 2005) while one trial used self-reported measures of weight, which were found to correlate well (0.99) with objective measures that were conducted in a subgroup (n = 202) of participants using beam scales (Johnson 2008).

All trials had some methodological weaknesses (see 'Risk of bias in included studies'). In the methodologically strongest trial, the TTM SOC used as a framework for an intervention including assessment, advice and 'prescription' of dietary changes and physical activity (alongside anthropometric evaluation) compared to usual care resulted in early (at 12 months) mean weight loss for both the intervention and control groups; however, the mean difference of -0.5 kg (95% CI -1.3 to 0.3) between the groups at 12 months was not statistically significant (Logue 2005). Furthermore, at the end of the intervention (24 months) 60% of all participants regained the lost weight and returned to their baseline weight. The mean weight change was slightly higher in the intervention group (-0.4 kg; 95% CI -1.1 to 0.4) compared to the control group (- 0.2 kg; 95% CI -1.0 to 0.7) at 24 months, though this difference was statistically non-significant (P = 0.17). The weight change between the intervention and control groups was -0.2 kg (95% CI -1.0 to 0.9; P = 0.50) at 24 months of the trial, indicating no statistically significant effect on sustainable weight loss at either 12 or 24 months (Logue 2005). Although weight change was measured at 6, 12, 18 and 24 months, short-term (six months) results were not provided for this outcome (results for 6 and 12 months were combined, as were those for 18 and 24 months). This trial had a high risk of selective reporting and other bias.

Another trial applied the TTM SOC in combination with diet, physical activity and stress management interventions (Johnson 2008). Participants in the treatment group were categorised into three subgroups for three types of behaviour: healthy eating (that is reducing dietary fat to 30% of calories and calorie reduction of 500 calories per day), physical exercise (that is at least 30 minutes of moderate exercise per day, five days per week or more) and addressing emotional stress (that is using healthy strategies rather than eating to cope with the reduction in food intake). The study showed a statistically significant sustained self-reported weight loss in the treatment group among those who were in a pre-action stage for both healthy eating and exercise (n = 617) compared to the control group (mean difference (MD) -2.1 kg; P < 0.05) at 24 months (Johnson 2008). For those in the healthy eating behaviour group, a weight loss of at least 5% of one's body weight was more frequent amongst participants in the treatment group (27.4%) compared to those in the control group (20.3%) with a statistically significant overall effect at 24 months (OR 1.22 (95% CI 1.01 to 1.48); P < 0.05). Similarly, for the exercise behaviour intervention, a weight loss of 5% or more was more frequent in the treatment group (28.8%) than in the control group (19.4%) with a trend toward significantly increasing differences over time (OR 1.32 (95% CI 0.99 to 1.75); P = 0.05). In the intervention that combined healthy eating and exercise behaviours, a weight loss of 5% or more was more frequent amongst participants in the intervention group (30%) compared to those in the control group (18.6%) at 24 months. The overall intervention effect appeared to increase over time (OR 1.35 (95% CI 1.01 to 1.81); P = 0.05). Although weight loss was self-reported, the investigators collected objective weight measures from a subgroup of 202 participants, which were found to correlate well (0.99) with self-reported data. In addition, despite the fact that participants in both groups completed assessments at baseline, 6, 12 and 24 months, short-term

(six months) or minimally sustainable (12 months) weight loss results were not presented in the report as the scope of the report focused on sustained weight loss only (Johnson 2008). This trial was associated with a high risk of performance and detection bias for this outcome and also had a high risk of selective reporting and other bias.

Finally, a trial used the TTM SOC with diet and blood testing strip interventions to assess participants' readiness to change their behaviour with regards to self-monitoring of blood glucose (SMBG), healthy eating and smoking cessation (Jones 2003). Participants received one or more of the above interventions (SMBG, healthy eating, smoking cessation). The study reported greater sustained weight reduction amongst participants in the healthy eating group who progressed to an action stage (that is individuals who had changed their behaviour) than participants who remained in a pre-action stage (that is individuals in the pre-contemplation, contemplation or preparation stages) for the intervention group at 12 months (1.4 kg versus 0.7 kg), but this did not reach statistical significance (Jones 2003). There was a statistically significant weight loss amongst participants progressing to an action stage compared to those remaining in a pre-action stage for the intervention group (1.8 kg versus 0.3 kg; P < 0.01) in both the SMBG and healthy eating groups at 12 months. Assessments were obtained at 3, 6, 9 and 12 months for the intervention groups and at baseline and 12 months for participants in the control groups. However, the data for the outcomes measured, such as short-term weight loss at three, six and nine months in the healthy eating and both healthy eating and SMBG combined intervention groups, were not reported. In addition, no comparison between the intervention and control groups was reported (Jones 2003). This trial had a high risk of selective reporting and other bias.

Health-related quality of life

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

Secondary outcomes

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

The TTM SOC combined with diet or physical activity, or both, and other interventions often resulted in statistically significant self-reported changes in dietary consumption (measured as change in daily energy or calorie intake or change in daily fruit and vegetable intake, or both) as reported in the included trials (Johnson 2008; Jones 2003; Logue 2005). Dietary consumption was measured using validated Food Frequency Questionnaires (FFQ). All studies employed self-administered retrospective data collection methods to measure the effect of TTM SOC interventions on dietary consumption and thus the results need to be interpreted with caution due to the possibility of recall, performance and detection bias.

Change in daily calorie intake

A trial using the TTM SOC combined with diet and blood testing strip interventions reported significantly lower calorie intake from fat (that is consuming a diet with < 30% fat) amongst participants in the intervention group compared to the control group (35.2% versus 36.1%; P = 0.004) for healthy eating at 12 months (Jones 2003).

In addition, in another trial the TTM SOC application in combination with diet, physical activity and stress management interventions showed a statistically significant overall change (OR 1.61 (95% CI 1.33 to 1.94); P < 0.001) in the number of participants who progressed to the action or maintenance stages in the intervention group compared to the control group for healthy eating behaviour at 6 (43.9% versus 31.3%), 12 (43.1% versus 35.2%) and 24 months (47.5% versus 34.3%) (Johnson 2008). Healthy eating was defined as reducing dietary fat to 30% of calories as well as a reduction of 500 calories per day. The term 'progress to action or maintenance stage' refers to an individual's readiness to engage in a healthy behaviour (Johnson 2008). Dietary calorie intake data for the intervention and control groups at 6 and 12 months were not explicitly reported. In addition, no overall comparison between the TTM SOC and control groups was reported (Johnson 2008).

Finally, a trial that combined the TTM SOC with diet, physical activity and monetary reward interventions reported no statistically significant mean change in energy intake per day in the intervention group compared to the control (P = 0.69) at 24 months (Logue 2005). There was a statistically significant reduction in the mean energy intake per day for both groups combined (- 250 kcal/day; P < 0.0001) throughout the 6 to 24 months follow-up. The mean energy intake values for the intervention and control groups were not provided (Logue 2005).

Change in fruit and vegetable consumption

Two trials reported statistically significant changes in fruit and vegetable consumption at 6, 12 and 24 months. In one trial, when the TTM SOC was applied with a diet intervention a resulting significant (P = 0.016) between-groups change in servings of fruits per day was observed at 12 months, with an average of 1.9 servings for the intervention group compared to 1.7 servings for the control group (Jones 2003). There was also a significant (P = 0.011) increase in vegetable servings in the intervention group (+2.2 servings per day) compared to the control group (+2.1 servings per day) at 12 months (Jones 2003).

In addition, a trial that used the TTM SOC in combination with diet, physical activity and stress management interventions showed

a statistically significant overall change (OR 1.63 (95% CI 1.34 to 1.97); P < 0.0001) in fruit and vegetable consumption for participants progressing to the action and maintenance stage in the intervention group compared to those in the control group at 6 (44.0% versus 31.4%), 12 (45.3% versus 39.6%) and 24 months (48.5% versus 39.0%) (Johnson 2008). Short-term (up to 12 months) fruit and vegetable consumption data for the intervention and control groups were not explicitly reported. Again, no overall comparison between the intervention and control groups was provided (Johnson 2008).

Meta-analysis for this outcome was not appropriate mainly due to the variability in the types of outcomes used (dichotomous versus continuous data).

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

There were two trials (Johnson 2008; Logue 2005) reporting uptake of physical activity using the TTM SOC in combination with diet, physical activity and stress management interventions at 24 months. The outcomes reported were changes in physical activity frequency (that is per cent increased uptake per week) (Johnson 2008) as well as changes in exercise duration (that is minutes per week) and energy expenditure (kcal/kg per day) (Logue 2005). Both studies used validated questionnaires (Johnson 2008; Logue 2005). However, the use of self-reported retrospective data subjected these studies to risk for recall bias, performance and detection bias.

Change in physical activity frequency

In one trial, the TTM SOC in combination with diet, physical activity and stress management interventions showed an increase in exercise habits (that is 30 minutes per day, 5 to 7 days per week) amongst participants progressing to the action and maintenance stage in the intervention group compared to the control group at 6 (43.0% versus 34.6%), 12 (37.7% versus 35.9%) and 24 months (44.9% versus 38.1%) (Johnson 2008). There was a significant group effect among those in the pre-action stages for exercise at baseline, beginning at six months, which was maintained at all time points (OR 1.27 (95% CI 1.03 to 1.57); P < 0.05) (Johnson 2008). No overall comparison between the TTM SOC and usual care groups was provided (Johnson 2008).

Change in physical activity duration

The TTM SOC combined with diet, physical activity and monetary reward interventions resulted in a statistically significant increase in the mean self-reported exercise (minutes per week) in the intervention group versus the control group (P = 0.008) from 6 to 24 months; the mean difference between the intervention and the usual care groups over the total duration of the study (between 6 and 24 months) was 31.5 minutes (95% CI 7.98 to 55.02) (Logue 2005).

Change in energy expenditure

Energy expenditure was measured using weekly physical activity recalls in one study (Logue 2005). The findings showed a significant increase in mean energy expenditure per day (+2 kcal/kg per day; P = 0.04) for both groups combined (Logue 2005). However, the difference in energy expenditure for the intervention group versus the control group was not statistically significant (P = 0.31) at 24 months (Logue 2005). The data on energy expenditure at 6, 12 and 18 months were not explicitly reported. Moreover, the mean energy expenditure values for the intervention and control groups were not provided (Logue 2005).

Change in weight loss measures

Change in other weight loss measures (for example skin fold measurement, waist measurement and waist-to-hip ratio) was reported in one study (Logue 2005). In this study, the TTM SOC in combination with diet, physical activity and monetary rewards interventions showed no significant mean waist girth change in the intervention group compared to the control group (P = 0.57); however, the effects for both groups combined showed a significant decrease in mean waist girth (1.7 cm (95% CI 0.9 to 2.5 cm); P = 0.0001) at 24 months (Logue 2005).

Progression through the SOC

Two trials reported progression through the SOC as an outcome (Johnson 2008; Jones 2003). The term 'progress to action stage' refers to individuals who have changed behaviour within the last six months, whereas 'maintenance stage' refers to individuals who have maintained the behaviour change for at least six months. One trial using the TTM SOC in combination with diet and blood testing strip interventions reported that more participants in the SMBG intervention groups (43.4% for 'pathway to change' plus strips and 30.5% for 'pathway to change' only) progressed to the action or maintenance stages in comparison to the control group (27.0% for treatment as usual plus strips and 18.4% for treatment as usual only) at 12 months (P < 0.001) (Jones 2003). Similarly, there was a greater proportion of participants who moved to the action or maintenance stages in the intervention (32.5%) versus control (25.8%) groups for healthy eating behaviour (P < 0.001). Some of the information for the outcomes measured in the intervention and control groups was not complete, specifically sample size and proportions of no events (Jones 2003).

In addition, in another trial the TTM SOC used in combination with diet, physical activity and stress management interventions showed that a greater proportion of participants progressed to action or maintenance stages (individuals' readiness to engage in healthy behaviour) in the intervention group than the control

group for healthy eating behaviour at 6 (43.9% versus 31.3%), 12 (43.1% versus 35.2%) and 24 months (47.5% versus 34.3%) (Johnson 2008). The overall group effect for all time points was statistically significant (OR 1.61 (95% CI 1.33 to 1.94); P < 0.001). With regards to exercise outcomes, participants in the intervention group were more likely to move to action or maintenance stages compared to the control group at 6 (43.0% versus 34.6%), 12 (37.7% versus 35.9%) and 24 months (44.9% versus 38.1%). There was a significant group effect at six months that was maintained at all time points (OR 1.27 (95% CI 1.03 to 1.57); P < 0.05). In addition, in comparison with the control group, more participants in the intervention group moved to action or maintenance stages in the fruit and vegetable outcome at 6 (44.0% versus 31.4%), 12 (45.3% versus 39.6%) and 24 months (48.5% versus 39.0%). Based on the overall group effect, the association between the intervention and outcome was statistically significant at all time points (OR 1.63 (95% CI 1.34 to 1.97); P < 0.0001). Data on this outcome measure were not adequately reported for the 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.

Weight gain

There was significant weight gain for both the intervention and control groups combined after 12 months (from 12 to 24 months) in one trial (P < 0.0001), but there were no other data reported on the given outcome (Logue 2005). Most participants lost weight during the first 6 to 12 months but then relapsed.

Costs

None of the included trials reported any kind of economic cost as an outcome.

Reporting bias

In this review, it was not possible to assess reporting bias using funnel plots because there were only three trials included, the types of outcomes varied and the estimated effect measures used in each trial differed.

DISCUSSION

Summary of main results

Three trials were identified that met the criteria for the review and were relatively recent (published in the last 10 years). The trials were heterogeneous, particularly in terms of interventions and outcomes and had different sample sizes (from 665 to 1277 participants), with 2971 participants evaluated in total. They were mostly conducted in primary care settings (apart from one intervention which was delivered at home), were mainly delivered by health professionals, and had short to medium term follow-up (24 months or less). Weight in kilograms was the primary body weight measure used in the trials. Waist girth was also used in one trial. The TTM SOC was used as a framework for intervention to assess participants' stage of change. All included trials were performed on an intention-to-treat (ITT) basis.

When looking at the available evidence on sustained weight loss one study using self-reported measures reported a statistically significant difference of 2.1 kg (P < 0.05) in favour of the intervention group (Johnson 2008), while the other study using objective measures found a non-significant difference of 0.2 kg (P = 0.17) when comparing the intervention to the control group (Logue 2005). However, due to the small number of studies and their variable methodological quality (especially with regards to selective reporting), it is challenging to draw solid conclusions about the effectiveness of dietary, physical activity and other TTM SOC-based interventions in producing sustainable (one year and longer) weight loss in overweight and obese adults. Specifically, sustainability of weight loss was not sufficiently assessed in the included studies. Only one study measured weight loss at 12 months follow-up (Johnson 2008), while the other two studies did not include a post-intervention assessment to measure weight loss beyond the end of the intervention (Jones 2003; Logue 2005). In addition, selective reporting was observed with some weight loss and other outcome data not adequately reported. One study provided 12-month weight loss data for the intervention groups only (Jones 2003); another trial just reported post-intervention weight loss data (Johnson 2008); while only one trial provided results at both 12 and 24 months (Logue 2005). Heterogeneity in the measures employed to estimate weight loss was also evident. One study used self-reported weight loss measures with objective measures applied to a subsample of participants (Johnson 2008), while the rest of the included trials used objective measures only (Jones 2003; Logue 2005). The varying levels of weight loss in combination with the limited number and the heterogeneity of studies do not allow firm conclusions about sustainable weight loss.

The review also shows that the TTM SOC combined with physical activity or diet, or both, and other interventions (for example stress management) can produce statistically significant effects on other outcome measures, particularly changes in dietary consumption and physical activity levels. One study reported significant treatment effects for calorie intake (47.5% versus 34.3%; P < 0.001), fruit and vegetable consumption (48.5% versus 39.0%; P < 0.001) and physical activity frequency (44.9% versus 38.1%;

P < 0.05) in the intervention group progressing to action and maintenance stages compared to control at 24 months (Johnson 2008); another study found significant between-group differences for calorie intake from fat (35.2% versus 36.1%; P = 0.004), fruit consumption (1.9 versus 1.7 servings; P = 0.016) and vegetable consumption (2.2 versus 2.1 servings; P = 0.011) at 12 months (Jones 2003); while one trial found non-significant reductions in energy intake (P = 0.69) and expenditure (P = 0.31) but significant differences in exercise duration (31.5 minutes; 95% CI 7.98 to 55.02; P = 0.008) between the intervention and control groups at 24 months (Logue 2005). Although the small number of studies and the use of self-reported measures in these studies did not permit us to collate conclusive evidence about the impact of TTM SOC interventions on dietary and physical activity changes, the available evidence demonstrates some significant improvements in dietary and exercise habits among those receiving a TTM SOC intervention, which is worth noting.

Overall completeness and applicability of evidence

Relevance of the evidence

The TTM SOC is a useful theoretical and pragmatic intervention framework for some aspects of lifestyle modification in overweight and obese individuals. This review aimed to demonstrate the effectiveness of TTM SOC diet or physical activity, or both, and other interventions in producing sustained weight loss. The included studies do not provide strong evidence to judge whether such interventions can lead to sustainable weight loss. The small number of studies and the clinical and methodological heterogeneity among the studies reduce the likelihood of drawing conclusive evidence. Nevertheless, there are some early signs of positive effects of TTM SOC lifestyle modification interventions on diet and physical activity, with participants in the intervention groups significantly reducing calorie intake from fat while increasing fruit and vegetable consumption as well as exercise levels at 12 and 24 months.

External validity

All trials included male and female adult participants from diverse backgrounds and were conducted in community settings. From this aspect, 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 delivered in community settings, including at home. However, the small number of studies, the methodological weaknesses among those studies (for example use of self-reported outcome measures) and the limited contextual heterogeneity (studies were conducted in Canada and the US) hinder the replicability and applicability of findings in other settings. In addition, one trial recruited participants from a selected population, namely people with diabetes, which might affect its generalizability to other settings (Jones 2003). Another trial included obese participants with a number of co-morbidities, such as hypertension, hypercholesterolaemia, arthritis and diabetes (Logue 2005). The two trials that contained participants with co-morbidities (Jones 2003; Logue 2005) did not present analyses by co-morbidity subgroups; therefore, it is unclear whether there would be any significant differences in outcomes with co-morbidities versus without co-morbidities.

Relevance to review's objectives

The included studies provide insufficient information to examine the effectiveness of dietary or physical activity interventions, or both, in some instances also combined with other interventions, based on the TTM SOC for weight loss in overweight and obese adults. Two studies reported between-group differences in weight loss at 24 months and their results varied (Johnson 2008; Logue 2005). Another study provided 12-month weight loss data for the intervention group only (Jones 2003). The review may benefit from studies with at least 12 months duration of intervention and 12 months follow-up to assess the sustainability of weight loss, particularly at 24 months and beyond. 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, clinicians and administrators in health systems across the world. This review can be used to improve the design and evaluation of TTM SOC lifestyle interventions by informing those involved in such programmes about the current limitations in the planning, implementation and evaluation of TTM SOC lifestyle modification programmes and the need for well-designed interventions that apply the principles of the model appropriately to produce sustainable health benefits. It also informs practitioners on existing evidence and expected outcomes (such as weight loss, change in physical activity and dietary intake) when using the TTM SOC with weight management programmes. Finally, it can also serve to inform and enhance patients' understanding of the effectiveness and limitations of TTM SOC weight loss programmes.

The TTM SOC is a promising model of behaviour change. It can lead to improvements in dietary and physical activity habits when combined with diet, physical activity and other interventions. However, there is weak evidence on the impact of TTM SOC interventions on weight loss.

Quality of the evidence

Three randomised controlled trials (including a total of 2971 participants) were evaluated in this systematic review following the use of 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 the intervention and control groups for each outcome were not completely reported in the published reports. There were also variations in the intervention content, frequency and duration, as well as timing of outcome measurement, in the included trials. The Summary of findings for the main comparison provides an assessment of the quality of evidence for weight loss (low quality), physical activity (very low quality evidence) and dietary habits (very low quality evidence). Although the table includes six outcomes, we have been unable to undertake an assessment of quality of life, adverse events and cost data due to inadequate information.

One of the key methodological limitations in the included trials was the selective reporting of weight loss data, hindering assessment of the effectiveness of TTM SOC lifestyle interventions in producing short and long-term weight loss. Selective data disclosure was also observed in the reporting of diet and physical activity outcomes. We considered imprecision to affect the quality of evidence across all the outcomes. Two of the three interventions did not include a post-intervention assessment and therefore it was challenging to assess long-term weight loss sustainability, prompting us to downgrade the outcome for indirectness. There was also inadequate reporting of information on methods of randomisation, allocation concealment and blinding in most trials, to the extent that most studies were categorised as 'unclear' in terms of bias. Other potential sources of bias were also identified (for example recall bias due to self-reported data gathering). The trials were performed on an intention-to-treat basis but the aforementioned bias issues affected the internal validity of the results, leading us to downgrade the evidence due to risk of bias across the outcomes reported in the Summary of findings for the main comparison.

Potential biases in the review process

The ways in which potential biases in the review process were minimised include well-defined inclusion and exclusion criteria; independent data extraction by two assessors; and use of the Cochrane risk of bias tool (Higgins 2009). Though not necessarily a limitation, conclusions on sustainable weight loss beyond two years cannot be made since only a small number of studies met the inclusion criteria and these studies measured weight loss up to two years. It was not possible to assess reporting bias using funnel plots primarily because the types of outcomes and the estimated effect measures used in each trial were different. Furthermore, due to the heterogeneity across the studies and the lack of ability to combine the trials into a meta-analysis, it is challenging to make a firm judgement about sustainable weight loss up to two years when one study reports significant effects, one finds no significant sustainable weight loss, and another trial does not report an overall between-group comparison.

Agreements and disagreements with other studies or reviews

The included studies do not provide conclusive evidence about the effectiveness of the TTM SOC in combination with physical activity or diet, or both, and other interventions in producing sustainable weight loss (the mean difference in the included studies was between 2.1 kg and 0.2 kg at 24 months). Several reviews support this finding, although they did not look specifically at the TTM SOC as a theoretical framework, and emphasize the need for well-designed clinical trials to assess the effectiveness of such interventions. A large systematic review of dietary and lifestyle therapy interventions showed a mean weight loss of 3.5 (SD 2.4) kg after two to three years amongst overweight and obese individuals, which was increased to 3.6 (SD 2.6) kg after four to seven years (Douketis 2005). However, the authors concluded that the methodological limitations in the included studies hinder the applicability of the findings to obese participants assessed in everyday clinical practice and that additional research is needed to assess the effectiveness and clinical significance of such interventions. Similarly, 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). Again, the review author pointed out potential methodological flaws in the included studies (for example unclear randomisation, lack of blinding, high attrition rates) that can bias the results and the author highlighted the need for high quality clinical trials that fulfil the requirements of evidence-based medicine. Another large systematic review argued that exercise combined with diet resulted in a greater weight reduction than diet alone or physical activity alone (MD -1.0 kg) (Shaw 2006). However, the authors recognised that no conclusive evidence can be drawn from the included trials as their duration varied from 3 to 12 months, hindering evaluation of weight loss sustainability.

In addition, this review provides early evidence that the TTM SOC combined with diet or physical activity, or both, and other interventions can improve exercise and dietary habits, in particular reduced fatty food intake and increased fruit and vegetable consumption, which were sustainable over relatively long periods (12 to 24 months). This finding contrasts with the results from an earlier TTM SOC and diet review which reported mixed evidence on dietary change amongst overweight and obese adults. However, the authors of 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 the studies (Ni Mhurchu 1997). The studies

included in the review were not specifically randomised controlled trials and the limited number of trials at that time, combined with the use of a less robust review methodology, may have affected the results.

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 community settings, including at home. This review aimed to assess the use of the TTM SOC as a theoretical framework for dietary interventions or physical activity interventions, or both, in weight loss management for overweight and obese adults. The small number of studies and the clinical and methodological heterogeneity among the studies reduce the ability to draw firm conclusions. The included studies provide low quality evidence on the impact of TTM SOC interventions on sustainable weight loss (the mean difference between the intervention and control groups ranged from 2.1 kg to 0.2 kg at 24 months). There is very low quality evidence that TTM SOC and a combination of physical activity or diet, or both, and other interventions (such as stress management and self-monitoring of blood glucose) can result in significant improvements in dietary (that is reducing dietary fat by 30% and increasing fruit and vegetable servings) and physical activity (that is an increase in mean self-reported exercise (minutes per week) by around 30 minutes) habits. The review highlights the need for well-designed randomised controlled trials, applying the principles of the TTM SOC appropriately to produce sustainable health benefits, in order to judge the effectiveness of such interventions. Nevertheless, health managers, administrators and practitioners can use evidence from this review to improve the design and evaluation of TTM SOC lifestyle interventions as well as to better plan, implement and evaluate weight management programmes. In addition, consumers can use the review to enhance their understanding of the effectiveness and limitations of TTM SOC weight loss interventions. Overall, the review may help to improve knowledge, understanding and practice in tackling the important global health challenge of obesity.

Implications for research

Only three randomised controlled trials with 9 to 24 months duration of intervention and follow-up were included in the review. This may have affected the strength of the evidence. The review may have shown different outcomes, particularly on sustainable weight loss, if all the included trials had applied the principles of the TTM SOC appropriately and assessed weight loss sustainability in follow-up periods (with at least one-year intervention and one-year follow-up). In addition, the trials were heterogeneous, specifically in terms of interventions and outcomes. It is vital that trials report clear and detailed descriptions of their intervention(s) and the primary and secondary outcome measures to minimise the issue of heterogeneity and to enable meta-analyses, 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). Using a protocol when conducting and reporting research may reduce potential biases and enhance the quality of the study.

There is a need for well-designed randomised controlled trials, preferably with large sample sizes and long durations of intervention and follow-up, to evaluate the effectiveness of the TTM SOC for sustainable weight loss in overweight and obese adults. Future trials need to formulate specific and objective outcome measures, especially patient-important outcomes such as health-related quality of life, so that appropriate statistical analyses can be conducted to measure their independent impact on sustained weight loss. Finally, a robust systematic review of non-randomised controlled trials to assess the effectiveness of the 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]*

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 and 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) **Diagnostic criteria**: BMI was 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:** used TTM SOC as assessment and feedback construct for diet (healthy eating - reducing dietary fat to 30% of calories and calories reduction of 500 calories per day), physical activity (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	**Outcomes** (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 (t (1, 614) = 2.12kg, P < 0.05, df 0.17) at 24 months In healthy eating group - weight loss of at least 5% of body weight was higher in intervention (27.4%) versus control (20.3%) (t (1, 1119) = 2.07, P < 0.05, OR 1.22, 95% CI 10.1 to 1.48) at 24 months. In exercise behaviour - weight loss 5% or more was higher in intervention (28.8%) than control (19.4%) (t (1, 711) = 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 loss 5% or more was higher amongst participants in intervention (30%) versus control (18.6%) groups at 24 months (t (1, 615) = 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%); 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) 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%); overall group effect

	at all time points (t (1, 856) = 5.01, P < 0.0001, OR 1.63, 95% CI 1.34 to 1.97) In exercise behaviour - more participants progressed to action and maintenance stage in the intervention group compared to control group 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 for all time points (t (1, 711) = 2.25, P < .05, OR 1.27, 95% CI 1.03 to 1.57) **Additional outcomes**: management of emotional distress was higher in intervention group compared with control group at 6 (44% versus 25.3%), 12 (45% versus 38.3%), and 24 months (49.7% versus 30.3%)
Study details	**Duration of intervention**: 9 months **Duration of follow-up**: 12 and 24 months **Study terminated before regular end**: not stated
Publication details	**Language of publication**: English **Non-commercial funding**: NHLBI grant **Publication status (peer review journal)**: full article
Stated aim for study	"To conduct the first randomised effectiveness trial with a one-year extended follow-up to examine the impact of fully tailored, home-based, TTM-based multiple behavior interventions targeting behaviours essential to healthy weight management in a population of overweight and obese adults"
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 from publication: "Overweight or obese adults were randomised to no-treatment control or home-based. A sample of 1277 were recruited nationwide and randomized to treatment or control" Comment: no other details given
Allocation concealment (selection bias)	Unclear risk	Comment: method of concealment is not described
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: not applicable in this study (there were no objective measures)
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: the study design could have introduced bias for subjective outcomes

Johnson 2008 (*Continued*)

Blinding of outcome assessment (detection bias) Objective outcomes	Unclear risk	Comment: not applicable in this study (there were no objective measures)
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: the study design could have introduced bias for subjective outcome
Incomplete outcome data (attrition bias) Objective outcomes	Unclear risk	Comment: not applicable in this study (there were no objective measures)
Incomplete outcome data (attrition bias) Subjective outcomes	Unclear risk	Quote from publication: "Multiple imputation was used to estimate missing data for the 6, 12, and 24 months assessments" Comment: high attrition rates
Selective reporting (reporting bias)	High risk	Comment: although the study protocol was not available, it seems that all expected outcomes were included in the report. However, some outcome data (e.g. short-term weight loss and weight loss of at least 5%) were not completely reported
Other bias	High risk	Comment: there is no information on sample power calculations to support the significance of findings. Additionally, there is no reference to participants giving informed consent. The trial employed subjective measures only (e.g. Fred Hutchinson FFQ, Godin Leisure-Time Exercise Questionnaire). Risk of recall bias due to the use of self-reported instruments However, investigators also performed objective measures of weight, physical activity, and food intake in a subsample of participants (n = 202/1277) which were found to correlate well with self-reported measures

Jones 2003

Methods	**Factorial randomised controlled clinical trial (stratification according to insulin or oral antidiabetic use; randomisation to treatment with PTC or TAU as well as regarding receipt of free blood testing strips)**
Participants	**Inclusion criteria**: adults (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 and others (on diet therapy alone, if could not respond to

	English, if required more than usual care, no telephone **Diagnostic criteria**: BMI, dietary intake using food frequency questionnaire and others (blood glucose meter, SOC algorithms, venous blood sample) **Co-morbidities**: type 1 and type 2 diabetes **Co-medications**: insulin or oral antihyperglycaemic agents
Interventions	**Number of study centres**: general diabetes population **Country/location**: Canada/Southern Ontario, Nova Scotia **Setting**: delivered by investigators and healthcare 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 (stage-matched PTC, assessed at baseline, 3, 6, 9 and 12 months), self-help manuals for diabetes, monthly newsletters and telephone counselling, staged-based personalised 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**: none
Outcomes	**Outcomes** (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 versus 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 (35.2% versus 36.1%, P < 0.004) at 12 months; significant increased servings of fruit per day for PTC versus usual diabetes treatment (OR 1.89 vs OR 1.68, P < 0.01); and higher vegetables servings for PTC versus usual diabetes treatment (OR 2.24 versus 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%) versus 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%) versus usual diabetes treatment (25.8%) group (P < 0.001) at 12 months
Study details	**Duration of intervention**: 12 months **Duration of follow-up**: 3, 6, 9 and 12 months, no follow-up after end of intervention **Study terminated before regular end**: no
Publication details	**Language of publication**: English **Commercial funding**: LifeScan, a Johnson & Johnson Company **Publication status (peer review journal)**: full article
Stated aim for study	"To determine whether the Pathways to Change (PTC) intervention would result in greater readiness to change, greater increase self-care and improved diabetes control"

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 PTC: pathways to change; SMBG: self-monitoring blood glucose; TAU: treatment as usual

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote from publication: "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 other details given
Allocation concealment (selection bias)	Unclear risk	Comment: the method of concealment is not described
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: no information provided
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: the study design could have introduced bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Comment: no information provided; however, it is unlikely that objective outcomes (i.e. weight loss measures) have been affected by unblinded outcome assessors
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: the study design could have introduced bias for subjective outcome
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: "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... Participants who did not complete the study were coded as remaining in pre-action for the intention-to-treat (ITT) analyses" Comment: all participants were included in the final analyses

Jones 2003 (*Continued*)

Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: "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... Participants who did not complete the study were coded as remaining in pre-action for the intention-to-treat (ITT) analyses" Comment: all participants were included in the final analysis
Selective reporting (reporting bias)	High risk	Comment: although it appears that all expected outcomes were included in the report (the study protocol was not available) weight loss data were not completely reported
Other bias	High risk	Comment: there is no information on power calculation and informed consent. The study used valid instruments, but there is risk for recall bias due to the use of self-administered questionnaires (e.g. NCI Block FFQ)

Logue 2005

Methods	**Parallel randomised controlled clinical trial**
Participants	**Inclusion criteria**: adults (40 - 69 years), male and female, BMI > 27, waist-to-hip ratio > 0.95 for men or > 0.80 for women **Exclusion criteria**: age and BMI not stated and 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) **Diagnostic criteria**: BMI, waist girths and other criteria (blood lipids, blood pressure, daily energy intake and 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**: USA/Ohio **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 vegeta-

	bles) every 2 months; assessment on anthropometric, dietary and exercise 6 monthly; 10 min counselling on diet; prescriptions (dietary and exercise); monetary reward for completing each post baseline assessment **Control**: augmented usual care; assessment on anthropometric; dietary and exercise 6 monthly; 10 min counselling on diet; prescriptions (dietary and exercise); monetary reward for completing each post baseline assessment **Treatment before study**: none
Outcomes	**Outcomes** (as stated in the protocol/registered trial documents) **Primary outcome(s)**: early mean weight loss greater in I group 0.5 kg (SE = 0.4 kg) vs C group at 6 and 12 months; higher mean weight loss in I group (-0.39 kg, SE 0.38 kg, 95% CI -1.1 to 0.4) versus C group (-0.16 kg, SE 0.42 kg, 95% CI -1.0 to 0.7) and weight loss difference was 0.23 kg (P = 0.50, 95% CI -1.4 to 0.9); weight mean change for I group and C group combined was -0.29 kg (95% CI -0.9 to 0.3) at 24 months; no significant mean waist girth change for I group versus C group; decreased mean waist girth for I group and C group combined (1.7 cm, 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 mean energy intake per day for I and C groups combined (-250 kcal/d, P < 0.0001) throughout the 6 to 24 months; mean energy expenditure for I group compared to C group not significant (P = 0.31); energy expenditure mean increased (~2 kcal/kg per day, P = 0.04) for I and C groups combined at 24 months; significant increase 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 lipids showed no difference; mean blood pressure showed no difference
Study details	**Duration of intervention**: 24 months **Duration of follow-up**: assessment done at 6, 12, 18 and 24 months, no follow-up after end of intervention **Study terminated before regular end**: no
Publication details	**Language of publication**: English **Non-commercial funding**: Agency for Healthcare Research and Quality and the National Institute of Diabetes, Digestive, and Kidney Diseases Grants, Nutrition and Exercise Studies grants from the Summa Health System Foundation **Publication status (peer review journal)**: full article
Stated aim for study	"To compare health benefits achieved in a transtheoretical model-chronic disease minimal intervention for obesity versus augmented usual care"
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	

Logue 2005 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from publication: "Participants were randomised by opening an envelope with a set of ordered tickets indicating "TM-CD" or "Traditional" care. The Office of Biostatistics prepared the ordered randomisation tickets using permuted blocks of 10" Comment: random sequence generation not exactly described; however, because the office of biostatistics prepared the lists we assume correct randomisation
Allocation concealment (selection bias)	Unclear risk	Quote from publication: ""Participants were randomised by opening an envelope with a set of ordered tickets indicating "TM-CD" or "Traditional" care. The Office of Biostatistics prepared the ordered randomisation tickets using permuted blocks of 10... Participants and research staff at each practice were blind to the assignment of patients while obtaining baseline measures" Comment: unclear whether envelopes were sealed and opaque
Blinding of participants and personnel (performance bias) Objective outcomes	Unclear risk	Comment: no information is provided to allow judgement of performance bias
Blinding of participants and personnel (performance bias) Subjective outcomes	High risk	Comment: the study design could have introduced bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective outcomes	Low risk	Comment: no information is provided; however, it is unlikely that objective outcomes (i.e. weight loss measures) have been affected by unblinded outcome assessors
Blinding of outcome assessment (detection bias) Subjective outcomes	High risk	Comment: the study design could have introduced bias for subjective outcome
Incomplete outcome data (attrition bias) Objective outcomes	Low risk	Quote from publication: "'An intention-to-treat analysis including all randomised participants was performed using linear models and linear mixed (repeated-mea-

		sures) models using baseline variables, unstructured covariance matrices, and a missing at random (MAR) assumption" Comment: baseline weight was used for 12% of patients with missing weights for month 18 or 24 months
Incomplete outcome data (attrition bias) Subjective outcomes	Low risk	Quote from publication: "An intention-to-treat analysis including all randomised participants was performed using linear models and linear mixed (repeated-measures) models using baseline variables, unstructured covariance matrices, and a missing at random (MAR) assumption" Comment: attrition was adequately addressed
Selective reporting (reporting bias)	High risk	Comment: although it appears that all expected outcomes were included in the report (the study protocol was not available) , it is clear that some outcome data (e.g. short-term weight loss) were not completely reported
Other bias	High risk	Comment: the trial used valid measures and provided detailed information on sample power and participant informed consent. However, there is risk for recall bias due to the use of self-reported instruments (e.g. Stanford 7-Day Recall Questionnaire)

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

Study	Reason for exclusion
Albright 2012	Ineligible participants and use of TTM in combination with other theoretical framework: randomised controlled trial with with non-overweight and obese participants included in the study using the TTM SOC and the social cognitive theory as framework for intervention
Annunziato 2009	Other theoretical framework: randomised controlled trial using the cognitive behaviour therapy as framework for intervention
Anton 2011	Other theoretical framework: randomised controlled trial, the TTM SOC was not used as framework for intervention

(*Continued*)

Arrebola 2011	Ineligible study design and use of other theoretical framework: non-randomised pilot clinical trial with unspecified theoretical framework for intervention
Bennett 2010	Other theoretical framework: randomised controlled trial using the self-efficacy theory and obesogenic behaviour change principles as framework for intervention
Bibeau 2008	Ineligible participants: randomised controlled trial with children as participants included
Blalock 2002	Ineligible study participants: randomised controlled trial with participants' body mass index (BMI) status not specified
Bonner 1997	Ineligible study design and participants: non-randomised experimental design with participants' BMI not stated
Bourke 2011	Other theoretical framework: randomised controlled trial using the self-monitoring theory as framework for intervention
Burke 2002	Other theoretical framework: randomised controlled trial with unspecified theoretical framework for intervention
Carlson 2012	TTM SOC and other theoretical framework: randomised controlled trial using the TTM and the social cognitive theory as framework for intervention
Chin 2002	Ineligible participants and use of other theoretical framework: randomised controlled trial with participants' BMI less than or equal to 25 and TTM SOC not used as framework for intervention
Christensen 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Clark 2011	Ineligible participants: study design and methodology paper describing an intervention to promote the maintenance of both exercise and healthful eating in older adults (BMI not stated)
Cleanthous 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Coday 2002	Other theoretical framework: randomised controlled trial using the social action theory as framework for intervention
Coleman 2012	Ineligible study outcomes: randomised controlled trial using the TTM SOC as framework of intervention, weight change is not measured
Collins 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Craigie 2011a	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Craigie 2011b	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention - study protocol

(*Continued*)

Dallow 2003	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the self-efficacy theory as frameworks for intervention
De Vet 2007	Ineligible participants: randomised controlled trial with non-overweight and obese participants included in the study
Dekkers 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Demark-Wahnefried 2008	Other theoretical framework: randomised controlled trial using the social cognitive theory as framework for intervention
Demark-Wahnefried 2012	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the social cognitive theory as frameworks for intervention
Desouza 2012	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Digenio 2009	Other theoretical framework: randomised controlled trial using behaviour treatment strategies as framework for intervention
Dinger 2007	Ineligible study outcomes: randomised controlled trial using the TTM SOC as framework of intervention, weight change is not measured
Donnelly 2008	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
DPPRG 2009	Other theoretical framework: randomised clinical trial using lifestyle curriculum strategies as framework for intervention
Drieling 2011	TTM SOC + other theoretical framework: randomised controlled trial using the TTM SOC and the social cognitive theory as framework for intervention
Eriksson 2009	Ineligible participants: randomised controlled trial using the TTM SOC as framework for intervention with normal weight participants included
Estabrook 2012	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Feldman 2000	Ineligible participants: randomised controlled trial among women with unspecified BMI status
Fernandez 2009	Ineligible participants: randomised controlled trial applying the TTM SOC with normal weight participants included
Ferrara 2011	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the social cognitive theory as framework for intervention
Ferre 2012	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention

(*Continued*)

Finckenor 2000	Ineligible study design and participants: non-randomised experimental design with non-equivalent control group and participants' BMI status not stated
Fitch 2012	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Folta 2009	Ineligible participants and use of other theoretical framework: randomised controlled trial using the social cognitive theory as framework for intervention and participants with normal weight included
Fortier 2011	Other theoretical framework: randomised controlled trial using the self-determination theory as framework for intervention
Fox 2009	Other theoretical framework: randomised controlled trial using the social cognitive theory as framework for intervention
Foy 2011	Other theoretical framework: randomised controlled trial using the social cognitive theory as framework for intervention
Frisch 2009	Other theoretical framework: randomised controlled trial using telemedicine principles as framework for intervention
Gill 1998	Ineligible study design and use of other theoretical framework: non-randomised experimental design using biopsychosocial model as framework for intervention
Glanz 1994	Ineligible study design: cross-sectional prospective study
Greene 1998	Ineligible participants: randomised controlled trial with normal weight participants included in the study
Groeneveld 2011a	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Groeneveld 2011b	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Gusi 2008	Other theoretical framework: randomised controlled trial using no explicit behaviour model or theory as framework for intervention
Gögebakan 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Hageman 2011	Other theoretical framework: randomised controlled trial using the health promotion model as framework of intervention
Heideman 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Hersberger 2006	Ineligible study design: prospective evaluation study with no intervention and control group, using diabetes risk assessment and TTM SOC as framework for intervention

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Hughes 2011	Ineligible participants: randomised controlled trial using TTM SOC as framework for intervention, some normal-weight participants were included in the study
Hui 2012	Ineligible participants: randomised controlled trial, some normal-weight participants are included in the study
Huisman 2009	Other theoretical framework: randomised controlled trial using self-regulation principles as framework for intervention
Hussien 2007	Other theoretical framework: randomised controlled trial with no theoretical model use as framework for intervention
Imayama 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Irvine 2011	TTM SOC and other theoretical framework: randomised control trial using the TTM SOC, the social cognitive theory and the theory of reasoned action as framework for intervention
Irwin 2004	Ineligible participants and TTM SOC used in combination with other theoretical framework: randomised controlled trial using TTM SOC and self efficacy as theoretical frameworks for intervention and participants with normal weight included
Jackson 2011	Ineligible participants: randomised controlled trial with normal-weight participants included
Jacobs 2011a	Other theoretical framework: randomised controlled trial using the theory of planned behaviour and the self-determination theory as framework for intervention
Jacobs 2011b	Other theoretical framework: randomised control trial using the theory of planned behaviour and the self-determination theory as framework for intervention
Jakicic 2012	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Jeffery 1999	Ineligible study design and participants: a follow-up prospective study design of a randomised controlled trial with participants within normal BMI range
Jeffery and French 1999	Other theoretical framework: randomised controlled trial with no theoretical model use as framework for intervention
Jimmy 2005	Ineligible participants: randomised controlled trial with normal weight participants aged below 18 included in the study
Johnson 2006	Ineligible participants: randomised controlled trial with undefined participants' weight categories
Jones 2005	Ineligibel study design using the TTM SOC and other theoretical framework: prospective study using the self efficacy theory and the TTM SOC as frameworks for intervention

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Jonsson 2009	Other theoretical framework: randomised controlled trial using Paleolithic diet principles as framework for intervention
Kallings 2009	TTM SOC and other theoretical framework: randomised controlled trial using social cognitive theory, TTM SOC, motivational interviewing and supportive environment as theoretical frameworks for intervention
Katula 2011	Other theoretical framework: randomised control trial using the social cognitive theory as framework for intervention
Kelly 2005	Ineligible study design using the TTM SOC and Other theoretical framework: cross-sectional study using the TTM SOC and the decisional balance theory as framework for intervention
Kennedy 2009	Other theoretical framework: randomised controlled trial using unspecified theoretical framework for intervention
Keranen 2009	Other theoretical framework: randomised controlled trial using effective counselling principles as theoretical framework for intervention
Kim 2011	Ineligible participants: randomised controlled trial using the TTM SOC as framework of intervention with normal-weight participants included in the study
Kim 2013	Pilot study, not a randomised controlled trial
Kirk 2003	Ineligible participants: randomised controlled trial with normal-weight participants included in the study
Korpi-Hyovalti 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Kraschnewski 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Kris-etherton 2002	Other theoretical framework: randomised controlled trial using unspecified theoretical framework for intervention
Kumanyika 2011	Other theoretical framework: randomised controlled trial using the social learning theory as framework for intervention
Laforge 1994	Ineligible study design: cross-sectional study using the TTM SOC as framework for intervention
Latka 2009	Ineligible participants: randomised controlled trial using the TTM SOC as framework for intervention with normal weight participants included
Lee 1996	Ineligible study design and participants: non-randomised prospective experimental study with participants' BMI status not stated
Lee 2009	Other theoretical framework: randomised controlled trial using counselling principles as framework for intervention

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Lee 2012	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the social cognitive theory as framework for intervention
Leichtle 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Lim 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Luley 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Luoto 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Ma 2009	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the social cognitive theory as theoretical framework for intervention
Macrodimitris 2005	Ineligible study design and participants: 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
Mardones 2009	Ineligible study design: cross-sectional descriptive study to assess participants' TTM SOC
Martin 2007	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the social cognitive theory
McDermott 2012	Ineligible participants and use of other theoretical framework: randomised controlled trial using the social cognitive theory as framework for intervention and including some normal-weight participants
McTiernan 1999	TTM SOC and other theoretical framework: randomised controlled trial using the cognitive-behavioural skills framing and the TTM SOC as theoretical framework for intervention
Merriam 2009	Other theoretical framework: randomised controlled trial using the social cognitive theory as framework for intervention
Methapatara 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Monteiro 2011	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC, the social cognitive theory and the Precede-Proceed Framework - unclear if all participants are overweight/obese
Morgan 2009	Other theoretical framework: randomised controlled trial using the social cognitive theory as framework for intervention
Morgan 2011	Other theoretical framework: randomised controlled trial using the social cognitive theory and the family systems theory as framework for intervention

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Munakata 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Nakade 2012	TTM SOC and other theoretical framework: randomised controlled trial, the TTM SOC used in combination with other behavioural approach
Nakata 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Nanchahal 2009	Other theoretical framework: randomised controlled trial using unspecified theoretical framework for intervention
Nicklas 2012	Other theoretical framework: randomised controlled trial using unspecified theory as framework for intervention
Nilsen 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Oden 2005	Ineligible study design and participants: experimental study with underweight and normal-weight participants included in the study
Ostbye 2009	TTM SOC and other theoretical framework: randomised controlled trial using the social cognitive theory, the stages of readiness and motivation models as framework for intervention
Ostbye 2011	Other theoretical framework: randomised controlled trial using self-regulatory techniques as framework for intervention
Ostendorf 1998	Ineligible study design: cross-sectional exploratory descriptive study
O'Connell 1988	Ineligible study design and participants: cross-sectional study among graduate and undergraduate students with participants' BMI status not specified
Pace 2013	The TTM SOC used in combination with other behavioural approach (TTM + motivational interviewing / small changes approach): practices were randomized to an enhanced practice approach that involved both clinicians and office staff making personal changes and creating a healthy practice environment. The enhanced practices were compared with traditional practices, which were trained and asked to use the tools directly with patients
Parikh 2012	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Parra 2010	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the social cognitive theory as framework for intervention with normal-weight participants included
Partick 2009	Other theoretical framework: randomised controlled trial using behavioural and dietary strategies as framework for intervention
Pekmezi 2009	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the social cognitive theory as framework for intervention

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Pellegrini 2012	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Petrofsky 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Petry 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Pett 2013	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the social cognitive theory / ecological theory of human development as frameworks for intervention
Pettman 2009	Other theoretical framework: randomised controlled trial using unspecified theoretical framework for intervention
Pinto 2002	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the social cognitive theory as framework for intervention
Pinto 2005	Ineligible participants: randomised control trial with normal weight participants included
Prestwich 2010	Ineligible participants and use of other theoretical framework: randomised controlled trial using the Intention behaviour gap theory and the theory of goal systems as framework for intervention - normal-weight participants included
Prochaska 2008	Ineligible participants: randomised controlled trial with normal weight participants included
Provencher 2009	Other theoretical framework: randomised controlled trial using a health-centred approach as framework for intervention
Rejeski 2011	Other theoretical framework: randomised controlled trial using self-regulatory techniques as framework for intervention
Retterstol 2009	Other theoretical framework: randomised cross-over study using dietary strategies as framework for intervention
Rimmer 2009	Other theoretical framework: randomised controlled trial using unspecified theoretical framework for intervention
Robinson 2007	Ineligible participants: randomised controlled trial with normal-weight participants included
Roesch 2010	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the social cognitive theory as framework for intervention
Ross 2009	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the social cognitive theory as framework for intervention
Ross 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention

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Ross 2012	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the social cognitive theory as framework for intervention
Ruusunen 2012	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Saito 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Salinero-Fort 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Sarkin 2001	Ineligible study design: cross-sectional study design
Schelling 2009	Other theoretical framework: randomised controlled trial using cognitive behavioural strategies as framework for intervention
Schlenk 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Schumann 2006	Ineligible participants: randomised controlled trial among smokers with specified BMI status
Shahnazari 2013	The TTM SOC used in combination with motivational interviewing (SOCMMI)
Shuger 2011	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the social cognitive theory as framework for intervention
Siegel 2010	Other theoretical framework: randomised controlled trial using the social cognitive and self-efficacy theories as framework for intervention
Silva 2008	Other theoretical framework: randomised controlled trial using the self-determination theory as framework for intervention
Silva 2010	Other theoretical framework: randomised controlled trial using the self-determination theory as framework for intervention
Silva 2011	Other theoretical framework: randomised controlled trial using the self-determination theory as framework for intervention
Smith 2007	Ineligible study design: cross-sectional study design
Soureti 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Staudter 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Steptoe 2001	Ineligible study outcomes: randomised controlled trial using the TTM SOC as framework of intervention - weight change is not measured

(*Continued*)

Stewart 2011a	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Stewart 2011b	Other theoretical framework: the TTM SOC is not used as framework of intervention (pilot study)
Straznicky 2012	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Surkan 2012	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC, the social learning theory and the social support model as framework for intervention
Sutton 2003	Ineligible study design: a trial's baseline assessment study
ter Bogt 2011a	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
ter Bogt 2011b	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Turner 2011	Other theoretical framework: randomised controlled trial using the social cognitive theory as framework for intervention
Unick 2011	Other theoretical framework:randomised controlled trial, the TTM SOC is not used as framework of intervention
Vallis 2003	Ineligible study design: cross-sectional study comparing patients at entry into an intervention trial
Van der Vee 2002	Ineligible participants: randomised controlled trial with normal-weight participants included in the study and a duplicate publication
van Genugten 2012	Other theoretical framework: randomised controlled trial using the self-regulation theory as framework for intervention
van Wier 2011	Other theoretical framework: randomised controlled trial using the social cognitive theory as framework for intervention
Vazquez 2009	Other theoretical framework: randomised controlled trial using unspecified theoretical framework for intervention
Verheijden 2004	Ineligible participants: randomised controlled trial with normal-weight participants included
Vermunt 2011	Ineligible study design: non-randomised controlled trial, alternate allocation of participants to intervention and control group
Veverka 2003	Ineligible participants: randomised controlled trial with normal-weight participants included in the study
Vinter 2011	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention

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Waddden 2009	Other theoretical framework: randomised controlled trial using unspecified theoretical framework for intervention
Wadden 2011	Other theoretical framework: randomised controlled trial using the social cognitive theory and behavioural self-management theories as framework for intervention
Watson 2012	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
Webber 2010	Other theoretical framework: randomised controlled trial using self-efficacy theory and motivational interviewing principles as framework for intervention
Weber 2012	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention, methodology paper
Wee 2005	Ineligible study design and participants: cross-sectional design with normal-weight, overweight and obese participants included
West 2011a	Other theoretical framework: randomised controlled trial, the TTM SOC is not used as framework of intervention
West 2011b	Other theoretical framework: randomised controlled trial using motivational interviewing strategies as framework for intervention
White 2004	Ineligible participants and use of other theoretical framework: randomised controlled trial using unspecified theoretical framework for intervention and adolescent participants included
Wijesuriya 2011	Ineligible participants: a study protocol describing a lifestyle intervention based on the TTM SOC with participants between 5-40 years of age
Wilcox 2011	Other theoretical framework: randomised controlled trial using social cognitive, social support and relapse prevention behavioural strategies as framework for intervention
Williamson 2010	Other theoretical framework: randomised controlled trial using behaviour modification methods as framework for intervention
Wing 2010	Other theoretical framework: randomised controlled trial using the social learning theory as theoretical framework for intervention
Wright 2011	TTM SOC and other theoretical framework: randomised controlled trial using the TTM SOC and the precaution adoption process model as framework for intervention - unclear whether all participants are overweight/obese
Yassine 2009	Other theoretical framework: randomised controlled trial using unspecified theoretical framework for intervention
Yoo 2012	Ineligible participants: randomised controlled trial using the TTM SOC as framework for intervention with some participants having a BMI < 25.0 kg/m^2

BMI: body mass index; TTM SOC: transtheoretical model stages of change

DATA AND ANALYSES

This review has no analyses.

ADDITIONAL TABLES

Table 1. Overview of study populations

Characteristic Study ID	Intervention(s) and control(s)	Sample size [a]	Screened [N]	Randomised [N]	ITT [N]	Complete data or finishing study [N]	Randomised with complete data or finishing study [%]	Follow-up[b]
Johnson 2008[c]	I: SOC + diet, physical activities + stress management	-	4290	628		335	53.7	24 mo
	C: usual care			649		426	66.7	
			total:	1277	1277	761		
Jones 2003[d]	I1: PTC	-	-	250		-	-	12 mo
	I2: PTC + blood test strips			260				
	C1: usual diabetes treatment			250				
	C2: usual diabetes treatment + blood test strips			269				
			total:	1029	1029			
Logue 2005	I: TM-CD	540 (90% power to detect a difference of 4.5 kg; α = 0.05; 20% drop-out rate))	-	329		266	79.2 (62.2)[e]	24 mo

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

	C: augmented usual care			336		271	82.4 (68.7)[e]	
			total:	665	665	537		
Grand total	***All interventions***			***1467***				
	All comparators			***1504***				
	All interventions and comparators			***2971***				

"-" denotes not reported
[a]According to power calculation in study publication or report
[b]Duration of intervention or follow-up, or both, under randomised conditions until end of study
[c]Minor mismatch between N with complete data and % as reported in figure 2 of the publication (Johnson 2008)
[d]Data on drop-outs, losses to follow-up and missing were not reported
[e]Values in parentheses indicate measured weight (versus measured weight or weight abstracted from chart)
C: control; I: intervention; ITT: intention-to-treat; mo: months; PTC: pathways to change; SOC: stages of change; T: total; TM-CD: transtheoretical model-chronic disease

APPENDICES

Appendix 1. Transtheoretical model stages of change (TTM SOC)

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.

(*Continued*)

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 stuck 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-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 and databases
Unless otherwise stated, search terms are free text terms. Abbreviations: '$': stands for any character; '?': substitutes one or no character; adj: adjacent (i.e. number of words within range of search term); exp: exploded MeSH; MeSH: medical subject heading (MEDLINE medical index term); pt: publication type; sh: MeSH; tw: text word
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

(*Continued*)

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))
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.

(*Continued*)

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$.ab,ti,ot.
23 (diet$ 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.

(*Continued*)

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$.ab,ti,ot.
16 behavio?r theor$.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

(*Continued*)

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$).tw,ot.
10 (weight adj3 (cyc$ 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

Characteristic Study ID	Intervention(s): application of TTM	Control(s): usual advice on diet, exercise or both
Johnson 2008	Assessment and feedback on fat intake, physical activities per week and stress management at baseline, 3, 6, 9 months. The TTM SOC was used as framework for intervention and assessment (stage-matched multiple behaviour interventions for up to three behaviours related to weight management) for diet (healthy eating - reducing dietary fat to 30% of calories and calories reduction of 500 calories per day), physical activity (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). Four series of tailored TTM-based reports were mailed to all participants at 0, 3, 6, 9 months	Usual care
Jones 2003	I1: PTC (diabetes manuals, monthly newsletters, telephone counselling, staged-based personalized assessment report quarterly and dietary intake assessment) I2: PTC (diabetes manuals, monthly newsletters, telephone counselling, staged-based personalized assessment report quarterly and dietary intake assessment) + blood testing strips The TTM-SOC was used as framework for intervention and assessment (staged-matched pathways to change) for diet (healthy eating), self-monitoring of blood glucose and/or smoking cessation. Personalised, stage-based assessment reports were sent to all participants at baseline, 3, 6, 9, 12 months	C1: usual diabetes treatment (family physician visits, diabetes education) C2: usual diabetes treatment (family physician visits, diabetes education) + blood testing strips
Logue 2005	TM-CD: psychosocial evaluation every 6 months; SOC assessment for five target behaviours every 2 months; assessment on anthropometric, dietary and exercise every 6 months; 10 min counselling on diet; dietary and exercise prescriptions; monetary reward for completing each post baseline assessment The TTM SOC was used as framework for intervention and assessment for five target behaviours (increased exercise, increased usual activity, increased dietary portion control, decreased dietary fat and increased fruits and vegetables). Stage-based individualised workbooks were mailed to all participants at 0, 6, 12, 18, 24 months	Augmented usual care: assessment on anthropometric, dietary and exercise every 6 months; 10 min counselling on diet; dietary and exercise prescriptions; monetary reward for completing each post-baseline assessment

(*Continued*)

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

Appendix 4. Matrix of study endpoints

Characteristic Study ID	Primary[a] endpoint(s):	Secondary[b] endpoint (s)	Other[c] endpoint(s)	
Johnson 2008	Healthy eating, exercise	Managing emotional stress, weight	SOC progression (action/maintenance)	
Jones 2003	-	-	Readiness to change, increases in self-care, improved diabetes control, weight loss, decreased calories (fat), increase in fruits and vegetables servings, quit smoking, SOC progression	
Logue 2005	Body weight change from baseline at or near the end of 24-month follow-up	-	Waist girths, energy intake, energy expenditure, self-reported exercise, blood pressure and blood lipids, psychosocial measurements, SOC and PRIME-MD scores	

Footnotes
"-" denotes not reported
[a,b]As stated in the publication
[c]Not stated as primary or secondary endpoint(s) in the publication
BMI: body mass index; C: control; I: intervention; PRIME-MD: primary care evaluation of mental disorders; PTC: pathways to change; SOC: stages of change; TM-CD: transtheoretical model-chronic disease; TTM: transtheoretical model

Appendix 5. Baseline characteristics (I)

Characteristic Study ID	Intervention (s) and control(s)	Duration of intervention (duration of follow-up)	Participating population	Country	Setting	Ethnic groups [%]	Duration of condition [mean/range years (SD), or as reported]
Johnson 2008	I: SOC + diet, physical activities + stress management	9 months (12, 24 months)	Overweight and obese adults	USA	Personnel not stated, home-based (using telephone and mail)	White, not Hispanic: 79 Hispanic: 7 Black not Hispanic: 7 Asian or other Pacific Islander: 1 American Indian or Alaskan Native: 1 Others: 5 Missing: 0.3	-
	C: usual care						
Jones 2003	I1: PTC	12 months (no follow-up, assessments at 3, 6, 9, 12 months)	Diabetic adults with a body mass index ≥ 27	Canada	Delivered by investigators and health care professionals (counsellors, family physicians), using mail and telephone call	-	-
	I2: PTC + blood test strips						
	C1: usual diabetes treatment						
	C2: usual diabetes treatment + blood test strips						
Logue 2005	I: TM-CD	24 months (no follow-up, assessments at 6, 12, 18, 24 months)	Adults with a body mass index > 27	USA	Delivered by weight loss advisor and dietician; telephone-based; primary care practices	African American: I: 28, C: 27	-
	C: augmented usual care						

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

Appendix 6. Baseline characteristics (II)

Characteristic Study ID	Intervention(s) and control(s)	Sex [female %]	Age [mean/range years (SD), or as reported]	BMI [mean kg/m^2 (SD)]	Co-medications / Co-interventions [%]	Co-morbidities [%]
Johnson 2008	I: SOC + diet, physical activities + stress management	47	45.4	30.8	-	-
	C: usual care					
Jones 2003	I1: PTC	48	I1: 55.1	I1: 32.2	Insulin, oral antidiabetic drugs	Type 1 and 2 diabetes: 100
	I2: PTC + blood test strips		I2: 54.6	I2: 32		
	C1: usual diabetes treatment		C1: 54.6	C1: 31.6		
	C2: usual diabetes treatment + blood test strips		C2: 54.9	C2: 31.4		
Logue 2005	I: TM-CD	70	40 to 49: 42% 50 to 59: 42% 60 to 69: 16%	BMI 25-29.9: 20% BMI 30-34.5: 34% BMI 35-39.0: 23% BMI 40.0+: 23%	Prior/current psychotropic medication: I: 26, C: 24	Hypertension: I: 44, C: 48 Hypercholesterolaemia: I: 36, C: 38 (Osteo)arthritis: I: 35, C: 33 Stomach problems: I: 25, C: 19 Diabetes: I: 14, C: 17
	C: augmented usual care	67	40 to 49: 38% 50 to 59: 42% 60 to 69: 20%			

Footnotes
"-" denotes not reported,
* denotes figure for number of participants analysed (not randomised)
BMI: body mass index; C: control; F: female; I: intervention; M: male; PTC: pathways to change; SD: standard deviation; SOC: stages of change; TM-CD: transtheoretical model-chronic disease

Appendix 7. Primary and secondary outcomes (results)

Study ID Characteristic	Johnson 2008	Jones 2003	Logue 2005
	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
Data for primary outcomes of this Cochrane review			
Objectively measured weight-loss (short-term and sustained)		In healthy eating group at 12 months: I: - 1.38 kg (moving to action stage) I: - 0.65 kg (remaining in pre-action stage) Difference of 0.73 kg not statistically significant C: - Both SMBG and healthy eating groups at 12 months: I: - 1.78 kg (moving to action stage) I: - 0.26 kg (remaining in pre-action stage) Difference of 1.52 kg: P < 0.01 C: -	Early mean weight loss (6 and 12 months): I: - 0.5 kg (SE 0.4) more than C T (combined): P < 0.0001 Mean weight loss at 24 months: I: - 0.39 kg (SE 0.38 kg, 95% CI -1.1 to 0.4) C: - 0.16 kg (SE 0.42 kg, 95% CI -1.0 to 0.7) T (I vs C): 0.23 kg (95% CI -1.4 to 0.9; P = 0.50) T (combined): - 0.29 kg (95% CI -0.9 to 0.3)
Self-measured weight loss (sustained)	Absolute weight loss at 24 months: Treatment group weight loss versus control at 24 months: -2.12 kg; P < 0.05 At least 5% of body weight for healthy eating behaviour at 24 months: I: 27.4%; C: 20.3% Overall effect over time: 2.07 kg; 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% Overall effect with increasing differences over time: 1.96 kg; P = 0.05; OR 1.32 (95% CI 0.99 to 1.75) Weight lost 5% or more for		-

(*Continued*)

	healthy eating + exercise behaviours at 24 months: I: 30%; C: 18.6% Overall group effect for intervention had increased over time: 2.05 kg; P < 0.05; OR 1.35 (95% CI 1.01 to 1.81)		
Health-related quality of life	-	-	Measured but not reported
Data for secondary outcomes of this Cochrane review			
Self-reported change in dietary habit and measured change in dietary habit	Increased healthy eating behaviour (reduced calories intake per day) At 6 months: I: 43.9%; C: 31.3% At 12 months: I: 43.10%; C: 35.2% At 24 months: I: 47.5%; C: 34.3% Overall group effect for all time points: P < 0.001; OR 1.61 (95% CI 1.33 to 1.94) Greater fruit and vegetables intake (progression to action/maintenance) At 6 months: I: 44%; C: 31.4% At 12 months: I: 45.3%; C: 39.6% At 24 months: I: 48.5%; C: 39.0% Overall group effect for all time points: P < 0.0001; OR 1.63 (95% CI 1.34 to1.97)	Lower calories intake from fat in healthy eating behaviour at 12 months: I: 35.2% C: 36.1% Difference: P = 0.004 Higher daily vegetable servings intake per day at 12 months: I: 2.24 C: 2.06 Difference: P = 0.011 Higher daily fruit servings intake at 12 months: I: 1.89 C: 1.68 Difference: P < 0.01	Decrease in mean energy intake per day at 6 to 24 months: difference between groups P = 0.69 T (combined): ~250 kcal/d (P < 0.0001) Increase in mean energy expenditure per day at 24 months: difference between groups P = 0.31 T (combined): ~2 kcal/kg per day; P = 0.04
Self-reported uptake in physical activity and measured change in physical activity	Increased exercise habit (progression to action/maintenance stage) at 6 months: I: 43%; C: 34.6% Increased exercise habit (progression to action/maintenance stage) at 12 months: I: 37.7%; C: 35.9% Increased exercise habit (progression to action/maintenance stage) at 24 months: I: 44.9%; C: 38.1% Overall group effect for all time	-	Increase in mean self-reported exercise minutes per week (from 6 to 24 months): Mean difference between groups 31.5 min (SE 12); P = 0.008 (additional minutes in the intervention groups)

(*Continued*)

	points: P < 0.05; OR 1.27 (95% CI 1.03 to 1.57)		
Objectively measured change in other weight loss measures	-	-	Decrease in mean waist girth at 24 months: difference between groups P = 0.57 T (combined): 1.7 cm (SE 0.4) ; P = 0.0001
Self-reported progression through SOC	Progressed to action or maintenance stage for healthy eating outcome At 6 months: I: 43.9%; C: 31.3% At 12 months: I: 43.1%; C: 35.2% At 24 months: I: 47.5%; C: 34.3% Overall group effect for all time points: 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% At 12 months: I: 37.7%; C: 35.9% At 24 months: I: 44.9%; C: 38.1% Overall group effect for all time points: P < 0.05; OR 1.27 (95% CI 1.03 to 1.57) Progressed to action or maintenance stage for fruit and vegetable outcome At 6 months: I: 44%; C: 31.4% At 12 months: I: 45.3%; C: 39.6% At 24 months: I: 48.5%; C: 39.0% Overall group effect at all time points: P < 0.0001; OR 1.63 (95% CI 1.34 to 1.97)	Progressed to action/maintenance stage in SMBG at 12 months (n = 860): I1: 30.5%; C1: 18.4%; I2: 43.4%; C2: 27% (P < 0.001) Progressed to action/maintenance stage for healthy eating behaviour at 12 months (n = 445): I1: 32.5%; C1: 25.8% (P < 0.001)	-
Adverse events	-	-	Significant combined weight gain at 12 months (P < 0.0001)
Morbidity	-	-	-

(*Continued*)

Economic costs	-	-	-

Footnotes
"-" denotes not reported
% E: percentage of total energy intake; BMI: body mass index; C: control (usual advice on diet, exercise or both); f: females; I: intervention (application of transtheoretical model); m: males; MD: mean difference; PTC: pathways to change; SE: standard error; SMBG: self monitoring blood glucose; SOC: stages of change; T: total; TM-CD: transtheoretical model-chronic disease; TTM: transtheoretical model

Appendix 8. Adverse events

Characteristic Study ID	Intervention (s) and controls(s)	Relapse into unhealthy behaviour and weight gain [%]	Serious adverse events [%]	Left study due to adverse events [%]	Hospitalisation [%]	Out-patient treatment [%]	Symptoms [%]
Johnson 2008	I: SOC + diet, physical activities + stress management C: usual care	-	-	-	-	-	-
Jones 2003	I1: PTC I2: PTC + blood test strips C1: usual diabetes treatment C2: usual diabetes treatment + blood test strips	-	-	-	-	-	-
Logue 2005	I: TM-CD C: augmented usual care	Significant combined weight gain at 12 months ($P < 0.0001$)	-	-	-	-	-

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

Appendix 9. Survey of authors' providing information on trials

Characteristic Study ID	Study author contacted	Study author replied	Study author asked for additional information	Study author provided data
Johnson 2008	Y	Y	Y	N
Jones 2003	Y	N	N	N
Logue 2005	Y	N	N	N

Footnotes
N: no; Y: yes

FEEDBACK

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

Summary

On Wednesday, October 5th, 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.

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(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 included studies', 'Appendix 2', '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 for considering studies for this review: types of outcome measures' in page 4).
The authors agreed to include Dinger et al (2007) because the article met the inclusion criteria, particularly in applying TTM SOC (as explained in page 298 of the article) and reporting changes in physical activities (PA) as an outcome (stated in page 301 of the article). Although, there is no information on 'weight loss', 'changes in diet', 'health-related quality of life' and 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 page 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 page 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, that is 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/m^2' in the 'inclusion criteria' for self monitoring blood glucose (SMBG) and health eating interventions (as clearly stated in page 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 pages 734-5 of the article). We have explained issues related to outcomes measured throughout the review (in particular in pages 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 pages 3, 35 and 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 page 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…' (page 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' (page 8). All the studies (Jones et al 2003 and Logue et al 2005) met the given criteria.
For Logue et al (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' (pages 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 (pages 733-4) and 'conclusion' (page 736). We have considered this point in the review (page 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 (page 243) together with the statistical values (which are stated in page 17 of the review). Two assessors used the data extraction templates generated based on Cochrane review guidelines and recommended by the CRG (for example Appendix 7 'primary and 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 (for example 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 (pages 5-6) and the characteristics are stated in Appendix 1 (page 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 (page 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…' (page 298) and more information is given in table 1 'Curriculum outline for COMBO group' (page 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 (pages 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 (for example prior exposure, lack of blinding) of using the RCT design for behavioural intervention particularly at community settings when conducting the review (as stated in page 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 (page 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 (page 7), the 'unit of analysis' section of the review and please refer to table 1 'overview of study populations' (page 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/m^2..' (page 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….' (page 734).
(k) Disagree. The comment is an inaccurate interpretation of our statements about 'delivery of intervention' in the review (page 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 page 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...' (page 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 (page 28).

(l) Disagree. The reference is listed in page 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 (page 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 (page 12) and 'Characteristics of included studies' table (pages 28-35) as well as 'Descriptions of interventions' table (page 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 (pages 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 pages 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 (page 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 (for example '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 (page 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 pages 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 (pages 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 (page 27):

Prochaska JO, DiClemente CC, Norcross JC. In search of how people change: Applications to addictive behaviors. American Psychologist. 1992;47(9):1102-14.

Prochaska JO, Redding CA, Evers KE. 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 edition. San Francisco Jossey-Bass; 1997.

Prochaska JO, Redding CA, Evers KE. 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 edition. 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 (pages 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 (page 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…' (pages 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 pages 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…' (page 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 (pages 33-34), matrix of study endpoints (Appendix 5, page 51) and the 'primary and secondary outcomes' table (Appendix 7, page 52).

(s) Disagree. We have explicitly defined the terms 'progress to action stage' and 'maintenance stage' in the review (page 17) as defined in the study by Steptoe 2001 (page 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.

Contributors

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Email Address: sjohnson@prochange.com
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.

Cochrane review response rebuttal, 9 February 2012

Summary

On Wednesday, October 5th, 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.
First of all, the authors have divided our critique in to statements that they ordered "a, b, c… etc." While we are not opposed to them re-organizing our statements for the purposes of clarity, they actually divided our comments up in ways that increased confusion in some cases. The first sentence of section "b" would more appropriately fall under statement "a.." The first sentence of statement "c" is clearly referring to the articles in statement "b." These mistakes actually caused the authors of the review to defend their article against claims we did not make (e.g., we did not argue that Jones et al., 2003 did not include overweight adults).
(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.
The first sentence of statement "c" is referring to the articles in statement "b."
(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.
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(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 in 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.
We are not disputing that the authors' objective was "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". We are, however, disputing that the studies included allow an adequate examination of the effectiveness of the interventions given that two out of the five did not measure weight loss at all; two included participants who were not all overweight; and only one measures weight loss beyond the end of treatment. Nor are we are arguing that the inclusion criteria for PICO/Cochrane were incorrect, but rather that at least three of the studies included do not meet the specified inclusion criteria (as the authors acknowledge below). Thus, the aims, description, and conclusions of the study do not accurately represent the literature that was actually reviewed (e.g. "true" TTM interventions were not used in the majority of studies, not all adults in the literature were overweight or obese, and not all of the studies measured weight loss as an outcome).
(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 page 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 page 298 of the article) and reporting changes in physical activities (PA) as an outcome (stated in page 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 page 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 page 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, that is 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.
Here, in section B, the authors themselves acknowledge that they in fact misapplied the inclusion criteria. On Page 9, the authors state that relevant population and intervention characteristics were extracted from studies that fulfilled the inclusion criteria. On page 7, the authors stated that the inclusion criteria are: "Adults, aged 18 and over, who are overweight or obese

according to any standard parameters…". Under the heading *Types of outcome measures, the authors state that weight loss measured at one month, three months, or six months after the intervention) is a primary outcome.*

Being overweight or obese was not a stated inclusion criterion for Dinger et al. (page 298 of the original article) and only 57% of the sample was obese (page 301). Weight loss is not an outcome at all, let alone a primary outcome.

Being overweight or obese was not an inclusion criterion for Steptoe et al. (page 265), and weight loss was not reported as an outcome.

Thus, the title, abstract, and objectives of this review are misleading. This review repeatedly states that its objective 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.' (*See title, abstract, and objectives section, pg 7). If the authors were going to include studies about stage progression among more general populations, a number of other important studies were omitted.*

On page 7 under the section *Why it is important to do this review the authors clearly state "The 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 life modification (with diet and physical exercise) resulting in weight loss amongst the target population."*

The authors argue in their rebuttal that more detailed information about each study's outcomes is provided in appendices and tables throughout the review, but this does not change the fact that the authors provide contradictory and misleading information about the scope of this review in the most salient sections of their article. In addition, they draw conclusions about the effectiveness of the TTM on weight loss based on only three studies. Stated in another way, we believe it is irresponsible that 40% of the studies (2 out of 5) included in this review do not include weight loss as an outcome given the stated objectives and conclusions drawn. In addition, three weight-loss studies is arguably too few to draw a conclusion about the effectiveness of the TTM on this area of behavior change.

(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/m^2' in the 'inclusion criteria' for self monitoring blood glucose (SMBG) and health eating interventions (as clearly stated in page 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 pages 734-5 of the article). We have explained issues related to outcomes measured throughout the review (in particular in pages 17-21).

The authors are refuting a statement we did not make. They incorrectly edited our statement into sections "b" and "c" and then erroneously associated the Jones reference with a statement we were clearly making about two different articles (see Dinger et al., 2007 & Steptoe et al., 2001). The issue at hand is that two articles (Dinger et al., 2007 & Steptoe et al., 2001) did not exclusively include adults who were overweight or obese despite the fact that this review claims that the selection criteria included "participants who were overweight or obese." See title, abstract, plain language summary (page 2), types of participants section (page 7). It is true that those articles included other outcomes such as physical activity. What is of concern is that the reviewers in fact drew conclusions on intervention effectiveness for a myriad of outcomes based on very few studies. On page 13 in the section on Participants and Setting*the authors state "The trials were conducted amongst overweight and obese adults participants only."*

The authors response here, does not change the fact that the inclusion criteria for the Dinger et al. (2007) article and Steptoe et al., (2001) did not include being overweight or obese. The authors inaccurately list the inclusion criteria for Dinger et al., (2007) as BMI > 30 (See characteristics of studies, page 30). In fact, only 57% of participants in the Dinger et al., (2007) study had a BMI > 30. This is clearly stated on page 301 of the original article.

Similarly Steptoe et al., (2001) included participants based on any one of three risk factors including cigarette smoking, high cholesterol, or a combination

of a high body mass index and low physical activity (see page 266 of the original article). Only 79% fell in to the overweight category. The inclusion criteria for this study are misstated on Page 37 of the review in the 'Characteristics of Studies' section.

(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 pages 3, 35 and 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 page 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…' (page 919).

On page 919, Logue et al. state the goal was increased exercise, increased usual activity, increased dietary portion control, decreased dietary fat, and increased fruits and vegetables. As we highlighted initially, these are non-specific increases (increase

to what frequency of exercise, what % of calories from fat, etc.). Furthermore, Logue et al. repeat their assertion that the intervention examined was minimal in the Discussion on page (925).

(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' (page 8). All the studies (Jones et al, 2003 and Logue et al, 2005) met the given criteria.

For Logue et al (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' (pages 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 (pages 733-4) and 'conclusion' (page 736). We have considered this point in the review (page 14). The information is stated in the 'intervention' and 'outcome' sections of the 'Characteristics of included studies' table.

Weight is reported in the Logue study in Figure 1, but the intervention and follow-ups took place at the same time, with no additional follow-ups beyond the end of the intervention. Loge reports on page 918 that the participants receive 100 weeks of treatment, elaborating on page 919 that assessment occurred every 6 months.

Jones et al. report on page 733 that participants completed quarterly assessments and received an "integrated, multicomponent intervention program that provides monthly mail or telephone contact for 12 months". As is reported on page 734, all participants completed a final, end of study assessment at 12 months. Thus, there was no assessment at an extended follow-up. Thus, only one study meets the criteria of having a follow-up post-intervention.

(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 (page 243) together with the statistical values (which are stated in page 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 and 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.

This statement does not pertain to our point which is that only one study in this review reported long-term weight-loss outcomes.

(g) Disagree. We have clearly described TTM SOC in the 'description of intervention' section of the review (pages 5-6) and the characteristics are stated in Appendix 1 (page 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 (page 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…' (page 298) and more information is given in table 1 'Curriculum outline for COMBO group' (page 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 (pages 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.

We understand the authors had difficulty finding articles with suitable statistical approaches that measure stage-based outcomes. This fact should have deterred them from writing a review. We fully agree that the literature is lacking and echo the point that well-designed studies on the TTM on weight loss are needed to make conclusions about its effectiveness. The authors also claim that this review addresses how the TTM works "as a theoretical and pragmatic (real-life tested) framework." We do not agree that misapplying the TTM as a Stage of Change "model" constitutes "real-life testing". The Transtheoretical Model of Change has 14 constructs, one of which is Stage of Change. This article misrepresents decades of research and development by consistently calling the TTM the TTM SOC "model." Real-world tests of interventions should not mean applying one aspect of a complex model to draw conclusions about that model's efficacy.

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 page 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 (page 22).

Page 22 does not report details on the power of studies, it states (in the conclusion section) that many of the studies had small sample sizes and lacked statistical power. This is exactly our point. The conclusions the authors draw about the efficacy of the TTM, or lack thereof, are based on inconclusive research for which null findings may simply be the reflection of study design. We believe this makes the conclusions of this review stated on page 22 invalid and premature.

(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 (page 7), the 'unit of analysis' section of the review and please refer to Table 1 'Overview of study populations' (page 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/m^2..' (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….' (page 734).

A careful reading of Jones et al. indicates that only subjects with a BMI of 27 or more were enrolled in the healthy eating intervention and that only those who were in a pre-action stage for healthy eating (n=445) were included in the analyses (page 733). Given that the review criteria was to examine the effect of healthy eating and physical activity interventions, it seems that only the 445 who received the healthy eating intervention could possibly be included.

(k) Disagree. The comment is an inaccurate interpretation of our statements about 'delivery of intervention' in the review (page 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 page 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...' (page 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 (page 28).

While the authors may correctly report intervention delivery in table 1 (on page 31; not page 29) this does not change the fact that they provide contradictory information in the text on page 6: The statement reads:

"For this review…… 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 and schools."

If this was in fact the inclusion criteria, two studies that delivered interventions by computer and e-mail should have been excluded.

Correctly reporting study methodology in one part of the review does not negate misreporting in another. Inconsistency in reporting propagates poor science and confuses readers.

(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 (page 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 (page 12) and 'Characteristics of included studies' table (pages 28-35) as well as 'Descriptions of interventions' table (page 48).

This statement is in the review: See page 6: The statement reads

"For this review…… 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 centeres and schools."

On page 13: see section on Participants and Setting

The trials were conducted amongst overweight and obese adult participants only."

(m cont….) 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 (pages 298-299).

As can be seen clearly on 299, all participants received the same intervention messages regardless of their stage of change. Our point is that TTM-based interventions *tailor interventions to Stage of Change (i.e. people in different stages get intervention messages matched to or targeted for their stage).*

(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 pages 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 (page 30).

This does not change the fact that the authors erroneously reported on page 13 in the participants and settings section: ***"All participants in the analysed trials were on the basis of intention to treat (ITT)"***

(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.

Nonetheless, incorrect information appears on both pages 6 and 13. The methodology was correctly reported only in Table 1. The authors incorrectly extrapolated information from this table repeatedly throughout the review.

(q) Disagree. The comment is an inaccurate assessment of our results on the 'secondary outcomes' in the review (page 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 pages 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 (pages 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 (page 27):

Prochaska JO, DiClemente CC, Norcross JC. In search of how people change: Applications to addictive behaviors. American Psychologist. 1992;47(9):1102-14.

Prochaska JO, Redding CA, Evers KE. 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 edition San Francisco Jossey-Bass; 1997.

Prochaska JO, Redding CA, Evers KE. 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 edition San Francisco Jossey-Bass; 2008.

The definition of Action as provided by Prochaska et al. (1992) on page 1104 of "In Search of How People Change" is: "*Action is the stage in which individuals modify their behavior, experiences, or environment in order to overcome their problems. Action involves the most overt behavioral changes and requires considerable commitment of time and energy." On page 17, the authors mistakenly report that Action is defined as ready to change).*

(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 (pages 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 (page 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…' (pages 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 pages 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…' (page 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 (pages 33-34) , matrix of study endpoints (Appendix 5, page 51) and the 'primary and secondary outcomes' table (Appendix 7, page 52).

(s) Disagree. We have explicitly defined the terms 'progress to action stage' and 'maintenance stage' in the review (page 17) as defined in the study by Steptoe 2001 (page 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."

The authors agree that there are errors in the Abstract and body of this review regarding study conclusions. These are not minor mistakes, but in fact, can lead to and have led to major misunderstandings about the conclusions of this review, which will subsequently be cited in other papers. Combined with the consistent contradictions in this paper, we believe these errors justify a retraction.

(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.

The authors agree that there were several typos and mis-statements in this article. They disagree with many of our other statements by referring to a Table in which study methodology is accurately reported. This in no way changes the fact that they reported methodology incorrectly in the body of the article repeatedly. We remain resolute in our belief that a retraction is needed.

(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.

The approved protocol and review process in this case failed to uncover many errors, typos, and contradictions in this review. As scientists, it is our responsibility to correctly represent research results and retract misleading and erroneous information from the literature base.

Reply

From the Editorial Base: Authors shall reply to this feedback and amend their Cochrane review.

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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.

WHAT'S NEW

Last assessed as up-to-date: 17 December 2013.

Date	Event	Description
17 December 2013	New search has been performed	Updated review
17 December 2013	New citation required but conclusions have not changed	Update search did not detect new trials. Two studies included in former review were excluded

HISTORY

Protocol first published: Issue 4, 2009

Review first published: Issue 10, 2011

Date	Event	Description
10 July 2012	Feedback has been incorporated	New feedback received on 09 February 2012, authors shall reply and amend their Cochrane review
18 January 2012	Amended	Abstract, results section; description of studies (interventions); implications for practice
18 January 2012	Feedback has been incorporated	New feedback received on 16 November 2011, authors replied on 11 and 17 January 2012

CONTRIBUTIONS OF AUTHORS

Nikolaos Mastellos (NM): trial selection, data extraction, data analysis, data interpretation, review and update draft.

Laura Gunn (LG): trial selection, data analysis, data interpretation and review draft.

Lambert Felix (LF): trial selection, data extraction, data analysis, data interpretation and update draft.

Josip Car (JC): protocol draft, search strategy development, data interpretation and review draft.

Azeem Majeed (AM): protocol draft, search strategy development, trial selection, data interpretation and review 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 the 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 estimated effect measures used in each trial were different. Lastly, acknowledgements are added to highlight contributions of individuals throughout the project.

Differences between the original and the updated version of the review

There were also some differences between the original and the revised version of the review. First, the title of the review has changed from "Transtheoretical model for dietary and physical exercise modification in weight loss management for overweight and obese adults" to "Transtheoretical model stages of change for dietary and physical exercise modification in weight loss management for overweight and obese adults" to reflect the criteria for inclusion in the review (see Description of the intervention). Second, two studies that were originally included (Dinger 2007; Steptoe 2001) have been excluded from the updated review in response to criticisms that one study did not measure weight loss as an outcome (Dinger 2007) and the other included both healthy and overweight or obese adults in the analysis (Steptoe 2001). In addition, the primary outcome of the study was redefined (without, though, changing the outcome itself) to avoid confusion about the timing and outcome measurement. 'Death from any cause' was excluded from the list of adverse effects as it does not constitute a potential adverse effect of the TTM SOC. Finally, numerous inconsistencies from the original review have been resolved in this revised version.

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