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Psychological interventions delivered as a single component intervention for children and adolescents with overweight or obesity aged 6 to 17 years (Protocol)

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[Intervention Protocol]

Psychological interventions delivered as a single component intervention for children and adolescents with overweight or obesity aged 6 to 17 years

Heidi Vanden Brink[1], Lorena S Pacheco[2], Charlotte L Bahnfleth[1], Erin Green[1], Lynn M Johnson[3], Katherine Sanderson[4], Alessandro R Demaio[5,6], Nathalie Farpour-Lambert[7], Louisa J Ells[8], Andrew J Hill[9]

[1]Division of Nutritional Sciences, Cornell University, Ithaca, NY, USA. [2]Family Medicine and Public Health, University of California, San Diego, La Jolla, California, USA. [3]Cornell Statistical Consulting Unit, Cornell University, Ithaca, NY, USA. [4]School of Health & Social Care, Teesside University, Middlesbrough, UK. [5]Melbourne School of Population and Global Health, University of Melbourne, Melbourne, Australia. [6]Center for a Livable Future, Johns Hopkins Bloomberg School of Public Health, Baltimore, USA. [7]Hospital University de Geneve, Geneve, Switzerland. [8]School of Clinical and Applied Sciences, Leeds Beckett University, Leeds, UK. [9]Division of Psychological and Social Medicine, University of Leeds, Leeds, UK

Contact address: Heidi Vanden Brink, hv63@cornell.edu.

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To assess the effects of psychological interventions delivered as a single component intervention on the management of overweight or obesity in children and adolescents aged 6 to 17 years.

BACKGROUND

The prevalence of overweight and obesity in children and adolescents is recognized as a global health concern affecting both high- and low-income countries (Cole 2000; Ng 2014). In high-income countries, the prevalence of overweight and obesity considered together using the International Obesity Task Force (IOTF) definition is approximately 23.8% for boys and 22.6% in girls (Ng 2014). In low- and middle-income countries, the prevalence is approximately 12.9% for boys and 13.4% for girls (Ng 2014). The WHO Childhood Obesity Surveillance Initiative (COSI) reported a range in the prevalence of overweight and obesity between 18% to 57% for boys six to nine years and 18% to 50% among girls aged six to nine years (Wijnhoven 2014). Furthermore, using the World Health Organization (WHO) definition of obesity, the global age-standardized prevalence of girls with obesity alone has increased from 0.7% (0.4% to 1.2%) to 5.6% (4.8% to 6.5%) and from 0.9% (0.5% to 1.3%) to 7.8% (6.7% to 9.1%) in boys over the past four decades (NCD 2017). Although varying definitions of obesity (WHO, IOTF, Centers for Disease Control and Prevention (CDC)) limit the comparability of studies, it is apparent that the prevalence of children and adolescents with overweight and obesity is high and varies widely by age and geography.

Several factors may mediate the relationship between overweight and obesity in children and adolescents. The prevalence of children and adolescents with overweight or obesity varies by sex, socioeconomic status (SES), and age within high- and low-income regions (NCD 2017). For example, lower SES individuals in high-income countries and higher SES individuals in low-income countries are at greater risk of obesity (WHO 2016). Moreover, COSI has identified that avoidable factors, such as urbanization and economic development, are associated with overweight and obesity in childhood (Djordjic 2016; Hassapidou 2017).

Additionally, there is a discrepancy in changing overweight and obesity rates by country classification based on gross national income. Whereas the rate of increase in children and adolescents with overweight or obesity has slowed or ceased, particularly in high-income countries, rates of overweight and obesity continue to increase in many low-income countries (NCD 2017; Ng 2014; Ogden 2016; Wabitsch 2014). Policy implementation contributes to the decreasing rate of overweight and obesity in high-income countries, which accentuates the disparities in resources and interventions for the management of overweight and obesity (NCD 2017). However, despite the observed plateau in high-income countries, the prevalence of overweight and obesity remains high and future projections reinforce the global health burden of overweight and obesity in childhood and adolescence; current trends suggest that 57.3% of US American children and adolescents 2 to 19 years will be obese by the age of 35 (Ward 2017). Additionally, predictions forecast that the combined global prevalence of children aged 5 to 17.9 years with overweight and obesity will rise from 13.9% in 2010 to 15.8% by 2025 (Lobstein 2016).

Description of the condition

Obesity is an accumulation of excess body weight, is multifactorial in nature, and results from an interplay of genetic predispositions, excess caloric intake, decreased physical activity, and environmental factors (Silventoinen 2009). Overweight and obesity in childhood imparts both short- and long-term health risks, such as musculoskeletal concerns, cardiometabolic risk factors such as hypertension, insulin resistance and dyslipidemia, (Kim 2017; Reilly 2003; Reilly 2011; Umer 2017), sleep apnea (Narang 2012), and may impact reproductive development (Solorzano 2010). Overweight or obesity during childhood can also impart negative psychological consequences. Psychological factors, such as depression, anxiety, emotional and behavioral problems, and emotional overeating are associated with childhood overweight and obesity (Griffiths 2010; Hebebrand 2009; Mallan 2017; Puder 2010). Additionally, overweight and obesity during childhood and adolescence may contribute to stigmatization (Puhl 2008; Tang-Peronard 2008), victimization (Hill 2017), and perceived low self-worth in children and adolescents (Griffiths 2010; Hill 2017).

Description of the intervention

Psychological interventions are used as a stand-alone treatment or in tandem with behavior-changing interventions ('lifestyle' interventions), pharmacological, or surgical interventions to reduce or obviate barriers for behavior change. They have been employed in an attempt to achieve long-term maintenance of behavioral change regarding weight loss and weight loss maintenance (De Miguel-Etayo 2013). Yet, psychological interventions vary in their approach. Behavioral therapies are most common in weight management settings and are designed to identify learned behaviors and use techniques based on classical and operant conditioning to improve an individual's functioning (Leftwich 2008). Cognitive therapies focus on identifying dysfunctional and maladaptive thoughts and changing these thoughts to promote improved functioning (Leftwich 2008). Psychological interventions often draw from multiple approaches and/or incorporate different techniques, such as cognitive-behavioral therapy (CBT), a variation of behavioral therapy which addresses and modifies dysfunctional emotions, thoughts, and behaviors (Lawyer 2008; Licht 2008). Third wave CBT approaches such as acceptance and commitment therapy (ACT) and compassion-focused therapy (CFT) draw on techniques such as mindfulness and de-centering to change negative thought patterns (Hayes 2004; O'Reilly 2014). In addition, motivational interviewing is a method which evolved from person-centered therapy and aims to resolve ambivalence and increase motivation to initiate behavior changes (Armstrong 2011; Borrello 2015; Miller 2009). Psychological interventions also vary in their format and setting. Common formats for psychological interventions include individual, family, and group therapy, delivered in a clinic, school, or community setting.

Adverse effects of the intervention

Adverse effects of psychological interventions are not widely discussed or reported. A past Cochrane review evaluating similar treatments in adults found no adverse effects of the intervention (Shaw 2005), and a recent systematic review did not address adverse effects of psychological interventions (Bogle 2011). Two recent reviews evaluating the impact of diet, physical activity and behavioral interventions for the treatment of overweight and obesity in children (Mead 2017) and adolescents (Al-Khudairy 2017), reported two and zero adverse effects which were associated with the intervention, respectively. The adverse effects identified in children included a significant reduction in body mass index (BMI) and standardized BMI in a control participant (Croker 2012) and cardiometabolic abnormalities (Kirk 2012) which were not attributed to the behavioral aspect of the intervention. It is plausible that a participant may experience an increase in anxiety

or emotional distress resulting from delivery of a psychological intervention. However, we presume this would be the identification of pre-existing emotional distress and not the consequence of a psychological intervention.

How the intervention might work

The intrinsic constituent of weight loss and weight management in children and adolescents is the same as in adults (i.e. reduction in energy intake and increase in energy expenditure). The overarching objective of psychological interventions for children and adolescents with overweight and obesity is to reduce psychological barriers needed for behavior change supporting weight loss, weight management or both. For example, successful weight loss and maintenance may depend on adjusting coping mechanisms in stressful situations, increasing self-efficacy, and improving self-awareness about eating behaviors, all of which are therapeutic targets of psychological interventions (Elfhag 2005). A variety of psychological interventions have been used for child and adolescent weight loss or weight maintenance including CBT, motivational interviewing, and interpersonal psychotherapy. How each psychological intervention might work depends on the type of intervention and the target of the intervention. For example, CBT uses a combination of behavioral therapy techniques to modify behavior and cognitive techniques to identify and change dysfunctional cognitions and beliefs which are acting as a barrier to behavior change (Tsiros 2008). In contrast, motivational interviewing utilizes a variety of approaches, such as reflective listening and shared decision-making to assist individuals experiencing ambivalence towards behavior change gain motivation (Resnicow 2006). Additionally, psychological interventions can emphasize cognitive components that may modify thinking processes, tackle distorted or inadequate thoughts, and help develop problem-solving skills (Herrera 2004), or behavioral components that may reduce excessive intake and promote energy expenditure, thereby reducing body weight (Epstein 2008; Herrera 2004; Luzier 2010). Moreover, cortisol, an endocrinologic biomarker of stress, has been shown to moderate the relationship between stress and adiposity (Michels 2015), which provides evidence for a physiologic mechanism by which reduced cortisol may lead to weight loss or weight management. Hence, psychological interventions may reduce stress, improve motivation and health-related quality of life, and therefore increase the likelihood of success in behavioral changes needed for the management of overweight and obesity. Although not all children or adolescents with overweight and obesity experience psychological distress (Hill 2017), psychological interventions may also be effective to motivate behavior change and support behavior change maintenance.

Why it is important to do this review

The heightened prevalence of children and adolescents with overweight and obesity is a global public health challenge with both short- and long-term adverse physical and psychological outcomes. Therefore, interventions which effectively target short-term weight loss or maintenance, and long-term behavior change are imperative. The most recent Cochrane Reviews assessing weight management in children and adolescents examined diet, physical activity and behavioral interventions (Al-Khudairy 2017; Colquitt 2016; Mead 2017), interventions delivered to parents only (Loveman 2015), surgical (Ells 2015), and drug interventions (Mead 2016) for the treatment of overweight or obesity in children and adolescents. Multi-component interventions which include a psychological component were evaluated in separate Cochrane reviews (Al-Khudairy 2017; Mead 2017). However, the efficacy of single-component psychological interventions for weight management in overweight and obese children and adolescents has not been systematically assessed in a Cochrane Review. Another review examined the effect of psychological interventions in the treatment of obesity in children, but it only included studies up to 2008 (Bogle 2011). As a result, an up-to-date review specifically evaluating psychological interventions in the treatment of overweight and obesity in this population is needed.

OBJECTIVES

To assess the effects of psychological interventions delivered as a single component intervention on the management of overweight or obesity in children and adolescents aged 6 to 17 years.

METHODS

Criteria for considering studies for this review

Types of studies

We will include RCTs, including cluster-randomized trials.

Types of participants

Participants are children or adolescents aged 6 to 17 years at the commencement of the intervention. Trials involving children or adolescents with obesity due to a secondary or syndromic cause will be excluded. Trials involving participants with comorbid disorders are eligible for inclusion as long as the intervention's primary focus was to manage overweight and obesity.

Diagnostic criteria

Any diagnostic criteria that use a national or international growth reference standard which incorporates sex and age for overweight or obesity during childhood or adolescence will be accepted. Given the heterogeneity in international definitions of overweight and obesity, restricting the definition to one accepted reference standard may lead to a geographical bias in the study selection. We anticipate that most interventions will define overweight as a BMI-for-age more than one standard deviation (SD) above a national or internationally defined growth reference median, or at/above the 85th percentile for height and age and that obesity will be defined as a BMI-for-age more than two SDs above a national or internationally defined growth reference median, or at/above the 95th percentile for height and age.

Types of interventions

We plan to investigate the following comparisons of intervention versus control/comparator.

Intervention

We will include psychological interventions with the purpose of weight loss or management, delivered as a single component intervention. The psychological intervention will be delivered by an individual, such as a psychologist or healthcare worker, who is trained to deliver the intervention. We will include all types of psychological interventions as long as the specific type of intervention or therapy is clearly defined and can be identified, such as psychotherapy, CBT, and motivational interviewing.

Comparisons

- No treatment or waiting-list control
- Usual care

Concomitant interventions will have to be identical in both the intervention and comparator groups to establish fair comparisons. If a trial includes multiple arms, we will include any arm that meets the inclusion criteria for this review.

Minimum duration of intervention

There is no minimum duration of the intervention.

Minimum duration of follow-up

Minimum duration of follow-up will be six months from baseline.

We will define extended follow-up periods (open-label extension studies) as follow-up of participants once the original trial, as specified in the trial protocol, has been terminated.

Summary of specific exclusion criteria

- Trials that include children with a secondary or syndromic cause of obesity.
- Interventions that include any form of pharmacotherapy as a part of the intervention intended to modify weight or metabolism.
- Trials in which the intervention is delivered solely to the parent.
- Trials designed to treat eating disorders.
- Trials with a follow-up duration of less than six months from baseline.
- Trials that include a psychological intervention in a multi-component intervention.

Types of outcome measures

We will not exclude a trial if it fails to report one or several of our primary or secondary outcome measures. If none of our primary or secondary outcomes is reported in the trial, we will not include the trial but provide some basic information in the "Characteristics of awaiting classification" table.

We will extract the following outcomes, using the methods and time points specified below.

Primary outcomes

- Change in body weight and/or BMI
- Health-related quality of life (HRQoL)
- Adverse events

Secondary outcomes

- Anthropometric measures other than body weight or BMI
- All-cause mortality
- Morbidity
- Socioeconomic effects
- Psychosocial measures of well-being
- Intervention adherence and compliance
- Health-related behavior change

Method of outcome measurement

- Changes in body weight (kg) and/or BMI (kg/m^2), measured but not self-reported: BMI standardized unit (BMI z-score, or BMI percentile for age).
- HRQoL: child- or parent-reported and evaluated by a validated instrument such as CDC HRQoL–14 "Healthy Days Measure". If multiple outcomes of HRQoL are reported, weight-specific HRQoL will be selected in preference to general HRQoL.
- Adverse events: event defined as adverse that occurred during or after the intervention, such as the referral of a child or adolescent to additional mental health services not incorporated into the intervention.
- Anthropometric measures other than change in body weight or BMI: defined as any indicator of body mass other than body weight or BMI measured using validated anthropometry measurements such as skinfold thickness, bioelectrical impedance, waist circumference, dual-energy X-ray absorptiometry (DEXA).
- All-cause mortality: defined as death that occurred and was recorded during or after the intervention.
- Morbidity: defined as illness or harm (e.g. diagnosis of a mental health condition, eating disorder, or diabetes) associated with the intervention.
- Socioeconomic effects: defined as a validated measure of socioeconomic status such as parental education or income level.
- Psychosocial measures of well-being (mood and self-esteem): evaluated by a validated instrument such as the Rosenberg Self-Esteem Scale (RSES) and Mood and Feelings Questionnaire (MFQ).
- Intervention adherence and compliance: defined as investigator-documented adherence and compliance of participants to the intervention.
- Health-related behavior change (including diet and physical activity): defined as validated measures of diet or physical activity.

Timing of outcome measurement

- Changes in measured body weight (kg) and/or BMI, HRQoL, anthropometric measures other than change in body weight or BMI, socioeconomic effects, psychosocial measures of well-being, health-related behavior change: measured at baseline and any time point on or after six months' follow-up.
- Adverse events: measured at any time after participants were randomized to intervention and comparator group.
- All-cause mortality, morbidity: measured at any time point during follow-up.
- Intervention adherence and compliance: measured at each time point per protocol to assess change.

Search methods for identification of studies

Electronic searches

We will search the following sources from the inception of each database to the specified date and will place no restrictions on the language of publication.

- Cochrane Central Register of Controlled Trials (CENTRAL) via the Cochrane Register of Studies Online (CRSO);

- MEDLINE Ovid (Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily and Ovid MEDLINE; from 1946 onwards);
- PsycINFO Ovid (1806 - present);
- LILACS (Latin American and Caribbean Health Science Information database);
- ClinicalTrials.gov (www.clinicaltrials.gov); and
- World Health Organization International Clinical Trials Registry Platform (ICTRP) (www.who.int/trialsearch/).

We will not include Embase in our search, as RCTs indexed in Embase are now prospectively added to CENTRAL via a highly sensitive screening process (Cochrane 2018).

For detailed search strategies, see Appendix 1. We continuously apply an email alert service for MEDLINE via OvidSP to identify newly published studies using the search strategy detailed in Appendix 1.

Searching other resources

We will attempt to identify other potentially eligible trials or ancillary publications by searching the reference lists of included trials, systematic reviews, meta-analyses and health technology assessment reports. In addition we will contact authors of included trials to obtain additional information on the retrieved trials and establish whether we may have missed further trials.

We will not use abstracts or conference proceedings for data extraction because this information source does not fulfil the CONSORT requirements which is "an evidence-based, minimum set of recommendations for reporting randomized trials" (CONSORT 2018; Scherer 2018) unless full data are available from trial authors. We will present information on abstracts or conference proceedings in the 'Characteristics of studies awaiting classification' table. We define grey literature as records detected in ClinicalTrials.gov or WHO ICTRP.

Data collection and analysis

Selection of studies

Three of four review authors (LP, CB, HV, EG) will independently screen the abstract, title or both, of every record we retrieve in the literature searches in duplicate, to determine which trials we should assess further. We will obtain the full text of all potentially relevant records. We will resolve any disagreements through consensus or by recourse to a fifth review author (LE). If we cannot resolve a disagreement, we will categorize the trial as a 'study awaiting classification' and will contact the trial authors for clarification. We will present an adapted PRISMA flow diagram to show the process of trial selection (Liberati 2009). We will list all articles excluded after full-text assessment in a 'Characteristics of excluded studies' table and will provide the reasons for exclusion.

Data extraction and management

For trials that fulfil our inclusion criteria, three out of four review authors (LP, CB, HV, EG) will independently extract key information on participants, interventions and comparators. We will describe interventions by use of the 'template for intervention description and replication' (TIDieR) checklist (Hoffmann 2014; Hoffmann 2017).

We will report data on efficacy outcomes and adverse events using standardized data extraction sheets from the Cochrane Metabolic and Endocrine Disorders Group. We will resolve any disagreements by discussion or, if required, we will consult a fifth review author (LE).

We will provide information, including the trial identifier for potentially relevant ongoing trials, in the 'Characteristics of ongoing trials' table and in a joint appendix entitled 'Matrix of trial endpoint (publications and trial documents)'. We will attempt to find the protocol for each included trial and we will report in a joint appendix the primary, secondary, and other outcomes from these protocols, alongside the data from the study publications.

We will email all authors of included trials to enquire whether they would be willing to answer questions regarding their trials. We will present the results of this survey in an appendix. We will thereafter seek relevant missing information on the trial from the primary trial author(s), if required.

Dealing with duplicate and companion publications

In the event of duplicate publications, companion documents or multiple reports of a primary trial, we will maximize the information yield by collating all available data and we will use the most complete data set aggregated across all known publications. We will list duplicate publications, companion documents, multiple reports of a primary trial and trial documents of included trials (such as trial registry information) as secondary references under the study identifier (ID) of the included trial. Furthermore, we will also list duplicate publications, companion documents, multiple reports of a trial and trial documents of excluded trials (such as trial registry information) as secondary references under the study ID of the excluded trial.

Data from clinical trials registers

If data from included trials are available as study results in clinical trials registers, such as ClinicalTrials.gov or similar sources, we will make full use of this information and extract the data. If there is also a full publication of the trial, we will collate and critically appraise all available data. If an included trial is marked as a completed study in a clinical trial register but no additional information (study results, publication or both) is available, we will add this trial to the table 'Characteristics of studies awaiting classification'.

Assessment of risk of bias in included studies

Three out of four review authors (LP, CB, HV, EG) will independently assess the risk of bias for each included trial. We will resolve any disagreements by consensus or by consulting a fifth review author (LE). In the case of disagreement, we will consult the remainder of the review author team and make a judgment based on consensus. If adequate information is unavailable from the publications, trial protocols or other sources, we will contact the trial authors for more detail to request missing data on 'Risk of bias' items.

We will use the Cochrane 'Risk of bias' assessment tool (Higgins 2019b), assigning assessments of low, high or unclear risk of bias (for details see Appendix 2; Appendix 3). We will evaluate individual bias items as described in the *Cochrane Handbook for Systematic Reviews of Interventions* according to the criteria and associated categorizations contained therein *(* Higgins 2019b).

We will present a 'Risk of bias' graph and a 'Risk of bias' summary figure. We will distinguish between self-reported and investigator-assessed and adjudicated outcome measures. We will consider the following self-reported outcomes.

- Adverse events.
- Child- or parent reported HRQoL, self-esteem, and mood.

We will consider the following outcomes to be investigator-assessed.

- Change in body weight or BMI.
- Change in body composition.
- Adverse events.
- All-cause mortality.
- Morbidity.
- Behavior change.
- Socioeconomic effects.

Summary assessment of risk of bias

Risk of bias for a study across outcomes

Some risk of bias domains, such as selection bias (sequence generation and allocation sequence concealment), affect the risk of bias across all outcome measures in a trial. In case of high risk of selection bias, we will mark all endpoints investigated in the associated trial as being at high risk. Otherwise, we will not perform a summary assessment of the risk of bias across all outcomes for a trial.

Risk of bias for an outcome within a study and across domains

We will assess the risk of bias for an outcome measure by including all entries relevant to that outcome (i.e. both study-level entries and outcome-specific entries). We consider low risk of bias to denote a low risk of bias for all key domains, unclear risk to denote an unclear risk of bias for one or more key domains and high risk to denote a high risk of bias for one or more key domains.

Risk of bias for an outcome across studies and across domains

To facilitate our assessment of the certainty of evidence for key outcomes, we will assess risk of bias across trials and domains for the outcomes included in the 'Summary of findings' table. We will define the evidence as being at low risk of bias when most information comes from trials at low risk of bias, unclear risk of bias when most information comes from trials at low or unclear risk of bias, and high risk of bias when a sufficient proportion of information comes from trials at high risk of bias.

Measures of treatment effect

When at least two included trials are available for a comparison and a given outcome, we will try to express dichotomous data as a risk ratio (RR) or odds ratio (OR), with 95% confidence interval (CI). For continuous outcomes measured on the same scale (e.g. weight loss in kg) we will estimate the intervention effect using the mean difference with 95% CI. For continuous outcomes that measure the same underlying concept (e.g. HRQoL) but use different measurement scales, we will calculate the standardized mean difference (SMD). We will express time-to-event data as a hazard ratio (HR) with 95% CI.

Unit of analysis issues

We will take into account the level at which randomization occurred, such as cross-over trials, cluster-randomized trials, and multiple observations for the same outcome. If more than one comparison from the same trial is eligible for inclusion in the same meta-analysis, we will either combine groups to create a single pairwise comparison or appropriately reduce the sample size so that the same participants do not contribute data to the meta-analysis more than once (splitting the 'shared' group into two or more groups). While the latter approach offers some solution to adjusting the precision of the comparison, it does not account for correlation arising from the same set of participants being in multiple comparisons (Higgins 2019a).

We will attempt to reanalyze cluster-RCTs that have not appropriately adjusted for potential clustering of participants within clusters in their analyses. The variance of the intervention effects will be inflated by a design effect. Calculation of a design effect involves estimation of an intra-cluster correlation coefficient (ICC). We will obtain estimates of ICCs through contact with authors or impute them by using either estimates from other included trials that report ICCs or external estimates from empirical research (e.g. Bell 2013). We plan to examine the impact of clustering using sensitivity analyses.

Dealing with missing data

If possible, we will obtain missing data from the authors of the included trials. We will carefully evaluate important numerical data such as screened, randomly assigned participants as well as intention-to-treat, and as-treated and per-protocol populations. We will investigate attrition rates (e.g. dropouts, losses to follow-up and withdrawals), and we will critically appraise issues concerning missing data and use of imputation methods (e.g. last observation carried forward).

In trials where the SD of the outcome is not available at follow-up or cannot be recreated, we will standardize by the average of the pooled baseline SD from those trials that reported this information.

Where included trials do not report means and SDs for outcomes and we do not receive the necessary information from trial authors, we will impute these values by estimating the mean and variance from the median, range, and the size of the sample (Hozo 2005).

We will investigate the impact of imputation on meta-analyses by performing sensitivity analyses and we will report per outcome which trials were included with imputed SDs.

Assessment of heterogeneity

In the event of substantial clinical or methodological heterogeneity, we will not report trial results as the pooled effect estimate in a meta-analysis.

We will identify heterogeneity (inconsistency) by visually inspecting the forest plots and by using a standard Chi^2 test with a significance level of $\alpha = 0.1$ (Deeks 2019). In view of the low power of this test, we will also consider the I^2 statistic, which quantifies inconsistency across trials to assess the impact of heterogeneity on the meta-analysis (Higgins 2002; Higgins 2003). When we identify heterogeneity, we will attempt to determine the possible reasons for it by examining individual characteristics of the trial and subgroup.

Assessment of reporting biases

If we include 10 or more trials that investigate a particular outcome, we will use funnel plots to assess small-trial effects. Several explanations may account for funnel plot asymmetry, including true heterogeneity of effect with respect to trial size, poor methodological design (and hence bias of small trials) and selective non-reporting (Kirkham 2010). Therefore we will interpret the results carefully (Sterne 2011).

Data synthesis

We plan to undertake (or display) a meta-analysis only if we judge the participants, interventions, comparisons, and outcomes to be sufficiently similar to ensure a result that is clinically meaningful. Unless good evidence shows homogeneous effects across trials of different methodological quality, we will primarily summarize data that are of low risk of bias using a random-effects model (Wood 2008). We will interpret random-effects meta-analyses with due consideration to the whole distribution of effects and present a prediction interval (Borenstein 2017a; Borenstein 2017b; Higgins 2009). A prediction interval needs at least three trials to be calculated and specifies a predicted range for the true treatment effect in an individual trial (Riley 2011). For rare events such as event rates below 1%, we will use the Peto's odds ratio method, provided that there is no substantial imbalance between intervention and comparator group sizes and intervention effects are not exceptionally large. In addition, we will perform statistical analyses according to the statistical guidelines presented in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2019).

Subgroup analysis and investigation of heterogeneity

We anticipate specific subgroups may modify the effect of psychological interventions on weight maintenance in children and adolescents. We plan to carry out subgroup analyses for these, including investigation of interactions (Altman 2003).

- Age (6 to 11 years, and 12 to 17 years based on mean age of study group at baseline).
- Weight status at baseline, defined as being above or below severe obesity. Severe obesity is defined as a BMI z-score of 2.67, or ≥ 99th percentile of weight for age and height.
- Duration of intervention, defined as 0 to 12 months or greater than 12 months.
- Length of post-intervention follow-up, defined as 6 to 12 months follow-up, and post-interventional follow-up 12 months or longer.
- Type of psychological intervention, defined as behavioral, CBT, third wave CBT, motivational interviewing, and other.
- Mode of delivery, defined as family-delivered, group-delivered, and child- or adolescent-only interventions.
- Intervention delivery setting, defined as at a hospital, in a clinic, or in the community.
- Who delivers the intervention, defined as trained psychologists/psychiatrists versus non-psychologists/psychiatrists.
- Socioeconomic status of the country of delivery, as defined by the Human Development Index.

Sensitivity analysis

When applicable, we plan to explore the influence of important factors on effect sizes, by performing sensitivity analyses in which we restrict the analyses to the following.

- Published trials.
- The effect of risk of bias, as specified in the Assessment of risk of bias in included studies section.
- Very long or large trials to establish the extent to which they dominate the results.

We will use of the following filters, if applicable: diagnostic criteria, imputation used, language of publication (English versus other languages), source of funding (industry versus other), or country (depending on data).

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

Certainty of the evidence

We will present the overall certainty of evidence for each outcome specified below, according to the GRADE approach, which takes into account issues related not only to internal validity (risk of bias, inconsistency, imprecision, publication bias) and external validity (such as directness of results). Two review authors (selected from HV, LP, CB, EG, KS) will independently rate the certainty of evidence for each outcome. We will resolve any differences in assessment by discussion or consultation with a third researcher (LE).

We will include an appendix entitled 'Checklist to aid consistency and reproducibility of GRADE assessments', to help with standardization of the 'Summary of findings' tables (Meader 2014). Alternatively, we will use the GRADEpro GDT software and will present evidence profile tables as an appendix (GRADEproGDT 2015). We will present results for the outcomes as described in the Types of outcome measures section. If meta-analysis is not possible, we will present the results in a narrative format in the 'Summary of findings' table. We will justify all decisions to downgrade the quality of trials using footnotes, and we will make comments to aid the reader's understanding of the Cochrane Review when necessary.

'Summary of findings' table

We will present a summary of the evidence in a 'Summary of findings' table. This will provide key information about the best estimate of the magnitude of the effect, in relative terms and as absolute differences, for each relevant comparison of alternative management strategies; the numbers of participants and trials addressing each important outcome; and a rating of overall confidence in effect estimates for each outcome. We will create the 'Summary of findings' table based on the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2019) using Review Manager 5 software (RevMan 2014).

Interventions presented in the 'Summary of findings' table will be psychological interventions delivered as a single component intervention. The comparators will be no treatment or waiting-list control, and usual care.

We will report the following outcomes, listed according to priority.

1. Change in body weight, BMI, BMI z-score, BMI percentile.
2. HRQoL.
3. Adverse events.
4. Pschosocial well-being.
5. Health-related behaviour change.
6. All-cause mortality.
7. Morbidity.

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APPENDICES

Appendix 1. Search strategies

MEDLINE (Ovid)

Part I: Obesity

1. Obesity/
2. Obesity, Morbid/
3. Obesity, Abdominal/
4. Pediatric Obesity/
5. Overweight/
6. (adipos* or obes*).tw.
7. (overweight* or over weight*).tw.
8. (weight adj1 (reduc* or control* or manage* or maint* or loss)).tw.
9. or/1-8

Part II: Intervention

10. exp Psychotherapy/
11. exp Behavior Therapy/
12. Counseling/
13. exp Directive Counseling/
14. exp School Health Services/
15. School Nursing/
16. psychotherap*.tw.
17. (psycho* adj3 (therap* or treatment* or intervention* or counsel* or support*)).tw.
18. (behav* adj3 (therap* or treatment* or intervention* or counsel*)).tw.
19. (cognitiv* adj3 (therap* or treatment* or intervention*)).tw.
20. (motivation* adj3 (counsel* or interview*)).tw.
21. ((acceptance or child cent* or client cent* or commitment* or compassion* or emotion* focus* or family* or focus* oriented or group or insight or integrative or interpersonal or mindful* or nondirective or non directive or person cent* or persuasion or problem focused or problem solving or psychodynamic or relax* or schema* or self control* or social skill* or socio environmental or socioenvironmental or solution focused or stress manage* or validation) adj3 therap*).tw.

(Continued)

22. (counsel?ing or psychoanaly* or psychoeducat* or relaxation techni* or role play* or self analysis or sociotherap* or stress manag* or support group*).tw.

23. (school nurs*).tw.

24. or/10-23

Part III: Obesity + Intervention

25. 9 and 24

Part IV: Population [adapted from Leclercq 2013 *]*

26. Adolescent/

27. Child/

28. Pediatrics/

29. minors.tw.

30. (boy or boys or boyhood).tw.

31. girl*.tw.

32. (kid or kids).tw.

33. (child or childs or children* or childhood* or childcare* or schoolchild*).tw.

34. adolescen*.tw.

35. juvenil*.tw.

36. youth*.tw.

37. (teen* or preteen*).tw.

38. (underage* or under age*).tw.

39. pubescen*.tw.

40. p?ediatric*.tw.

41. or/26-40

Part V: Part III AND IV

42. 25 and 41

Part VI: Study filter [Lefebvre 2019 *Cochrane Handbook RCT filter - sensitivity max. version without "drug therapy.fs"]*

43. randomized controlled trial.pt.

44. controlled clinical trial.pt.

45. randomi?ed.ab.

46. placebo.ab.

47. randomly.ab.

48. trial.ab.

49. groups.ab.

50. or/43-49

51. exp animals/ not humans/

(Continued)

52. 50 not 51

Part VII: Part V + Part VI

53. 42 and 52

Cochrane Central Register of Controlled Trials (Cochrane Register of Studies Online)

Part I: Obesity

1. MESH DESCRIPTOR Obesity

2. MESH DESCRIPTOR Obesity, Morbid

3. MESH DESCRIPTOR Obesity, Abdominal

4. MESH DESCRIPTOR Pediatric Obesity

5. MESH DESCRIPTOR Overweight

6. (adipos* OR obes*):TI,AB,KY

7. (overweight* OR over weight*):TI,AB,KY

8. (weight ADJ1 (reduc* OR control* OR manage* OR maint* OR loss)):TI,AB,KY

9. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8

Part II: Intervention

10. MESH DESCRIPTOR Psychotherapy EXPLODE ALL TREES

11. MESH DESCRIPTOR Behavior Therapy EXPLODE ALL TREES

12. MESH DESCRIPTOR Counseling

13. MESH DESCRIPTOR Directive Counseling EXPLODE ALL TREES

14. MESH DESCRIPTOR School Health Services EXPLODE ALL TREES

15. MESH DESCRIPTOR School Nursing

16. psychotherap*:TI,AB,KY

17. (psycho* ADJ3 (therap* OR treatment* OR intervention* OR counsel* OR support*)):TI,AB,KY

18. (behav* ADJ3 (therap* OR treatment* OR intervention* OR counsel*)):TI,AB,KY

19. (cognitiv* ADJ3 (therap* OR treatment* OR intervention*)):TI,AB,KY

20. (motivation* ADJ3 (counsel* OR interview*)):TI,AB,KY

21. ((acceptance OR child cent* OR client cent* OR commitment* OR compassion* OR emotion* focus* OR family* OR focus* oriented OR group OR insight OR integrative OR interpersonal OR mindful* OR nondirective OR non directive OR person cent* OR persuasion OR problem focused OR problem solving OR psychodynamic OR relax* OR schema* OR self control* OR social skill* OR socio environmental OR socioenvironmental OR solution focused OR stress manage* OR validation) ADJ3 therap*):TI,AB,KY

22. (counsel?ing OR psychoanaly* OR psychoeducat* OR relaxation techni* OR role play* OR self analysis OR sociotherap* OR stress manag* OR support group*):TI,AB,KY

23. (school nurs*):TI,AB,KY

24. #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23

Part III: Obesity + Intervention

25. #9 AND #24

(Continued)

Part IV: Population [adapted from Leclercq 2013 *]*

26. MESH DESCRIPTOR Adolescent

27. MESH DESCRIPTOR Child

28. MESH DESCRIPTOR Pediatrics

29. minors:TI,AB,KY

30. (boy OR boys OR boyhood):TI,AB,KY

31. girl*:TI,AB,KY

32. (kid OR kids):TI,AB,KY

33. (child OR childs OR children* OR childhood* OR childcare* OR schoolchild*):TI,AB,KY

34. adolescen*:TI,AB,KY

35. juvenil*:TI,AB,KY

36. youth*:TI,AB,KY

37. (teen* OR preteen*):TI,AB,KY

38. (underage* OR under age*):TI,AB,KY

39. pubescen*:TI,AB,KY

40. p?ediatric*:TI,AB,KY

41. #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40

Part V: Part III AND IV

42. #25 AND #41

PsycINFO (Ovid)

Part I: Obesity

1. Obesity/

2. Overweight/

3. Weight Control/

4. (adipos* or obes*).tw.

5. (overweight* or over weight*).tw.

6. (weight adj1 (reduc* or control* or manage* or maint* or loss)).tw.

7. or/1-6

Part II: Intervention

8. exp Psychotherapy/

9. exp Behavior Therapy/

10. exp Cognitive Behavior Therapy/

11. Cognitive Therapy

12. exp Counseling/

(Continued)

13. Support Groups/

14. psychotherap*.tw.

15. (psycho* adj3 (therap* or treatment* or intervention* or counsel* or support*)).tw.

16. (behav* adj3 (therap* or treatment* or intervention* or counsel*)).tw.

17. (cognitiv* adj3 (therap* or treatment* or intervention*)).tw.

18. (motivation* adj3 (counsel* or interview*)).tw.

19. ((acceptance or child cent* or client cent* or commitment* or compassion* or emotion* focus* or family* or focus* oriented or group or insight or integrative or interpersonal or mindful* or nondirective or non directive or person cent* or persuasion or problem focused or problem solving or psychodynamic or relax* or schema* or self control* or social skill* or socio environmental or socioenvironmental or solution focused or stress manage* or validation) adj3 therap*).tw.

20. (counsel?ing or psychoanaly* or psychoeducat* or relaxation techni* or role play* or self analysis or sociotherap* or stress manag* or support group*).tw.

21. (school nurs*).tw.

22. or/8-21

Part III: Part I + Part II

23. 7 and 22

Part IV: Population [adapted from Leclercq 2013 *]*

24. minors.tw.

25. (boy or boys or boyhood).tw.

26. girl*.tw.

27. (kid or kids).tw.

28. (child or childs or children* or childhood* or childcare* or schoolchild*).tw.

29. adolescen*.tw.

30. juvenil*.tw.

31. youth*.tw.

32. (teen* or preteen*).tw.

33. (underage* or under age*).tw.

34. pubescen*.tw.

35. p?ediatric*.tw.

36. or/24-35

Part V: Part III AND IV

37. 23 and 36

Part VI: Study filter [Eady 2008 *"PsycInfo Search Strategies" filter - best sensitivity version]*

38. control*.tw. OR random*.tw. OR exp Treatment/

Part VII: Part V + Part VI

39. 37 and 38

(Continued)

LILACS (iAHx)
((((MH:"Obesity" OR MH:"Obesity, Morbid" OR MH:"Obesity, Abdominal" OR MH:"Pediatric Obesity" OR MH:"Overweight" OR adipos$ OR obes$ OR overweight$ OR "over weight" OR sobrepes$ OR "exceso de peso" OR "excesso de peso" OR "weight reduction" OR "weight loss" OR "weight control" OR "control de peso") **AND** (MH:"Psychotherapy" OR MH:"Behavior Therapy" OR MH:"Counseling" OR MH:"Family Therapy" OR MH:"School Health Services" OR MH:"School Nursing" OR terapia OR psycoterap$ OR orienta$)**)** OR (MH:"Obesity/psychology" OR MH:"Obesity, Morbid/psychology" OR MH:"Overweight/psychology")**) AND** (MH:"Adolescent" OR MH:"Child" OR MH:"Pediatrics" OR minors OR boy OR boys OR girl$ OR kid OR kids OR child OR childs OR children$ OR childhood$ OR childcare$ OR schoolchild$ OR escolar$ OR adolescen$ OR preadolescen$ OR juvenil$ OR juventud$ OR youth$ OR teen$ OR preteen$ OR underage$ OR pubescen$ OR paediatri$ OR pediatri$ OR joven$ OR jovem$ OR niños OR niñas OR crianca$ OR menin$ OR "menor de edad" OR "menores de edad" OR "menor de idade" OR "menores de idade")**)** OR MH:"Pediatric Obesity/prevention & control" OR MH:"Pediatric Obesity/therapy" OR MH:"Pediatric Obesity/psychology" + Controlled Clinical Trial
WHO ICTRP (Standard search)
(activated "Search for clinical trials in children") obes* AND psycho* OR obes* AND cognitiv* OR obes* AND behavi* OR obes* AND motivation* OR obes* AND counsel* OR obes* AND emotion* OR overweight* AND emotion* OR overweight* AND psycho* OR overweight* AND cognitiv* OR overweight* AND behavi* OR overweight* AND motivation* OR overweight* AND counsel* OR overweight* AND emotion*
ClinicalTrials.gov (Expert search)
AREA[ConditionSearch] (obese OR overweight OR obesity OR EXPAND[Concept] "weight reduction" OR EXPAND[Concept] "weight control" OR EXPAND[Concept] "weight loss" OR EXPAND[Concept] "weight management") AND AREA[InterventionSearch] (psychotherapy OR EXPAND[Concept] "psycho therapy" OR psychotherapeutic OR psychotherapeutical OR psychological OR cognitive OR behavioral OR behavioural OR behavior OR behaviour OR motivational OR counseling OR counselling OR acceptance OR commitment OR compassion OR emotion OR focussed OR focused OR EXPAND[Concept] "problem solving" OR psychodynamic OR schema OR stress OR validation OR psychoanalysis OR psychoanalytical OR sociotherapy) AND AREA[StdAge] EXPAND[Term] COVER[FullMatch] "Child"

Appendix 2. Assessment of risk of bias

Risk of bias domains
Random sequence generation (selection bias due to inadequate generation of a randomized sequence) For each included trial, we will describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. • Low risk of bias: the trial authors achieved sequence generation using computer-generated random numbers or a random numbers table. Drawing of lots, tossing a coin, shuffling cards or envelopes, and throwing dice are adequate if an independent person per-

(Continued)

formed this who was not otherwise involved in the trial. We will consider the use of the minimisation technique as equivalent to being random.

- Unclear risk of bias: insufficient information about the sequence generation process.
- High risk of bias: the sequence generation method was non-random or quasi-random (e.g. sequence generated by odd or even date of birth; sequence generated by some rule based on date (or day) of admission; sequence generated by some rule based on hospital or clinic record number; allocation by judgment of the clinician; allocation by preference of the participant; allocation based on the results of a laboratory test or a series of tests; or allocation by availability of the intervention).

Allocation concealment (selection bias due to inadequate concealment of allocation prior to assignment)

We will describe for each included trial the method used to conceal allocation to interventions prior to assignment and we will assess whether intervention allocation could have been foreseen in advance of or during recruitment, or changed after assignment.

- Low risk of bias: central allocation (including telephone, interactive voice-recorder, web-based and pharmacy-controlled randomization); sequentially numbered drug containers of identical appearance; sequentially numbered, opaque, sealed envelopes.
- Unclear risk of bias: insufficient information about the allocation concealment.
- High risk of bias: used an open random allocation schedule (e.g. a list of random numbers); assignment envelopes used without appropriate safeguards; alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure.

We will also evaluate trial baseline data to incorporate assessment of baseline imbalance into the 'Risk of bias' judgment for selection bias (Corbett 2014). Chance imbalances may also affect judgments on the risk of attrition bias. In the case of unadjusted analyses, we will distinguish between trials that we rate as being at low risk of bias on the basis of both randomization methods and baseline similarity, and trials that we judge as being at low risk of bias on the basis of baseline similarity alone (Corbett 2014). We will reclassify judgments of unclear, low or high risk of selection bias as specified in Appendix 3.

Blinding of participants and study personnel (performance bias due to knowledge of the allocated interventions by participants and personnel during the trial)

We will evaluate the risk of detection bias separately for each outcome (Hróbjartsson 2013). We will note whether endpoints were self-reported, investigator-assessed or adjudicated outcome measures (see below).

- Low risk of bias: blinding of participants and key study personnel was ensured, and it was unlikely that the blinding could have been broken; no blinding or incomplete blinding, but we judge that the outcome is unlikely to have been influenced by lack of blinding.
- Unclear risk of bias: insufficient information about the blinding of participants and study personnel; the trial does not address this outcome.
- High risk of bias: no blinding or incomplete blinding, and the outcome is likely to have been influenced by lack of blinding; blinding of trial participants and key personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.

Blinding of outcome assessment (detection bias due to knowledge of the allocated interventions by outcome assessment

We will evaluate the risk of detection bias separately for each outcome (Hróbjartsson 2013). We will note whether endpoints were self-reported, investigator-assessed or adjudicated outcome measures (see below).

- Low risk of bias: blinding of outcome assessment is ensured, and it is unlikely that the blinding could have been broken; no blinding of outcome assessment, but we judge that the outcome measurement is unlikely to have been influenced by lack of blinding.
- Unclear risk of bias: insufficient information about the blinding of outcome assessors; the trial did not address this outcome.
- High risk of bias: no blinding of outcome assessment, and the outcome measurement was likely to have been influenced by lack of blinding; blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement was likely to be influenced by lack of blinding.

Incomplete outcome data (attrition bias due to amount, nature or handling of incomplete outcome data)

For each included trial and/or each outcome, we will describe the completeness of data, including attrition and exclusions from the analyses. We will state whether the trial reported attrition and exclusions, and report the number of participants included in the analysis at each stage (compared with the number of randomized participants per intervention/comparator groups). We will also note if the trial reported the reasons for attrition or exclusion and whether missing data were balanced across groups or were related to outcomes. We will consider the implications of missing outcome data per outcome such as high dropout rates (e.g. above 15%) or disparate attrition rates (e.g. difference of 10% or more between trial arms).

- Low risk of bias: no missing outcome data; reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to introduce bias); missing outcome data balanced in numbers across intervention groups, with similar reasons

(Continued)

for missing data across groups; for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk was not enough to have a clinically relevant impact on the intervention effect estimate; for continuous outcome data, plausible effect size (mean difference or standardized mean difference) among missing outcomes was not enough to have a clinically relevant impact on observed effect size; appropriate methods, such as multiple imputation, were used to handle missing data.

- Unclear risk of bias: insufficient information to assess whether missing data in combination with the method used to handle missing data were likely to induce bias; the trial did not address this outcome.
- High risk of bias: reason for missing outcome data was likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in the intervention effect estimate; for continuous outcome data, plausible effect size (mean difference or standardized mean difference) among missing outcomes enough to induce clinically-relevant bias in observed effect size; 'as-treated' or similar analysis done with substantial departure of the intervention received from that assigned at randomization; potentially inappropriate application of simple imputation.

Selective reporting (reporting bias due to selective outcome reporting)

We will assess outcome reporting bias by integrating the results of the appendix 'Matrix of trial endpoints (publications and trial documents)' (Boutron 2014; Jones 2015; Mathieu 2009), with those of the appendix 'High risk of outcome reporting bias according to the Outcome Reporting Bias In Trials (ORBIT) classification' (Kirkham 2010). This analysis will form the basis for the judgment of selective reporting.

- Low risk of bias: the trial protocol was available and all the trial's prespecified (primary and secondary) outcomes that were of interest to this review were reported in the prespecified way; the study protocol was unavailable, but it was clear that the published reports included all expected outcomes (ORBIT classification).
- Unclear risk of bias: insufficient information about selective reporting.
- High risk of bias: not all the trial's prespecified primary outcomes were reported; one or more primary outcomes were reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not prespecified; one or more reported primary outcomes were not prespecified (unless clear justification for their reporting was provided, such as an unexpected adverse effect); one or more outcomes of interest in the Cochrane Review were reported incompletely so that we cannot enter them in a meta-analysis; the trial report failed to include results for a key outcome that we would expect to have been reported for such a trial (ORBIT classification).

Other bias

- Low risk of bias: the trial appears to be free from other sources of bias.
- Unclear risk of bias: there was insufficient information to assess whether an important risk of bias existed; insufficient rationale or evidence that an identified problem introduced bias.
- High risk of bias: the trial had a potential source of bias related to the specific trial design used; the trial was claimed to be fraudulent; or the trial had some other serious problem.

Appendix 3. Selection bias decisions

Selection bias decisions for trials that reported unadjusted analyses: comparison of results obtained using method details alone with results using method details and trial baseline information[a]

Reported randomization and allocation concealment methods	Risk of bias judgment using methods reporting	Information gained from study characteristics data	Ris of bias using baseline information and methods reporting
Unclear methods	Unclear risk	Baseline imbalances present for important prognostic variable(s)	**High risk**
		Groups appear similar at baseline for all important prognostic variables	**Low risk**

(Continued)

		Limited or no baseline details	Unclear risk
Would generate a truly random sample, with robust allocation concealment	Low risk	Baseline imbalances present for important prognostic variable(s)	**Unclear risk** [b]
		Groups appear similar at baseline for all important prognostic variables	Low risk
		Limited baseline details, showing balance in some important prognostic variables[c]	Low risk
		No baseline details	**Unclear risk**
Sequence is not truly randomized, or allocation concealment is inadequate	High risk	Baseline imbalances present for important prognostic variable(s)	High risk
		Groups appear similar at baseline for all important prognostic variables	**Low risk**
		Limited baseline details, showing balance in some important prognostic variables[c]	**Unclear risk**
		No baseline details	High risk

[a]Taken from Corbett 2014; judgments highlighted in bold indicate situations in which the addition of baseline assessments would change the judgment about risk of selection bias, compared with using methods reporting alone.
[b]Imbalance identified that appears likely to be due to chance.
[c]Details for the remaining important prognostic variables are not reported.

HISTORY

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CONTRIBUTIONS OF AUTHORS

All review authors contributed to, read and approved the final protocol draft.

DECLARATIONS OF INTEREST

Heidi Vanden Brink (HV): received a training fellowship from the Canadian Institutes for Health Research (CIHR). Support from this fellowship was used for a training workshop on the conduct of Cochrane systematic reviews.

Lorena S Pacheco (LSP): grants from the National Heart, Lung, and Blood Institute, during the preparation of the work being considered for publication.

Charlotte L Bahnfleth (CLB): none known.

Louisa J Ells (LJE): is seconded to Public Health England (PHE) as part time specialist obesity advisor but undertook this review within her role as Professor of Obesity at Leeds Beckett University

Andrew J Hill (AJH): received personal fees from 'Slimming World'. AJH is an advisor for 'Slimming World'. According to AJH 'Slimming World' is one of the companies that the Department of Health recognise as non-NHS providers of weight management in the UK.

Katherine Sanderson (KS): none known.

Alessandro R Demaio (ARD): Chief Executive Officer (CEO) of the Victorian Health Promotion Foundation (VicHealth), Australia. VicHealth has a Board of Governance that is responsible to the Victorian Minister for Health. The authors alone are responsible for the views expressed in this publication and they do not necessarily represent the decisions, policy or views of VicHealth.

Lynn M Johnson (LJ): none known.

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NOTES

We have based parts of the Methods, as well as Appendix 1, Appendix 2 and Appendix 3 of this Cochrane Protocol on a standard template established by the CMED Group.