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[Intervention Protocol]

Health, not weight loss, focused programmes versus conventional weight loss programmes for cardiovascular risk factors

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The aim of this review is to compare the effects of HNWL programmes with those of CWL programmes on cardiovascular risk factors in adults with a BMI greater than 25 kg/m^2.

BACKGROUND

Description of the condition

The World Health Organization (WHO) defines cardiovascular diseases (CVDs) as a collection of conditions affecting the heart and blood vessels in the body. More individuals die from CVDs annually than from any other disease, making it the leading cause of mortality across the globe. It is no longer just a disease of developed nations, as over 80% of CVD mortality now occurs in developing countries (WHO 2013). Approximately 17.3 million people died from CVDs in 2008; this is predicted to rise to 23.3 million by 2030, with CVDs projected to remain the foremost cause of death globally (WHO 2013).

Cardiovascular events, such as myocardial infarctions and strokes, are primarily triggered by a blood clot in an artery narrowed by atherosclerosis, which restricts the flow of blood to the heart or the brain. They are usually acute events, but the risk of such an event is attributed to long-term health behaviours. In more than 90% of cases worldwide, the risk of a first myocardial infarction is related to nine independent, potentially modifiable, risk factors: an abnormal blood lipid profile, smoking, hypertension, diabetes mellitus, abdominal obesity, diet, alcohol, physical activity and psychosocial factors such as depression (Yusuf 2004).

The effect of modifying these risk factors is clearer for some behaviours than for others. For example, there is substantial evidence that smoking cessation (Novello 1999); treatment to reduce blood pressure, treatment to reduce blood lipids and adequately control diabetes (Graham 2007); adopting a Mediterranean diet (Estruch

2013; Rees 2013); and increasing levels of physical fitness (Lee 2011) reduce cardiovascular mortality. However, findings regarding intentional weight loss are less clear. Although a body mass index (BMI) above 25 kg/m^2 is associated with a 23% increased risk of developing CVD (WHO 2013), limited success at achieving long-term weight loss, together with repeated attempts to lose weight followed by weight gain, may not only limit the potential benefits of weight loss, but may be associated with harm, although the evidence surrounding this is conflicting.

A 15-year prospective cohort study in 1160 men suggested that weight fluctuations result in a higher risk of all-cause mortality compared to steady weight maintenance, based on an adjusted hazard rate ratio of 1.86 (95% confidence interval (CI) 1.31 to 2.66). This study adjusted for pre-existing illness, but did not adjust for intentionality of weight loss (Rzehak 2007). Two further prospective studies, which adjusted for intentionality of weight loss, did not find a significantly higher all-cause mortality rate in those with a history of severe weight cycling than in those whose weight remained stable (Field 2009; Stevens 2012). A meta-analysis of 26 prospective studies by Harrington 2009 found that intentional weight loss had a small benefit in obese individuals with comorbidities (relative risk (RR) 0.84, 95% CI 0.73 to 0.97). However, weight loss appeared to be associated with slightly higher mortality in healthy individuals (RR 1.11, 95% CI 1.00 to 1.22) and those who were overweight but not obese (RR 1.09, 95% CI 1.02 to 1.17). The analysis showed no evidence that weight loss conferred either benefit or risk in healthy obese individuals. Therefore, the evidence supporting the benefit of intentional weight loss, particularly in individuals without comorbidities, or the risk of associated weight cycling in this population is unclear.

The problem of recurrent weight cycling and the difficulty in achieving and maintaining weight loss may lie in the complex aetiology of overweight and obesity. Although the concept of energy balance is simple - when an individual's energy intake exceeds their energy expenditure, weight is gained (Söderlund 2009) - the factors that cause intake to exceed expenditure are varied and complex. They comprise interrelated personal and environmental influences that were described in the 2007 Foresight report on tackling obesities to cluster into seven themes (Foresight 2007). The first of these themes, food consumption, encompasses personal food preferences, food habits and portion control, which may be either self-determined or influenced by current social norms. Food production is a theme that encompasses factors such as the availability of cheap, palatable, energy-dense foods. Demand for these foods fuels food production, which leads to further societal acceptance and higher demand, and so the cycle continues. Another theme is physiological factors, which result from an individual's biological and genetic composition. These may, for example, partially determine an individual's regulatory mechanisms of hunger and satiety. However, the mechanisms may be overridden by external factors such as the availability of food. Individual physical activity is another theme and includes individual barriers to engaging in physical activity; for example, learned patterns of activity, sedentary occupations and commuting needs. Physical activity environment, also a theme, relates to barriers within the environment, such as the cost of formal exercise and the perceived safety of being out alone. Another key theme is individual psychology; this encompasses stress levels, confidence and self-esteem, and the associated emotive drive to eat, which again may override physiological mechanisms. The last theme is social psychology. This is related to the thoughts and opinions that permeate society and are prevalent in printed media, television and education. For example, the societal perception of obesity and pressure related to body image has psychological consequences of stress and low self-esteem, and overeating may develop as a coping strategy to deal with these issues (Foresight 2007).

As the factors that contribute to the development of obesity are many, multicomponent interventions that tackle several of these areas have been developed for the effective prevention and management of obesity, so as to reduce the burden of diseases such as CVD and diabetes. The National Institute for Health and Clinical Excellence (NICE 2006) recommend that interventions for obese individuals comprise components that address diet and physical activity, and incorporate behavioural change techniques. It recommends that individuals should strive to reach and maintain a realistic target weight loss of 5% to 10% of their original weight through a weekly weight loss of 0.5 kg to 1 kg (NICE 2006). Although many overweight or obese people are able to lose weight in this way, however, a large proportion of these people are unable to maintain these new health behaviours or this weight loss. Several meta-analyses of randomised trials (Curioni 2005; McTigue 2003; Turk 2009) have shown that about one-third of weight lost is regained within one year and almost all of the weight lost is regained within five years (Katzer 2008). Sometimes, this weight gain continues; a review of 31 long-term studies found that between one- and two-thirds of dieters gained more weight than they had lost originally (Mann 2007).

Lack of a sustained change in weight and, hence, a lack of a reduction in long-term chronic disease risk, may be due to an emphasis on food restriction. Food restriction can lead to hunger and feelings of deprivation or preoccupation with food, which in turn trigger overconsumption. Overconsumption and weight gain may lead to feelings of low self-esteem, depression and guilt. To manage feelings of guilt associated with overconsumption, further attempts are made to restrict eating, and a cycle of dieting and bingeing, weight loss and weight gain is perpetuated, with little long-term gain in risk reduction (Cole 2010; Hawley 2008; Neumark-Sztainer 2000; Rapoport 2000).

This leads us to question what is the best approach to reducing the chronic disease risk associated with obesity? Should we continue to focus on weight loss in all who are overweight or obese, or is there a possibility that some individuals would achieve a greater improvement in their cardiovascular risk profile through greater emphasis being placed on the maintenance of a healthy lifestyle

and improved psychosocial well being, irrespective of weight loss?

Description of the intervention

Interventions that have been developed to focus on the health gains of dietary change, physical activity and psychosocial well being in those who are overweight or obese, rather than on weight loss only, we have termed 'health, not weight loss, focused' (HNWL) programmes. Among these is the Health At Every Size (HAES) programme. Randomised controlled trials (RCTs) have shown that HNWL programmes may have a greater effect on reducing cardiovascular risk factors, such as improving the blood lipid profile and blood pressure, and reducing depression, compared with conventional weight loss (CWL) programmes (Bacon 2002; Bacon 2005; Carroll 2007; Gagnon-Girouard 2010; Provencher 2007; Provencher 2009).

HNWL programmes promote healthy lifestyle change and foster a positive body image, irrespective of BMI or weight loss success. Behaviour change techniques help individuals adopt more healthy food choices and engage in more physical activity, with the enjoyment of food and exercise as an important focus. Techniques include cognitive restructuring, and attentive and intuitive eating. A holistic approach is taken that seeks to address the multifactorial aspects of achieving a healthy lifestyle, including emotional, spiritual and social needs. Promoting mental well being through encouraging self-acceptance and promoting feelings of self-worth are all part of this approach.

CWL programmes include behaviour change techniques that facilitate adopting a healthy diet and increasing physical activity for the purpose of achieving a weekly weight loss target (NICE 2006). The weight loss target is a priority of the interventions, unlike HNWL programmes, which focus on the benefits of a healthy lifestyle, improved mental well being and self-acceptance, regardless of the amount of weight loss achieved. Any weight loss that does occur through these changes is a bonus rather than a target.

How the intervention might work

In taking the focus away from weight loss and food restriction, the HNWL approach engages in a more holistic method of promoting healthy behavioural change. The combination of addressing psychological and spiritual, as well as physical, well being may lead to greater contentment and more-sustained lifestyle changes, resulting in a greater reduction in cardiovascular risk factors than CWL programmes. A key element of HNWL is teaching individuals to think positively about food, and also to recognise and respond to internal cues, such as hunger and satiety (Bacon 2005). Responding to internal cues to eat is called intuitive eating (IE). This helps people to eat in response to genuine hunger and not to consume food for other reasons (e.g. in response to emotion). This may work as feelings of satisfaction through eating a healthy diet replace feelings of deprivation. In addition, recognising the body's natural desires for food and working in tune with these may improve body satisfaction, self-image and mental well being (Katzer 2008; Miller 2001; Robison 2005).

Why it is important to do this review

As described above, we are aware of several RCTs comparing HNWL with CWL programmes. While two narrative review papers have been published (Bacon 2011; King 2007), these do not use robust quantitative methodology to combine and analyse the whole body of evidence in this area. To do this, a systematic review and meta-analysis is needed. A scoping review of the literature showed that to date no systematic review or meta-analysis has been conducted in this area and, as such, no clinical recommendation for or against the effectiveness of HNWL approaches can be made. Undertaking a systematic review with meta-analysis will inform clinical practice regarding whether HNWL approaches show the potential to improve cardiovascular risk factors compared with CWL programmes.

OBJECTIVES

The aim of this review is to compare the effects of HNWL programmes with those of CWL programmes on cardiovascular risk factors in adults with a BMI greater than 25 kg/m^2.

METHODS

Criteria for considering studies for this review

Types of studies

We will include RCTs comparing HNWL programmes with CWL programmes. We will also include cluster randomised trials and take these different study designs into account in the analysis.

Types of participants

We will include adults, 18 years old and over, with a BMI greater than 25 kg/m^2.

Types of interventions

We will include trials comparing HNWL programmes with CWL programmes.

Study group

HNWL programmes

Any programme that promotes an increase in physical activity and improved healthy eating without a primary focus on weight loss, whether the intervention is branded HAES or not. The focus will instead be on improving physical and mental health through addressing a variety of factors, which may include lifestyle, emotional, social and spiritual factors.

Control group

CWL programmes

Any diet, exercise or behavioural programme, or a combination of these, focusing on achieving weight loss of between 0.5 kg/week and 1 kg/week.

We have devised a checklist from the descriptions of interventions in studies already known to us in order to identify suitable programmes and differentiate between programme types. We have paid particular attention to the behaviour change techniques that are unique to each programme (Table 1).

Types of outcome measures

Our outcome measures are based on seven of the nine main risk factors described previously (Yusuf 2004). Trials need to include at least one of these outcome measures. The seven risk factors chosen are those most typically measured as part of weight management interventions and exclude the assessment of changes in the prevalences of smoking and diabetes. Included studies must have a minimum follow-up period of two months after the end of treatment.

Primary outcomes

Our primary outcomes are the following physiological markers of cardiovascular risk:

1. blood lipids;
2. blood pressure;
3. body weight.

In trials using more than one measure for any outcome, we will prefer the measure with the strictest criteria (e.g. measured over self-reported weight).

Secondary outcomes

Our secondary outcomes are those risk factors that may mediate the primary outcomes, but that are also known independent cardiovascular risk factors. They may include a variety of dimensions and may be measured in a variety of ways. We will pool together measures of the same dimension and include only those studies that have measured these outcomes with validated tools:

1. diet;
2. physical activity;
3. alcohol intake;
4. psychosocial well being;
5. adverse events.

Search methods for identification of studies

Our search for trials will begin in 1970, the time when the concept of HNWL was first developed.

Electronic searches

We will identify trials through systematic searches of the following bibliographic databases:

- Cochrane Central Register of Controlled Trials (CENTRAL) on The Cochrane Library;
- MEDLINE (Ovid);
- EMBASE (Ovid);
- PsycINFO (Ovid);
- CINAHL (Ebsco);
- ASSIA (Applied Social Sciences Index and Abstracts).

We will adapt the preliminary search strategy for MEDLINE (Ovid) (Appendix 1) for use with the other databases. We will apply the Cochrane sensitivity-maximising RCT filter (Lefebvre 2011) to MEDLINE (Ovid) and adaptations of it to the other databases, with the exception of CENTRAL. We will search all databases from 1970 to the present, and we will impose no restriction on language of publication.

Searching other resources

We will identify any relevant ongoing trials through searching trial registers and trial result registers, which are the best sources for trials that are either ongoing or unpublished:

- ClinicalTrials.gov (www.ClinicalTrials.gov);
- WHO International Clinical Trials Registry Platform Search Portal (http://apps.who.int/trialsearch/);
- National Institute for Health Research search portal (https://portal.nihr.ac.uk/Pages/NIHRResearchInfoStatement.aspx);
- UK Clinical Trials Gateway - Current Controlled Trials (www.controlled-trials.com/ukctr/);
- National Research Register Archive (portal.nihr.ac.uk/Pages/NRRArchive.aspx);
- University Hospital Medical Information Network Clinical Trials Registry (www.umin.ac.jp/ctr/).

We will handsearch the reference list of all included studies, background articles and the narrative review articles described above, to identify any additional relevant studies.

We will search commercial and non-profit organisation websites for additional information that may be relevant to us:

- HAES UK (http://www.healthateverysize.org.uk/);
- Association for Size Diversity and Health (https://www.sizediversityandhealth.org/);
- National Association to Advance Fat Acceptance (NAAFA) (http://www.naafaonline.com/dev2/);
- the resource list for the HAES curriculum (http://haescurriculum.files.wordpress.com/2013/07/haes-curriculum-resource-list.pdf).

We will keep and maintain a hard or electronic copy of findings and study details, with specific reference to the date when we accessed the websites.

We will contact the authors of relevant papers where trials are ongoing or data are missing.

Data collection and analysis

Selection of studies

NK and DL will check the titles and abstracts of studies generated by the search. We will obtain full-text copies of papers reporting relevant trials and have them translated if necessary. NK and DL will independently review the trials, either accepting or rejecting them in accordance with the eligibility criteria (Table 2). We will resolve any disagreement regarding study inclusion through discussion with a third author (GF). In the case of different reports of the same study, we will use the data only once.

Data extraction and management

For each trial, NK will extract the data and DL will check them. We will use a data collection form to record the study methods, participant characteristics and outcomes. We will present this information in a 'Characteristics of included studies' table. The information collected will include the following.

Methods

- Design of the trial, for example RCT or cluster RCT
- Method of randomisation
- Method of randomisation concealment
- How participants were selected
- Details of ethical approval and when consent forms and information sheets were given to participants
- The location and setting of the study
- The date of the study
- Total duration of the study
- Time elapsed before following up with participants or any withdrawal of participants
- Details of any 'run in' period used with HNWL or weight loss programmes. For example, individuals may be required to avoid weight loss attempts in the months preceding the trial

Participants

- The number of participants randomly assigned to each intervention group
- Baseline demographic information relating to participants (age, gender, ethnicity)
- Baseline BMI of participants
- Presence of comorbidities
- Whether having any treatment or taking any medication that may influence the cardiovascular risk factors being measured
- Inclusion and exclusion criteria used in the study

Interventions

- Description and duration of any form of HNWL programme used
- Aherence to the intervention
- Description and duration of any form of CWL programme used
- Supplementary interventions (e.g. low calorie diets or extreme exercise) that might result in weight loss of more than 1 kg/week
- Whether any other forms of intervention were used and further details if relevant
- Details of any dietary, physical activity, psychological or behavioural support provided to participants
- Behaviour change techniques, using the taxonomy of behaviour change (Michie 2011), used in the control and intervention groups
- Details of any HNWL philosophy discussed
- Details of who delivered the intervention

Outcomes

- Outcomes measured
- Tools and methods used to record outcomes and whether these are validated
- Timepoints when outcomes were measured
- Whether intention-to-treat (ITT) analysis was used/how dropout was dealt with in the analysis
- Dropout rates
- Reasons for withdrawal
- Details of any adverse events in each group
- Additional outcome results
- Amount of missing data in both groups

Assessment of risk of bias in included studies

We will assess risk of bias using the guidelines given in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). We will include assessments of the domains of random sequence generation, allocation concealment and incomplete outcome data. NK will assess the risk of bias in each study. DL will check this, and GF will, if necessary, assist in resolving any disputes that arise during this process. We will grade each potential source as having a high, low or unclear risk of bias, and provide a quote from the study report together with a justification for our judgement in the 'Risk of bias' table (Table 3). We will summarise our 'Risk of bias' judgements across different studies for each of the domains listed. Where information on risk of bias relates to unpublished data or to correspondence with a trialist, we will note this in the 'Risk of bias' table. We will also note any other type of bias (e.g. where there are financial conflicts of interest).

When considering treatment effects, we will consider whether the contributing studies have a high, low or unclear risk of bias.

Measures of treatment effect

Most of our outcomes (e.g. weight, blood pressure, lipids) will be continuous data. We will analyse continuous data as mean differences with 95% confidence intervals, in order to compare the change in outcome between the intervention and control arms. We will enter data presented as a scale with a consistent direction of effect. We will narratively describe skewed data reported as medians and interquartile ranges. Some of our outcomes may use ordinal scales (e.g. measures of psychosocial well being, levels of physical activity). Where possible (i.e. with scales of five or more ordinal categories) we will treat these as continuous data. If there is variation in the scales used to measure the same outcome, we will analyse these outcomes using standardised mean differences and 95% confidence intervals.

Unit of analysis issues

In the case of cluster RCTs we will either reduce the size of the trial to its effective sample size by taking into account the intracluster correlation coefficient or we will calculate an inflated standard error, whichever is most appropriate to the trial.

Dealing with missing data

We will contact investigators or study sponsors in order to verify key study characteristics and obtain missing numerical outcome data where possible. Where this is not possible, and the missing data are thought to introduce serious bias, we will explore the impact of including such studies on the overall assessment of the results using sensitivity analyses. It may be necessary to analyse separately those studies that used ITT analyses from those that carried out completer analyses.

Assessment of heterogeneity

We will identify and analyse inconsistencies across study results through an examination of the forest plots. We will observe the overlapping confidence intervals and will use the I^2 statistic to measure the heterogeneity among trials in each analysis. Significant heterogeneity will be defined as a P value of less than 0.05 for the Chi^2 statistic (Q). Heterogeneity will be described as a percentage using the I^2 statistic (I^2 = [(Q - degrees of freedom)/Q] x 100%). If I^2 is over 75% we will use a random-effects model and we will provide the pooled estimate for this analysis.

Regardless of the model used, where there is significant heterogeneity we will explore possible causes through prespecified subgroup analyses, as described below. We will pay particular attention to those studies that have a poor overlap of confidence intervals.

Assessment of reporting biases

This is a controversial area of treatment for those with obesity and some relevant studies may not have been published as a result of this controversy. We will assess the risk of selective outcome reporting across the studies using a funnel plot, if sufficient studies are available.

Data synthesis

We will use the Mantel-Haneszel fixed-effect model for pooling results provided there is no significant heterogeneity that would prevent us doing so. We will deal with anticipated sources of heterogeneity by the appropriate use of standardised mean differences and subgroup analyses.

Subgroup analysis and investigation of heterogeneity

We will stratify our findings according to outcomes and length of follow up. We may also need to stratify our analyses to analyse trial data separately, according to whether the intervention had an element of enhanced care, which may influence the effect size (e.g. weight loss medication), or where populations have specific characteristics (e.g. eating disorders, female gender or a specific ethnicity).

Sensitivity analysis

We plan to carry out sensitivity analyses to review the influence of studies with a low risk of bias on our findings. We may need to analyse separately those studies that used ITT analyses from those that carried out completer analysis. We may also need to analyse separately those trials that were cluster randomised.

REFERENCES

Additional references

Bacon 2002

Bacon L, Keim NL, Van Loan MD, Derricote M, Gale B, Kazaks A, et al.Evaluating a 'non-diet' wellness intervention for improvement of metabolic fitness, psychological well-being and eating and activity behaviors. *International Journal of Obesity and Related Metabolic Disorders* 2002;**26**(6):854–65.

Bacon 2005

Bacon L, Stern JS, Van Loan MD, Keim NL. Size acceptance and intuitive eating improve health for obese, female chronic dieters. *Journal of the American Dietetic Association* 2005;**105**(6):929–36.

Bacon 2011

Bacon L, Aphramor L. Weight science: evaluating the evidence for a paradigm shift. *Nutrition Journal* 2011;**10**(1):9.

Carroll 2007

Carroll S, Borkoles E, Polman R. Short-term effects of a non-dieting lifestyle intervention program on weight management, fitness, metabolic risk, and psychological well-being in obese premenopausal females with the metabolic syndrome. *Applied Physiology, Nutrition, and Metabolism* 2007;**32**(1):125–42.

Cole 2010

Cole R, Horacek T. Effectiveness of the "My Body Knows When" intuitive-eating pilot program. *American Journal of Health Behaviour* 2010;**34**(3):286-97.

Curioni 2005

Curioni CC, Lourenço PM. Long-term weight loss after diet and exercise: a systematic review. *International Journal of Obesity* 2005;**29**(10):1168–74.

Estruch 2013

Estruch R, Ros E, Salas-Salvadó J, Covas MI, Corella D, Arós F, et al.Primary prevention of cardiovascular disease with a mediterranean diet. *The New England Journal of Medicine* 2013;**368**(14):1279–90.

Field 2009

Field AE, Malspeis S, Willett WC. Weight cycling and mortality among middle-aged or older womem. *Archives of Internal Medicine* 2009;**169**(9):881–6.

Foresight 2007

Foresight. Tackling obesities: future choices - project report (2nd edition). www.bis.gov.uk/assets/foresight/docs/obesity/17.pdf (accessed 17 October 2013).

Gagnon-Girouard 2010

Gagnon-Girouard MP, Bégin C, Provencher V, Tremblay A, Mongeau L, Boivin S, et al.Psychological impact of a "health-at-every-size" intervention on weight-preoccupied overweight/obese women. Journal of Obesity 2010; Vol. 2010. [DOI: 10.1155/2010/928097]

Graham 2007

Graham I, Atar D, Borch-Johnsen K, Boysen G, Burell G, Cifkova R, et al.European guidelines on cardiovascular disease prevention in clinical practice: executive summary. Fourth Joint Task Force of the European Society of Cardiology and other societies on cardiovascular disease prevention in clinical practice (constituted by representatives of nine societies and by invited experts). *European Journal of Cardiovascular Prevention and Rehabilitation* 2007;**14**(Suppl 2):E1–40.

Harrington 2009

Harrington M, Gibson S, Cottrell RC. A review and meta-analysis of the effect of weight loss on all-cause mortality risk. *Nutrition Research Reviews* 2009;**22**(1):93–108.

Hawley 2008

Hawley G, Horwath C, Gray A, Bradshaw A, Katzer L, Joyce J, et al.Sustainability of health and lifestyle improvements following a Non- Dieting randomised trial in overweight women. *Preventive Medicine* 2008;**47**(6):593–9.

Higgins 2011

Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2100]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Katzer 2008

Katzer L, Bradshaw AJ, Horwath CC, Gray AR, O'Brien S, Joyce J. Evaluation of a "nondieting" stress reduction program for overweight women: a randomized trial. *American Journal of Health Promotion* 2008;**22**(4):264–74.

King 2007

King C. Health at every size approach to health management: The evidence is weighed. *Topics in Clinical Nutrition* 2007;**22**(3):274–85.

Lee 2011

Lee DC, Sui X, Artero EG, Lee IM, Church TS, McAuley PA, et al.Long-term effects of changes in cardiorespiratory fitness and body mass index on all-cause and cardiovascular disease mortality in men: the Aerobics Centre Longitudinal Study. *Circulation* 2011;**124**(23):2483-90.

Lefebvre 2011

Lefebvre C, Manheimer E, Glanville J. Chapter 6: Searching for studies. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011 Available from www.cochrane–handbook.org.

Mann 2007

Mann T, Tomiyama AJ, Westling E, Lew AM, Samuels B, Chatman J. Medicare's search for effective obesity treatments: diets are not the answer. *The American Psychologist* 2007;**62**(3):220–33.

McTigue 2003

McTigue KM, Harris R, Hemphill B, Lux L, Sutton S, Bunton AJ, et al.Screening and interventions for obesity in

adults: summary of the evidence for the U.S. preventive services task force. *Annals of Internal Medicine* 2003;**139** (11):933–49.

Michie 2011
Michie S, Ashford S, Sniehotta FF, Dombrowski SU, Bishop A, French DP. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: the CALO-RE taxonomy. *Psychology & Health* 2011;**26**(11):1479–98.

Miller 2001
Miller WC, Jacob AV. The health at any size paradigm for obesity treatment: the scientific evidence. *Obesity Reviews* 2001;**2**(1):37–45.

Neumark-Sztainer 2000
Neumark-Sztainer D, Rock CL, Thornquist MD, Cheskin LJ, Neuhouser ML, Barnett MJ. Weight-control behaviors among adults and adolescents: associations with dietary intake. *Preventive Medicine* 2000;**30**(5):381-91.

NICE 2006
National Institute for Health and Clinical Excellence. Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children. www.nice.org.uk/nicemedia/pdf/cg43niceguideline.pdf (accessed: 17 October 2013).

Novello 1999
Novello AC. Surgeon General's report on the health benefits of smoking cessation. *Public Health Reports* 1990;**105**(6): 545-8.

Provencher 2007
Provencher V, Bégin C, Tremblay A, Mongeau L, Corneau L, Boivin S, et al.Short-term effects of a "health-at-every-size" approach on eating behaviors and appetite ratings. *Obesity (Silver Spring, Md.)* 2007;**15**(4):957–66.

Provencher 2009
Provencher V, Bégin C, Tremblay A, Mongeau L, Corneau L, Dodin S, et al.Health-at-every-size and eating behaviors: 1-year follow-up results of a size acceptance intervention. *Journal of the American Dietetic Association* 2009;**109**(11): 1854–61.

Rapoport 2000
Rapoport L, Clark M, Wardle J. Evaluation of a modified cognitive-behavioural programme for weight management. *International Journal of Obesity and Related Metabolic Disorders* 2000;**24**(12):1726–37.

Rees 2013
Rees K, Hartley L, Flowers N, Clarke A, Hooper L, Thorogood M, et al.'Mediterranean' dietary pattern for the primary prevention of cardiovascular disease. *Cochrane Database of Systematic Reviews* 2013, Issue 8. [DOI: 10.1002/14651858.CD009825.pub2]

Robison 2005
Robison J. Health at every size: toward a new paradigm of weight and health. *MedGenMed: Medscape General Medicine* 2005;**7**(3):13.

Rzehak 2007
Rzehak P, Meisinger C, Woelke G, Brasche S, Strube G, Heinrich J. Weight change, weight cycling and mortality in the ERFORT male cohort study. *European Journal of Epidemiology* 2007;**22**(10):665–73.

Stevens 2012
Stevens VL, Jacobs EJ, Juzhong S, Patel AV, McCullough ML, Teras LR, et al.Weight cycling and mortality in a large prospective US study. *American Journal of Epidemiology* 2012;**175**(8):785-92.

Söderlund 2009
Söderlund A, Fischer A, Johansson J. Physical activity, diet and behaviour modification in the treatment of overweight and obese adults; a systematic review. *Perspectives in Public Health* 2009;**129**(3):132–42.

Turk 2009
Turk MW, Yang K, Hravnak M, Sereika SM, Ewing LJ, Burke LE. Randomized clinical trials of weight loss maintenance: a review. *The Journal of Cardiovascular Nursing* 2009;**24**(1):58–80.

WHO 2013
World Health Organization. Obesity and overweight. www.who.int/mediacentre/factsheets/fs311/en/index.html (accessed: 17 October 2013).

Yusuf 2004
Yusuf S, Hawken S, Ounpuu S, Dans T, Avezum A, Lanas F, et al.Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study. *Lancet* 2004; **364**(9438):937–52.

* *Indicates the major publication for the study*

ADDITIONAL TABLES

Table 1. The checklist for HNWL (health, not weight loss, focused) and conventional weight loss (CWL) programmes

HNWL programmes	CWL programmes
• Primary focus on improving physical health and mental well being • No weight loss goals are set • Weight monitoring does not form part of treatment (although weight may be measured at beginning and end of intervention for research purposes) • Internal signals of hunger and satiety determine level of energy consumption • Participants are supported by sharing their common experiences • Participants are asked to complete coursework throughout the process • Groups are led by interveners, who organise activities to raise awareness about biological, sociocultural and psychological factors through discussion, lectures and exercises • Educational and psychotherapeutic workshops are offered to participants by qualified counsellors who focus on mental well being	• Primary focus on weight loss • Weight loss goals are set • Regular weight monitoring is an important part of the programme • Energy consumption is planned to create a 500 Kcal to 600 Kcal deficit through, for example, calorie counting, point system, portion sizes, meal plans, fat restriction • Food restriction, exercise or a combination of both, designed to achieve a weight loss of 0.5 kg to 1 kg/week • Participants are supported by educational materials and expert advice (e.g. understanding food labels) • Participants are educated on behavioural change techniques, cognitive restructuring and problem-solving skills to help them reach their weight loss goal
• A focus on behavioural change to achieve healthy eating and increase physical activity are part of both types of programmes	

Table 2. - The criteria for considering studies for review

Inclusion criteria	Exclusion criteria
• RCTs with at least 3 months of follow up • Published since 1970 • Must contain participants with a BMI >25 kg/m^2 • Must contain participants aged 18 years or over • Must contain a programme that promotes a healthy behavioural change around eating and or physical activity, without a focus on weight loss • Must contain a programme focusing on weight loss through behavioural change • Outcomes include: blood lipids, blood pressure, fasting blood glucose, waist-to-hip ratio, weight, depression, stress, anxiety, change in diet, change in physical activity, eating behaviours (cognitive dietary restraint, disinhibition and susceptibility to hunger), self-esteem, body image or mental well being	• Non-RCTs • Observational studies • RCTs with less than 3 months of follow up • Published before 1970 • Participants have a BMI <25 kg/m^2 • Participants aged less than 18 years only • Without a programme that promotes a healthy behavioural change around eating and or physical activity, without a focus on weight loss • Without a programme focusing on weight loss through behavioural change • Outcomes do not include: blood lipids, blood pressure, fasting blood glucose, waist-to-hip ratio, weight, depression, stress, anxiety, change in diet, change in physical activity, eating behaviours (cognitive dietary restraint, disinhibition and susceptibility to hunger), self-esteem, body image or mental well being

BMI = body mass index
RCT = randomised controlled trial

Table 3. - The Cochrane Collaboration's tool for assessing risk of bias

Domain	Support for judgement	Review authors' judgement
Selection bias		
Random sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups	Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence
Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment
Attrition bias		
Incomplete outcome data *Assessments should be made for each main outcome (or class of outcomes)*	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomised participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the authors	Attrition bias due to amount, nature or handling of incomplete outcome data

APPENDICES

Appendix 1. Preliminary search strategy - MEDLINE (Ovid)

1."health at every size".tw.
2.HAES.tw.
3.(weight adj4 (manag* or accept* or centred* or centered*)).tw.
4.(health* adj6 (size or weigh*)).tw
5."Non diet*".tw.
6."non-diet*".tw.
7."nondiet*.tw.
8.(Wholistic or holistic) adj4 weight.tw.
9.((Intuitiv* or attentiv* or mindful*) adj4 eat*).tw.
10.or/1-9
11.exp Hypertension/
12.hypertensi*.tw.
13.blood pressure.tw.

14.Blood Pressure/
15.Cholesterol/
16.cholesterol*.tw.
17.Cholesterol, HDL/
18.Cholesterol, LDL/
19.Triglycerides/
20.triglyceride*.tw.
21.triacylglycerol*.tw.
22.lipoprotein*.tw.
23.bmi.tw.
24.overweight.tw.
25.body mass index/
26.exp Abdominal Fat/
27.exp Overweight/
28.obes*.tw.
29.exp Obesity/
30.(weight adj2 (gain* or chang* or los* or maint*)).tw.
31.(body mass adj (index or indexes or indices)).tw.
32.abdominal fat.tw.
33.quetelet* index.tw.
34.((reduc* or increas* or decreas* or los* or gain*) adj2 weight).tw.
35.Body fat.tw.
36.Fat mass.tw.
37.Waist.tw.
38.Diet*.tw.
39.Intake.tw.
40.Consumption.tw.
41.exp food and beverages/
42.exp drinking behavior/
43.physical adj activit*.tw.
44.exp exercise/
45.exp Affective symptoms/
46.exp depression/
47.exp stress, psychological/
48.well-being.tw.
49.Binge*.tw.
50.Three-factor.tw.
51.Disinhibition.tw.
52.Hunger.tw.
53.Restraint.tw.
54.Psychological adj $stress.tw.
55.Body adj (image or satisfaction or dissatisfaction).tw.
56.or/11-55
57. randomized controlled trial.pt.
58. controlled clinical trial.pt.
59. randomized.ab.
60. placebo.ab.
61. drug therapy.fs.
62. randomly.ab.
63. trial.ab.
64. groups.ab.
65. 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64
66. exp animals/ not humans.sh.

67. 65 not 66
68. 10 and 56
69. 67 and 68

CONTRIBUTIONS OF AUTHORS

NK, supervised by DL, drafted the protocol. ACF, APT, NL-H and GF reviewed and revised the draft protocol.

DECLARATIONS OF INTEREST

Amanda Farley is employed by the University of Birmingham as a Lecturer in epidemiology and carries out research in the area of smoking cessation, weight control and lung cancer. She had also done consultancy work for the Department of Health and has been paid as a guest speaker at various training events.

Nicola Lindson-Hawley is funded by a research grant awarded by the NIHR HTA programme (09/110/01), investigating the use of pre-quit nicotine patches for smoking cessation. The excess treatment provided for this research are nicotine patches supplied by GlaxoSmithKline.

Deborah Lycett, Andy Turner, Nazanin Khasteganan, and Gill Furze have no known conflict of interest.

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- Professor Gill Furze, UK.

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