Title

Clinical effectiveness of weight loss and weight maintenance interventions for men: a systematic review of men-only randomised controlled trials (The ROMEO Project)

Short Title

Systematic review of weight loss and weight maintenance interventions for men: The ROMEO project

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Conflict of Interest

All authors declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Contribution of Authors

CR wrote the first draft of this manuscript. FS developed and ran the electronic literature search. CR and AA conducted the eligibility screening, data extraction and quality assessment. All authors contributed to the study design, manuscript preparation and revisions.

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Abstract

Men are under-represented in obesity services, suggesting current weight-loss service provision is sub-optimal. This systematic review evaluated evidence-based strategies for treating obesity in men.

Eight bibliographic databases and four clinical trials' registers were searched to identify randomised controlled trials (RCTs) of weight loss interventions in men only, with mean/median BMI of ≥30kg/m^2 (or ≥28 kg/m^2 with cardiac risk factors), with a minimum mean/median duration of ≥52 weeks. Interventions included diet, physical activity, behaviour change techniques, orlistat or combinations of these; compared against each other, placebo or a no intervention control group; in any setting.

21 reports from 14 RCTs were identified. Reducing diets produced more favourable weight loss than physical activity alone (mean weight change after 1 year from a reducing diet compared with an exercise programme –3.2 kg, 95% CI –4.8 to –1.6 kg, reported $p<0.01$). The most effective interventions combined reducing diets, exercise and behaviour change techniques (mean difference in weight at 1 year compared with no intervention was -4.9kg, 95% CI –5.9 to -4.0, reported $p<0.0001$). Group interventions produced favourable weight

loss results. The average reported participant retention rate was 78.2%, ranging from 44% to 100% retention, indicating that, once engaged, men remained committed to a weight loss intervention.

Weight loss for men is best achieved and maintained with the combination of a reducing diet, increased physical activity, and behaviour change techniques. Strategies to increase engagement of men with weight loss services to improve the reach of interventions are needed.

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Introduction

Obesity increases the risk of many serious illnesses, such as coronary heart disease, type 2 diabetes and osteoarthritis. Men with a body mass index (BMI) of 30kg/m^2 or more and waist circumference of 102cm or greater have an increased risk of at least one symptom of impaired physical, psychological or sexual function (Han et al., 2011; Prospective Studies Collaboration 2009; Renehan, Tyson, Egger, Heller, & Zwahlen 2008). Men appear more likely than women to misperceive their weight, less likely to consider their body weight a risk for health, and less likely to consider trying to manage their weight (Duncan et al., 2011; Gregory, Blanck, Gillespie, Maynard, & Serdula 2008).

Men are under-represented in weight loss research. A recent systematic review of male inclusion in randomised controlled trials (RCT) of weight loss reported that men made up only 27% of participants in RCTs, although the percentage rose to 36% when interventions were targeted at participants with obesity related co-morbidities (Pagoto et al., 2012). In the US National Weight Control Registry (NWCR Facts [webpage on the Internet] 2014) only 20% of participants are men. The average woman in the registry is aged 45 years age and weighs 145 lbs, while the average man is 49 years of age and weighs 190 lbs (NWCR Facts [webpage on the Internet] 2014). Given the dominance of weight loss interventions that appear to target women, it is unsurprising that fewer men than women are recruited to weight loss services. Where men are recruited to mixed-sex programmes, active components are often the same for both sexes despite a lack of understanding about whether men and women will respond to differently to interventions, or an understanding of why interventions that are

effective for men work well (Lovejoy & Sainsbury 2009). For example, a recent systematic review conducted by Young and colleagues (Young, Morgan, Plotnikoff, Callister, & Collins 2012) concluded that men-only interventions may appeal to men but that more high quality research in this area was required.

Similarly, men have been under-represented in physical activity research, where interventions designed to increase physical activity have also largely targeted women (George et al., 2012; Kassavou, Turner, & French 2013) and, consequently, may not appeal to men (Kassavou, Turner, & French 2013; Wong, Gilson, van Uffelen, & Brown 2012). Increased weight has been reported to be a significant determinant of future physical inactivity (Golubic et al., 2013) and physical activity is recognised as being important for the prevention of obesity and other negative health outcomes (Biswas et al., 2015; Byberg et al., 2009). Physical activity also has a recognised role in lifestyle management programmes aimed at promoting weight loss or preventing weight regain (PH46: Assessing body mass index and waist circumference thresholds for intervening to prevent ill health and premature death among adults from black, Asian and other minority ethnic groups in the UK [document on the Internet] 2013; PH53: Managing overweight and obesity in adults - lifestyle weight management services [document on the Internet] 2013). That men have been neglected in the field of physical activity research is particularly pertinent as, when men do attempt to manage their weight, they are more likely to use exercise as a weight management strategy than women (George et al., 2012).

It, therefore, seems likely that current weight loss and maintenance service provision is sub-optimal for men. This systematic review of the evidence base for the management of obesity

in men aimed to understand which interventions are effective for achieving long-term weight loss in men to inform service provision.

Methods

This study is an update of one of six systematic reviews undertaken for the ROMEO (Review Of MEn and Obesity) project, a mixed-methods synthesis of evidence for weight loss management for men (Robertson et al., 2014) (PROSPERO number CRD 42011001479), which searched for evidence up to May 2012. All of the reviews were undertaken according to a pre-specified protocol (Systematic reviews and integrated report on the quantitative, qualitative and economic evidence base for the management of obesity in men [protocol on the Internet] 2012). The review presented here is an update of our original search strategy to identify RCTs of weight loss and weight management interventions for men only and considers evidence up to March 2014. Four additional reports, three of which are from two newly identified RCTs, are included in this review. Ethical approval was not required for this study.

Search Strategy

Highly sensitive searches of MEDLINE, MEDLINE-in-Process and Other Non-Indexed Citations and Embase for a previous review of RCTs were updated (Avenell et al., 2004). Additional searches were run in CINAHL, PsycINFO, the Cochrane Library, and the Database of Abstracts of Reviews of Effects (latest search March 2014). No language restrictions were imposed on the searches. The example literature search strategy is provided in Appendix A. The full search strategies are available from the first author.

Types of study.

RCTs or quasi-randomised trials (including trials with a cluster design) with a mean or median duration of 52 weeks or over were considered. This duration of data follow-up was chosen to ensure that long-term weight loss and maintenance interventions were evaluated for their associated effects on weight and obesity-related co-morbidities (Avenell et al., 2004).

Types of participants.

The types of participants included were men aged 16 years or over, with no upper age limit, with a mean or median BMI of $\geq$30kg/m^2 (or $\geq$28 kg/m^2 with cardiac risk factors based on criteria for receiving orlistat) (Avenell et al., 2004). Studies particularly examining men with obesity related to psychotropic medication, learning disability or diagnosed eating disorder were excluded. Studies that recruited both men and women were excluded as these studies typically recruit far fewer men than women and interventions have typically been developed with women in mind.

Types of interventions and comparators.

Interventions in the form of diet, physical activity, behaviour change techniques, orlistat or combinations of any of these, in any setting were considered. Interventions of complementary therapy, e.g. acupuncture, or non-diet products promoted for weight loss available solely over the counter were excluded, as were studies evaluating bariatric surgery as only studies concerned with lifestyle management interventions were eligible for inclusion. Studies examining interventions for a combination of health-related conditions, e.g. smoking cessation and weight loss at the same time were also excluded.

Types of outcomes.

Studies had to explicitly mention weight loss or maintenance as a main aim to be eligible for inclusion. The following types of outcome were considered:

Primary outcome: weight change

Secondary outcomes*:* waist circumference; cardiovascular risk factors (total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, triglycerides, fasting glucose, glycosylated haemoglobin (HbA1c), systolic and diastolic blood pressure); disease specific outcomes (e.g. diabetes); adverse events; quality of life outcomes; process outcomes.

Data Extraction Strategy

One reviewer (CR) independently screened titles and abstracts of all potentially relevant reports and extracted details of study design, methods, participants, interventions and outcomes of the included studies. The data extraction was then checked by a second reviewer (AA) and any errors were corrected.

Quality Assessment Strategy

AA and CR assessed the methodological quality of the included RCTs using the Cochrane Collaboration's tool for assessing risk of bias (Higgins & Green 2011). An adapted version of the Campbell and Cochrane Equity Methods Group checklist was used to assess the effect of interventions on disadvantaged groups and/or their impact on reducing socioeconomic inequalities (Ueffing et al., 2011). Any disagreements or uncertainty were resolved by discussion between the two reviewers. A third reviewer was not required to act as an arbitrator.

Data analysis

Where data were suitable for inclusion in a meta-analysis, we imported data into Review Manager Software (version 5.1) for data synthesis. For continuous outcomes, mean difference (MD) and risk ratio (RR) for dichotomous data, with 95% confidence intervals (CIs) are reported. Due to the inherent heterogeneity in studies of obesity interventions, random effects meta-analysis was used throughout. Visual inspection and the I^2 statistic were used to assess heterogeneity in forest plots (Systematic reviews: CRD's guidance for undertaking reviews in health care [document on the Internet] 2009). Planned funnel plot analysis to investigate reporting biases for forest plots was not possible owing to the limited number of studies. Methods reported in our previous technology assessment (Avenell et al., 2004) were used to derive weight changes and standard deviations, where missing and are detailed in Appendix B.

Subgroup analyses were planned to explore whether the effectiveness of interventions differed for participants with newly diagnosed or pre-existing obesity related co-morbidities (e.g. diabetes, hypertension) compared to those without. This was not possible owing to the limited quantity of data and heterogeneity of the studies. Sufficient data were not available to explore the effect of deprivation, age and ethnicity on effectiveness; or to explore the effect of assumed values for weight on meta-analyses.

Results

Quantity of Evidence

Our primary literature search identified 14382 potentially relevant titles and abstracts, from which265 reports were selected for full text assessment. Of these, 21 reports (14 RCTs

(Benassi-Evans, Clifton, Noakes, Keogh, & Fenech 2009; Borg, Kukkonen-Harjula, Fogelholm, & Pasanen 2002; Esposito et al., 2004; Hunt et al., 2014; Jeffery, Gerber, Rosenthal, & Lindquist 1983; Khoo et al., 2011; King, Frey-Hewitt, Dreon, & Wood 1989; Morgan, Lubans, Collins, Warren, & Callister 2011; Patrick et al., 2011; Pavlou, Krey, & Steffee 1989; Van Aggel-Leijssen, Saris, Hul, & van Baak 2001; Wood et al., 1988; Wycherley, Brinkworth, Clifton, & Noakes 2012) with seven linked reports (Multiple risk factor intervention trial. Risk factor changes and mortality results. Multiple Risk Factor Intervention Trial Research Group 1982; Collins et al., 2013; Fortmann, Haskell, & Wood 1988; Jeffery, Bjornson-Benson, Rosenthal, Lindquist, & Johnson 1984; Kukkonen-Harjula, Borg, Nenonen, & Fogelholm 2005; Lejeune, Aggel-Leijssen, van Baak, & Westerterp-Plantenga 2003; Lutze et al., 2013; Van Aggel-Leijssen, Saris, Hul, & van-Baak 2002)) were eligible for inclusion. Details of the flow chart for the results of the literature search and a description of all the included trials are provided in Appendices C and D.

Six trials were conducted in the USA (Jeffery, Gerber, Rosenthal, & Lindquist 1983; King, Frey-Hewitt, Dreon, & Wood 1989; Patrick et al., 2011; Pavlou, Krey, & Steffee 1989; Wood et al., 1988). Four trials were carried out in Australia (Benassi-Evans, Clifton, Noakes, Keogh, & Fenech 2009; Khoo et al., 2011; Morgan, Lubans, Collins, Warren, & Callister 2011; Wycherley, Brinkworth, Clifton, & Noakes 2012); and studies conducted by Borg (Borg, Kukkonen-Harjula, Fogelholm, & Pasanen 2002), Esposito (Esposito et al., 2004), Hunt (Hunt et al., 2014) and van Aggel-Leijssen (Van Aggel-Leijssen, Saris, Hul, & van Baak 2001) were conducted in Finland, Italy, the UK and the Netherlands respectively. The majority of trials investigated weight loss interventions. Two trials were conducted by the same authors and published in the same report (Pavlou, Krey, & Steffee 1989). Only two investigated interventions for weight maintenance (Borg, Kukkonen-Harjula, Fogelholm, &

Pasanen 2002; King, Frey-Hewitt, Dreon, & Wood 1989). Most men included in the trials were middle-aged with a median (range) reported age of 46 years (36–62 years), weight of 112.7 kg (93.0–112.7 kg) and BMI of 32.4 kg/m^2 (30.1–36.9 kg/m^2). The mean reported participant retention rate for all trials was 78.2%, ranging from 44% to 100% retention.

Quality of the Evidence.

Risk of bias.

The assessments of risk of bias and equity and sustainability for the individual trials are provided in Appendix E.

Trials were of moderate quality with poor reporting of sequence generation and allocation concealment. Few reports gave details of the method of randomisation. It is therefore not possible to judge the success of the randomisation for these trials. Similarly, few authors used intention to treat analysis, choosing instead to present data for completers only both at baseline and for final outcome measurement. Equity and sustainability items, such as sociodemographic differences between withdrawals and exclusions, process measures or fidelity checks, were mostly not considered or reported.

Assessment of Effectiveness

Low fat reducing diet with behaviour change techniques and exercise advice or programme versus control.

Four studies examined low fat reducing diets, exercise and behaviour change training in comparison with a control group (Esposito et al., 2004; Hunt et al., 2014; Morgan, Lubans, Collins, Warren, & Callister 2011; Patrick et al., 2011).

In the Self-Help, Exercise and Diet using Information Technology (SHED-IT) trial by Morgan and colleagues (Morgan, Lubans, Collins, Warren, & Callister 2011), men followed a free internet-based weight loss programme, with support and exercise advice for three months. The control group received an information booklet only. At 12 months, the internet group had lost more weight than the control group, mean difference of -2.2kg (95% CI -5.7 to 1.3), but the difference in weight was not statistically significant. Change in erectile dysfunction of sexually active men was compared between groups; however data were reported at six months only (Collins et al., 2013). Men in the intervention group reported significant improvements in erectile function, as measured by the International Index of Erectile Function-5 (IIEF-5) questionnaire, compared with the control group (mean difference 1.4 [95% CI 0.3 to 2.4] reported p=0.018). Secondary analyses of only those sexually active men reporting dysfunction at baseline also showed a significant intervention effect (mean difference 4.2 [95% CI 1.7 to 6.6] reported p=0.004). It should be noted that whether this beneficial effect remained at 12 months is unknown.

Patrick and colleagues (Patrick et al., 2011) also used the internet to deliver dietary and physical activity advice and behaviour change training. Their intervention was developed by interviewing male weight loss experts and holding focus groups with men described as overweight. This resulted in an intervention that was individualised, fact-based, flexible, simple to understand and used "business-like" language. Pedometers were provided to encourage physical activity and were enjoyed by the men for their novelty and assistance with self-monitoring their behaviour. Men in the control group were given access to a website detailing general male-related health advice that was unlikely to lead to lifestyle changes that would promote weight loss (e.g. dealing with stress, hair loss and worksite injury prevention). Men receiving the weight loss intervention lost more weight than the

control group but differences between groups at 12 months were also reported as not significant (mean -0.9kg [SD 6.17] versus -0.2kg [SD 5.97] between group difference -0.69kg [-1.52,0.14] reported p=0.101).

Hunt and colleagues (Hunt et al., 2014) developed the Football Fans In Training (FFIT) intervention to appeal to men in terms of the context of traditionally male-dominated football (soccer) clubs. The intervention included a simple presentation of the science of weight loss and a style of delivery that encouraged male banter (joshing). The authors reported that delivering the intervention in a humorous way facilitated the discussion of sensitive subjects amongst the men. Men were recruited through 13 professional soccer clubs and were randomised to receive either the FFIT weight loss programme or to a waiting list control group, who received FFIT 12 months later. Men in the FFIT programme attended 12 weekly sessions at their club training ground where they received personalised dietary, healthy eating and behaviour change advice, followed by structured exercise classes delivered by the club's community coaches. Men were also encouraged to increase their walking activity gradually through the use of pedometers and were taught behavioural change techniques that are known to be effective at promoting improvements in physical activity and weight loss (e.g. goal setting and self-monitoring). The 12-week active phase was followed by a weight maintenance phase, which comprised six post-programme email prompts over nine months and a group reunion at nine months after pre-programme baseline measurements. The attrition rate was low, with 89% of the menwho were randomly allocated to undertake the FFIT programme and 95% of those allocated to the control waiting list arm remaining in the trial at 12 months.

After adjusting for baseline weight and club, the mean difference in weight loss was 4.9kg (95% CI – 5.9 to -3.9, reported p<0.0001) and 4.4% (95% CI -3.6 to -5.1, p<0.0001) for percentage weight loss at 12 months, both in favour of the FFIT intervention. Changes in cardiovascular risk factors and some measures of psychological health and physical, but not mental, quality of life were also significantly in favour of the intervention. Participants in the FFIT trial were provided with vouchers for their football club shop to the value of £40 for trial completers and £20 for drop-outs if they provided 12-month measurements. Whether this incentive impacted on the effectiveness of the intervention is unclear.

The 12-month results from these three RCTs, where the intervention comprised a low fat reducing diet, behaviour change techniques and either structured exercise advice or an exercise programme compared with a control, were pooled in a meta-analysis to establish the overall effect (see Figure 1). Only the FFIT trial (Hunt et al., 2014) reported a significant effect in favour of the intervention. The I^2 statistic of 97% indicates the presence of marked statistical heterogeneity, probably relating to differences between internet and football venue settings.

A further trial by Esposito and colleagues (Esposito et al., 2004) examined a low fat reducing diet, behaviour change techniques and advice for increasing physical activity. The men were recruited because they were obese and had erectile dysfunction (determined by a score of 21 or less on the IIEF-5) (Rosen et al., 1997). The men met in groups but received advice tailored to their individual requirements. The control group received general oral and written advice regarding healthy food choices and exercise at baseline. Results are not presented in the meta-analysis in Figure 2 due to differences in timing of outcome measurement. At two years, the intervention group had lost significantly more weight with a mean difference of -

13kg (95% CI [-18, -11] reported p=0.007) and reported statistically significant improvements for cardiovascular risk factors compared with the control group. Esposito and colleagues (Esposito et al., 2004) also reported that 17/55 men in the intervention group compared with 3/55 in the control group reported an International Index of Erectile Dysfunction score of 22 or higher, indicating regained sexual function at two years (reported p=0.001).

Exercise versus diet versus control.

Wood and colleagues (Wood et al., 1988) compared men in an exercise programme with men in an energy-reducing diet and a control group. Men in the exercise programme participated in supervised exercise three times per week in one hour sessions. Exercise activities included calisthenics, muscle stretching, brisk walking and jogging. Men in the diet group had a daily deficit of 300-500kcal/day and made no alteration to their level of physical activity. The control group made no change to either their diet or levels of physical activity.

At one year, the authors reported significant differences in weight in favour of the exercise and diet groups versus the control group (mean difference of -4.6kg [95%CI -6.2 to -3.0] and -7.8kg [95% CI -9.4 to -6.2] reported p<0.01). Both exercise and diet groups significantly lowered their triglyceride levels and improved their HDL cholesterol compared with the control group (reported p<0.05 and p<0.01 respectively). Participants in the diet group lost significantly more weight than those in the exercise group, producing a mean difference in weight of -3.2kg (95% CI -4.8 to -1.6, reported p<0.01).

Diet and exercise programme versus diet only.

Calorie reducing diet and exercise programme versus calorie reducing diet only.

Two trials reported the effect of adding an exercise programme to a calorie reducing diet compared with a calorie reducing diet only (Pavlou, Krey, & Steffee 1989; Van Aggel-Leijssen, Saris, Hul, & van Baak 2001). In the first trial, men followed a very low energy (500 kcal/day) formula diet for six weeks (Van Aggel-Leijssen, Saris, Hul, & van Baak 2001). For weeks seven to eight, men consumed 330 kcal/day of the formula diet and 840 kcal/day from foods of their choice. During weeks nine to ten, men consumed 170 kcal/day of the formula diet and 1170 kcal/day from their chosen food. The men were then instructed to stabilise their body weights for weeks 11 to 12. Men in the diet and exercise group followed the same dietary pattern but also participated in a low-intensity exercise programme (40% VO_2max) for 12 weeks, which was then continued to week 52. The men trained four times per week in one hour sessions. Three of these sessions were supervised by a personal trainer in the research laboratory and the other session was unsupervised at home. The exercise sessions consisted of cycling, walking and aqua-jogging. Attendance for supervised exercise sessions was 57% (SD 20%). Two of the men in the exercise group had to withdraw from the study due to knee injuries. At 12 months, men in the diet and exercise group did not lose as much weight as men in the diet only group (mean difference 4.2kg, 95% CI -1.5 to 9.9) (Lejeune, Aggel-Leijssen, van Baak, & Westerterp-Plantenga 2003).

In their main trial, Pavlou and colleagues (Pavlou, Krey, & Steffee 1989) investigated the effects of adding an exercise programme to a variety of different diets ranging from 420kcal to 1000kcal/day, including one very low carbohydrate diet, over 8-12 weeks, with long-term follow-up in a group of public sector workers in a police department. Combining results for all diet groups, the effect of adding exercise to diet was highly significant at 18 months (mean

difference -7.6kg, 95% CI -10.3 to -4.9) and at 36 months (mean difference -8.2kg, 95% CI -15.3 to -1.2). There were no significant differences in weight lost between any of the types of calorie reducing diets at 18 or 36 months. At 18 months, systolic (mean difference -8.90mmHg, 95% CI 13.7 to -4.2) and diastolic (mean difference -12.1mmHg, 95% -15.2 to -9.0) blood pressure were significantly lower in the diet and exercise groups compared with the diet only groups.

Types of calorie reducing diet compared.

The pilot trial conducted by Pavlou and colleagues (Pavlou, Krey, & Steffee 1989) and three other trials (Benassi-Evans, Clifton, Noakes, Keogh, & Fenech 2009; Khoo et al., 2011; Wycherley, Brinkworth, Clifton, & Noakes 2012) examined varying the protein, carbohydrate and fat proportions of reducing diets, or examined a more stringent initial calorie prescription of 900kcal for 8 weeks followed by a 600kcal/day deficit to 600kcal/day deficit alone. None of the trials identified significant differences between the different dietary approaches after 12 months.

Group versus individual monetary contracts.

The trial conducted by Jeffery and colleagues (Jeffery, Gerber, Rosenthal, & Lindquist 1983) recruited men to a 15-week financial incentive intervention for weight loss with a goal of achieving a total weight loss of 30lbs (13.6kg). Using a factorial design, men in the trial were randomised to pay monetary deposits of US$30, $150 or $300 and to either a group or an individual contract. Men in the individual contract groups received refunds based on individual weight loss, whilst those with group contracts were refunded based on the mean weight loss of their group. Group contracts produced significantly more weight loss than individual contracts both at one and two years (reported $p<0.05$). The size of contract did not

have a significant effect at one (Jeffery, Gerber, Rosenthal, & Lindquist 1983) or two years (Jeffery, Bjornson-Benson, Rosenthal, Lindquist, & Johnson 1984).

Weight maintenance.

Calorie reducing diet and exercise versus diet for weight maintenance.

The trial conducted by Borg and colleagues (Borg, Kukkonen-Harjula, Fogelholm, & Pasanen 2002) examined whether adding walking or resistance training to a diet compared with diet alone improved weight maintenance following a weight reduction period. During the weight reduction period, participants followed a very low calorie diet of 500 kcal/day for two months. The mean weight loss at the end of the weight reduction period was 14.2kg. Participants were then randomised to follow a low fat diet of 1200 kcal/day only; or to diet and walking; or diet and resistance training exercise groups. Exercise sessions were held three times a week and lasted 45 minutes, each aiming to expend 300-400kcal per session. No statistically significant differences between any of the groups were reported for weight after 31 months, apart from HDL cholesterol and waist to hip ratio, which were better in the resistance training than the walking group.

Behaviour change techniques for weight maintenance versus control.

The trial conducted by King and colleagues (King, Frey-Hewitt, Dreon, & Wood 1989) randomised men from the diet only or exercise only arms at the end of the one year Wood trial (Wood et al., 1988). Men were randomised within their original intervention groups to receive behavioural change techniques or a control. The behavioural change techniques comprised monthly mailed information packs including a supportive letter, list of coping strategies for problems relevant to their original intervention, e.g. holiday eating for dieters or finding time to engage in physical activity for exercisers. The men were telephoned regularly

to discuss any concerns or questions related to their problem areas and were weighed at six-monthly intervals. Men in the control group were given written information about their original weight loss method from the Wood trial (Wood et al., 1988) at the start of the weight maintenance period. The men received no other contact apart from the six-monthly weight assessments.

The behaviour change techniques produced greater weight maintenance success for the exercise only group compared with the control group than it did for the diet only group. After one year, exercisers who received the behavioural intervention had significantly lower weight than controls (-3.10kg, 95% CI -5.0 to -1.2). Dieters in the behavioural intervention group were not significantly different from controls after one year (0.60kg, 95% -1.3 to 2.5).

Discussion

Results from this systematic review should be treated with caution due to the limited number of trials, and thus limited statistical power. Nevertheless, the evidence indicates that weight reduction for men is best achieved through a combination of a reducing diet, physical activity advice or an activity programme and behaviour change training. The high trial participant retention rates indicate that, although it might be harder to attract men to join weight loss programmes than for women, once engaged, men will commit to the programme. It is therefore important that programmes are appealing to men to promote the effectiveness of interventions.

Tailoring the style of delivery could be as important as the content of the intervention, with men preferring simple, fact-based language with individual feedback (Hunt et al., 2014; Morgan, Lubans, Collins, Warren, & Callister 2011; Patrick et al., 2011). A preference for

individualised interventions and personal goals has also been reported in the physical activity literature (George et al., 2012; Newton Jr, Griffith, Kearney, & Bennett 2015). It could be that tailoring interventions for individual requirements or preferences offers men a greater sense of personal control than interventions that lack this personalised element, and this may appeal to men more than to women (Robertson et al., 2014). The inclusion of a physical activity element could also increase the appeal of interventions for men (Patrick et al., 2011). The trial by Borg and colleagues (Borg, Kukkonen-Harjula, Fogelholm, & Pasanen 2002) did not clearly demonstrate that the type of physical activity was important for weight maintenance,. Interventions situated in sporting contexts, such as the FFIT trial (Hunt et al., 2014), may particularly encourage engagement through the association of long-standing loyalty, commitment and camaraderie attained from collectively supporting a sports team. The motivation for supporting a team could consciously or subconsciously become associated with the motivation to lose weight with fellow team supporters. It is also possible that the sense of belonging and cohesiveness of the group was influential (Hoddinott, Allan, Avenell, & Britten 2010). The success of this trial may be limited to men who enjoy physical activity or have a keen interest in sport. How best to engage men who are not sports fans, or prefer more sedentary activities, is still a challenging topic that should be addressed. Health benefits associated with weight loss could also help motivate men to lose weight, for example the potential benefit on erectile function is not well known to men.

Trials of group interventions produced beneficial weight loss results. This is in keeping with findings of a systematic review comparing group and individual treatments for obesity in both men and women, which also reported that group-based interventions were more effective than interventions delivered to individuals only, although the reviewed population was predominantly female (Paul-Ebhohimhen & Avenell 2009). Men tend to be reluctant to

join groups (Jolly et al., 2011), and it may be important to ensure that groups are designed and tailored specifically to attract, engage and retain men; however, very few trials reported that they had consulted men during the development of their interventions. Providing men with the opportunity to attend programmes in men-only groups, in settings where they feel comfortable and are able to discuss individual concerns and receive individualised advice could enhance men's engagement with weight loss services (Robertson et al., 2014). The use of humour in groups can also encourage men to discuss sensitive or personal issues (Hunt et al., 2014), although humour should be used carefully to ensure issues or concerns are not trivialised as this can have an alienating effect (Paula Carroll, Men's Health Forum Ireland, 4 December 2012, personal communication).

The strengths of this study are the systematic and rigorous methods taken to review the evidence. Despite these efforts, very few eligible studies were identified. Furthermore, data on men from deprived areas, ethnic minorities, or men who were unemployed, younger, disabled, gay, bisexual, transgender and other minority groups were lacking. It therefore remains unclear what types of interventions or engagement strategies work best with hard to reach men or men from minority groups. Similarly, it is unclear whether the sex of the intervention provider contributes to intervention engagement and/or effectiveness. Future research should address these areas of uncertainty, whilst gathering information on patient reported quality of life, clinical and economic outcomes to assess the full value of an intervention other than amount of weight lost. Future research is also required to develop effective weight maintenance interventions to prevent men regaining weight in the long-term following successful weight loss.

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