Title

Should weight loss and maintenance programmes be designed differently for men? A systematic review of long-term randomised controlled trials presenting data for men and women: The ROMEO Project

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Keywords

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Conflict of interest

The authors have no conflict of interests to declare.

Contribution of authors

CR drafted the manuscript under the supervision of AA. 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 and manuscript preparation.

Abstract

We systematically reviewed the randomised controlled trial (RCT) evidence for long-term (≥12 months) weight management interventions for obese men in contrast to women to help understand whether programmes should be designed differently for men.

We searched 11 databases up to October 2014. Twenty-two RCTs reported data separately for men and women in weight loss or weight maintenance interventions.

We found men were under-represented in RCTs of weight loss interventions open to both sexes. Men comprised 36% of participants (4771 from 13,305 participants). Despite this, men were 11% (95% CI 8% to 14%, p<0.001) more likely to be trial completers compared to women. The trials did not report service user consultation and none were designed to investigate whether men and women responded differently to given interventions. Our meta-analysis of 13 trials showed no significant difference in weight loss between men and women, either for weight loss in kg (p=0.90) or percentage weight loss (p=0.78), although men tended to lose more weight with intensive low fat reducing diets, with or without meal replacements, and structured physical activity/exercise programmes than women. Orlistat was less beneficial for men for weight maintenance. Individual support and tailoring appeared more helpful for men than women.

We found evidence that men and women respond differently to, and have different preferences for, varying types of weight management programme. We suggest that it is important to understand men's views on weight loss, as this is likely to also improve the uptake and effectiveness of programmes for men.

Key words: Weight loss, weight maintenance, men and women, systematic review

Introduction

US data from 2007 to 2010 show that 35.1% of men and 36.4% of women were obese [1]. In England in 2013, 26% of men and 24% of women were obese [2], with the UK Foresight Report [3] predicting that more men (47%) will be obese than women (36%) by 2025. Yet men are under-represented in randomised trials of weight loss interventions, and in both health care based and commercial weight management programmes.

In a systematic review, Pagoto and colleagues [4] found that only 27% of participants in randomised trials were men, although the percentage was higher in interventions for obesity with related co-morbidities (36% men). There was also a trend towards lower participation by men in group-based interventions (24%), compared with individual counselling (29%) or mail/e-mail/internet (34%); however, the male/female mix of the group-based interventions was not specified. In another systematic review [5], sex was not a predictor of dropout in weight loss interventions, suggesting that where men are included in intervention studies, they are no more or less likely than women to withdraw.

In the weight loss Counterweight programme in 65 general practices in seven UK regions, only 23% of participants were men [6]. When services were not sex-specific, men comprised only 10.7% of 34,271 adults referred from primary health care to one UK commercial weight loss programme (Slimming World) [7], and 10.5% of 29,326 adults referred to a different commercial programme (Weight Watchers) [8]. Thus UK figures suggest men may be even less likely than women to attend commercial weight loss programmes than programmes provided by the National Health Service (NHS). Similarly, in the US National Weight Control Registry [9] only 20% of participants are men. Thus perceptions about the content of weight loss interventions may influence attendance, as has been demonstrated by the success of the Football Fans In Training (FFIT) weight loss trial [10], where the content of the trial was designed to attract men.

Other reasons for the under-representation of men may include a greater reluctance to change their current lifestyle than women [11] or sociocultural influences encouraging men to maintain a larger, more muscular, masculine body size [12]. Furthermore, masculinity, as a culturally normative ideal of male behaviour, is constructed as the opposite of femininity [13] and weight loss programmes and facilities, could be seen as feminised spaces [14,15]. Similarly, men could distance themselves from the feminised realm of dieting, where women are the 'experts' and dieting is viewed as a feminine activity that is about looking slim and pretty, which is linked to vanity [13,16].

A recent systematic review [17] of the effectiveness of men-only weight loss and weight maintenance interventions concluded that men-only programmes may effectively engage and assist men with weight loss but the evidence base for men-only interventions was lacking.

As part of a series of quantitative and qualitative systematic reviews on the evidence for weight management for men funded by the National Institute for Health Research Health Technology Assessment programme (http://www.nets.nihr.ac.uk/projects/hta/0912701), we systematically reviewed the randomised trial evidence for weight management interventions for men in contrast to women to help better understand whether programmes should be designed differently for men and women.

Methods

This was 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. All of the reviews were undertaken according to a pre-specified protocol (PROSPERO number CRD 42011001479).

Search strategy

Searches were run in CINAHL, PsycINFO, the Cochrane Library, the Database of Abstracts of Reviews of Effects, as well as hand searching the reference lists of included studies (latest search October 2014). No language restrictions were imposed on the searches. Publications prior to 2001 were excluded from this database search, as we hand-searched the continuously updated database of long-term randomised controlled trials (RCTs) initiated for our previous health technology assessment [18], for publications prior to 2001. This incorporates results from highly sensitive searches of MEDLINE, MEDLINE-in-Process, and Embase. We contacted the UK Association for the Study of Obesity, Dieticians in Obesity Management (DOM UK), commercial organisations and the Men's Health Forum project advisory group from the UK and Republic of Ireland for studies. An example of the literature search strategy is provided in supplementary information, Table S1. The full search strategies are available from the first author.

Study inclusion criteria

We included RCTs of men and women with BMI of $\geq$30kg/m^2 (or BMI $\geq$28 kg/m^2 and cardiac risk factors) where outcome data were presented separately by sex in each trial, to allow direct, and therefore more scientifically reliable, comparison between men and women. Trials had to have a duration and/or follow-up of at least one year. We considered diet, physical activity, behaviour change and orlistat interventions or combinations of any of these, compared with control treatment, alternative interventions or placebo comparators. We did not consider bariatric surgery, complementary therapy, non-diet products for weight loss available solely over the counter, or smoking cessation and weight loss interventions given together. Studies with participants selected

because they all had psychotropic medication, learning disability or diagnosed eating disorders were excluded.

Types of outcomes

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

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 and quality assessment

One reviewer (CR) independently screened titles and abstracts of all identified items. Full text copies of all potentially relevant reports were obtained and independently assessed for eligibility (AA, CR). One reviewer extracted details of study design, methods, participants, interventions and outcomes (CR). The data extraction was then checked by a second reviewer (AA) and any errors were corrected. Two reviewers (CR, AA) independently assessed the quality of studies with the Cochrane Collaboration's tool for assessing risk of bias [19]. We used the Cochrane-Campbell Methods Group Equity Checklist [20] to assess the effect of interventions reported upon disadvantaged groups and/or considerations of impact on reducing socioeconomic inequalities, which we modified for use with primary studies, in keeping with guidance from the Cochrane Public Health Group [21]. 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 possible, we imported data into Review Manager Software (version 5.1) for data synthesis. For continuous outcomes we report mean difference (MD) and risk ratio (RR) for dichotomous data, with

95% confidence intervals (CIs). Due to the inherent heterogeneity in studies of obesity interventions, where study results could be quantitatively pooled we used random effects meta-analysis throughout. For meta-analysis plots of only one study we used fixed effects. We used visual inspection and the I^2 statistic to assess heterogeneity in forest plots [22]. Planned funnel plot analysis to investigate reporting biases for forest plots was not possible owing to the limited number of studies. We used the methods reported in our previous technology assessment [18] to derive weight changes and standard deviations, where missing.

We analysed the proportion of participants completing the study including studies that reported the rate of drop-out. The risk difference and its confidence interval between men and women were calculated.

For the analysis of differences in weight change between men and women, MD was calculated for both men and women where more than one group was reported. Studies with no baseline weight values were excluded from the analysis of weight difference; in the analysis of percent weight loss the MD was divided by the baseline weight. For each study, the number of participants, N, MD of weight or percent weight loss from baseline and its standard deviation were entered into Review Manager in a random effects model.

Planned subgroup analyses

Subgroup analyses were planned to explore whether the effectiveness of interventions differed according to whether all participants were selected on the basis of newly diagnosed or pre-existing obesity related co-morbidities (e.g. diabetes, hypertension) or not. This was not possible owing to the limited quantity of data and heterogeneity of the studies. Sufficient data were also 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

Description of the trials

Details of the flow chart for the result of the literature search are provided in supplementary information, Figure S1. A detailed description of all the characteristics of the included trials is provided in supplementary information Table S2.

Twenty-two RCTs were included. Men comprised 36% of participants in 18 of the trials (4771 from a total of 13,305 participants); in four trials numbers of men recruited were unclear [23-26]. Eleven trials [23,26-35] were conducted in the USA; six [24,25,36-39] in Finland and one trial from each of the following locations: Canada [40], Israel [41], Scandinavia [42], Sweden [43,43]and the UK [44].

The majority of trials considered interventions for weight loss, rather than weight loss maintenance. No trials were designed to directly address our research question: do men and women respond differently to weight loss interventions? Seven trials [24,25,31-34,39] considered low fat reducing diets (LFRDs) either alone or in conjunction with physical activity and/or behavioural therapy. Ross and colleagues [40] examined physical activity and healthy eating advice with behavioural therapy. Three trials [27,35,41] considered different types of reducing diet. Heitzmann [23] considered different types of behaviour change techniques. Two trials compared intensive inpatient rehabilitation programmes with community programmes [36,37]. Two trials [38,44] considered different types of weight loss service provider. The remaining trials considered spouse involvement [26], modification of the home environment [28], telephone or mail contact [30], and varying monetary contracts [29].

Three trials considered weight loss maintenance: lifestyle counselling including a 600kcal/day deficit low fat diet and orlistat or placebo [42], intermittent versus on demand very low calorie diets [43], and monetary contracts [29].

Of the seven linked reports, five were identified as relevant ancillary studies for this review. These included two trials examining spousal effects [45,46]; one investigating differences in body image between men and women [47] and one investigating the effects of weight loss interventions on bone

mineral density [48]. One report provided additional data for risk factors not included in the main trial report [49] and one provided extended follow-up data [50]. One linked report only provided data for men [51], and is not discussed here.

Nine trials recruited participants with concomitant medical conditions: six [23,25,26,33,35,38] recruited participants with type 2 diabetes, two [34,39] recruited participants with impaired glucose tolerance, one recruited participants who were either diagnosed with pre-diabetes mellitus or metabolic syndrome [27] and one [42] recruited participants with hyperlipidaemia. In total, 13,305 men and women were enrolled in the trials. Where age was reported by sex [25,29,36-38,40,47,48], mean ages ranged from 39 to 62 years for men and 37 to 59 years for women (median 53 years for men and 51 years for women). The highest reported mean BMI for men was 42.7 [36] and 43.6 for women [36], while the lowest was 29.7 [39] and 30.53 [29] respectively. The period of follow up ranged from one to eight years (median two years).

Quality of the trials

Trials were of moderate quality with poor reporting of sequence generation and allocation concealment. Most trials failed to use full intention to treat analysis or blinded outcome assessment. Equity and sustainability items, such as sociodemographic differences between withdrawals and exclusions, process measures or fidelity checks were mostly not considered or reported. A detailed summary of the quality assessment for the individual trials is provided in supplementary information Tables S3 and S4.

Engagement of men and women

Recruitment and attrition of men and women

Nine trials [27,29,34,36-38,40,43,44] provided data that could be included in the analysis comparing the number of men and women who completed the trials. The total analysis included 3943 participants, with 1255 men (31.8%) and 2688 women (68.2%) (Tables 1 and 2). The results show

that men were 11% (95% CI 8% to 14%, p<0.001) more likely to be trial completers compared to women.

Table 1 Studies included in the analysis of attrition by sex

	% men randomised	**Number randomised**		**Number completed**		**% completed of number randomised by sex**	
		Men	**Women**	**Men**	**Women**	**Men**	**Women**
Evans 2012 [27]	44.6	58	72	31	40	53	56
Hakala 1993 [36]	33.3	20	40	18	35	90	88
Hakala 1994 [37]	30.0	18	42	13	30	72	71
Jeffery 1984 [29]	48.7	55	58	53	55	96	95
Jolly 2011 [44]	30.7	227	513	162	182	71	36
Korhonen 1987 [38]	50.0	40	40	38	33	95	83
Lantz 2003 [43]	25.8	86	248	35	82	41	33
Ross 2012 [40]	29.8	146	344	121	275	83	80
West 2008 [34]	31.3	605	1331	416	889	69	67
Total	*31.8*	*1255*	*2688*	*887*	*1621*	*71*	*60*

Table 2 Contingency table and analysis results for studies included in the analysis of attrition for men and women

	Completed study	**Did not complete study**	**Total**	**Proportion completing**
Male	887	368	1255	0.71
Female	1621	1067	2688	0.60
Total	2508	1435	3943	0.64
Difference in proportion between men and women (95% CI)				0.11 (0.08, 0.14)
				$p < 0.001$

Comparison of weight loss in men compared with women across trials

For the analysis comparing mean weight loss between men and women, a total of 13 studies had eligible data [24-27,29,31-34,36-38,40]. There were a total of 5890 participants with 2213 (37.6%) men and 3677 (62.4%) women (Figures 1- 2). There were two analyses for comparing mean weight change in kg and percentage weight change between the sexes. Both analyses showed there were no significant differences in weight change between men and women recruited to these studies. There was considerable heterogeneity in both meta-analyses. Few studies gave sufficient information on the actual prescribed calorie deficit, or whether this took account of sex. It is, therefore, unclear whether prescribed calorie deficit had any impact on our result. Similarly, it is unclear whether men or women adhere better to lifestyle prescription, and consequently it is unclear whether adherence had any influence on this result.

Figure 1 Difference between mean weight loss in kg between men and women

Figure 2 Difference in percentage weight loss from baseline between men and women

Low fat reducing diet with/without exercise with/without behaviour change

Six trials [24,25,32-34,39] investigated a low fat reducing diet (LFRD) compared with exercise and/or behavioural therapy or in combination with these comparators.

Low fat reducing diet and behaviour change training

One trial [24] examined LFRD and behaviour change training compared to control after one year (men -11.80kg, 95% CI -16.86 to -6.74; women -5.60kg, 95% CI -8.74 to -4.57). The dietary prescription of 1200kcal/day for weight reduction and 1880kcal/day for maintenance was not reported to differ by sex. Women had greater reductions in systolic blood pressure. At seven years, the mean weight reduction in the intervention group was 8.7kg in men and 3.5kg in women (control data not available).

Low fat reducing diet and exercise

It was unclear in the Finnish Diabetes Prevention Study whether men and women at high risk of developing type 2 diabetes responded differently to a LFRD and an exercise programme, individually tailored to achieve 5% weight loss compared to controls. Both sexes had a reduced incidence of diabetes after a median follow up of four years (hazard ratio for diabetes incidence 0.43, 95% CI 0.22 to 0.81 for men; 0.61, 95% CI 0.39 to 0.97 for women; no statistically significant interaction between sex and intervention) [39]. Weight change data by sex for this trial have not so far been published.

Vanninen and colleagues [25,49] investigated the effects of LFRD and exercise advice against a control group involving basic conventional education materials only. Details of the exact dietary prescription were not provided. All participants in this trial were non-insulin dependent, type 2 diabetics. Women in the trial had higher average BMI than men (34kg/m^2 versus 31kg/m^2, respectively). After one year, men in the intervention group had lost significantly more weight than men in the control group ($p = 0.04$). Women in the intervention group also lost more weight than women in the control group, although the difference was not significant. Women in the intervention group were reported to have improved HbA1c, fasting glucose and cholesterol compared to controls,

but results are difficult to interpret in this small study as the control group had much poorer glycaemic control and cholesterol at baseline.

Volpe and colleagues [32] investigated the effects of a supervised exercise programme for an initial six months versus LFRD, or both interventions together. The goal was for participants to lose 0.5 to 1.0kg per week, although it is unclear whether this related to the dietary prescription alone or also took account of the exercise programme. By 12 months, there were no significant weight differences between the different intervention groups for women or men. The effects of the interventions on cardiovascular risk factors and waist circumference were also inconsistent in men and women at 12 months.

Low fat reducing diet, exercise and behaviour change training

The Diabetes Prevention Program [34,52] randomised individuals at high risk for diabetes to an intensive LFRD with an exercise programme and behavioural therapy, metformin or placebo treatment groups with an average follow-up of 2.8 years. For the purposes of this review, we present data for the intensive intervention and placebo groups only. The aim of the intensive lifestyle programme was to lose 7% of initial body weight and maintain this weight loss throughout the trial. The calorie goals were calculated based on initial weight loss and a deficit of 500-1000kcal/day, together with an increase in physical activity equivalent to 700kcal/week. After one year, men in the intensive lifestyle group had lost an average of 8% (6.0kg) of body weight, compared to 7% (4.6kg) for women (reported $p = 0.02$) [53]. By the end of follow-up, the average weight change for the intensive lifestyle group was -4.43kg (SD 7.30) [34]. The 58% reduction in development of type 2 diabetes from the intensive lifestyle intervention compared to placebo did not differ by sex (reported $p = 0.71$) [53]. Race and sex were reported as significant influences on weight loss in the intensive lifestyle group, with black women reported as having a significantly lower weight loss pattern than other groups [34].

Ma and colleagues [31] evaluated two adaptations to the DPP lifestyle intervention for use with participants with pre-diabetes and/or metabolic syndrome: a coach-led, group-based intervention and a self-directed, DVD-based intervention. A usual care comparison group acted as the control group. The intervention was delivered in 12 weekly face-to-face classes to the coach-led group or via a home-based DVD to the self-directed participants. As with the DPP intensive lifestyle intervention, the goals of the active interventions were to achieve 7% weight loss and engage in 150 minutes of moderate physical activity per week. At 15 months, men had lost more weight than women in the self-directed group (-5.1kg, SE 1.0 versus -3.9kg, SE1.1) whereas women lost more weight than men in the coach-led group (-6.9kg, SE 1.1 versus -5.6, SE 1.1) and the usual care group (-3.0kg, SE 1.1 versus -2.0kg, SE 1.1). Differences by group between men and women were reported as not statistically significant.

The Look AHEAD (Action for Health in Diabetes) study [33] recruited overweight or obese type 2 diabetics to a trial comparing an intensive lifestyle intervention, comprising a LFRD, some meal replacements, exercise advice and intensive behavioural therapy. The intensive lifestyle intervention was designed to produce a minimum weight loss of 7% of initial body weight during the first year, with dietary instructions tailored to initial body weight. The control group received diabetes support and education. The trial was designed to examine the effect of the intensive lifestyle intervention on cardiovascular morbidity and mortality, and was stopped early at a median follow-up of 9.6 years on the basis of a futility analysis [54]. Wadden and colleagues [33,50] reported 4-year and 8-year weight data by sex for the active intervention group. The men in this group consistently lost more weight than the women at each annual assessment, except year eight (men -9.3kg (8.5%) at year 1 follow-up, -5.2kg (4.8%) year 4 and -4.6kg (9.7%) at year 8; women -8.1kg (8.5%) year 1, -4.4kg (4.6%) year 4 and -4.8kg (7.8%) at year 8), although differences were not statistically significant. The prescribed calorie intake was based on weight but it is not clear whether the calorie intake also took account of sex. Attendance and treatment contacts were similar for men and women.

Several ancillary studies have reported sex effects in the Look AHEAD study. Stewart and colleagues [47] investigated changes in body image in men and women in one centre. Both men and women in

the intervention group had significant reductions in body image dissatisfaction compared with the control group after one year (reported P<0.05, P< 0.01, respectively). Men in both the intervention and control groups showed greater reduction in dissatisfaction compared to women (-8.1 (SE 1.59) versus -6.3 (SE 0.94) for the intervention group and -3.3 (SE 1.66) versus -2.3 (SE 0.96) for the control group).

Schwartz and colleagues [48] investigated the effect of the weight loss intervention on bone mineral density (BMD) in five of the Look AHEAD centres. After one year, at the total hip, the difference in bone loss between the two treatment groups was significantly greater for men (-1.48% versus 0.02% in controls) than for women (-1.44% versus -0.61%) (reported p for interaction = 0.04). The authors reported that there was no evidence of an interaction by sex at the other bone sites.

Gorin and colleagues [46] assessed the impact of the intervention and control treatments on untreated spouses of the Look AHEAD participants in three sites. Spouses were not formally involved in either treatment group and were not expected to attend group meetings but their weight was measured by the trial outcome assessors. Participants in the active intervention group were taught ways to enhance social support to promote their weight loss efforts (e.g. how to communicate assertively with family members about desired food modifications). Participants in the control group received no such training. After one year, spouses of the intensive lifestyle participants had a weight change of -2.4kg (SD 4.5) compared to -0.2kg (SD 3.3) for spouses of control participants (reported p < 0.001). The authors reported no effect by sex or baseline weight of the spouse.

Physical activity and healthy diet advice and behavioural therapy versus usual care for weight loss

The PROACTIVE trial [40] randomised abdominally obese participants to receive an intervention offering physical activity and individually tailored counselling or to usual care (lifestyle advice from a primary care physician). Calorie reduction was not explicitly mentioned in either group. Both men and women lost more weight in the intervention group initially but, after two years, only men in the intervention group continued with significant weight and waist circumference reduction compared to

the usual care group. Weight losses were small and mean group changes from baseline did not exceed 2.5kg at any time point. No significant differences between the intervention or usual care groups were seen for cardiometabolic risk factors for either men or women, apart from metabolic syndrome which was significantly reduced in men after two years.

Comparisons of different types of diet for weight loss

Shai and colleagues [41] investigated the effectiveness of a LFRD (1500kcal/day for women, 1800kcal/day for men), a Mediterranean diet with equivalent calories, and a low carbohydrate (20g per day initially increasing to 120g per day) non-restricted calorie diet in the Dietary Intervention Randomised Controlled Trial (DIRECT). At the end of the two year trial, the only significant difference between men and women occurred in the LFRD group. Men lost significantly more weight than women in this group (mean change -3.4kg (SD 4.34) versus -0.1kg (SD 4.06) reported p=0.004).

Wing and colleagues [35] compared an intermittent very low calorie diet (400-500kcal/day) with a low calorie, low fat diet (1000-1200kcal/day) in a one year trial in participants with type 2 diabetes. Both groups also received behavioural therapy, physical activity advice and deposited $150, which was refunded depending on compliance. Women in the very low calorie diet group lost significantly more weight after one year than women in the low calorie, low fat diet group (14.1kg versus 8.6kg, reported $p<0.023$) whereas men had comparable losses in both treatment groups (15.4kg and 15.5kg respectively, p not reported).

Evans and colleagues [27] evaluated sex differences resulting from weight loss achieved via a high protein (dietary protein approximately 30% of energy intake with a carbohydrate/protein ratio <1.5) or high carbohydrate diet (dietary protein approximately 15% of energy intake, carbohydrate/protein ratio >3.5). Both diets were equal in energy, providing 1700 kcal/day for women and 1900 kcal/day for men, with 30% of energy from total fat. Participants attended weekly 1-hour meetings with a research dietician and each group followed an education programme focused on diet compliance and exercise guidance, monitored by 3-day weighed food records, daily activity logs and armband accelerometers.

At 12 months, men lost more weight in the high carbohydrate group (-14.2kg, SD 9.4) than the high protein group (-10kg, SD 6.3), whereas women had slightly greater weight loss in the high protein group (-7.5kg, SD 4.7 versus -7kg, SD 4.1). Although men lost more total weight than women, there was no reported statistical interaction of diet and sex for percent weight loss at 12 months.

Types of behaviour change training for weight loss

Heitzmann and colleagues [23] randomised participants with type 2 diabetes to behavioural, cognitive or cognitive behavioural therapy weight loss conditions or to a control group who received muscle relaxation training and factual diabetes information only. Participants in all groups received dietary advice from a registered nutritionist and were given individual physical activity advice, but details of the advice were not provided. At 18 months across all intervention groups it was reported that men lost an average of 3.63kg while women gained an average of 0.04kg. There was a borderline significant interaction (reported $p=0.057$) for weight loss by sex. Men experienced significantly greater reduction in HbA1c than women, indicating better control of blood glucose (reported $p<0.05$), but this difference was not significant between experimental groups.

Intensive inpatient rehabilitation versus community programmes for weight loss

Two trials by Hakala and colleagues [36,37] investigated the effectiveness of interventions with an initial inpatient rehabilitation setting against a community setting, for people at least 50% overweight. The rehabilitation interventions included a dietary intervention (1200kcal/day), intensive group behavioural and educational sessions along with prescribed physical activity programmes and occupational therapy, as well as individual nutritionist and physician counselling. Details of the programmes after the initial 1200kcal/day prescription were not provided.

In the earlier trial [36], men lost more weight in the community setting than the inpatient setting, possibly due to individual counselling, differences were statistically significant for years one and two (mean change -13.1kg (SD 8.8) versus -26.2kg (SD 10.3) reported $p<0.01$ and -1.8kg (7.4) versus -

15.6kg (SD 12.0) reported p<0.01, respectively). Differences were not significantly different for women.

In the trial by Hakala and colleagues from 1994 [37], a similar comparison between initial intensive inpatient rehabilitation was compared with a community setting, delivered in group format only. When both rehabilitation and community interventions were delivered to men in groups, the rehabilitation setting produced favourable results, although differences were statistically significant over the first two years but not at five years (men at two years -8.50kg, 95% CI -16.67 to -0.33). For women, the rehabilitation setting produced no significant benefit in weight loss over the community intervention for any time point from one to five years.

Type of provider and tailoring for dietary intervention for weight loss

No obvious difference between type 2 diabetic men and women was observed for weight loss at one year when health care was provided by a doctor with an initial written leaflet or a nurse specialist with individual dietary instructions and further follow-up (men -0.75kg, 9%% CI -4.93 to 3.43; women -2.19kg, 95% CI -6.66 to 2.28) [38].

When given a choice between attending a weight loss programme delivered by a commercial provider or the UK NHS, women were more likely to choose a commercial provider than men, despite some commercial groups being labelled as 'male friendly' (81% versus 47%) [44]. The Lighten Up trial [44] randomised participants to one of three weight loss programmes run by commercial companies (Weight Watchers, Slimming World and Rosemary Conley) or to one of three programmes delivered via the NHS (NHS Size Down, a General Practitioner or a pharmacist), or participants were randomised to a choice group where they were able to choose one of the six programmes depending on their preference. For the control group, participants received vouchers for 12 free sessions at a council-leisure centre.

At one year, only Weight Watchers produced weight loss significantly different from the control group (adjusted mean difference -2.49kg, 95% CI -4.15 to -0.83, baseline observation carried forward for drop outs, BOCF). The authors found no statistically significant interaction between sex and weight loss programme.

Further BOCF data supplied by the authors show significant weight losses from baseline for women for the choice programme, Size Down, Rosemary Conley, Slimming World and Weight Watchers, and the control group. For men, Size Down, Rosemary Conley and Weight Watchers produced significant weight losses from baseline. The control group and Slimming World also produced significant changes from baseline for men, but only in the last observation carried forward analysis (where missing data are imputed with the last recorded weight).

Spouse involvement in programme

Wing and colleagues [26] randomised obese type 2 diabetic participants to receive a behavioural weight loss programme either with their obese spouse (together) or without their spouse (alone). All participants received behavioural therapy consisting of stimulus control, problem solving, assertion, goal setting and cognitive techniques. Participants were also advised to monitor calorie intake to between 1200-1500 kcals/day and set stepwise goals for walking. Weight loss of participants treated alone and together was not significantly different after one year, although men lost more weight when treated alone (men alone -7.25kg, together -1.25kg) whereas women did better when treated together (women alone -2.26kg, together -5.89kg). Spouses of both sexes lost more weight in the together condition than the alone condition ($p<0.05$).

Golan and colleagues (Golan 2010) also described the 'halo' effect of the DIRECT dietary interventions on 74 wives of men participating in the trial. The wives were not randomised to any treatment group but were invited to attend the 90 minute support group meetings held every two months for the DIRECT participants. At the end of the trial, men whose wives had attended support meetings lost more weight than men who did not have spousal support both as an entire group and

within each diet group but differences were not significant. For both the wives of the DIRECT husbands and the female DIRECT participants, differences in weight loss were significantly greater in the Mediterranean and low carbohydrate groups than for the LFRD group (reported p=0.034 and p<0.05 respectively). Husbands of the DIRECT women did not participate in the sub-study.

Similarly, Gorin and colleagues [46] assessed the impact of the intervention and control treatments on untreated spouses of the Look AHEAD participants in three sites. Spouses were not formally involved in either treatment group and were not expected to attend group meetings. After one year, spouses of the intensive lifestyle participants had a weight change of -2.4kg (SD 4.5) compared to -0.2kg (SD 3.3) for spouses of control participants. The authors reported no effect by sex or baseline weight of the spouse.

Modification of the home environment

Gorin and colleagues [28] randomised overweight and obese participants and an overweight or obese household member willing to act as a support partner, mostly spouses, to a LFRD with exercise advice and behavioural therapy or to the same treatment package but with modifications made to the home environment. Modifications targeted physical and social cues in the home. Only participants received treatment in the standard programme while both participants and partners received treatment in the modified programme. At 18 months, women lost significantly more weight in the modified programme than in the standard programme (-8.1kg (SD 1.1) versus -4.2kg (SD 1.1) reported p=0.014). Men lost more weight in the standard programme, however (-10.0kg (SD 2.3) versus -4.6kg (SD 2.2) although differences were not significant (reported p=0.065). Partners in the modified programme lost more weight than partners in the standard programme at 18 months, regardless of sex.

Telephone versus mail advice and behaviour change for weight loss

Jeffery and colleagues [30] compared the effectiveness of an intervention including weight reduction, physical activity advice and behaviour change techniques delivered via telephone or mail. A control group received usual care. Details of the dietary and physical activity advice were unclear. Only men

lost significantly more weight at one year compared to usual care [telephone -1.42kg (95% CI -2.71 to -0.13), mail -1.38kg (95%CI -2.61 to -0.15)]. There were no significant differences in weight losses between telephone and mail groups for men or women.

Varying monetary contracts for weight loss and maintenance

Jeffery and colleagues [29] investigated the effect of financial contracts for weight loss and weight maintenance in men and women. All participants paid a $150 deposit at the start of a 16-week weight loss phase consisting of nutrition, physical activity and behaviour change technique education sessions with a weight loss goal of 0.9kg/week. Participants in the constant contract groups were refunded $30 for each successive group average weight loss of 5lb (2.27kg) and participants in the increasing contract groups were refunded $5, $10, $20, $40 and $75 for successive 5lb group weight losses.

Following the weight loss phase, 17 men and 25 women were randomised to receive either intensive or non-specific weight maintenance sessions. Those enrolling in the maintenance phase paid a $100 deposit, which was returned in $25 increments for attendance at quarterly group sessions. Those not enrolling in the maintenance phase were contacted at the one year follow-up assessment only. The authors reported that weight loss at one year was not statistically associated with recruitment source, contract type or sex. However, percentage change in weight showed that women lost significantly more weight than men (reported $p<0.05$, data not provided). During weight maintenance it was reported that the only significant effect was for women in the intensive maintenance condition who outperformed men for this contract type (reported $p<0.006$, data not provided).

On demand diet versus regularly repeated diet for weight loss maintenance

Lantz and colleagues [43] randomised participants to receive either an on-demand very low calorie diet (VLCD) (450kcal/day), after 16 weeks of the VLCD, or a regularly repeated VLCD. After the initial 16 weeks, participants in the intermittent on demand group followed a 500 kcal/day deficit diet but changed to the 450kcal/day diet when their individual body weight reached predetermined cut-off levels throughout the trial period. Participants in the regularly repeated group followed the same 500

kcal/day deficit diet but used the VLCD for a fortnight every third month. At two years, men in the on-demand intermittent diet group had significantly better weight change than men in the regularly repeated diet group (-10.50kg, 95%CI -16.6 to -4.84). There were no significant differences between diets for women (1.80kg, 95% CI 5.23 to 1.63).

Orlistat versus placebo for weight maintenance

Richelsen and colleagues [42] investigated the effect of orlistat in people with type 2 diabetes, impaired fasting glucose or dyslipidaemia. Before randomisation, participants all initially lost at least 5% of their body weight by following a very low calorie diet of 600-800 kcal/day over an eight week period. All participants were then randomised to receive lifestyle counselling including a 600kcal/day deficit low fat diet with either orlistat 120mg three times daily or matching placebo capsules. Weight change from the start of the diet to three years, analysed using last observation carried forward for dropouts, was reported as significantly greater for women in the orlistat group compared to the placebo group [-9.7kg (-8.4%) versus -6.3kg (-5.3%) $P<0.02$], although for men the difference was reported as not significant; orlistat versus placebo groups [-8.9kg (-8.3%) versus -8.1kg (-7.5%)].

Discussion

Despite the very large number of long-term RCTs of weight loss interventions, we found only 22, mostly underpowered, RCTs that provided outcomes separately for men and women in the same trial. Almost all trials reported data only for completers, inflating the effectiveness of interventions. Reporting was poor for blinding of outcome assessment, details of randomisation, and equity and sustainability items.

Men represented around a third of the participants in these trials. It is unclear why fewer men than women were recruited. The variety of different interventions, and small size of many of the studies, means that conclusions about best study designs for men, and whether services should be different, can only be very tentative from this review. Few of the trials considered truly comparable interventions and, in most cases, data were unsuitable for pooling in a formal meta-analysis.

Our analyses of trial retention showed that men were significantly more likely to complete trials than women, with only one small trial [27] showing better retention for women than men. We are unable to comment on possible explanations for differential drop out between men and women from the available data. Nevertheless, this finding suggests that, while fewer men are likely to join weight loss programmes, once they do join they show commitment to 'stick with' the programme. This highlights the importance of understanding which weight loss programmes are likely to attract and retain men.

Our analyses of weight loss showed no significant overall differences between men and women, although this was based on a limited number of trials. However, this result must be interpreted with considerable caution as in most of the trials it was impossible to conclude that men and women were being managed in a comparable fashion. Dietary and physical activity prescriptions were rarely described, with little evidence that allowance was made for the greater body size and muscle mass of obese men in the prescription of the calorie deficit. Our findings are in contrast to recent meta-analyses conducted by Stroebele-Benschop and colleages [55] and Williams and colleagues [56], which found significantly higher relative weight loss for men than women, although both analyses

contained few studies, effect sizes were small and both authors note that results are not conclusive. Neither review examined the details of the individual studies to see if the prescribed energy deficit and exercise regime would have led to different weight loss by sex. As with our review, most of the included studies did not consider gender differences as their primary outcome. Although Williams argues that there is little evidence to support different weight loss strategies for men and women, we argue that the within-study differences found in our review do show variation in response to interventions between men and women.

There was no clear evidence that the type of diet influenced long term weight loss in men [35], apart from a better response to LFRDs in one trial [41] and for LFRD (in some cases with meal replacements), exercise advice and behaviour change training [33]. Men outperformed women when they had to reduce their calorie intake in response to body weight cues rather than following a VLCD at regular intervals [43]. Regulating calorie intake by responding to one's own body may offer a greater sense of personal control over weight loss, which might be more important to men than to women. It could be that this form of weight regulation was seen as less regimented by the men and was therefore favoured due to the tendency for men to be reluctant to follow formal diet plans [57]. Diabetic men following LFRDs may be at greater risk of developing osteoporosis than diabetic women [48].

Although men performed well in terms of weight loss in group settings [24,29,33,37,44], more favourable results were produced where individual support or tailored advice were delivered to men as well as the group intervention. This may also offer men a greater sense of personal control or men may have greater educational needs for weight loss reduction than women. Tailoring by ethnicity may be more important for women than men [33], although whether this is true for ethnic groups outside the US requires further investigation.

Support from a spouse [45] or partner and learning how to enhance social support from family members [46] may also be particularly helpful for men, but having a spouse attend the same programme was not helpful for men [26].

In the Lighten up trial [44] the authors noted that, while men performed well in the programmes delivered by commercial companies, fewer than half picked these programmes when choice of provider was freely available. The authors suggested that commercial companies may appear more female-orientated. By contrast, NHS delivered programmes may have been perceived by men as purely concerned with improving health rather than physical appearance, which may be more acceptable to traditional concepts of masculinity. Whether programmes are GP or nurse-led seems unimportant [38].

There was some suggestion from the trials of Richelsen and colleagues for orlistat [42], and of Jeffery and colleagues for financial contracts [29] that men may do less well than women in weight maintenance with these interventions.

Our data confirm those of Pagoto and colleagues' systematic review [4]; that men are less likely to take part in RCTs, and comprised 27% of all participants in their RCTs, compared with 37% in the studies providing data here. The Pagoto and colleagues' review did not focus on recruitment by sex in the same trial. They noted that very few (19/244) studies reported interaction effects by sex.

Moroshko and colleagues did not find that being male or female was a significant influence on dropping out of weight loss interventions [5]. However, they did not use meta-analysis of sex-specific data from within randomised trials. From the 16 studies they found, three reported higher attrition in women, one in men, and the rest found no significant association with sex.

It is possible that the style of delivery could be as important as the content of the intervention for men and women, with men preferring simple, fact-based language with individual feedback [10,58,59].

Two recent trials [10,60] of men-only interventions achieved effective long-term weight loss results. Both trials developed interventions that were designed to appeal to men both in content and through the use of carefully targeted, male-orientated humour and sporting affiliation. The success of these trials highlights how providing gender-tailored interventions can improve the effectiveness of weight loss interventions. Young and colleagues [17] reviewed the effectiveness of male-only weight loss and maintenance interventions,. Although the authors included studies of shorter duration than those included in our review, they reported that the characteristics associated with more effective interventions included younger age of participants, greater frequency of contact, group face-to-face contact, and prescribed energy restriction. All but one of our trials appeared to have prescribed a dietary energy deficit. We did not have sufficient data to examine factors such as age, group settings or frequency of contact.

Conclusions

Notwithstanding the limitations of our evidence base, we found some evidence that men and women do respond differently to weight management programmes. Weight reduction for men is best achieved and maintained with a low fat reducing diet, with or without physical activity or behaviour change training (e.g. self-monitoring goal setting, prompting self-monitoring, providing feedback, review of goals). Some individual support and tailoring appears to be more useful to men than women. Support of a spouse or partner may also be beneficial. Men are less likely to engage in weight loss interventions than women, but are less likely to drop out once engaged. Given these differences, it is important that future mixed-sex trials report results separately for men and women. As discussed by Lovejoy [61], it would also be helpful if unadjusted results were reported along with results that have been adjusted for sex so as to avoid obscuring any sex-related differences in treatment effects.

Given the lower proportion of men in weight loss programmes, we suggest that having a better idea of the views, of what is an essentially a heterogeneous group, is important in weight loss or weight maintenance endeavours, as it is likely to improve the uptake and effectiveness of programmes intended for men. Interventions that are appealing to men are likely to encourage men to join weight

loss programmes and promote greater adherence, thus improving the effectiveness of the intervention. We did not find explicit evidence suggesting men had been consulted in the design of studies or interventions, yet it has been argued for some decades [62-66] that health improvement programmes are more likely to appear relevant and salient if they are informed by the views of the intended beneficiaries. Consideration needs to be given to interventions that are appealing to men, delivered in environments where men feel comfortable, and reflect the differing requirements for individual advice and support between men and women. This may be best delivered via men-only interventions and further research should explore this option. Services need to be formally evaluated, not only for effectiveness, but also to establish whether they reflect the diversity of their population. Presently, the evidence from RCTs is limited in quality and quantity. Rigorous feasibility studies and piloting with service user input at all stages is required prior to definitive long-term (at least one year follow-up) randomised controlled trials that make a distinction between support for the initial weight loss and a different or modified programme to help maintain that weight loss.

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