

## Treatment Outcomes/Obesity Comorbidities

# Effectiveness of weight loss interventions – is there a difference between men and women: a systematic review

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### Summary

Effective strategies are required to reduce the prevalence of overweight and obesity; however, the effectiveness of current weight loss programmes is variable. One contributing factor may be the difference in weight loss success between men and women. A systematic review was conducted to determine whether the effectiveness of weight loss interventions differs between men and women. Randomized controlled trials published up until March 2014 were included. Effect sizes (Hedges'  $g$ ) were used to examine the difference in weight outcomes between men and women. A total of 58 studies met the eligibility criteria with 49 studies of higher quality included in the final data synthesis. Eleven studies that directly compared weight loss in men and women reported a significant sex difference. Ten of these reported that men lost more weight than women; however, women also lost a significant amount of weight. Analysis of effect sizes found small differences in weight loss favouring men for both diet ( $g = 0.489$ ) and diet plus exercise ( $g = 0.240$ ) interventions. There is little evidence from this review to indicate that men and women should adopt different weight loss strategies. Current evidence supports moderate energy restriction in combination with exercise for weight loss in both men and women.

**Keywords:** Sex differences, systematic review, weight loss.

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### Introduction

Overweight and obesity are now the fifth leading risk factors contributing to global mortality (1). In 2012, the Organisation for Economic Co-operation and Development (OECD) reported that in many countries, one in two people is overweight or obese (2). Each year, approximately 2.8 million adults die as a direct result of being overweight or obese (1). With the prevalence continuing to rise both in Australia (3) and worldwide (1), effective population-based strategies to reduce this burden need to be identified. Overweight and obesity are defined by excessive accumulation

of body fat (1), often contributing to the development of chronic diseases such as cardiovascular disease (CVD) and type 2 diabetes (4). Weight loss remains the primary strategy for reducing the risks associated with overweight and obesity, but the effectiveness of weight loss programmes is variable, within and between programmes (5). One possible explanation for this variation could be the difference in weight loss success between men and women and the lack of direct comparison between them.

There are a number of characteristics that differ between men and women that may contribute to the difference in weight loss success. Characteristics favouring greater

weight loss in men include a greater percentage of muscle mass compared with fat mass, contributing to higher resting and total energy expenditure (6,7) and a greater potential impact of exercise on weight loss (8). On the contrary, women have higher concentrations of leptin, an appetite regulation hormone that reduces energy intake (9). While research supports these points, there is still no consensus on whether these physiological mechanisms lead to differences in weight loss success between men and women. Other considerations contributing to weight loss variability between men and women include the study design and nature of the lifestyle interventions implemented in the current weight loss interventions.

There are a number of systematic reviews that have investigated the effectiveness of lifestyle interventions with a focus on either men or women, or men and women combined (10–14), but this is the first to focus on the differences in weight loss between men and women. A systematic review published in 2012 sought to determine intervention characteristics associated with weight loss and maintenance in men (14). The review by Young *et al.* found that a prescribed energy-restricted diet, frequent contact and group face-to-face contact were features associated with weight loss success in men. Young *et al.* also conducted a meta-analysis that demonstrated that weight loss interventions were effective compared with no-intervention controls (14). Another systematic review, published in 2013, sought to determine the effectiveness of weight management programmes in young women (13) and found that just over 60% of the studies ( $n = 8$ ) reported a significant weight loss in the intervention groups compared with controls. However, with few studies identified, the authors could not determine a particular type of intervention that was more beneficial for weight loss (13). Of the studies conducting reviews of men and women combined, reduced energy diets, diet plus exercise, weight loss medications and weight loss surgery have been found to be effective for weight loss, with advice-only or exercise-only interventions less effective (10–12). Although pharmacotherapy and surgical interventions have been shown to result in large weight losses (15–18), the safety of weight loss medications and the sustainability of surgery as a population-based strategy have come under scrutiny, along with the cost of these options, both short- and long-term (19). Therefore, this current review will address only lifestyle interventions, such as diet and exercise, along with meal replacements and nutritional supplements, given these are widely used in conjunction with lifestyle interventions.

Although published literature on weight loss interventions is vast, there is still no consensus on which lifestyle interventions are best for weight loss, particularly for men or women. Therefore, the aim of this review was to determine whether the effectiveness of particular weight loss

interventions differs between men and women, and if they do, which are more effective for men or for women.

## Methods

### Study selection

Only randomized controlled trials (RCTs) were eligible for inclusion. Studies were required to have included both male and female participants,  $\geq 18$  years of age, with a body mass index (BMI [ $\text{kg m}^{-2}$ ])  $\geq 25$ , and to report weight change for both men and women separately. Studies were included if participants had existing co-morbidities associated with overweight and obesity such as type 2 diabetes and CVD, but excluded if they were taking medications known to influence weight (e.g. hypoglycaemic agents) or were diagnosed as having an eating disorder. Studies were required to have a primary aim of weight loss. Eligible interventions included diet (whole foods, meal replacements or natural supplements) and/or physical activity (PA) prescriptions. Interventions that were surgical or used pharmacological agents as methods of weight loss were excluded. This review considered overweight/obesity-related outcomes such as change in weight (kg), change in BMI ( $\text{kg m}^{-2}$ ), change in waist circumference (cm), percent weight loss and percent body fat loss.

### Search strategy

Published and unpublished studies until March 2014 were identified from a literature search of nine online databases. Databases included Medline, Embase, PsycINFO, CINAHL, Web of Science, Scopus, Cochrane Library, DARE, and Dissertations and Theses. Bibliographies of selected studies were also searched. The undertaking of this review adhered to PRISMA (preferred reporting items for systematic reviews and meta-analyses) guidelines (20). The first phase of study identification included assessment of study inclusion based upon the title and abstract. Full texts were retrieved for those papers seen to meet inclusion criteria from the title and abstract. Two assessors independently decided on inclusions based upon the full texts. If there was disagreement, a third independent reviewer was used.

*Search terms included* (overweight OR 'over weight' OR 'obes\*'), ('weightloss' OR 'weightchange' OR 'weightreduc\*'), ('randomisedcontrolledtrial' OR 'clinicaltrial' OR 'randomizedcontrolledtrial'), (male\* AND female\*).

### Assessment of methodological quality

Two independent reviewers assessed the methodological quality of studies using a critical appraisal tool from the

American Dietetic Association (Appendix 1) (21). A third reviewer was consulted if there was discrepancy. If most (six or more) of the answers to the validity questions were 'No', the study was designated with a minus (-); if the answers to questions 2, 3, 6 and 7 did not indicate that the study was exceptionally strong, the report was designated with a neutral ( $\emptyset$ ) symbol; and if most of the answers to the all validity questions were 'Yes' (including criteria 2, 3, 6, 7 and at least one additional 'Yes'), the study was designated with a plus symbol (+).

### Data collection and synthesis

Data extraction was performed by one reviewer using a standardized form developed by the researchers. Extraction was checked for accuracy and consistency by a second reviewer. Participant and intervention characteristics were extracted as well as data in relation to weight-related outcomes. All data were described in narrative synthesis, and where possible, effect sizes for the effect of interventions on the difference in absolute weight loss, percent weight loss and change in BMI between men and women were calculated. Any study where mean change and standard deviation were reported separately for men and women was included in this calculation. For results presented with standard errors or confidence intervals, standard deviations were calculated from these values (22). For each intervention, the data and effect size were reported separately. The primary interventions investigated were diet alone, exercise alone and diet plus exercise. Effect sizes were calculated for these interventions using Hedges' *g* equation to assess the difference in mean weight loss between men and women using a weighted standard deviation (by group sample size) (23) to account for the differences in the proportion of men and women in each study. Results were interpreted using effect size definitions described by Cohen *et al.*, with an effect size of 0.2 defined as small, 0.5 medium and 0.8 large (24). Additionally, if studies were sufficiently similar and change scores were reported and presented as means with standard deviations, data were pooled in a meta-analysis using Review Manager 5.1 Analyses (25). To determine the most appropriate meta-analysis model, statistical heterogeneity was assessed using chi square with a significant heterogeneity assigned at  $P < 0.05$ . If significant heterogeneity existed, the random effects model was used for statistical analysis; if homogeneous, the fixed effect model was used.

### Results

The initial search identified 7,739 potential studies. A total of 68 papers representing 58 studies met all the inclusion criteria (Fig. 1). There were 50 studies excluded for not reporting data to support statements made regarding sex-specific intervention effectiveness or differences between

men and women. Of these 50 excluded studies, 44 reported that sex was not a predictor of weight change.

### Study characteristics

Table S1 summarizes the characteristics of each included study ( $n = 58$ ) (irrespective of critical appraisal). Characteristics include sample size and proportion of men vs. women, age, weight status, the duration of the study, description of the intervention and retention rate.

Eighteen studies (31%) were published before 1999 (26–43) with the remaining (69%) published from 2000 onwards (44–84). Of the 58 studies, 32 (55%) were conducted in the USA (26,27,29,30,32–37,39,41,43–45,49–52,54,57,60,62,65,72,75,76,78–80,83,84); 7 in Australia (47,53,58,59,61,63,73); 3 in Canada (28,42,67); 2 in each of China (74,77) and Denmark (82,85); and 1 each in Italy (69), Norway (64), Iceland (70), Israel (68), Sweden (38), the Netherlands (71), Finland (31), Japan (81), Germany (40), Spain (46) and Turkey (48), with one study conducted as a multi-country study (Iceland, Ireland and Spain) (66).

There were 15,341 participants across the 58 included studies. Individual study sample sizes varied markedly ranging from 8 (26) to 2,921 (84) participants, with 48% ( $n = 28$ ) of the studies having 100 or less participants. The percentage of women within study samples ranged from 14% (68) to 91% (28), and of those reporting sex distribution, 71% ( $n = 41$ ) had >50% female distribution, with 21% ( $n = 13$ ) having  $\geq 70\%$  female distribution. Only five studies had more men than women (26,46,49,68,73), and only one of these had >70% male. Of the studies that reported the age of men and women separately, the mean age of male participants ranged from 22 (52) to 63 years (62) and female participants from 21 (52) to 65 (62) years. BMI ( $\text{kg m}^{-2}$ ) for male participants ranged from 27  $\text{kg m}^{-2}$  (51) to 43  $\text{kg m}^{-2}$  (31) and female participants from 26  $\text{kg m}^{-2}$  (51) to 44  $\text{kg m}^{-2}$  (31). The duration of active weight loss interventions ranged from 6 weeks (78) to 24 months (31,38,68,86,87), with six studies conducting further follow-up (31,40,59,65,81,84).

### Critical appraisal

Studies were assessed for quality (Table S2) using a critical appraisal tool developed by the Academy of Nutrition and Dietetics (21). The average quality score was positive with nine studies classed as negative. Any study found to be of negative quality was excluded from the remainder of the review, leaving a total of 49 studies included. Of the 49 studies still included following critical appraisal, the criteria not met by more than 50% were those pertaining to blinding of allocators and appropriate statistical analysis. Other quality criteria that were poorly met were the

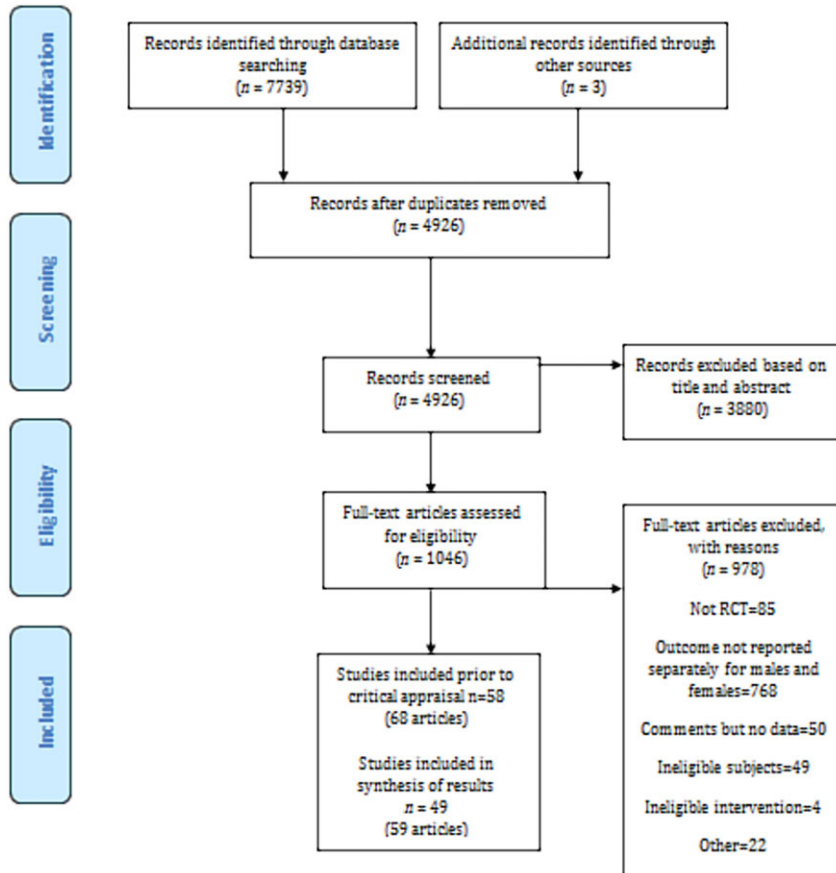


Figure 1 Flow chart of study selection.

description of biases and limitations and also whether bias was due to funding (<65% of studies met these criteria).

### Outcomes and interventions

Of the final 49 studies, 33 reported multiple weight outcomes and 16 reported a single weight outcome (Table S3). Weight change (kg) or weight (kg) as baseline and final values were the primary weight outcomes reported by the majority of studies ( $n = 45/49$ ). Weight change as a percentage of baseline weight was reported by only 10 studies. Nineteen of the 49 studies reported change in fat mass (kg/lb/%) and 14 studies reported change in fat-free mass (kg/lb/%) or volume (L). Seventeen of the 49 studies reported changes in waist or hip circumference or waist to hip ratio, and 15 reported either change in BMI ( $\text{kg m}^{-2}$ ) or BMI as baseline and final values. Change in site-specific fat distribution (visceral/subcutaneous) was reported in 6 of the 49 studies. Three studies reported reaching goal weight as an additional outcome.

Of the 49 studies, 34 made a single comparison (two groups), while 15 made multiple comparisons. Of the 34 making a single comparison, 19 compared similar interventions (i.e. diet vs. diet). Of these, 10 compared dietary

interventions (27,35,46,53,58,61,72,78,82,83), 2 compared PA (48,49) and 7 compared combinations of diet and PA interventions (31,45,50,62,63,65,79). Two studies compared different interventions (i.e. diet vs. diet plus meal replacements) (38,40). The remaining studies ( $n = 13$ ) compared intervention to control (26,30,34,36,37,44,47,52,54,59,64,67,71,76,77,81,84). The intervention groups in these studies consisted of PA ( $n = 1$ ) (52), combined diet and PA ( $n = 7$ ) (34,36,37,59,71,81,84), and supplements ( $n = 5$ ) (26,47,64,67,77). Three of the supplement groups received the supplement plus dietary intervention. The control groups were either minimal interventions ( $n = 5$ ), true controls ( $n = 3$ ) or placebo ( $n = 5$ ; 3 of these received dietary intervention as well as placebo). Of the 15 studies comparing multiple interventions, there were 14 dietary interventions, 2 exercise interventions, 27 diet plus exercise interventions, 1 supplement group and 7 controls (2 minimal intervention, 4 true controls and 1 placebo).

Overall, diet plus exercise and diet alone were the main interventions investigated (diet and exercise groups [ $n = 48$ ]; diet groups [ $n = 36$ ], exercise groups [ $n = 7$ ], supplement groups [ $n = 6$ ] and control groups [total  $n = 19$ : minimal intervention  $n = 7$ ; true control  $n = 6$ ; placebo  $n = 6$ ]).

## Effectiveness of interventions

The effectiveness of interventions for men and women was reported in two ways. Twenty-one studies directly compared the weight loss responses of men and women. Of these studies, 11 reported significant differences *between* men and women for change in weight (34,36,46,50,53,61,65,68,73,79). The remaining studies reported that there were no significant differences in weight change between men and women. The second approach reported the effects of the interventions on men and women separately (i.e. *within* sex group effects) but there was no statistical comparison of the magnitude of these responses. Twenty-nine studies reported *within* sex effects and 28 studies reported significant intervention effects *within* men and/or women (29,31,35,37–40,42,45,47,48,52, 54,58,59,61,62,64,66,67,71,76,77,79,81,83,84,86). The one remaining study reported that there were no significant intervention effects for either sex (49). Six studies did not report whether the differences were significant (26,27,30,75,80,82).

## Direct comparison of differences between men and women

### Overview

Overall, of the 11 studies reporting significant *male vs. female* sex differences in weight (kg or %) change (34,36,46,50,53,61,65,68,73,79,84), 10 reported that men lost significantly more weight (kg) than women (34,36,46,50,53,61,65,73,79,84); one study reported that men lost significantly more weight than women with one intervention but women lost significantly more weight than men in another intervention group (68). Of these 11 studies, 4 investigated the effectiveness of dietary interventions (46,53,61,68), 6 investigated the effects of combined diet and exercise prescription (29,31,50,65,79,84) and 1 reported between sex differences for a combination of interventions but not for each intervention (73).

### Effectiveness of diet only interventions

Four studies investigated *between* sex differences for the effects of dietary interventions on weight loss (46,53,61,68). The mean difference in weight loss between men and women ranged from 1.2 kg (68) to 3.5 kg (53); the mean weight losses for men ranged from 4.1 to 10.8 kg and for women from 2.9 to 7.8 kg. The duration of the active weight loss interventions ranged from 5 weeks (46) to 24 months (68).

The first study (53,56) compared a standard protein (SP; 15% protein, 55% carbohydrate, 30% fat) diet to a high protein (HP; 30% protein, 40% carbohydrate, 30% fat) diet over 16 weeks (12-week weight loss, 4-week weight loss maintenance). Men in both groups lost significantly

more weight than women ( $P = 0.003$ ); however, when expressed as a percentage of baseline weight, this difference was no longer significant. Additionally, men lost significantly more fat mass ( $P < 0.03$ ) and fat-free mass ( $P < 0.02$ ) than women.

The second study (61,88) also compared an SP diet to HP diet over 16 weeks but with different macronutrient distributions to the previous study (SP: 40% protein, 30% carbohydrate, 30% fat; HP: 20% protein, 30% carbohydrate, 50% fat). Again, both men and women lost weight, but overall, men lost significantly more weight (kg and %) than women ([11 kg vs. 8 kg;  $P = 0.028$ ]; [2% greater weight lost in men;  $P = 0.03$ ]). Men also lost significantly more abdominal fat mass than women ( $P = 0.039$ ).

Another study that investigated the effects of macronutrients on weight compared three diet arms over 24 months (68). The three arms were low-fat calorie-restricted diet (30% fat, 1,500–1,800 kcal), a calorie-restricted Mediterranean diet (35% fat, 1,500–1,800 kcal) and a low carbohydrate diet with no calorie restriction (20 g carbohydrate). Men lost significantly more weight (kg) than women in interventions 1 (3.3-kg difference;  $P < 0.001$ ) and 3 (2.5-kg difference;  $P < 0.001$ ); however, women lost more weight in intervention 2 (2.2-kg difference;  $P < 0.001$ ). When baseline weight was adjusted for in the analysis, these treatment differences by sex were no longer significant.

The final study compared two intervention arms over 8 weeks (46); one group was prescribed a diet composed of seven meals per day with a macronutrient distribution of 40% total energy from carbohydrates, 30% from proteins and 30% from fats, and the second group was instructed to consume three to five meals per day with a macronutrient distribution of 50–55% total energy from carbohydrates, 15% from proteins and 30% from fats (46). Both groups were requested to improve healthy fatty acid profiles, increase intake of fiber to 20–25 g d<sup>-1</sup> and reduce cholesterol <300 mg d<sup>-1</sup>. Men lost significantly more weight (kg) than women in both intervention groups (group 1: 1.2 kg difference; group 2: 2.0 kg difference;  $P < 0.007$ ).

### Effectiveness of combined diet and exercise interventions

Six studies investigated sex differences in the effectiveness of diet and exercise interventions (34,36,50,65,79,84). Of those reporting weight loss (kg), the mean difference between men and women ranged from 1.4 kg (50) to 3.9 kg (65), with the mean weight losses for men ranging from 4.2 to 7.3 kg and for women from 0.3 to 5.9 kg. The duration of the active weight loss interventions ranged from 12 weeks to 18 months (36,65).

The first study compared two intervention groups, one high protein (HP) and one low protein (LP) (79). Participants were recommended 30-min walking, 5 d week<sup>-1</sup> and



attended weekly educational sessions for the duration (79). With results from both interventions pooled, men lost significantly more weight than women (M 2.7 kg > F;  $P = 0.04$ ) after 4 months; however, when expressed as a percentage of baseline weight, this was no longer significant.

Andersen *et al.* (50) compared two exercise programmes with both groups following the same calorie-restricted diet. One group performed moderate-vigorous aerobic activity for 45 min, 3–4 d week<sup>-1</sup> with the other group performing moderate PA (mostly walking) for 30 min 5 d week<sup>-1</sup>. Men lost significantly more weight (kg) than women ( $-7.3 \pm 3.3$  vs.  $-5.9 \pm 2.9$ ;  $P = 0.027$ ) over the 12 weeks (50).

The next study (61) of 30-month duration consisted of an 18-month weight loss phase with 12-month passive follow-up. The two intervention groups were prescribed the same type of exercise; however, group 1 had an exercise energy expenditure goal of 1,000 kcal week<sup>-1</sup> and group 2 of 2,500 kcal week<sup>-1</sup>. Both groups were instructed to consume an energy-restricted diet of 1,000–1,500 kcal d<sup>-1</sup>. There was no difference between the interventions so data were pooled to examine sex differences. Men had significantly greater weight loss (kg) than women ( $-4.2 \pm 7.1$  vs.  $-0.29 \pm 9.5$ ;  $P$ -value not reported) at 30 months (61).

Stevens *et al.* (34) compared a diet and exercise intervention group to a no-intervention control group over a 6-month weight loss phase and 12-month weight loss maintenance. The intervention group was asked to reduce calorie intake to no less than 1,200 kcal d<sup>-1</sup>, prescribed an exercise goal of 30–45 min of moderate intensity PA on 4–5 d week<sup>-1</sup>, and attended behaviour change sessions (goal setting, self-monitoring, relapse prevention). The control group maintained their normal diet and exercise patterns. Men in the intervention group lost significantly more weight (kg) than women in the intervention group from baseline to post-weight loss phase (M  $-6.5$  vs. F  $-3.7$ ;  $P < 0.01$ ), post-weight loss to mid-weight maintenance phase (M  $-5.6$  vs. F  $-2.7$ ;  $P < 0.01$ ) and post-weight maintenance phase (M  $-4.7$  vs. F  $-1.6$ ;  $P < 0.01$ ). When expressed as a percentage of baseline weight, these differences remained significant at each time point ( $P < 0.05$ ) (34).

Wing *et al.* (36) compared a diet and exercise intervention of calorie restriction (1,000–1,500 kcal d<sup>-1</sup>), with an emphasis on increasing complex carbohydrates and decreasing fat, and an exercise goal of 1,000 kcal week<sup>-1</sup> and educational sessions to a minimal intervention group that received diet and exercise information (no prescription) but did not attend any sessions (36). Men in the intervention group lost a significantly greater amount of weight (kg) at 6, 12 and 18 months (6 months  $-11.3$  vs.  $-8.4$ ; 12 months  $-8.5$  vs.  $-6.3$ ; 18 months  $-7.3$  vs.  $-4.6$ ;  $P < 0.05$ ) and body fat (%) at 6 and 18 months (6 months  $-7.2$  vs.  $-5.2$ ; 18 months  $-4.7$  vs.  $-3.1$ ;  $P < 0.05$ ) than women in the intervention group.

The final study (84) of 30-month duration compared an intensive lifestyle intervention of diet and PA with individual fortnightly visits for the first 6 months, then monthly to bi-monthly for the remaining duration, to a minimal intervention group who had annual visits only. The lifestyle intervention included goals of 7% reduction in weight, at least 150 min of moderate PA per week, and a reduction of dietary fat to 25% of total energy intake. Overall, women in the lifestyle group had a significantly lower weight loss than men. When results were reported for the six sex-race groups (Caucasian men, Caucasian women, African-American men, African-American women and Hispanic men and Hispanic women), African-American women had a significantly lower percent weight loss than all other sex-race groups ( $-2.0 \pm 6.2$ ;  $P < 0.01$ ), except for African-American men ( $P = 0.356$ ); however, the weight loss of African-American men was not significantly different from any other sex-race group.

#### Multiple interventions

The final study compared three groups over 12 weeks: diet alone, diet and exercise, or no-intervention control. Both intervention groups were prescribed a modified Dietary Approach to Stop Hypertension (DASH) diet plan with a 600 kcal d<sup>-1</sup> energy restriction. The exercise consisted of 40 min of cycling on an ergometer on alternate days at 65% maximum heart rate. The control group was advised not to change their diet or PA for the 12 weeks but visited the research clinic for assessment sessions. Pooled data from the two interventions and one control showed that men had a significantly greater weight loss (kg) ( $-8.8 \pm 0.8$  vs.  $-6.2 \pm 0.8$ ;  $P < 0.05$ ) than women (73).

#### Effect sizes comparing changes in weight outcomes between men and women

Effect sizes to compare the differences in absolute weight loss achieved by men and women for diet alone, exercise alone or diet plus exercise are shown in Table 1a. Additional effect sizes were calculated for percent weight change and change in BMI to determine if effect sizes remained the same after adjusting for baseline weight and body composition (Table 1b). For *absolute weight loss*, the mean effect sizes for diet (Hedges'  $g$ :  $-0.489$ ) were moderate and diet-plus-exercise interventions (Hedges'  $g$ :  $-0.240$ ) were small, although the difference in weight loss between men and women ranged from trivial to large. There was no difference in weight loss between men and women using exercise alone (Hedges'  $g$ :  $-0.105$ ). Effect sizes for *percent weight change* were small for dietary interventions (Hedges'  $g$ :  $-0.254$ ) and diet plus exercise interventions (Hedges'  $g$ :  $-0.225$ ). However, an increase from no difference to a small difference favouring women was found for exercise only interventions (Hedges'  $g$ :  $-0.339$ ). For *change in BMI*,

**Table 1a** Mean weight changes in men and women plus effect size for the difference between men and women within intervention groups

Intervention	Study	Men		Women		Hedge's <i>g</i>	
		Mean	SD	Mean	SD		
Diet alone	Bowen <i>et al.</i> (a), 2005 (58)	-9.4	4.1	-9.4	3.9	0.000	
	Bowen <i>et al.</i> (b), 2005 (58)	-12	4.7	-7.8	2.3	-1.220	
	Ditschuneit <i>et al.</i> (a), 1999 (40)	-8.4	3.9	-6.8	3.3	-0.464	
	Ditschuneit <i>et al.</i> (b), 1999 (40)	-1.1	2.6	-1.2	2.1	0.046	
	Dow <i>et al.</i> 2012 (78)	-0.3	2.1	-0.6	1.8	0.189	
	Farnsworth <i>et al.</i> (a), 2003 (53)	-9.6	1.7	-7.4	0.5	-2.373	
	Farnsworth <i>et al.</i> (b), 2003 (53)	-11.4	2.1	-6.6	0.5	-4.364	
	Thorsdottir <i>et al.</i> (a), 2008 (66)	-6.5	2.8	-4.4	2.3	-0.830	
	Thorsdottir <i>et al.</i> (b), 2008 (66)	-7	3.5	-3.9	2.3	-1.047	
	Janssen and Ross 1999 (42)	-11.7	3.5	-10.7	3.8	-0.270	
	Lopez-Legarrea <i>et al.</i> (a), 2013 (46)	-7.7	2.6	-6.5	3.1	-0.419	
	Lopez-Legarrea <i>et al.</i> (b), 2013 (46)	-7.6	3.3	-5.6	2.5	-0.671	
	Luscombe-Marsh <i>et al.</i> (a), 2005 (61)	-11.2	6.1	-7.9	5.4	-0.577	
	Luscombe-Marsh <i>et al.</i> (b), 2005 (61)	-10.5	5.9	-7.8	3.2	-0.592	
	Shea <i>et al.</i> 2011 (76)	-5.3	4.8	-4.6	4.2	-0.156	
	Stocks <i>et al.</i> 2012 (82)	-7.9	3.8	-6.5	3.2	-0.412	
	St-Onge <i>et al.</i> (a), 2012 (83)	-5.6	1.5	-3.4	2	-1.180	
	St-Onge <i>et al.</i> (b), 2012 (83)	-2.9	1.5	-3.3	2.2	0.203	
	Torgerson <i>et al.</i> (a), 1997 (38)	-15.5	17.2	-5.6	11	-0.728	
	Torgerson <i>et al.</i> (b), 1997 (38)	-5.3	9.8	-6.8	9.3	0.158	
	Wood <i>et al.</i> (a), 1991 (29)	-5.1	5.8	-4.1	5.5	-0.175	
		<b>Mean weight loss</b>	<b>-7.7</b>	-	<b>-5.8</b>	-	-
		<b>Pooled* effect size</b>	-	-	-	-	<b>-0.489</b>
Exercise alone	Donnelly <i>et al.</i> (a), 2013 (44)	-3.8	5.7	-4.1	4.3	0.060	
	Donnelly <i>et al.</i> (b), 2013 (44)	-5.9	6.6	-4.4	4.2	-0.270	
		<b>Mean weight loss</b>	<b>-4.9</b>	-	<b>-4.3</b>	-	-
	<b>Pooled* effect size</b>	-	-	-	-	<b>-0.105</b>	
Diet + exercise	Andersen <i>et al.</i> 2002 (50)	-7.3	3.3	-5.9	2.9	-0.467	
	Byrne <i>et al.</i> 2006 (63)	-7.3	2.2	-5.7	3.9	-0.516	
	Dansinger <i>et al.</i> 2005 (60)	-3.3	6.4	-2.4	5.1	-0.155	
	De Jonge <i>et al.</i> 2012 (86)	-7.6	5.1	-5.9	6.1	-0.293	
	Gabriele <i>et al.</i> (a), 2011 (75)	-6.7	5.3	-2.4	3	-1.274	
	Gabriele <i>et al.</i> (b), 2011 (75)	-6.6	6.6	-2.5	3.4	-0.983	
	Gabriele <i>et al.</i> (c), 2011 (75)	-3.4	5.9	-4.5	3.7	0.273	
	Gorin <i>et al.</i> (a), 2013 (45)	-10	10.5	-4.2	9.7	-0.588	
	Gorin <i>et al.</i> (b), 2013 (45)	-4.6	10.6	-8.1	9.8	0.351	
	Hakala <i>et al.</i> (a), 1993 (31)	-1.8	7.4	-5.4	10.9	0.363	
	Hakala <i>et al.</i> (b), 1993 (31)	-15.6	12	-10.4	13.4	-0.402	
	Janssen and Ross (a), 1999 (42)	-12.7	3.8	-10	2.8	-0.809	
	Janssen and Ross (b), 1999 (42)	-11.4	3.8	-11.5	3.2	0.028	
	Jeffery <i>et al.</i> (a), 2003 (54)	-2.6	5.7	-1.7	4.1	-0.193	
	Jeffery <i>et al.</i> (b), 2003 (54)	-3.8	5.7	-1.9	18.7	-0.116	
	Stewart <i>et al.</i> 2005 (62)	-2.2	2.7	-2.3	3.4	0.032	
	Tate <i>et al.</i> 2007 (65)	-4.2	7.1	-0.3	9.5	-0.453	
	ter Bogt <i>et al.</i> 2009 (71)	-2.1	4.8	-1.5	4.1	-0.133	
	West <i>et al.</i> (a), 2008 (84)	-5.7	7.6	-4.2	7.5	-0.199	
	West <i>et al.</i> (b), 2008 (84)	-4.8	3.5	-2.1	6.3	-0.465	
	West <i>et al.</i> (c), 2008 (84)	-6.3	6.6	-5.1	8.3	-0.154	
	Williams <i>et al.</i> (a), 1998 (39)	-1.5	6.9	-7.8	3.7	1.283	
	Williams <i>et al.</i> (b), 1998 (39)	-11.6	5	-7	5.7	-0.866	
Williams <i>et al.</i> (c), 1998 (39)	-14.7	5.5	-8.2	4.1	-1.420		
Wood <i>et al.</i> (b), 2001 (29)	-8.7	5.7	-5.1	5.3	-0.655		
	<b>Mean weight loss</b>	<b>-6.7</b>	-	<b>-5.1</b>	-	-	
	<b>Pooled* effect size</b>	-	-	-	-	<b>-0.240</b>	
<b>Overall pooled† effect size</b>		-	-	-	-	<b>-0.315</b>	

\*Pooled effect sizes for intervention type.

†Overall pooled diet; exercise and diet + exercise effect size; effect size of 0.2 defined as small, 0.5 medium and 0.8 large.

The effect sizes are weighted based upon the sample sizes of men and women.

**Table 1b** Mean percent weight changes and changes in body mass index (BMI) in men and women plus effect size for the difference between men and women within intervention groups

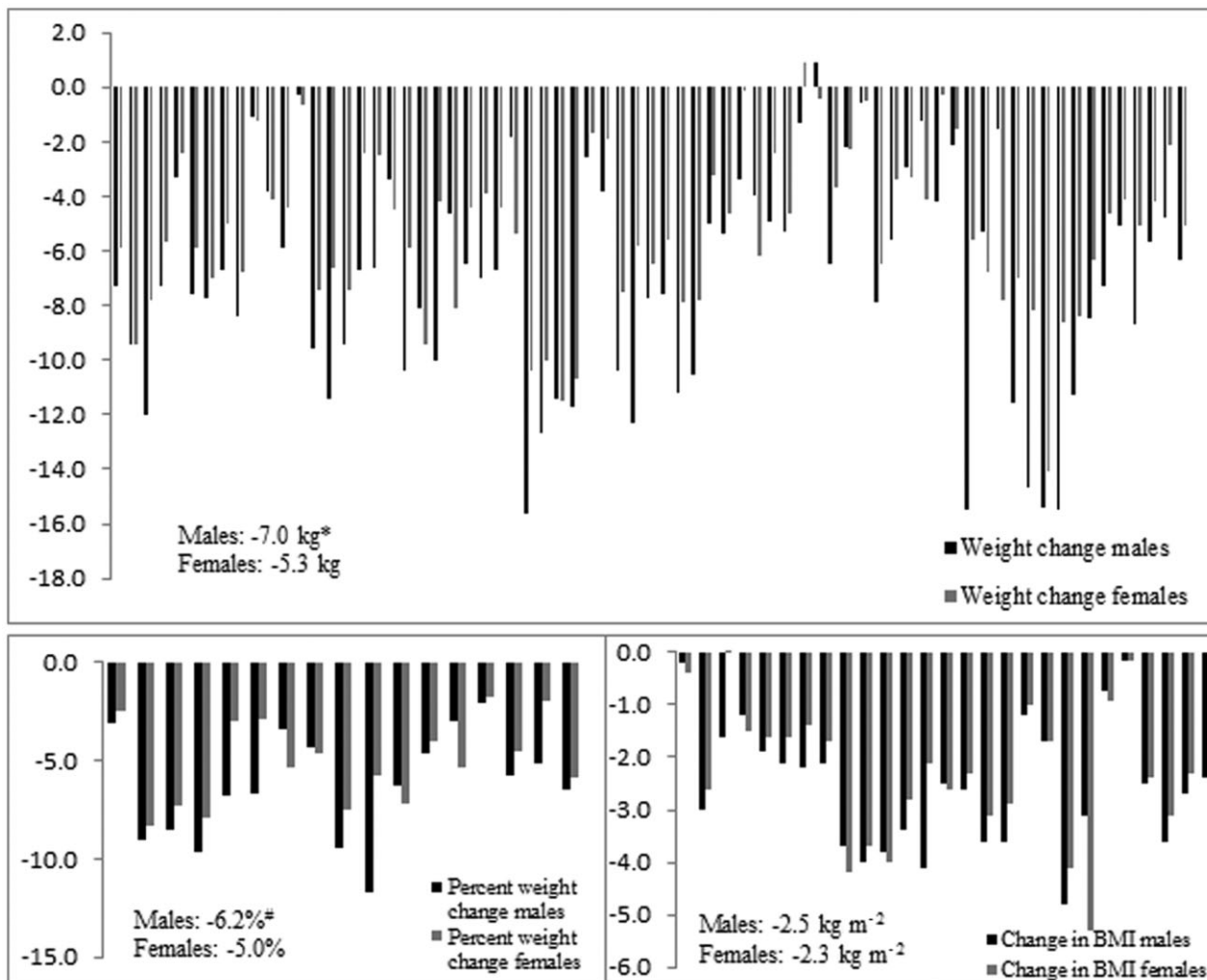
Percent weight change						
Intervention	Study	Men		Women		Hedge's g
		Mean	SD	Mean	SD	
Diet alone	Evans <i>et al.</i> (a), 2012 (79)	-9	3.4	-8.3	3.2	-0.213
	Evans <i>et al.</i> (b), 2012 (79)	-8.5	4	-7.3	3.8	-0.309
	<b>Mean percent weight loss</b>	<b>-8.8</b>	-	<b>-7.8</b>	-	-
	<b>Pooled* effect size</b>	-	-	-	-	<b>-0.254</b>
Exercise alone	Sanal <i>et al.</i> (a), 2013 (48)	-4.6	2.5	-4	2.4	-0.245
	Sanal <i>et al.</i> (b), 2013 (48)	-3	2.8	-5.3	3	0.906
	<b>Mean percent weight loss</b>	<b>-3.8</b>	-	<b>-4.7</b>	-	-
	<b>Pooled* effect size</b>	-	-	-	-	<b>0.339</b>
Diet + exercise	Gabriele <i>et al.</i> (a), 2011 (75)	-6.8	5.2	-3	3.8	-0.950
	Gabriele <i>et al.</i> (b), 2011 (75)	-6.7	7.1	-2.9	4	-0.805
	Gabriele <i>et al.</i> (c), 2011 (75)	-3.4	5.8	-5.3	4	0.349
	ter Bogt <i>et al.</i> 2009 (71)	-2.1	4.8	-1.7	4.9	-0.082
	West <i>et al.</i> (a), 2008 (84)	-5.8	7.1	-4.5	7.6	-0.175
	West <i>et al.</i> (b), 2008 (84)	-5.1	3.7	-2	6.2	-0.539
	West <i>et al.</i> (c), 2008 (84)	-6.5	6.3	-5.9	9.2	-0.072
	<b>Mean percent weight loss</b>	<b>-5.2</b>	-	<b>-3.6</b>	-	-
	<b>Pooled* effect size</b>	-	-	-	-	<b>-0.225</b>
<b>Overall pooled† effect size</b>	-	-	-	-	<b>-0.193</b>	
Change in BMI						
Intervention	Study	Men		Women		Hedge's g
		Mean	SD	Mean	SD	
Diet alone	Thorsdottir <i>et al.</i> (a), 2008 (66)	-2.1	0.9	-1.6	0.8	-0.591
	Thorsdottir <i>et al.</i> (b), 2008 (66)	-2.2	1.1	-1.4	0.9	-0.796
	Janssen and Ross 1999 (42)	-3.8	0.9	-4	1.3	0.179
	Lopez-Legarrea <i>et al.</i> (a), 2013 (46)	-2.5	1.1	-2.6	0.1	0.128
	Lopez-Legarrea <i>et al.</i> (b), 2013 (46)	-2.6	1.1	-2.3	1	-0.284
	Luscombe-March <i>et al.</i> (a), 2005 (61)	-3.6	2.2	-3.1	1.2	-0.292
	Luscombe-March <i>et al.</i> (b), 2005 (61)	-3.6	2.1	-2.9	1.9	-0.352
	Stocks <i>et al.</i> 2012 (82)	-2.5	1.2	-2.4	1.2	-0.083
	<b>Mean BMI change</b>	<b>-2.9</b>	-	<b>-2.5</b>	-	-
	<b>Pooled* effect size</b>	-	-	-	-	<b>-0.183</b>
Exercise alone	Donnelly <i>et al.</i> (a), 2013 (44)	-1.2	1.8	-1.5	3.1	0.118
	Donnelly <i>et al.</i> (b), 2013 (44)	-1.9	3.9	-1.6	3.1	-0.085
	Sanal <i>et al.</i> (a), 2013 (48)	-4.8	2.7	-4.1	2.5	-0.269
	Sanal <i>et al.</i> (b), 2013 (48)	-3.1	2.8	-5.3	3	0.867
	<b>Mean BMI change</b>	<b>-2.8</b>	-	<b>-3.1</b>	-	-
<b>Pooled* effect size</b>	-	-	-	-	<b>0.153</b>	
Diet + exercise	De Jonge <i>et al.</i> 2012 (86)	-3	1.8	-2.6	1.8	-0.222
	Janssen and Ross (a), 1999 (42)	-3.7	1.3	-4.2	1.3	0.385
	Janssen and Ross (b), 1999 (42)	-4	1.3	-3.7	0.9	-0.268
	Stewart <i>et al.</i> 2005 (62)	-0.8	0.9	-0.9	1.3	0.089
	<b>Mean BMI change</b>	<b>-3.9</b>	-	<b>-3.5</b>	-	-
<b>Pooled* effect size</b>	-	-	-	-	<b>-0.072</b>	
<b>Overall pooled† effect size</b>	-	-	-	-	<b>-0.131</b>	

\*Pooled effect sizes for intervention type.

†Overall pooled diet; exercise and diet + exercise effect size; effect size of 0.2 defined as small, 0.5 medium and 0.8 large.

The effect sizes are weighted based upon the sample sizes of men and women.





**Figure 2** Mean changes in absolute weight loss, percent weight loss and body mass index (BMI) in men and women in those studies reporting mean data.

\*Significant difference between men and women. #No significant difference between men and women.

all intervention categories showed no difference between men and women (Hedges'  $g$ : diet  $-0.183$ ; diet plus exercise  $-0.072$ ; exercise  $0.153$ ). For those studies that reported mean change (irrespective of significance) in absolute weight, percent weight and change in BMI, an illustration can be seen in Fig. 2.

### Meta-analyses comparing changes in weight outcomes between men and women

In addition to the above effect sizes, meta-analyses were also conducted to investigate the differences in change in weight outcomes between men and women (Supporting information Fig. S1a–c). Meta-analysis showed that when comparing the difference in absolute weight loss in men and women for diet-only, exercise-only and combined diet and exercise interventions, weight loss was significantly

greater for men in the diet-only and diet plus exercise interventions. When meta-analysis was conducted for percent weight change, greater percent weight loss was still significant in men for the diet plus exercise interventions but not diet-only; however, this is possibly due to the small number of diet-only studies. Meta-analysis of change in BMI for each of the intervention categories showed that men had a significantly greater reduction in BMI in the diet-only interventions; however, change in BMI for exercise-only and diet plus exercise interventions were not different between men and women.

### Characteristics of studies with insignificant between sex differences

Of the 10 studies (42,44,47,48,60,63,70,72,78,86) that reported no sex differences in weight loss, men tended to

have slightly greater improvement in weight outcomes than women but not sufficient to reach statistical significance. The duration of these studies ranged from 6 weeks to 24 months. Within these 10 studies, sex differences in weight loss were compared in 25 interventions (diet plus exercise,  $n = 12$ ; diet-only,  $n = 8$ ; exercise-only,  $n = 4$ ; supplement,  $n = 1$ ).

### Effectiveness of interventions for men and women reported separately

Significant *within* sex differences were reported in 28 studies (29,31,35,37–40,42,45,47,48,52,54,58,59,61,62,64,66,67,71,76,77,79,81,83,84,86), and of these, 17 compared differences in weight loss between intervention groups (29,31,35,38–40,45,47,52,54,59,66,71,76,81,83,84) and four reported differences for each intervention but did not compare interventions (48,58,62,66,67). Within the first 17 studies, the following comparisons were made (24 interventions within 17 studies): diet plus exercise vs. minimal intervention ( $n = 6$ ); diet plus exercise vs. control ( $n = 2$ ); diet plus exercise vs. diet plus exercise ( $n = 3$ ); diet plus exercise vs. diet ( $n = 1$ ); diet vs. control ( $n = 1$ ); diet vs. minimal intervention ( $n = 1$ ), diet vs. diet ( $n = 3$ ); diet plus meal replacements vs. diet ( $n = 2$ ); exercise vs. control ( $n = 1$ ), diet vs. placebo ( $n = 2$ ) and supplement vs. placebo ( $n = 2$ ). The four reporting results for each intervention but not directly comparing interventions reported both men and women lost significant amounts of weight in diet-only, exercise-only, diet plus exercise and supplement interventions. Supporting information Table S4 shows the comparisons of interventions that were effective for men and/or women. The remaining seven studies reported significance for pooled intervention data; therefore, information on the effectiveness of individual interventions could not be extracted. However, of these studies, four reported that both men and women lost a significant amount of weight and the other three reported only women lost a significant amount of weight.

As *within* sex differences do not directly answer our research question, these results are not discussed further.

### Discussion

This is the first systematic review investigating whether particular weight loss interventions are more effective for men than women or vice versa. In total, the results of 49 studies were consolidated in order to address this question. The interest in sex differences in weight loss resulting from lifestyle interventions has grown in recent years, with 65% ( $n = 32$ ) of the final 49 included studies conducted since the year 2000 and over 40% of these conducted in the last 4 years.

After methodological evaluation of study quality, nine studies assessed as having very poor methodological quality were excluded. With the release of the Consolidated Standards of Reporting Trials (CONSORT) statement in 1996 (89) and updates released in both 2001 and 2010, it is surprising to see studies still not meeting the criteria during quality assessment. Of these nine excluded studies, five were conducted after 1996 with two as late as 2009/2010. However, the overall quality of the studies included in this review was generally positive ( $n = 27/49$ ). The main areas for improvement were description of the method of handling withdrawals, blinding of assessors, conducting appropriate statistical analysis, description of study limitations and whether bias occurred due to funding.

The average sample size of studies in this review was 265 participants; however, 43% had fewer than 100 and a number of studies had as few as 30. When investigating sex differences, larger numbers are required as sample sizes are essentially halved during statistical analysis. A small sample size leads to lower power, which reduces ability to conclude that results are valid, reliable and generalizable (90). Although all studies in this review included men and women, there were a number of studies that had low proportions of either men or women in comparison to the other sex; therefore, results from these unmatched studies need to be treated with caution. One study in particular reported that men lost significantly more weight than women; however, the proportion of women in this sample was only 14% (68). On the contrary, over 70% of the studies in this review had less than 50% of men in their sample and more than 20% of studies had less than 30% men. Similar results have been reported previously. A review of weight loss trials in men found that study samples were predominantly women, with, on average, only 23% of men (91). This variation in sample size of men and women within studies contributes to the difficulty in determining whether sex differences in weight loss exist.

The length of studies ranged from 6 weeks to 30 months of active weight loss with 47% ( $n = 23$ ) less than 6 months in duration. It has been suggested that weight loss plateaus at approximately 6 months (12), suggesting that lifestyle interventions should be conducted over a 6-month period to ensure maximum weight loss is achieved; however, any longer than this may not be necessary. One study included in this review reported data at 6 monthly time points up to 30 months and some sex-race sub-groups continued to lose weight up to 18 months, suggesting longer interventions may be of benefit for some populations. Weight loss did plateau around 6–12 months in other sex-race sub-groups, but these groups also started to regain weight, highlighting the importance of weight maintenance programmes (84). It remains unclear whether men lose weight at a faster rate than women (after adjusting for initial body weight); therefore, 6 months may be sufficient for maximal weight loss in

men but not women. Research does suggest that women are better at maintaining weight loss (12), possibly due to a more gradual initial weight decrease than men. It has been reported that differences in weight loss between men and women early on in an intervention do not exist at completion of the study (92). These patterns of weight loss in men and women may be of importance for determining the most suitable weight loss interventions and also for maintenance of lost weight.

Although 80% of the studies directly comparing weight loss (kg) between men and women found that men lost significantly more weight than women, it should be noted that women also lost weight during these interventions. Also, two of the studies (53,79) reported significant differences in weight loss (kg) between men and women, but when adjusted for baseline weight, this was no longer significant. Of the studies reporting weight loss as a percentage of baseline weight, only two reported a significant sex difference with men losing more percent weight over 16 weeks (61) and 30 months (84). Both analysis of effect sizes and meta-analyses of the differences in change in weight outcomes between men and women showed greater differences for men when using absolute weight change. However, when percent weight change or change in BMI was used, results indicating greater weight loss in men were less convincing, but not absent. This is likely because percentage weight change accounts for the baseline differences that exist in weight and height, which absolute weight change does not. Therefore, reporting only absolute weight loss rather than weight change as a percentage of baseline weight or BMI may lead to an incorrect conclusion regarding whether a meaningful sex difference exists. The capacity to directly compare results between absolute weight change, percent weight change and BMI change was also limited because all outcomes were not reported in all studies, thus different studies were included in the analysis of effect sizes and meta-analyses of each weight outcome. Additionally, the number of studies reporting these outcomes, particularly percent weight change and BMI, was relatively small. Therefore, whether differences in weight loss between men and women are due to differences in absolute size remains unclear; future reporting of percent weight loss or change in BMI will allow this to be explored more thoroughly.

There were many more diet or diet plus exercise interventions than exercise alone or dietary supplement interventions. It has previously been reported that the effectiveness of interventions producing a clinically significant weight loss were improved by the inclusion of both diet and PA (93). Over 85% of the interventions in this review consisted of diet alone or diet plus exercise interventions. Energy restriction through diet is often more effective for weight loss than exercise alone (94) and this was observed in the differences in mean weight loss

between diet vs. exercise interventions in both sexes. However, with energy restriction difficult to maintain, the inclusion of exercise for increased energy expenditure means less energy restriction from foods and possibly greater adherence. This might explain why those who include both diet and exercise are more likely to maintain weight loss after 1 year (94). Hence, we could recommend that both men and women adopt a lifestyle of moderate energy restriction with the inclusion of exercise for weight loss.

Within those studies prescribing diet or diet plus exercise interventions, there were some common features that likely contributed to weight loss success in both sexes. Energy intake was tailored by sex, in that women were prescribed 1,200 kcal d<sup>-1</sup> and men 1,500–1,800 kcal d<sup>-1</sup>. This is important due to the baseline differences in energy expenditure between men and women (6,7). Exercise recommendations were not extreme with protocols generally ranging from 30 to 60 min of exercise on 3–5 d week<sup>-1</sup> with a number of studies increasing frequency and intensity over time. This is in line with exercise recommendations for overweight individuals with initial durations of 20–30 min d<sup>-1</sup> working up to 60 min d<sup>-1</sup> recommended and initial intensities of 50–60% working up to 60–80% of heart rate reserve recommended (95). This ensures that participants are able to complete exercise prescriptions safely but also ensures protocols change enough to ensure the benefits of exercise continue with increasing fitness. A large RCT investigating the effectiveness of an intensive lifestyle intervention in over 5,000 participants with type 2 diabetes examined weight losses over a 4-year period (92). This study was not included in the review because a considerable number of participants were currently using insulin, which is known to impact on weight. Nonetheless, it is interesting to note that participants with better dietary and PA practices were more likely to maintain their 1-year weight losses at 4 years further highlighting the importance of diet and PA, not only for weight loss but also weight maintenance.

A number of limitations were identified in this review, with the main ones being the availability of so few studies reporting weight loss as a percentage of baseline weight and the lack of direct comparison of men and women in the statistical analysis. There was also a high rate of heterogeneity between study interventions, making conclusions difficult. Additionally, although a large number of studies were retrieved and included, the search strategy did not include grey literature or unpublished work. However, this review did have a number of strengths including this being the first known systematic review on sex differences in weight loss. This review included a substantive number of studies and also adhered to PRISMA guidelines when conducting and reporting this review. There are a number of factors that need to be addressed in future research. Studies

need to be powered to assess differences in weight loss between men and women, and outcomes need to be reported as a percentage of baseline weight or change in BMI rather than absolute weight loss only.

Men do appear to lose more weight than women during weight loss attempts, although it is possible that this is due to the greater baseline weight of men rather than the specific lifestyle interventions. Despite men showing greater weight loss than women in the majority of studies, women have still had significant weight losses meaning lifestyle interventions which include dietary and exercise prescription appear effective for both men and women. There is little evidence that men and women should adopt different weight loss strategies and the differences in weight loss seen in the short term may have little significance long term. To facilitate weight loss in overweight and obese men and women, health professionals need to focus on the inclusion of both diet and exercise in weight loss attempts and need to provide support for individuals to assist with implementation of programmes which has the potential to increase long-term success.

### Conflict of interest statement

The authors declare that they have no conflicts of interest.

### Authors' contributions

RLW has made substantial contributions to conception and design, data collection and analysis, interpretation of data and has been involved in drafting the manuscript. RC has made substantial contributions to conception and design, interpretation of data and revising it critically for important intellectual content. CEC has made substantial contributions to interpretation of data and revising it critically for important intellectual content. LW has made substantial contributions to interpretation of data and revising it critically for important intellectual content. RLW, RC, CEC and LW have given final approval of the version to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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### Supporting information

Additional Supporting Information may be found in the online version of this article, <http://dx.doi.org/10.1111/obr.12241>

**Figure S1.** (a) Meta-analysis comparing absolute weight change in men and women. (b) Meta-analysis comparing percent weight change in men and women. (c) Meta-analysis comparing change in body mass index (BMI) in men and women.

**Table S1.** Study characteristics.

**Table S2.** Critical appraisal of RCTs included in review.

**Table S3.** Weight outcomes and results.

**Table S4.** Description of effective\* interventions for weight loss in men and/or women.

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## Appendix 1

**Symbols Used**

- +** Positive: Indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.
- Negative: Indicates that these issues have not been adequately addressed.
- ∅** Neutral: Indicates that the report is neither exceptionally strong nor exceptionally weak.

**Quality Criteria Checklist: Primary Research**

RELEVANCE QUESTIONS					
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)	Yes	No	Unclear	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes	No	Unclear	N/A
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes	No	Unclear	N/A
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes	No	Unclear	N/A
<i>If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.</i>					
VALIDITY QUESTIONS					
1.	<b>Was the <u>research question</u> clearly stated?</b>	Yes	No	Unclear	N/A
	1.1 Was the specific intervention(s) or procedure (independent variable(s)) identified?				
	1.2 Was the outcome(s) (dependent variable(s)) clearly indicated?				
	1.3 Were the target population and setting specified?				
2.	<b>Was the <u>selection</u> of study subjects/patients free from bias?</b>	Yes	No	Unclear	N/A
	2.1 Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?				
	2.2 Were criteria applied equally to all study groups?				
	2.3 Were health, demographics, and other characteristics of subjects described?				
	2.4 Were the subjects/patients a representative sample of the relevant population?				
3.	<b>Were <u>study groups</u> comparable?</b>	Yes	No	Unclear	N/A
	3.1 Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)				
	3.2 Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?				
	3.3 Were concurrent controls used? (Concurrent preferred over historical controls.)				
	3.4 If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?				
	3.5 If case control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)				
	3.6 If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?				
4.	<b>Was method of handling <u>withdrawals</u> described?</b>	Yes	No	Unclear	N/A
	4.1 Were follow up methods described and the same for all groups?				
	4.2 Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)				
	4.3 Were all enrolled subjects/patients (in the original sample) accounted for?				
	4.4 Were reasons for withdrawals similar across groups?				

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