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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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

Weight loss, weight maintenance, men and women, systematic review

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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**

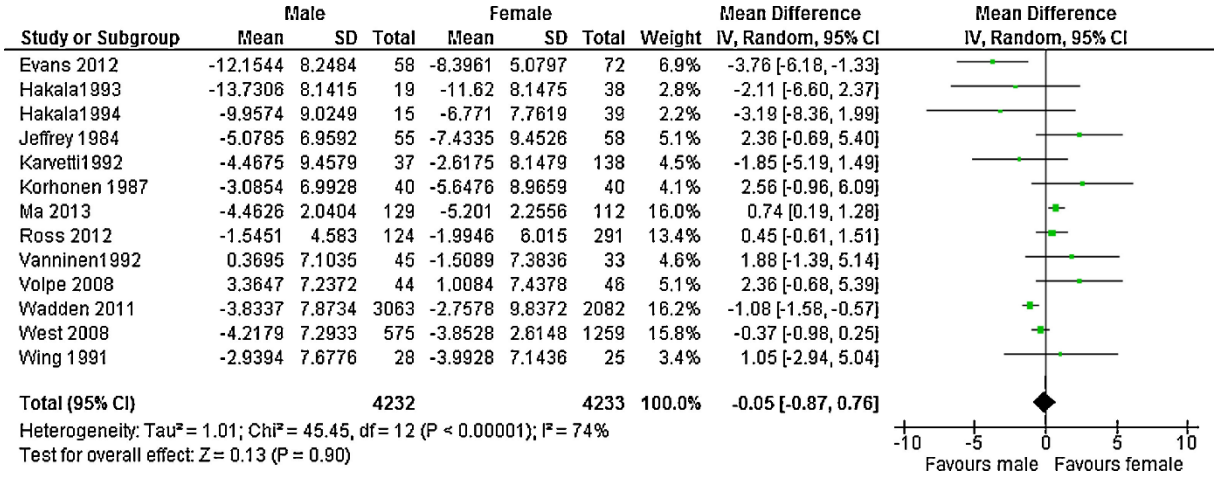
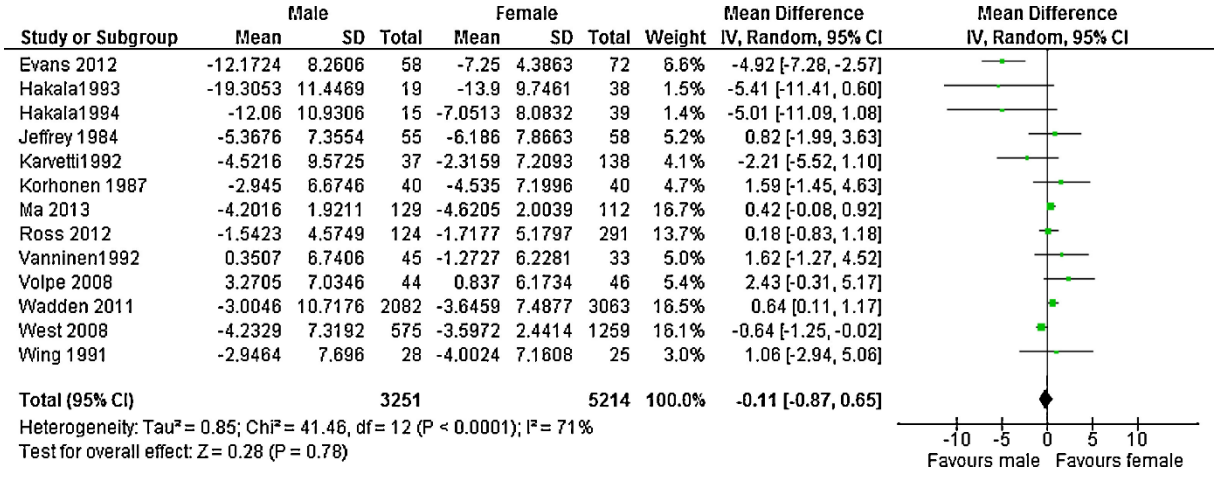


Figure 2 **Difference in percentage weight loss from baseline between men and women**



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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76. Diabetes Prevention Program The Diabetes Prevention Program (DPP): description of lifestyle intervention. *Diabetes Care* 2002; **25**: 2165-71.

Table S1 Example of literature search in MEDLINE and Embase

Details of literatures searches in other databases are available from the authors

MEDLINE 1948 to 29th October 2014

MEDLINE In-Process 29th October 2014

Embase 1980 to 2014 Week 44

Ovid multifile search: http://shibboleth.ovid.com/

1. obesity/
2. (obesity adj2 (morbid or diabet$)).tw.
3. obesity, morbid/ use prmz
4. morbid obesity/ use emez
5. obes$.tw.
6. weight loss/ use prmz
7. weight reduction/ use emez
8. (weight adj1 (los$ or reduc$ or maint$ or control)).tw.
9. (diet adj5 weight).tw.
10. overweight.tw.
11. or/1-10
12. exp clinical trial/
13. Randomized Controlled Trials as Topic/
14. randomized controlled trial.pt.
15. controlled clinical trial.pt.
16. randomi?ed.ab.
17. randomization/ use emez
18. placebo.ab.
19. drug therapy.fs.
20. randomly.ab.
21. trial.ab.
22. groups.ab.
23. or/12-22
24. exp animals/ not humans/
25. 23 not 24
26. 11 and 25
27. (letter or editorial or comment or note).pt.
28. 26 not 27
29. limit 28 to ("all infant (birth to 23 months)" or "all child (0 to 18 years)" or "newborn infant (birth to 1 month)" or "infant (1 to 23 months)" or "preschool child (2 to 5 years)" or "child (6 to 12 years)" or "adolescent (13 to 18 years)")
30. limit 28 to (embryo or infant or child or preschool child <1 to 6 years> or school child <7 to 12 years> or adolescent <13 to 17 years>)
31. 28 not 29
32. 28 not 30
33. 31 or 32
34. limit 33 to yr="2001 - current"

Table S2 Characteristics of included trials

Study ID	Participants	Interventions	Outcomes	Notes
Evans 2012 [1]	**Location:** Georgia, USA **Period of study:** NR **Inclusion criteria:** NR **Exclusion criteria:** BMI <26, body weight >140kg (due to DXA scanning bed constraints), smoking, any existing medical conditions that impact primary/secondary outcomes (i.e. use of oral steroids or anti-depression medication) **Age, years*:** mean, SE Men a: 46.5, 1.5; b: 46.0, 1.9 Women a: 45.6, 1.2; b:44.5, 1.7 **Weight, kg:** mean, SD Men a:100.1, 11.1 ; b: 100.2, 16.4 Women a: 88.3, 11.8 ; b: 85.1, 12.0 **BMI*:** mean, SE Men a: 32.6, 0.7; b: 31.8, 0.8 Women a: 32.8, 0.7; b: 32.8, 0.8 **Baseline comparability:** Yes	**Details of interventions** **a. Individual or group:** Individual **Description:** CARB diet providing dietary protein equal to 0.8g·kg^{-1}·d (approximately 15% of energy intake) with a carbohydrate/protein ratio >3.5 and total fat approximately 30% of energy intake. Education guidelines followed the USDA Food Guide Pyramid [2] and emphasized restricting dietary fat and cholesterol with use of whole grain breads, rice, cereals and pasta. **b. Individual or group:** Individual **Description:** PRO diet providing 1.6g·kg^{-1}·d (approximately 30% of energy intake) with a carbohydrate/protein ratio <1.5 and dietary lipids approximately 30% of energy intake. Education guidelines emphasized use of high quality low fat proteins including lean meat, reduced fat dairy and eggs or egg substitutes. Both a and b were formulated to be equal in energy (1700 kcal per day for females and 1900 kcal per day for men), total fat intake (30% of energy) and fiber (17g/1000kcal). Each diet group received a menu plan with meals for each meeting established nutritional and dietary fat guidelines. Diet differences were designed to reflect direct substitution of foods in the protein group for foods with high carbohydrate content. Both diets included 5 vegetable servings per day and 2to 3 fruit servings per day.	**Length of follow-up:** 12 months **Outcomes by sex:** Weight	*Baseline data reported in Layman 2009 [3]

		All participants received specific diet programme instructions from a research dietician including menus, food substitutions and portion sizes. Participants attended a 1-hour once weekly meeting with the dietician to provide diet and exercise information, answer questions and review diet records for treatment compliance at the weight management research facility. Activity guidelines recommended a minimum of 30 mins of walking 5 days per week. Physical activity was monitored using daily activity ogs and armband accelerometers (BodyMedia, Cincinatti, OH) worn 3 days per month. **Timing of active intervention:** a: 4 months; b: 4 months **Number of times contacted:** a: 57 ; b: 57 **Number allocated*:** Men: a: 30 ; b: 28 , Women: a: 36 ; b: 36 **Number completed:** Men: a: 12; b: 19, Women: a: 24; b: 22 **% dropout:** Men: a:60%; b:32% , Women a:33% ; b: 39% **Number assessed:** Men: a:30; b: 28 , Women: a: 36 ; b: 36		
Gorin 2013 [4]	**Location:** Home environment, Providence, Rhode Island, USA **Period of study:** NR **Inclusion criteria:** Aged 21-70 years, BMI 25-50 and have a household member willing to participate in the study as a support partner – support partners had to reside in the same home as the participant and be interested in weight loss. Partner inclusion/exclusion criteria as per	**Details of interventions** **a**. **Individual or group:** Individual **Description:** Standard behavioural weight loss treatment (participants only). Standard caloric and fat-restricted diet (e.g. 1200-1800 kcal/day and 30% fat, depending on initial weight) to achieve a 10% weight loss goal. Sample meal plans and a calorie guidebook, and gradually increase physical activity until achieved $\geq$ 200	**Length of follow-up:** 18 months **Outcomes by sex:** Weight	

	participant criteria except lower age range of 15-70 years old. **Exclusion criteria (for participants and partners):** Heart condition, chest pain during activity or rest, loss of consciousness, unable to walk two blocks without stopping, current participation in another weight loss programme, taking weight loss medication, current pregnancy or planned in the next 18 months, or any condition judged by the research team to impede completion of the study protocol (i.e. plans to relocate, substance abuse). Individuals with joint problems, using prescription medication or other conditions that could limit exercise were required to obtain written physician consent to participate. **Age, years:** mean, SD Participants a: 50.4, 9.3; b: 47.5, 11.3; Partners a: 47.9, 13.3; b: 47.8, 13.0 **Weight, kg:** NR **BMI:** mean, SD Participants a: 36.1, 6.1; b: 36.7, 6.2; Partners a: 33.1, 5.7; b: 32.8, 6.1 **Baseline comparability:** Yes	min of moderate intensity physical activity per week. Given pedometers and goal of 10,000 steps per day. Instruction in core behavioural skills was provided through daily diaries for recording all food and beverage intake with corresponding calories, fat grams, minutes of physical activity, daily steps and participant weight. Interventionists provided weekly written feedback. Stimulus control, problems solving, goal setting, cognitive restructuring skills were also taught. The focus of treatment shifted to weight loss maintenance and relapse-prevention in the latter months of the programme. **b**. **Individual or group:** Individual plus one household partner **Description:** Standard behavioural weight loss treatment plus modifications to the home environment (participants and partners). Standard treatment as described above but additionally manipulated physical and social aspects within participants' households. Partner was encouraged to attend all weight loss groups and make the same diet and exercise changes as participants. Modifying type and amount of food consumed: Once monthly participants conducted a "cabinet cleanout" removing any items listed on a high-fat foods checklist. A complementary "filling up with fit foods" exercise using a provided checklist of foods consistent with the dietary prescription was also completed monthly. To increase cues for healthy food choices, participants were		

		provided with a low calorie cookbook, a subscription to a healthy recipe magazine and motivational posters. Appropriately sized dishware and glasses, a food scale and set of measuring cups and spoons were provided to limit portions and decrease passive eating. Participants were also encouraged to use a commercially available online grocery order and home delivery service to limit impulse purchases. Participants paid for their own groceries but were reimbursed for the delivery fee. Modifying availability of exercise equipment and sedentary activities: treadmill or stationary bicycle was provided for home use, participants asked to decrease time spent watching television and restrict viewing to one location. Each television in the home was fitted with a TV allowance device that provided feedback about weekly viewing habits. Exercise videotapes, resistance bands, a subscription to an exercise related magazine and motivation posters were also provided to further increase cues for physical activity. Increasing saliency of consequences: Participants were given a digital body weight scale and a full length mirror with instructions to place these in prominent locations to serve as daily cues to self-weigh and limit overeating/engage in physical activity. Both conditions had weekly group meetings for 6 months followed by bi-weekly meetings for 12 months. Participants and partners in both a and b each received $25 for completing the 6-month assessment and $50 for completing the		

		18-month assessment. **Timing of active intervention:** 18 months **Number of times contacted:** 51 **Number allocated:** Participants a: Men: 21; Women: 78; b: Men: 23; Women: 79; Partners a: Men: 52; Women: 47; b: Men: 55; Women: 47 **Number completed:** Participants a: 86; b: 99; Partners a: 82; b: 99 **% dropout:** Participants a: 13%; b: 3%; Partners a: 17%; b: 3% **Number assessed:** Participants a: Men: 21; Women: 78; b: Men: 23; Women: 79; Partners a: Men: 52; Women: 47; b: Men: 55; Women: 47		
Hakala 1993 [5]	**Location:** One rehabilitation centre, Finland **Period of study:** NR **Inclusion criteria:** At least 50% overweight, aged 20-54 years **Exclusion criteria:** Cardiovascular disease, metabolic disease, psychiatric disease, hypothyroidism **Age, years:** mean, SD (range) Men a: 39, 9 (28-53); b: 40, 10 (27-51) Women a: 41, 8 (25-54); b: 37, 6 (24-52) **Weight, kg:** mean, SD (range) Men a: 121.9,10.3 (109-141); b: 120.2, 9 (109-131) Women a: 104.0, 12.2 (83-132); b: 104.3, 10.6 (87-126) **BMI:** mean, SD (range) Men A: 42.7, 4.0 (37.4-50.3); B: 41.7, 3.1 (38.3-49.2) Women A: 43.6, 4.8 (36.3-56.7)	**Details of interventions** **a**. **Individual or group:** Group **Description:** 2-week, in-patient treatment in a rehabilitation centre. Weight reduction programme consisted of 1200 kcal/day diet and group counselling sessions led by a nutritionist, physiotherapist and occupational therapist (10 participants per group) including: 15 hours nutrition counselling 15 hours physical activity 12 hours occupational therapy 1 hour individual nutritionist counselling Physician led lecture and examination Followed by 4-monthly individual physician appointments for 2 years. **b. Individual or group:** Individual **Description:** 1200 kcal/ day diet and individual physician led counselling in 20 minute	**Length of follow-up:** 5 years **Outcomes by sex:** Weight	Weight reduction programme based on that used in Karvetti 1992 [6]

	Baseline comparability: Yes	sessions, monthly for the first year and 4 monthly over the second year. The physician provided advice and information leaflets concentrating on weight reduction for the first 6 months and concentrating on changes in body weight and health status after 6 months. No anorexigenic drugs used in either group. **Timing of active intervention:** A: 2 week intensive weight reduction followed by counselling up to 2 years; B: 2 years counselling **Number of times contacted:** a: 40; b:15 **Number allocated:** Men a: 10; b: 10, Women a: 20; b: 20 **Number completed:** Men a: 9; b: 9, Women a: 19; b: 16 **% dropout:** Men a:10%; b: 10%. Women a:5%; b: 20% **Number assessed:** Men a:9; b: 9, Women: a: 19; b: 16		
Hakala 1994 [7]	**Location:** one rehabilitation centre and one health centre, Finland **Period of study:** NR **Inclusion criteria:** At least 54% overweight, no participation in a weight reduction course in the previous 2 years **Exclusion criteria:** Epilepsy, cardiac failure **Age, years:** mean, SD (range) Men a: 40, 11 (25-52); b: 44, 6 (38-53) Women a:40, 7 (26-51); b: 40, 8 (25-52) **Weight, kg:** mean, SD (range) Men a: 143.6, 17.1 (127-174); b: 137.6, 11.0 (120-156)	**Details of interventions** **a**. **Individual or group:** Group **Details:** 3-week, in-patient treatment in a rehabilitation centre. Programme consisted of a low-fat, high fibre diet of 1200 kcal/day and group counselling sessions led by a nutritionist, physician and occupational therapist (10 participants per group) including: 21 hours nutrition & behaviour counselling 16 hours recreational activity 15 hours physical activity 6 hours food preparation advice 6 hours social counselling	**Length of follow-up:** 5 years **Outcomes by sex:** Weight	Weight reduction programme based on that used in Karvetti 1992 [6]

	Women a: 120.7, 9.3 (106-146); b: 119.2, 12.6 (101-144) **BMI:** mean, SD (range) Men a: 40.5, 3.9 (36-48); b: 37.7, 2.3 (34-40) Women a: 39.8, 4.3 (35-51); b: 39.2, 3.5 (34-46) **Baseline comparability:** Yes	1 hour lecture 1 hour individual nutritionist led counselling 1 individual physician appointment Following the intensive weight reduction period, participants had appointments with their GP at 1-2 monthly intervals **b. Individual or group:** Individual Description: 10-week low-fat, high fibre diet of 1200 kcal per day and group counselling in a health centre setting led by 3 specially trained public health nurses. The group leader gave instruction and motivation according to a weight reduction plan based mainly on nutrition education and dietary counselling. 3 lectures (1 physician led, 1 psychologist led, 1 physiotherapist led) provided encouragement and support. Following the intensive weight reduction period, participants had appointments with their GP at 1-2 monthly intervals Drug treatment for obesity was not used in any phase of the study. **Timing of active intervention:** A: 3weeks followed by GP counselling up to 2 years; B: 10 weeks followed by GP counselling up to 2 years **Number of times contacted:** a: 13-21; b: 23-34 **Number allocated:** Men: a: 9; b: 9, Women: a: 21; b: 21 **Number completed:** Men: a:7; b:6, Women: a:16; b: 14 **% dropout:** Men: a:22%; b: 33%, Women a:		

		24%; b: 33% **Number assessed:** Men: a:7; b:6, Women: a:16; b: 14		
Heitzman 1987 [8]	**Location:** California, USA **Period of study:** Prior to Nov 1985 **Inclusion criteria:** Fasting blood glucose >140mg/dl or blood glucose >200mg/dl 2hrs after administration of 75g carbohydrate; medically safe to participate in exercise regimens **Exclusion criteria:** Significant heart or vascular disease **Age, years:** Mean, SD, Men+women: 52.94, 12.08 **Weight**, **kg**: mean, Men: 90.13kg; Women: 72.43kg **BMI:** NR **Baseline comparability:** Unclear	**Details of interventions** All participants were given dietary advice by a registered nutritionist and a prescribed exercise regimen based on exercise tolerance tests **a**. **Individual or group:** Group **Description:** Relaxation training (control) – participants offered muscle relaxation training and factual information about diabetes **b. Individual or group:** Group **Description:** Behaviour modification (self-control) – based on Ferguson's *Habits not diets* [9] Participants kept daily records of weight, type and amount of food eaten, events surrounding eating, time allocated/time spent exercising and place where exercised. **c. Individual or group:** Group **Description:** Cognitive modification (goal setting and role of cognitions) – based on Mahoney & Mahoney [10] Participants instructed to set reasonable goals and keep a diary of their self-statements during eating and exercise **d. Individual or group:** Group **Description:** Cognitive-Behaviour modification (goal setting and behaviour monitoring) – participants instructed to keep daily records, set goals and keep a diary of self-statements as in b and c.	**Length of follow-up:** 18 months **Outcomes by sex:** Weight, HbA1	

		Timing of active intervention: a-d: 7 weeks **Number of times contacted:** a-d: 13 **Number allocated:** Men + Women: a: 14; b: 13; c: 13; d: 15 **Number completed:** Men + Women: a: 12; b: 10; c: 10; d: 12 **% dropout:** Men + Women: a: 14.3%; b: 23.1; c: 10; d: 12 **Number assessed:** a-d: Men + Women 46		
Jeffery 1984 [11]	**Location:** University of Minnesota, USA **Period of study:** 1983-1984 **Inclusion criteria:** Men 30lbs (13.6kg), Women 20 lbs (9.1kg) over ideal body weight **Exclusion criteria:** Medical or behavioural contraindications **Age, years:** Mean: Self-referred group; Men: 44.3; Women: 44.5; Population sample; Men: 52.3; Women: 50.3 **Weight, kg:** Mean: Self-referred group; Men: 127.82; Women: 83.96; Population sample; Men: 106.46; Women: 82.46 **BMI:** Mean: Self-referred group; Men: 32.61; Women: 31.50; Population sample; Men: 32.97; Women: 30.53 **Baseline comparability:** Men and women in the self-referred group were younger than in the population sample, higher number previously participated in weight control programmes and had earlier age of onset of being overweight	**Details of interventions** Weight loss Phase: All groups participated in a 16-week educational programme emphasising reduced eating and increased exercise equally. All paid $150 deposit **a. Individual or group:** Group **Description:** Self-referred population – recruited through newspaper advertisement (i) Control – deposit refunded at initial session (ii) Constant contract – deposit refunded in $30 increments for every 5lb (2.3kg) group average weight loss (iii) Increasing contract – deposit refunded for successive 5lb (2.3kg) lost in increments of $5, $10, $20, $40 and $75 **b. Individual or group:** Group **Description:** Population sample - referred from Jeffery 1983 population sample	**Length of follow-up:** 1 year **Outcomes by sex:** Weight	1 year data not reported by participants randomised/ not randomised to the maintenance phase.

		(i) Control – deposit refunded at initial session (ii) Constant contract – deposit refunded in $30 increments for every 5lb (2.3kg) group average weight loss (iii) Increasing contract – deposit refunded for successive 5lb (2.3kg) lost in increments of $5, $10, $20, $40 and $75 Weight maintenance phase: 17 men and 25 women randomised to either intensive weekly problem solving sessions or to non-specific 3 monthly weight maintenance sessions. Both groups paid a $100 deposit, which was returned in $25 increments for attendance at quarterly sessions. Those remaining participants who were not randomised to the maintenance phase were contacted at the 1 year follow up assessment only. **Timing of active intervention:** 16 weeks + 8 month weight maintenance period **Number of times contacted:** a-b: 20; intensive maintenance 26; non-specific maintenance 22 **Number allocated:** a: men (i) 10; (ii) 7; (iii) 11; Women 31, numbers allocated unclear b: Men (i) 10; (ii) 9; (iii) 8; Women (i) 11; (ii) 9; (iii) 9 **Number completed:** a+b: men 53; women 57 **% dropout: :** a+b: men 3.6%; women 5.3% **Number assessed:** NR		
Jeffery 2003 [12]	**Location:** Four managed care organisation clinics, USA	**Details of interventions**	**Length of follow-up:** 24 months	

	Period of study: NR **Inclusion criteria:** Age ≥ 18 years; BMI > 27 **Exclusion criteria:** NR **Age, years:** Mean, SEM, Men + Women a: 50.8, 0.5; b: 50.7, 0.5; c: 50.6, 0.5 **Weight, kg:** NR **BMI:** Mean, SEM, Men + Women a: 34.0, 0.2; b: 33.5, 0.2; c: 34.1, 0.2 **Baseline comparability:** Participants randomised to the telephone group more likely to report taking medication for depression (P<0.002)	**a. Individual or group:** Individual **Description:** Control (usual care): Participants had access to weight management services generally available to members of HealthPartners private health insurance. **b. Individual or group:** Individual **Description:** Telephone group: Participants were given a telephone number to activate the intervention. Materials for 10 lessons mailed at the beginning of the programme. The telephone counsellor provided guidance for each lesson and gave feedback about progress including discussion of behavioural strategies tried since the last session, advice to improve/maintain lifestyle behaviour and a verbal description of the assignment for the next lesson. Average length of telephone call was 19 minutes. **c. Individual or group:** Individual **Description:** Mail group: Participants activated the intervention by sending a postcard to the study office. Materials and lessons as the telephone group but interactions between counselling staff and participants were completed via mailed progress reports detailing behaviour change goals, perceived progress and action steps to achieve goals. The counsellor reviewed the report, made comments and returned by mail along with the next lesson. Process repeated until all 10 lessons were completed. Lessons were carried out at a rate of one per	**Outcomes by sex:** Weight loss at 12 months	

		week or at the participant's own pace. Follow up options were available to both groups b and c from a health counsellor. Topics covered included nutrition, physical activity, goal setting, stimulus control, social support and self-motivation. If participants discontinued contact before completing 10 lessons, they were contacted at 30d, 60d and then 6 month intervals for 2 years. Those choosing not to activate programme also contacted at 6 month intervals for 2 years. Completers of 10 week programme followed up at 6, 12, 18 and 24 months. **Timing of active intervention:** 10 weeks **Number of times contacted:** a:5, b: 15; c: 15 **Number allocated:** Men a:163; b:159; c:186; Women a:437; b: 442; c: 414 **Number completed:** NR **% dropout:** NR **Number assessed:** Men a:163; b:159; c:186; Women a:437; b: 442; c: 414		
Jolly 2011 [13]	**Location:** 17 general practices, South Birmingham Care Trust, UK **Period of study:** 2009 **Inclusion criteria:** $\geq$ 18 years; raised BMI in previous 15 months; BMI $\geq$ 25 for South Asians and BMI $\geq$ 30 for participants of all other ethnicities without obesity related co-morbidity; BMI $\geq$ 23 for South Asians and BMI $\geq$ 28 for participants of all other ethnicities with obesity related co-morbidity **Exclusion criteria:** Presence of serious co-morbidities; unable to understand English;	**Details of interventions** **a. Individual or group:** Individual **Description:** Control – Participants were sent vouchers for 12 free sessions at a local authority run leisure centre. Participants were given no other advice or contact. **b. Individual or group:** Either individual or group **Description:** Participants were able to choose allocation to one of six interventions (C to H).	**Length of follow-up:** One year **Outcomes by sex:** Weight loss	

	pregnant; unwilling to be randomised **Age, years:** Mean (SD) Men+Women, a: 49.67 (13.83); b: 47.45 (14.35); c: 50.71 (14.56); d: 48.84 (14.91);e: 49.76 (14.51); f: 48.75 (15.63); g: 50.48 (13.79); h: 48.94 (15.82) **Weight, kg:** NR **BMI:** Men+Women, n(%) **BMI <30**: a: 14 (14); b: 14 (14); c: 12 (12); d: 11 (11); e: 17 (17); f: 14 (14); g: 11 (16); h: 9 (13) **BMI 30-34:** a: 48 (48); b: 54 (54); c: 51 (51); d: 51 (51); e: 49 (49); f: 51 (51); g: 39 (56); h: 35 (50) **BMI 35-39:** a: 25 (25); b: 28 (28); c: 29 (29); d: 32 (32); e: 27 (27); f: 27 (27); g: 18 (26); h: 20 (29) **BMI ≥ 40:** a: 6 (6); b: 4 (4); c: 8 (8); d: 5 (5); e: 4 (4); f: 5 (5); g: 2 (3); h: 3 (4) **Baseline comparability:** Yes	**c. Individual or group:** Group **Description:** Weight Watchers – Group based programme with one-to-one support. One hour meetings delivered by a group leader with discussion at community venues. Core programme based on a food points system aiming for a 500 kcal deficit per day, leading to a 0.5-1.0kg weight loss per week. Physical activity encouraged with goal of achieving 10,000 steps daily. Rewards given for every 3.2kg lost and for 5% and 10% of body weight lost. Behaviour change strategies include stages of change, food and activity diaries, goal setting and evaluation of progress. **d. Individual or group:** Group **Description:** Slimming World – Group based programme with one-to-one telephone support available. Ninety minute meetings held in community venues. Members are encouraged to eat low energy density foods plus extras rich in calcium and fibre. Weight loss goals were set by the individual. Physical activity encouraged with build up to 30 mins of moderate activity 5/7 days per week. Also included access to a website and magazines. Awards given for 3.2 kg lost and loss of 10% of body weight. Behaviour change theory based on transactional analysis, motivational interviewing, weekly weighing, group support, group praise, continued commitment in absence of weight loss, self-monitoring, visualisation techniques and personal eating plans.		

		e. Individual or group: Group **Description:** Rosemary Conley – Group based with one-to-one support. Additional support available by email or telephone. Ninety minute meetings took place in community venues. Sessions include a 45 minute optional exercise class. Goals were staged: either 1-1.5kg loss per week with a goal of 6.35kg or 0.5-1kg loss per week with a goal of 3.2kg. Behaviour change theory based on role modelling, group support, visualisation and reframing. Rewards given for slimmers who maintained or lost weight, including slimmer of the week and certificates for 3.2 kg and 6.35kg weight loss milestones. f. **Individual or group**: Group Description: NHS Size Down – Group based programme run by support workers trained by the NHS dietetics service. Programme consisted of 2-hour sessions held weekly over 6 weeks, with follow up sessions at 9 and 12 weeks. Focus on long term changes in eating behaviour patterns to achieve a balanced diet and increase physical activity. **g. Individual or group:** Individual **Description:** General Practice – One-to-one, client-led sessions in NHS general practice. Initial session lasted 30 minutes with follow up sessions lasting 15-20 minutes. Problem solving approach to explore goals and expectations, weight and dieting history, the eatwell plate, goal setting, self-monitoring through food diaries and planning strategies to		

		deal with challenging situations and maintaining weight loss. Weight loss goals were 5-10% of body weight at a rate of 0.5-1kg per week over 3 to 6 months followed by maintenance. Physical activity goals were to increase activity levels to 30 minutes of moderate activity 5/7 days per week. Homework provided for discussion or personal reflection. Participants were encouraged to reward themselves for success. **h. Individual or group:** Individual **Description:** Pharmacy – As general practice but delivered from NHS pharmacy setting. **Timing of active intervention:** 12 weeks **Number of times contacted:** a: 1, b; as chosen provider; c, d, e, g: 12; f: 8; h: 11 **Number allocated:** Men a: 25; b: 30; c:28; d: 35; e: 31; f: 36; g: 23; h: 19 Women a: 75; b: 70; c: 72; d: 65; e: 69; f: 64; g: 47; h 51 **Number completed:** Men a: 22; b: 17; c: 24; d: 24; e: 23; f: 28; g:14; h 10 Women a: 24; b: 22; c: 18; d: 28; e: 27; f: 26; g: 15; h: 22 **% dropout:** Men a: 12; b: 43.3; c: 14.3; d 31.4; e: 25.8; f: 22.2; g: 39.1; h: 47.4 Women a: 32; b: 31.4; c: 25; d: 43.1; e: 39.1; f: 40.6; g: 31.9; h: 43.1 **Number assessed:** Men a: 25; b: 30; c:28; d: 35; e: 31; f: 36; g: 23; h: 19 Women a: 75; b: 70; c: 72; d: 65; e: 69; f: 64; g: 47; h: 51		
Karvetti 1992	**Location:** One research centre, Finland	**Details of interventions**	**Length of follow-**	Control group

[6]	**Period of study:** NR **Inclusion criteria:** NR **Exclusion criteria:** Diabetes, any disease preventing compliance with the weight reduction programme **Age, years:** mean, Men + Women a: 47.8; b 48.5 **Weight, kg:** mean, Men a: 101.83; b: 100.65; Women a: 87.08; b: 90.0 **BMI:** mean, Men + Women a: 33.5; b: 34.4 **Baseline comparability:** Yes	**a. Individual or group:** Individual **Description:** Control group – participants given no instruction but were informed that they were selected to participate in a weight reduction course to be held after the 1 year follow up assessment. **b. Individual or group:** Group **Description:** Low-fat, low-sugar, high fibre 1200 kcal/ day diet combined with a group based weight reduction programme (8 subgroups with 12-18 participants in each group) based on nutrition education and counselling to modify counterproductive dietary habits, organised through the 1 year intervention period by 7 trained public health nurses. 3 lectures (1 physician led, 1 psychologist led, 1 physiotherapist led) provided encouragement and support. Eventual weight maintenance diet of 1800 kcal/day. **Timing of active intervention:** 1 year **Number of times contacted:** a: 2; b: 12 **Number allocated:** Men + Women a: 117; b: 126 **Number completed:** Men a: 20; b: 21; Women a: 76; b: 71 **% dropout:** (% defaulters) Men + Women a: 18%; b: 26% **Number assessed:** Men a: 20; b: 21; Women a: 76; b: 71	**up:** 1 year **Outcomes by sex:** Weight, systolic & diastolic BP	acted as a control for the first year of follow up only. Paper reports data for 7 years. Weight data derived from graph.
Korhonen 1987 [14]	**Location:** One hospital outpatient clinic, Finland **Period of study:** NR **Inclusion criteria:** Newly diagnosed non-insulin dependent diabetes: fasting venous blood glucose	**Details of interventions** Prior to randomisation, a doctor described the general outline of therapy and stressed the	**Length of follow-up:** 1 year **Outcomes by sex:** Weight	

	≥ 7.0 mmol/l and/or 2 hour blood glucose ≥ 10.0 mmol/l in oral glucose tolerance test **Exclusion criteria:** NR **Age, years:** Mean, SEM; Men: a: 54.8, 1.3; b: 53.6, 1.3; Women: a: 57.8, 1.0; b: 59.1, 1.2 **Weight, kg:** Mean, SEM; Men: a: 97.5, 3.6; b: 93.4, 3.4; Women: a: 81.9, 3.6; b: 78.7, 2.2 **BMI:** Mean, SEM; Men: a: 31.7, 1.0; b 31.3, 0.8; Women: a: 32.7, 1.9; 31.8, 0.8 **Baseline comparability:** Yes	importance of diet and weight reduction in diabetes control to all participants. **a. Individual or group:** Individual **Description:** Doctor only: Short, written information leaflet giving dietary instruction in weight reduction provided by a doctor, general leaflet used for obese non-diabetic patients. No additional instruction given at follow-up visits. **b. Individual or group:** Individual **Description:** Specialist Nurse: Nurse assessed diet history of each participant and gave individual instruction for following a hypocaloric diet. Instructions repeated at follow up visits. **Timing of active intervention:** 12 months **Number of times contacted:** a: 5; b: 5 **Number allocated:** Men: a: 20; b: 20; Women a: 20; b: 20 **Number completed:** Men: a: 19; b: 19; Women a: 15; b: 18 **% dropout:** Men: a: 5%; b: 5%; Women a: 25%; b: 10% **Number assessed:** Men: a: 19; b: 19; Women a: 15; b: 18	change	
Lantz 2003 [15]	**Location:** One hospital outpatient clinic, Sweden **Period of study:** January 1996 to February 1999 **Inclusion criteria:** Age 18 to 60 years; BMI > 30 **Exclusion criteria:** Participation in other ongoing clinical trial; concomitant serious disease (e.g. type I diabetes, renal or hepatic failure, unstable angina, recent myocardial infarction, chronic infections, psychotic disorder & bulimia);	**Details of interventions** Both groups exposed to a 16-week pre-treatment phase where participants consumed a very low calorie diet (VLCD) of 450 kcal/day supplied by Modifast®, Novartis Nutrition. Treatment phase followed by a 3 week re-feeding phase where ordinary food was	**Length of follow-up:** 2 years **Outcomes by sex:** weight loss	

	previous obesity surgery; drug abuse **Age, years:** Mean, SD; Men+ Women: a: 41.9, 10.6; b: 41.4, 11.3 **Weight, kg:** Mean: Men, a: 117.65; b: 125; Women a:111.11; b: 110.71 **BMI:** Mean, SD; Men+ Women: a: 39.9, 5.6; b: 40.1, 5.7 **Baseline comparability:** Yes	introduced. **a. Individual or group:** Individual **Description:** Repeated VLCD every 3 months for 2weeks. Recommended to follow an individualised hypocaloric diet, providing a 500 kcal/day deficit, at other times. **b.Individual or group:** Individual **Description:** Recommended to follow an individualised hypocaloric diet providing a 500 kcal per day deficit. Advised to use VLCD when body weight passed an individual, predetermined cut-off (individual body weight after pre-treatment phase plus 3kg). The cut-off level was reduced during the trial for those who continued to lose weight. Cut-off level remained unchanged for those who regained weight. **Timing of active intervention:** up to 24 months **Number of times contacted:** a: 69; b: 69 **Number allocated:** Men: a: 42; b: 44; Women: a: 119; b: 129 **Number completed:** Men: a: 14; b: 21; Women: a: 43; b: 39 **% dropout:** Men: a: 66.7%; b: 52.3%; Women: a: 63.9%; b: 69.8% **Number assessed:** Men: a: 14; b: 21; Women: a: 43; b: 39		
Lindstrom 2008 [16]	**Location:** Five diabetes centres, Finland **Period of study:** 1993-2000 **Inclusion criteria:** 40-65 years, BMI>25 kg/m2, IGT (2 hour plasma glucose 7.8-11.0 mmol/L),	**Details of interventions** **a. Individual or group:** Individual **Description:** General advice: at baseline	**Length of follow-up:** median 4 years **Outcomes by**	Finnish Diabetes Prevention Study

	OGTT 75g with a non-diabetic fasting glucose concentration (plasma glucose less than 7.8 mmol/L), mean value of 2 OGTTs **Exclusion criteria:** previous diagnosis of diabetes mellitus (other than gestational diabetes mellitus), persons involved regularly in vigorous exercise programme, subjects receiving treatment to lower blood glucose (other than routine dietary and health advice), chronic disease making 6 year survival improbable, other medical characteristics likely to interfere with study participation, unbalanced clinical conditions such as thyroid and liver disease **Age, years:** Mean (SD), Men+Women, a: 55.0 (7.0); b: 55.0 (7.0) **Weight, kg:** NR **BMI:** Mean (SD); Men a 29.7 (3.6); b: 30.1 (3.5); Women a: 31.7 (4.7); b: 32.1 (4.9) **Baseline comparability:** Significant difference in systolic BP ((mm Hg, SD): 136, 17 (group a) vs 140, 18 (group b) (p=0.03)	participants advised to adjust total energy intake to reduce BMI to below 25, also less than 30% of energy intake from fat, reduce alcohol intake and stop smoking, verbal and written dietary advice, verbal general information regarding health benefits of recreational exercise, additional routine advice at yearly follow-up where 3 day food record assessed and 2 km walking test performed **b. Individual or group:** Individual **Description:** Lifestyle modification: participants informed at start of risk factors for diabetes, 3 day food diary at baseline provided basis for dietary advice in second session, advised to reduce weight to goal of BMI less than 25 but in practice weight targets were 5-10kg weight loss; advised to consume >50% CHO, <10% saturated fat, 20% mono and polyunsaturated fat or up to 25% if surplus is from monounsaturated fat; <300mg/day cholesterol and 1g protein per kg IBW per day, encouraged to increase fibre intake to 15g per 1000kcals, encouraged to use low fat milk products, low fat meat products, soft margarine and vegetable oil rich in MUFA (primarily rapeseed oil); energy content re-evaluated if no weight loss at visits, if no weight loss in first 6-12 months and BMI>30 a VLCD was considered (6-12 week duration with group meetings every 1-2 weeks); dietary advice individually tailored and person responsible for preparing meals in family invited to attend sessions (if not the participant), advice tailored to participants educational level, participants	**sex:** diabetes incidence	(methods from Tuomilehto 2001 [17]) All participants had impaired glucose tolerance

		individually guided to increase endurance exercise (programme differed between study centres) also when possible there was a supervised progressive individually tailored circuit type resistance training twice weekly, encouraged to perform 30 minutes daily moderate exercise, 3 day food diary kept every 3 months, 24 hour exercise diary kept every 3 months and 12 month physical activity history completed on annual visit along with 2 km walking test **Timing of active intervention:** 2-6 years **Number of times contacted:** a: 5; b: 29 **Number allocated:** Men a: 81; b: 91; Women a: 176; b: 174 **Number completed:** at 2 years Men+Women a: 242; b: 240 **% dropout:** at 2 years Men+Women a:6%; b: 8% **Number assessed:** Men a: 81; b: 91; Women a: 176; b: 174		
Ma 2013 [18]	**Location:** California, USA **Period of study:** July 2009 to June 2010 **Inclusion criteria:** ≥18 years of age, BMI ≥25, presence of pre-diabetes mellitus or metabolic syndrome. **Exclusion criteria:** serious medical or psychiatric conditions (e.g. stroke, psychotic disorder) or special life circumstances (e.g. pregnancy, planned move). **Age, years:** mean, SD a: 52.5, 10.9; b: 54.6, 11.0; c: 51.8, 9.9 **Weight, kg:** mean, SD a: 92.6, 18.1; b: 95.3, 18.0; c: 93.6, 17.1	**Details of interventions** **a. Individual or group:** Individual **Description:** Usual care. Participants were not provided with information about weight loss or weight loss goals and their primary care providers were not involved in the conduct of the study. **b. Individual or group:** Group **Description:** Coach-led. Group Lifestyle Balance (GLB) intervention delivered face-to-face in 12-weekly classes led by the study lifestyle coach, a dietician and exercise	**Length of follow-up:** 15 months **Outcomes by sex:** Weight	

	BMI: mean SD Men a: 30.8, 4.8 ; b: 30.3, 3.7; c:31.1, 5.0 Women a: 34.4, 7.2 ; b: 33.5, 5.9; c: 32.4, 4.3 **Baseline comparability:** Women had higher BMI than men in a and b.	physiologist. In addition to the GLB materials, participants had food tastings and 30-45 minutes of guided physical activity at weekly meetings. In the maintenance phase, the dietician provided individualized counselling via secure messaging on a monthly basis. **c. Individual or group:** Individual **Description:** Self-directed. Participants attend a single group orientation session (equivalent to class one in the coach-led intervention). Following this session, participants are given the GLB programme on DVD to follow at home. Participants are encouraged to use the study secure email messaging service to contact the dietician with comments or questions as they are completing the DVD programme. The dietician responded to messages within 1-2 working days and provided general support and encouragement. In the maintenance phase, participants received a reminder email every fortnight. The dietician responded to participant enquires via secure messaging but did not initiate contact. Participants in b and c completed a 3-month intensive intervention phase and 12-month maintenance phase. Intensive phase: The GLB programme delivered over 12 weekly sessions lasting 90-12 minutes each. Sessions include weight measurement; review of self-monitoring records and progress; identification of personal barriers; presentation of new content area; goal		

		setting and action plans for the next week. Maintenance phase: The GLB programme is derived from Social Cognitive Theory and the Transtheoretical Model of Behaviour Change. Participants are set goals of gradually achieving 7% weight loss and 150 minutes of moderate physical activity per week by week five of the intervention or as soon as possible thereafter. Participants are encouraged to track their weight and physical activity using the American Heart Association's online self-management portal at www.heart360.com. Recommendations are also given for total fat reduction to 25% of calories from fat; calorie restriction to a 500 to 1000 calorie reduction diet; reduction of saturated fat to <10% of calorie intake; lower cholesterol intake to <300mg per day; reduce intake of high glycemic index carbohydrates and consume a high plant-based diet including a variety of fruits, vegetables, whole grains and low-fat dairy products. Strategies promoted to achieve calorie and fat goals included portion control; advice for low-energy, nutrient-dense snacks, healthy food preparation techniques and careful selection of restaurants. **Timing of active intervention:** a:none; b: 3 months; c: 3 months **Number of times contacted:** a: 7 ; b: 34; c: 38 **Number allocated:** Men: a:44 ; b: 41; c: 44 , Women: a: 37 ; b: 38; c: 37		

		Number completed: a: 66; b: 64; c: 64 **% dropout:** a: 18.5% ; b: 19%; c: 21% **Number assessed:** Men: a:44 ; b: 41; c: 44 , Women: a: 37 ; b: 38; c: 37		
Richelsen 2007 [19]	**Location:** Nine clinical research centres, Scandinavia **Period of study:** NR **Inclusion criteria:** 18-65 years; abdominal obesity BMI 30-45 and waist circumference ≥102 cm (men) ≥92cm (women); and one or more of the following risk factors: impaired fasting glucose (plasma glucose ≥6.1 mmol/L), diet-treated type 2 diabetes (plasma glucose ≥7.0 mmol/L) or dyslipidemia (HDL cholesterol ≤0.9 mmol/L [men]; ≤1.1 mmol/L [women] and/or serum triglycerides between ≥2.0mmol/L and ≤10.0mmol/L); 5% weight loss achieved during 8 week VLED pre-randomisation **Exclusion criteria:** During the randomised phase, participants with deterioration in glucose control were prescribed metformin. If metformin failed to keep A1C level <10% the participant was withdrawn. **Age, years:** Mean, range, Men+Women a: 46.7, 19-63; b: 47.2, 20-64 **Weight, kg:** Mean: Men+Women a: 97.5; b: 95.7 **BMI:** (Pre-randomisation) Mean, range, Men+Women a: 37.6 (30.0-45.0); b: 37.4 (30.1-45.2) **Baseline comparability:** Yes	**Details of interventions** Pre-randomisation all participants prescribed VLCD (Modifast or Nutrilett) of 600-800 kcal/day for 8 weeks. Those achieving 5% weight loss were randomised as follows: **a. Individual or group:** Individual **Description:** Placebo **b. Individual or group:** Individual **Description:** Orlistat 120mg 3 times daily Both groups instructed to following a standard energy restricted diet consisting of a 600 k/cal per day deficit and advised to reduce fat intake to approx 30% of total energy, especially saturated fat, and increase fruit and vegetable intake. Participants also advised to increase daily physical activity. **Timing of active intervention:** a+b: 36 months **Number of times contacted:** a+b 24 **Number allocated:** Men a: 76; b: 76; Women a: 80; b: 77 **Number completed:** Men+Women a: 98; b: 102	**Length of follow-up:** 36 months **Outcomes by sex:** weight	Sponsored by Roche

		% dropout: Men+Women a: 37.2%; b: 33.3% **Number assessed:** NR		
Ross 2012 [20]	**Location:** Three primary health care clinics, Ontario, Canada **Period of study:** December 2004 – January 2008 **Inclusion criteria:** 25-75years; sedentary (≤ one physical activity per week); BMI 27-39.9; abdominally obese (waist circumference ≥102cm for men and ≥ 88cm for women); weight stable to within 2kg in last 6 months **Exclusion criteria:** Serious medical conditions preventing increased daily activity, including significant cardiovascular disease, planning for pregnancy in next two years or pregnant **Age, years:** Mean (SD): Men, a: 55.7 (11.5); b: 53.2 (10.7); Women, a: 50.9 (11.7): 50.5 (11.1) **Weight, kg:** Mean (SD): Men, a: 98.2 (13.5); b: 101.4 (13.2); Women, a: 85.3 (12.5); b: 86.9 (12.1) **BMI:** Mean (SD): Men, a32.0 (4.0); b: 32.4 (3.7); Women, a: 32.0 (4.3); b: 32.7 (4.3) **Baseline comparability:** yes	**Details of interventions** **a. Individual or group:** Individual **Description:** Usual care: GP gave advice regarding lifestyle strategies for obesity reduction. GPs followed their usual appointment schedule and counselling approach. **b. Individual or group:** Individual **Description:** Behavioural intervention: Motivational interviewing and individual stage-based tailored counselling based on transtheoretical model and social cognitive theory. Counselling sessions were provided by health educators who were educated to degree level in kinesiology and had received behavioural counselling training from a clinical psychologist prior to the start of the trial. During months 0-6, participants were given knowledge and skills to increase physical activity and consume a healthy diet through 15 one-to-one information sessions. During months 7-12, participants attended 6 sessions where they were encouraged to maintain healthy eating patterns and 45-60 minutes of physical activity daily. During months 13-24, participants attended 12 sessions but duration of each was determined by the participant's waist circumference and physical activity level. **Timing of active intervention:** 2 years **Number of times contacted**: a: ≥5; b: 38	**Length of follow-up:** 2 years **Outcomes by sex:** Weight, BMI, waist circumference, LDL and HDL cholesterol, triglycerides, systolic and diastolic blood pressure, fasting plasma glucose, adverse events	

		Number allocated: Men, a:72; b: 74; Women, a 169; b: 175 **Number completed:** Men, a+b: 121 ; Women, a+b: 275 **% dropout:** Men, a+b: 17.1% ; Women, a+b: 20.0% **Number assessed:** Men, a:72; b: 74; Women, a169; b: 175		
Shai 2008 [21]	**Location:** Workplace (one research medical clinic) Israel **Period of study:** July 2005 to June 2007 **Inclusion criteria:** Age 40-65 years; BMI $\geq$ 27 or presence of type 2 diabetes or coronary heart disease regardless of age or BMI **Exclusion criteria:** Pregnant or lactating women; serum creatinine $\geq$ 2mg/dl; liver dysfunction; gastrointestinal problems preventing patients from following the trial diets; active cancer or participation in another diet trial **Age, years:** Mean (SD): Men + Women a: 51.0 (7.0); b: 53.0 (6.0); c: 52.0 (7.0) **Weight, kg:** Mean (SD): Men a: 92.9 (11.9); b: 91.5 (13.6); c: 93.2 (14.0); Women a: 81.7 (10.6); b: 89.4 (13.6); c: 77.9 (9.0) **BMI:** Mean (SD): Men + Women a: 30.6 (3.2); b: 31.2 (4.1); c: 30.8 (3.5) **Baseline comparability:** Yes	**Details of interventions** **a. Individual or group:** Group **Description:** Low-fat, restricted calorie diet: 1500 kcal per day for women and 1800 kcal/day for men with 30% of calories obtained from fat, 10% from saturated fat and an intake of 300mg cholesterol per day. Participants were counselled to consume low fat grains, vegetables, fruit and legumes and to limit additional fats, sweets and high fat snacks. Based on American Heart Association guidelines [22] **b. Individual or group:** Group **Description:** Mediterranean, restricted calorie diet: 1500 kcal/day for women and 1800 kcal per day for men with a goal of no more than 35% of calories obtained from fat. Main sources of fat were 30-45g olive oil and <20g nuts per day. Participants were counselled to consume a diet rich in vegetables and low in red meat. Based on recommendations of Willett and Skerrett [23]. **c. Individual or group:** Group **Description:** Low carbohydrate, non-restricted calorie diet: Aimed to provide 20g	**Length of follow-up:** 2 years **Outcomes by sex:** weight loss	Data for wives of trial participants published separately - DIRECT spousal study Golan 2010 [25]

		carbohydrates per day for a 2-month induction phase and immediately after religious holidays with a gradual increase to a maximum of 120g per day to maintain weight loss. Total calorie, protein and fat intakes were not limited but participants were counselled to choose vegetarian sources of fat and protein to avoid trans fat. Based on the Atkins diet [24]. Each diet group was assigned a registered dietician who led all 6 subgroups of that group. There were 18 group meetings in total lasting 90 minutes each. Another dietician conducted 10-15 minute telephone calls 6 times over the two year trial period with participants experiencing adherence difficulties. A summary of each call was given to the group dietician. A sample of 74 wives of husbands in each group attended support meetings for the first 6 months (assignment not randomised). **Timing of active intervention:** 2 years **Number of times contacted:** a-c: 48 **Number allocated:** Men a: 89; b: 89; c: 99; Women a: 15; b: 20; c: 10 **Number completed:** Men + Women a: 94; b: 93; c: 85 **% dropout:** Men + Women a: 9.6%; b: 14.7%; c: 22% **Number assessed:** Men a: 89; b: 89; c: 99; Women a: 15; b: 20; c: 10		
Golan 2010 [25]	74 wives of DIRECT husbands (who were not part of the trial) were followed up for two years.	Interventions as above. Every two months during the first six months of DIRECT,	**Length of follow-up:** 2 years	Ancillary spouse study

(Linked to Shai 2008 [21])	**Age, years:** Mean (SD): Wives; a: 50.5 (6.0); b: 52.0 (5.57); c: 49.4 (6.97) **Weight, kg:** Mean (SD): Wives; a:67.8 (10.51); b: 73.1 (15.92); c: 73.18 (14.07) **BMI:** Mean (SD): Wives; a: 24.9 (3.69); b: 27.81 (4.98); c: 27.79 (5.14) **Baseline comparability:** Yes	participating wives were invited to a 90 minute support group meeting specific to the relevant dietary arm for their husband. The weight of the 74 husbands was compared with the weight of the 248 DIRECT men whose wives did not take part in the group sessions.	**Outcomes by sex:** Weight loss	
Vanninen 1992 [26] Vanninen 1993 [27]	**Location:** one outpatient clinic and five community health centres, Finland **Period of study:** 1987 to 1989 **Inclusion criteria:** 40-64 years; repeated fasting venous blood glucose >6.7 mmol/l **Exclusion criteria:** Chronic disease affecting glucose tolerance; unwilling to participate **Age, years:** Mean (SD): Men A+B: 53 (7); Women A+B: 5 (6) **Weight, kg:** Mean (SD): Men 95 (12); Women 88 (16) **BMI:** Mean (SD): Men a: 30.1 (3.1); b: 31.1 (3.7)Women a: 34.2 (6.2); b: 33.4 (6.7) **Baseline comparability:** Women had higher mean BMI than men. Women in the conventional care group had higher HbA1c and fasting plasma glucose levels compared with women in the intensified diet and exercise group following the pre-treatment phase (baseline).	**Details of interventions** Both groups underwent a three month basic education programme giving diet and exercise advice and information pre-randomisation. **a. Individual or group:** Individual **Description:** Conventional care: no further educational materials given. Attended community health centre at intervals of 2-3 months and the outpatient clinic at 6 and 12 months. No access to a dietician. **b Individual or group:** Individual **Description:** Intensified diet and exercise education: Attended Diabetes specialist led outpatient clinics 6 times every 2 months. A physician gave printed and oral instruction and gave general motivation and follow up; a dietician gave intensified diet education and a nurse was responsible for further patient education and metabolic control follow up. Goals of dietary education were weight reduction, normoglycaemia, correction of dyslipidaemias, individually planned energy restriction, restricted total fat intake (especially saturated) and dietary cholesterol, moderate increment of unsaturated fats and foods containing complex carbohydrates, and to	**Length of follow-up:** 12 months **Outcomes by sex:** BMI, total & HDL cholesterol, triglycerides, HbA1c, fasting plasma glucose	All participants non-insulin dependent type 2 diabetes mellitus at baseline

		encourage regular eating patterns and moderate consumption. Participants also encouraged to increase physical activity to 30-60 minute sessions 3-4 times per week, with a recommended average heart rate of 110-140 beats per minute. Types of exercise recommended included walking, jogging, cycling, swimming or cross-country skiing. Activity monitored by daily exercise records. No written exercise instruction or supervision given. **Timing of active intervention:** 12 months **Number of times contacted:** a: 7-9; b: 7 **Number allocated:** Men+Women, a+b: 90 **Number completed:** Men A: 24; B: 21; Women a: 16; b: 17 **% dropout:** Men+Women, a+b: 13.3% **Number assessed:** Men a: 24; b: 21; Women a: 16; b: 17		
Volpe 2008 [28]	**Location:** One university research centre, Pennsylvania, USA **Period of study:** NR **Inclusion criteria:** 24-62 years; sedentary (exercising no more than one day per week); non-smoker; BMI 27-35; no acute illness or trauma within previous 6 months; no history of cardiovascular disease, hypertension, hyper/hypothyroidism or any other type of chronic disease **Exclusion criteria:** Participation in any weight reduction programme within previous 3 months; taking supplements for weight reduction (e.g. physician prescribed or over the counter medication) within previous 3 months **Age, years:** Unclear if data reported for women	**Details of interventions** All participants underwent 1-2 week pre-randomisation phase where participants were habituated to the NordicTrack™ indoor skiing apparatus, fitness levels were measured using the NordicTrack™ home fitness test and baseline measurements were taken. **a Individual or group:** Group **Description:** Diet: Participants attended intensive nutrition classes advising on adhering to a low energy, heart healthy diet with a goal of losing 0.5-1.0kg body weight per week. After 7 months classes were replaced by monthly telephone/email messages up to month	**Length of follow-up:** 12 months **Outcomes by sex:** Weight, waist circumference, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, systolic & diastolic BP	NordicTrack™ sponsored the study. The authors declare no conflict of interest.

	only **Weight, kg:** Unclear if data reported for women only **BMI:** Unclear if data reported for women only **Baseline comparability:** Unclear	9 to check dietary adherence. **b Individual or group:** Group **Description:** Exercise: Exercise sessions supervised by trained graduate/undergraduate students 3 days per week for 6 weeks, increasing to 5 times per week for months 4-6. At 7 months participants were given exercise equipment to continue unsupervised exercise in their own homes. Classes were replaced by monthly telephone/email messages up to month 9 to check exercise adherence. **c. Individual or group:** Group **Description:** Diet + Exercise: As a and b. **Timing of active intervention:** 9 months **Number of times contacted:** a: 19; b: 83; c: 83 **Number allocated:** Men a-c: 44; Women a: 15; b: 17; c: 14 **Number completed:** NR **% dropout:** NR **Number assessed:** Men a-c: 44; Women a: 15; b: 17; c: 14		
Wadden 2011 [29] Look AHEAD	**Location:** 16 health centres, USA **Period of study:** NR **Inclusion criteria:** 45-74 years, changed to 55-74 later and reported as 76 later also; BMI ≥25 (≥27 if currently taking insulin); Type 2 diabetes mellitus (determined by self-report with verification); able to complete 12/14 daily diet and exercise records during 2 week self-monitoring phase **Exclusion criteria:** ≥ 75 years; HbA1c >11%; BP ≥ 160/100; fasting triglycerides ≥600mg/dL;	**Details of interventions** All participants required to complete daily diet and exercise records during 2-week self-monitoring phase prior to randomisation. All subsequent eligible participants received an initial 1 hour diabetes education session including general recommendations for healthy eating, physical activity and diabetes care. Smokers encouraged to quit but did not receive formal smoking cessation counselling.	**Length of follow-up: 4 years** (year 1 weight reduction, years 2-4 weight maintenance) **Outcomes by sex:** Weight	Look AHEAD study – outcomes reported by sex for ILI group only

	Inadequate control of comorbid conditions; factors limiting adherence/conduct of trial; underlying disease likely to limit lifespan and/or affect safety of interventions; type 1 diabetes **Age, years:** Mean (SD) Men+Women: a: 58.9 (6.9); b: 58.6 (6.8) **Weight, kg:** Mean (SD): Men, a: 109.0 (18.0); b: 108.9 (19.0); Women, a: 95.4 (17.3); b: 94.8 (17.9) **BMI:** Mean (SD): Men, a: 35.1 (5.2); b: 35.3 (5.7); Women, a: 36.6 (6.0); b: 36.3 (6.2) **Baseline comparability:** Yes	**a. Individual or group:** Group **Description:** Diabetes support and education (DSE): Participants attended 3 group education/social support sessions per year. One session covered diet/nutrition, one exercise, one social support. Support sessions allowed participants to discuss issues related to living with diabetes. Attendance at sessions encouraged but not required. **b. Individual or group:** Group **Description:** Intensive lifestyle intervention (ILI): Group lifestyle meetings held for the first 3 weeks of each month with one individual meeting with interventionists (registered dieticians, psychologists and exercise specialists) in the 4th week. Group meetings replaced by individual lifestyle counselling in year 2. Individuals encouraged to lose $\geq$10% of their initial body weight by 6 months. Participants not meeting this goal or who regained weight were offered Orlistat. Each centre had a goal of inducing a minimum mean loss of 7% of initial body weight. Centres achieving <5% loss given extra assistance to improve weight loss outcome. Participants followed a portion controlled diet with calories goals of 1200-1800 kcal/day depending on initial body weight for the first year. Participants consumed meal replacements and structured meal plans for the first 4 months, followed by one meal and one snack replacement in the form of liquid shakes and meal bars for months 5-12. Participants also		

		given an exercise goal of ≥175 minutes per week unsupervised activity by 6 months. Taught behavioural techniques included problem solving, motivational interviewing, self-regulation theory and relapse prevention. **Timing of active intervention:** 4 years **Number of times contacted:** a: 16; b: 199 **Number allocated:** Men a: 1038; b: 1044; Women a: 1537; b: 1526 **Number completed:** ongoing **% dropout:** ongoing **Number assessed:** Men a: 1038; b: 1044; Women a: 1537; b: 1526		
Wadden 2014 [30] (8-year Look AHEAD follow-up)	**Location:** As above **Period of study:** NR **Inclusion criteria:** As above **Exclusion criteria:** As above **Age, years:** As above **Weight, kg:** As above **BMI:** As above **Baseline comparability:** Yes	**Details of interventions** As Look Ahead post-randomisation for first year. a. DSE: For the first 4 years, participants were provided with three 1-hour group meetings per year that discussed diet, physical activity and social support respectively. Years 5-8 provided one yearly session. Participants who desired more help with weight loss were referred to their primary care provider, who was free to recommend whatever intervention was considered appropriate. b. ILI: In years 2-8, the intervention focused principally on maintaining the weight losses and duration of physical activity achieved during the first year, as well as helping unsuccessful individuals achieve study goals. Lifestyle counselling was provided in individual monthly on-site meetings. Further email or telephone contact from a second	**Length of follow-up:** 8 years **Outcomes by sex:** Weight	

		individual approximately 2 weeks later was provided until year 5. Participants had individualized calorie goals based on desire to maintain weight loss, lose more weight if BM >23, or reverse weight gain. All were encourage to continue to replace one meal or snack per day using free meal replacements, to exercise ≥200 minutes per week and to monitor weight at least weekly. All sites offered monthly group meetings where members weighed-in, reviewed diet and activity records and participated in a lifestyle modification session. Sites also offered at least one yearly refresher group, typically lasting 6-8 weeks. **Timing of active intervention:** 1 year **Number of times contacted:** a: at least 189; b: 24 **Number allocated:** Men a: 1038; b: 1044; Women a:1537; b: 1526 **Number completed:** Men+Women a: 2275; b: 2310 **% dropout:** Men+Women a: 11.7%; b: 10.1% **Number assessed:** Men a: 1038; b: 1044; Women a:1537; b: 1526		
Gorin 2008 [31] (Linked to Look AHEAD)	**Location:** 3/16 Look Ahead centres **Period of study:** NR **Inclusion criteria:** Untreated spouse of Look Ahead participants, willing to participate **Exclusion criteria:** None **Age, years:** Mean (SD), Men+Women a: 59.8 (9.0); b: 58.6 (7.5) **Weight, kg:** Mean (SD): Men, a: 93.04 (19.03); b: 95.94 (16.76); Women, a: 76.97 (14.96); b:	**Details of interventions** As Look Ahead post-randomisation a. DSE b. ILI **Timing of active intervention:** 1 year **Number of times contacted:** a+b: 2 **Number allocated:** Men a: 85; b: 69; Women	**Length of follow-up:** 1 year **Outcomes by sex:** Weight	Look Ahead ancillary spouse study

	81.52 (18.98) **BMI:** Mean (SD) Men+Women a: 30.1 (6.0) b: 31.0 (6.2) **Baseline comparability:** Yes	a:103; b: 100 **Number completed:** NR **% dropout:** NR **Number assessed:** Men a: 85; b: 69; Women a:103; b: 100		
Schwartz 2012 [32] Look AHEAD	**Location:** 5/16 Look Ahead Centres, USA **Period of study:** NR **Inclusion criteria:** Participating in Look Ahead at the PBRC **Exclusion criteria:** see Look Ahead **Age, years:** Mean (SD), Men a: 60.0 (6.4); b: 60.4 (6.5); Women a: 57.8 (6.5); b: 57.0 (6.6) **Weight, kg:** Mean (SD), Men, a: 104.9 (14.3); b: 102.9 (15.3); Women a: 93.5 (16.0); b: 92.1 (16.7) **BMI:** Mean (SD), a: Men 34.0 (4.3); b: Men 33.9 (4.6); a:Women 36.3 (5.5); b: Women 35.8 (5.7) **Baseline comparability:** Women had higher BMI than men	**Details of interventions** As Look Ahead post-randomisation a. DSE b. ILI **Timing of active intervention:** 1 year **Number of times contacted:** a+b: 2 **Number allocated:** Men a: 246; b: 237; Women a:386; b: 405 **Number completed:** NR **% dropout:** NR **Number assessed:** Men a: 246; b: 237; Women a:386; b: 405	**Length of follow-up:** 1 year **Outcomes by sex:** weight, bone loss	Look Ahead ancillary bone mineral density study
Stewart 2011 [33] Look AHEAD	**Location:** 1/16 Look Ahead Centres - Pennington Biomedical Research Centre (PBRC), USA **Period of study:** NR **Inclusion criteria:** Participating in Look Ahead at the PBRC **Exclusion criteria:** see Look Ahead **Age, years:** Mean (SD), Men a:61.9 (5.2); b: Men 61.4 (5.8); a:Women 59.0 (6.1); b:Women 59.4 (6.9) **Weight, kg:** Mean, Men a: 105.1; b: 108.0; Women a: 96.5; b: 96.4 **BMI:** Mean (SD), Men a: 33.1 (4.4); b: Men 33.9 (5.1); a: Women 36.4 (5.3); b:Women 36.4 (5.6) **Baseline comparability:** Women had higher BMI than men	**Details of interventions** As Look Ahead post-randomisation a. DSE b. ILI **Timing of active intervention:** 1 year **Number of times contacted:** a+b: 2 **Number allocated:** Men a: 33; b: 36; Women a:43; b: 45 **Number completed:** Men+Women a: 70; b: 70 **% dropout:** Men+Women a:7.89%; b:13.58% **Number assessed:** Men a: 33; b: 36; Women a:43; b: 45	**Length of follow-up:** 1 year **Outcomes by sex:** Weight	Look Ahead ancillary body image study

<table>
<tr>
<td>Wing 2010 [34]
Look AHEAD</td>
<td>Location: 5/16 Look Ahead centres
Period of study: NR
Inclusion criteria: Male Look Ahead participants who reported being sexually active in the previous 6 months
Exclusion criteria: As Look Ahead
Age, years: mean (SD) a: 60.3 (6.6); b: 60.7 (6.5)
Weight, kg: mean (SD), a: 109.2 (17.7); b: 110.6 (18.4)
BMI: mean (SD) a: 35.1 (5.2); b: 35.6 (5.5)
Baseline comparability: Yes</td>
<td>Details of interventions

As Look Ahead
a: DSE
b: ILI

Timing of active intervention: 1 year
Number of times contacted: As Look Ahead but with 2 additional assessments at baseline and 1 year
Number allocated: a: 185; b: 187
Number completed: a: 153; b: 153
% dropout: a: 17.3; b: 18.2
Number assessed: a: 153; b: 153</td>
<td>Length of follow-up: 1 year
Outcomes by sex: (all male pts) weight loss, total cholesterol, LDL & HDL cholesterol, systolic & diastolic BP, HbA1c change, erectile function</td>
<td>Sub-group of Look Ahead study (erectile function)</td>
</tr>
<tr>
<td>West 2008 [35]</td>
<td>Location: 27 diabetes outpatient clinics, USA
Period of study: NR
Inclusion criteria: ≥ 25 years; BMI ≥24; Fasting plasma glucose concentration 5.3-6.9mmol/l ; plasma glucose concentration 12 hours post oral glucose test 7.8-11.0mmol/l
Exclusion criteria: Taking medications known to alter glucose tolerance or had significant illness that could reduce life expectancy or trial participation
Age: n/%

<table>
<tr><td>Years</td><td>White Men</td><td>Black Men</td><td>Hispanic Men</td></tr>
<tr><td><40</td><td>a:20/10.9
b:19/9.6</td><td>a:6/10.5
b:10/17.2</td><td>a:2/3.5
b:6/12.0</td></tr>
<tr><td>40-49</td><td>a:43/23.4
b:44/22.1</td><td>a:18/31.6
b:20/34.5</td><td>a:21/36.8
b:10/20.0</td></tr>
<tr><td>50-59</td><td>a:55/29.9
b:54/27.1</td><td>a:19/33.3
b:19/32.8</td><td>a:23/40.4
b:19/38.0</td></tr>
<tr><td>60+</td><td>a:66/35.9</td><td>a:14/24.6</td><td>a:11/19.3</td></tr>
</table>
</td>
<td>Details of interventions

a. Individual or group: Individual
Description: Standard lifestyle + placebo: Placebo tablet given once daily and increased to twice daily after 1 month. Lifestyle recommendations given in written form with annual 20-30 minute sessions with individual participants emphasizing a healthy lifestyle, food pyramid, National Cholesterol Education Programme step 1 diet, to lose 5-10% of body weight, through diet and exercise, with eventual goal of 30min of an activity such as walking 5 days per week, avoid excessive alcohol.

b Individual or group: Both
Description: Intensive Lifestyle: 16 sessions over 24 weeks with individual participants focusing on dietary changes to promote weight loss of at least 7% of initial body weight with</td>
<td>Length of follow-up: 30 months
Outcomes by sex: Weight loss</td>
<td>Main DPP trial included standard lifestyle + metformin 850mg twice daily treatment arm
Methods detailed in other publications [36,37].</td>
</tr>
</table>

	b:82/41.2	b:9/15.5	b:15/30.0

Years	White Women	Black Women	Hispanic Women
<40	a:51/12.7 b:65/17.1	a:26/23.4 b:27/22.5	a:33/20.3 b:32/20.8
40-49	a:163/40.6 b:138/36.2	a:48/43.2 b:47/39.2	a:61/37.4 b:66/42.9
50-59	a:113/28.1 b:107/28.1	a:29/26.1 b:29/24.2	a:52/31.9 b:30/19.5
60+	a:75/18.7 b:71/18.6	a:8/7.2 b:17/14.2	a:17/10.4 b:26/16.9

Weight, kg: mean, sd

White Men	Black Men	Hispanic Men
a:102.8, 18.9 b: 100.5, 20.1	a: 93.0, 18.5 b: 95.7, 17.9	a: 100.5, 17.8 b: 104.4, 22.1
White Women	Black Women	Hispanic Women
a:93.7, 20.3 b: 95.1, 21.2	a: 85.2, 19.1 b: 82.0, 14.8	a: 98.9, 20.2 b: 97.1, 20.8

BMI: n/%

	White Men	Black Men	Hispanic Men
<30	a:73/39.7 b:92/46.2	a:23/40.4 b:25/43.1	a:20/35.1 b:15/30.0
30-34.99	a:60/32.6 b:63/31.7	a:21/36.8 b:17/29.3	a:20/35.1 b:21/42.0
35+	a:51/27.7 b:44/22.1	a:13/22.8 b:16/27.6	a:17/29.8 b:14/28.0

low calorie, low fat diet and increasing physical activity to achieve 150 minutes per week moderate exercise (e.g. walking & bicycling). Sessions included topics and lessons covering lifestyle change, self-monitoring, goal setting, stimulus control, nutrition, environmental change and problem solving/coping strategies. A tool box approach was used to add new strategies to help achieve goals. Group sessions available after initial 16 sessions completed. Optional short courses lasting 4-6 weeks offered after 6 months covering nutrition, exercise and behavioural topics. Also three or four motivational campaigns per year.
Timing of active intervention: a: one session at baseline, repeated annually; b: at least 16 individual sessions over 24 weeks. Two supervised group exercise sessions offered each week. Group courses offered quarterly lasting 4-6 weeks to help with weight loss and exercise goals. Also seen usually individually once every two months for remainder of trial, and contacted by phone at least once between visits.
Number of times contacted: a: 3; b: 30
Number allocated: n/%

White Men	Black Men	Hispanic Men
a:184/18.9 b:199/20.7	a:57/5.9 b:58/6.0	a:57/5.9 b:50/5.2
White Women	Black Women	Hispanic Women
a:402/41.3 b:381/39.6	a:111/11.4 b:120/12.5	a:163/16.7 b:154/16.0

<table>
<tr>
<td></td>
<td>
<table>
<tr><th></th><th>White Women</th><th>Black Women</th><th>Hispanic Women</th></tr>
<tr><td><30</td><td>a:111/27.6
b:100/26.3</td><td>a:32/28.8
b:32/26.7</td><td>a:32/19.6
b:37/24.0</td></tr>
<tr><td>30-34.99</td><td>a:104/25.9
b:101/26.5</td><td>a:39/35.1
b:50/41.7</td><td>a:35/21.5
b:46/29.9</td></tr>
<tr><td>35+</td><td>a:187/46.5
b:180/47.2</td><td>a:40/36.0
b:38/31.7</td><td>a:96/58.9
b:71/46.1</td></tr>
</table>
Baseline comparability: Higher proportion of obese participants were female and black. Higher proportion white participants.
</td>
<td>
Number completed: (at 30 months) n/%
<table>
<tr><td>White Men</td><td>Black Men</td><td>Hispanic Men</td></tr>
<tr><td>a:124/13.2
b:135/14.4</td><td>a:44/4.7
b:41/4.4</td><td>a:39/4.2
b:31/3.3</td></tr>
<tr><td>White Women</td><td>Black Women</td><td>Hispanic Women</td></tr>
<tr><td>a:269/13.6
b:261/13.2</td><td>a:76/3.8
b:77/3.9</td><td>a:104/5.3
b:102/5.2</td></tr>
</table>
% dropout:
<table>
<tr><td>White Men</td><td>Black Men</td><td>Hispanic Men</td></tr>
<tr><td>a:32.6
b:32.2</td><td>a:22.8
b:29.3</td><td>a:31.6
b:38.0</td></tr>
<tr><td>White Women</td><td>Black Women</td><td>Hispanic Women</td></tr>
<tr><td>a:33.1
b:31.5</td><td>a:31.5
b:35.8</td><td>a:36.2
b:33.8</td></tr>
</table>
Number assessed:
<table>
<tr><td>White Men</td><td>Black Men</td><td>Hispanic Men</td></tr>
<tr><td>a:124/13.2
b:135/14.4</td><td>a:44/4.7
b:41/4.4</td><td>a:39/4.2
b:31/3.3</td></tr>
<tr><td>White Women</td><td>Black Women</td><td>Hispanic Women</td></tr>
<tr><td>a:269/13.6
b:261/13.2</td><td>a:76/3.8
b:77/3.9</td><td>a:104/5.3
b:102/5.2</td></tr>
</table>
</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wing 1991 [38]</td>
<td>Location: One University, USA
Period of study: NR
Inclusion criteria: 30-65 years; >20% over ideal body weight; type 2 diabetes, i.e. fasting glucose 140mg/dL or more, or 200mg d/L or more 2</td>
<td>Details of interventions

All participants received behavioural weight loss programme consisting of stimulus control, problem solving, assertion, goal setting and</td>
<td>Length of follow-up: 72 weeks
Outcomes by sex: Weight (participants only)</td>
<td>All type 2 diabetes, obese spouse</td>
</tr>
</table>

	hours after oral glucose load; spouses 15% or more above IBW and 30-70 years; $150 deposit per couple, could be earned back in full **Exclusion criteria:** NR **Age, years:** Mean (SD), Men+Women a: 51.2 (7.3) b: 53.6 (7.7) **BMI:** Mean (SD), Men+Women a: 36.64 (5.77);b: 35.68 (5.76) **Baseline comparability:** Yes	cognitive techniques; participants advised to monitor calorie intake to between 1200-1500 kcals/day with a reduction in fat intake and simple carbohydrates and increase in complex carbohydrates and fibre; stepwise goals for walking with final goal to expend 1000kcals/ week; deposit refunded according to weight loss and attendance **a.Individual or group:** Group **Description:** Alone: Participants attended the programme alone. Spouses were not permitted to attend but attended assessment sessions after 20-weeks and at 1 year follow up. Deposit refund contingent on participant's weight loss and participant/spouse attendance at assessments. **b. Individual or group:** Group **Description:** Together: spouse participated in all aspects of programme and no distinction made in treatment between participant and spouse, half of therapy sessions focused on social support and behavioural marital therapy literature, e.g. mutual positive reinforcement. Deposits by both patient and spouse contingent on participant and spouse weight loss and attendance at assessments. **Timing of active intervention:** 72 weeks **Number of times contacted:** a+b: 21 **Number allocated:** Men+Women, a: 25; b: 24 **Number completed:** Men a: 10; b: 8; Women a: 13; b: 12 **% dropout:** a+b Men+Women, 12.3%; a+b spouses, 13.3%		

		Number assessed: Men a: 10; b: 8; Women a: 13; b: 12		
Wing 1994 [39]	**Location:** University of Pittsburgh, Pennsylvania **Period of study:** Prior to November 1993 **Inclusion criteria:** Either sex, 30-70 years, >30% or >18 kg IBW (based on Metropolitan Life Insurance Tables), NIDDM (criteria according to National Diabetes Data Group) **Exclusion criteria:** health problems that would interfere with the use of VLCDs **Age, years:** Mean (SD): Men + Women 51.8 (9.6) **BMI:** Mean (SD): Men+ women 37.9 (6.3) **Baseline comparability:** Yes	**Details of interventions** **a. Individual or group:** Group **Description:** 1000-1200 kcal/day consisting of <30% energy intake from fat from baseline to week 50 **b. Individual or group:** Group **Description:** 500kcal/day either as liquid supplement (Optifast) or lean meat, fish or fowl for weeks 0-12 and weeks 24-36; other foods gradually reintroduced over following 4 weeks to consume 1000-1200kcal/d at weeks 13-23 and weeks 37-50 **a + b Individual or group:** Group **Description:** all participants kept self-monitoring records which were reviewed at weekly group meetings along with detailed discussion on nutrition which included focusing on reducing fat content and increasing intake of complex CHO and fibre; exercise which stressed walking or behavioural techniques which included stimulus control, goal setting and self-monitoring of intake and exercise, preplanning, relapse prevention and modifying cognitions; included role playing and individual discussion and questions; all participants encouraged to increase walking to 2 miles per day 5 days per week; all participants kept 3 day food diaries at baseline, 6 months and 12 months; all diabetes medications discontinued at start and algorithm	**Length of follow-up:** 2 years **Outcomes by sex:** weight change	Baseline weight by sex not reported. Denominator by sex not reported at 1 year follow up. Weight not reported by sex at 2 years.

		used to determine if and when to restart medication; all participants given vitamin/mineral supplements throughout study; all participants deposited $150 which was refunded in full for reaching behavioural goals and attending assessments at baseline, 6 months and 50 weeks; **Timing of active intervention:** a + b: 50 weeks plus follow-up at 1 year later **Number of times contacted:** a: 52; b: 78 **Number allocated:** Men: a: 18; b: 15; Women: a: 30; b: 30 **Number completed at 2 years:** Men+Women a: 38; b: 36 **% dropout:** Men+Women a: 20.8%; b: 20% **Number assessed at 1 year:** Men+Women a: 41; b: 38		

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Table S3 Risk of bias assessment for individual studies

	Evans 2012 [27]	Gorin 2012 [28]	Hakala 199 3[36]	Hakala 1994 [37]	Heitzman 198 7[23]	Karvetti 1992 [24]	Korhonen 1987 [38]	Lindstrom 2008 [39]	Jeffery 1984 [29]	Jeffery 2003 [30]	Jolly 2011 [44]	Lantz 2003 [43]	Ma 2013 [31]	Richelsen 2007 [42]	Ross 2012 [40]	Shai 2008 [41]	Vannine n 1992 [25]	Volpe 2008 [32]	Wadden 2011 [33]	West 2008 [34]	Wing 1991 [26]	Wing 1994 [35]
Sequence generation (selection bias)	?	?	?	?	×	?	?	✓	?	✓	✓	?	✓	✓	✓	?	?	?	?	?	?	?
Allocation concealment (selection bias)	?	?	?	?	✓	?	?	✓	?	✓	✓	?	✓	?	✓	?	?	?	?	?	?	?
Blinding of participants (performance bias)	×	×	×	×	×	×	×	×	×	×	×	×	×	✓	×	×	×	×	×	×	×	×
Blinding of health care providers (performance bias)	×	×	×	×	×	×	×	×	×	×	×	×	×	?	×	×	×	×	×	×	×	×
Blinding of outcome assessment (detection bias)	?	?	?	?	?	?	?	✓	?	?	✓	?	✓	?	?	✓	?	?	?	✓	?	?
Groups treated identically (performance bias)	?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	×	✓	×
Incomplete outcome data (attrition bias)	✓	?	×	×	?	×	✓	✓	?	?	✓	?	✓	?	✓	✓	?	?	✓	×	✓	?
Intention to treat (attrition bias)	✓	✓	×	×	?	×	×	✓	?	✓	✓	×	✓	×	✓	✓	×	?	✓	×	×	×
Selective reporting (reporting bias)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Other bias	×	?	✓	✓	✓	?	?	✓	?	✓	✓	?	✓	?	✓	?	✓	✓	✓	✓	?	✓

✓= low risk of bias, ×= high risk of bias, ? = unclear risk of bias

Table S4 Equity and sustainability assessment for individual studies

	Evans 2012 [27]	Gorin 2013 [28]	Hakala 1993 [36]	Hakala 1994 [37]	Heitzman 1987 [23]	Karvetti 1992 [24]	Korhonen 1987 [38]	Lindstrom 2008 [39]	Jeffery 1984 [29]	Jeffery 2003 [30]	Jolly 2011 [44]	Lantz 2003 [43]	Ma 2013 [31]	Richelsen 2007 [42]	Ross 2012 [40]	Shai 2008 [41]	Vanninen 1992 [25]	Volpe 2008 [32]	Wadden 2011 [33]	West 2008 [34]	Wing 1991 [26]	Wing 1994 [35]
Equity pointer:	?	×	×	×	×	×	×	×	✓	✓	×	×	✓	×	×	✓	×	×	×	×	✓	×
Representativeness of sample:	✓	×	?	?	✓	×	✓	✓	×	✓	✓	✓	✓	?	✓	✓	✓	×	✓	✓	✓	✓
Sociodemographic differences between withdrawals and exclusions?	×	✓	×	×	×	×	×	×	×	×	×	×	?	×	×	×	×	×	×	×	×	×
PROGRESS categories reported at baseline	✓	✓	×	×	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Did the intervention include strategies to address diversity/disadvantage?	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	✓	?	×	×
Was there a fidelity check?	×	×	×	×	×	×	×	×	×	×	✓	×	?	×	×	×	×	×	✓	×	×	×
Were process measures taken?	×	×	×	×	×	✓	×	×	×	×	✓	×	×	×	×	×	×	×	×	×	×	×
Details of intervention providers given	?	✓	✓	✓	?	✓	✓	✓	×	✓	✓	✓	?	✓	✓	✓	✓	✓	✓	✓	?	✓
Sustainability of the intervention discussed?	×	×	×	×	×	×	×	×	×	×	✓	×	×	×	×	×	×	×	×	×	×	×
Authors described any political/organisational context?	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×
Were any partnerships referred?	×	×	×	×	×	×	×	×	×	×	✓	×	×	×	×	×	×	×	×	×	×	×
Was there potential for author conflict	✓	×	?	×	×	?	×	×	×	×	×	?	×	?	?	×	×	×	×	×	×	×
Harms/unintended effects of the intervention described?	×	×	×	×	×	×	×	×	×	×	✓	×	✓	✓	✓	×	×	×	×	×	×	×

✓= yes, ×= no,? = unclear/not reported

Figure S1 Flow chart of the number of potentially relevant reports of identified studies and the number subsequently included and excluded from the review