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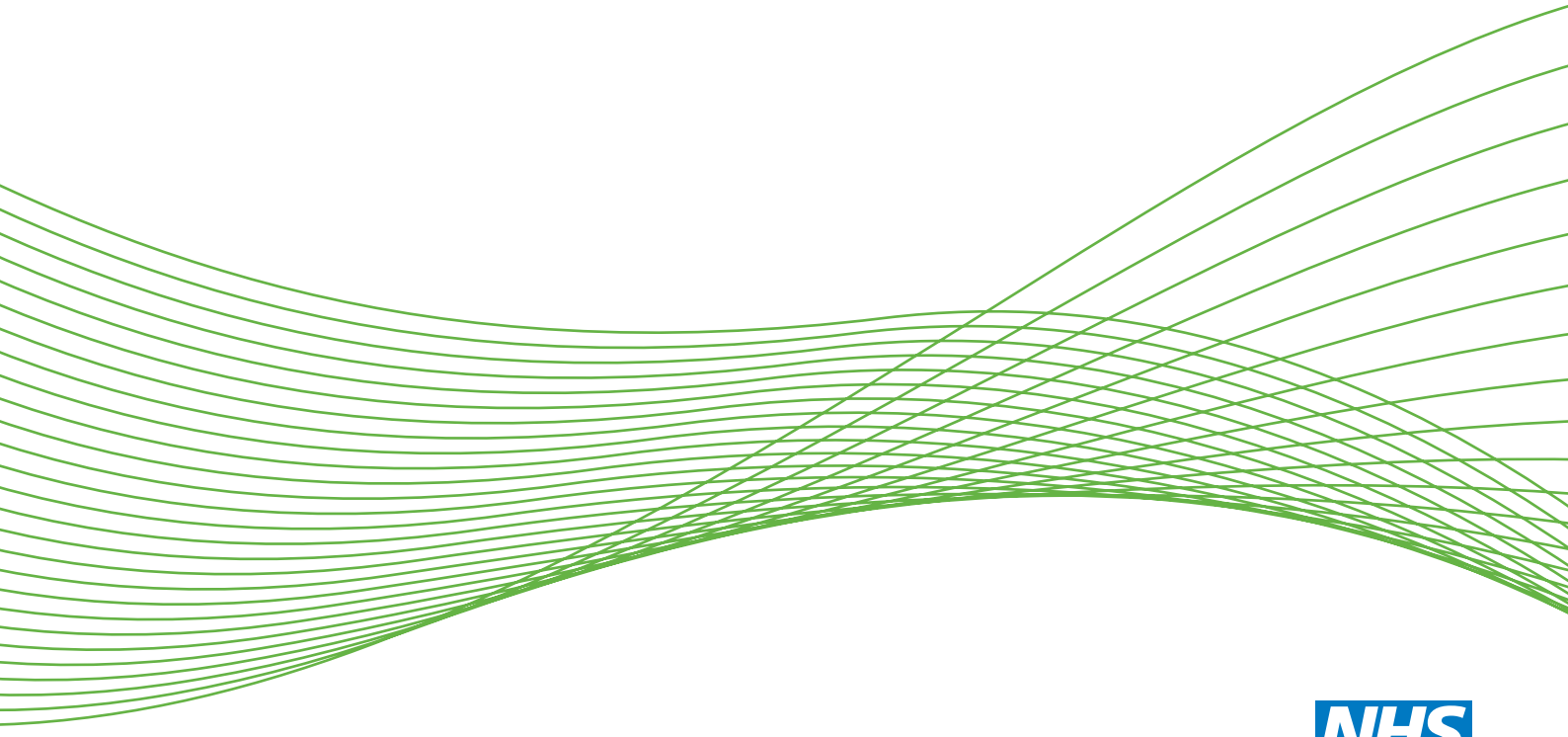

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Abstract

Systematic reviews of and integrated report on the quantitative, qualitative and economic evidence base for the management of obesity in men

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Background: Obesity increases the risk of many serious illnesses such as coronary heart disease, type 2 diabetes and osteoarthritis. More men than women are overweight or obese in the UK but men are less likely to perceive their weight as a problem and less likely to engage with weight-loss services.

Objective: The aim of this study was to systematically review evidence-based management strategies for treating obesity in men and investigate how to engage men in obesity services by integrating the quantitative, qualitative and health economic evidence base.

Data sources: Electronic databases including MEDLINE, EMBASE, PsycINFO, the Cochrane Central Register of Controlled Trials, the Database of Abstracts of Reviews of Effects and the NHS Economic Evaluation Database were searched from inception to January 2012, with a limited update search in July 2012. Subject-specific websites, reference lists and professional health-care and commercial organisations were also consulted.

Review methods: Six systematic reviews were conducted to consider the clinical effectiveness, cost-effectiveness and qualitative evidence on interventions for treating obesity in men, and men in contrast to women, and the effectiveness of interventions to engage men in their weight reduction. Randomised controlled trials (RCTs) with follow-up data of at least 1 year, or any study design and length of follow-up for UK studies, were included. Qualitative and mixed-method studies linked to RCTs and non-randomised intervention studies, and UK-based, men-only qualitative studies not linked to interventions were included. One reviewer extracted data from the included studies and a second reviewer checked data for omissions or inaccuracies. Two reviewers carried out quality assessment. We undertook meta-analysis of quantitative data and a realist approach to integrating the qualitative and quantitative evidence synthesis.

Results: From a total of 12,764 titles reviewed, 33 RCTs with 12 linked reports, 24 non-randomised reports, five economic evaluations with two linked reports, and 22 qualitative studies were included. Men were more likely than women to benefit if physical activity was part of a weight-loss programme. Reducing diets tended to produce more favourable weight loss than physical activity alone (mean weight change after 1 year from a reducing diet compared with an exercise programme –3.2 kg, 95% CI –4.8 kg to –1.6 kg). The type of reducing diet did not affect long-term weight loss. A reducing diet plus physical activity and behaviour change gave the most effective results. Low-fat reducing diets, some with meal replacements, combined with physical activity and behaviour change training gave the most effective long-term weight change in men [–5.2 kg (standard error 0.2 kg) after 4 years]. Such trials may prevent type 2 diabetes in men and improve erectile dysfunction. Although fewer men joined weight-loss programmes, once recruited they were less likely to drop out than women (difference 11%, 95% CI 8% to 14%). The perception of having a health problem (e.g. being defined as obese by a health professional), the impact of weight loss on health problems and desire to improve personal appearance without looking too thin were motivators for weight loss amongst men. The key components differ from those found for women, with men preferring more factual information on how to lose weight and more emphasis on physical activity programmes. Interventions delivered in social settings were preferred to those delivered in health-care settings. Group-based programmes showed benefits by facilitating support for men with similar health problems, and some individual tailoring of advice assisted weight loss in some studies. Generally, men preferred interventions that were individualised, fact-based and flexible, which used business-like language and which included simple to understand information. Preferences for men-only versus mixed-sex weight-loss group programmes were divided. In terms of context, programmes which were cited in a sporting context where participants have a strong sense of affiliation showed low drop out rates and high satisfaction. Although some men preferred weight-loss programmes delivered in an NHS context, the evidence comparing NHS and commercial programmes for men was unclear. The effect of family and friends on participants in weight-loss programmes was inconsistent in the evidence reviewed – benefits were shown in some cases, but the social role of food in maintaining relationships may also act as a barrier to weight loss. Evidence on the economics of managing obesity in men was limited and heterogeneous.

Limitations: The main limitations were the limited quantity and quality of the evidence base and narrow outcome reporting, particularly for men from disadvantaged and minority groups. Few of the studies were undertaken in the UK.

Conclusions: Weight reduction for men is best achieved and maintained with the combination of a reducing diet, physical activity advice or a physical activity programme, and behaviour change techniques. Tailoring interventions and settings for men may enhance effectiveness, though further research is needed to better understand the influence of context and content. Future studies should include cost-effectiveness analyses in the UK setting.

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Glossary

Glycated haemoglobin Glucose sticks to the haemoglobin in red blood cells to make a 'glycated haemoglobin' molecule called haemoglobin A_{1c} (HbA_{1c}). The higher the level of glucose in the blood long term, the higher the level of HbA_{1c}.

List of abbreviations

BMI	body mass index
CASP	Critical Appraisal Skills Programme
CEA Registry	Cost-Effectiveness Analysis Registry
CEAC	cost-effectiveness acceptability curve
CG	clinical guideline
CHF	Swiss francs
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
DIRECT	Dietary Intervention Randomized Controlled Trial
DPP	Diabetes Prevention Program
EMA	European Medicines Agency
FDPS	Finnish Diabetes Prevention Study
FFIT	Football Fans in Training
GP	general practitioner
HbA_{1c}	glycated haemoglobin
HDL	high-density lipoprotein
HMIC	Health Management Information Consortium
ICER	incremental cost-effectiveness ratio
IIEF-5	International Index of Erectile Function – 5
IQR	interquartile range
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
LDL	low-density lipoprotein
Look AHEAD	Action for Health in Diabetes
LYG	life-year gained
MHRA	Medicines and Healthcare products Regulatory Agency
NE	north-east (quadrant of the cost-effectiveness plane)
NHS EED	NHS Economic Evaluation Database
NICE	National Institute for Health and Care Excellence
NW	north-west (quadrant of the cost-effectiveness plane)
PROGRESS	place of residence, race/ethnicity, occupation, gender, religion, education, socioeconomic status or social capital
QALY	quality-adjusted life-year
RCT	randomised controlled trial
ReBIP	Review Body for Interventional Procedures
RePEc	Research Papers in Economics
RevMan	Review Manager
SD	standard deviation
SE	south-east (quadrant of the cost-effectiveness plane)
SF-12	Short Form questionnaire-12 items
SHED-IT	Self-Help, Exercise and Diet using Information Technology
SIGN	Scottish Intercollegiate Guidelines Network
SPL	Scottish Premier League
SW	south-west (quadrant of the cost-effectiveness plane)
TA	technology appraisal
TMH	Tackling Men's Health
UKPDS	UK Prospective Diabetes Study
VO_2 max.	maximal oxygen consumption
WMD	weighted mean difference
WTP	willingness to pay
XENDOS	XENical in the prevention of Diabetes in Obese Subjects

Scientific summary

Background

Obesity increases the risk of many serious illnesses such as coronary heart disease, type 2 diabetes and osteoarthritis. More men than women are overweight or obese in the UK and this difference is projected to continue. Men appear more likely than women to misperceive their weight, less likely to consider their body weight a risk for health and less likely to consider trying to manage their weight. Perceptions of dieting and weight-loss programmes as a feminised realm have been cited as a possible explanation for men's under-representation in weight-loss services. That men are under-represented suggests that methods to engage men in services, and the services themselves, are currently not optimal.

The aim of this study was to systematically review evidence-based management strategies for treating obesity in men and investigate how to engage men in these obesity services. The overarching objective was to integrate the quantitative, qualitative and health economic evidence base for the management of men with obesity and their engagement in weight-loss services, researching concurrently to systematically review:

- the clinical effectiveness and cost-effectiveness of interventions for obesity in men, and men in contrast to women
- the clinical effectiveness and cost-effectiveness of interventions to engage men in their weight reduction
- qualitative research with men about obesity management, and providers of such services for men.

Methods

We undertook six systematic reviews:

1. a systematic review of long-term randomised controlled trials (RCTs) of interventions with men only
2. a systematic review of long-term RCTs of interventions in which the results were presented separately for men and women
3. a systematic review of interventions for men, or for men and women compared, in the UK, including any setting, any study design and any duration
4. a systematic review of interventions to increase the engagement of men with services for obesity management, including any study design
5. a systematic review of economic evaluations of obesity interventions in which data were presented either for men only or for men compared with women
6. a systematic review of qualitative research with men with obesity, or with men compared with women, and with providers of services.

The reviews were integrated in a mixed-method synthesis.

Data sources

The following electronic databases were searched with no language restrictions from inception to January 2012 with an updated search of 15 databases carried out in July 2012: MEDLINE, MEDLINE-In-Process & Other Non-Indexed Citations, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Database of Systematic Reviews (CDSR), the Database of Abstracts of Reviews of Effects (DARE), the NHS Economic Evaluation Database (NHS EED), Health Technology Assessment (HTA), Applied Social Sciences Index and Abstracts (ASSIA), Education Resources Information Center (ERIC), Anthropology Plus, British Nursing Index,

Social Sciences Citation Index (SSCI), Health Management Information Consortium (HMIC), Conference Proceedings Citation Index – Social Science & Humanities (CPCI-SSH), Cost-Effectiveness Analysis Registry (CEA Registry), Research Papers in Economics (RePEc), ClinicalTrials.gov, CenterWatch, Current Controlled Trials and International Clinical Trials Registry. Subject-specific websites were also consulted and reference lists were searched. Additionally, we contacted professional health-care organisations and commercial organisations to identify published and unpublished UK studies.

Participants

Obese men with a body mass index (BMI) of ≥ 30 kg/m^2 (or overweight men with a BMI of ≥ 28 kg/m^2 with cardiac risk factors).

Study designs and interventions

Studies had to be carried out in societies relevant to the UK setting.

- Interventions explicitly promoting weight loss or weight maintenance as their main outcome. We considered lifestyle changes (e.g. diet, physical activity, behaviour change techniques or combinations of any of these) and orlistat for the management of obesity in men. Studies evaluating complementary therapy, over-the-counter non-diet products promoted for weight loss, or bariatric surgery, or examining a combination of interventions, for example smoking cessation and weight loss at the same time, were not included. We included RCTs with follow-up data of at least 1 year, but for UK studies any study design and length of follow-up were acceptable.
- Evaluations of interventions to increase the participation of men in any services aiming to reduce obesity, for example community outreach services, incentive schemes and web-based initiatives. Any study design was considered.
- Qualitative and mixed-method studies linked to RCTs and non-randomised intervention studies. UK-based, men-only qualitative studies not linked to interventions were also included.

Outcome measures

The primary aim of the evidence synthesis was to uncover how effective interventions work and to describe key intervention ingredients, processes and environmental and contextual factors that contribute to effectiveness. Outcome measures were weight, waist circumference, cardiovascular risk factors, disease-specific outcomes, adverse events, quality of life, process outcomes and economic costs.

We also aimed to identify the barriers and facilitators that men experience when engaging with a weight management intervention. The following a priori research questions were developed to initially guide our investigation:

1. What are the best evidence-based management strategies for treating obesity in men?
2. How can men's engagement in obesity services be improved?

In addition to these a priori research questions we also developed more detailed research questions, which emerged inductively from the initial findings of the effectiveness reviews:

1. How are men initially motivated to lose weight?
2. How are men attracted to taking part in the trial/intervention?
3. Are men consulted in the design of the intervention?
4. If it is found that interventions for men should be different from those for women, how should they be different and why?
5. Are group-based interventions for men found to be more effective for weight loss than interventions delivered to individual men?
6. Are certain features of diets found to be more attractive for obese men?
7. Are certain features of physical activity stated to be more attractive for obese men? How and why are these features more attractive?

8. What efforts are made to help men continue with the programme?
9. Do men state who they believe to be the best person/persons to deliver the intervention?
10. Are programmes deliberately involving partners/families more effective?

Study appraisal

For each systematic review one reviewer extracted data from the included studies and a second reviewer checked the data for omissions or inaccuracies. Two reviewers carried out the quality assessment.

Synthesis

For quantitative data we reported means or changes in means or proportions between groups. For continuous outcomes we reported the mean difference or standardised mean difference (different scales for the same outcome) and for dichotomous outcomes we reported risk ratio data with 95% confidence intervals (CIs). For the analysis of mean weight loss, the mean difference between men and women and the weighted mean difference were calculated for both men and women when more than one group was reported. Because of the inherent heterogeneity in studies of obesity interventions, when study results from more than one study could be quantitatively pooled we used random-effects meta-analysis.

We undertook a realist approach to integrating the qualitative and quantitative evidence synthesis, conceptualising interventions by the:

1. *context* that an intervention/programme will be situated within so that factors that might inhibit or enhance its effectiveness can be identified
2. *mechanisms* of the intervention/programme and how the intended programme beneficiaries will interact and react to the intervention processes and mechanisms
3. *outcomes*, both positive and negative, that may arise from an individual's engagement with the proposed intervention.

Both deductive and inductive analytical approaches were employed throughout the review process.

Results

Data were included for 1238 men from 11 trials and six linked reports for our review of men-only RCTs; 12,934 men and women from 20 RCTs and six linked reports for our review of RCTs in men and women; and 11,426 men and 63,990 women from 26 reports of UK interventions; five economic evaluations and two linked reports; 13 qualitative studies linked to interventions; and nine qualitative studies not linked to interventions. We found no eligible studies for our review of interventions to increase the engagement of men. We found some consistent findings across reviews and we present an integrated synthesis of our results. Our findings should be interpreted with the knowledge that the evidence base, particularly in the UK setting, is currently limited in the quality and number of studies and mainly reflects white, middle-class, middle-aged men. In addition, few UK studies included long-term data and our results may not necessarily be applicable to all men. We also had difficulties retrieving studies and it is possible that the studies that we found had more promising results than those that we were not able to access.

Types of effective interventions

Men may do well if physical activity is part of a weight-loss programme. One intensive supervised exercise programme produced a mean weight change after 1 year of –4.6 kg (95% CI –6.2 kg to –3.0 kg). Men may like exercise programmes and may be more likely to respond to them than women. Men enjoyed the use of pedometers to monitor their physical activity. Reducing diets tended to produce more favourable weight loss than physical activity alone (mean weight change after 1 year from a reducing diet compared with an exercise programme –3.2 kg, 95% CI –4.8 kg to –1.6 kg). Reducing diets are more effective if an exercise programme is also provided. Low-fat reducing diets, some with meal replacements, combined

with physical activity and behaviour change training gave the most effective long-term weight change [–5.2 kg (standard error 0.2 kg) after 4 years].

The type of reducing diet, such as increasing the protein content, was not shown to affect long-term weight loss in men. Some men expressed a dislike of 'strict' diets. However, for men, intermittent periods of very low-calorie dieting, as required, may be more effective than regular periods of dieting (mean difference after 2 years –10.5 kg, 95% CI –16.2 kg to –4.8 kg).

Interventions including behaviour change training improved long-term weight loss and maintenance for men (e.g. self-monitoring, goal setting, prompting self-monitoring, providing feedback, review of goals). Behaviour change training significantly improved weight-loss maintenance over the second year for men who had used exercise to lose weight over the first year (mean difference –3.1 kg, 95% CI –5.0 kg to –1.2 kg) but not for men who had used diet to lose weight over the first year (mean difference 0.6 kg, 95% CI –1.3 kg to 2.5 kg). Men might like less monitoring than women and too many sessions may be counterproductive. Support by telephone and mail could be useful (mean difference after 1 year –1.4 kg, 95% CI –2.7 kg to –0.1 kg).

After a very low-calorie diet, men may be less likely than women to do well with orlistat to help long-term weight-loss maintenance (for men: mean change after 3 years with orlistat –8.9 kg, with placebo –8.1 kg; reported as not significant).

Motivators to lose weight

Although fewer men joined weight-loss programmes, once recruited they were significantly less likely to drop out than women (difference 11%, 95% CI 8% to 14%). The evidence suggested that middle-aged men were motivated to lose weight once they perceived that they had a problem with their health, for example being diagnosed or labelled as obese by a health professional. The health benefits of losing weight can act as a further motivator for men. Trials found that successful weight reduction with low-fat reducing diets or physical activity advice or programmes, with or without behaviour change training, may improve health problems, for example erectile dysfunction in men with and without type 2 diabetes (reported $p = 0.06$ and $p = 0.001$ respectively). This type of intervention can also prevent diabetes (hazard ratio for diabetes incidence 0.43, 95% CI 0.22 to 0.81). Successful weight loss might increase the risk of osteoporosis for type 2 diabetics by reducing total hip bone density. The desire to improve personal appearance was also cited as a motivator, although men were also keen to avoid looking too thin.

Intervention setting and delivery and support

Group compared with individual programmes

Group-based weight management programmes were found to facilitate peer or social support amongst men with similar health problems, despite the fact that some men were initially reluctant to take part in a group. Some individual tailoring of advice or counselling for men could also assist with weight loss. Some men found that being accountable to oneself and having to account for food choices to others within the programme facilitated adherence. Some men stated that men-only group settings were important whereas others stated that this was unimportant or preferred mixed-sex groups. Group-based programmes can be logistically difficult with regard to scheduling; programmes offering evening meetings at fixed, regular times were desirable. Group-based financial contracts were reported to be significantly more effective for weight loss over 2 years than individual financial contracts (reported $p < 0.05$), although the size of the contract did not appear to be a significant influence.

Setting

Interventions situated in sporting contexts, for which men have a strong sense of affiliation and belonging, have been instrumental in engaging men. Interventions with football fans have had low dropout rates and have shown very positive responses from participants. Men largely welcomed the use of humour in intervention design or delivery, although it was recognised that men's health issues could be trivialised if

humour was used insensitively or inappropriately. Generally, men preferred interventions that were individualised, fact based and flexible, which used business-like language and which included simple to understand information.

Some men favoured programmes delivered by the NHS in comparison to commercial companies, and in contrast to female preferences, but data showed that commercial programmes were effective in helping men to lose weight. Weight-loss programmes delivered in the NHS for men only have so far been few, with limited follow-up, although feedback has generally been positive. The comparative effectiveness of NHS and commercial programmes for long-term weight loss was unclear for men. In a 1-year UK-based randomised trial of commercial and NHS-based programmes, only 31% of the participants were men. In this trial only one intervention from a commercial weight-loss organisation, in which 28% of the participants were men, resulted in significantly greater weight loss than in the comparator arm (adjusted mean difference –2.5 kg, 95% CI –4.2 kg to –0.8 kg).

Delivery

Studies generally did not report the sex of the person delivering the intervention and whether or not this was an influence. The benefits of internet-based advice for men were unclear (mean difference for internet-based advice after 1 year –0.9 kg, 95% CI –1.9 kg to 0.2 kg).

Support from family and friends

The effect of support from partners to aid weight loss was inconsistent. There was evidence to suggest that having a partner involved in a weight-loss programme might be beneficial for weight loss but the opposite effect was also found. Equally, the social role of food in maintaining relationships with family members or friends was raised as a barrier to weight loss. Participating in a weight-loss intervention appeared to encourage men's partners (not signed up to the intervention) to lose weight through a halo effect.

Economics

No evidence was retrieved relating to the cost-effectiveness of interventions to tackle obesity in UK men. Five studies in a European, Australian or American setting evaluated cost-effectiveness in men as a subgroup analysis. Formal meta-analysis of the studies was not possible because of heterogeneity in the study designs, modelling methods used and study populations. There was, however, some evidence that general practitioner counselling interventions were more cost-effective than interventions delivered by a dietitian. Lifestyle interventions also proved to be cost-effective as were group-based interventions. Orlistat was found to be cost-effective in addition to a lifestyle intervention and was particularly cost-effective if targeted at high-risk groups, especially people with type 2 diabetes. The results should be interpreted in the light of the variable methodological quality of the studies.

Strengths and limitations

The strengths of this study are the systematic and rigorous methods taken to review and integrate the evidence. Exhaustive searches were undertaken with the aim of identifying all relevant published and grey literature. Despite these efforts we identified limited data, especially for the UK, which were of moderate quality. Furthermore, the diversity of men was not well-represented by the narrow evidence base as the majority of participants considered by the included studies were white, middle class and middle aged. The results should therefore be interpreted with caution.

Conclusions

Implications for health care

1. Weight reduction for men is best achieved and maintained with the combination of a reducing diet, physical activity advice or a physical activity programme, and behaviour change techniques (e.g. self-monitoring, goal setting, prompting self-monitoring, providing feedback, review of goals). These key components differ from those found for women, with men preferring more factual information on how to lose weight and more emphasis on physical activity programmes. Weight-loss programmes can prevent type 2 diabetes and improve cardiovascular risk factors, erectile dysfunction, self-esteem and quality of life.
2. For some men, but not all, the opportunity to attend men-only groups may enhance the effectiveness of interventions. Individual tailoring and feedback may also be features of more effective services.
3. Weight-loss programmes for men may be better provided in social settings, such as sports clubs and workplaces, which may be more successful at engaging men. Innovative means of delivering services are needed for hard-to-reach groups.

Recommendations for research

1. Research is needed to examine the effectiveness and cost-effectiveness of new approaches to engaging men with weight-loss services and the best design for those services.
2. Men (and women) are a heterogeneous group. Rigorous methods are needed to test more complex interventions. Men should be consulted on how to optimise engagement and make interventions more user-friendly, and these services need to be formally evaluated. The experiences and perspectives of men (and women) who are black or from ethnic minority backgrounds, who are unemployed or on low incomes, who are gay, bisexual or transgender or who are from rural and/or remote locations need to be addressed. Rigorous feasibility studies and piloting with service user input at all stages is required before undertaking definitive RCTs.
3. Health concerns, which may prompt contact with health service staff, motivate men to address their obesity. Research is required to examine the most effective interventions delivered at these pivotal health service encounters when an obesity-related diagnosis is made.
4. Although we found relatively few long-term RCTs, there were even fewer UK studies that provided outcome data for men of more than a few months' follow-up. As was clear from our reviews, men would value longer-term support and there is a need to provide longer-term outcome data (at least 1 year of follow-up). These outcome data should include cardiovascular risk factors, the impact on comorbidities and quality of life and economic outcomes. There is also a need to look specifically at ways to enhance the maintenance of weight loss. The majority of the programmes did not make a distinction between support for the initial weight loss and a different or modified programme to help maintain that weight loss.
5. Qualitative research is needed with men to inform all aspects of intervention design, including the setting, optimal recruitment processes and reasons for, and how processes might minimise, attrition. Process evaluation of intervention studies should seek feedback on the marketing, content and delivery of interventions and how the macro, meso and micro context interacts with the intervention.
6. Future research studies should adhere to best practice guidelines for health economic decision modelling and particular attention should be given to assumptions regarding the continuation of treatment effect and the modelled link between weight loss and longer-term costs and outcomes (e.g. health events such as diabetes and myocardial infarction).

Study registration

This study was registered as PROSPERO CRD42011001479.

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Chapter 1 Background

In this chapter we briefly discuss definitions, epidemiology and risks of obesity and possible benefits of reducing obesity in men. We show that men are under-represented in weight-loss programmes in developed countries and briefly discuss the growing literature on possible explanations. Evidence from qualitative and quantitative research is starting to accumulate on how men who are obese may be helped to lose weight, but there has been little systematic research to synthesise the evidence base. This project attempts to provide the current evidence base for engaging obese men with weight loss and provide pointers to designing successful services. The literature is still limited and we acknowledge that, although we would have liked to explore the effects of diversity, such as age, ethnic group, socioeconomic status, disability or sexual orientation, the evidence for these was sparse.

In this report we have tried to stick to accepted definitions of the words 'sex' and 'gender':[1]

> *The word 'gender' is used to define those characteristics of women and men that are socially constructed, while 'sex' refers to those that are biologically determined. People are born female or male but learn to be girls and boys who grow into women and men.*

Definitions of obesity in men and women

A body mass index (BMI) of ≥ 30 kg/m^2 [weight in kg/(height in m)^2] is widely used to define obesity in both men and women, with a BMI of ≥ 25 kg/m^2 and < 30 kg/m^2 defining overweight. The term 'morbid obesity' is used to denote a BMI ≥ 40 kg/m^2. BMI is widely used as an easy practical measure to classify the degree of obesity, predict the risk of obesity-related diseases and identify individuals or communities at risk. However, BMI does not distinguish between differences in body composition affected by sex, physique or ethnicity. For example, men will have a lower percentage of fat than women of an equivalent BMI.[2]

Waist circumference is also used to assess increased body fat, particularly intra-abdominal fat. Unlike BMI, waist circumference cut-offs for risks of disease are sex specific. The National Institute for Health and Care Excellence (NICE)[3] has advised that both BMI and waist circumference should be used to assess the risk of health problems (such as type 2 diabetes, coronary heart disease, osteoarthritis) in people with a BMI of < 35 kg/m^2; above this BMI, risk will be high irrespective of waist circumference (*Table 1*).

Demographics of obesity in men and women

Based on BMI, more men than women are overweight or obese in the UK and this difference is projected to continue. In the Health Survey for England 2011,[4] 65% of men had a BMI of ≥ 25 kg/m^2 whereas 58% of women fell into this category. As the prevalence of obesity continues to increase, it is likely that people who are overweight will become obese in the future. Thus, the Foresight report[5] predicts that 36% of men and 28% of women will be obese by 2015 and 47% of men and 36% of women by 2025 in England. Figures from Wales[6] (64% and 53%), Scotland[7] (69.2% and 59.6%) and Northern Ireland[8] (67% and 56%) show similar differences (men vs. women for overweight or obese respectively). In the UK, only in England do figures show that the prevalence of obesity in men is less than that in women,[4] whereas in Scotland, Northern Ireland and Wales it is similar or higher in men.[6,7,8] However, morbid obesity tends to be less prevalent in men.[4,7] Worldwide, fewer men are obese than women but men have a higher BMI than women in high-income countries.[9]

TABLE 1 Table for assessing increased risk of obesity-related disease

	Waist circumference		
BMI (kg/m²)	Low[a]	High[b]	Very high[c]
Normal: < 25	No increased risk	No increased risk	Increased risk
Overweight: 25 to < 30	No increased risk	Increased risk	High risk
Obese: 30 to < 35	Increased risk	High risk	Very high risk

a < 94 cm (men), < 80 cm (women).
b 94–102 cm (men), 80–88 cm (women).
c > 102 cm (men), > 88 cm (women).
Source: NICE.[3]

However, if waist circumference alone is used to define risks from obesity then women are more at risk, with 47% of women and 34% of men at risk in 2011 in England.[4] Using both BMI and waist circumference to define health risk, 18% of men had an increased risk, 15% had a high risk and 21% had a very high risk compared with 15%, 18% and 26% of women respectively.[4] Thus, measures of risk in men and women differ depending on the obesity measure used.

In England, the age-standardised prevalence of obesity and raised waist circumference for men and women was higher in households in lower quintiles than in households in higher quintiles of equivalised household income.[4] Some occupations, such as bus driving, may be at higher risk of obesity because of the work environment.[10] Work-related stress has different effects in men and women, increasing the risk of type 2 diabetes in obese women but not apparently for obese men.[11]

Figures for different ethnic groups are not available from the recent Health Survey for England.[4] However, lower BMI and waist circumference cut-offs have been recommended for some ethnic groups, such as South Asian populations, as a measure of risk, particularly for type 2 diabetes, and have recently been recommended by NICE.[12] If existing BMI cut-offs are used, then data from the Health Survey for England from 2004[13] show lower prevalences of obesity in men from black African, Indian, Pakistani, Bangladeshi and Chinese groups.

In England the prevalence of overweight and obese individuals using BMI increases with age in men and women, with 29% of men and 32% of women aged ≥ 75 years being obese.[4]

Risks of obesity in men and women

Collaborative analyses from 57 prospective studies, mainly from Western Europe and North America, with a mean recruitment age of 46 years, have found that mortality in both men and women is lowest for a baseline BMI of 22.5–25 kg/m².[14] Each additional 5 kg/m² was approximately associated with 30% higher overall mortality, 40% higher vascular mortality, 60–120% higher diabetic, renal and hepatic mortality, 20% higher respiratory disease mortality and 10% higher cancer mortality. Median survival was reduced by 2–4 years for a BMI of 30–35 kg/m² and by 8–10 years for a BMI of 40–45 kg/m². However, others have found that all-cause mortality does not appear to increase relative to normal weight until BMI is ≥ 35 kg/m².[15]

Pischon and colleagues[16] found that waist circumference or waist-to-hip ratio enhanced the ability of BMI to predict risk of death in men and women in nine countries in Europe. However, the Emerging Risk Factors Collaboration[17] found little difference in the ability of BMI, waist circumference and waist-to-hip ratio to predict cardiovascular disease in men and women in developed countries, but BMI had greater

reproducibility. Similarly, there was little difference in the ability of BMI or waist circumference to predict the risk of developing type 2 diabetes in men, which is so strongly associated with obesity.[18] However, Cameron and colleagues[19] considered that including both waist and hip circumference together, rather than as a ratio, may improve risk prediction models for mortality and type 2 diabetes.

Positive associations have been found between increasing BMI and subsequent risk of death from liver, kidney, prostate, breast, endometrial and large bowel cancer.[14] Others have found strong associations between obesity in men and subsequent oesophageal, thyroid, colon and renal cancer.[20]

Obesity is a risk factor for a very wide range of diseases impacting on health and quality of life. Men with a BMI $\geq$ 30 kg/m^2 and a waist circumference $\geq$ 102 cm have an increased risk of at least one symptom of impaired physical, psychological or sexual function, and these symptoms are also more likely in men with a raised waist circumference but a BMI of < 30 kg/m^2.[21] Men who are overweight or obese in midlife also have a higher risk of frailty in old age.[22]

Costs of obesity

Although the Foresight report[5] predicted that future costs to the NHS of elevated BMI could be £6.4B per year by 2015 and £9.7B per year by 2050, no breakdown by sex was given, despite there being clear differences for the risk of diseases related to obesity, such as coronary heart disease and type 2 diabetes.

Benefits of weight loss in men and women

Although there are many diseases associated with obesity, it has been difficult to demonstrate that prevention or treatment of obesity reduces the risk of disease long term, despite beneficial changes in cardiovascular risk factors in randomised controlled trials (RCTs) of lifestyle interventions.[23] The evidence for a reduction in mortality from long-term weight loss from cohort studies and randomised trials is strongest for both overweight or obese men and overweight or obese women with diabetes.[24] There is some evidence that intentional weight loss may reduce mortality in women, but benefits in men are not clear.[24] Maintaining or increasing physical activity seems to be particularly beneficial to survival.[25]

Randomised trials of lifestyle interventions for weight loss have confirmed the long-term prevention of type 2 diabetes in men and women.[26–28] Randomised trials of weight-loss interventions in men and women have also shown significant reductions in blood pressure or cardiovascular events.[23]

Under-representation of men in weight-loss programmes

Men are under-represented in randomised trials of weight-loss interventions and in health services and commercial programmes for weight loss. In a systematic review, Pagoto and colleagues[29] found that only 27% of participants in randomised trials were men, although the percentage was higher in interventions for obesity with related comorbidities (36% men). There was also a trend towards lower participation by men in group formats (24%) compared with individual counselling (29%) or mail/e-mail/internet formats (34%); however, the male/female mix of the groups was not specified. In another systematic review, Moroshko and colleagues[30] did not find sex to be a predictor of dropout in weight-loss interventions.

Services for the treatment of adults with obesity in the UK have consistently shown an under-representation of men. In the Counterweight programme in 65 general practices in seven UK regions, only 23% of participants were men.[31] Men made up only 27.6% of referrals to the NHS Glasgow and Clyde Weight Management Service and, once referred, women were slightly more likely to opt in (73.6% vs. 69.4%), but there was no significant difference in completion rates by sex.[32]

Commercial programmes in the UK, such as Weight Watchers,[33] Slimming World[34] and LighterLife,[35] and some NHS organisations have only recently started to evaluate men-only weight-loss groups. When services were not sex specific, men made up only 10.7% of 34,271 adults in a slimming on referral scheme between Slimming World and 77 primary care trusts or NHS trusts,[36] and 10.5% of 29,326 adults referred from NHS primary care to Weight Watchers.[37] Thus, UK figures suggest that men may be even less likely to attend commercial weight-loss programmes than programmes provided by the NHS.

Two systematic reviews have examined the qualitative evidence on people's views and experiences of weight management.[38,39] Most of the evidence came from studies with women or studies with groups of men and women in which the majority of participants were women. The authors did not specifically examine the evidence from male participants in these studies, or men compared with women, so it is unclear whether or not their conclusions can be applied to men. There is evidence that since 1999 increasing numbers of both men and women in the UK are failing to recognise that they are overweight or obese.[40] Men may be more likely than women to misperceive their weight, less likely to consider their body weight a risk for their health and less likely to consider managing or be actively trying to manage their weight.[41,42]

Men's attitudes to lifestyle behaviour change

Men may be more reluctant to change their current lifestyle than women[43] and may be cynical about government health messages.[44] Media and other sociocultural influences may also encourage men to maintain a larger, more muscular, masculine body size.[45] Men could be less interested in gaining an ideal body weight, according to the medical definition, and more interested in physical activity and regaining fitness and a masculine body shape.[46] There may also be differences in the way that men and women view physical activity as a means of becoming stronger, fitter and healthier.[47]

Weight-loss programmes and facilities, including commercial weight-loss programmes, could be seen as feminised spaces,[46,47] and there is some evidence to suggest that men may prefer masculine spaces, such as their workplace, for such programmes.[48,49] Fear and embarrassment may particularly deter men from taking part in weight-loss programmes and could mean that talking to an advisor on a one-to-one basis, rather than working in a group, is preferred.[49] Some men have also cited that having a male advisor for lifestyle change is important in the health-care setting.[50]

Men could be less interested in undertaking weight-loss diets, which are perceived as tasting poor and failing to satisfy the appetite.[44] Men could distance themselves from the feminised realm of dieting, in which women are viewed as the experts.[51]

Previous evidence associated with weight-loss management programmes and men

Given that there are difficulties in encouraging men to undertake weight management, what is the evidence for improving their engagement in services and should weight-loss programmes be designed differently for men and women?

The National Institute for Health and Care Excellence[3] and the Scottish Intercollegiate Guidelines Network (SIGN)[52] have not provided specific guidance for men, as opposed to women, for the prevention and treatment of obesity. NICE guidance on behaviour change interventions called for research on the cost-effectiveness of behaviour change interventions for men and women separately, but did not provide evidence on the effectiveness of lifestyle interventions separately by sex.[53]

The Men's Health Forum convened a conference in 2005 with 23 health and social policy researchers to discuss men and weight issues; the outcomes of this conference were subsequently published in a book entitled *Hazardous Waist: Tackling Male Weight Problems*.[54] Evidence of effective interventions was not reviewed, although several examples of innovative approaches in the UK were presented. The conference conclusions included a need to invest in 'male-sensitive approaches', that 'men's attitudes to weight and weight loss need to be more fully understood' and that the 'existing, broadly "unisex", approach is failing men' (pp. 218–19).[54]

A systematic review was conducted by Robertson and colleagues[55] in 2008 to explore the effectiveness of male-specific health-promoting interventions covering a wide range of health behaviours. However, it did not identify any intervention studies (at the time that the review was conducted) that had focused on men and weight management or weight loss.

More recently, Young and colleagues[56] systematically reviewed men-only weight-loss or weight-maintenance interventions of any duration, limiting their review to the 18–65 years age group and people without obesity-related morbidity, for example diabetes. Only 12 of the 23 identified studies were RCTs and six included a follow-up of approximately a year or longer. Thirty-one different interventions were identified with a median weight loss of 6.25%. A high frequency of contact (three or more per month), group programmes, a mean age of ≤ 43 years in the sample and prescribing an energy-restricted diet were associated with greater programme effectiveness. Only five of the studies tested interventions that were specifically designed for men.

Aims of this project

The evidence briefly discussed in this chapter suggests that methods to engage men in services, and the services themselves, are currently not optimal. We set out to systematically review evidence-based management strategies for treating obesity in men and how to engage men with obesity in weight management programmes. Where we use the term 'engagement', this is to denote obese men deciding to start using services to help them lose weight.

We asked the following questions:

- What works for obesity management for men?
- How can men be engaged with services?
- Should services for men and women be different?

Our overarching objective was to integrate the quantitative and qualitative evidence base by systematically reviewing:

- the clinical effectiveness and cost-effectiveness of interventions for obesity in men, and in men compared with women
- the clinical effectiveness and cost-effectiveness of interventions to engage men in their weight reduction
- qualitative research with men about obesity management and with providers of such services for men.

This report is structured in the following way:

- *Chapter 2* presents the methods for the quantitative and qualitative systematic reviews and the mixed-methods synthesis of these reviews.
- *Chapter 3* presents the systematic review of RCTs of interventions [lifestyle and/or the UK licensed medication orlistat (a pharmaceutical agent to aid weight loss)] in any setting with men only who are obese with a BMI of ≥ 30 kg/m^2 (or overweight with a BMI of ≥ 28 kg/m^2 and with cardiac risk factors based on orlistat guidance) and with follow-up of at least 1 year. *Chapter 3* also presents the systematic review of RCTs of interventions (as above) in any setting including both men and women who are obese with a BMI of ≥ 30 kg/m^2 (or overweight with a BMI of ≥ 28 kg/m^2 and with cardiac risk factors based on orlistat guidance) in which the results are presented separately for men and women in the same trial. We use trials with both men and women to look for differences in effectiveness.
- *Chapter 4* presents the results of the systematic review of interventions for men with obesity in the UK, of any setting, study design or duration. This includes data from UK studies with men and women in which data are presented separately for men and women. This chapter also contains details of the search carried out for the systematic review of studies to increase the engagement of men with obesity services; however, no studies fitting the inclusion criteria were found. However, information on engaging men with services is available and discussed in the first review in this chapter.
- *Chapter 5* presents the systematic review of economic evaluations of obesity interventions, including studies in which data were presented either for men only or for men compared with women.
- *Chapter 6* presents the systematic review of qualitative studies that have explored men's engagement and experiences associated with weight management interventions linked to RCTs and other intervention studies. We also included qualitative studies on obesity from the UK that were not linked to interventions. This review focused on questions relating to the context of these interventions and well as their mechanisms and outcomes. The findings from the qualitative studies were combined with the findings from all of the quantitative reviews in a mixed-methods synthesis.
- *Chapter 7* presents our overall discussion of the results from all of the reviews.
- *Chapter 8* draws out the implications for health care and makes recommendations for future research.

Chapter 2 Methods

We undertook six systematic reviews as follows:

- a systematic review of RCTs of interventions with men only
- a systematic review of RCTs of interventions in which the results were presented separately for men and women in the same trial
- a systematic review of interventions for men, or men and women compared, with obesity in the UK in any setting, using any study design and of any duration
- a systematic review of interventions to increase the engagement of men with services for obesity management, using any study design
- a systematic review of the cost-effectiveness of alternative strategies for the management of obesity in adult men
- a systematic review of qualitative research with obese men, or obese men compared with obese women, and with health professionals and commercial organisations managing obesity.

We prepared a priori protocols detailing the objectives; types of study design, participants, interventions and outcomes considered; and the inclusion/exclusion criteria for all reviews. For quantitative reviews we followed methodological guidance recommended by The Cochrane Collaboration[57] and Centre for Reviews and Dissemination.[58] Details of the methods used for the cost-effectiveness review are provided in *Chapter 5*.

Inclusion and exclusion criteria

Types of study

The systematic reviews of men only and men and women compared included RCTs or quasi-randomised trials (including trials with a cluster design) with a mean or median duration of ≥ 52 weeks for all groups. This duration of follow-up for data was to ensure that long-term weight-loss and weight-maintenance interventions were evaluated for their associated effects on weight- and obesity-related morbidities.[23] This was also the minimum duration of studies adopted by NICE for its review of obesity.[3]

For the systematic review of UK interventions, any study design and duration were considered to include and evaluate as much UK-relevant research as possible. We included studies of men only and studies of men and women if data were presented separately for men.

For the systematic review of interventions to increase engagement, we included any study design that examined interventions to increase the engagement of men with services for obesity management.

Types of participants

Men aged ≥ 16 years were included, with no upper age limit. Participants in studies included in the systematic reviews of men only, men and women compared and UK interventions had to have a mean or median BMI of ≥ 30 kg/m^2 (or ≥ 28 kg/m^2 with cardiac risk factors based on criteria for receiving orlistat). When body weight was reported instead of BMI, we calculated BMI using relevant population data for heights to assess study eligibility.[23] We recognised that the BMI of men targeted in systematic reviews of engagement and cost-effectiveness may not have been clearly stated.

Types of interventions and comparators

Systematic reviews of studies of men only, men and women compared and the UK interventions considered interventions in the form of orlistat (but not sibutramine or rimonabant, which no longer have UK licences), diet, physical activity, behaviour change techniques or combinations of any of these. For the

reviews of men-only RCTs and RCTs of men and women compared, we considered any of these interventions along with placebo and 'no treatment' as comparators. For the systematic review of engagement we considered any form of intervention to increase the engagement of men with services for obesity management.

Setting

We considered all settings for the lifestyle and drug interventions, including hospitals, primary care, the community (including a community pharmacy), commercial organisations, the voluntary sector, leisure centres, workplaces, the internet and other digital domains, for example mobile phone networks. This is because there is increasing collaboration between the NHS and non-NHS organisations in the delivery of services. It may also be the case that increasing the participation of men in obesity services requires their engagement in settings outside primary and secondary care.

Types of outcome measures

We developed our rationale for outcome measurement from our existing knowledge of the topic area and in consultation with the project advisory group. Studies had to explicitly mention weight loss or weight-loss maintenance as a main outcome to be eligible for inclusion.

We considered the following types of outcome:

- Primary outcome: weight change
- Secondary outcomes:
    - waist circumference
    - cardiovascular risk factors [decreases in these are generally beneficial for cardiovascular risk, with the exception of high-density lipoprotein (HDL) cholesterol]: total cholesterol, HDL cholesterol, low-density lipoprotein (LDL) cholesterol, triglycerides, fasting glucose, glycated haemoglobin (HbA_{1c}), systolic and diastolic blood pressure
    - disease-specific outcomes (e.g. erectile function)
    - adverse events
    - quality of life outcomes
    - process outcomes (e.g. staff involvement, setting, type of intervention, timing, frequency, individual and/or group setting, couple or family setting, proportion recruited and dropping out, participants' evaluations)
    - economic costs.

Exclusion criteria

We did not consider interventions including complementary therapy, for example acupuncture, or non-diet products promoted for weight loss available solely over the counter. Studies evaluating bariatric surgery or examining a combination of interventions, for example smoking cessation and weight loss at the same time, or examining men with obesity receiving psychotropic medication, with learning disabilities or with a diagnosed eating disorder, were also excluded.

Search strategies

For the search strategies there were no language restrictions and studies had to be set in societies relevant to the UK setting. We maintained the comprehensive electronic search conducted in MEDLINE and EMBASE in our previous systematic review[23] of RCTs of lifestyle interventions for weight loss in obese adults with 1 year of follow-up. From our existing searches for this review and subsequent updates we identified approximately 800 potentially relevant reports, in any language, for full-text assessment for the review of men-only RCTs and RCTs of men and women compared. In addition to this search we conducted comprehensive electronic searches based on our existing search strategy to identify RCTs of

interventions for obesity in men. To avoid unnecessary overlap with the pre-existing results from the review by Avenell and colleagues,[23] the search strategy for reviews of men-only RCTs and RCTs of men and women compared excluded studies published before 2001.

Highly sensitive electronic searches were undertaken to inform the reviews of UK interventions and interventions to increase engagement. The searches were designed to identify studies of interventions for obese men in the UK, studies of interventions to increase the engagement of men with obesity management services and qualitative research with obese men or obese men compared with obese women. The searches for all reviews were designed to identify systematic reviews and other background information relevant to the management of obesity in men. Additionally, a separate search was undertaken to identify studies examining the cost-effectiveness of interventions for obese men. The searches for each of the reviews were designed to be mutually exclusive, with the results of each new search being deduplicated against the results of the previous searches. *Table 2* details the databases searched for each review.

The database searches were conducted over the following time periods:

- MEDLINE In-Process & Other Non-Indexed Citations: 1948 to 30 July 2012
- MEDLINE: 1948 to 2012 Week 31
- EMBASE: 1980 to 2012 Week 31
- Cumulative Index to Nursing and Allied Health Literature (CINAHL): 1981 to July 2012
- PsycINFO: 1800s to July 2012
- Social Sciences Citation Index (SSCI): 1970 to July 2012
- Conference Proceedings Citation Index – Social Science & Humanities (CPCI-SSH): 1990 to July 2012
- Cochrane Central Register of Controlled Trials (CENTRAL): The Cochrane Library, Issue 5, 2012
- Cochrane Database of Systematic Reviews (CDSR): The Cochrane Library, Issue 5, 2012
- ClinicalTrials.gov: September 2011
- CenterWatch: September 2011
- Current Controlled Trials: September 2011
- World Health Organization International Clinical Trials Registry: September 2011
- Applied Social Sciences Index and Abstracts (ASSIA): 1987 to July 2012
- Education Resources Information Center (ERIC): 1966 to July 2012
- Anthropology Plus: 1957 to July 2012
- British Nursing Index: 1994 to October 2011
- NHS Economic Evaluation Database (NHS EED): July 2012
- Health Technology Assessment (HTA) database: July 2012
- Database of Abstracts of Reviews of Effects (DARE): July 2012
- Health Management Information Consortium (HMIC): 1979 to November 2011
- Cost-Effectiveness Analysis Registry (CEA Registry): January 2012
- Research Papers in Economics (RePEc): January 2012.

Hand searching

Reference lists of all included studies were scanned to identify any additional potentially relevant reports. We also searched the internet for online weight-loss programmes specifically targeted at men (e.g. www.fatmanslim.com) and the Picker Institute and Joanna Briggs Institute websites for grey literature.

Other methods of ascertaining relevant information sources

When contact details were available, we contacted all authors of men-only RCTs to identify any qualitative or other relevant published or unpublished reports. Our advisory group members provided details of potentially relevant reports and further potentially useful contacts and information sources. Each of the Men's Health Forum representatives included articles in their newsletters highlighting our project and providing details for readers to contact us with any relevant reports. The English Men's Health Forum also publicised the project through its Twitter account. Furthermore, we contacted the Association for the

TABLE 2 Databases searched for each review

Database	Men-only RCTs	RCTs of men and women compared	UK interventions	Engagement	Cost-effectiveness	Qualitative research
MEDLINE	✓	✓	✓	✓	✓	✓
EMBASE	✓	✓	✓	✓	✓	✓
Cumulative Index to Nursing and Allied Health Literature (CINAHL)	✓	✓	–	✓	–	✓
PsycINFO	✓	✓	✓	✓	–	✓
Cochrane Central Register of Controlled Trials (CENTRAL)	✓	✓	–	–	–	–
Cochrane Database of Systematic Reviews (CDSR)	✓	✓	–	–	–	–
Database of Abstracts of Reviews of Effects (DARE)	✓	✓	–	–	–	–
NHS Economic Evaluation Database (NHS EED)	✓	✓	–	–	✓	–
Health Technology Assessment (HTA) database	✓	✓	–	–	–	–
Applied Social Sciences Index and Abstracts (ASSIA)	–	–	–	✓	–	✓
Education Resources Information Center (ERIC)	–	–	–	–	–	✓
Anthropology Plus	–	–	–	–	–	✓
British Nursing Index	–	–	–	–	–	✓
Social Sciences Citation Index (SSCI)	–	–	✓	–	–	✓
Health Management Information Consortium (HMIC)	–	–	–	–	✓	–
Conference Proceedings Citation Index – Social Science & Humanities (CPCI-SSH)	–	–	✓	–	–	✓
Cost-Effectiveness Analysis Registry (CEA Registry)	–	–	–	–	✓	–
Research Papers in Economics (RePEc)	–	–	–	–	✓	–
ClinicalTrials.gov	✓	✓	–	–	–	–
CenterWatch	✓	✓	–	–	–	–
Current Controlled Trials	✓	✓	–	–	–	–
International Clinical Trials Registry	✓	✓	–	–	–	–

Study of Obesity, Dietitians in Obesity Management and other commercial organisations to identify published and unpublished UK studies (see *Appendix 1*).

Quantitative reviews of randomised controlled trials and other intervention studies

Data extraction strategy

One reviewer (CR) independently screened the titles and abstracts of all identified items. Full-text copies of all potentially relevant reports were obtained and independently assessed for eligibility (CR assessed reviews of men-only RCTs, RCTs of men and women compared and interventions to increase engagement; AA assessed the review of UK interventions). One reviewer (CR) extracted details of study design, methods, participants, interventions and outcomes using a data extraction form (see *Appendix 2*). The data extraction was then checked by a second reviewer (AA) and any errors were corrected.

Quality assessment strategy

We assessed the methodological quality of included RCTs using The Cochrane Collaboration's tool for assessing risk of bias[57] (see *Appendix 3*). We assessed the methodological quality of non-randomised comparative studies using a 17-item checklist, with the same checklist minus four questions used to assess the quality of case series (see *Appendix 4*). The checklist was developed for NICE through the Review Body for Interventional Procedures (ReBIP) and was adapted from several sources, including the NHS Centre for Reviews and Dissemination's guidance for those conducting or commissioning systematic reviews,[58] Verhagen and colleagues,[59] Downs and Black[60] and the Generic Appraisal Tool for Epidemiology (GATE).[61] Individual items within these tools were rated as 'yes', 'no' or 'unclear' so that a rating of 'yes' denoted the optimal rating for methodological quality. Two reviewers independently assessed the quality of all included full-text primary studies. In addition, we used an adapted version of the Campbell & Cochrane Equity Methods Group checklist[62] for each of the reviews to assess the effect of interventions reported in the included studies on disadvantaged groups and/or their impact on reducing socioeconomic inequalities (see *Appendices 8*, *10* and *12*). Individual items were worded as 'yes', 'no' or 'unclear/not reported.' Conference abstracts and poster presentations were excluded unless sufficient details were reported to carry out quality, equity and sustainability assessments (e.g. protocols, internal reports). Any disagreements or uncertainty were resolved by discussion between the two reviewers. A third reviewer acted as an arbitrator when consensus could not be reached.

Data analysis

We imported data into Review Manager (RevMan) software (version 5.1; The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark) for data synthesis. We reported means or changes in means or proportions between groups. For continuous outcomes we reported the mean difference or standardised mean difference (different scales for the same outcome) and for dichotomous data we presented the risk ratio with 95% confidence intervals (CIs). Because of the inherent heterogeneity in studies of obesity interventions, when 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[57] and planned funnel plot analysis to investigate reporting biases for forest plots with ≥ 10 studies.

We planned to explore the role of sex as a treatment modifier by conducting a meta-analysis of the treatment by sex interaction effect across trials in which outcomes were presented separately by sex,[63] but this was not possible because of the heterogeneous nature of the interventions, particularly in terms of dietary calorie prescription. For statistics on the proportion of participants completing the study, only studies that reported the rate of dropout were included. The risk difference and its CI between men and women were calculated with the *p*-value.

For the analysis of mean weight difference between men and women, the weighted mean difference (WMD) was calculated for both men and women when more than one group was reported. The standard deviation (SD) for the WMD was calculated using the formulae for calculating SD for grouped data. Studies with no baseline weight values were excluded from the analysis of weight difference. In the analysis of percentage weight loss the WMD was divided by the baseline weight. For each study the number of participants, the WMD of weight or percentage weight loss from baseline and its SD were entered into RevMan software. The random-effects model was used.

Subgroup analyses were planned to explore whether the effectiveness of interventions differed according to whether participants were selected on the basis of newly diagnosed or pre-existing obesity-related comorbidities (e.g. diabetes, hypertension). This was not possible because of the limited quantity of data and the heterogeneity of the studies. Sufficient data were not available to explore the effect of deprivation, age and ethnicity on effectiveness nor were there sufficient data to explore the effect of assumed values for weight on meta-analyses.

The methods for incorporating economics evidence into the reviews followed those recommended in The Cochrane Handbook.[57] A narrative synthesis is presented.

Integrated qualitative and quantitative evidence synthesis

We undertook a realist integrated qualitative and quantitative evidence synthesis to investigate what weight management interventions work for men, with which men and under what circumstances. From a realist perspective, it is important to conceptualise any intervention intended to improve health by considering the:

1. *context* that an intervention/programme will be situated within so that factors that might inhibit or enhance its effectiveness can be identified
2. *mechanisms* of the intervention/programme and how the intended programme beneficiaries will interact and react to the intervention processes and mechanisms
3. *outcomes*, both positive and negative, that may arise from an individual's engagement with the proposed intervention.

A body of literature has emerged over recent years that has stressed the importance of considering public health problems (such as obesity) from a so-called socioecological perspective.[5,64–69] Hence, our methodological approach investigated issues relating to the *macro-*, *meso-* and *micro-level* influences that shape and influence men's perspectives and experiences related to engaging with weight management programmes. By macro-level influences we mean the wider social, cultural, economic and political factors that overarch and influence the meso level of workplace, community, family, friends and peers, whereas micro level refers to the individual psychological and biological determinants of health and well-being.

A priori research questions

The primary aim of the evidence synthesis was to uncover how effective interventions work and to describe key intervention ingredients, processes and environmental and contextual factors that contribute to effectiveness.[70] We also aimed to identify the barriers and facilitators that men experience when engaging with a weight management intervention. Both deductive and inductive analytical approaches were employed throughout the review process and as such the following a priori research questions were developed to guide our initial investigation:

1. What are the best evidence-based management strategies for treating obesity in men?
2. How can men's engagement in obesity services be improved?

In addition to these a priori research questions we also developed a series of 10 more detailed research questions that emerged inductively from the initial findings of the review of men-only RCTs (see *Chapter 3*) and also the expertise, knowledge and previous research of the chief investigator (AA) and principal investigators (FD, PH, EvT). Generating inductive research questions in this way is an inherent property of qualitative research and particularly of a grounded theory approach in which data collection and analysis proceed iteratively to confirm or refute an emerging theory:

1. How are men initially motivated to lose weight?
2. How are men attracted to taking part in the trial/intervention?
3. Are men consulted in the design of the intervention?
4. If it is found that interventions for men should be different from those for women, how should they be different and why?
5. Are group-based interventions for men found to be more effective for weight loss than those delivered to individual men?
6. Are certain features of diets found to be more attractive for obese men?
7. Are certain features of physical activity stated to be more attractive for obese men? How and why are these features more attractive?
8. What efforts are made to help men continue with the programme?
9. Do men state who they believe to be the best person/persons to deliver the intervention?
10. Are programmes deliberately involving partners/families more effective?

These questions were incorporated into our data extraction form (see *Appendix 15*) to code the data from studies linked to interventions to identify a priori themes. A full description of the data analysis cycle is provided in *The analysis cycle and thematic synthesis*.

Inclusion and exclusion criteria

We included any study reporting qualitative research with obese men, or obese men in contrast to obese women. In addition we included qualitative data from both health professionals and commercial organisations involved in managing obesity. The search included studies published from 1990 onwards and no language restrictions were placed on any of the searches.

As stated above in the description of methods for quantitative reviews, the studies included men who were 16 years or over, with no upper age limit, who had a mean or median BMI of 30 kg/m^2. We included data from qualitative and mixed method studies linked to the identified RCTs and linked to RCTs not included in the quantitative reviews for this report. We also included any qualitative data reported as part of papers reporting quantitative outcomes. Furthermore, we included data from qualitative studies linked to non-randomised intervention studies and qualitative data from studies that were not linked to any specific UK-based, men-only interventions that had reported on men's experiences of weight-loss attempts.

Studies conducted in developed countries were included if they contributed relevance to the UK context and all settings for lifestyle and drug interventions were considered. These included workplaces, football and rugby clubs, primary care, the internet, and religious and community settings.

We did not consider studies where men were not included and where obesity and weight management were not the prime focus. In addition, studies that did not contain primary qualitative research with obese men were not considered.

Identification of studies

The search methods for the review of qualitative studies have been reported earlier (see *Search strategies*). Two researchers independently screened abstracts for inclusion and all eligible study reports were entered into NVivo 9 qualitative data management software (QSR International, Southport, UK). Two researchers then grouped the final included studies into three categories:

1. qualitative and mixed-method studies linked to eligible RCTs, including any qualitative data reported as part of papers reporting quantitative outcomes
2. qualitative and mixed-method studies linked to ineligible RCTs and identified non-randomised intervention studies, including any qualitative data reported
3. UK-based qualitative studies not linked to any specific interventions that contained men-only samples.

Although it could be argued that separation of the studies into groups could cause further decontextualisation, as the focus of this project is to assess the evidence for weight management interventions, grouping the studies in this way assisted in the integration of the quantitative and qualitative review processes.

Data extraction strategy

For the studies linked to interventions, one reviewer (DA) used a data extraction form (see *Appendix 15*) to extract details of study design, methods, participants, interventions, findings, data pertaining to area and setting, and quality. Completed data extraction forms were checked by a second reviewer (either FD or EvT). Any disagreements over the interpretation of extracted data were discussed at group meetings. After agreement was reached the extraction forms were imported into NVivo 9 for analysis.

Following the analysis of the intervention study data, a further process of data extraction was applied to the nine theoretical studies not linked to interventions to investigate whether these studies contained data to confirm, refute or add any new thematic insights. Three researchers (DA, FD and EvT) screened three of the non-intervention studies each and extracted and inserted data into a Microsoft Excel spreadsheet (2007; Microsoft Corporation, Redmond, WA, USA) containing our interpretive themes derived from the intervention study data as headings. Data extraction of the non-intervention studies was cross-checked by other researchers in the group.

Quality assessment strategy

There is a great diversity of approaches to data collection and data analysis within qualitative research and also a multiplicity of theoretical perspectives. This has made it difficult to develop consensus over which criteria are the most useful when assessing the quality of qualitative studies.[1,71,72] At present, some qualitative synthesis methods such as framework synthesis and thematic synthesis undertake highly specified forms of quality appraisal that can result in the exclusion of studies that are judged to be of poor methodological quality. However, other methods such as critical interpretive synthesis do not exclude papers as long as they meet basic relevance criteria.[73]

With this in mind, there appears to be a growing argument amongst certain researchers[72,74–77] that qualitative studies should not be excluded from qualitative evidence syntheses based on quality assessment. They argue that excluding studies because of methodological flaws or incomplete reporting may result in the loss of valuable new insights, whereas studies that are methodologically sound may suffer from poor interpretation of data, leading to an insufficient insight into the phenomenon under study.[76] In addition, Carroll and colleagues[74] contend that a quality appraisal instrument can assess only what is reported in a publication; thus, aspects such as the style of journal or word limits may have a bearing on whether or not studies have adequate space to describe fully certain elements of a study that a quality assessment tool may be investigating. For example, Garip and Yardley[39] note that papers published in medical journals were often rated poorly using the Critical Appraisal Skills Programme (CASP) tool[78] because of the lack of space to provide full methodological details. We found these arguments against excluding studies to be convincing and therefore did not exclude any of the 13 qualitative studies linked to

interventions on the basis of quality. Instead, we elected to formulate and apply a quality appraisal tool during the process of data extraction.

Our quality assessment tool was formulated following a consultation of the following critical appraisal checklists: CASP,[78] the Consolidated Criteria for Reporting Qualitative Research[79] and the Joanna Briggs Institute Qualitative Assessment and Review Instrument.[80] We included criteria from these that we considered were key in terms of methodological rigour and also in terms of importance for our a priori research questions, which are specifically concerned with informing policy and practice.

The criteria that we selected were:

1. Aims and methods:
    - Research questions – stated explicitly or implicitly within the general text/topic guide? In what section(s) of the paper are questions mentioned? Are they prospective or retrospective?
    - Theoretical and epistemological perspective underpinning the qualitative research?
    - Theoretical perspective underpinning the intervention?
    - Qualitative methods used?
    - Data analysis technique and procedure?
2. Sample:
    - Sample size?
    - Sample characteristics?
    - Sample selection process?
    - Sample inclusion and exclusion criteria?
3. Reflexivity:
    - Evidence of researcher reflexivity?
4. Ethics:
    - Evidence of attention to ethical issues?
5. General criteria:
    - Are the findings adequately supported by the data presented?
    - Is there potential for a 'charisma effect' with this study? (this relates to the potential influence of the principal investigator)
    - Any other quality issues not covered by previous items?

The quality appraisal tool was integrated into the data extraction form and was applied by one researcher (DA). The quality assessments were subsequently cross-checked by another researcher (either FD or EvT). The findings and conclusions of our quality assessment are discussed in *Chapter 6*.

The analysis cycle and thematic synthesis

We developed an analysis cycle that started with coding of the qualitative data from studies linked to interventions followed by the development of initial descriptive themes and finally the development of higher-order analytical and interpretive themes and concepts. This cyclical and iterative process was conducted to identify the promising 'ingredients' of interventions that are likely to be effective in male weight reduction, both in terms of essential and necessary contextual/environmental variables and intervention processes.

Development of a thematic index

To develop a thematic index, one researcher (DA) coded the findings reported in the included qualitative studies linked to interventions line by line for content and meaning and categorised these according to whether they corresponded to the a priori themes or whether they appeared to represent emergent themes unconnected to the a priori themes.

After undertaking this process for all studies linked to interventions the coding was cross-checked by another researcher (FD). The data then underwent a second importing process within NVivo 9 into framework matrices for comparison of the a priori and emergent themes for effective and non-effective interventions. Framework matrices were used to facilitate the use of the constant comparative method to search for patterns and relationships and assist with developing theory. All qualitative researchers (DA, FD, PH and EvT) then developed the descriptive thematic index over a series of meetings, with a tree structure of themes and subthemes to enable us to remain close to the reported study findings. The thematic framework was discussed at a meeting with the Men's Health Forum representatives to ascertain service users' perspectives. The qualitative researchers decided that one of the 10 a priori themes ('Are programmes deliberately involving partners/families more effective?') was not supported by the data and it was rejected. To develop a thematic index, one researcher (DA) coded the findings reported in the qualitative studies line by line.

The development of interpretive themes

We then generated a more refined set of interpretive themes from the a priori and emergent themes for the effective management of obesity in men and the barriers to and facilitators of engaging in weight management programmes. In meta-ethnography these are described as 'third-order interpretations'.[81] Following the completion of the analytical cycle for studies linked to interventions, the theoretical studies not linked to interventions were then read to ascertain whether they provided disconfirming evidence or added any new perspectives and all relevant data from these studies were extracted. This process was conducted to test the robustness of the synthesis and has been recommended in previous narrative synthesis methods literature.[82]

The final stage of the analysis involved integrating the qualitative findings with findings from the quantitative reviews. This was achieved through a process of in-depth reading of each results chapter by all members of the research group to identify where qualitative findings were supported or refuted by quantitative findings. The supporting or disconfirming quantitative data were then integrated into the findings.

Researcher perspectives

It is important to be aware of the researchers' backgrounds and associated perspectives when interpreting our findings. DA is a health services researcher with a background in sociology and mixed-methods research methodologies. FD is a public health researcher with a background in health promotion and nursing, with an interest in health inequalities and the social determinants of health outcomes and behaviours. EvT is a medical sociologist with a background in qualitative and mixed-methods research and an interest in public health in general and health promotion in particular. PH is an academic general practitioner (GP) with expertise in qualitative and mixed-methods research, particularly when applied to RCTs of complex interventions. None of the qualitative researchers can be considered obese. Throughout the study reflexivity took place through weekly research team discussions until a consensus was reached.

Chapter 3 Systematic reviews of men-only randomised controlled trials and randomised controlled trials with data for men and women compared

In this chapter we present two systematic reviews. The first is a systematic review of RCTs of interventions (lifestyle and/or the UK-licensed medication orlistat) in any setting with men only who are obese with a BMI of ≥ 30 kg/m^2 (or overweight with a BMI of ≥ 28 kg/m^2 and cardiac risk factors based on orlistat guidance) and for which there are follow-up data for at least 1 year.

The second is a systematic review of RCTs of interventions (as above) in any setting with both men and women who are obese with a BMI of ≥ 30 kg/m^2 (or overweight with a BMI of ≥ 28 kg/m^2 and cardiac risk factors based on orlistat guidance) in which the results are presented separately for men and women in the same trial. We use trials with both men and women to look for differences in effectiveness.

Quantity of evidence

Our primary literature search identified 5498 potentially relevant titles and abstracts (*Figure 1*). In addition to this, we identified 17 potentially relevant reports from other sources, such as commercial organisations and expert opinion. We selected 255 reports for full-text assessment, of which 11 RCTs[83–93] were included in the review of men-only RCTs and 20 RCTs[94–113] were included in the review of RCTs of men and women, along with six reports[114–119] linked to the review of men-only RCTs and six reports[120–125] linked to the review of RCTs of men and women.

Review of men-only randomised controlled trials

Number and type of studies

Eleven RCTs including men only were identified as eligible for inclusion, nine of which investigated weight-loss interventions.[83,85–87,89–93] One trial examined a reducing diet for weight loss.[93] Three trials investigated the type of reducing diet to use.[83,87,91] Three trials looked at the use of physical activity in weight reduction.[91–93] Three trials examined a diet plus behaviour therapy and exercise advice for weight loss.[85,89,90] Jeffery and colleagues[86] investigated the use of various monetary contracts for individual or group weight loss. Two trials investigated exercise or behaviour change training for weight maintenance.[84,88] The weight-maintenance trial conducted by King and colleagues[88] randomised men who had received active weight-loss interventions in the trial by Wood and colleagues.[93] This was the only weight-maintenance trial found that was linked to one of the eligible weight-loss intervention trials identified by our screening process. Details of the interventions investigated by the individual trials are presented in *Table 3*. None of the trials reported involving male service users in the design of the intervention. The period of follow-up for all of the trials ranged from 12 to 36 months (median 15 months), with five trials[83,88,89,92,93] having a follow-up period of 1 year only.

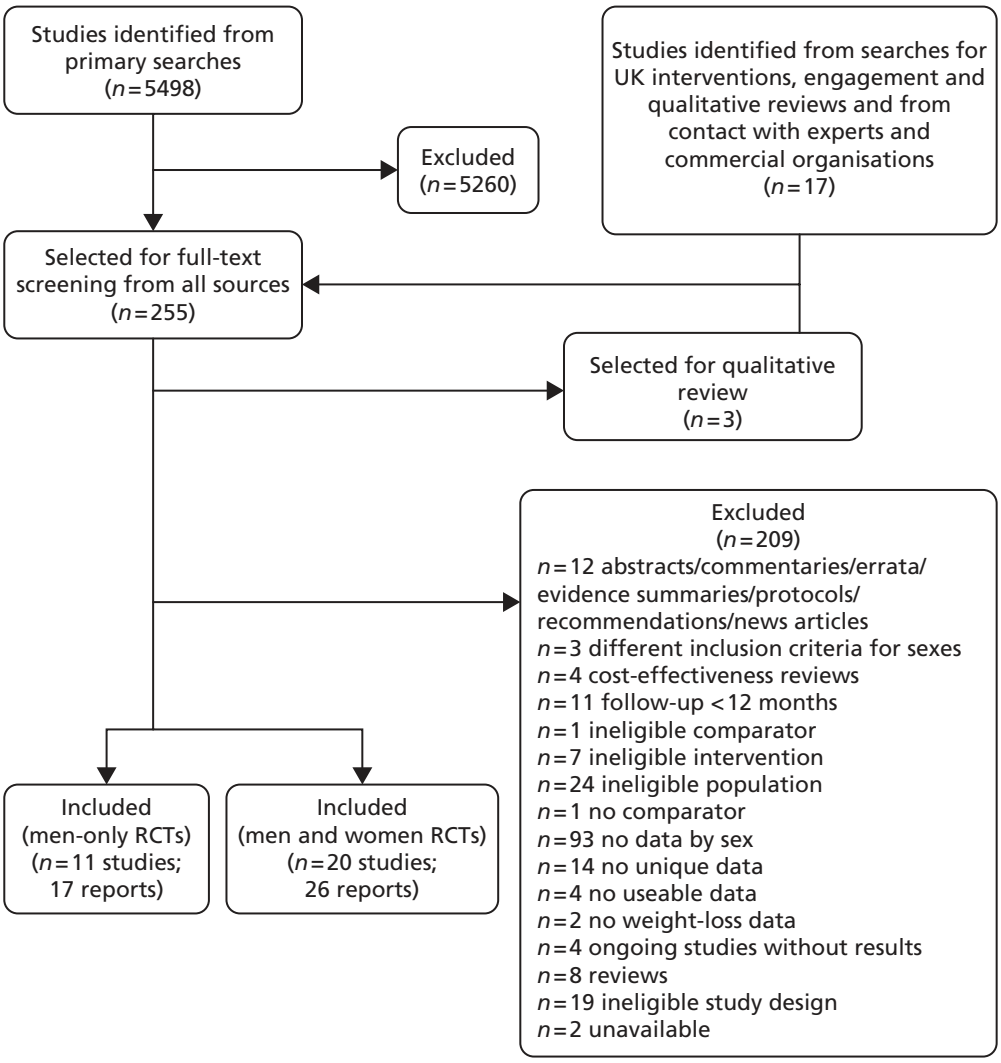

FIGURE 1 Flow chart of the number of potentially relevant reports and the numbers subsequently included and excluded from the reviews.

TABLE 3 Characteristics of the trials included in the review of men-only RCTs

Study ID	Participants	Interventions	Outcomes	Notes
Benassi-Evans 2009[83]	Location: One nutrition clinic in Adelaide, Australia Period of study: NR Inclusion criteria: Male, age 20–65 years, BMI 27–40 kg/m^2, at least one cardiovascular disease risk factor other than obesity Exclusion criteria: History of metabolic or coronary disease, type 1 or 2 diabetes Age (years), mean (SEM): a: 54.94 (1.17); b: 52.94 (1.5) BMI (kg/m^2), mean (SEM): a: 32.42 (0.79); b: 31.47 (0.96) Weight (kg), mean (SEM): a: 99.84 (2.45); b: 99.58 (3.61) Baseline comparability: Yes	Description of interventions: a: High-protein (red meat) diet comprising 35% protein, 40% carbohydrate, 25% fat, 7 MJ with some adjustment in energy to achieve approximate weight loss of 1 kg per week b: High-carbohydrate diet comprising 17% protein, 58% carbohydrate, 25% fat, 7 MJ with some adjustment in energy to achieve approximate weight loss of 1 kg per week Timing of active intervention: a + b: 0–12 weeks intensive weight loss with fortnightly clinic visits followed by monthly weight-maintenance visits up to 1 year No. of times contacted: a + b: 15 No. allocated: a: 16; b: 17 No. completed: a: 16; b: 17 Dropout (%): 0 No. assessed: a: 16; b: 17	Length of follow-up: 1 year Outcome: Weight	

continued

TABLE 3 Characteristics of the trials included in the review of men-only RCTs (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Borg 2002,[84] Kukkonen-Harjula 2005[116]	Location: Single research clinic, Finland Period of study: NR Inclusion criteria: age 35–50 years, BMI 30–40 kg/m^2, waist circumference > 100 cm, clinically healthy other than obesity Exclusion criteria: Regular medication, participation in leisure time exercise more than twice weekly, smoker, resting blood pressure > 160/105 mmHg Age (years), mean (SD): a + b + c: 42.6 (4.6) BMI (kg/m^2) (after 2 months of very low-calorie diet and before randomisation), mean (SD): a: 33.1 (2.7); b: 33.3 (2.8); c: 32.4 (2.4) Weight (kg), mean (SD): a + b + c: 106.0 (9.9) Baseline comparability: Yes	Description of interventions: All men participated in a 2-month weight reduction programme consisting of a very low energy diet (Nutrilett, Leiras Oy, Turku, Finland) of 2 MJ per day for 8 weeks followed by a low energy diet of 5 MJ per day. Men attended small group weekly meetings led by a nutritionist. Men were then randomised to groups a, b and c: a: Control: Men advised not to increase their physical activity b: Walking: An exercise instructor supervised one group training session per week – 10-minute warm-up + 45 minutes' training + 5-minute cool down. Heart rate monitors used to ensure target training intensity of 60–70% maximum oxygen consumption. Energy expenditure per exercise session 1.7 MJ c: Resistance exercise: An exercise instructor supervised one group training session per week – 10-minute warm-up + 45 minutes' training + 5-minute cool down. Resistance load set at 60–80% of one repetition maximum with eight repetitions and three sets in each exercise. Each session included six exercises aimed at large muscle groups. Energy expenditure per exercise session 1.2 MJ	Length of follow-up: 21 months Outcomes: BMI, WHR, LDL and HDL cholesterol, systolic and diastolic blood pressure, fasting plasma glucose	

Study ID	Participants	Interventions	Outcomes	Notes
		Men continued to meet weekly in small groups in their intervention group throughout the 6-month weight-maintenance phase. Men in all groups were given the same instruction to follow ad libitum a high-carbohydrate, low-fat diet and received written material. No special instructions for diet or physical activity were given during follow-up after the weight-maintenance period Timing of active intervention: 6 months (preceded by 2-month pretreatment phase) No. of times contacted: a: 24 times, weekly for 6 months; b + c: 96 times, with exercise sessions up to three times per week for 6 months No. allocated: a: 30; b: 30; c: 30 No. completed: a: 22; b: 20; c: 26 Dropout (%): a: 27; b: 33; c: 13 No. assessed: a: 22; b: 20; c: 26	

continued

TABLE 3 Characteristics of the trials included in the review of men-only RCTs (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Esposito 2004[85]	Location: One university hospital, Naples, Italy Period of study: 2000–3 Inclusion criteria: Age 35–55 years with erectile dysfunction (IIEF-5 score < 22), no participation in diet reduction programmes within previous 6 months, sedentary (< 1 hour per week physical activity), BMI ≥ 30 kg/m^2 Exclusion criteria: Diabetes mellitus/ impaired glucose tolerance, impaired renal function/ macroalbuminuria, pelvic trauma, prostatic disease, peripheral neuropathy, hypertension, cardiovascular disease, psychiatric problems, drug/alcohol abuse, taking medication for erectile dysfunction Age (years), mean (SD): a: 43 (5.1); b: 43.5 (4.8) BMI (kg/m^2), mean (SD): a: 36.4 (2.3); b: 36.9 (2.5) Baseline comparability: Yes	Description of interventions: a: General oral and written advice regarding healthy food choices and exercise given at baseline b: Group sessions led by a nutritionist and exercise trainer providing individually tailored advice about reducing calorie intake, goal setting and self-monitoring to achieve a 10% reduction in body weight. Dietary advice and guidance for increasing physical activity tailored to each individual man. Behavioural and psychological counselling offered. Diet composition per 1000 kcal comprised carbohydrate 50–60%, protein 15–20%, total fat < 30% and fibre 18 g Timing of active intervention: a + b: 2 years – monthly visits for year 1, bimonthly visits for year 2 No. of times contacted: a + b: 18 No. allocated: a: 55; b: 55 No. completed: a: 52; b: 52 Dropout (%): a: 5.5; b: 5.5 No. assessed: a: 55; b: 55	Length of follow-up: 2 years Outcomes: Weight, BMI, total cholesterol, HDL cholesterol, triglycerides, systolic and diastolic blood pressure, erectile function, glucose	The trial objective was to determine the effect of weight loss and increased physical activity on erectile function in obese men

Study ID	Participants	Interventions	Outcomes	Notes
Jeffery 1983,[86,114] Jeffery 1984[117]	Location: One university research centre, MN, USA Period of study: 1974–5 Inclusion criteria: Age 35–75 years, self-reported body weight > 30 lb (13.6 kg) above ideal weight Exclusion criteria: Uncontrolled diabetes, heart disease, concurrent dietary or psychological treatment, self-report of six or more alcoholic drinks per day Age (years), mean: a: (i) 52.0, (ii) 53.8, (iii) 52.4; b: (i) 54.1, (ii) 50.5, (iii) 53.8 BMI (kg/m^2), mean: a: (i) 30.5, (ii) 31.8, (iii) 32.8; b: (i) 31.0, (ii) 32.3, (iii) 32.7 Weight (kg), mean: a: (i) 93.07, (ii) 99.38, (iii) 104.83; b: (i) 96.17, (ii) 102.87, (iii) 107.86 Baseline comparability: Yes	Description of interventions: All groups participated in a 15-week educational programme emphasising reduced eating and increased exercise equally. Three levels of monetary deposit were made at the first meeting a: Individual monetary contracts: (i) US$30, (ii) US$150, (iii) US$300 b: Group monetary contracts: (i) US$30, (ii) US$150, (iii) US$300 Refunds at a rate of US$1, US$5 or US$10 per pound, up to a maximum cumulative weight loss of 2 lb per week. Individual contracts based on individual weight loss. Group contracts based on average group weight loss Timing of active intervention: 0–15 weeks No. of times contacted: a + b: 16 No. allocated: a: (i) 16, (ii) 15, (iii) 14; b: (i) 17, (ii) 14, (iii) 13 No. completed: a: (i) 16, (ii) 14, (iii) 14; b: (i) 17, (ii) 13, (iii) 12 Dropout (%): a: 2.2; b: 4.5 No. assessed: a: (i) 16, (ii) 15, (iii) 14; b: (i) 17, (ii) 14, (iii) 13	Length of follow-up: 2 years Outcome: Weight	1-year data reported in Jeffery *et al.*;[86] 2-year data reported in Jeffery *et al.*[117]

continued

TABLE 3 Characteristics of the trials included in the review of men-only RCTs (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Khoo 2011[87]	Location: Community, Adelaide, Australia Period of study: June 2007–May 2008 Inclusion criteria: BMI > 30 kg/m^2, waist circumference ≥ 102 cm, type 2 diabetes mellitus, HbA_{1c} on diet or oral medication stable for 3 months ≤ 7% Exclusion criteria: Smoker, previous or current treatment for sexual problems or lower urinary tract symptoms, glomerular filtration rate < 60 ml per minute, alcohol > 500 g per week in previous 12 months Age (years), mean (SD): a: 58.1 (11.4); b: 62.3 (5.9) BMI: NR Weight (kg), mean (SD): a: 112.7 (19.2); b: 109.6 (14.9) Baseline comparability: Poorer IIEF-5 score in a	Description of interventions: a: Low-calorie diet: Total intake of 900 kcal per day from two liquid meal replacements consumed daily (Kicstart, Pharmacy Health Solutions), providing a maximum of 450 kcal, 0.8 g protein per kg of ideal body weight and the recommended daily allowance of vitamins, minerals and omega 3 and 6 fatty acids, plus one other small meal. After 8 weeks men changed to follow b b: High-protein, low-fat diet: Daily energy reduction of approximately 600 kcal per day. Daily consumption of 300 g lean meat, poultry or fish, three servings of cereals/breads and low-fat dairy and two servings of fruit and vegetables All men received a written plan with diet information, a menu plan, recipes and advice for cooking and eating out and all maintained their usual daily activity levels Timing of active intervention: a + b: 1 year No. of times contacted: a + b: 16–29 No. allocated: a: 19; b:12 No. completed: a: 9; b: 7 Dropout (%): a: 52.63; b: 41.67 No. assessed: a: 9; b:7	Length of follow-up: 1 year Outcomes: Weight, waist circumference, erectile function, adverse events	

Study ID	Participants	Interventions	Outcomes	Notes
Morgan 2011[89]	Location: One university centre, University of Newcastle, Australia Period of study: 2007–8 Inclusion criteria: BMI 25–37 kg/m^2 Exclusion criteria: History of major medical problems preventing physical activity, recent weight loss of $\geq$ 4.5 kg, taking medications that might affect body weight Age (years), mean (SD): a: 34 (11.6), b: 37.5 (10.4) BMI (kg/m^2), mean (SD): a: 30.5 (3.0), b: 30.6 (2.7) Weight (kg), mean (SD): a: 99.2 (13.7); b: 99.1 (12.2) Baseline comparability: Yes	Description of interventions: a: Researcher delivered one 60-minute face-to-face weight-loss information session. Participants given a self-help weight-loss programme booklet b: Researcher delivered one 75-minute information session (60 minutes on weight loss + 15 minutes' internet instruction). Participants given self-help weight-loss programme booklet and 3 months' online support from the study website, Calorie King. Participants received personalised online feedback and responses to any questions posted on the website noticeboard, including anecdotes and weight-loss strategies for men Weight-loss information sessions in both groups covered instruction relating to the modification of diet and physical activity habits and behaviour change, based on Bandura's social cognitive theory Timing of active intervention: 3 months No. of times contacted: a: four times for 3-monthly assessments; b: 11 times for 3-monthly assessments and seven feedback sessions No. allocated: a: 31; b: 34 No. completed: a: 20; b: 26 Dropout (%): a: 35.5; b: 23.5 No. assessed: a: 31; b: 34	Length of follow-up: 12 months Outcomes: Weight change, waist circumference, BMI, systolic and diastolic blood pressure	

continued

TABLE 3 Characteristics of the trials included in the review of men-only RCTs (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Patrick 2011[90]	Location: Universities of California, and San Diego, San Diego State, USA Period of study: February 2004–March 2005 Inclusion criteria: BMI ≥ 25 kg/m^2, age 25–55 years Exclusion criteria: NR Age (years), mean (SD): a: 42.8 (8.0); b: 44.9 (7.8) BMI (kg/m^2), mean (SD): a: 34.3 (4.0); b: 34.2 (4.2) Weight (kg), mean (SD): a: 104.6 (15.3); b: 104.7 (15.3) Baseline comparability: Yes	Description of interventions: a: Wait list/general internet advice: Participants given access to a website giving general male health advice that was unlikely to produce a change in diet or physical activity (e.g. stress, hair loss, worksite injury prevention). Men were given the option to swap to the weight-loss intervention after 12 months b: Internet-based diet and physical activity advice and behavioural support; based on social cognitive theory and informed by the behavioural determinants model and designed to improve diet and physical activity in five key areas to promote weight loss, rather than directly targeting calorie restriction: increase fruit and vegetable intake to five to nine servings per day, decrease saturated fat intake to ≤ 20 g per day, increase wholegrain intake to three or more servings per day, increase physical activity to > 10,000 steps per day using a pedometer for at least 5 days per week and participate in upper and lower body strength training at least twice per week Men met with a case manager to set goals at baseline and completed weekly web-based activities, including behaviour change skills and reading diet and physical activity information. Men also had the opportunity to e-mail study experts (dietitian, physical activity expert and a clinical psychologist). Both groups paid US$20 for completing 6 months and US$100 for completing 12 months	Length of follow-up: 12 months Outcomes: weight, BMI	Trial conducted focus groups with men and two weight-loss experts to tailor the intervention for men (not published)

Study ID	Participants	Interventions	Outcomes	Notes
		Timing of active intervention: 12 months No. of times contacted: a: 3; b: 55 No. allocated: a: 217; b: 224 No. completed: a + b: 309 Dropout (%): a + b: 29.9 No. assessed: a: 217; b: 224		
Pavlou 1989[91] (main trial)	Location: One university centre, Boston University Medical Centre, MA, USA Period of study: NR Inclusion criteria: Male, age 26–52 years, euthyroid, free from any physical, psychological or metabolic impairment Exclusion criteria: NR Age (years), mean (SD): a: 41.5 (7.59); b: 42.9 (6.63); c: 45.1 (10.0); d: 49.6 (8.4); e: 41.8 (10.44); f: 41.8 (7.57); g: 46.1 (9.33); h: 44.5 (9.6) (completers) BMI (kg/m^2), mean: a: 32.54; b: 32.4; c: 32.07; d: 31.5; e: 30.13; f: 34.82; g: 31.89; h: 33.78 (completers)	Description of interventions: Subjects were randomly assigned to four diets and exercise and non-exercise groups for 8 weeks Exercise consisted of a 90-minute supervised exercise programme three times a week from baseline to week 8, which consisted of 35–60 minutes of aerobic activity, e.g. walk–jog–run (70–85% max. heart rate), calisthenics and relaxation techniques. Non-exercise groups were instructed to continue normal daily activity and not to participate in any form of additional supervised and/or unsupervised physical activity during the initial 8 weeks a: Balanced caloric-deficit, low-calorie diet (BCDD). 1000 kcal per day selected from usual four food groups in quantities thought to meet basic requirements	Length of follow-up: 18 months Outcomes: Weight, total cholesterol, HDL cholesterol, triglycerides, systolic and diastolic blood pressure	

continued

TABLE 3 Characteristics of the trials included in the review of men-only RCTs (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
	Weight (kg), mean, SEM (SD): a: 103.1, 3.1 (9.80); b: 105.0, 4.4 (14.59); c: 100.8, 2.3 (9.2); d: 98.8, 2.6 (10.4); e: 96.1, 3.3 (10.44); f: 103.0, 3.7 (13.34); g: 100.8, 2.3 (9.76); h: 105.7, 3.4 (13.6) (completers) Baseline comparability: Yes	b: BCDD + exercise c: Protein-sparing modified fast, low carbohydrate (PSMF). Ketogenic diet of meat, fish and fowl used as only dietary source to provide equivalent of 1.2 g high biological value protein per kg of ideal body weight or 1000 kcal per day, no carbohydrate and all fat ingested from meat, fish and fowl. Participants prescribed 2.8 g potassium chloride daily d: PSMF + exercise e: DPC-70: A very low-calorie diet of 420 kcal powdered protein carbohydrate mix derived from calcium caseinate, egg albumin and fructose, formulated with vitamins and minerals to meet the US recommended dietary allowances (RDA) dissolved in water or other non-caloric liquid. Fat content zero. Participants instructed to consume five packets a day and to consume no other nutrients. Participants prescribed 2.8 g potassium chloride daily f: DPC-70 + exercise g: DPC 800: A very low-calorie diet of 800 kcal per day provided in powdered form consumed similarly to DPC-70, providing a complete mixture of nutrients and similar nutritionally to BCDD except for fewer calories		

Study ID	Participants	Interventions	Outcomes	Notes
		h: DPC-800 + exercise All participants attended weekly education sessions up to week 8 that included behaviour modification, diet and general nutrition and exercise education. All participants were given multivitamins and daily food and activity records up to week 8. Non-caloric liquids, including coffee, were allowed in unrestricted amounts Timing of active intervention: 8 weeks + 18 months' follow up No. of times contacted: a–h: 11 times, weekly 0–8 weeks then at 8 and 18 months No. allocated: 160 men (20 in each intervention group) No. completed: a: 10; b: 11; c: 16; d: 16; e: 10; f: 13; g: 18; h: 16 (18 months post treatment) Dropout (%): 31 (18 months) No. assessed: a: 10; b: 11; c: 16; d: 16; e: 10; f: 13; g: 18; h: 16 (18 months; completers)		

continued

TABLE 3 Characteristics of the trials included in the review of men-only RCTs (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Pavlou 1989[91] (pilot)	Location: As above Period of study: As above Inclusion criteria: As above Exclusion criteria: As above Age (years), mean (SD): a: 49.2 (6.48); b: 44.8 (7.84); c: 46.1 (5.14); d: 48.1 (4.65) (data for completers) BMI (kg/m^2), mean: a: 31.75; b: 31.92; c: 31.11; d: 30.4 (completers) Weight (kg), mean (SEM): a: 102.3 (2.1); b: 99.2 (4.2); c: 101.7 (3.1); d: 97.3 (4.1) Baseline comparability: Yes	Description of interventions: As above but a, b, c and d only Timing of active intervention: 12 weeks No. of times contacted: 16 times, weekly 0–12 weeks and then at 6, 18 and 36 months No. allocated: a–d: 24 No. completed: a: 5; b: 6; c: 5; d: 5 (36 months post treatment) Dropout (%): 13 (36 months post treatment) No. assessed: a: 5; b: 6; c: 5; d: 5 (36 months post treatment)	Length of follow-up: 162 weeks Outcome: Weight	
van Aggel-Leijssen 2001,[92] van Aggel-Leijssen 2002,[118] Lejeune 2003[119]	Location: One university research department, Maastricht, the Netherlands Period of study: Not reported Inclusion criteria: Good health, ≤ 2 hours per week of sports activities, stable body weight over previous 3 months (< 3 kg change)	Description of interventions: a: 12-week energy restriction period followed by 40-week weight-maintenance period: Weeks 1–6: Very low energy diet of 2.1 MJ per day protein-enriched formula diet (Modifast, Novartis) consisting of 50 g carbohydrate, 52 g protein, 7 g fat	Length of follow-up: 52 weeks Outcomes: Weight, BMI	

Study ID	Participants	Interventions	Outcomes	Notes
	Exclusion criteria: Physically demanding job, taking medication known to influence measured variables Age (years), mean (SD): a: 38.6 (6.5); b: 39.3 (7.7) BMI (kg/m^2), mean (SD): a: 32.0 (2.1); b: 32.6 (2.5) Weight (kg), mean (SD): a: 103.6 (11.7); b: 102.6 (9.8) Baseline comparability: Yes	Weeks 7–8: 1.4 MJ per day formula + 3.5 MJ per day free choice Weeks 9–10: 0.7 MJ per day formula + 4.9 MJ per day free choice Weeks 11–12: Participants received dietary instruction to stabilise their body weight and not to change their habitual activity pattern b: 12-week energy restriction period (as in a) combined with an exercise training programme [40% maximal oxygen consumption (VO_2 max.)] for 1 hour, four times a week – cycling, walking or aqua-jogging (three sessions supervised by a personal trainer in the lab and one session at home). Exercise training programme continued during the weight-maintenance period to week 52 Timing of active intervention: a: weeks 0–12; b: weeks 0–12 No. of times contacted: a: 12 times at weekly intervals; b: 168 times up to four times per week for 52 weeks No. allocated: a: 20; b: 20 No. completed: a: 15; b: 14 Dropout (%): a: 25; b: 30 No. assessed: a: 15; b: 14		

continued

TABLE 3 Characteristics of the trials included in the review of men-only RCTs (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Wood 1988,[93] Fortmann 1988[115]	Location: One research centre, Stanford, CA, USA Period of study: NR Inclusion criteria: 120–160% ideal body weight, non-smoker, plasma total cholesterol < 8.28 mmol/l, triglycerides < 5.65 mmol/l, normal electrocardiogram, alcohol intake less than four drinks per day, sedentary activity, weight stable (±5 lb) over the past year Exclusion criteria: Blood pressure > 160/100 mmHg, taking medications affecting lipids, plasma cholesterol > 300 mg/dl, triglycerides > 500 mg/dl, exercise three or more times per week Age (years), mean (SD): a: 45.2 (7.2); b: 44.2 (8.2); c: 44.1 (7.8) BMI: NR Weight (kg), mean (SD): a: 95.4 (10.6); b: 93.0 (8.8); c: 94.1 (8.6) Baseline comparability: Yes	Description of interventions: a: Control: Weight stable, no added energy restriction or exercise b: Diet: Energy restriction (reduced food quantity but not proportions of fat, carbohydrate, protein and alcohol). Energy intake reduced by 300–500 kcal per day depending on weight-loss goals, energy needs and baseline food intake to achieve approximately 0.3–0.6 kg fat loss per week. No added exercise weight-loss goals c: Exercise: Increased activity with instruction to maintain exercising heart rate of 65–85% of peak heart rate (approx. caloric output of 8–10 cal per minute). Supervised sessions three times per week starting with fast walking for 25 minutes, gradually adding jogging for 0–3 months with continuous jogging increasing to 40–50 minutes. Two additional days of unsupervised walking or jogging added by month 6. Programme aimed to decrease body fat by 2–3 kg in the first 3 months, 4–5 kg in months 3–6 and the remainder in months 6–9 Timing of active intervention: b + c: 0–9 months No. allocated: a: 52; b 51; c: 52 No. completed: a: 51; b: 49; c: 49 Dropout (%): a 1.9%; b: 5.8%; c: 3.9% No. assessed: a: 44; b: 41; c: 36	Length of follow-up: 1 year Outcomes: Mean change in weight, mean change in systolic and diastolic blood pressure	

Study ID	Participants	Interventions	Outcomes	Notes
King 1989[88] (continuation of Wood 1988[93])	At the end of the 1-year trial phase[93] participants from groups a and b were randomised within intervention groups to weight-maintenance follow-up interventions Age (years), mean (SD): a: (i): 45.5 (9.6), (ii): 44.4 (4.8); b: (i) 46.1 (7.6); (ii) 42.9 (7.3) BMI: NR Weight (kg), mean (SD): a: (i): 85.7 (9.1), (ii): 83.4 (8.8); b: (i): 91.0 (10.6), b (ii): 86.2 (7.6) Baseline comparability: Yes	Description of interventions: a (i): Diet mail and telephone contact. Participants received monthly mailings consisting of a supportive letter, self-scored assessment of an energy restriction problem area and list of energy restriction coping suggestions (e.g. holiday eating, emotional eating, eating away from home, stress eating). Mailings supplemented by telephone calls monthly for the first 3 months, then at 6, 9 and 12 months a (ii): Diet control. Participants received no mailings or telephone calls b (i): Exercise mail and telephone contact. As in a (i) but self-scored assessment of an exercise problem area and list of exercise coping strategies (e.g. time pressure, boredom, illness or injury) b (ii): Exercise control [as in a (ii)] At the beginning of the weight-maintenance phase, participants in all groups were given written information for the weight control method that they received during the weight-loss trial period and were encouraged to seek support from members of their original intervention group	Length of follow-up: 1 year Outcome: Mean change in weight	

continued

TABLE 3 Characteristics of the trials included in the review of men-only RCTs (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
		Timing of active intervention: 1-year weight-maintenance phase following end of 1-year weight-loss phase No. of times contacted: a: three times at 6-monthly intervals; b: 21 times at monthly intervals No. allocated: a: (i) 24, (ii) 20; b: (i) 24, (ii) 22 No. completed: a: (i) 20, (ii) 16; b: (i) 21, (ii) 15 Dropout (%): a: (i) 16.7, (ii) 20%; b: (i) 12.5, (ii) 31.8 No. assessed: a: (i) 20, (ii) 16; b: (i) 21, (ii) 15		

BCDD, balanced caloric-deficit, low calorie diet; IIEF-5, International Index of Erectile Function – 5; NR, not reported; PSMF, protein-sparing modified fast, low carbohydrate; SEM, standard error of the mean; VLCD, vey low-calorie diet; WHR, waist-to-hip ratio.

The trials conducted by Jeffery and colleagues,[86] Patrick and colleagues,[90] Pavlou and colleagues[91] and Wood and colleagues[88,93] were carried out in the USA. Trials conducted by Benassi-Evans and colleagues,[83] Khoo and colleagues[87] and Morgan and colleagues[89] were carried out in Australia; and studies conducted by Borg and colleagues,[84] Esposito and colleagues[85] and van Aggel-Leijssen and colleagues[92] were conducted in Finland, Italy and the Netherlands respectively. All trials were single-centre RCTs. Seven trials reported interventions aimed at men individually.[83,87–92] Men received group interventions in three trials.[84,85,93] Only one trial[86] directly compared the effectiveness of group and individual interventions. Details of the exact settings for the trials were generally not well described; most appeared to be in a research setting. Only the trial by Esposito and colleagues[85] appears to have been conducted in a outpatient health service setting. One trial was conducted amongst university staff[89] whereas Pavlou and colleagues[91] recruited public sector workers, including those in the police department.

When e-mail addresses were valid,[84–86,89] we contacted the authors requesting any additional relevant reports and publications as well as any process or qualitative evaluations that they may have published elsewhere. Of these, only the SHED-IT (Self-Help, Exercise and Diet using Information Technology)[89] study authors replied. We did not identify any additional eligible publications for inclusion in any of our reviews, other than those we had already identified.

Characteristics of the men

Men were mainly recruited through mass media advertising.[83,84,87,90,92,93] Two studies recruited men through the workplace (university staff in the SHED-IT trial[89] and the police department and Metropolitan District Commission in the trial by Pavlou and colleagues[91]) and one study[85] recruited men from a hospital outpatient clinic for weight loss. The studies conducted by Jeffery and colleagues[86] and King and colleagues[88] recruited men from ongoing RCTs.[93,114] All studies reported mean age, weight and, with the exception of that by King and colleagues,[88] BMI at baseline. Excluding data from the trial conducted by King and colleagues,[88] because of overlap of the participants with those in the trial by Wood and colleagues,[93] the majority of men were middle-aged with trials' median (range) age of 46 years (36–62 years), weight of 101.5 kg (93.0–112.7 kg) and BMI of 32.4 kg/m^2 (30.1–36.9 kg/m^2). A total of 1238 men were allocated to an intervention with 1098 included in the trial analyses. Details of the inclusion/exclusion criteria for the individual trials are presented in *Table 3*.

Overview of types of outcomes reported

Quantitative outcomes

All studies reported either baseline and end weights or changes in weight. Four studies reported change in BMI.[84,85,89,92] Three studies reported waist circumference[87,89,90] and one reported waist-to-hip ratio.[85]

For cardiovascular risk factors, only two studies reported total cholesterol,[85,91] three studies reported HDL cholesterol,[84,85,91] one study reported LDL cholesterol,[84] two studies reported triglycerides[85,91] and three studies reported systolic and diastolic blood pressure.[84,85,89] Systolic and diastolic blood pressure data for the trial by Wood and colleagues[93] were reported in a linked publication.[115] The trials by Borg and colleagues[84] and Esposito and colleagues[85] reported results for fasting plasma glucose.

Only two trials reported a male-specific disease outcome: erectile function following weight loss.[85,87] One trial[92] reported adverse events and one trial[84] reported lack of adverse events. The trials did not report quality of life, HbA_{1c} levels or any economic outcomes.

Quality of the evidence

Risk of bias

The risk of bias assessment for the individual trials is shown in *Appendix 8* (see *Table 56*). *Figure 2* summarises the assessment.

It was unclear whether random sequence generation was adequate in all but three studies,[89,90,93] which were judged to have adequately randomised participants. Five studies[84,85,90,91,93] were judged to have successfully concealed allocation, whereas this was unclear in the remaining trials. No trial was able to carry out blinding of participants and the majority did not blind health-care providers, although this item was uncertain in the trial by Benassi-Evans and colleagues[83]. This is because blinding of participants and health-care providers would have largely been impossible because of the nature of the interventions considered by the trials. Four trials did blind outcome assessors,[85,88–90] whereas the trial conducted by Borg and colleagues[84] did not. It was unclear whether outcome assessors were blinded in the remaining trials.

The majority of the trials (10/11, 90.9%) were judged to have treated participants similarly apart from the given intervention in each arm of the trial, with only the trial conducted by Esposito and colleagues[85] causing uncertainty for this item. Over half of the trials were judged to be at low risk for incomplete outcome data,[84–87,89,92] with this item being unclear in the other trials.[83,88,90,91,93] Only four trials[85,86,89,90] carried out intention-to-treat analysis with the majority (6/11, 54.5%) of the trials analysing data for trial completers only. It was unclear whether or not an intention-to-treat analysis was carried out in the trial conducted by Benassi-Evans and colleagues.[83]

The trial by Khoo and colleagues[87] was judged to be at high risk of selective reporting as the authors did not report HbA_{1c} outcomes. This was unclear for the SHED-IT trial[89] as outcomes considered in the trial protocol were not reported in the 6- and 12-month reports [e.g. Short Form questionnaire-12 items (SF-12) and sexual function data]. All other trials were judged to be at low risk for this item.

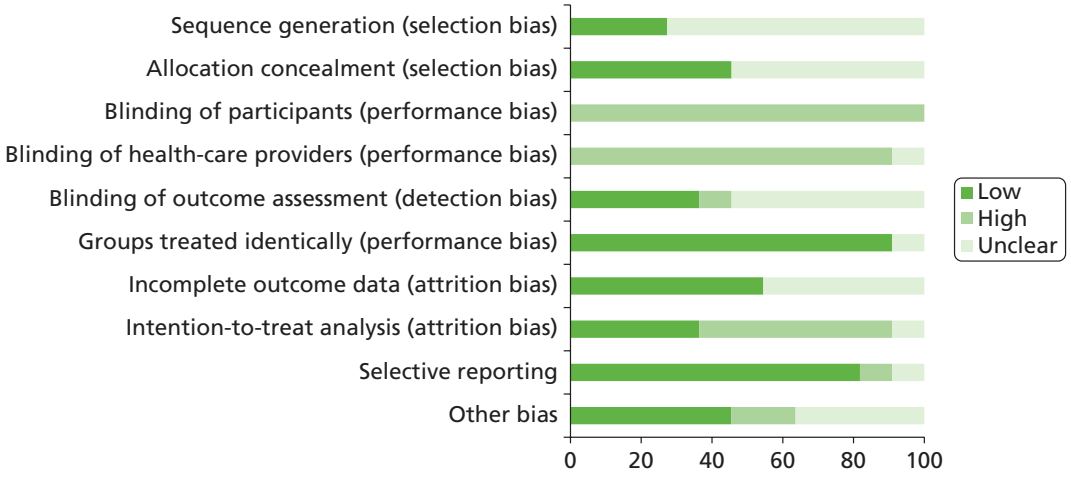

FIGURE 2 Summary of risk of bias assessment of trials included in the systematic review of men-only RCTs.

It was unclear for four studies[83,84,91,93] whether or not the trials were at risk of any other bias. Five trials[85,87,88,90,92] were judged to be at low risk for this item, with the trial by Jeffery and colleagues[86] considered to be at high risk as the participants paying larger monetary contracts in both the individual arm and the group arm had a higher mean baseline weight than the participants paying smaller deposits. The authors acknowledged that randomisation may have failed to equally distribute participants with respect to their weight. The authors also experienced difficulty recruiting people to this trial, as only 50% of those eligible signed monetary contracts. The SHED-IT trial[89] was also judged to be at high risk of other bias because of the limited generalisability of the participants, who were all staff or students recruited from a single university, and because of the potential for contamination between participants because of the work/student environment. It was unclear if the trial conducted by Pavlou and colleagues[91] was at a similar risk of workplace contamination.

Assessment of equity and sustainability

Figure 3 summarises the equity assessment. Results for the individual trials are detailed in *Appendix 8* (see *Table 57*).

The majority of equity items were not considered, were unclear or were not reported by the trial authors. The trials did not report on diversity, sustainability or political context and did not describe any partnerships.

Only three trials were considered to have been conducted in a way that could have excluded specific groups of men, therefore influencing equity of access. The trial conducted by Jeffery and colleagues[86] was considered to have excluded men who could not afford to pay a financial deposit. The SHED-IT trial[89] was also judged to have potentially limited the inclusion of non-academic men because of the university setting and the use of internet and mobile phone technologies. Similarly, the trial by Patrick and colleagues[90] required men to have internet access and to be computer literate.

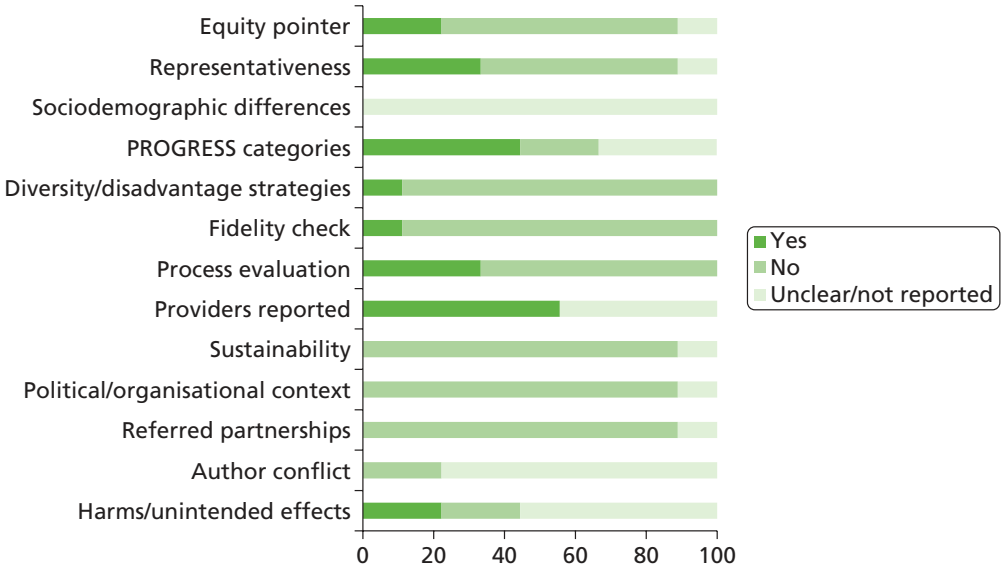

FIGURE 3 Summary of the equity and sustainability assessment of trials included in the systematic review of men-only RCTs.

Three trials considered unrepresentative samples of obese men: the trial by Esposito and colleagues[85] recruited men from a weight-loss outpatient clinic who all had erectile dysfunction; men in the SHED-IT trial[89] were all university staff or students; and men in the Pavlou trial[91] were all police officers. Similarly, the trials by Wood and colleagues[93] and King and colleagues[88] had very narrow inclusion criteria and therefore excluded a wide number of potentially relevant men from their samples. It was unclear whether or not the trial by Jeffery and colleagues[86] included a representative sample of obese men as there was insufficient detail in the report. Inclusion criteria were not reported by Patrick and colleagues.[90]

The SHED-IT trial[89] reported differences in compliance by occupation and age, with non-academic staff members and older men showing greater compliance. It is unclear whether or not any socioeconomic differences existed between withdrawals from each of the intervention groups. Patrick and colleagues[90] reported that younger, non-white men were more likely to withdraw from their trial. The remaining trials did not report on any socioeconomic differences between withdrawals and exclusions.

Only three trials[86,89,90] reported on categories relating to place of residence, race/ethnicity, occupation, gender, religion, education, socioeconomic status or social capital (PROGRESS). It was unclear in the trial by Patrick and colleagues[90] whether or not the authors had attempted to address diversity or disadvantage with their trial intervention. All other trials did not address or report these items.

Four studies[84,91–93] carried out fidelity checks for physical activity by monitoring heart rate or maximal oxygen consumption (VO_2 max.) of the men during the exercise sessions, thus ensuring that the men exercised at the required level of training intensity. The remaining studies did not report on fidelity checks, although the SHED-IT trial[89] reported qualitative data concerning the enthusiasm of men for the internet and control interventions.

Most trials[83,85,89,90,92,93] (6/11, 54.5%) reported details of who provided the interventions. The other trials did not report this item[86–88,91] or it was unclear.[84] Providers were dietitians, exercise instructors or research staff.

The trial conducted by Borg and colleagues[84] was partly funded by the Finnish pharmaceutical company Leiras Oy. As this company manufactures a weight-loss product it is unclear whether or not this created any author conflict. Patrick and colleagues[90] also reported that three of the trial authors were co-owners of Santech, Inc. (San Diego, CA, USA), which developed products related to the described research at the time of publication. Both San Diego State University and the University of California approved this arrangement in accordance with their conflict of interest policies. The other trials did not report whether or not there was potential for author conflict.

Assessment of effectiveness

An exercise programme compared with control

Wood and colleagues[93] compared men in an exercise programme with a control group of men who made no change to their diet or level of physical activity. Men in the exercise programme participated in supervised exercise three times per week in 1-hour sessions with the aim of reducing their total body fat by one-third over a 9-month period. Exercise activities included calisthenics, muscle stretching, brisk walking and jogging. At 1 year the authors reported a significant difference in weight in favour of a programme of exercise compared with the control group (no diet or exercise) (mean difference –4.60 kg, 95% CI –6.18 kg to –3.02 kg) (*Figure 4*).

FIGURE 4 Effect of an exercise programme vs. control on weight (kg).

At 1 year, exercisers significantly lowered their triglyceride levels compared with the control group (reported $p < 0.05$) and significantly improved their HDL cholesterol compared with the control group (reported $p < 0.01$) (*Table 4*). No other differences for cholesterol, LDL cholesterol or systolic or diastolic blood pressure (measured in the clinic) were reported as significant, although changes in the exercise group were all more beneficial than those in the control group.

A reducing diet compared with control

Wood and colleagues[93] also compared the control group with men who followed a reducing diet (300–500 kcal per day deficit) aimed at reducing total body fat by one-third over 9 months; this group also made no alteration to their level of physical activity. At 1 year the diet group had lost significantly more weight than the control group, with a mean difference of –7.80 kg (95% CI –9.38 kg to –6.22 kg) (*Figure 5*).

At 1 year, dieters showed significantly lower triglyceride levels (reported $p < 0.05$) and HDL cholesterol levels (reported $p < 0.001$) than the control group (*Table 5*). No other risk factor changes were reported as significantly different, although changes in the diet group were all more beneficial than changes in the control group.

TABLE 4 Mean change (SD) in cholesterol, triglycerides and blood pressure for the exercise programme group vs. the control group after 1 year

Outcome	Exercise ($n = 47$)	Control ($n = 42$)
Total cholesterol (mmol/l)	–0.25 (0.64)	–0.23 (0.65)
LDL cholesterol (mmol/l)	–0.25 (0.61)	–0.21 (0.67)
HDL cholesterol (mmol/l)	0.11 (0.15)	–0.02 (0.11) ($n = 41$)
Triglycerides (mmol/l)	–0.16 (0.53)	+0.08 (0.6)
Systolic blood pressure (mmHg)	–6.6 (8.4) ($n = 42$)	–4.1 (8.0) ($n = 35$)
Diastolic blood pressure (mmHg)	–4.1 (8.0) ($n = 42$)	–2.6 (8.1) ($n = 35$)

FIGURE 5 Effect of a reducing diet vs. control on weight (kg).

TABLE 5 Mean change (SD) in cholesterol, triglycerides and blood pressure for the reducing diet group vs. the control group after 1 year

Outcome	Diet (*n* = 42)	Control (*n* = 42)
Total cholesterol (mmol/l)	–0.36 (0.56)	–0.23 (0.65)
LDL cholesterol (mmol/l)	–0.31 (0.64)	–0.21 (0.67)
HDL cholesterol (mmol/l)	0.12 (0.16) (*n* = 41)	–0.02 (0.11) (*n* = 41)
Triglycerides (mmol/l)	–0.27 (0.72)	+0.08 (0.6)
Systolic blood pressure (mmHg)	–5.7 (7.9) (*n* = 38)	–4.1 (8.0) (*n* = 35)
Diastolic blood pressure (mmHg)	–5.6 (7.3) (*n* = 38)	–2.6 (8.1) (*n* = 35)

An exercise programme compared with a reducing diet

A reducing diet was shown to produce a significant reduction in weight compared with an exercise programme at 1 year, with a mean difference of –3.20 kg (95% CI –4.78 kg to –1.62 kg) (*Figure 6*).[93]

None of the risk factor differences between the reducing diet group and the exercise programme group (*Table 6*) were reported as statistically significant.

A low-fat reducing diet with behaviour therapy and exercise advice compared with control

Three studies examined behavioural therapy, exercise advice and low-fat reducing diets compared with a control group. In the SHED-IT trial by Morgan and colleagues,[89] participants were given support and advice through a free study website. The control group received an information booklet only. At 12 months the internet group had lost more weight than the control group, with a mean difference of –2.20 kg (95% CI –5.65 to 1.25 kg), but the difference in weight reduction was not significant.

Similarly, Patrick and colleagues[90] used the internet to deliver dietary and physical activity advice and behavioural therapy. The trial authors held interviews with two male weight-loss experts and held focus groups with men to tailor the intervention specifically for men described as overweight. The results of this developmental work showed that men wanted an intervention that was individualised, fact based, flexible and simple to understand. Men also indicated that they preferred the use of 'businesslike' language. Pedometers were provided to encourage physical activity and were enjoyed by the men for their novelty and assistance with self-monitoring of their behaviour. Men in the control group were given access to a website detailing general male-related health advice that was unlikely to lead to lifestyle changes that would promote weight loss (e.g. dealing with stress, hair loss, worksite injury prevention). Men receiving the weight-loss intervention lost more weight than men in the control group but the difference between the groups at 12 months was also not significant.

Study or subgroup	Exercise programme Mean	SD	Total	Reducing diet Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Wood 1988[93]	−4	3.9	47	−7.2	3.7	42	100.0%	3.20 (1.62 to 4.78)
Total (95% CI)			**47**			**42**	**100.0%**	**3.20 (1.62 to 4.78)**
Heterogeneity: not applicable								
Test for overall effect: z=3.97 (p<0.0001)								

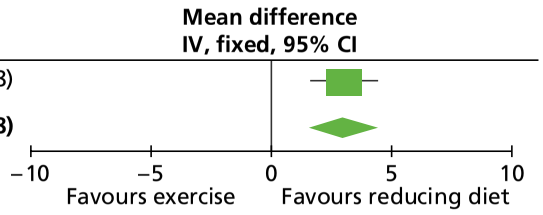

FIGURE 6 Effect of an exercise programme vs. a reducing diet on weight (kg).

Study or subgroup	Low fat, BT, exercise advice Mean	SD	Total	Control Mean	SD	Total	Weight	Mean difference IV, random, 95% CI
12 months								
Morgan 2011[89]	−5.3	7.41	34	−3.1	6.79	31	9.7%	−2.20 (−5.65 to 1.25)
Patrick 2011[90]	−0.9	6.17	224	−0.2	5.97	217	90.3%	−0.70 (−1.83 to 0.43)
Subtotal (95% CI)			**258**			**248**	**100.0%**	**−0.85 (−1.92 to 0.23)**
Heterogeneity: τ^2=0.00; χ^2=0.65, df=1 (p=0.42); I^2=0%								
Test for overall effect: z=1.54 (p=0.12)								
24 months								
Esposito 2004[85]	−15	10.16	55	−2	6.48	55	100.0%	−13.00 (−16.18 to −9.82)
Subtotal (95% CI)			**55**			**55**	**100.0%**	**−13.00 (−16.18 to −9.82)**
Heterogeneity: not applicable								
Test for overall effect: z=8.00 (p<0.00001)								

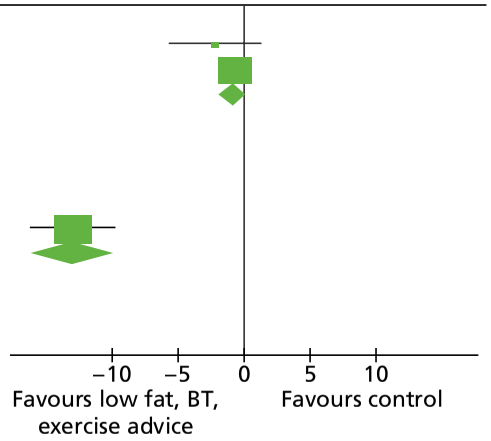

FIGURE 7 Effect of a low-fat reducing diet with behaviour therapy and exercise advice vs. control on weight (kg).

TABLE 6 Mean change (SD) in cholesterol, triglycerides and blood pressure for an exercise programme group vs. a reducing diet group after 1 year

Outcome	Exercise ($n = 47$)	Diet ($n = 42$)
Total cholesterol (mmol/l)	–0.25 (0.64)	–0.36 (0.56)
LDL cholesterol (mmol/l)	–0.25 (0.61)	–0.31 (0.64)
HDL cholesterol (mmol/l)	0.11 (0.15)	0.12 (0.16) ($n = 41$)
Triglycerides (mmol/l)	–0.16 (0.53)	–0.27 (0.72)
Systolic blood pressure (mmHg)	–6.6 (8.4) ($n = 42$)	–5.7 (7.9) ($n = 38$)
Diastolic blood pressure (mmHg)	–4.1 (8.0) ($n = 42$)	–5.6 (7.3) ($n = 38$)

The trial by Esposito and colleagues[85] examined behavioural therapy, advice on how to increase physical activity and a low-fat reducing diet. The men were recruited because they were obese and had erectile dysfunction [determined by a score of ≤ 21 on the International Index of Erectile Function (IIEF)[126]]. The men met in groups but received advice tailored to their individual requirements. The control group in this trial received general oral and written advice regarding healthy food choices and exercise at baseline only. At 2 years the intervention group had lost significantly more weight than the control group, with a mean difference of –13.00 kg (95% CI –16.18 kg to –9.82 kg) (*Figure 7*).

At 12 months the only significant difference between groups with regard to risk factors was in systolic blood pressure in favour of the intervention group (reported $p < 0.03$)[89] (*Table 7*).

At 24 months the intervention group in the trial by Esposito and colleagues[85] showed significant improvements compared with the control group for total cholesterol, triglycerides and fasting plasma glucose (reported $p \leq 0.05$). BMI, HDL cholesterol, systolic and diastolic blood pressure and waist-to-hip ratio were also significantly improved (reported $p \leq 0.01$) (see *Table 7*).

Esposito and colleagues[85] also reported that 17 out of 55 men in the intervention group compared with three out of 55 men in the control group reported an IIEF score of ≥ 22 (indicating regained sexual function; reported $p = 0.001$).

A diet and exercise programme compared with a diet only

Two trials reported the effect of adding an exercise programme to a diet compared with diet only. The trial by van Aggel-Leijssen and colleagues[92] was a small trial in which men were randomised to a diet only or a diet and exercise programme. All men followed a 10-week diet. For the first 6 weeks men followed a very low energy (500 kcal per day) formula diet (Modifast) of 50 g of carbohydrate, 52 g of protein and 7 g of fat. For weeks 7–8, men consumed 330 kcal per day of the formula diet and 840 kcal per day from foods of their choice. During weeks 9–10, men consumed 170 kcal per day of the formula diet and 1170 kcal per day from their chosen food. The men were then instructed to stabilise their body weight for weeks 11–12. Men in the diet and exercise group also participated in a low-intensity exercise programme (40% VO_2 max.) for 12 weeks, which was then continued to week 52. The men trained four times per week in 1-hour sessions. Three of these sessions were supervised by a personal trainer in the research laboratory and the other session was unsupervised at home. The exercise sessions consisted of cycling, walking and aqua-jogging. Attendance for supervised exercise sessions was 57% (SD 20%). Reasons for non-attendance included illness, holidays and work commitments. Two of the men in the exercise group

TABLE 7 Mean (95% CI) change in BMI, cholesterol, triglycerides, waist circumference and systolic and diastolic blood pressure for a low-fat reducing diet with behaviour therapy and exercise advice group vs. a control group

Outcome	Low-fat reducing diet, behaviour therapy and exercise advice	Total no. of men	Control	Total no. of men
BMI (kg/m²)				
12 months	–1.7 (–2.4 to –1.0)	34	–0.9 (–1.7 to –0.2)	31
24 months	–5.7	55	–0.7	55
Systolic blood pressure (mmHg)				
12 months	–11 (–14 to –7)	34	–6 (–10 to –2)	31
24 months	–3	55	–1	55
Diastolic blood pressure (mmHg)				
12 months	–6 (–10 to –2)	34	–4 (–9 to –1)	31
24 months	–4	55	0	55
Waist circumference (cm)				
12 months	–5.8 (–7.9 to –3.6)	34	–3.8 (–6.1 to –1.6)	31
Total cholesterol (mmol/l)				
24 months	–0.29	55	0.05	55
HDL cholesterol (mmol/l)				
24 months	0.23	55	0.03	55
Triglycerides (mmol/l)				
24 months	–0.22	55	–0.05	55
Fasting plasma glucose (mmol/l)				
24 months	–0.44	55	–0.06	55
Waist-to-hip ratio				
24 months	–0.09	55	0	55

12-month data taken from the study by Morgan and colleagues;[89] 24-month data taken from the study by Esposito and colleagues.[85]

had to withdraw from the study because of knee injuries. There were no other reported adverse events. Weight data for men at 12 months were reported in a linked report by Lejeune and colleagues.[119] Men in the diet and exercise group did not lose as much weight as men in the diet-only group (mean difference 4.20 kg, 95% CI –1.47 to 9.87 kg).

The study by Pavlou and colleagues[91] consisted of a pilot trial and the main trial. The pilot trial compared a low-calorie diet of 1000 kcal per day coupled with an exercise programme with a low-calorie diet only. The pilot trial also compared a low-calorie, low-carbohydrate diet of 1000 kcal per day plus an exercise programme with a very low-calorie diet only. The main trial compared the same two diets, with and without an exercise programme, as the pilot trial. The main trial additionally compared the effect of adding exercise to two types of very low-calorie diet (420 kcal per day and 800 kcal per day).

Combining results for all diet groups, the effect of adding an exercise programme to a diet was highly significant at 18 months (mean difference –7.63 kg, 95% CI –10.33 to –4.92 kg) and at 36 months (mean difference –8.22 kg, 95% CI –15.27 to –1.16 kg). There were no significant differences between the 1000 kcal per day low-carbohydrate diet and the 1000 kcal per day low-calorie diet, however, or for the two forms of very low-calorie diet (420 and 800 kcal per day) at 18 or 36 months (*Figure 8*).

In the main trial,[91] systolic (mean difference –8.90 mmHg, 95% CI 13.65 to –4.15 mmHg) and diastolic (mean difference –12.10 mmHg, 95% –15.20 to –9.00 mmHg) blood pressure were significantly lower in the diet and exercise groups compared with the diet only groups at 18 months.

Type of diet

A high-protein reducing diet compared with a high-carbohydrate reducing diet

The trial by Benassi-Evans and colleagues[83] compared a high-protein diet with a high-carbohydrate diet. Both diets consisted of 1670 kcal per day with some adjustment in energy to achieve an approximate weight loss of 1 kg per week. At 12 months the high-protein diet group had not lost as much weight as the high-carbohydrate diet group, although the difference between groups was not statistically significant (mean difference 1.55 kg, 95% CI –4.70 to 7.80 kg kg) (*Figure 9*).

A high-protein, low-fat diet compared with a low-calorie diet

Khoo and colleagues[87] randomised men with type 2 diabetes mellitus to a modified low-calorie diet or a high-protein, low-fat diet. By 12 months men in the low-calorie diet group had lost slightly more weight than men in the high-protein diet group (–9.5 kg vs. –9.0 kg). For both groups the men lost a significant amount of weight, reduced their waist circumference measurement and saw improvements in erectile function as measured by the IIEF-5, but the differences between groups were not statistically significant.

Monetary contracts: individual compared with group

The trial conducted by Jeffery and colleagues[86] recruited 89 men to receive a 15-week behaviourally oriented weight reduction programme with a goal of achieving a total weight loss of 30 lb (13.6 kg) at a rate of 2 lb (0.2 kg) per week. Using a factorial design, men in the trial were randomised to pay monetary deposits of US$30, US$150 or US$300 and to either a group contract or an individual contract. Refunds were made at a rate of US$1, US$5 or US$10 per lb lost up to a maximum cumulative weight loss of 2 lb per week. Men in the individual contract groups received refunds based on individual weight loss, whereas those with group contracts were refunded based on the mean weight loss of their group. Group contracts produced significantly more weight loss than individual contracts both at 1 year and 2 years (reported $p < 0.05$). Effects of contract size at 1 year[86] and 2 years[117] were reported as not significant. *Table 8* shows the mean weight loss for group and individual contracts by contract size at 1 and 2 years.

Study or subgroup	Diet and exercise programme Mean	SD	Total	Diet Mean	SD	Total	Weight	Mean difference IV, random, 95% CI
12 months								
Van Aggel-Leijssen 2001[92]	−4.5	7.19	14	−8.7	8.38	15	100.0%	4.20 (−1.47 to 9.87)
Subtotal (95% CI)			**14**			**15**	**100.0%**	**4.20 (−1.47 to 9.87)**
Heterogeneity: not applicable								
Test for overall effect: z=1.45 (p=0.15)								
18 months								
Pavlou 1989[91]	−9.19	8.52	10	−3.57	6.93	11	16.4%	−5.62 (−12.30 to 1.06)
Pavlou 1989[91]	−8.64	8.36	16	−1.13	6.23	16	28.1%	−7.51 (−12.62 to −2.40)
Pavlou 1989[91]	−9.68	8.65	10	−0.93	6.18	13	18.3%	−8.75 (−15.08 to −2.42)
Pavlou 1989[91]	−12.4	9.42	18	−3.45	6.89	16	24.2%	−8.95 (−14.46 to −3.44)
Pavlou 1989[91]	−11.83	9.26	5	−5.75	7.54	6	7.2%	−6.08 (−16.19 to 4.03)
Pavlou 1989[91]	−14.04	9.89	5	−7.29	7.98	5	5.9%	−6.75 (−17.89 to 4.39)
Subtotal (95% CI)			**64**			**67**	**100.0%**	**−7.63 (−10.33 to −4.92)**
Heterogeneity: τ^2=0.00; χ^2=0.80, df=5 (p=0.98); I^2=0%								
Test for overall effect: z=5.52 (p<0.00001)								
36 months								
Pavlou 1989[91]	−10.67	8.93	5	−3.25	6.83	6	54.6%	−7.42 (−16.97 to 2.13)
Pavlou 1989[91]	−13	9.59	5	−3.83	7.1	5	45.4%	−9.17 (−19.63 to 1.29)
Subtotal (95% CI)			**10**			**11**	**100.0%**	**−8.22 (−15.27 to −1.16)**
Heterogeneity: τ^2=0.00; χ^2=0.06, df=1 (p=0.81); I^2=0%								
Test for overall effect: z=2.28 (p=0.02)								

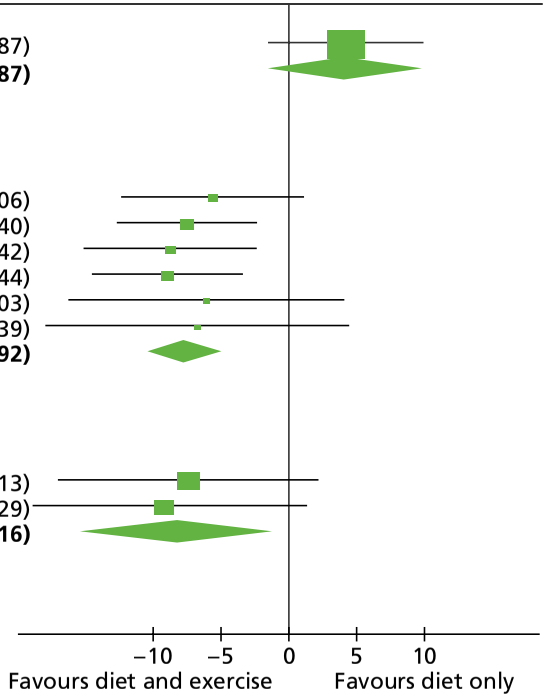

FIGURE 8 Effect of a diet and exercise programme vs. a diet on weight (kg, SDs assumed).

Study or subgroup	High protein Mean	SD	Total	High carbohydrate Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
12 months								
Benassi-Evans 2009[83]	−10.69	8.94	16	−12.24	9.38	17	100.0%	1.55 (−4.70 to 7.80)
Subtotal (95% CI)			**16**			**17**	**100.0%**	**1.55 (−4.70 to 7.80)**
Heterogeneity: not applicable								
Test for overall effect: z=0.49 (p=0.63)								

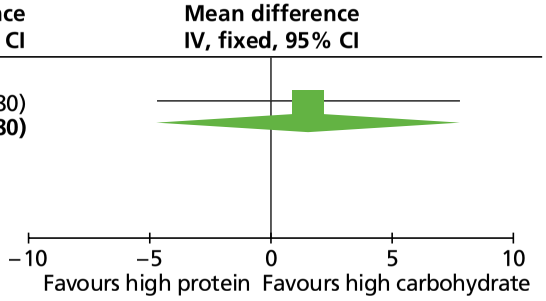

FIGURE 9 Effect of a high-protein diet vs. a high-carbohydrate diet on weight (kg) at 12 months.

TABLE 8 Effect of contract size and group vs. individual monetary contracts on weight reduction at 1 and 2 years

	Calculated mean weight loss (kg)	
Contract size	Group contract	Individual contract
1 year		
US$30	–8.55 ($n = 17$)	–5.35 ($n = 16$)
US$150	–10.02 ($n = 13$)	–7.39 ($n = 15$)
US$300	–6.60 ($n = 13$)	–6.24 ($n = 14$)
2 years		
US$30	–6.40 ($n = 17$)	–3.69 ($n = 16$)
US$150	–7.02 ($n = 13$)	–3.78 ($n = 15$)
US$300	–6.31 ($n = 13$)	–3.24 ($n = 14$)

Weight maintenance

Diet and exercise compared with diet for weight maintenance

The trial conducted by Borg and colleagues[84] examined whether or not adding walking or resistance training to diet compared with diet alone improved weight maintenance following a weight reduction period. During the weight reduction period, participants followed a very low-calorie diet (Nutrilett) of 500 kcal per day for 2 months. The mean weight loss at the end of the weight reduction period was 14.2 kg. Participants were then randomised to follow a low-fat diet of 1200 kcal per day only or to diet and walking or diet and resistance training exercise groups. Other than reduced fat and calorie intake, the diet was unrestricted in terms of choice or amount of food consumed. Exercise sessions were held three times a week and lasted 45 minutes each. The walking exercise was designed to produce an energy expenditure of 400 kcal per session, whereas the resistance training produced an expenditure of 300 kcal per session. Men in the diet-only group were advised not to increase their physical activity during the 6-month weight-maintenance phase. At 31 months the walking group showed the greatest increase in weight with an average weight gain of 10.1 kg. The resistance training and diet-only groups increased their weight by an average of 9.1 and 8.4 kg respectively. Differences between groups for weight gain were not statistically significant, although the waist-to-hip ratio for the resistance training group increased significantly less than that of the walking group despite the larger weight gain in this group (reported $p = 0.04$). Outcomes for waist-to-hip ratio, LDL cholesterol, HDL cholesterol, fasting plasma glucose and systolic and diastolic blood pressure were not significantly different between the exercise groups and the diet-only group at 13 months. HDL cholesterol improved significantly more in the resistance training group than in the walking group (reported $p = 0.03$) at 31 months (*Table 9*). The energy expenditure of both physical activities in the exercise groups decreased during the weight-maintenance period because of poor long-term adherence to the prescribed regimen.

A behavioural intervention for weight maintenance compared with control

The trial conducted by King and colleagues[88] randomised men from the diet and exercise arms of the trial by Wood and colleagues[93] at the end of the 1-year trial period. These men were randomised within their original intervention groups to receive behavioural support based on their original weight-loss method or to two assessment-only control groups. The behavioural support intervention comprised monthly mailed information packs including a supportive letter and a list of coping strategies for problems relevant to their original intervention, for example holiday eating for dieters or finding time to engage in physical activity for exercisers. The men were also telephoned regularly to discuss any concerns or questions related to their problem areas and were weighed at 6-monthly intervals. Men in the assessment-only groups were given written information about their original weight-loss method at the start of the weight-maintenance period. The men received no other contact apart from the 6-monthly weight assessments.

TABLE 9 Effect of diet and exercise vs. diet on risk factors [mean (SD)] at 31 months[116]

Outcome	Diet and resistance training (*n* = 24)	Diet and walking (*n* = 18)	Diet only (control) (*n* = 19)
BMI (kg/m^2)	32.0 (3.3)	32.0 (4.1)	31.3 (3.1)
Mean difference vs. control (95% CI)	–0.2 (–2.0 to 1.5)	0.2 (–1.6 to 2.1)	
Waist-to-hip ratio	0.98 (0.07)	1.01 (0.06)	1.00 (0.06)
Mean difference vs. control (95% CI)	–0.04 (–0.07 to –0.00)	0.01 (–0.03 to 0.04)	
Systolic blood pressure (mmHg)	136 (15)	131 (19)	132 (15)
Mean difference vs. control (95% CI)	1 (–8 to 10)	–2 (–11 to 8)	
Diastolic blood pressure (mmHg)	87 (10)	84 (10)	84 (10)
Mean difference vs. control (95% CI)	–0 (–6 to 6)	1 (–6 to 7)	
LDL cholesterol (mmol/l)	3.56 (0.58)	3.53 (0.93)	3.47 (0.74)
Mean difference vs. control (95% CI)	0.04 (–0.30 to 0.38)	–0.11 (–0.47 to 0.25)	
HDL cholesterol (mmol/l)	1.24 (0.31)	1.25 (0.20)	1.27 (0.27)
Mean difference vs. control (95% CI)	0.01 (–0.09 to 0.11)	–0.01 (–0.11 to 0.10)	
Fasting plasma glucose (mmol/l	5.01 (0.38)	5.00 (0.52)	5.12 (0.49)
Mean difference vs. control (95% CI)	–0.05 (–0.30 to 0.21)	–0.09 (–0.36 to 0.18)	

The behavioural therapy intervention produced greater weight-maintenance success for the exercise group compared with the control group than it did for dieters. After 1 year, exercisers who received the behavioural intervention weighed significantly less than control participants (–3.10 kg, 95% CI –5.04 kg to –1.16 kg). Dieters in the behavioural intervention group were not significantly different from control participants after 1 year (0.60 kg, 95% –1.27 kg to 2.47 kg) (*Figure 10*).

Discussion of results from the review of men-only trials

We identified very few long-term men-only randomised trials investigating interventions for reducing male obesity. Only two of our 11 included trials investigated weight maintenance in men. Results from this systematic review should therefore be treated with caution because of the limited evidence base. Nevertheless, it is possible to conclude that interventions containing a prescribed dietary regimen will produce greater reductions in weight for obese men than interventions that do not, for example interventions including exercise alone.[93] The type of reducing diet prescribed did not affect the amount of weight reduction, and higher protein intakes could not be demonstrated to be more effective for weight loss.[83,87,91] Adding an exercise component to a dietary regimen produced a marked effect in the long term, as reported in the trial conducted by Pavlou and colleagues (follow-up at 18 and 36 months).[91] Shorter-term results reported in the small trial by van Aggel-Leijssen and colleagues[92] seem to contradict this, although it should be noted that the exercise protocols for these studies differed greatly.

When frequency of contact varied between interventions, the intervention with the greatest frequency of contact (often supervised exercise classes) usually produced more favourable results. This is contradicted in the trial by van Aggel-Leijssen and colleagues[92] in which the diet and exercise group received more contacts but did not lose as much weight as the diet-only group.

Only one trial, that conducted by Jeffery and colleagues,[86] directly examined the effect of group compared with individual interventions for weight loss. This trial suggested that men lose more weight if they attend weight-loss sessions in groups, with group monetary contracts compared with individual contracts as incentives. This is in keeping with the findings of a systematic review[127] comparing group and individual treatments for obesity in both men and women. This review also found that group-based interventions were more effective, although the reviewed population was predominantly female.

Study or subgroup	Behaviour therapy Mean	SD	Total	Control Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Previous low fat diet								
King 1989[88]	3.2	2.9	20	2.6	2.8	16	51.8%	0.60 (–1.27 to 2.47)
Subtotal (95% CI)			**20**			**16**	**51.8%**	**0.60 (–1.27 to 2.47)**
Heterogeneity: not applicable								
Test for overall effect: z=0.63 (p=0.53)								
Previous exercise programme								
King 1989[88]	0.8	3.1	21	3.9	2.8	15	48.2%	–3.10 (–5.04 to –1.16)
Subtotal (95% CI)			**21**			**15**	**48.2%**	**–3.10 (–5.04 to –1.16)**
Heterogeneity: not applicable								
Test for overall effect: z=3.13 (p=0.002)								
Total (95% CI)			**41**			**31**	**100.0%**	**–1.18 (–2.53 to 0.16)**
Heterogeneity: χ^2=7.24, df=1 (p=0.007); I^2=86%								
Test for overall effect: z=1.72 (p=0.09)								
Test for subgroup differences: χ^2=7.24, df=1 (p=0.007), I^2=86.2%								

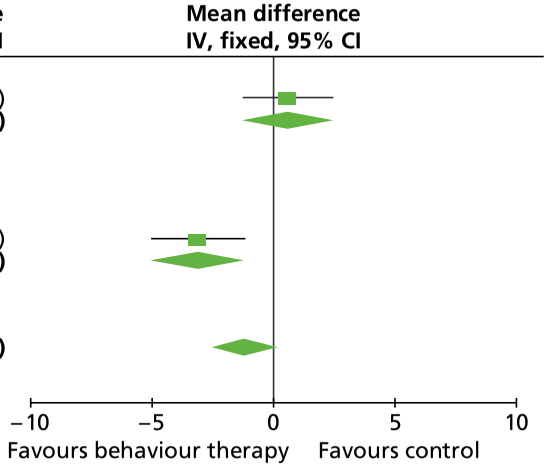

FIGURE 10 Effect of a behavioural intervention for weight maintenance vs. control on weight (kg) at 12 months.

Few interventions included a structured formal behaviour change programme although many included elements of behaviour change, for example self-monitoring and goal setting. Trials conducted by Esposito and colleagues,[85] Khoo and colleagues[87] and Morgan and colleagues[89] included behavioural support as part of a dietary-based intervention. The trials did not compare different types of behaviour change activity and consequently it is impossible to assess whether or not one type of activity is most effective. The trial by King and colleagues[88] showed that behavioural support can be beneficial for men during weight maintenance, although this seemed to be more effective at reducing weight regain by encouraging men to continue to engage in physical activity rather than restricting their dietary intake. The trial by Borg and colleagues[84] did not clearly demonstrate that the type of physical activity was important for weight maintenance, as resistance training was not associated with significantly less weight gain than walking, and neither type of exercise was significantly better than diet only for preventing weight gain.

Few reports gave details of the method of randomisation. It is therefore not possible to judge the success of randomisation for these trials. Similarly, few authors used intention-to-treat analysis, choosing instead to present data for completers only both at baseline and for final outcome measurements. It is therefore difficult to judge the level of attrition bias in these studies. The methodological quality of future trials could be improved by adopting an intention-to-treat approach, carrying out assiduous follow-up of participants and providing a conservative estimate of results by assuming weight regain to baseline for those who drop out. Reporting could also be improved by following the standards outlined in the Consolidated Standards of Reporting Trials (CONSORT) statement.[128,129] Similarly, few trials reported details concerning the equity or sustainability of the considered interventions. Providers of the interventions were described at an occupational level, for example nutritionist or physical activity trainer, but the sex of providers was not reported. It is subsequently unclear from the included studies whether the sex of the person providing a weight-loss intervention to men, either individually or in groups, is an important factor in the effectiveness of that intervention.

Future trials should also gather information on patient-reported quality of life and clinical and economic outcomes to assess the full value of an intervention other than for amount of weight lost. Future research is also required to develop effective interventions to prevent men regaining weight in the long term following successful weight loss.

Review of randomised controlled trials of men and women compared

This systematic review was of RCTs of interventions in any setting for men and women who are obese with a BMI of ≥ 30 kg/m^2 (or overweight with a BMI of ≥ 28 kg/m^2 and cardiac risk factors based on orlistat guidance) in which the results are presented separately for men and women in the same trial. We used trials including both men and women to look for differences in effectiveness.

Number and type of studies

Twenty RCTs[94–113] including both men and women, with six linked reports,[120–125] were identified as eligible for inclusion. Nine trials[94,97–99,109–113] were conducted in the USA; six[95,96,101,102,104,108] were conducted in Finland and one was conducted in each of the following locations: Canada,[106] Israel,[107] Scandinavia,[105] Sweden[103] and the UK.[100] The trial by Jolly and colleagues[100] in the UK evaluated commercial and NHS weight-loss services in primary care and the community. The study by Ross and colleagues[106] was conducted in a primary care setting in Canada. The remaining studies appeared to be conducted in research settings.

Table 10 details the characteristics of the included reports. A very diverse range of interventions was tested in the trials. The majority of trials investigated interventions for weight loss. Three trials investigated different types of reducing diet or when to use such diets.[103,107,113] Eight trials investigated a variety of dietary, physical activity and behaviour change interventions compared with control/usual care

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared

Study ID	Participants	Interventions	Outcomes	Notes
Gorin 2013[94]	Location: Home environment, Providence, RI, USA Period of study: NR Inclusion criteria: Age 21–70 years, BMI 25–50 kg/m^2 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 participant criteria except for lower age range of 15–70 years Exclusion criteria: 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 (kg/m^2), 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	Description of interventions: a: Standard behavioural weight-loss treatment (participants only). Standard calorie- and fat-restricted diet (e.g. 1200–1800 kcal per day and 30% fat, depending on initial weight) to achieve a 10% weight-loss goal. Sample meal plans and a calorie guidebook were provided, and the amount of physical activity was gradually increased until participants achieved $\geq$ 200 minutes of moderate intensity physical activity per week. Given pedometers and a 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 weight. Interventionists provided weekly written feedback. Stimulus control, problem-solving, goal-setting and cognitive restructuring skills were also taught. The focus of treatment shifted to weight-loss maintenance and relapse prevention in the later months of the programme b: 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. Partners were 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 a 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	Length of follow-up: 18 months Outcomes by sex: Weight	

Study ID	Participants	Interventions	Outcomes	Notes
		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: A treadmill or stationary bicycle was provided for home use and participants were asked to decrease time spent watching television and restrict viewing to one location. Each television in the home was fitted with a television allowance device that provided feedback about weekly viewing habits. Exercise videotapes, resistance bands, a subscription to an exercise-related magazine and motivational 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 biweekly meetings for 12 months. Participants and partners in both a and b each received US$25 for completing the 6-month assessment and US$50 for completing the 18-month assessment Timing of active intervention: 18 months No. of times contacted: 51 No. allocated: Participants: a: men: 21, women: 78; b: men: 23, women: 79; partners: a: men: 52, women: 47; b: men: 55, women: 47 No. completed: Participants: a: 86, b: 99; partners: a: 82, b: 99 Dropout (%): Participants: a: 13, b: 3; partners: a: 17, b: 3 No. assessed: Participants: a: men: 21, women: 78; b: men: 23, women: 79; partners: a: men: 52, women: 47; b: men: 55, women: 47		

continued

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Hakala 1993[95]	Location: One rehabilitation centre, Finland Period of study: NR Inclusion criteria: At least 50% overweight, age 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 (kg/m^2), 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); b: 43.4 (5.4) (33.9–51.9) Baseline comparability: Yes	Description of interventions: a: 2-week inpatient treatment in a rehabilitation centre. Weight reduction programme consisted of a 1200 kcal per day diet and group counselling sessions led by a nutritionist, physiotherapist and occupational therapist (10 participants per group) including 15 hours of nutrition counselling, 15 hours of physical activity, 12 hours of occupational therapy and 1 hour of individual nutritionist counselling. Physician-led lecture and examination. Followed by 4-monthly individual physician appointments for 2 years b: A 1200 kcal per day diet and individual physician-led counselling in 20-minute 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 changes in body weight and health status after 6 months No anorexigenic drugs were used in either group Timing of active intervention: a: 2-week intensive weight reduction followed by counselling for up to 2 years; b: 2 years of counselling No. of times contacted: a: 40; b:15 No. allocated: Men: a: 10, b: 10; women: a: 20, b: 20 No. completed: Men: a: 9, b: 9; women: a: 19, b: 16 Dropout (%): Men: a: 10, b: 10; women: a: 5, b: 20 No. assessed: Men: a: 9, b: 9; women: a: 19, b: 16	Length of follow-up: 5 years Outcomes by sex: Weight	Weight reduction programme based on that used in Karvetti and Hakala[101]

Study ID	Participants	Interventions	Outcomes	Notes
Hakala 1994[96]	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); women: a: 120.7 (9.3) (106–146), b: 119.2 (12.6) (101–144) BMI (kg/m^2), 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	Description of interventions: a: 3-week inpatient treatment in a rehabilitation centre. Programme consisted of a low-fat, high-fibre diet of 1200 kcal per day and group counselling sessions led by a nutritionist, physician and occupational therapist (10 participants per group) including 21 hours of nutrition and behaviour counselling, 16 hours of recreational activity, 15 hours of physical activity, 6 hours of food preparation advice, 6 hours of social counselling, a 1-hour lecture, 1 hour of individual nutritionist-led counselling and one individual physician appointment. Following the intensive weight reduction period, participants had appointments with their GP at 1- to 2-monthly intervals b: A 10-week low-fat, high-fibre diet of 1200 kcal per day and group counselling in a health centre setting led by three 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. Three lectures (one physician led, one psychologist led, one physiotherapist led) provided encouragement and support. Following the intensive weight reduction period, participants had appointments with their GP at 1- to 2-monthly intervals Drug treatment for obesity was not used in any phase of the study Timing of active intervention: a: 3 weeks followed by GP counselling for up to 2 years; b: 10 weeks followed by GP counselling for up to 2 years No. of times contacted: a: 13–21; b: 23–34 No. allocated: Men: a: 9, b: 9; women: a: 21, b: 21 No. completed: Men: a: 7, b: 6; women: a: 16, b: 14 Dropout (%): Men: a: 22, b: 33; women: a: 24, b: 33 No. assessed: Men: a: 7, b: 6; women: a: 16, b: 14	Length of follow-up: 5 years Outcomes by sex: Weight	Weight reduction programme based on that used in Karvetti 1992[101]

continued

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Heitzmann 1987[97]	Location: California, USA Period of study: Prior to November 1985 Inclusion criteria: Fasting blood glucose > 140 mg/dl or blood glucose > 200 mg/dl 2 hours after administration of 75 g of 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: 90.13; women: 72.43 BMI: NR Baseline comparability: Unclear	Description of interventions: All participants were given dietary advice by a registered nutritionist and a prescribed exercise regimen based on exercise tolerance tests a: Relaxation training (control) – participants were offered muscle relaxation training and factual information about diabetes b: Behaviour modification (self-control) – based on Ferguson and Ferguson's *Habits Not Diets*.[130] 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: Cognitive modification (goal setting and role of cognitions) – based on Mahoney and Mahoney.[131] Participants were instructed to set reasonable goals and keep a diary of their self-statements during eating and exercise d: 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 Timing of active intervention: a–d: 7 weeks No. of times contacted: a–d: 13 No. allocated: Men + women: a: 14; b: 13; c: 13; d: 15 No. completed: Men + women: a: 12; b: 10; c: 10; d: 12 Dropout (%): Men + women: a: 14.3; b: 23.1; c: 10; d: 12 No. assessed: Men + women: a–d: 46	Length of follow-up: 18 months Outcomes by sex: Weight, HbA_{1c}	

Study ID	Participants	Interventions	Outcomes	Notes
Jeffery 1984[98]	Location: University of Minnesota, USA Period of study: 1983–4 Inclusion criteria: Men 30 lb (13.6 kg), women 20 lb (9.1 kg) 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 (kg/m^2), 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 those in the population sample, a higher number had previously participated in a weight control programme and a higher number had an earlier age at onset of being overweight	Description of interventions: Weight-loss phase: All groups participated in a 16-week educational programme emphasising reduced eating and increased exercise equally. All paid a US$150 deposit a: Self-referred population – recruited through newspaper advertisement: (i) control – deposit refunded at initial session; (ii) constant contract – deposit refunded in US$30 increments for every 5 lb (2.3 kg) group average weight loss; (iii) increasing contract – deposit refunded for successive 5 lb (2.3 kg) lost in increments of US$5, US$10, US$20, US$40 and US$75 b: Population sample – referred from the population sample in Jeffery *et al.*:[86] (i) control – deposit refunded at initial session; (ii) constant contract – deposit refunded in US$30 increments for every 5 lb (2.3 kg) group average weight loss; (iii) increasing contract – deposit refunded for successive 5 lb (2.3 kg) lost in increments of US$5, US$10, US$20, US$40 and US$75 Weight-maintenance phase: 17 men and 25 women were randomised to either intensive weekly problem-solving sessions or non-specific 3-monthly weight-maintenance sessions. Both groups paid a US$100 deposit, which was returned in US$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 No. of times contacted: a + b: 20; intensive maintenance 26; non-specific maintenance 22 No. 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	Length of follow-up: 1 year Outcomes by sex: Weight	1-year data not reported by participants randomised/not randomised to the maintenance phase

continued

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
		No. completed: a + b: men: 53; women: 57 Dropout (%): a + b: men: 3.6; women: 5.3 No. assessed: NR		
Jeffery 2003[99]	Location: Four managed care organisation clinics, USA Period of study: NR Inclusion criteria: age ≥ 18 years, BMI > 27 kg/m^2 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 (kg/m^2), 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 were more likely to report taking medication for depression ($p < 0.002$)	Description of interventions: a: Control (usual care): Participants had access to weight management services generally available to members of Health Partners private health insurance b: Telephone group: Participants were given a telephone number to activate the intervention. Materials for 10 lessons were 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: Mail group: Participants activated the intervention by sending a postcard to the study office. Materials and lessons as for 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 them by mail along with the next lesson. The process was repeated until all 10 lessons were completed Lessons were carried out at a rate of one per 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 30 days,	Length of follow-up: 24 months Outcomes by sex: Weight loss at 12 months	

Study ID	Participants	Interventions	Outcomes	Notes
		60 days and then at 6-month intervals for 2 years. Those choosing not to activate the programme were also contacted at 6-month intervals for 2 years. Completers of the 10-week programme were followed up at 6, 12, 18 and 24 months Timing of active intervention: 10 weeks No. of times contacted: a: 5; b: 15; c: 15 No. allocated: Men: a: 163, b: 159, c: 186; women: a: 437, b: 442, c: 414 No. completed: NR Dropout (%): NR No. assessed: Men: a: 163, b:159, c: 186; women: a: 437, b: 442, c: 414	
Jolly 2011[100]	Location: 17 general practices, South Birmingham Care Trust, UK Period of study: 2009 Inclusion criteria: Age ≥ 18 years, raised BMI in previous 15 months, BMI ≥ 25 kg/m^2 for South Asians and ≥ 30 kg/m^2 for participants of all other ethnicities without obesity-related comorbidity, BMI ≥ 23 kg/m^2 for South Asians and ≥ 28 kg/m^2 for participants of all other ethnicities with obesity-related comorbidity Exclusion criteria: Presence of serious comorbidities, unable to understand English, pregnant, unwilling to be randomised	Description of interventions: a: 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: Participants were able to choose allocation to one of six interventions (c–h) c: 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 0.5–1.0 kg weight loss per week. Physical activity was encouraged with the goal of achieving 10,000 steps daily. Rewards were given for every 3.2 kg lost and for 5% and 10% of body weight	Length of follow-up: 1 year Outcomes by sex: Weight loss	

continued

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
	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 (kg/m^2), men + women, *n* (%): < 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) 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) 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) ≥ 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	lost. Behaviour change strategies included stages of change, food and activity diaries, goal setting and evaluation of progress d: Slimming World – group-based programme with one-to-one telephone support available. Meetings lasting for 90 minutes were held in community venues. Members encouraged to eat low energy density foods plus extras rich in calcium and fibre. Weight-loss goals were set by the individual. Physical activity was encouraged with build up to 30 minutes of moderate activity on 5 days a 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: Rosemary Conley – group based with one-to-one support. Additional support available by e-mail or telephone. Meetings lasting 90 minutes took place in community venues. Sessions included a 45-minute optional exercise class. Goals were staged: either 1–1.5 kg loss per week with a goal of losing 6.35 kg, or 0.5–1 kg loss per week with a goal of losing 3.2 kg. 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 6.35 kg weight-loss milestones f: 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		

Study ID	Participants	Interventions	Outcomes	Notes
		g: 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. Included 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 0.5–1 kg per week over 3–6 months followed by maintenance. Physical activity goals were to increase activity levels to 30 minutes of moderate activity on 5 days a week. Homework provided for discussion or personal reflection. Participants were encouraged to reward themselves for success h: Pharmacy – as general practice but delivered from NHS pharmacy setting Timing of active intervention: 12 weeks No. of times contacted: a: 1; b: as chosen provider; c–e, g: 12; f: 8; h: 11 No. 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 No. 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 No. 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		

continued

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Karvetti 1992[101]	Location: One research centre, Finland 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 (kg/m^2), mean: Men + women: a: 33.5; b: 34.4 Baseline comparability: Yes	Description of interventions: a: Control group – participants given no instruction but were informed that they had been selected to participate in a weight reduction course to be held after the 1-year follow-up assessment b: Low-fat, low-sugar, high-fibre 1200 kcal per day diet combined with a group-based weight reduction programme (eight 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 seven trained public health nurses. Three lectures (one physician led, one psychologist led, one physiotherapist led) provided encouragement and support. Eventual weight-maintenance diet of 1800 kcal per day Timing of active intervention: 1 year No. of times contacted: a: 2; b: 12 No. allocated: Men + women: a: 117; b: 126 No. completed: Men: a: 20, b: 21; women: a: 76, b: 71 Dropout (% defaulters): Men + women: a: 18; b: 26 No. assessed: Men: a: 20, b: 21; women: a: 76, b: 71	Length of follow-up: 1 year Outcomes by sex: Weight, systolic and diastolic blood pressure	Control group acted as a control for the first year of follow-up only. Paper reports data for 7 years. Weight data derived from graph

Study ID	Participants	Interventions	Outcomes	Notes
Korhonen 1987[102]	Location: One hospital outpatient clinic, Finland Period of study: NR Inclusion criteria: Newly diagnosed non-insulin-dependent diabetes: fasting venous blood glucose ≥ 7.0 mmol/l and/or 2-hour blood glucose ≥ 10.0 mmol/l on 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 (kg/m^2), 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	Description of interventions: Before randomisation, a doctor described the general outline of therapy and stressed the importance of diet and weight reduction in diabetes control to all participants a: 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: Specialist nurse: Nurse assessed the 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 No. of times contacted: a: 5; b: 5 No. allocated: Men: a: 20, b: 20; women a: 20, b: 20 No. completed: Men: a: 19, b: 19; women a: 15, b: 18 Dropout (%): Men: a: 5, b: 5; women a: 25, b: 10 No. assessed: Men: a: 19, b: 19; women: a: 15, b: 18	Length of follow-up: 1 year Outcomes by sex: Weight change	

continued

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Lantz 2003[103]	Location: One hospital outpatient clinic, Sweden Period of study: January 1996–February 1999 Inclusion criteria: Age 18–60 years, BMI > 30 kg/m^2 Exclusion criteria: Participation in other ongoing clinical trial, concomitant serious disease (e.g. type 1 diabetes, renal or hepatic failure, unstable angina, recent myocardial infarction, chronic infections, psychotic disorder and bulimia), 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 (kg/m^2), mean (SD): Men + women: a: 39.9 (5.6); b: 40.1 (5.7) Baseline comparability: Yes	Description of interventions: Both groups exposed to a 16-week pretreatment phase during which participants consumed a very low-calorie diet (VLCD) of 450 kcal per day supplied by Modifast (Novartis). The treatment phase was followed by a 3-week refeeding phase during which ordinary food was introduced a: Repeated VLCD every 3 months for 2 weeks. Recommended to follow an individualised hypocaloric diet, providing a 500 kcal per day deficit, at other times b: 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 pretreatment phase plus 3 kg). The cut-off level was reduced during the trial for those who continued to lose weight but remained unchanged for those who regained weight Timing of active intervention: Up to 24 months No. of times contacted: a: 69; b: 69 No. allocated: Men: a: 42, b: 44; women: a: 119, b: 129 No. 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 No. assessed: Men: a: 14, b: 21; women: a: 43, b: 39	Length of follow-up: 2 years Outcomes by sex: Weight loss	

Study ID	Participants	Interventions	Outcomes	Notes
Lindstrom 2008[104]	Location: Five diabetes centres, Finland Period of study: 1993–2000 Inclusion criteria: Age 40–65 years, BMI > 25 kg/m^2, impaired glucose tolerance [defined as plasma glucose 7.8–11.0 mmol/l 2 hours after administration of 75-g glucose in those with a non-diabetic fasting glucose concentration (plasma glucose < 7.8 mmol/l)], mean value of two glucose tolerance tests Exclusion criteria: Previous diagnosis of diabetes mellitus (other than gestational diabetes mellitus), persons involved regularly in a 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 (kg/m^2), 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 blood pressure (mmHg), mean (SD): a: 136 (17); b: 140 (18) ($p = 0.03$)	Description of interventions: a: General advice: At baseline participants were advised to adjust total energy intake to reduce BMI to < 25 kg/m^2, consume < 30% of energy intake from fat, reduce alcohol intake and stop smoking. They were also given verbal and written dietary advice, verbal general information regarding health benefits of recreational exercise and additional routine advice at the yearly follow-up when 3-day food record assessed and 2-km walking test performed b: Lifestyle modification: Participants informed at start of risk factors for diabetes. A 3-day food diary at baseline provided the basis for dietary advice in the second session. Participants were advised to reduce weight with a goal of a BMI of < 25 kg/m^2 but in practice weight targets were 5–10 kg of weight loss. Advised to consume > 50% carbohydrate, < 10% saturated fat, 20% monosaturated and polyunsaturated fat or up to 25% if surplus is from monounsaturated fat; to consume < 300 mg per day cholesterol and 1 g protein per kg ideal body weight per day; to increase fibre intake to 15 g per 1000 kcal; to use low-fat milk products, low-fat meat products, soft margarine and vegetable oil rich in monounsaturated fatty acids (primarily rapeseed oil). Energy content was re-evaluated if no weight loss at visits; if no weight loss in first 6–12 months and BMI > 30 kg/m^2 a very low-calorie diet was considered (6–12 weeks' duration with group meetings every 1–2 weeks). Dietary advice was individually tailored and the person responsible for preparing meals in the family was invited to attend sessions (if not the participant). Advice was tailored to participants' educational level. Participants were 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. participants were encouraged to perform 30 minutes of daily moderate exercise. A 3-day food diary and a 24-hour exercise diary	Length of follow-up: median 4 years Outcomes by sex: Diabetes incidence	Finnish Diabetes Prevention Study (methods from Tuomilehto 2001[132]) All participants had impaired glucose tolerance

continued

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
		were kept every 3 months and a 12-month physical activity history and 2-km walking test were completed at the annual visit Timing of active intervention: 2–6 years No. of times contacted: a: 5; b: 29 No. allocated: Men: a: 81, b: 91; women: a: 176, b: 174 Completed (at 2 years): Men + women: a: 242; b: 240 Dropout (%) (at 2 years): Men + women: a: 6; b: 8 No. assessed: Men: a: 81, b: 91; women: a: 176; b: 174		
Richelsen 2007[105]	Location: Nine clinical research centres, Scandinavia Period of study: NR Inclusion criteria: Age 18–65 years, abdominal obesity [BMI 30–45 kg/m^2 and waist circumference ≥ 102 cm (men) and ≥ 92 cm (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 dyslipidaemia [HDL cholesterol ≤ 0.9 mmol/l (men), ≤ 1.1 mmol/l (women) and/or serum triglycerides between ≥ 2.0 mmol/l and ≤ 10.0 mmol/l]; 5% weight loss achieved during the 8-week very low-calorie diet prerandomisation period Exclusion criteria: During the randomised phase, participants with deterioration in glucose control were prescribed metformin. If metformin failed to keep HbA_{1c} level at < 10% the participant was withdrawn	Description of interventions: Prerandomisation: All participants prescribed very low-calorie diet [Modifast (Novartis) or Nutrilett] of 600–800 kcal per day for 8 weeks. Those achieving 5% weight loss were randomised as follows: a: Placebo b: Orlistat 120 mg three times daily Both groups were instructed to follow a standard energy-restricted diet consisting of a 600 kcal per day deficit and were advised to reduce fat intake to approx. 30% of total energy, especially saturated fat, and increase fruit and vegetable intake. Participants were also advised to increase daily physical activity Timing of active intervention: a + b: 36 months No. of times contacted: a + b: 24	Length of follow-up: 36 months Outcomes by sex: Weight	Sponsored by Roche

Study ID	Participants	Interventions	Outcomes	Notes
	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 (kg/m^2) (prerandomisation), mean (range): Men + women: a: 37.6 (30.0–45.0); b: 37.4 (30.1–45.2) Baseline comparability: Yes	No. allocated: Men: a: 76, b: 76; women: a: 80, b: 77 No. completed: Men + women: a: 98; b: 102 Dropout (%): Men + women: a: 37.2; b: 33.3 No. assessed: NR		
Ross 2012[106]	Location: Three primary health-care clinics, Ontario, Canada Period of study: December 2004–January 2008 Inclusion criteria: Age 25–75 years, sedentary (one or fewer physical activity sessions per week), BMI 27–39.9 kg/m^2, abdominally obese (waist circumference ≥ 102 cm for men and ≥ 88 cm for women), weight stable to within 2 kg in last 6 months Exclusion criteria: Serious medical conditions preventing increased daily activity including significant cardiovascular disease, planning for pregnancy in the next 2 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)	Description of interventions: a: Usual care: GP gave advice regarding lifestyle strategies for obesity reduction. GPs followed their usual appointment schedule and counselling approach b: 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 before 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 six sessions in which 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 the duration of each was determined by the participant's waist circumference and physical activity level	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	

continued

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
	BMI (kg/m^2), mean (SD): Men: a: 32.0 (4.0), b: 32.4 (3.7); women: a: 32.0 (4.3), b: 32.7 (4.3) Baseline comparability: Yes	Timing of active intervention: 2 years No. of times contacted: a: ≥ 5; b: 38 No. allocated: Men: a: 72, b: 74; women: a: 169, b: 175 No. completed: Men: a + b: 121; women: a + b: 275 Dropout (%): Men: a + b: 17.1; women: a + b: 20.0 No. assessed: Men: a: 72, b: 74; women: a: 169, b: 175		
Shai 2008[107]	Location: Workplace (one medical research clinic), Israel Period of study: July 2005–June 2007 Inclusion criteria: Age 40–65 years, BMI ≥ 27 kg/m^2 or presence of type 2 diabetes or coronary heart disease regardless of age or BMI Exclusion criteria: Pregnant or lactating, serum creatinine ≥ 2 mg/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 (kg/m^2), mean (SD): Men + women: a: 30.6 (3.2); b: 31.2 (4.1); c: 30.8 (3.5) Baseline comparability: Yes	Description of interventions: a: Low-fat, restricted-calorie diet: 1500 kcal per day for women and 1800 kcal per day for men with 30% of calories obtained from fat, 10% from saturated fat and an intake of 300 mg 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[133] b: Mediterranean, restricted-calorie diet: 1500 kcal per 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 30–45 g olive oil and < 20 g 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[134] c: Low-carbohydrate, non-restricted-calorie diet: Aimed to provide 20 g carbohydrates per day for a 2-month induction phase and immediately after religious holidays with a gradual increase to a maximum of 120 g 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[135]	Length of follow-up: 2 years Outcomes by sex: Weight loss	Data for wives of trial participants published separately in Golan *et al.*[120] [Dietary Intervention Randomized Controlled Trial (DIRECT) spousal study]

Study ID	Participants	Interventions	Outcomes	Notes
		Each diet group was assigned a registered dietitian who led all six subgroups of that group. There were 18 group meetings in total lasting 90 minutes each. Another dietitian conducted 10- to 15-minute telephone calls six times over the 2-year trial period with participants experiencing adherence difficulties. A summary of each call was given to the group dietitian 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 No. of times contacted: a–c: 48 No. allocated: Men: a: 89, b: 89, c: 99; women: a: 15, b: 20, c: 10 No. completed: Men + women: a: 94; b: 93; c: 85 Dropout (%): Men + women: a: 9.6; b: 14.7; c: 22 No. assessed: Men: a: 89, b: 89, c: 99; women: a: 15, b: 20, c: 10		
Golan 2010[120] (linked to Shai 2008[107])	74 wives of Dietary Intervention Randomized Controlled Trial (DIRECT) study husbands (who were not part of the trial) were followed up for 2 years 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 (kg/m^2), mean (SD): Wives: a: 24.9 (3.69); b: 27.81 (4.98); c: 27.79 (5.14) Baseline comparability: Yes	Interventions as in Shai 2008[107]. Every 2 months during the first 6 months of the study, 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 study men whose wives did not take part in the group sessions	Length of follow-up: 2 years Outcomes by sex: Weight loss	Ancillary spouse study

continued

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Vanninen 1992,[108] Vanninen 1993[125]	Location: One outpatient clinic and five community health centres, Finland Period of study: 1987–9 Inclusion criteria: Age 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: 54 (6) Weight (kg), mean (SD): Men: 95 (12); women: 88 (16) BMI (kg/m^2), 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 a higher mean BMI than men. Women in the conventional care group had higher HbA_{1c} and fasting plasma glucose levels than women in the intensified diet and exercise group following the pretreatment phase (baseline)	Description of interventions: Both groups underwent a 3-month basic education programme pre randomisation giving diet and exercise advice and information a: 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 dietitian b: Intensified diet and exercise education: Attended diabetes specialist-led outpatient clinics six times every 2 months. A physician provided printed and oral instruction and general motivation and follow-up; a dietitian provided 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, a moderate increase in the consumption of unsaturated fats and foods containing complex carbohydrates and to encourage regular eating patterns and moderate consumption. Participants were also encouraged to increase physical activity to 30–60 minutes three to four 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 was monitored using daily exercise records. No written exercise instruction or supervision was given Timing of active intervention: 12 months No. of times contacted: a: 7–9; b: 7 No. allocated: Men + women: a + b: 90 No. completed: Men: a: 24, b: 21; women: a: 16, b: 17 Dropout (%): Men + women: a + b: 13.3 No. assessed: Men: a: 24, b: 21; women: a: 16, b: 17	Length of follow-up: 12 months Outcomes by sex: BMI, total and HDL cholesterol, triglycerides, HbA_{1c}, fasting plasma glucose	All participants had non-insulin-dependent type 2 diabetes mellitus at baseline

Study ID	Participants	Interventions	Outcomes	Notes
Volpe 2008[109]	Location: One university research centre, Pennsylvania, USA Period of study: NR Inclusion criteria: Age 24–62 years, sedentary (exercising no more than 1 day per week), non-smoker, BMI 27–35 kg/m^2, 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 only Weight (kg): Unclear if data reported for women only BMI: Unclear if data reported for women only Baseline comparability: Unclear	Description of interventions: All participants underwent a 1- to 2-week prerandomisation phase during which they were habituated to the NordicTrack™ (Chaska, MN, USA) indoor skiing apparatus, fitness levels were measured using the NordicTrack home fitness test and baseline measurements were taken a: Diet: Participants attended intensive nutrition classes advising on adhering to a low-energy, heart-healthy diet with a goal of losing 0.5–1.0 kg body weight per week. After 7 months classes were replaced by monthly telephone/e-mail messages up to month 9 to check dietary adherence b: Exercise: Exercise sessions supervised by trained graduate/undergraduate students 3 days per week for 6 weeks, increasing to five 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/e-mail messages up to month 9 to check exercise adherence c: Diet + Exercise: As a and b Timing of active intervention: 9 months No. of times contacted: a: 19; b: 83; c: 83 No. allocated: Men: a–c: 44; women a: 15, b: 17, c: 14 No. completed: NR Dropout (%): NR No. assessed: Men: a–c: 44; women a: 15, b: 17, c: 14	Length of follow-up: 12 months Outcomes by sex: Weight, waist circumference, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, systolic and diastolic blood pressure	NordicTrack sponsored the study. The authors declare no conflict of interest

continued

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Wadden 2011[110]	Location: 16 health centres, USA Period of study: NR Inclusion criteria: Age 45–74 years (changed to 55–74 years later and upper range reported as 76 years later), BMI ≥ 25 kg/m^2 (≥ 27 kg/m^2 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: Age ≥ 75 years, HbA_{1c} > 11%, blood pressure ≥ 160/100 mmHg, fasting triglycerides ≥ 600 mg/dl, inadequate control of comorbid conditions, factors limiting adherence to/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 (kg/m^2), 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	Description of interventions: All participants required to complete daily diet and exercise records during 2-week self-monitoring phase before 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 a: Diabetes support and education: Participants attended three group education/social support sessions per year. One session covered diet/nutrition, one exercise and one social support. Support sessions allowed participants to discuss issues related to living with diabetes. Attendance at sessions was encouraged but not required b: Intensive lifestyle intervention (ILI): Group lifestyle meetings held for the first 3 weeks of each month with one individual meeting with interventionists (registered dietitians, psychologists and exercise specialists) in the fourth week. Group meetings replaced by individual lifestyle counselling in year 2. Individuals were encouraged to lose ≥ 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 were given extra assistance to improve weight-loss outcomes. Participants followed a portion-controlled diet with calorie goals of 1200–1800 kcal per 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 were also given an exercise goal of ≥ 175 minutes per week of unsupervised activity by 6 months. Taught behavioural techniques included problem solving, motivational interviewing, self-regulation theory and relapse prevention	Length of follow-up: 4 years (year 1 weight reduction, years 2–4 weight maintenance) Outcomes by sex: Weight loss	Look AHEAD study – outcomes reported by sex for ILI group only

Study ID	Participants	Interventions	Outcomes	Notes
		Timing of active intervention: 4 years No. of times contacted: a: 16; b: 199 No. allocated: Men: a: 1038, b: 1044; women: a: 1537, b: 1526 No. completed: Ongoing Dropout (%): Ongoing No. assessed: Men: a: 1038, b: 1044; women: a: 1537, b: 1526		
Gorin 2008[121] (linked to Wadden 2011[110])	Location: 3/16 Look AHEAD centres, USA Period of study: NR Inclusion criteria: Untreated spouse of Look AHEAD participant, 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: 81.52 (18.98) BMI (kg/m^2), mean (SD): Men + women: a: 30.1 (6.0); b: 31.0 (6.2) Baseline comparability: Yes	Description of interventions: As for Wadden 2011[110] post randomisation Timing of active intervention: 1 year No. of times contacted: a + b: 2 No. allocated: Men: a: 85, b: 69; women: a: 103, b: 100 No. completed: NR Dropout (%): NR No. assessed: Men: a: 85, b: 69; women: a: 103, b: 100	Length of follow-up: 1 year Outcomes by sex: Weight	Look AHEAD ancillary spouse study

continued

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Schwartz 2012[124] (linked to Wadden 2011[110])	Location: 5/16 Look AHEAD centres, USA Period of study: NR Inclusion criteria: Participating in Look AHEAD study Exclusion criteria: As Wadden 2011[110] 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 (kg/m^2), mean (SD): Men: a: 34.0 (4.3), b: 33.9 (4.6); women: a: 36.3 (5.5), b: 35.8 (5.7) Baseline comparability: Women had a higher BMI than men	Description of interventions: As for Wadden 2011[110] post randomisation Timing of active intervention: 1 year No. of times contacted: a + b: 2 No. allocated: Men: a: 246, b: 237; women: a: 386, b: 405 No. completed: NR Dropout (%): NR No. 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[123] (linked to Wadden 2011[110])	Location: 1/16 Look AHEAD centres, USA Period of study: NR Inclusion criteria: Participating in Look AHEAD study Exclusion criteria: As Wadden 2011[110] Age (years), mean (SD): Men: a: 61.9 (5.2), b: 61.4 (5.8); women: a: 59.0 (6.1), b: 59.4 (6.9) Weight (kg), mean: Men: a: 105.1, b: 108.0; women: a: 96.5, b: 96.4 BMI (kg/m^2), mean (SD): Men: a: 33.1 (4.4), b: 33.9 (5.1); women: a: 36.4 (5.3), b: 36.4 (5.6) Baseline comparability: Women had a higher BMI than men	Description of interventions: As for Wadden 2011[110] post randomisation Timing of active intervention: 1 year No. of times contacted: a + b: 2 No. allocated: Men: a: 33, b: 36; women: a: 43, b: 45 No. completed: Men + women: a: 70; b: 70 Dropout (%): Men + women: a: 7.89; b: 13.58 No. 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

Study ID	Participants	Interventions	Outcomes	Notes
Wing 2010[122] (linked to Wadden 2011[110])	Location: 5/16 Look AHEAD centres, USA Period of study: NR Inclusion criteria: Male Look AHEAD participants who reported being sexually active in the previous 6 months Exclusion criteria: As Wadden 2011[110] 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 (kg/m^2), mean (SD): a: 35.1 (5.2); b: 35.6 (5.5) Baseline comparability: Yes	Description of interventions: As for Wadden 2011[110] post randomisation Timing of active intervention: 1 year No. of times contacted: As Wadden 2011[110] but with two additional assessments at baseline and 1 year No. allocated: a: 185; b: 187 No. completed: a: 153; b: 153 Dropout (%): a: 17.3; b: 18.2 No. assessed: a: 153; b: 153	Length of follow-up: 1 year Outcomes (all male patients): weight loss, total cholesterol, LDL and HDL cholesterol, systolic and diastolic blood pressure, HbA_{1c} change, erectile function	Subgroup of Look AHEAD study (erectile function)
West 2008[111]	Location: 27 diabetes outpatient clinics, USA Period of study: NR Inclusion criteria: ≥ 25 years, BMI ≥ 24 kg/m^2, fasting plasma glucose concentration 5.3–6.9 mmol/l, plasma glucose concentration 12 hours post oral glucose test 7.8–11.0 mmol/l Exclusion criteria: Taking medications known to alter glucose tolerance or had significant illness that could reduce life expectancy or trial participation	Description of interventions: a: 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- to 30-minute session with individual participants emphasising a healthy lifestyle, food pyramid, National Cholesterol Education Programme step 1 diet, the need to lose 5–10% of body weight through diet and exercise with an eventual goal of 30 minutes of an activity such as walking 5 days per week and the need to avoid excessive alcohol	Length of follow-up: 30 months Outcomes by sex: Weight loss	Main Diabetes Prevention Program trial included standard lifestyle + metformin 850 mg twice daily treatment arm Methods detailed in other publications[136,137]

continued

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
	Age, *n* (%): Men < 40: a: 20 (10.9); b: 19 (9.6); a: 6 (10.5); b: 10 (17.2); a: 2 (3.5); b: 6 (12.0) 40–49: a: 43 (23.4); b: 44 (22.1); a: 18 (31.6); b: 20 (34.5); a: 21 (36.8); b: 10 (20.0) 50–59: a: 55 (29.9); b: 54 (27.1); a: 19 (33.3); b: 19 (32.8); a: 23 (40.4); b: 19 (38.0) 60+: a: 66 (35.9); b: 82 (41.2); a: 14 (24.6); b: 9 (15.5); a: 11 (19.3); b: 15 (30.0) 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)	b: 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 including a low-calorie, low-fat diet and increasing physical activity to achieve 150 minutes per week of moderate exercise (e.g. walking and cycling). Sessions included topics and lessons covering lifestyle change, self-monitoring, goal setting, stimulus control, nutrition, environmental change and problem-solving/coping strategies. A toolbox approach was used to add new strategies to help achieve goals. Group sessions were available after the initial 16 sessions were 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 the trial and contacted by telephone at least once between visits No. of times contacted: a: 3; b: 30		

Study ID	Participants	Interventions	Outcomes	Notes

Weight (kg), mean (SD):

Sex	White	Black	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)
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 (kg/m^2), *n* (%)

BMI (kg/m^2)	White	Black	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)
Women			
< 30	a: 111 (27.6); b: 100 (26.3)	a: 32/28.8); b: 32/26.7)	a: 32 (19.6); b: 37 (24.0)
30–34.99	a: 104 (25.9); b: 101 (26.5)	a: 39/35.1); b: 50/41.7)	a: 35 (21.5); b: 46 (29.9)
35+	a: 187 (46.5); b: 180 (47.2)	a: 40/36.0); b: 38 (31.7)	a: 96 (58.9); b: 71 (46.1)

Baseline comparability: Higher proportion of obese participants were female and black. Higher proportion of white participants

No. allocated. *n* (%):

Sex	White	Black	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)
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)

Completed (at 30 months), *n* (%)

Sex	White	Black	Hispanic
Men	a: 124 (13.2); b: 135 (14.4)	a: 44 (4.7); b: 41 (4.4)	a: 39 (4.2); b: 31 (3.3)
Women	a: 269 (13.6); b: 261 (13.2)	a: 76 (3.8); b: 77 (3.9)	a: 104 (5.3); b: 102 (5.2)

Dropout (%):

Sex	White	Black	Hispanic
Men	a: 32.6; b: 32.2	a: 22.8; b: 29.3	a: 31.6; b: 38.0
Women	a: 33.1; b: 31.5	a: 31.5; b: 35.8	a: 36.2; b: 33.8

No. assessed, (%):

Sex	White	Black	Hispanic
Men	a: 124 (13.2); b: 135 (14.4)	a: 44 (4.7); b: 41 (4.4)	a: 39 (4.2); b: 31 (3.3)
Women	a: 269 (13.6); b: 261 (13.2)	a: 76 (3.8); b: 77 (3.9)	a: 104 (5.3); b: 102 (5.2)

continued

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Wing 1991[112]	Location: One university, USA Period of study: NR Inclusion criteria: Age 30–65 years, > 20% over ideal body weight, type 2 diabetes, i.e. fasting glucose ≥ 140 mg/dl or ≥ 200 mg/dl 2 hours after oral glucose load, spouses ≥ 15% above ideal body weight and age 30–70 years, US$150 deposit per couple, which 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 (kg/m^2), mean (SD): Men + women: a: 36.64 (5.77); b: 35.68 (5.76) Baseline comparability: Yes	Description of interventions: All participants received behavioural weight-loss programme consisting of stimulus control, problem solving, assertion, goal setting and cognitive techniques; participants advised to monitor calorie intake to between 1200 and 1500 kcal per 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 1000 kcal per week; deposit refunded according to weight loss and attendance a: 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: Together: Spouse participated in all aspects of the programme and no distinction was made in treatment between the participant and the spouse; half of therapy sessions focused on social support and behavioural marital therapy literature, e.g. mutual positive reinforcement. Deposit refunds contingent on participant and spouse weight loss and attendance at assessments Timing of active intervention: 72 weeks No. of times contacted: a + b: 21 No. allocated: Men + women: a: 25; b: 24 No. completed: Men: a: 10, b: 8; women a: 13; b: 12 Dropout (%): Overall patients 12.3; spouses 13.3 No. assessed: Men: a: 10, b: 8; women: a: 13, b: 12	Length of follow-up: 72 weeks Outcomes by sex: Weight (participants only)	All type 2 diabetes, obese spouse

Study ID	Participants	Interventions	Outcomes	Notes
Wing 1994[113]	Location: University of Pittsburgh, PA, USA Period of study: Prior to November 1993 Inclusion criteria: Either sex, age 30–70 years, > 30% or > 18 kg over ideal body weight (based on Metropolitan Life Insurance tables), on-insulin-dependent diabetes (criteria according to National Diabetes Data Group) Exclusion criteria: Health problems that would interfere with the use of very low-calorie diets Age (years), mean (SD): Men + women: 51.8 (9.6) BMI (kg/m^2), mean (SD): Men + women: 37.9 (6.3) Baseline comparability: Yes	Description of interventions: a: 1000–1200 kcal per day consisting of < 30% energy intake from fat from baseline to week 50 b: 500 kcal per day either as liquid supplement (Optifast 70; Sandoz Nutrition, Minneapolis, MN, USA) or lean meat, fish or fowl for weeks 0–12 and weeks 24–36; other foods gradually reintroduced over following 4 weeks to consume 1000–1200 kcal per day at weeks 13–23 and weeks 37–50 a + b: All participants kept self-monitoring records, which were reviewed at weekly group meetings. Meetings also included detailed discussion on nutrition, which included focusing on reducing fat content and increasing intake of complex carbohydrate and fibre, and exercise, which stressed walking or behavioural techniques, including stimulus control, goal setting and self-monitoring of intake and exercise, preplanning, relapse prevention and modifying cognitions. Also included role playing and individual discussion and questions. All participants were encouraged to increase walking to 2 miles per day for 5 days per week. All participants kept 3-day food diaries at baseline, 6 months and 12 months. All diabetes medications were discontinued at the start and an algorithm was used to determine if and when to restart medication. All participants were given vitamin/mineral supplements throughout the study. All participants deposited US$150, which was refunded in full for reaching behavioural goals and attending assessments at baseline, 6 months and 50 weeks	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

continued

TABLE 10 Characteristics of trials included in the review of RCTs of men and women compared (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
		Timing of active intervention: a + b: 50 weeks plus follow-up 1 year later No. of times contacted: a: 52; b: 78 No. allocated: Men: a: 18, b: 15; women: a: 30, b: 30 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		

Look AHEAD, Action for Health in DIabetes; NR, not reported; SEM, standard error of the mean; VLCD, very low-calorie diet.

interventions.[97,99–101,104,108,110,111] The study by Volpe and colleagues[109] compared a reducing diet, an exercise programme or both together. One trial examined which type of behaviour change programme to use.[97] One trial examined the effect of modifying the home environment.[94] The study by Jeffery and colleagues evaluated the delivery of a programme by mail or by telephone.[99] One study evaluated the delivery of a programme by doctors or by nurses.[102] Wing and colleagues[112] investigated whether or not weight loss was improved if a spouse also attended the programme. Two trials by Hakala and colleagues[95,96] examined the benefit of an initial inpatient rehabilitation programme.

One trial[105] solely investigated interventions for weight maintenance, comparing the effectiveness of orlistat with the effectiveness of placebo treatment. The period of follow-up ranged from 1 to 6 years (median 2 years). A trial published in 1984[98] included a weight-maintenance component in a subset of participants following a weight reduction phase. Both phases of this trial investigated the effect of financial contracts on weight loss and maintenance.

Of the six reports linked to RCTs, five were identified as ancillary studies to main trials. These included two studies examining spousal effects,[120,121] one study examining the effects of weight loss on erectile function in a subset of male participants,[122] one study investigating differences in body image between men and women[123] and one study investigating the effects of weight-loss interventions on bone mineral density.[124] One report provided additional data for risk factors not included in the main trial report.[125]

Characteristics of the men and women

Of the included reports we identified three large trials of weight-loss interventions for the prevention or treatment of type 2 diabetes: the Diabetes Prevention Program (DPP);[111] the Finnish Diabetes Prevention Study (FDPS)[104] and the Look AHEAD (Action for Health in Diabetes) trial.[110] A further five trials targeted participants with type 2 diabetes[97,102,108,112,113] and two included some people with diabetes or impaired glucose tolerance.[105,107] In total, 12,934 men and women were enrolled in the trials, with the mean age of participants ranging from 37 to 59 years (median 55 years). The highest reported BMI was 42.7 kg/m^2 for men[95] and 43.6 kg/m^2 for women,[95] whereas the lowest was 29.7 kg/m^2 [104] and 30.53 kg/m^2 [98] respectively. Only nine trials reported BMI by sex at baseline. In eight studies women had a higher BMI than men,[95,96,102,104,106,108,110,111] and in one study BMI was higher in men.[98]

Attrition in men compared with women

Eight trials[95,96,98,100,102,103,106,111] provided data that could be included in the analysis comparing the numbers of men and women who completed the trials. In total, there were 3813 participants; 1197 were men and 2616 were women (*Tables 11* and *12*). The results shows that men were 11% (95% CI 8% to 14%,

TABLE 11 Studies included in the analysis of attrition by sex

		No. randomised		No. completed	
Study ID	% men recruited	Men	Women	Men	Women
Hakala 1993[95]	33.3	20	40	18	35
Hakala 1994[96]	30.0	18	42	13	30
Jeffery 1984[98]	48.7	55	58	53	55
Lantz 2003[103]	25.8	86	248	35	82
Korhonen 1987[102]	50.0	40	40	38	33
Jolly 2011[100]	30.7	227	513	162	182
Ross 2012[106]	29.8	146	344	121	275
West 2008[111]	31.3	605	1331	416	889
Total	31.4	1197	2616	856	1581

TABLE 12 Contingency table and results for studies included in the analysis of male and female attrition

Sex	Completed study	Did not complete study	Total	Proportion completing
Male	856	341	1197	0.72
Female	1581	1035	2616	0.60
Total	2437	1376	3813	0.64
Difference in proportion between men and women (95% CI)				0.11 (0.08 to 0.14), $p < 0.001$

$p < 0.001$) more likely to complete the trial than women, suggesting men are highly motivated once commencing weight loss.

Overview of types of outcomes reported

Quantitative outcomes

All trials reported either baseline and end weights or changes in weight by sex except for the FDPS,[104] which reported incidence of diabetes by sex. Two studies reported waist circumference by sex[106,109] and two reported BMI by sex.[106,108] Cardiovascular risk factors were reported by sex in five trials: two reported HbA_{1c},[97,108] three reported systolic and diastolic blood pressure,[101,106,109] three reported triglycerides[106,108,109] and three reported total and HDL cholesterol.[106,108,109] LDL cholesterol was reported by Volpe and colleagues[109] and Ross and colleagues[106] and fasting plasma glucose was reported by Vanninen and colleagues[108] and Ross and colleagues.[106]

Process outcomes

Hakala[96] evaluated inpatient rehabilitation and health centre weight-loss programmes. The only reported difference by sex was that men in the health centre group were more likely to find GP appointments useful than women (63% of men vs. 23% of women). Both programmes met the expectations of participants. Participants in the rehabilitation group considered counselling by a nutritionist, physiotherapist and physician to be necessary and counselling from a social worker to be useful, although 62% wanted more individual counselling from the nutritionist. The majority (72%) of the rehabilitation participants felt that the 3-week inpatient period was satisfactory. The remaining 28% felt that it was too short. In comparison, the majority (72%) of the health centre participants felt the longer 10-week course was too short and 77% stated that they wanted more individual counselling with a greater emphasis on practical physical activity and dietary advice. No data were provided by sex for process outcomes.

Similarly, all nurses delivering the 6-week weight reduction programme in the trial by Karvetti and Hakala[101] and the majority (58%) of the participants responding to the evaluation assessment (86% response rate) felt that the weight-loss programme in this trial was too short. Most nurses suggested that the programme should be extended to 10 weeks. The programme met the expectations of 66% of the participants. The only reported difference by sex was that most men (80%) and just under half of the women (42%) felt that six weight assessments during the intervention year were adequate. The remainder would have preferred more frequent assessment. Group support was also reported as being important for successful weight reduction.

Of the GPs participating in the trial conducted by Hakala,[96] 65% responded to the evaluation exercise. Only 41% considered their role as a GP to be suitable for the follow-up of obese participants, with 47% feeling that they were not suitable. Many felt that the task was uninteresting and useless, with only 35% showing that they were motivated to support participants in their weight reduction efforts. Similarly, the authors of the Lighten Up trial[100] noted that GPs may have less faith in their ability to produce positive weight change in obese participants. Participants in this trial also noted that difficulty arranging regular appointment times with their general practice contributed to their failure to complete the full programme.

Commercial companies, on the other hand, were able to offer weekly meetings at the same time each week. Neither trial reported differences by sex.

Quality of the evidence

Risk of bias

The risk of bias assessment for the individual trials is shown in *Appendix 10* (see *Table 58*). *Figure 11* summarises the assessment.

Five trials[99,100,104–106] were judged to have adequate sequence generation but this was unclear for the majority of trials (14/20, 70%). Only one trial[97] was judged as having a high risk for this item. Similarly, only five trials[97,99,100,104,106] demonstrated successful allocation concealment and were considered at low risk for selection bias. Richelsen and colleagues[105] compared orlistat therapy with placebo for weight maintenance; therefore, blinding was possible in this trial, although it was unclear whether or not those administering treatment were blinded to the nature of the interventions and whether participants were unblinded by gastrointestinal effects or not. Blinding of participants or health-care providers was not possible for any of the remaining trials. Four trials[100,104,107,111] carried out blinding of outcome assessors. This was unclear for the remaining trials.

In three trials, groups were treated differently apart from the interventions received. For the trial conducted by Shai and colleagues,[107] fewer men in the low-fat diet group participated in the ancillary substudy; in the DPP trial[111] the standard lifestyle group received a placebo tablet whereas the intensive lifestyle group received no tablet; and in the trial conducted by Wing and colleagues[113] the very low-calorie diet group received physician monitoring, which was not given to the low calorie diet group. Although only four trials[95,96,101,111] were judged as being at high risk of attrition bias because of incomplete outcome data, the risk of bias for this item was unclear in just under half of all trial reports (9/20; 45%).[94,97–99,103,105,108,109,113] Only seven trials[94,99,100,104,106,107,110] carried out a full intention-to-treat analysis and for three trials[97,98,109] the method of analysis was unclear. The remaining trials analysed data for trial completers/compliers only. All trials were considered to be at low risk for selective reporting and only two trials were considered to be at unclear risk of other bias. Jeffery and colleagues[98] enrolled men from a previous weight-loss trial conducted by the same authors. Gorin and colleagues[94] provided free exercise equipment for use in the home and reimbursed participants in the intervention group for home delivery of grocery items; the control group received no similar 'incentives' or additional reason to feel obligated to complete the trial.

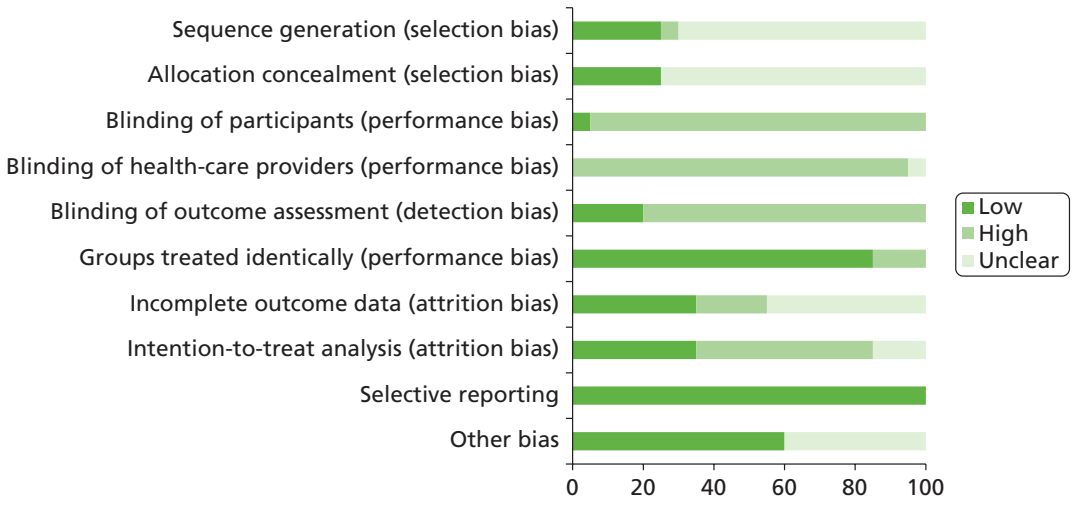

FIGURE 11 Summary of risk of bias assessment of trials included in the systematic review of men and women.

Assessment of equity and sustainability

Trial-level results are detailed in *Appendix 10* (see *Table 59*). *Figure 12* summarises the equity assessment.

As with our review of men-only RCTs, the majority of equity items were not considered, were unclear or were not reported by the trial authors. The trials mainly did not report on diversity, sustainability or political context and did not describe partnerships. The majority of trials included a representative participant spectrum with the exception of those conducted by Karvetti and Hakala,[101] Jeffery and colleagues,[98] Volpe and colleagues,[109] and Gorin and colleagues,[94] but none reported sociodemographic differences between participants withdrawing or excluded and those continuing. Four trials were considered to have occurred in settings that could have excluded specific population groups. The trials conducted by Jeffery and colleagues[98] and Wing and colleagues[112] both required financial deposits at trial entry, thus potentially excluding less affluent participants. Similarly, Jeffery and colleagues[99] recruited participants with private health-care insurance only. Shai and colleagues[107] conducted their trial in a work setting with on-site medical clinic facilities. Only two trials[100,110] carried out fidelity checks. Three trials reported adverse harms.[100,105,106] As discussed earlier, only three trials evaluated process outcomes.[96,100,101] None of the trial authors were considered to have conflicting interests although this was unclear for five reports.[95,101,103,105,106]

Assessment of effectiveness

An exercise programme compared with a low-fat reducing diet

Volpe and colleagues[109] compared a supervised exercise programme, a low-fat reducing diet, and a supervised exercise programme plus a low-fat reducing diet. The goal was for participants to lose 0.5–1.0 kg 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 the exercise group and the diet group had gained weight. Men in the exercise group gained more weight than men in the diet group whereas the reverse was true for women (*Figure 13*).

At 1 year, all groups showed little difference in changes to waist circumference. All groups showed a large deterioration in HDL cholesterol and an increase in LDL cholesterol. Similarly, all groups showed increases in triglycerides, with the exception of men in the diet group in which levels were lowered, although changes were more modest. Both men and women in the diet group and men in the exercise group

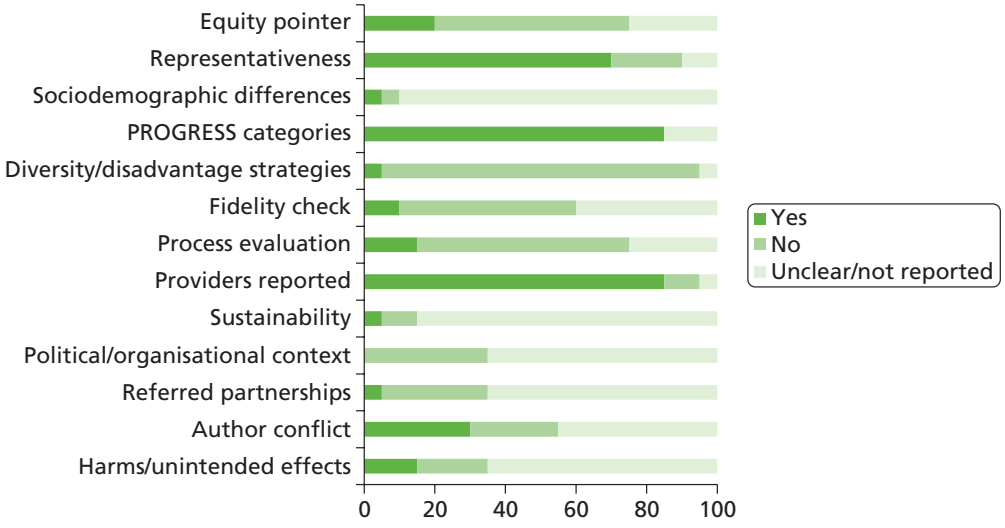

FIGURE 12 Summary of equity assessment of trials included in the systematic review of men and women.

Study or subgroup	Exercise Mean	SD	Total	Diet Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Male weight change in kg at 12 months								
Volpe 2008[109]	5.6	7.5	17	3.1	6.79	13	100.0%	2.50 (–2.63 to 7.63)
Subtotal (95% CI)			**17**			**13**	**100.0%**	**2.50 (–2.63 to 7.63)**
Heterogeneity: not applicable								
Test for overall effect: z=0.95 (p=0.34)								
Female weight change in kg at 12 months								
Volpe 2008[109]	0.5	6.1	17	2	6.48	15	100.0%	–1.50 (–5.88 to 2.88)
Subtotal (95% CI)			**17**			**15**	**100.0%**	**–1.50 (–5.88 to 2.88)**
Heterogeneity: not applicable								
Test for overall effect: z=0.67 (p=0.50)								

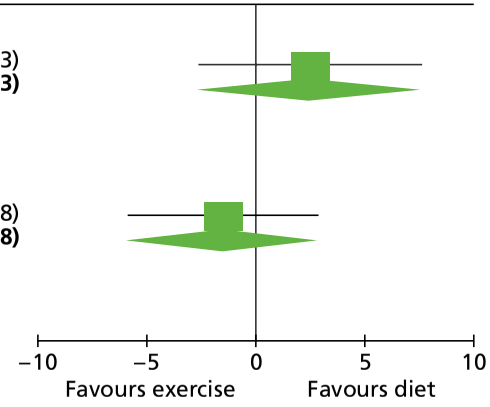

FIGURE 13 Effect of an exercise programme vs. a low-fat reducing diet on weight change in men and women.

lowered their systolic and diastolic blood pressure, with men showing greater decreases than women. Both types of blood pressure were raised for women in the exercise group, especially diastolic blood pressure. The difference in diastolic pressure between women in the diet group and women in the exercise group was significant after 1 year ($p = 0.01$) (*Table 13*).

A low-fat reducing diet plus an exercise programme compared with a low-fat reducing diet

In the same trial[109] a combination of a low-fat reducing diet and an exercise programme was compared with the same diet but without the exercise programme. At 12 months, men in the diet and exercise programme group gained less weight than men in the diet group. The protective effect of diet and exercise was repeated for the women (*Figure 14*).

The low-fat reducing diet and exercise programme resulted in modest reductions in waist circumference. Although both groups showed poorer LDL cholesterol levels, the diet and exercise group showed less deterioration than the diet group for both sexes. Women in the diet and exercise group and men in both groups reduced their triglyceride levels, with men in the combined group showing the greatest reduction. Men in both groups reduced their systolic and diastolic blood pressure with the greatest reduction shown in the diet and exercise group. Conversely, both diastolic and systolic blood pressure slightly increased in women in this group, whereas diastolic and systolic blood pressure slightly decreased in women in the diet group (*Table 14*).

TABLE 13 Calculated mean change in risk factors for the exercise programme and low-fat reducing diet groups after 1 year

	Exercise programme		Low-fat reducing diet	
Outcome	Men ($n = 17$)	Women ($n = 17$)	Men ($n = 13$)	Women ($n = 15$)
Waist circumference (cm)	–1.2	–3.9	–0.1	+0.9
Total cholesterol (mmol/l)	–0.18	+0.03	+0.01	+0.26
LDL cholesterol (mmol/l)	+0.37	+0.15	+0.21	+0.44
HDL cholesterol (mmol/l)	–0.18	–0.13	–0.19	–0.24
Triglycerides (mmol/l)	+0.07	+0.03	–0.06	+0.01
Systolic blood pressure (mmHg)	–14.4	+3.0	–13.3	–1.5
Diastolic blood pressure (mmHg)[a]	–7.9	+6.3[a]	–9.5	–2.6

a Significant difference vs. the low-fat reducing diet group (reported $p = 0.01$).

Study or subgroup	Low fat diet and exercise Mean	SD	Total	Low fat diet Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Male weight change in kg at 12 months								
Volpe 2008[109]	0.6	6.09	14	3.1	6.79	13	100.0%	−2.50 (−7.38 to 2.38)
Subtotal (95% CI)			**14**			**13**	**100.0%**	**−2.50 (−7.38 to 2.38)**
Heterogeneity: not applicable								
Test for overall effect: $z=1.00$ ($p=0.32$)								
Female weight change in kg at 12 months								
Volpe 2008[109]	0	6.2	14	2	6.48	15	100.0%	−2.00 (−6.62 to 2.62)
Subtotal (95% CI)			**14**			**15**	**100.0%**	**−2.00 (−6.62 to 2.62)**
Heterogeneity: not applicable								
Test for overall effect: $z=0.85$ ($p=0.40$)								

FIGURE 14 Effect of a low-fat reducing diet plus an exercise programme vs. a low-fat reducing diet on weight change in men and women.

TABLE 14 Calculated mean change in risk factors for the low-fat reducing diet plus exercise and the low-fat reducing diet only groups after 1 year

	Low-fat reducing diet and exercise programme		Low-fat reducing diet	
Outcome	Men ($n = 14$)	Women ($n = 14$)	Men ($n = 13$)	Women ($n = 15$)
Waist circumference (cm)	–1.9	–2.1	–0.1	+0.9
Total cholesterol (mmol/l)	–0.04	–0.18	+0.01	+0.26
LDL cholesterol (mmol/l)	+0.15	+0.10	+0.21	+0.44
HDL cholesterol (mmol/l)	–0.13	–0.23	–0.19	–0.24
Triglycerides (mmol/l)	–0.20	–0.16	–0.06	+0.01
Systolic blood pressure (mmHg)	–15.6	+2.1	–13.3	–1.5
Diastolic blood pressure (mmHg)	–12.3	+1.2	–9.5	–2.6

A low-fat reducing diet plus an exercise programme compared with an exercise programme

The trial by Volpe and colleagues[109] also compared diet plus exercise with exercise alone. The addition of a diet to exercise again provided greater benefits than exercise alone in terms of less weight gain for both sexes, although the difference was statistically significant for men only ($p = 0.04$) (*Figure 15*).

Modest reductions in waist circumference were also found for this comparison. LDL cholesterol levels in all groups worsened. The decrease in triglyceride levels for the diet and exercise group was not repeated in the exercise group, with both sexes showing increased levels. The combination of both diet and exercise produced the greatest reduction for this outcome. Again, only men benefited from a reduction in systolic and diastolic blood pressure, with the greatest reduction occurring in the combined intervention group. Both diastolic and systolic pressure were raised in women in both groups at 1 year (*Table 15*).

FIGURE 15 Effect of a low-fat reducing diet plus an exercise programme vs. an exercise programme on weight change in men and women.

TABLE 15 Calculated mean change in risk factors for the low-fat reducing diet plus exercise and the exercise-only groups after 1 year

	Low-fat reducing diet and exercise programme		Exercise programme	
Outcome	Men ($n = 14$)	Women ($n = 14$)	Men ($n = 17$)	Women ($n = 17$)
Waist circumference (cm)	–1.9	–2.1	–1.2	–3.9
Total cholesterol (mmol/l)	–0.04	–0.18	–0.18	+0.03
LDL cholesterol (mmol/l)	+0.15	+0.10	+0.37	+0.15
HDL cholesterol (mmol/l)	–0.13	–0.23	–0.18	–0.13
Triglycerides (mmol/l)	–0.20	–0.16	+0.07	+0.03
Systolic blood pressure (mmHg)	–15.6	+2.1	–14.4	+3.0
Diastolic blood pressure (mmHg)	–12.3	+1.2	–7.9	+6.3

A low-fat reducing diet with exercise advice compared with control

Vanninen and colleagues[108] investigated a low-fat reducing diet and exercise advice compared with basic conventional educational materials only. Details of the exact dietary prescription were not provided. All participants in this trial were non-insulin-dependent type 2 diabetics. After 1 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 (*Figure 16*). It should be noted that women had a higher mean BMI than men at baseline (34.2 and 33.4 kg/m^2 for women vs. 30.1 and 31.1 kg/m^2 for men for the control and intervention groups respectively).

Men in the intervention group showed a greater improvement in total cholesterol, triglyceride and HbA_{1c} levels than men in the control group, although the control group had a greater improvement in HDL cholesterol levels. Fasting plasma glucose levels increased for both groups of men but the control group saw the greatest increase. No significant differences between groups were reported for men (*Table 16*).

Women in the intervention group showed greater improvements than women in the control group for total cholesterol and triglycerides and also for HDL cholesterol. The control group showed a greater decrease in fasting plasma glucose levels, but the improvement in HbA_{1c} was the same in both women's groups. However, women in the control group had higher HbA_{1c} and fasting plasma glucose levels than women in the intensified diet and exercise group at baseline (see *Table 16*). In a later report,[125] the authors report a continuing reduction in BMI for the intervention groups at 15 months, with some reduction also seen in the control groups.

Study or subgroup	Diet and exercise Mean	SD	Total	Control Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Male weight change in kg at 12 months								
Vanninen 1992[108]	−1.82	6.43	21	2.25	6.55	24	100.0%	−4.07 (−7.87 to −0.27)
Subtotal (95% CI)			**21**			**24**	**100.0%**	**−4.07 (−7.87 to −0.27)**
Heterogeneity: not applicable								
Test for overall effect: $z=2.10$ ($p=0.04$)								
Female weight change in kg at 12 months								
Vanninen 1992[108]	−2	6.48	17	−0.5	6.06	16	100.0%	−1.50 (−5.78 to 2.78)
Subtotal (95% CI)			**17**			**16**	**100.0%**	**−1.50 (−5.78 to 2.78)**
Heterogeneity: not applicable								
Test for overall effect: $z=0.69$ ($p=0.49$)								

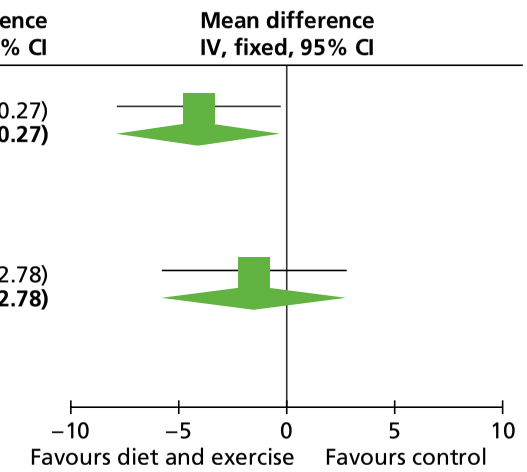

FIGURE 16 Effect of a low-fat reducing diet with exercise advice vs. control on weight change in men and women.

TABLE 16 Calculated mean change in risk factors from baseline in the low-fat reducing diet and exercise advice and control groups after 1 year

Outcome	Time (months)	Low-fat reducing diet and exercise advice		Control	
		Men ($n = 21$)	Women ($n = 17$)	Men ($n = 24$)	Women ($n = 16$)
Total cholesterol (mmol/l)	12	–0.3	0	+0.1	+0.2
HDL cholesterol (mmol/l)	12	+0.11	+0.12	+0.4	+0.04
Triglycerides (mmol/l)	12	–0.9	–0.1	0	+0.2
HbA_{1c} (%)	12	–0.1	–0.9	+0.1	–0.9
Fasting plasma glucose (mmol/l)	12	+0.1	–0.6	+0.6	–1.3

Diabetes incidence

The FDPS[104] included participants at high risk of developing type 2 diabetes based on a classification of being overweight and having impaired glucose tolerance. Participants were randomised to receive an individually tailored low-fat reducing diet plus an exercise programme to achieve 5% weight loss or to receive general advice. After a median follow-up period of 4 years, the active intervention group showed favourable results in reducing the incidence of diabetes. The incidence rate was 8.6 (95% CI 5.8 to 12.6) per 100 person-years for men in the control group compared with 3.7 (95% CI 2.2 to 6.2) per 100 person-years in the intervention group. For women the incidence rate was 6.9 (95% CI 5.2 to 9.2) in the control group and 4.3 (95% CI 3.0 to 6.2) in the intervention group. The hazard ratio for diabetes incidence was 0.43 (95% CI 0.22 to 0.81) for men and 0.61 (95% CI 0.39 to 0.97) for women, with no statistically significant interaction between sex and intervention. Other risk factors were not reported by sex in this study.

A low-fat reducing diet plus behavioural therapy compared with control

Karvetti and Hakala[101] investigated a low-fat reducing diet plus behavioural therapy delivered in the primary health-care setting. The dietary prescription of 1200 kcal per day for weight reduction and 1800 kcal per day for maintenance was not reported to differ by sex. Participants in the intervention group were supported by public health nurses with three lectures from a physician, a psychologist and a physiotherapist. Participants were also given encouragement and support. The control group received no instruction and was contacted for yearly assessment only. After 1 year both men (–11.80 kg, 95% CI –16.86 to –6.74 kg) and women (–5.60 kg, 95% CI –8.74 to –4.57 kg) in the intervention group had lost significantly more weight than men and women in the control group respectively (*Figure 17*).

Women in the intervention group showed a significant reduction in systolic blood pressure compared with women in the control group (reported $p < 0.05$) (*Table 17*). No other changes in risk factors were reported as being statistically significant between groups according to sex.

FIGURE 17 Effect of a low-fat reducing diet plus behavioural therapy vs. control on weight change in men and women.

TABLE 17 Calculated mean change in risk factors from baseline in the diet and behavioural therapy and control groups after 1 year

	Diet and behavioural therapy		Control	
Outcome	Men ($n = 22$)	Women ($n = 71$)	Men ($n = 20$)	Women ($n = 76$)
Total cholesterol (mmol/l)	+0.2	+0.2	+0.2	+0.3
HDL cholesterol (mmol/l)	+0.25	+0.18	+0.02	+0.04
Systolic blood pressure (mmHg)	0	–6.00[a]	–1.00	0
Diastolic blood pressure (mmHg)	–7.00	–6.00	–5.00	–3.00

a Significant difference vs. the control group (reported $p < 0.05$).

A low-fat reducing diet plus exercise advice, behavioural therapy and home environment modification compared with a low-fat reducing diet plus exercise advice and behavioural therapy only

The trial by Gorin and colleagues[94] randomised overweight and obese participants and an overweight household member, willing to act as a support partner, to a low-fat reducing diet with exercise advice and behavioural therapy or to the same treatment package but with modifications made to the home environment. Only participants received treatment in the standard programme whereas both participants and partners received treatment in the modified programme. Most participant–partner pairs were spouses or significant others (77.2%), with the remainder being participant–adult child (17.4%), participant–other relative (3.0%) and participant–roommate (2.5%) pairings. Modifications targeted physical and social cues in the home. At 18 months, women in the modified programme lost significantly more weight than women in the standard programme [–8.1 kg (SD 1.1 kg) vs. –4.2 kg (SD 1.1 kg), reported $p = 0.014$]. However, men in the standard programme lost more weight than men in the modified programme [–10.0 kg (SD 2.3 kg) vs. –4.6 kg (SD 2.2 kg)] 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. The authors reported that sex did not moderate weight regain for participants or partners, with men and women in both groups regaining weight at equivalent rates.

A low-fat reducing diet plus an exercise programme and behavioural therapy

Wing and colleagues[112] 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 and 1500 kcal per day and to set stepwise goals for walking. Participants in the together group attended with their spouses and both were targeted for weight loss. Participants in the alone group attended by themselves with spouses attending assessment sessions only. The weight loss of participants treated alone and together was not significantly different after 1 year, although men lost more weight when treated alone whereas women did better when treated together (*Table 18*). There was no evidence that marital satisfaction affected weight loss. Spouses of both sexes lost more weight in the together group than in the alone group ($p < 0.05$) but there were no differences between treatment groups for change in calorie intake or exercise.

TABLE 18 Effect of a behavioural weight-loss programme with/without spouse attendance on weight change at 1 year

	Together		Alone	
Outcome	Men ($n = 8$)	Women ($n = 12$)	Men ($n = 10$)	Women ($n = 13$)
Weight loss at 1 year (kg)	–1.25	–5.89	–7.25	–2.26

Note: Spouse weight-loss data not available by sex.

The Look AHEAD study[110] recruited overweight or obese type 2 diabetics to a trial comparing an intensive lifestyle intervention comprising a low-fat reducing diet, some meal replacements and exercise advice and intensive behavioural therapy with diabetes support and education. 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.

Wadden and colleagues[110] reported 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 up to 4 years' follow-up (*Table 19*). The prescribed calorie intake was based on weight but it is not clear whether or not the calorie intake also took account of sex. Attendance and treatment contacts were similar for men and women in the first 4 years.

Effect on body image of a low-fat reducing diet with exercise advice and behavioural therapy compared with control

Several ancillary studies have reported sex effects in the Look AHEAD study. Stewart and colleagues[123] investigated changes in body image in men and women. The authors recruited participants from one centre (Pennington Biomedical Research Centre, Los Angeles, CA, USA) and reported weight data by sex for both groups at 1 year. Women in this study had a higher baseline BMI than men in both treatment groups. Women in the intervention group had a slightly higher discrepancy between their current and their ideal body size (body dissatisfaction) than men (20.9 vs. 19.6), whereas men in the control group were slightly more dissatisfied than women with their body size (20.0 vs. 19.0). Both men and women in the intervention group lost significantly more weight than men and women in the control group respectively (reported $p < 0.001$) (*Figure 18*). Both men and women in the intervention group showed a significant reduction in body image dissatisfaction compared with the control group after 1 year ($p < 0.05$ and $p < 0.01$ respectively). Men in both the intervention group and the control group showed a greater reduction in dissatisfaction than women [–8.1 (standard error 1.59) vs. –6.3 (standard error 0.94) for the intervention group and –3.3 (standard error 1.66) vs. –2.3 (standard error 0.96) for the control group].

TABLE 19 Mean weight change (kg) for an intensive lifestyle intervention by sex

Follow-up period (year)	Men ($n = 1044$)	Women ($n = 1526$)
1	–9.3	–8.1
2	–7.1	–5.9
3	–5.9	–4.6
4	–5.2	–4.4

Study or subgroup	Diet with exercise and BT Mean	SD	Total	Control Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Male weight change in kg at 1 year								
Wadden 2011[110]	−10.19	8.8	36	0.98	6.19	33	100.0%	−11.17 (−14.74 to −7.60)
Subtotal (95% CI)			**36**			**33**	**100.0%**	**−11.17 (−14.74 to −7.60)**
Heterogeneity: not applicable								
Test for overall effect: z=6.14 (p<0.00001)								
Female weight change in kg at one year								
Wadden 2011[110]	−8.74	8.39	45	−0.13	5.95	43	100.0%	−8.61 (−11.64 to −5.58)
Subtotal (95% CI)			**45**			**43**	**100.0%**	**−8.61 (−11.64 to −5.58)**
Heterogeneity: not applicable								
Test for overall effect: z=5.57 (p<0.00001)								

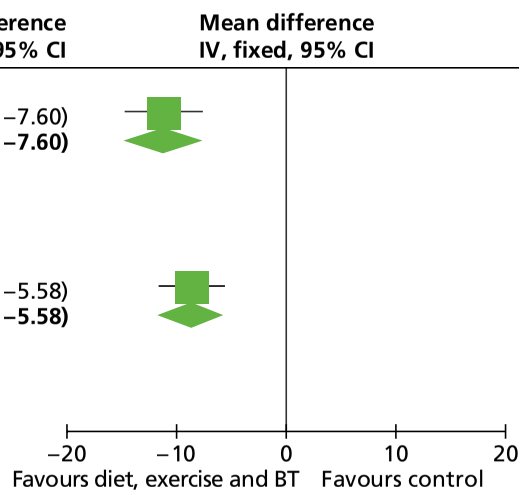

FIGURE 18 Effect of a low-fat reducing diet with exercise advice and behavioural therapy vs. control on weight change in men and women.

Effect on bone mineral density of a low-fat reducing diet with exercise advice and behavioural therapy compared with control

In a separate substudy Schwartz and colleagues[124] investigated the effect of the weight-loss intervention on bone mineral density in participants from five of the Look AHEAD centres. Hip, spine and whole-body dual-energy X-ray absorptiometry scans were obtained for 237 men and 405 women in the intervention group and 246 men and 386 women in the control group. After 1 year, at the total hip the difference in bone loss between the two treatment groups was significantly greater for men (–1.48% intervention vs. 0.02% control) than for women (–1.44% intervention vs. –0.61% control, $p = 0.04$). The authors reported that there was no evidence of an interaction by sex at the other bone sites.

Effect on erectile dysfunction of a low-fat reducing diet with exercise advice and behavioural therapy compared with control

Wing and colleagues[122] investigated the effect of weight loss on erectile function. Men with erectile dysfunction ($n = 153$ in the intervention group and $n = 150$ in the control group) were recruited from five of the 16 Look AHEAD centres. Sexual function was evaluated by self-reported completion of the IIEF.[126] The IIEF is a validated scale of erectile function, with five domains, with scores ≤ 10 denoting severe dysfunction, scores of 11–21 denoting moderate dysfunction, scores of 22–25 indicating mild dysfunction and scores ≥ 26 indicating no dysfunction. After 1 year men in the intervention group showed a greater weight change than men in the control group (*Figure 19*).

After adjusting for baseline differences in erectile function score, the authors reported an increase (improvement) in erectile function of 1.3 (SD 4.7) with the intensive lifestyle intervention at 1 year and 0.03 (SD 5.7) in the control group at 1 year (reported $p = 0.06$).

Using the cut-off values of ≤ 21 and ≥ 22 to denote worsening or improvement in erectile function, respectively, the greater weight loss achieved by the intervention group did not produce a significantly greater improvement in erectile function in men with moderate or severe dysfunction compared with the control group. For mild or no dysfunction, significantly fewer men in the intervention group than in the control group reported worsening of function (reported $p < 0.001$). The intervention group also showed significantly greater changes in HbA_{1c}, systolic and diastolic blood pressure and HDL cholesterol (all reported $p \leq 0.01$) (*Table 20*).

Effect on spouses of a low-fat reducing diet with exercise advice and behavioural therapy

Gorin and colleagues[121] assessed the impact of the intervention and control treatments on the untreated spouses of the Look AHEAD participants from three sites. There were no specific eligibility requirements for spouses other than a willingness to participate in the research. Spouses were not formally involved in either treatment group and were not expected to attend group meetings. 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. As in the full trial, intensive lifestyle participants lost more weight than control participants during the first year [–9.9 kg (SD 7.6 kg) vs. –1.2 kg (SD 4.9 kg), reported $p < 0.001$].

After 1 year, spouses of the intensive lifestyle participants had a weight change of –2.4 kg (SD 4.5 kg) compared with –0.2 kg (SD 3.3 kg) for spouses of control participants. The authors reported no effect by sex or baseline weight of the spouse.

Study or subgroup	Diet with exercise and BT Mean	SD	Total	Control Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Wing 2010[122]	−11.1	9.4	153	−0.7	4.5	150	100.0%	−10.40 (−12.05 to −8.75)
Total (95% CI)			**153**			**150**	**100.0%**	**−10.40 (−12.05 to −8.75)**

Heterogeneity: not applicable
Test for overall effect: z=12.32 (p<0.00001)

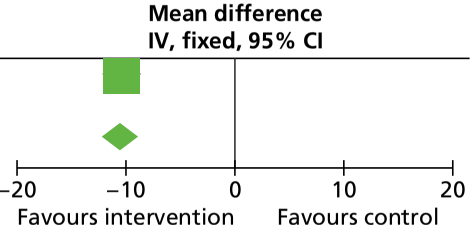

FIGURE 19 Effect of a low-fat reducing diet with exercise advice and behavioural therapy vs. control on weight change (kg) in men with erectile dysfunction.

TABLE 20 Mean change in risk factors from baseline in the diet and exercise with behavioural therapy and control groups after 1 year (men only)

Outcome	Diet and exercise with behavioural therapy ($n = 153$)	Control ($n = 153$)
Total cholesterol (mmol/l)	–0.26 ($n = 148$)	–0.22 ($n = 144$)
LDL cholesterol (mmol/l)	–0.18 ($n = 148$)	–0.14 ($n = 144$)
HDL cholesterol (mmol/l)[a]	0.09 ($n = 148$)	–0.03 ($n = 144$)
Systolic blood pressure (mmHg)[a]	–7.5 (SD 16.3)	–1.5 (SD 14.9) ($n = 150$)
Diastolic blood pressure (mmHg)[a]	–4.7 (SD 7.9)	–1.0 (SD 7.6) ($n = 150$
HbA_{1c} (%)[a]	–0.7 (SD 1.0)	–0.3 (SD 1.1) ($n = 150$)

a Between-group significance reported as $p \leq 0.01$.

A low-fat reducing diet with an exercise programme and behavioural therapy compared with placebo

The DPP[111] randomised individuals at high risk of diabetes to an intensive low-fat reducing diet with an exercise programme and behavioural therapy, metformin or placebo. 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 500–1000 kcal per day, together with an increase in physical activity equivalent to 700 kcal per week. By 30 months, both sexes had lost more weight in the intensive group than in the placebo group (reported $p < 0.001$).

The authors reported that, within the lifestyle treatment group, black women lost significantly less weight than all other race–sex groups (reported $p < 0.01$) with the exception of black men (*Table 21*). A higher proportion of women than men were obese at baseline (74% vs. 59%) and a higher proportion of black people than Hispanic and white people were obese at baseline (74% vs. 67% and 68% respectively).

Comparisons of different types of diet

Shai and colleagues[107] investigated the effectiveness of a low-fat reducing diet (1500 kcal per day for women, 1800 kcal per day for men), a Mediterranean diet with equivalent calories and a low carbohydrate (20 g per day initially increasing to 120 g per day) non-restricted calorie diet in the Dietary Intervention Randomized Controlled Trial (DIRECT). At the end of the 2-year trial, the only significant difference was for women in the Mediterranean reducing diet group, who lost significantly more weight than women in the low-fat reducing diet group ($p = 0.01$) (*Figures 20–22*).

Effect on Dietary Intervention Randomized Controlled Trial wives

Golan and colleagues[120] conducted a parallel study describing the 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 2 months for the DIRECT participants. The aim of the meetings was to update the wives about the principles of the diet strategy to which their husbands had been randomised rather than treating the wives directly. 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 (*Figure 23*).

Golan and colleagues[120] investigated whether or not the intervention had any indirect influence on the DIRECT wives, termed 'halo' effects by the authors (*Figures 24–26*). Differences in weight loss between groups were statistically significant between the low-carbohydrate diet and low-fat reducing diet groups only (reported $p < 0.05$).

TABLE 21 Effect of a low-fat reducing diet with an exercise programme and behavioural therapy vs. placebo on male and female weight change (kg) by ethnic group

		Low-fat reducing diet with exercise programme and behavioural therapy				Placebo			
Ethnic group		1 year	18 months	2 years	30 months	1 year	18 months	2 years	30 months
Men	White	–8.3 (7.9) (*n* = 192)	–7.4 (7.6) (*n* = 190)	–7.1 (7.7) (*n* = 182)	–5.7 (7.6) (*n* = 135)	–0.8 (4.7) (*n* = 177)	–0.6 (5.3) (*n* = 172)	–0.8 (5.8) (*n* = 169)	–0.7 (5.2) (*n* = 124)
	Black	–7.6 (6.9) (*n* = 43)	–7.5 (8.0) (*n* = 40)	–6.2 (8.4) (*n* = 41)	–4.8 (3.5) (*n* = 31)	–0.1 (5.7) (*n* = 54)	–0.0 (5.0) (*n* = 50)	0.1 (5.2) (*n* = 50)	0.5 (5.2) (*n* = 39)
	Hispanic	–7.5 (6.1) (*n* = 54)	–6.6 (7.0) (*n* = 53)	–6.8 (6.4) (*n* = 53)	–6.2 (6.6) (*n* = 41)	0.7 (3.5) (*n* = 55)	1.0 (3.1) (*n* = 54)	1.2 (3.3) (*n* = 54)	1.2 (3.3) (*n* = 44)
Women	White	–7.8 (7.4) (*n* = 367)	–6.6 (8.2) (*n* = 352)	–5.7 (8.7) (*n* = 344)	–4.2 (7.5) (*n* = 261)	–0.8 (5.2) (*n* = 385)	–0.5 (5.8) (*n* = 373)	–0.6 (6.4) (*n* = 359)	–0.9 (7.0) (*n* = 269)
	Black	–4.4 (6.0) (*n* = 144)	–3.9 (6.1) (*n* = 136)	–3.2 (5.8) (*n* = 131)	–2.1 (6.3) (*n* = 102)	0.2 (4.3) (*n* = 151)	0.5 (5.6) (*n* = 146)	0.7 (5.5) (*n* = 144)	1.3 (5.3) (*n* = 104)
	Hispanic	–5.8 (6.1) (*n* = 111)	–6.2 (6.5) (*n* = 107)	–5.5 (6.9) (*n* = 106)	–5.1 (8.3) (*n* = 77)	–1.1 (4.4) (*n* = 101)	–0.5 (4.7) (*n* = 100)	0.2 (4.0) (*n* = 95)	0.7 (4.3) (*n* = 76)

Study or subgroup	Low carbohydrate Mean	SD	Total	Low fat Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Male weight change at 24 months								
Shai 2008[107]	−4.9	6.57	99	−3.4	4.34	89	100.0%	−1.50 (−3.08 to 0.08)
Subtotal (95% CI)			**99**			**89**	**100.0%**	**−1.50 (−3.08 to 0.08)**
Heterogeneity: not applicable								
Test for overall effect: $z=1.86$ ($p=0.06$)								
Female weight change at 24 months								
Shai 2008[107]	−2.4	7.33	10	−0.1	4.06	15	100.0%	−2.30 (−7.29 to 2.69)
Subtotal (95% CI)			**10**			**15**	**100.0%**	**−2.30 (−7.29 to 2.69)**
Heterogeneity: not applicable								
Test for overall effect: $z=0.90$ ($p=0.37$)								

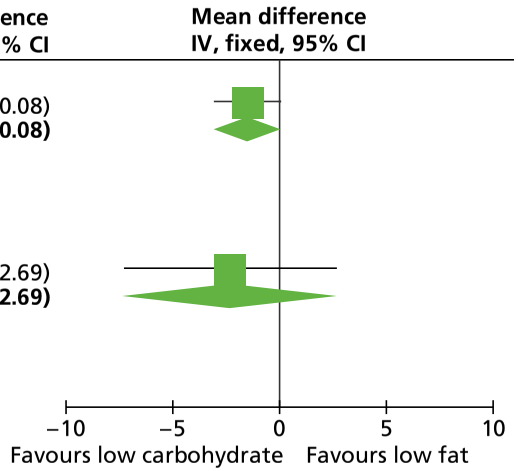

FIGURE 20 Effect of a low-carbohydrate diet vs. a low-fat reducing diet on weight change (kg) in men and women.

Study or subgroup	Low carbohydrate Mean	SD	Total	Mediterranean Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Male weight change in kg at 24 months								
Shai 2008[107]	−4.9	6.57	99	−4	5.09	89	100.0%	−0.90 (−2.57 to 0.77)
Subtotal (95% CI)			**99**			**89**	**100.0%**	**−0.90 (−2.57 to 0.77)**
Heterogeneity: not applicable								
Test for overall effect: $z=1.06$ ($p=0.29$)								
Female weight change in kg at 24 months								
Shai 2008[107]	−2.4	7.33	10	−6.2	9.48	20	100.0%	3.80 (−2.36 to 9.96)
Subtotal (95% CI)			**10**			**20**	**100.0%**	**3.80 (−2.36 to 9.96)**
Heterogeneity: not applicable								
Test for overall effect: $z=1.21$ ($p=0.23$)								

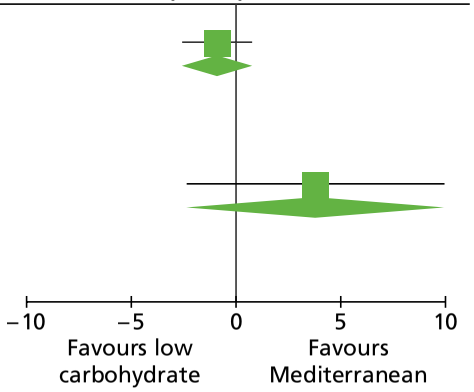

FIGURE 21 Effect of a low-carbohydrate diet vs. a Mediterranean reducing diet on weight change (kg) in men and women.

Study or subgroup	Mediterranean Mean	SD	Total	Low fat Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Male weight change in kg at 24 months								
Shai 2008[107]	−4	5.09	89	−3.4	4.34	89	100.0%	−0.60 (−1.99 to 0.79)
Subtotal (95% CI)			**89**			**89**	**100.0%**	**−0.60 (−1.99 to 0.79)**
Heterogeneity: not applicable								
Test for overall effect: $z=0.85$ ($p=0.40$)								
Female weight change in kg at 24 months								
Shai 2008[107]	−6.2	9.48	20	−0.1	4.06	15	100.0%	−6.10 (−10.73 to −1.47)
Subtotal (95% CI)			**20**			**15**	**100.0%**	**−6.10 (−10.73 to −1.47)**
Heterogeneity: not applicable								
Test for overall effect: $z=2.58$ ($p=0.010$)								

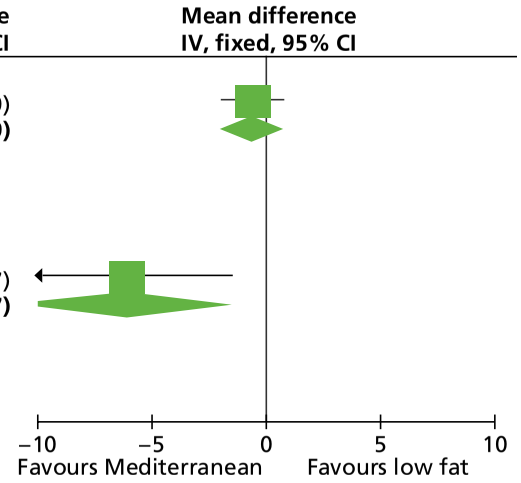

FIGURE 22 Effect of a Mediterranean reducing diet vs. a low-fat reducing diet on weight change (kg) in men and women.

Study or subgroup	With wife support Mean	SD	Total	Without wife support Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Low fat								
Golan 2010[120]	−4.83	7.82	28	−2.26	6.56	61	100.0%	−2.57 (−5.90 to 0.76)
Subtotal (95% CI)			**28**			**61**	**100.0%**	**−2.57 (−5.90 to 0.76)**
Heterogeneity: not applicable								
Test for overall effect: z=1.51 (p=0.13)								
Mediterranean								
Golan 2010[120]	−4.7	7.25	24	−4.35	7.15	65	100.0%	−0.35 (−3.73 to 3.03)
Subtotal (95% CI)			**24**			**65**	**100.0%**	**−0.35 (−3.73 to 3.03)**
Heterogeneity: not applicable								
Test for overall effect: z=0.20 (p=0.84)								
Low carbohydrate								
Golan 2010[120]	−6.41	7.73	22	−4.27	7.12	77	100.0%	−2.14 (−5.74 to 1.46)
Subtotal (95% CI)			**22**			**77**	**100.0%**	**−2.14 (−5.74 to 1.46)**
Heterogeneity: not applicable								
Test for overall effect: z=1.16 (p=0.24)								

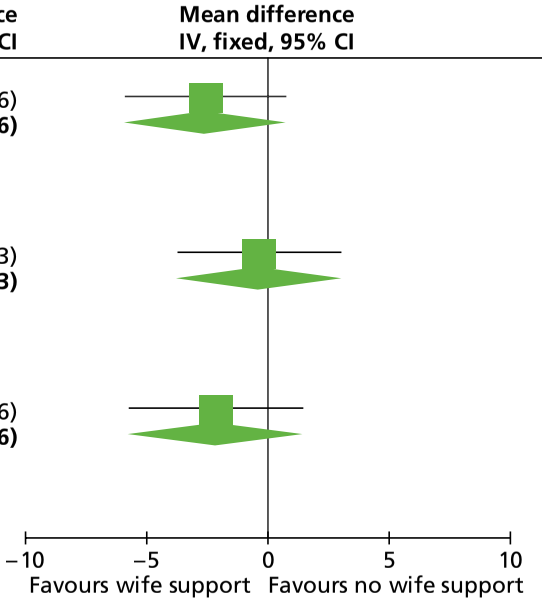

FIGURE 23 Effect of spousal support on weight change (kg) in DIRECT husbands at 2 years.

Study or subgroup	Low carbohydrate Mean	SD	Total	Low fat Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Low carbohydrate vs. low fat								
Golan 2010[120]	−2.3	2.39	15	0.39	3.71	24	100.0%	−2.69 (−4.60 to −0.78)
Subtotal (95% CI)			**15**			**24**	**100.0%**	**−2.69 (−4.60 to −0.78)**

Heterogeneity: not applicable
Test for overall effect: z=2.75 (p=0.006)

Test for subgroup difference: not applicable

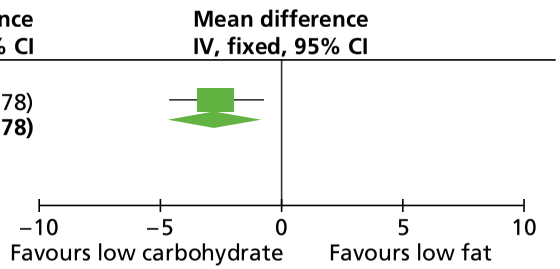

FIGURE 24 Effect of a low-carbohydrate diet vs. a low-fat reducing diet on weight change (kg) in DIRECT wives.

Study or subgroup	Low carbohydrate Mean	SD	Total	Mediterranean Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Low carbohydrate vs. Mediterranean								
Golan 2010[120]	−2.3	2.39	15	−3	6.21	14	100.0%	0.70 (−2.77 to 4.17)
Subtotal (95% CI)			**15**			**14**	**100.0%**	**0.70 (−2.77 to 4.17)**

Heterogeneity: not applicable
Test for overall effect: z=0.40 (p=0.69)

Test for subgroup difference: not applicable

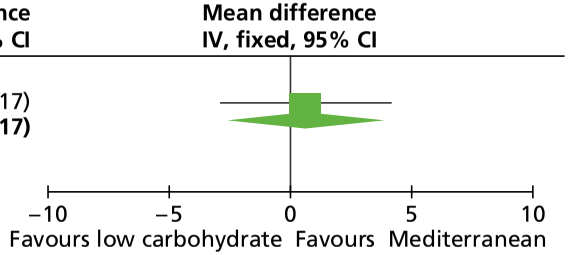

FIGURE 25 Effect of a Mediterranean reducing diet vs. a low-carbohydrate diet on weight change (kg) in DIRECT wives.

Study or subgroup	Mediterranean Mean	SD	Total	Low fat Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
DIRECT wives weight change in kg at 2 years								
Golan 2010[120]	−3	6.21	14	0.39	3.71	24	100.0%	−3.39 (−6.97 to 0.19)
Subtotal (95% CI)			**14**			**24**	**100.0%**	**−3.39 (−6.97 to 0.19)**

Heterogeneity: not applicable
Test for overall effect: z=1.86 (p=0.06)

Test for subgroup difference: not applicable

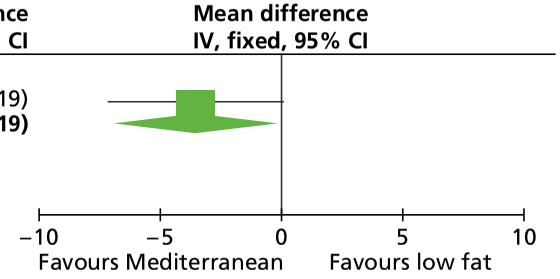

FIGURE 26 Effect of a Mediterranean reducing diet vs. a low-fat reducing diet on weight change (kg) in DIRECT wives.

Wing and colleagues[113] compared an intermittent very low-calorie diet (400–500 kcal per day) with a low-calorie, low-fat diet (1000–1200 kcal per day) in a 1-year trial including participants with type 2 diabetes. Both groups also received behavioural therapy and exercise advice and deposited US$150, which was refunded depending on compliance. Women in the very low-calorie diet group lost significantly more weight after 1 year than women in the low-calorie, low-fat diet group (14.1 kg vs. 8.6 kg, reported $p < 0.023$) whereas men showed comparable weight loss in both treatment groups (15.4 kg and 15.5 kg respectively).

An on-demand diet compared with a regularly repeated diet

After 16 weeks of a 450 kcal per day diet, Lantz and colleagues[103] randomised participants to receive either an on-demand very low-calorie diet (450 kcal per day) or a regularly repeated diet. After the initial 16 weeks, participants in the intermittent on-demand group followed a 500 kcal per day deficit diet but changed to the 450 kcal per day diet when their individual body weight reached a predetermined cut-off level throughout the trial period. Participants in the regularly repeated group followed the same 500 kcal per day deficit diet but used the 450 kcal per day diet for a fortnight every third month.

At 2 years, men in the on-demand intermittent diet group showed significantly more weight change than men in the regularly repeated diet group (mean difference –10.50 kg, 95% CI –4.84 to –16.16 kg). There was no significant difference in weight loss between diets for women (mean difference 1.80 kg, 95% CI 5.23 to –1.63 kg) (*Figure 27*).

Types of behaviour change for weight loss

Heitzmann and colleagues[97] randomised participants with type 2 diabetes to a behavioural, cognitive or cognitive–behavioural therapy or 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 exercise advice. At 18 months across all intervention groups, it was reported that men lost an average of 3.63 kg whereas women gained an average of 0.04 kg (*Table 22*). That men may benefit more from weight reduction programmes than women was shown by a borderline significant interaction (reported $p = 0.057$). Men also experienced a significantly greater reduction in HbA_{1c} than women (reported $p < 0.05$) but this difference was not significant between experimental groups. The effects of the individual programmes by sex were not reported.

Study or subgroup	Intermittent Mean	SD	Total	Repeated Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Male weight change in kg at 2 years								
Lantz 2003[103]	−14.5	10.02	21	−4	7.05	14	100.0%	−10.50 (−16.16 to −4.84)
Subtotal (95% CI)			**21**			**14**	**100.0%**	**−10.50 (−16.16 to −4.84)**
Heterogeneity: not applicable								
Test for overall effect: z=3.64 (p=0.0003)								
Female weight change in kg at 2 years								
Lantz 2003[103]	−6.2	7.67	39	−8	8.18	43	100.0%	1.80 (−1.63 to 5.23)
Subtotal (95% CI)			**39**			**43**	**100.0%**	**1.80 (−1.63 to 5.23)**
Heterogeneity: not applicable								
Test for overall effect: z=1.03 (p=0.30)								

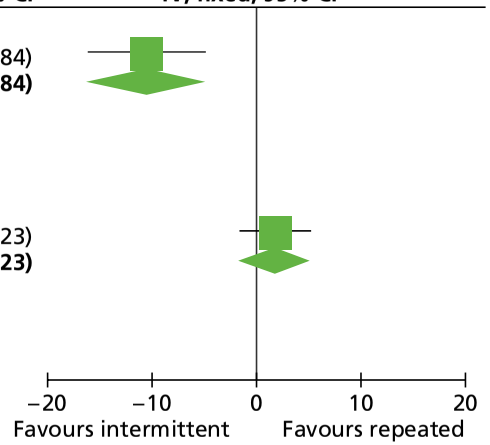

FIGURE 27 Effect of intermittent vs. repeated very low-calorie diets on weight change in men and women.

TABLE 22 Weight change (kg) for men and women in the behaviour change intervention groups and the control group at 18 months

Intervention	Men ($n = 22$ for all groups)	Women ($n = 24$ for all groups)
Control	+0.6	+1.4
Behavioural	–4.2	–0.7
Cognitive	–2.5	–1.5
Cognitive–behavioural	–0.7	–2.0

Note: Data derived from graph format.

An intensive inpatient rehabilitation setting compared with a community setting

Hakala and colleagues[95,96] investigated the effectiveness of an intervention carried out in an initial inpatient rehabilitation setting compared with an intervention carried out in a community setting for people who were at least 50% overweight. The rehabilitation intervention included intensive behavioural and educational group sessions along with a prescribed physical activity programme and occupational therapy, as well as individual nutritionist (1200 kcal per day) and physician counselling. The community intervention involved the same dietary intervention but included either individual physician counselling[95] or group-based counselling delivered in the health centre setting.[96]

In the earlier trial,[95] men did better in the community setting than in the inpatient setting, possibly because of more individual counselling, although differences were statistically significant only for years 1 and 2 ($p < 0.01$). There were no significant differences between groups for women (*Figure 28*).

In the later trial by Hakala and colleagues,[96] a similar comparison was carried out between an intervention in an initial intensive inpatient rehabilitation setting and an intervention in 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 again statistically significant only over the first 2 years ($p = 0.02$ and $p = 0.04$ respectively). For women, the rehabilitation setting produced no significant benefit in weight loss over the community intervention for any time point from 1 to 5 years (*Figure 29*).

Study or subgroup	Rehabilitation Mean	SD	Total	Community Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Male weight change in kg at 1 year								
Hakala 1993[95]	−13.1	8.8	10	−26.2	10.3	10	100.0%	13.10 (4.70 to 21.50)
Subtotal (95% CI)			**10**			**10**	**100.0%**	**13.10 (4.70 to 21.50)**
Heterogeneity: not applicable								
Test for overall effect: z=3.06 (p=0.002)								
Male weight change in kg at 2 years								
Hakala 1993[95]	−1.8	7.4	10	−15.6	12	10	100.0%	13.80 (5.06 to 22.54)
Subtotal (95% CI)			**10**			**10**	**100.0%**	**13.80 (5.06 to 22.54)**
Heterogeneity: not applicable								
Test for overall effect: z=3.10 (p=0.002)								
Male weight change in kg at 5 years								
Hakala 1993[95]	−3	11.9	10	−12.9	15.8	10	100.0%	9.90 (−2.36 to 22.16)
Subtotal (95% CI)			**10**			**10**	**100.0%**	**9.90 (−2.36 to 22.16)**
Heterogeneity: not applicable								
Test for overall effect: z=1.58 (p=0.11)								
Female weight change in kg at 1 year								
Hakala 1993[95]	−15.7	9	20	−11.9	10.4	18	100.0%	−3.80 (−10.02 to 2.42)
Subtotal (95% CI)			**20**			**18**	**100.0%**	**−3.80 (−10.02 to 2.42)**
Heterogeneity: not applicable								
Test for overall effect: z=1.20 (p=0.23)								
Female weight change in kg at 2 years								
Hakala 1993[95]	−5.4	10.9	20	−10.4	13.4	18	100.0%	5.00 (−2.82 to 12.82)
Subtotal (95% CI)			**20**			**18**	**100.0%**	**5.00 (−2.82 to 12.82)**
Heterogeneity: not applicable								
Test for overall effect: z = 1.25 (p = 0.21)								
Female weight change in kg at 5 years								
Hakala 1993[95]	−2.1	12.4	20	−3.4	16.7	18	100.0%	1.30 (−8.14 to 10.74)
Subtotal (95% CI)			**20**			**18**	**100.0%**	**1.30 (−8.14 to 10.74)**
Heterogeneity: not applicable								
Test for overall effect: z=0.27 (p=0.79)								

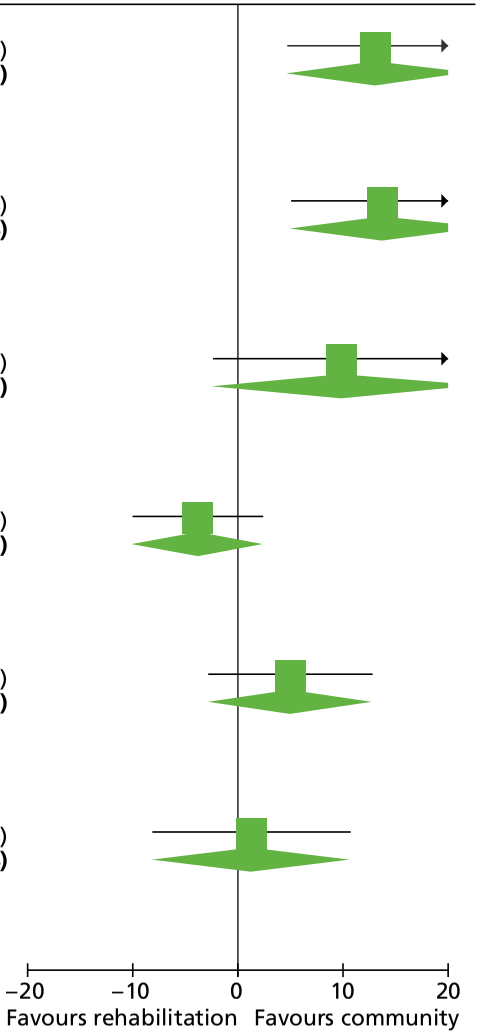

FIGURE 28 Effect of an intervention in an intensive rehabilitation setting vs. an intervention in a community setting, including individual counselling, on weight change in men and women.

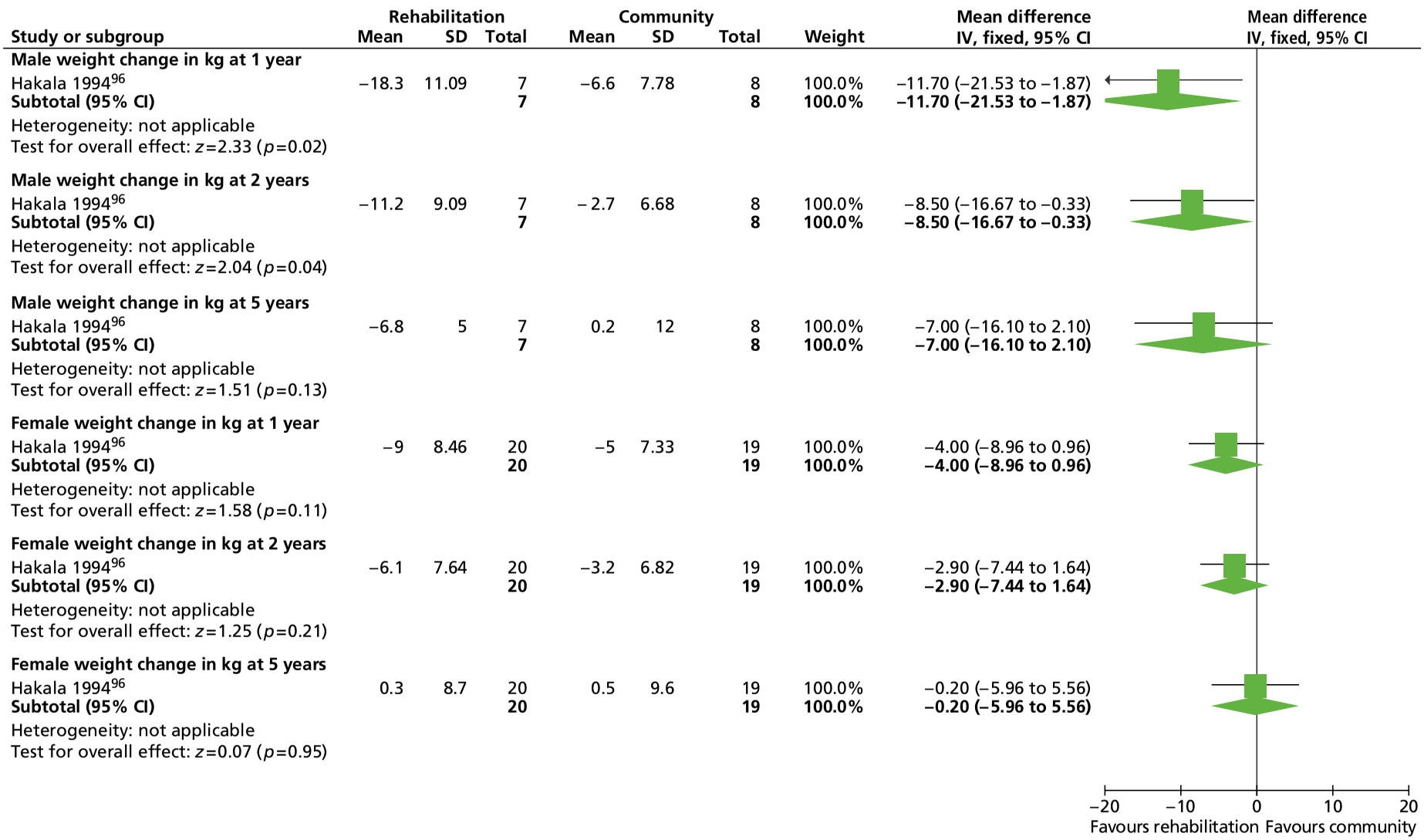

FIGURE 29 Effect of an intervention in an intensive rehabilitation setting vs. an intervention in a community setting on weight change in men and women.

Type of provider and tailoring for dietary intervention

A tailored nurse intervention compared with a doctor-provided leaflet for weight loss

Korhonen and colleagues[102] randomised type 2 diabetic patients to receive care from either a doctor or a specialist nurse to investigate the effect of provider and individual tailoring of a diet and weight reduction intervention on achievement of weight loss. Participants randomised to the care of a doctor were given general concise written information on diet and weight reduction with no further instruction thereafter. Participants randomised to the care of the nurse were given individual assessments and tailored dietary instruction. Nurse interventions were repeated at follow-up visits. At 12 months there were no significant differences between groups for either sex for weight change (*Figure 30*).

Commercial providers compared with NHS providers

The Lighten Up trial[100] 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 through the NHS (NHS Size Down, a GP or a pharmacist) or to a choice group in which they were able to choose one of the six programmes depending on their preference. For the control group (minimal interventional) participants received vouchers for 12 free sessions at a council-run leisure centre. All programmes lasted for 12 weeks and provided advice on exercise, but only the Rosemary Conley group had an exercise class provided. The Weight Watchers and Rosemary Conley programmes tailor advice by sex. The investigators did label some of the commercial groups as 'male friendly' so that men would know that they would not be the only ones present. For the Rosemary Conley programme, a group walk was available for people who did not want to undertake the group exercise. Women were more likely to choose a commercial provider than men (81% vs. 47%). Men in the choice arm were more likely to choose a NHS programme.

Statistically significant weight loss at 1 year from baseline was found for all groups except for the general practice and pharmacy groups (complete case analysis, baseline observation carried forward and last observation carried forward). Only the Weight Watchers group was significantly different from the control group for men and women combined (adjusted mean difference –2.49 kg, 95% CI –4.15 kg to –0.83 kg). The authors found no statistically significant interaction between sex and weight-loss programme.

Further data supplied by the authors show significant weight loss from baseline for women in the choice, NHS Size Down, Rosemary Conley, Slimming World, Weight Watchers and control groups, for all methods of analysis. For men, the NHS Size Down, Rosemary Conley and Weight Watchers programmes produced significant weight loss from baseline for all analyses. For men, the control and Slimming World programmes also produced significant weight loss from baseline, but only in the last observation carried forward analysis (*Table 23*).

Telephone compared with mail advice and behaviour change techniques

Jeffery and colleagues[99] compared the effectiveness of an intervention including weight reduction advice, physical activity advice and behaviour change techniques delivered by telephone or mail. A control group received usual care. Details of the dietary and exercise advice are unclear. Men in both the telephone group and the mail group had lost significantly more weight at 1 year than men in the control group ($p = 0.03$). By contrast, there were no significant differences between women in the telephone or mail group and women in the control group. There were no significant differences for either sex for the telephone group or the mail group (*Figures 31–33*).

Study or subgroup	Nurse Mean	Nurse SD	Nurse Total	Doctor Mean	Doctor SD	Doctor Total	Weight	Mean difference IV, fixed, 95% CI
Male weight change in kg at 12 months								
Korhonen 1987[102]	−3.32	6.86	20	−2.57	6.64	20	100.0%	−0.75 (−4.93 to 3.43)
Subtotal (95% CI)			**20**			**20**	**100.0%**	**−0.75 (−4.93 to 3.43)**
Heterogeneity: not applicable								
Test for overall effect: z=0.35 (p=0.73)								
Female weight change in kg at 12 months								
Korhonen 1987[102]	−5.63	7.51	20	−3.44	6.89	20	100.0%	−2.19 (−6.66 to 2.28)
Subtotal (95% CI)			**20**			**20**	**100.0%**	**−2.19 (−6.66 to 2.28)**
Heterogeneity: not applicable								
Test for overall effect: z=0.96 (p=0.34)								

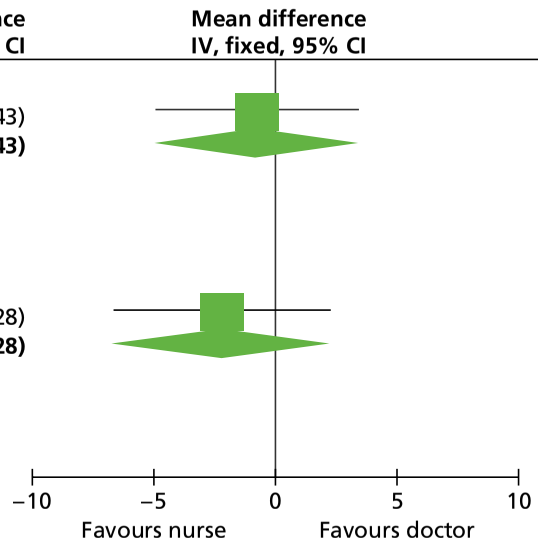

FIGURE 30 A tailored nurse intervention vs. a doctor-provided leaflet for men and women.

TABLE 23 Mean weight change (95% CI) (kg) and number of participants at 1 year of follow-up in the Lighten Up trial[100]

			NHS			Commercial		
Type of analysis	Choice	Minimal intervention	General practice	Size Down	Pharmacy	Rosemary Conley	Slimming World	Weight Watchers
Men								
Complete cases	–0.52 (2.49 to –3.52) (*n* = 17)	–2.23 (–1.22 to 5.68) (*n* = 22)	–1.27 (1.61 to –4.15) (*n* = 14)	–4.59 (–2.19 to –6.99) (*n* = 28)[b]	–1.32 (2.15 to –4.79) (*n* = 10)	–2.69 (–0.46 to –4.91) (*n* = 23)[a]	–2.91 (0.05 to –5.86) (*n* = 24)	–6.05 (–2.77 to –9.32) (*n* = 24)[b]
BOCF	–0.35 (1.62 to –2.32) (*n* = 25)	–1.64 (0.86 to –4.14) (*n* = 30)	–0.77 (0.91 to –2.45) (*n* = 23)	–3.57 (–1.62 to –5.53) (*n* = 36)[b]	–0.69 (0.99 to –2.38) (*n* = 19)	–1.99 (–0.32 to –3.67) (*n* = 31)[a]	–1.99 (0.04 to –4.02) (*n* = 35)	–5.18 (–2.28 to –8.08) (*n* = 28)[a]
LOCF	–1.09 (1.12 to –3.30) (*n* = 25)	–2.65 (–0.06 to –5.23) (*n* = 30)[a]	–1.25 (0.49 to –3.00) (*n* = 23)	–4.03 (–2.09 to –5.98) (*n* = 36)[b]	–2.53 (0.15 to –5.20) (*n* = 19)	–2.93 (–0.59 to –5.28) (*n* = 31)[a]	–3.52 (–1.29 to –5.76) (*n* = 35)[a]	–5.61 (–2.72 to –8.50) (*n* = 28)[b]
Women								
Complete cases	–2.06 (–0.20 to –3.92) (*n* = 48)[a]	–3.25 (–1.22 to –5.28) (*n* = 51)[a]	–1.25 (1.16 to –3.68) (*n* = 32)	–3.06 (–0.55 to –5.56) (*n* = 38)[a]	–1.15 (0.09 to –3.49) (*n* = 29)	–3.58 (–0.90 to –6.27) (*n* = 42)[a]	–3.22 (–1.34 to –5.10) (*n* = 37)[a]	–3.71 (–1.07 to –5.72) (*n* = 54)[b]
BOCF	–1.32 (–0.12 to –2.51) (*n* = 75)[a]	–2.37 (–0.86 to –3.88) (*n* = 70)[a]	–0.86 (0.77 to –2.49) (*n* = 47)	–1.81 (–0.31 to –3.32) (*n* = 64)[a]	–0.65 (0.65 to –1.96) (*n* = 51)	–2.18 (–0.52 to –3.84) (*n* = 69)[a]	–1.84 (–0.71 to –2.96) (*n* = 65)[a]	–2.78 (–1.24 to –4.32) (*n* = 72)[b]
LOCF	–1.41 (–0.09 to –2.72) (*n* = 75)[a]	–3.10 (–1.54 to –4.65) (*n* = 70)[b]	–1.07 (0.66 to –2.81) (*n* = 47)	–2.57 (–1.00 to –4.14) (*n* = 64)[a]	–1.59 (0.05 to –3.24) (*n* = 51)	–3.27 (–1.57 to –4.97) (*n* = 69)[b]	–3.14 (–1.94 to –4.35) (*n* = 65)[b]	–3.86 (–2.31 to –5.42) (*n* = 72)[b]

BOCF, baseline observation carried forward; LOCF, last observation carried forward.
a Paired *t*-test from baseline: $p < 0.05$.
b Paired *t*-test from baseline: $p = 0.001$.

Study or subgroup	Telephone Mean	SD	Total	Control Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Male weight change in kg at 1 year								
Jeffery 2003[99]	−3.05	5.93	159	−1.63	5.87	163	100.0%	−1.42 (−2.71 to − 0.13)
Subtotal (95% CI)			**159**			**163**	**100.0%**	**−1.42 (−2.71 to − 0.13)**
Heterogeneity: not applicable								
Test for overall effect: z=2.16 (p=0.03)								
Female weight change in kg at 1 year								
Jeffery 2003[99]	−2	5.26	442	−2.02	5.23	437	100.0%	0.02 (−0.67 to 0.71)
Subtotal (95% CI)			**442**			**437**	**100.0%**	**0.02 (−0.67 to 0.71)**
Heterogeneity: not applicable								
Test for overall effect: z=0.06 (p=0.95)								

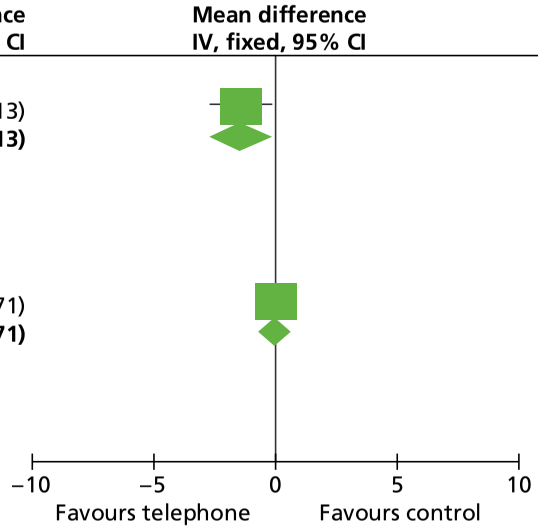

FIGURE 31 Effect of telephone advice and a behaviour change intervention vs. control on weight change in men and women.

Study or subgroup	Mail Mean	SD	Total	Control Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Male weight change in kg at 1 year								
Jeffery 2003[99]	−3.01	5.86	186	−1.63	5.87	163	100.0%	−1.38 (−2.61 to −0.15)
Subtotal (95% CI)			**186**			**163**	**100.0%**	**−1.38 (−2.61 to −0.15)**
Heterogeneity: not applicable								
Test for overall effect: z=2.19 (p=0.03)								
Female weight change in kg at 1 year								
Jeffery 2003[99]	−1.97	5.09	414	−2.02	5.23	437	100.0%	0.05 (−0.64 to 0.74)
Subtotal (95% CI)			**414**			**437**	**100.0%**	**0.05 (−0.64 to 0.74)**
Heterogeneity: not applicable								
Test for overall effect: z=0.14 (p=0.89)								

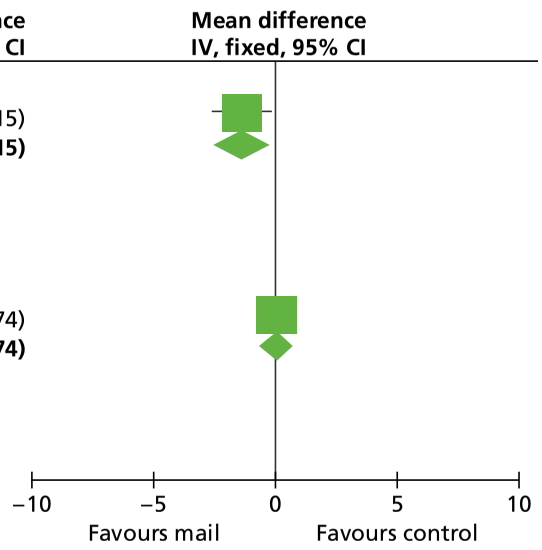

FIGURE 32 Effect of mail advice and a behaviour change intervention vs. control on weight change in men and women.

Study or subgroup	Telephone Mean	SD	Total	Mail Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Male weight change in kg at 1 year								
Jeffery 2003[99]	−3.05	5.93	159	−3.01	5.86	186	100.0%	−0.04 (−1.29 to 1.21)
Subtotal (95% CI)			**159**			**186**	**100.0%**	**−0.04 (−1.29 to 1.21)**
Heterogeneity: not applicable								
Test for overall effect: z=0.06 (p=0.95)								
Female weight change in kg at 1 year								
Jeffery 2003[99]	−2	5.26	442	−1.97	5.09	414	100.0%	−0.03 (−0.72 to 0.66)
Subtotal (95% CI)			**442**			**414**	**100.0%**	**−0.03 (−0.72 to 0.66)**
Heterogeneity: not applicable								
Test for overall effect: z=0.08(p=0.93)								

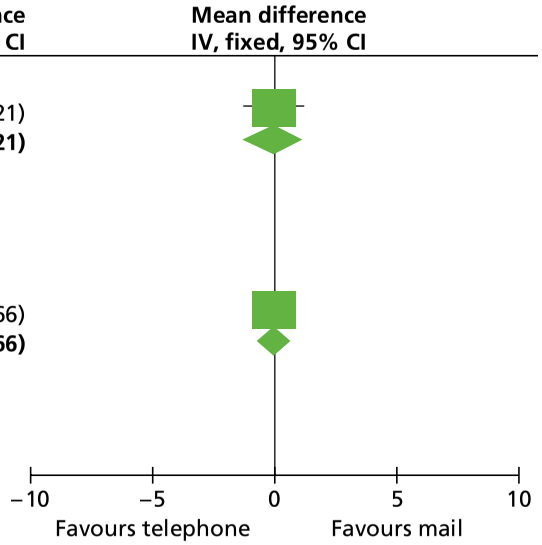

FIGURE 33 Effect of telephone advice vs. mail advice and a behaviour change intervention on weight change in men and women.

Physical activity advice, a healthy diet and behavioural therapy compared with usual care

The Prevention and Reduction of Obesity Through Active Living (PROACTIVE) trial[106] randomised abdominally obese participants to receive an intervention offering physical activity and behavioural therapy or to usual care. Participants in the intervention group received individually tailored counselling based on motivational interviewing to provide the knowledge and skills to increase physical activity and adopt a healthy diet and eating patterns. Calorie reduction was not explicitly mentioned. Participants receiving usual care were given lifestyle advice for reducing obesity from their primary care physician following the usual appointment schedule and counselling approach. After 2 years, men in the intervention group had lost significantly more weight and significantly reduced their BMI and waist circumference compared with men in the usual care group. Women in the intervention group significantly reduced their waist circumference compared with women in the usual care group after 1 year but the effect was lost by 2 years. There were no other significant differences between groups (*Figure 34* and *Table 24*).

Varying monetary contracts for weight loss

Jeffery and colleagues[98] investigated the effect of financial contracts on weight loss and weight maintenance in men and women recruited from a previously identified population or people self-referred through newspaper advertisements. All participants paid a US$150 deposit at the start of a 16-week weight-loss phase consisting of nutrition, exercise and behaviour change technique education sessions. Details of the dietary and exercise advice are unclear but the aim was to lose 2 lb (0.9 kg) per week. Participants randomised to the control groups were refunded their entire deposit at the initial session. Participants in the constant contract groups were refunded $30 for each successive group average weight loss of 5 lb (2.27 kg) and participants in the increasing contract groups were refunded US$5, US$10, US$20, US$40 and US$75 for successive 5-lb 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 US$100 deposit, which was returned in US$25 increments for attendance at quarterly group sessions. Those not enrolling in the maintenance phase were contacted at the 1-year follow-up assessment only. *Table 25* details the weight loss for all participants at 1 year. Eleven participants gave a self-reported weight at this assessment. The trial authors added 5 lb to these weights for their analyses. Two participants who were lost to follow-up were recorded as having lost 0 lb and three participants were excluded from the analyses.

The authors reported that weight loss at 1 year was not statistically associated with recruitment source, contract type or sex. Analysis of percentage change in weight showed that women lost significantly more weight than men (reported $p < 0.05$). 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 $p < 0.006$).

Study or subgroup	Intervention Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean difference IV, fixed, 95% CI
Male weight change in kg at 1 year								
Ross 2012[106]	−2.34	4.53	61	−0.77	4.52	63	100.0%	−1.57 (−3.16 to 0.02)
Subtotal (95% CI)			**61**			**63**	**100.0%**	**−1.57 (−3.16 to 0.02)**
Heterogeneity: not applicable								
Test for overall effect: $z=1.93$ ($p=0.05$)								
Male weight change in kg at 18 months								
Ross 2012[106]	−1.59	4.88	60	0.11	4.88	62	100.0%	−1.70 (−3.43 to 0.03)
Subtotal (95% CI)			**60**			**62**	**100.0%**	**−1.70 (−3.43 to 0.03)**
Heterogeneity: not applicable								
Test for overall effect: $z=1.92$ ($p=0.05$)								
Male weight change in kg at 2 years								
Ross 2012[106]	−1.48	4.8	58	0.39	4.84	63	100.0%	−1.87 (−3.59 to −0.15)
Subtotal (95% CI)			**58**			**63**	**100.0%**	**−1.87 (−3.59 to −0.15)**
Heterogeneity: not applicable								
Test for overall effect: $z=2.13$ ($p=0.03$)								
Female weight change in kg at 1 year								
Ross 2012[106]	−2.49	5.08	146	−0.94	5.18	145	100.0%	−1.55 (−2.73 to −0.37)
Subtotal (95% CI)			**146**			**145**	**100.0%**	**−1.55 (−2.73 to −0.37)**
Heterogeneity: not applicable								
Test for overall effect: $z=2.58$ ($p=0.010$)								
Female weight change in kg at 18 months								
Ross 2012[106]	−2.02	5.94	141	−1.38	5.94	141	100.0%	−0.64 (−2.03 to 0.75)
Subtotal (95% CI)			**141**			**141**	**100.0%**	**−0.64 (−2.03 to 0.75)**
Heterogeneity: not applicable								
Test for overall effect: $z=0.90$ ($p=0.37$)								
Female weight change in kg at 2 years								
Ross 2012[106]	−1.24	6.09	132	−1.24	6.34	143	100.0%	0.00 (−1.47 to 1.47)
Subtotal (95% CI)			**132**			**143**	**100.0%**	**0.00 (−1.47 to 1.47)**
Heterogeneity: not applicable								
Test for overall effect: $z=0.00$ ($p=1.00$)								

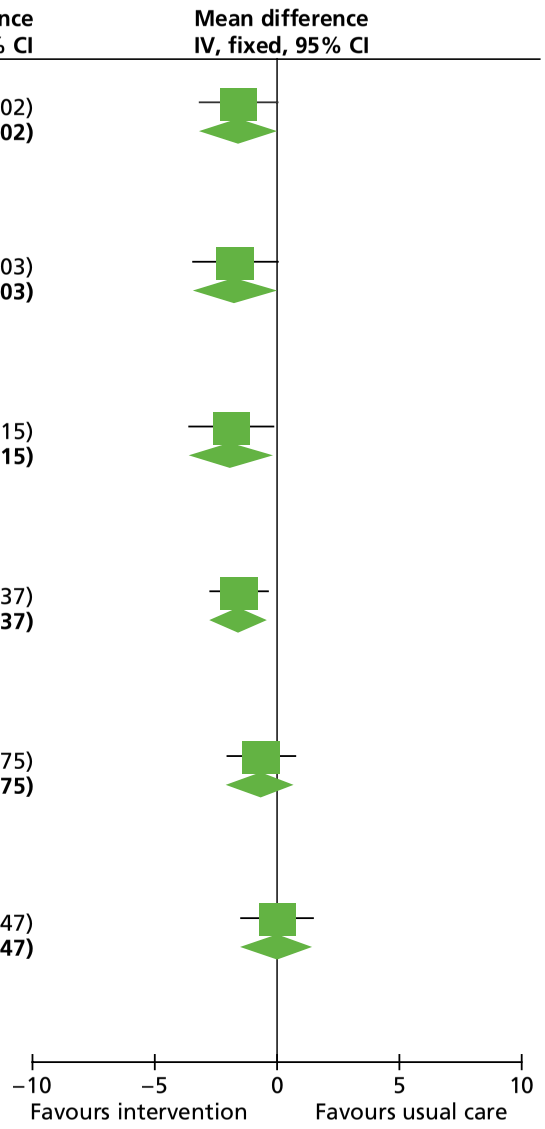

FIGURE 34 Effect of physical activity advice, a healthy diet and behavioural therapy vs. usual care on weight change in men and women.

TABLE 24 Mean change in risk factors and adverse events in the physical activity advice, healthy diet and behavioural therapy group and the usual care group by sex (denominators unclear)

Outcome	Sex	Follow-up	Healthy diet, physical activity and behavioural therapy	Usual care
BMI (kg/m^2)	Men	1 year	–0.72	–0.23
		18 months	–0.50	+0.04
		2 years[a]	–0.56	+0.12
	Women	1 year	–0.93	–0.34
		18 months	–0.73	–0.49
		2 years	–0.50	–0.45
Waist circumference (cm)	Men	1 year	–2.9	–1.3
		18 months	–2.2	–0.5
		2 years[b]	–1.6	+0.1
	Women	1 year[c]	–2.4	–0.8
		18 months	–1.6	–0.4
		2 years	–0.6	+0.3
Total cholesterol (mmol/l)	Men	1 year	–0.08	–0.13
		18 months	–0.14	–0.10
		2 years	–0.29	–0.24
	Women	1 year	+0.31	–0.11
		18 months	–0.28	–0.14
		2 years	+0.35	–0.30
HDL cholesterol (mmol/l)	Men	1 year	–0.06	–0.07
		18 months	–0.09	–0.13
		2 years	–0.20	–0.19
	Women	1 year	–0.14	–0.13
		18 months	–0.19	–0.18
		2 years	–0.27	–0.25
LDL cholesterol (mmol/l)	Men	1 year	+0.15	–0.004
		18 months	+0.13	+0.07
		2 years	+0.08	+0.03
	Women	1 year	–0.10	+0.07
		18 months	–0.01	+0.12
		2 years	+0.02	+0.04
Triglycerides (mmol/l)	Men	1 year	–0.38	–0.15
		18 months	–0.38	–0.13
		2 years	–0.35	–0.20

continued

TABLE 24 Mean change in risk factors and adverse events in the physical activity advice, healthy diet and behavioural therapy group and the usual care group by sex (denominators unclear) (*continued*)

Outcome	Sex	Follow-up	Healthy diet, physical activity and behavioural therapy	Usual care
	Women	1 year	–0.17	–0.08
		18 months	–0.17	–0.16
		2 years	–0.19	–0.19
Systolic blood pressure (mmHg)	Men	1 year	–2.92	–3.46
		18 months	–0.99	–1.06
		2 years	–1.69	–0.31
	Women	1 year	–2.39	–1.43
		18 months	–0.89	–2.67
		2 years	–0.01	–0.70
Diastolic blood pressure (mmHg)	Men	1 year	–2.98	–2.53
		18 months	–1.81	–2.27
		2 years	–2.26	–0.88
	Women	1 year	–1.63	–1.02
		18 months	–1.32	–1.77
		2 years	–0.71	–0.61
Fasting plasma glucose (mmol/l)	Men	1 year	–0.12	+0.11
		18 months	+0.27	+0.05
		2 years	+0.07	+0.23
	Women	1 year	–0.06	+0.09
		18 months	+0.05	+0.22
		2 years	+0.09	+0.22
No. of musculoskeletal adverse events	Men	Total	96	96
		Requiring physician visit	51	50
		Requiring hospitalisation	2	2
	Women	Total	204	215
		Requiring physician visit	124	110
		Requiring hospitalisation	3	10
No. of potential cardiovascular adverse events	Men	Total	46	39
		Requiring physician visit	36	29
		Requiring hospitalisation	7	9
	Women	Total	69	98
		Requiring physician visit	40	54
		Requiring hospitalisation	2	9

a Between-group difference significant at 2 years (reported $p = 0.01$).
b Between-group difference significant at 2 years (reported $p = 0.049$).
c Between-group difference significant at 1 year (reported $p = 0.01$).

TABLE 25 Effect of financial contracts on mean weight change after 1 year in a self-referred and population sample of men and women

Sample		Weight change (kg)	*n*
Self-referred			
Control	Men	–4.27	10
	Women	–9.21	9
Constant contract	Men	–4.44	7
	Women	–8.24	10
Increasing contract	Men	–6.63	11
	Women	–4.30	10
Population			
Control	Men	–2.82	10
	Women	–2.71	11
Constant contract	Men	–5.43	9
	Women	–3.87	9
Increasing contract	Men	–8.93	8
	Women	–9.54	9

Orlistat compared with placebo for weight maintenance

Richelsen and colleagues[105] 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 per day over an 8-week period. Participants were then randomised to receive lifestyle counselling with either 120 mg of orlistat three times daily or matching placebo capsules. Weight change from the start of the diet to 3 years, analysed using the last observation carried forward for dropouts, was reported as significantly greater for women in the orlistat group than for women in the placebo group [–9.7 kg (–8.4%) vs. –6.3 kg (–5.3%), $p < 0.02$]. For men the difference between groups was not significant [orlistat vs. placebo: –8.9 kg (–8.3%) vs. –8.1 kg (–7.5%)].

Comparison between weight loss in men and weight loss in women across trials

For the analysis comparing weight loss between men and women a total of 11 studies had data available,[95,96,98,101,102,106,108–112] including a total of 5519 participants, 3493 women and 2026 men. Two analyses were carried out comparing mean weight change and percentage weight loss between men and women. Both analyses show that there were no significant differences in weight change between men and women recruited to these studies (*Figures 35* and *36*). However, few studies provided sufficient data to allow us to be sure that men and women were prescribed the same calorie deficit. Whether men or women adhere better to lifestyle prescription is unclear.

Study or subgroup	Male Mean	Male SD	Male Total	Female Mean	Female SD	Female Total	Weight	Mean difference IV, random, 95% CI
Hakala 1993[95]	−19.3053	11.4469	19	−13.9	9.7461	38	1.7%	−5.41 (−11.41 to 0.60)
Hakala 1994[96]	−12.06	10.9306	15	−7.0513	8.0832	39	1.6%	−5.01 (−11.09 to 1.08)
Jeffery 1984[98]	−5.3676	7.3554	55	−6.186	7.8663	58	6.2%	0.82 (−1.99 to 3.63)
Karvetti 1992[101]	−4.5216	9.5725	37	−2.3159	7.2093	138	4.8%	−2.21 (−5.52 to 1.10)
Korhoner 1987[102]	−2.945	6.6746	40	−4.535	7.1996	40	5.5%	1.59 (−1.45 to 4.63)
Ross 2012[106]	−1.5423	4.5749	124	−1.7177	5.1797	291	18.5%	0.18 (−0.83 to 1.18)
Vannien 1992[108]	0.3507	6.7406	45	−1.2727	6.2281	33	5.9%	1.62 (−1.27 to 4.52)
Volpe 2008[109]	3.2705	7.0346	44	0.837	6.1734	46	6.5%	2.43 (−0.31 to 5.17)
Wadden 2011[110]	−9.3	6.5	1044	− 8.1	7.81	1526	23.2%	−1.20 (−1.76 to −0.64)
West 2008[111]	−4.2329	7.3192	575	−3.5972	2.4414	1259	22.6%	−0.64 (−1.25 to −0.02)
Wing 1991[112]	−2.9464	7.696	28	−4.0024	7.1608	25	3.5%	1.06 (−2.94 to 5.06)
Total (95% CI)			**2026**			**3493**	**100.0%**	**−0.24 (−1.04 to 0.56)**

Heterogeneity: τ^2=0.64; χ^2=22.66, df=10 (p=0.01); I^2=56%
Test for overall effect: z=0.58 (p=0.56)

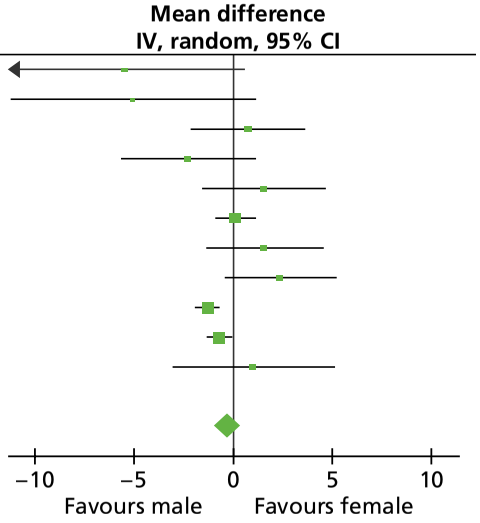

FIGURE 35 Difference in mean weight loss (kg) between men and women.

Study or subgroup	Male Mean	Male SD	Male Total	Female Mean	Female SD	Female Total	Weight	Mean difference IV, random, 95% CI
Hakala 1993[95]	−13.7306	8.1415	19	−11.62	8.1475	38	1.6%	−2.11 (−6.60 to 2.37)
Hakala 1994[96]	−9.9574	9.0249	15	−6.771	7.7619	39	1.2%	−3.19 (−8.36 to 1.99)
Jeffery 1984[98]	−5.0785	6.9592	55	−7.4335	9.4526	58	3.4%	2.36 (−0.69 to 5.40)
Karvetti 1992[101]	−4.4675	9.4579	37	−2.6175	8.1479	138	2.8%	−1.85 (−5.19 to 1.49)
Korhoner 1987[102]	−3.0854	6.9928	40	−5.6476	8.9659	40	2.6%	2.56 (−0.96 to 6.09)
Ross 2012[106]	−1.5451	4.583	124	−1.9946	6.015	291	18.0%	0.45 (−0.61 to 1.51)
Vannien 1992[108]	0.3695	7.1035	45	−1.5089	7.3836	33	3.0%	1.88 (−1.39 to 5.14)
Volpe 2008[109]	3.3647	7.2372	44	1.0084	7.4378	46	3.4%	2.36 (−0.68 to 5.39)
Wadden 2011[110]	−8.5399	5.9688	1044	−8.5443	8.2384	1526	32.1%	0.00 (−0.55 to 0.55)
West 2008[111]	−4.2179	7.2933	575	−3.8528	2.6148	1259	30.0%	−0.37 (−0.98 to 0.25)
Wing 1991[112]	−2.9394	7.6776	28	−3.9928	7.1436	25	2.0%	1.05 (−2.94 to 5.04)
Total (95% CI)			**2026**			**3493**	**100.0%**	**0.15 (−0.43 to 0.73)**

Heterogeneity: τ^2=0.19; χ^2=13.72, df=10 (p=0.19); I^2=27%
Test for overall effect: z=0.50 (p=0.62)

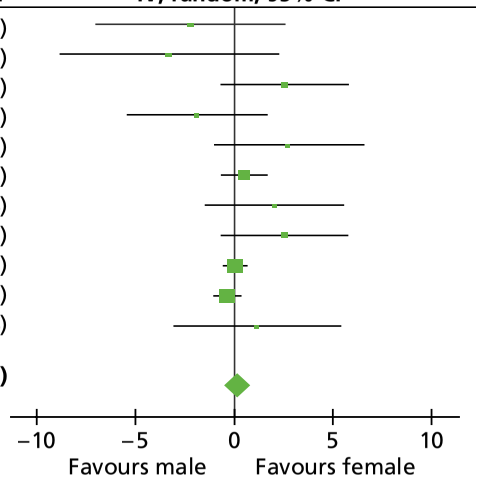

FIGURE 36 Percentage weight loss from baseline in men and women.

Discussion of the results from the review of trials with data for men and women

We identified a modest number of trials reporting outcomes by sex, the majority of which recruited many more women than men. The variety of different interventions, and the small size of many of the studies, mean that conclusions about the best study design for men, and whether or not services should be different for men and women, can only be tentative. 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 weight loss showed no significant differences between men and women, although it should be noted that this was based on only a handful of trials. Dietary and physical activity prescriptions were rarely described well, with little evidence of allowances made for the greater body size and muscle mass of obese men. Authors often did not report baseline weight or BMI by sex, reporting only weight change data between the sexes at varying time points. This makes comparisons between men and women problematic as men tend to be heavier with proportionately greater muscle mass than women and will therefore lose more weight than women if prescribed the same calorie intake and if adherence is similar. Only the DIRECT trial[107] reported a more generous calorie allowance for men than for women with the Look AHEAD trial[110] reporting a 1200–1800 kcal per day diet depending on initial body weight. Similarly, the Weight Watchers and Rosemary Conley programmes also take account of body size and sex for calorie allowances.

From our results it is possible to conclude that interventions encompassing both diet and exercise components are more successful in achieving weight loss and preventing weight gain than interventions including diet or exercise only.[109] Men outperformed women when they had to reduce their calorie intake in response to body weight cues rather than following a very low-calorie diet at regular intervals.[103] Regulating calorie intake by responding to one's own body may offer a greater sense of personal control over weight loss, which could be more important to men than to women. This could partly be explained by evidence suggesting that physical vulnerability or health issues are often a key motivator for men,[44] and so evidence of increased body weight acted as a better motivator for the men in this trial. Alternatively, it could be that this form of weight regulation was seen as less regimented or imposing by the men and was therefore favoured because of the tendency for men to be reluctant to follow formal diet plans.[44]

There was no clear evidence that type of diet influenced long-term weight loss in men.[107,113]

Men have benefited from training in behaviour change techniques alongside diet and physical activity interventions.[97,99,101,102,110,111] Although men performed well in terms of weight loss in group settings,[96,98,100,101,110] more favourable results were produced when individual support or tailored advice was delivered to men as well as the group intervention. This personalising of the intervention could be more important for men than for women.[95,99,106] This may also offer men a greater sense of personal control or men may have greater educational needs in terms of weight-loss reduction techniques than women. Results from the Look AHEAD trial[110] suggest that tailoring by ethnicity may be more important for women than men for certain ethnic groups, although whether or not this is true for ethnic groups outside the USA requires further investigation.

When group programmes are offered both sexes lost more weight in an intense rehabilitation setting than in a community setting, with men in particular losing more weight in this setting.[96] Support from a spouse[120] and learning how to enhance social support from family members[121] may also be favourable for men. Having a partner participate in a weight reduction programme also produces favourable weight-loss results but this effect appears to be greater for women than for men.[94,112] Gorin and colleagues[94] suggest that this may be explained in part by households in which women are more likely to be responsible for food shopping and preparation. Having a partner who is following the same diet plan reduces the burden of preparing additional meals and the likelihood of purchasing foods that are inconsistent with weight-loss

efforts. Men, on the other hand, may assume more responsibility for their own behaviour change if they attend on their own. The authors admit that their interpretation is speculative and that other factors may act as important moderators. When 'traditional' gender roles are less evident, programmes involving participating partners could produce different results.

Altering weight reduction activities to be compatible with perceptions of feminine and masculine behaviours also appears to be important for achieving successful results. In the Lighten up trial[100] the authors noted that, although men performed well in the programmes delivered by commercial companies, fewer than half picked these programmes when the choice of provider was freely available. The authors suggest that commercial companies may appear more female orientated. By contrast, NHS-delivered programmes may be perceived by men as purely concerned with improving health rather than physical appearance and may therefore appear more masculine in this regard. Men in the choice group had poorer results than women in this group, which could reflect men's greater educational needs. Of the NHS programmes, the Size Down programme produced results that were comparable with those of some of the commercial companies. Size Down was the only NHS programme to offer group sessions, again suggesting a benefit from group interactions.

Of the commercial programmes, men appeared to do best with Weight Watchers, but numbers of participants were limited. A specific area of the Weight Watchers website is dedicated to men only. The success of Weight Watchers may be in allowing men to feel that they are following a programme that is targeted to their needs. Having the flexibility to adapt programmes in this way may encourage greater programme engagement among men. Unlike commercial companies, primary care may lack the resources required to provide sufficient support to patients to produce effective weight-loss results. Results from the Hakala[96] and Lighten Up[100] trials also suggest that general practice staff may perceive themselves as unsuitable for arranging weight-loss care for obese patients. Although the staff in the Lighten Up trial received specific training, they were less experienced in a weight management role than providers of commercial weight-loss programmes. This suggests that health service staff may benefit from greater education and training in weight loss if weight management services are to be delivered by the primary health-care system in this way. Similarly, patients may be too inhibited to discuss problems experienced with weight-loss techniques if they feel that they are constrained to the limited time available during a GP consultation.

Our analyses of trial retention showed that men were significantly more likely to complete a trial than women. We are unable to comment on possible explanations for the differential dropout between men and women from the available data. Nevertheless, this finding suggests that, although fewer men are likely to join weight-loss programmes, once they do join they show the motivation and commitment to 'stick with' the programme. This highlights the importance of finding successful strategies to engage men in weight-loss services and will be discussed further in *Chapter 4*.

Overall summary from both reviews in this chapter

We summarise in the following sections the main points that have arisen from both reviews in this chapter.

General issues relating to methodology

1. We identified very few randomised trials examining weight loss in men-only groups. Few mixed-sex trials reported weight-loss outcomes by sex, and trials recruited much greater proportions of women. Despite this sex bias, men were rarely consulted beforehand about the design of studies or asked their views on the programmes that they undertook.
2. Male study participants tended to be middle-aged, white and not morbidly obese. Men from minority groups were under-represented. Relatively few interventions involved men who were obese with existing health problems, such as type 2 diabetes, cardiovascular disease or osteoarthritis. Few trials presented data on changes in cardiovascular risk factors, or clinical outcomes.
3. Most of the interventions were not described in sufficient detail such that they could be replicated. Few studies reported conducting fidelity checks for intervention delivery. Interventions tended to be intensive in terms of time required from participants and those delivering the programme.
4. Providers of the interventions were described at an occupational level, for example nutritionist or physical activity trainer, but the sex of providers was not reported. It is unclear from the included studies whether or not the sex of the person providing a weight-loss intervention to men, either individually or in groups, is an important factor in the effectiveness of that intervention.
5. There were particularly few studies that looked at the long-term maintenance of weight loss.
6. There were very few data on quality of life or clinical and economic outcomes to assess the full value of an intervention.
7. Details of trial methodology were often inadequately reported, for example method of randomisation. Reporting could also be improved by following the standards outlined in the CONSORT statement.[128,129] Few authors presented data for the entire cohort (e.g. baseline observation carried forward, last entry carried forward), choosing instead to present data for completers only both at baseline and for final outcome measurement. It is therefore difficult to judge the level of attrition bias in these studies. Similarly, few trials reported details concerning the equity or sustainability of the considered interventions.

Pointers for effective interventions

Although few trials were available, there are some pointers for factors that may contribute to effective programmes for men:

1. The type of reducing diet, for example providing more protein, has not been shown so far to affect long-term weight loss.[83,87,91,107,113] However, intermittent periods of very low-calorie dieting, as required, may be better than regular periods of such dieting.[103]
2. Men may do well if physical activity is part of a weight-loss programme and may be more likely to respond to this than women.[93,106,109] Men like using pedometers[90] but weight loss is better with a reducing diet than with physical activity alone, and better if both are provided.[91,93,109] However, one small trial did not find that a physical activity programme and a reducing diet were better than the diet alone.[92]
3. Behaviour change training improves long-term weight loss, and weight maintenance for men after a physical activity programme.[88,101]
4. Health concerns could help motivate men. Intensive programmes with low-fat reducing diets and physical activity with or without behaviour change training can reduce weight and improve erectile dysfunction in men with and without type 2 diabetes,[85,110,122] and prevent diabetes,[104] although in type 2 diabetes successful weight loss might increase the risk of osteoporosis.[124]
5. Once recruited, men appear less likely to drop out from programmes than women. Men may like less monitoring than women.[96] Telephone and mail support could be useful.[99]
6. The effect of support from partners to aid weight loss is inconsistent.[94,112,120]

7. Men may be particularly less likely to choose a commercial weight-loss programme than women.[100] Health service programmes appear to be favoured by men with obesity.[96,100] The comparative effectiveness of NHS and commercial weight-loss programmes for men in the trial by Jolly and colleagues[100] is unclear.
8. Men do well in groups of men, but some individual tailoring of advice or counselling may also aid weight loss.[85,90,95,96] Too many weight-loss sessions may be counterproductive.[101] Group financial contracts were associated with better weight loss than individual contracts, but the size of the contract has not been found to be a significant factor.[86,98]
9. Men like individualised, fact-based, flexible and simple to understand information.[90]
10. Men are less likely than women to do well using orlistat to help long-term weight-loss maintenance.[105]
11. The benefits of internet-based advice for men are presently unclear.[89,90]

Chapter 4 Systematic review of UK interventions with data for men or for men and women compared

In this chapter we provide the results of the systematic review of UK interventions for men with obesity, including any setting, study design or duration. This review also includes data from mixed-sex UK studies in which data were provided separately for men and women.

This chapter also contains details of the systematic review of studies that specifically investigated increasing the engagement of men with obesity services (i.e. increasing the take-up of services by men); no studies fitting the inclusion criteria for this review were found. However, information on engaging men with services is available and discussed in the first review in this chapter.

Quantity of evidence

Our primary literature searches identified 2057 potentially relevant titles and abstracts (*Figure 37*). In addition to this, we identified 20 potentially relevant reports from other sources listed in *Appendix 1*, such as commercial organisations, professional organisations, and from grey literature. For our review of UK studies of any design, we selected 140 reports for full-text assessment, of which we identified 15 eligible reports of men-only studies[33–35,138–149] (two of which were RCTs[141,146]). We also found 11 eligible reports[31,36,37,150–157] (including one linked report[157]) of mixed-sex studies in which the results were reported by sex. Of these included reports, one was an abstract[141] and four were poster presentations.[148,151–153] The remaining reports were full-text publications. Three of the full-text reports were written as evaluation reports of public health initiatives[139,147,149] and were not published in an academic journal. One other mixed-sex UK RCT by Jolly and colleagues[100] has already been discussed in *Chapter 3* in the review of interventions for men and women compared. No eligible reports were identified for inclusion in our review of interventions to promote the engagement of men with weight-loss services.

Characteristics of included studies

Tables 26 and *27* detail the characteristics of the included studies. Of the men-only studies, we identified two RCTs with follow-up periods of 12[141] and 24 weeks[146] and seven prospective cohort studies[33,138–140,142,147,149] with follow-up ranging from 6 weeks[149] to 49 months.[142] There were two retrospective cohort studies that included follow-up periods of 10[148] and 24[34] weeks. Of the mixed-sex reports, seven were retrospective cohort studies with follow-up periods ranging from 12 weeks[150] to 24 months.[31] We included two prospective cohort studies,[31,155] which reported data for men at 6 weeks and 12 months respectively.

Four reports were of studies using male-orientated sports settings to facilitate recruitment and intervention delivery; two involved four Scottish Premier League (SPL) football clubs[138,141] and two involved one Rugby League club.[139,149] Four reports were of interventions provided by commercial organisations[34,148,154,156] and five reports were of NHS referrals to commercial organisations.[33,36,37,150,157] A further three reports[151–153] were of a commercial computer package for use by health-care professionals in the NHS primary and secondary care setting. Two studies were set in men's health clinics run by NHS primary care[142,147] and two were set in the workplace.[140,146] One study was set in the NHS GP setting[31] and one examined the promotion of dietary carbohydrate intake in individuals in the community.[155]

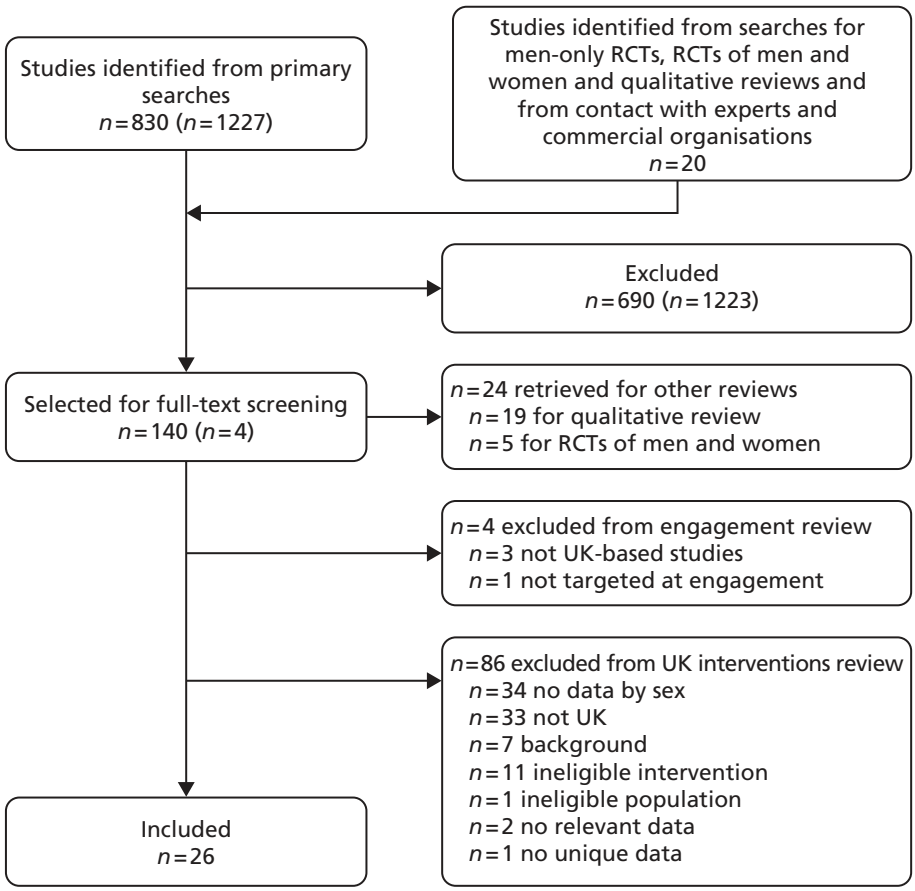

FIGURE 37 Flow chart of the number of potentially relevant reports and the numbers of reports subsequently included and excluded from the reviews of UK interventions and interventions to increase engagement (numbers for engagement review are in parentheses).

TABLE 26 Characteristics of studies of men only included in the review of UK interventions

Study ID	Participants	Interventions	Outcomes	Notes
Brady 2010[138]	Study design: Prospective cohort Location: Two SPL football clubs, Glasgow, UK Period of study: Prior to 2010 Inclusion criteria: Age 40–60 years Exclusion criteria: Inability to exercise, overt cardiovascular or any other disease precluding participation Age: NR Weight (kg), mean: 95 BMI: NR Baseline comparability: NA	Description of intervention: Diet and exercise – dietary adjustment consisted of adopting a Mediterranean-style diet with less red meat and dairy and moderation of alcohol intake. Dietary emphasis was on reducing saturated fat and salt with calorie reduction when required. The exercise programme was designed for each individual using a safe zone of 60–80% of the maximum predicted heart rate. Heart rate monitors were used when exercising to ensure that exercise was carried out in the safe zone. Men were instructed to exercise for 20 minutes at the appropriate heart rate three to four times weekly. Additionally, men attended their respective club stadiums once weekly for a 2-hour session. The first hour consisted of a general health discussion (cardiovascular health, alcohol, obesity, dental health, diabetes, urological and prostatic disease, stress management and diet). For the second hour men rotated between 20 minutes' pitch-side exercise, a 20-minute cardiovascular workout and 20 minutes of dietary advice and discussion. Exercise classes were run by professional SPL coaching staff. Health lectures were delivered by physicians from Glasgow hospitals. Dietary advice was provided by research dietitians and nurses Duration of active intervention: 10 weeks No. of times contacted: 12	Length of follow-up: 15 months Outcomes: Weight, total cholesterol, blood pressure	Glasgow Rangers and Celtic football clubs

continued

TABLE 26 Characteristics of studies of men only included in the review of UK interventions (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
		No. allocated: 40 No. completed: 36 Dropout (%): 10 No. assessed: 36		
Drummond 2004[140]	Study design: Prospective cohort Location: Workplace/community, Birmingham, Edinburgh, London, UK Period of study: NR Inclusion criteria: Registered taxi driver, waist circumference ≥ 96 cm, free from illness Exclusion criteria: Special diet for medical/other reason, weight-reducing diet in previous 3 months Age (years), mean (range): 42 (20–64) Weight (kg), mean (SD): 106 (21) BMI (kg/m^2), mean (SD): 34.6 (6.2) Baseline comparability: NA	Description of intervention: Diet – nutritional advice given based on 7-day unweighed diet diaries completed at baseline. Diet consisted of a low-fat, high-carbohydrate (sugar-containing), energy-restricted diet, high in fruit and vegetables. Individualised plans to produce an energy deficit of 600–700 kcal daily, producing an approximate weight loss of 7–8 kg over 3 months (5–10% of body weight). Men were advised to consume small high-carbohydrate, sugar-containing Carb Boosters™ snacks frequently. Each snack contained 20 g of sugar. The aim of the snacks was to increase total carbohydrate intake in a palatable way and prevent a 'starve and binge' pattern of dieting Duration of active intervention: 12 weeks No. of times contacted: 5 No. allocated: 107 No. completed: 76 Dropout (%): 29 No. assessed: 76	Length of follow-up: 12 weeks Outcomes: Weight	Study sought to recruit both male and female taxi drivers but only men volunteered to participate In addition to participant informed consent, the partner/wife of each man signed a consent form stating they would support the participant in the study

Study ID	Participants	Interventions	Outcomes	Notes
Gray 2009[142]	Study design: Prospective cohort Location: Multiple local community men's health clinics, Grangemouth, UK Period of study: NR Inclusion criteria: BMI ≥ 30 kg/m^2 or waist circumference ≥ 102 cm Exclusion criteria: NR Age (years), mean (range): 50.9 (23–74) Weight: NR BMI (kg/m^2), *n* (%): < 30: 7 (7) 30–34.9: 62 (59.3) 35–39.9: 26 (24.4) > 40: 10 (9.3) Baseline comparability: NA	Description of intervention: Low-fat diet and physical activity advice delivered in men-only groups over 12 weekly sessions. Men were provided with a weight management booklet and informed that they were personally responsible for their own weight management. Men were educated about a healthy balanced diet and healthy portion sizes by comparison between individual diaries and the food plate model. Men were also given examples of daily eating plans and discussed the role of alcohol consumption, physical activity in weight management and potential barriers to exercise. Men could apply for a free pass to a local authority-run sports centre to assist with increasing physical activity. The psychology of behaviour change and value of social support were discussed and men set individual SMART goals for weight loss (aimed to lose 0.5–1 kg per week), exercise and alcohol consumption. Men also met with a previous programme completer midway through the course. Feedback was given in the form of sandbags representing each man's personal midpoint weight loss and through comparison between week 1 and week 10 food diaries. Advice on dealing with relapses and how to manage weight long term was provided and men were invited to join organised post-programme meetings Duration of active intervention: 12 weeks No. of times contacted: 14	Length of follow-up: 49 months Outcomes: Weight, BMI, waist circumference	BMI entry criteria stated in methods as > 30 kg/m^2 but seven men reported to have a BMI < 30 kg/m^2

continued

TABLE 26 Characteristics of studies of men only included in the review of UK interventions (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
		No. allocated: 109 No. completed (at 12 weeks): 80 Dropout (%): Unclear No. assessed: 80		
Gray 2011[141]	Study design: RCT Location: Two SPL football clubs, UK Period of study: September 2010 Inclusion criteria: Age 35–65 years, BMI ≥ 27 kg/m^2, consent to randomisation and weight, height and waist measurements Exclusion criteria: Contraindications for vigorous physical exercise (e.g. systolic blood pressure ≥ 160 mmHg, diastolic blood pressure ≥ 100 mmHg) Age (years), mean (range): a + b: 47.1 (32–68) Weight (kg), mean (SD): a: 107.6 (15.0); b: 107.5 (19.5) BMI: NR Baseline comparability: Yes (personal communication from author)	Description of interventions: a: 'Gender-sensitised' weight management, physical activity and healthy living programme based on control theory[158] and components of behavioural change techniques.[159,160] Men attended 12 weekly classroom-based group discussions held at their SPL club training ground where they received personalised advice on diet (portion control and healthy eating) to suit individual circumstances and preferences. Following these discussions men engaged in pitch-side/in-stadia structured aerobic, muscle strengthening and flexibility exercise training sessions, which were tailored to individual fitness and ability. Weekly sessions lasted 90 minutes. Outside the weekly sessions men were given an incremental walking programme. Pedometers were issued to the men to monitor individual daily goals and progress was reported at the weekly meetings. Men were encouraged to supplement walking with more strenuous activity if they were able to and to meet up outside the programme to train together. The aim was to achieve 45 minutes of moderate physical activity most days. Avoidance of behaviours that would undermine weight loss was also encouraged	Length of follow-up: 12 weeks Outcomes: Weight, waist circumference	FFIT feasibility pilot RCT. The main trial was ongoing at the time of publication

Study ID	Participants	Interventions	Outcomes	Notes
		b: Waiting list: A comparison group were randomised to receive the FFIT intervention 4 months later Duration of active intervention: 12 weeks No. of times contacted: 13 No. allocated: a: 51; b: 52 No. completed: a: 44; b: 42 Dropout (%): a: 13.7; b: 19.2 No. assessed: a: 44; b: 42		
Leslie 2002[146]	Study design: RCT Location: One petrochemical worksite, Glasgow, UK Period of study: NR Inclusion criteria: BMI ≥ 25 kg/m^2 Exclusion criteria: Under supervision of the worksite medical officer, diabetic requiring insulin, any condition requiring prescribed foods or specialist dietary intervention, intentional weight loss > 3 kg in the previous 3 months Age (years), mean (SD): a: 41.3 (8.1); b: 42.1 (7.8) Weight (kg), mean (SD): a: 98.2 (13.9); b: 94.6 (13.3)	Description of interventions: Weight-loss phase: weeks 0–12 a: Energy-deficient diet – individualised energy prescriptions calculated taking age, sex and body weight into account to induce a daily 600-kcal deficit using Schofield equations and 1.3 × basal metabolic rate activity factor b: Generalised low calorie diet – generalised 1500 kcal per day diet Participants within a and b were randomised to meat and no meat groups. Participants in the meat group consumed red meat at least five times per week. Participants in the non-meat group substituted red meat with fish, eggs and cheese	Length of follow-up: 24 weeks Outcomes: Weight, BMI, total, LDL and HDL cholesterol, triglycerides	

continued

TABLE 26 Characteristics of studies of men only included in the review of UK interventions (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
	BMI (kg/m^2), mean (SD): a: 31.5 (3.7); b: 30.4 (3.7) Baseline comparability: Group a heavier with higher triglyceride levels	Weight-maintenance phase: weeks 12–24: Diet and energy requirements recalculated for weight stability rather than loss Duration of active intervention: 12 weeks No. of times contacted: 12 No. allocated: a: 61; b: 61 No. completed: a: 45; b: 40 Dropout (%): a: 26.2; b: 34.4 No. assessed: a: 61; b: 61		
Witty 2010[149]	Study design: Prospective cohort Location: Stadium and training ground for Leeds Rhinos Rugby League Club, Leeds, UK Period of study: 2009 rugby league season Inclusion criteria: NR Exclusion criteria: NR Age: NR Weight (kg), mean (SD): 105.5 (28.5) BMI: NR Baseline comparability: NA	Description of intervention: The Tackling Men's Health initiative was developed out of a partnership between the Department of Health, Leeds Rhinos Rugby League Club and Leeds Metropolitan University. The pilot health programme was a multicomponent health promotion intervention designed to be delivered alongside league fixtures and targeted at men attending Leeds Rhinos Headingley Carnegie Stadium with the aim of promoting engagement with local and national health services and promoting health and well-being. The original intervention design consisted of 12 themed match days. Themes included mental health, diet and nutrition, exercise and sexual health. Match-day themes were chosen to link in with a common theme	Length of follow-up: 6 weeks Outcomes: Weight	

Study ID	Participants	Interventions	Outcomes	Notes
		spanning the length of the rugby league season. The theme for the pilot season was obesity and a weight-loss group was run at the Kirkstall Road training ground Duration of active intervention: 6 weeks No. of times contacted: 7 No. allocated: 7 No. completed: 7 Dropout (%): 0 No. assessed: 7		
Department of Health and Leeds Metropolitan University 2010[139]	Study design: Prospective cohort Location: Stadium and training ground for Leeds Rhinos Rugby League Club, Leeds, UK Period of study: 2010 rugby league season Inclusion criteria: NR Exclusion criteria: NR Age: NR Weight (kg), mean (SD): 108.03 (18.69) BMI (kg/m^2), mean (SD): 35.24 (5.75) Baseline comparability: NA	Description of intervention: In continuation of the Leeds Rhinos programme (described in Witty and White[149]), NHS Leeds ran an 8-week men-only '10% Lifestyle Course' from 21 April to 9 June 2010. The course consisted of eight weekly sessions each lasting for 90 minutes. The first 45 minutes consisted of a theory session, covering the following issues: session 1 – introduction, physical activity screening, food/activity diaries; session 2 – review of food/activity diaries, goal setting; session 3 – making changes to lifestyle; session 4 – Eatwell plate/portion size; session 5 – physical activity – why do it, how much, how hard?; session 6 – maintaining changes; session 7 – Leeds Rhinos session (nutrition of a rugby player) – had to be postponed; session 8 – way forward/evaluation session. The remaining 45 minutes were for physical activity. Sessions consisted of a mixture of	Length of follow-up: 8 weeks Outcomes: Weight, BMI, waist circumference	Men's Health Plus provided the names of the six men who attended the weight management group run during the 2009 season who wished to continue attending a group to facilitate further weight loss. Unclear if these men were recruited to the 2010 season programme

continued

TABLE 26 Characteristics of studies of men only included in the review of UK interventions (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
		activities such as gym sessions, walking and circuits: session 1 – introduction, physical activity screening; session 2 – circuit-based class, combination of aerobic and resistance training; sessions 3–5 – gym sessions: men spent 5 minutes on four different machines; they were provided with a record sheet so that they could monitor levels worked at and how far they travelled on cardio machines; for resistance the attendees could use either light weights or dynabands; session 6 – following risk assessment a walk from the Kirkstall Road training ground along the canal; a member of Leeds Rhinos staff acted as a back marker and carried a first aid kit; consisted of a 10-minute gradual warm-up, 20 minutes' walking at moderate intensity, 5–10 minutes' slowing down (low intensity) and 5 minutes' stretching on the training ground; session 7 – led by staff from Leeds Rhinos (supported by weight management physical activity staff); took place outside on the training field and included small games and rugby drills; session 8 – poor weather so a final gym session was completed Duration of active intervention: 8 weeks No. of times contacted: 9 No. allocated: 12 No. completed: 10 Dropout (%): 16.7 No. assessed: 10		

Study ID	Participants	Interventions	Outcomes	Notes
Holt 2007[145]	Study design: Retrospective cohort Location: Multiple community locations, UK Period of study: 1998–2005 Inclusion criteria: BMI > 29 kg/m^2, completed brief medical questionnaire during GP consultation Exclusion criterion: Contraindications for a very low-calorie diet (VLCD) Age: NR Weight (kg), mean: 121.5 BMI (kg/m^2), mean: 38.5 Baseline comparability: NA	Description of intervention: VLCD and behavioural therapy delivered to men-only groups by a commercial provider, LighterLife. VLCD formula diet of three food packs per day, 550 kcal per day, 50 g protein, 50 g carbohydrate and 100% recommended daily allowances for vitamin and minerals. Behavioural therapy based on transactional analysis and cognitive–behavioural therapy and addiction/change theory. Men abstained from conventional foods replacing them with fortified 'Man Plan' food packs for 8 weeks initially. Men were also advised to avoid alcohol consumption. LighterLife counsellors provided support to help men explore reasons for their overeating, develop practical and psychological strategies for long-term weight management and help them implement and sustain healthy lifestyle changes. Men were required to have GP check-ups every 28 days whilst using a VLCD for total nutrition. Once men had achieved their target weight they were encouraged to attend a weight management group for at least 1 year free of charge (VLCD formula foods were available to purchase if required) Duration of active intervention: 8 weeks No. of times contacted: 11 No. allocated: NR No. completed: 1279 Dropout (%): NR No. assessed: 1279	Length of follow-up: 8 weeks Outcomes: Weight, BMI, motivating factors	

continued

TABLE 26 Characteristics of studies of men only included in the review of UK interventions (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Hallam Spencer 2008[143]	Study design: Retrospective cohort Location: Multiple community locations, UK Period of study: 2007 Inclusion criteria: BMI > 29 kg/m^2, completed brief medical questionnaire during GP consultation Exclusion criterion: Contraindications for a VLCD Age: NR Weight (kg), mean: 121.3 BMI (kg/m^2), mean: 38.0 Baseline comparability: NA	Description of intervention: LighterLife VLCD programme as described in Holt *et al.*[145] Duration of active intervention: 8 weeks No. of times contacted: 11 No. allocated: NR No. completed: 1000 Dropout (%): NR No. assessed: 1000	Length of follow-up: 8 weeks Outcomes: Weight, BMI	
Salsbury 2009[148]	Study design: Retrospective cohort Location: Multiple community locations, UK Period of study: 2008 Inclusion criteria: BMI > 29 kg/m^2, completed brief medical questionnaire during GP consultation	Description of intervention: LighterLife VLCD programme as described in Holt *et al.*[145] Duration of active intervention: 8 weeks No. of times contacted: 11 No. allocated: NR	Length of follow-up: 8 weeks Outcomes: Weight, BMI	

Study ID	Participants	Interventions	Outcomes	Notes
	Exclusion criterion: Contraindications for a VLCD Age: NR Weight (kg), mean 119.17 BMI (kg/m^2), mean: 37.35 Baseline comparability: NA	No. completed: 2200 Dropout (%): NR No. assessed: 2200		
Hallam 2010[144]	Study design: Retrospective cohort Location: Multiple community locations, UK Period of study: January–September 2009 Inclusion criteria: BMI > 29 kg/m^2, completed brief medical questionnaire during GP consultation Exclusion criterion: Contraindications for a VLCD Age: NR Weight (kg), mean: 123.2 BMI (kg/m^2), mean: 38.6 Baseline comparability: NA	Description of intervention: LighterLife VLCD programme as described in Holt *et al.*[145] Duration of active intervention: 8 weeks No. of times contacted: 11 No. allocated: NR No. completed: 950 Dropout (%): NR No. assessed: 950	Length of follow-up: 8 weeks Outcomes: Weight, BMI	

continued

TABLE 26 Characteristics of studies of men only included in the review of UK interventions (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Hallam 2011[35]	Study design: Retrospective cohort Location: Multiple community locations, UK Period of study: January–August 2010 Inclusion criteria: BMI > 29 kg/m^2, completed brief medical questionnaire during GP consultation Exclusion criterion: Contraindications for a very low-calorie diet (VLCD) Age: NR Weight (kg), mean: 124.0 BMI (kg/m^2), mean: 39.0 Baseline comparability: NA	Description of intervention: LighterLife VLCD programme as described in Holt *et al.*[145] Duration of active intervention: 8 weeks No. of times contacted: 11 No. allocated: NR No. completed: 1006 Dropout (%): NR No. assessed: 1006	Length of follow-up: 8 weeks Outcomes: Weight, BMI	

Study ID	Participants	Interventions	Outcomes	Notes
McFarlane 2006[147]	Study design: Prospective cohort Location: One community centre, Arbroath, UK Period of study: March 2006 Inclusion criteria: NR Exclusion criteria: NR Age (years), mean: 59 Weight: NR BMI (kg/m^2), mean: 32.4 Baseline comparability: NA	Description of intervention: Men-only weight management programme (Bloke's Weigh) jointly developed by the NHS Angus Weight Management Project Facilitator and the MACH4 (Male Checks for Health) Men's Health Project. Group meetings were held in a church hall where men were given information and advice about weight-loss topics, including healthy eating/basic nutrition, causes of weight gain, benefits of weight loss, fat and sugar content of foods, food labelling advice, the role of alcohol in weight gain, the importance of exercise, exercise referral and the importance of adequate fluid intake. Behaviour change topics such as self-monitoring, hunger scores and decisional balance were also discussed Duration of active intervention: 10 weeks No. of times contacted: 10 No. allocated: 38 No. completed: 18 Dropout (%): 52.6 No. assessed: 23 (regular attenders)	Length of follow-up: 10 weeks Outcomes: Weight, BMI, waist circumference	

continued

TABLE 26 Characteristics of studies of men only included in the review of UK interventions (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Bye 2005[34]	Study design: Retrospective cohort Location: Multiple community locations, UK Period of study: NR Inclusion criterion: Membership of a men-only Slimming World group Exclusion criterion: Attendance < 8 weeks Age (years), mean, median (range): 49.4, 47 (29–71) Weight (kg), mean, SD (range) 114.7, 19.9 (79.6–210.7) BMI (kg/m^2), mean, SD (range): 35.9, 6.1 (27.9–53.6) Baseline comparability: NA	Description of intervention: Men-only commercial weight management programme (Slimming World). Standard open-sex programme adapted to offer men-only group meetings. Programme consisted of an individualised diet plan including unlimited 'free foods' and advice for satisfying appetite and recipe and menu ideas. Men were also given advice for increasing physical activity and increasing motivation. Support and encouragement obtained through group motivating sessions led by trained Slimming World consultants Duration of active intervention: At least 8 weeks No. of times contacted: ≥ 8 No. allocated: 125 No. completed: Unclear Dropout (%): Unclear No. assessed: 16 in programme at 24 weeks	Length of follow-up: 24 weeks Outcomes: Weight, BMI	

Study ID	Participants	Interventions	Outcomes	Notes
Poulter 2012[33]	Study design: Prospective cohort Location: Three NHS primary care trust communities, UK Period of study: NR Inclusion criteria: Overweight/obese, NHS referral to Weight Watchers Exclusion criteria: NR Age (years), mean (SD): 47.6 (12.7) Weight: NR BMI (kg/m^2), mean (SD): 36.1 (5.8) Baseline comparability: NA	Description of intervention: NHS-funded referral to a commercial weight-loss programme (Weight Watchers; as described for Ahern *et al.*[37]) but the standard open-gender model was adapted to provide men-only meetings. No other changes made except in two of three locations a 30-minute 'add-on' exercise class led by qualified local authority fitness instructors was delivered after the standard Weight Watchers meeting Duration of active intervention: 12 weeks No. of times contacted: 12 No. allocated: 62 No. completed: 39 Dropout (%): 37.1 No. assessed: 62	Length of follow-up: 12 weeks Outcomes: Weight, BMI	

FFIT, Football Fans in Training; NA, not applicable; NR, not reported; SMART, specific, measurable, achievable, realistic and time limited; VLCD, very low calorie diet.

TABLE 27 Characteristics of studies of men and women included in the review of UK interventions

Study ID	Participants	Interventions	Outcomes	Notes
Ross 2008[31]	Study design: Prospective cohort Location: 56 NHS GP practices, UK Period of study: 1 January 2001–31 December 2004 Inclusion criteria: Age 18–75 years, BMI $\geq$ 30 kg/m^2 (or $\geq$ 28 kg/m^2 with obesity related comorbidities), participant at the contemplative or action stage of the transtheoretical model of behaviour change Exclusion criteria: NR Age (years), mean (SD): Men + women: 49.4 (13.5) Weight: NR BMI (kg/m^2), mean (SD): Men + women: 37.1 (6.0) Baseline comparability: NR	Description of intervention: Primary care weight management programme (Counterweight) based on the transtheoretical model of behaviour change. Programme was delivered by GP practice nurses and health-care assistants usually as part of nurse appointments for managing comorbid conditions or through dedicated weight management clinics. Involved a prescribed eating plan delivered individually or in groups to achieve an energy deficit of $\geq$ 500 kcal per day and weight loss of 5–10%. Participants were taught behaviour change skills and provided with tools to achieve individual or group goals: daily living diary, healthy eating quizzes, personal weight-loss plans, prescribed number of food group servings, advice for reading food labels, meal planning and eating out. Reasons for emotional eating and social pressure to eat were discussed. Advice for increasing physical activity was also given and participants were offered referral to a GP exercise scheme if this was appropriate/ available. Participants were also counselled to reshape negative thoughts and to enable successful weight maintenance and prevent relapse Duration of active intervention: 12 weeks No. of times contacted: 12 No. eligible at 1 year: Men: 438; women: 1468 No. completed at 1 year: Men: 171; women: 471	Length of follow-up: 24 months (outcomes by sex reported at 12 months) Outcomes by sex: Weight	

Study ID	Participants	Interventions	Outcomes	Notes
		Dropout (%): Men: 51.0; women: 67.9 No. assessed: Men: 171; women: 471		
Dixon 2012[150]	Study design: Retrospective, non-randomised, comparative cohort (service evaluation) Location: 12 GP surgeries, England, UK Period of study: December 2007–May 2010 Inclusion criteria: Age > 16 years, BMI ≥ 30 kg/m^2 with either a raised waist measurement > 94 cm or one or more comorbidity or other reason stated by the clinician, ready to lose weight. Some clinicians referred patients with a BMI < 30 kg/m^2 using the 'other reason' option. All patients were included in the evaluation Exclusion criterion: Attended a slimming club in the previous 6 months Age (years), mean: Men + women: 47.1 Weight (kg), mean (SD): Men + women: Slimming World: 104.7 (19.8); Weight Watchers: 104.3 (19.8); Rosemary Conley: 100.6 (16.8) BMI (kg/m^2), mean (SD): Men + women: Slimming World: 37.7 (5.8); Weight Watchers: 37.9 (6.2); Rosemary Conley: 37.6 (5.7) Baseline comparability: Yes	Description of intervention: Pilot NHS slimming on referral scheme. Participants were offered 12 free weekly sessions at one of three commercial providers: Weight Watchers, Slimming World or Rosemary Conley Diet and Fitness Clubs. All providers used group sessions lasting 60–90 minutes allowing for brief one-to-one support during weighing. Participants received information plus optional support by telephone or through websites. Weight Watchers and Rosemary Conley aimed for a set amount of weight loss whereas Slimming World set individual weight-loss goals. All providers encouraged a balanced diet and an increase in levels of physical activity. Rosemary Conley also included an optional 45-minute exercise class Duration of active intervention: 12 sessions No. of times contacted: 12 No. allocated: Men: 150; women: 907 Number completed: Men: 63; women: 414 Dropout (%): Men: 58.0; women: 54.4 No. assessed: Men: 150; women: 907 (last observation carried forward)	Length of follow-up: 12 weeks Outcomes by sex: Likelihood of achieving 5 kg or 5% weight loss	

continued

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TABLE 27 Characteristics of studies of men and women included in the review of UK interventions (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Johnson 2011[154]	Study design: Retrospective cohort/audit Location: UK Period of study: July 2005–November 2008 Inclusion criteria: Paying at least 1 month's subscription to the Nutracheck internet weight-loss programme (NutraTech Ltd, Nottingham, UK), record of two or more weights in a 28-day period Exclusion criterion: Participation in the Nutracheck programme for too short a time to give reliable weight change data Age (years), mean (SD): Men: 39.2 (10.1); women: 35.5 (10.5) Weight (kg), mean (SD): Men: 99.0 (16.9); women: 78.0 (16.3) BMI (kg/m^2), mean (SD): Men: 31.0 (4.7); women: 28.9 (5.8) Baseline comparability: Men were heavier and had a higher BMI than women	Description of intervention: Internet-based diet and exercise advice – a commercial, online platform for completing food and exercise diaries in return for a monthly subscription charge. Personalised daily calorie targets are set, adjusting for an individual's activity level and chosen rate of weight loss up to a maximum loss of 0.9 kg per week. A daily online food diary calculates an estimated daily calorie intake by linking to a database of > 40,000 branded and unbranded food items. A daily exercise diary calculates estimated energy expenditure from participant records. A target of 200 kcal per day energy expenditure is encouraged. Behaviour change supported through weight charting, self-monitoring and access to health and nutrition information and an online social community providing support and motivation Duration of active intervention: Mean 186.7 days No. of times contacted: Daily diary completion recommended and participants had voluntary access to the online social forum No. allocated: NR No. completed: Men: 642; women: 2979 Dropout (%): NR No. assessed: Men: 642; women: 2979	Length of follow-up: Mean 186.7 days Outcomes by sex: Weight	

Study ID	Participants	Interventions	Outcomes	Notes
Kirk 2000[155]	Study design: Prospective cohort Location: One university, Edinburgh, UK Period of study: January–March 1999 Inclusion criteria: Age 20–45 years, in good health, BMI 25–35 kg/m^2, not on a special diet for medical reasons, not recently participated in a weight reducing diet, light to moderate habitual physical activity levels Exclusion criteria: Taking prescribed medication that might influence body weight, given up smoking in the previous 3 months Age (years), mean (SD): Men: 35.7 (9.0); women: 41.1 (12.2) Weight (kg), mean (SD): Men: 93.8 (8.0); women: 80.8 (8.9) BMI, mean (SD): Men: 30.6 (2.1); women: 31.2 (3.9) Baseline comparability: Women were older and had a higher BMI than men	Description of intervention: An initial 2-week period of modest energy restriction followed by a 4-week high-carbohydrate dietary regime. During the initial 2 weeks, participants replaced one main meal, lunch or dinner, with a 45-g serving of a Kellogg's breakfast cereal of the participant's choice with 125 ml semi-skimmed milk. Following the energy restriction phase, meal replacement ended but participants were encouraged to eat breakfast cereals as snacks if desired. Participants were also given advice about increasing their carbohydrate intake and how to consume at least five portions of fruit and vegetables per day. Dietary advice was tailored to suit individual eating habits based on data obtained from participant food diaries. Participants were asked to maintain their normal levels of physical activity throughout Duration of active intervention: 6 weeks No. of times contacted: 3 No. allocated: Men + women: 29 No. completed: Men: 6; women: 16 Dropout (%): Men + women: 24 No. assessed: Men: 6; women: 16	Length of follow-up: 6 weeks Outcomes by sex: Weight loss	

continued

TABLE 27 Characteristics of studies of men and women included in the review of UK interventions (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Rolland 2013[156]	Study design: Retrospective cohort Location: Multiple community locations, UK Period of study: 2009–10 Inclusion criteria: Asian men and women recruited to LighterLife with 12-week weight change data available, completed brief medical questionnaire during GP consultation Exclusion criterion: Contraindications for a very low-calorie diet Age (years), mean (SD): Men: Asian: 39.8 (10.9), Caucasian: 39.9 (10.6); women: Asian: 35.9 (11.4), Caucasian: 35.9 (11.3) Weight (kg), mean (SD): Men: Asian: 117.0 (21.5), Caucasian: 126.5 (22.0); women: Asian: 91.7 (12.6), Caucasian: 95.4 (12.0) BMI (kg/m^2), mean (SD): Men: Asian: 37.8 (5.8), Caucasian 38.5 (6.1); women: Asian: 35.4 (4.0), Caucasian: 35.4 (4.0) Baseline comparability: Asian men and women matched to a LighterLife Caucasian population for age, BMI and sex	Description of intervention: As described for Salsbury *et al.*[148] delivered in same-sex groups Duration of active intervention: 12 weeks No. of times contacted: 15 No. allocated: Men: Asian: 81 (66 Indian, 15 Pakistani); women: 429 (316 Indian, 113 Pakistani). Both sexes matched to a Caucasian population No. completed: Men: 36; women: 166 Dropout (%): Men: 55.6; women: 61.3 No. assessed: Men: 36; women: 166	Length of follow-up: 12 weeks Outcomes by sex: Weight, waist circumference	Substudy analysis

Study ID	Participants	Interventions	Outcomes	Notes
Evans 2011a[152]	Study design: Retrospective cohort Location: 26 GP practices and four leisure centres within Hertfordshire NHS Primary Care Trust, UK Period of study: January 2009–December 2010 Inclusion criteria: Age ≥ 18 years, BMI ≥ 30 kg/m^2 (or ≥ 28 kg/m^2 with comorbidities) Exclusion criteria: Pregnant/ breastfeeding women, history of eating disorder Age (years), mean (range) (attending five or more appointments): Men: 55 (27–81); women 52 (19–87) Weight (kg), mean (range) (attending five or more appointments): Men: 117.4 (77.0–203.0); women: 97.9 (60.2–164.0) BMI (kg/m^2), mean (range) (attending five or more appointments): Men: 37.6 (26.6–71.1); women: 36.9 (25.5–60.3) Baseline comparability: Yes	Description of intervention: Computer-based programme (ProHealth*Clinical*) involving dietary and physical advice with behavioural therapy available to primary health-care professionals and offered to patients in dedicated sessions or integrated with chronic illness clinics (e.g. diabetes, cardiovascular disease). ProHealth*Clinical* was developed by KasTech Ltd and allows health-care professionals to provide comprehensive, personalised guidance through structured healthy eating plans, physical activity advice, realistic goal setting, self-monitoring, positive reinforcement, personalised feedback and long-term support. The food and activity database can be customised for cultural preferences and to incorporate local community health and well-being initiatives Duration of active intervention: 12 weeks (six appointments) No. of times contacted: 6 No. allocated: NR No. completed (attended five or more appointments within 14 weeks): Men: 246; women: 677 Dropout (%): NR No. assessed: Men: 246; women: 677	Length of follow-up: 14 weeks Outcomes by sex: Weight	Data by gender presented at the National Obesity Forum Eastern Regional Obesity Network meeting, December 2011

continued

TABLE 27 Characteristics of studies of men and women included in the review of UK interventions (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Evans 2011b[151]	Study design: Retrospective cohort Location: GP practices within NHS Cambridgeshire Primary Care Trust, UK Period of study: 2007–11 Inclusion criteria: NR Exclusion criteria: NR Age (years), mean (range) (attending six or more appointments): Men: 61 (34–80); women: 55 (18–84) Weight (kg), mean (range) (attending six or more appointments): Men: 115.3 (77.5–163.9); women: 95.4 (65.8–169.5) BMI (kg/m^2), mean (range) (attending six or more appointments): Men: 37.1 (27.0–53.2); women: 35.6 (24.5–54.1) Baseline comparability: Men slightly older and had a higher BMI than women	Description of intervention: ProHealth*Clinical* (as described in Evans[152]) delivered as a group-based community health improvement programme. Lifestyle intervention workshops aimed to help participants achieve permanent changes through gradually changing their eating and activity routines through goal setting, self-monitoring, identifying/discussing barriers to change, positive feedback, problem-solving techniques and 2-week lifestyle challenges (e.g. consuming fruit and vegetable snacks only). Participants met fortnightly in small teams to support individual changes Duration of active intervention: 12 weeks (eight workshops) No. of times contacted: 8 No. allocated: NR No. completed (attended six or more workshops within 12 weeks): Men: 33; women: 123 Dropout (%): NR No. assessed: Men: 33; women: 123	Length of follow-up: 12 weeks Outcomes by sex: Weight	Data not reported by sex in abstract. Received through personal communication from author

Study ID	Participants	Interventions	Outcomes	Notes
Evans 2012[153]	Study design: Retrospective cohort Location: 23 GP surgeries, Cambridgeshire, UK Period of study: February 2010–October 2011 Inclusion criteria: Age ≥ 18 years, BMI ≥ 30 kg/m^2 or ≥ 28 kg/m^2 with comorbidities (high blood pressure, impaired glucose tolerance, type 2 diabetes) Exclusion criterion: Participants who did not demonstrate the motivation to lose weight in the first 4 weeks were discharged Age (years), mean (range) (attending five or more appointments): Men: 61 (26–82); women: 56 (20–81) Weight (kg), mean (range) (attending five or more appointments): Men: 117.9 (81.2–213.4); women: 98.1 (70.4–173.7) BMI (kg/m^2), mean (range) (attending five or more appointments): Men: 37.5 (27.4–61.4); women: 37.3 (28.4–61.3) Baseline comparability: Yes	Description of intervention: Peripatetic level 1 weight management services (Weigh2Go). Commissioned by Cambridgeshire Association to Commission Health (CATCH) using ProHealth*Clinical* (as described in Evans[152]). The Cambridgeshire Community Services NHS Trust Dietetic Business Unit were responsible for training and supporting the primary care staff who delivered the intervention Duration of active intervention: 3 months No. of times contacted: 6 No. allocated (attending four or more appointments): Men: 627; women: 444 No. completed (attending five or more appointments): Men: 118; women: 294 Dropout (%): NR No. assessed (attending five or more appointments): Men: 118; women: 294	Length of follow-up: 12 months (outcomes by sex reported at 3-month follow-up) Outcomes by sex: Weight	

continued

TABLE 27 Characteristics of studies of men and women included in the review of UK interventions (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Stubbs 2011[36]	Study design: Retrospective cohort Location: 77 primary care and NHS trust communities, UK Period of study: May 2004–November 2009 Inclusion criteria: Each participating primary care/NHS trust set its own referral criteria, which varied depending on local weight management care pathways; data on weight, height, age and sex available; had sufficient time to complete the 12-week programme Exclusion criteria: Age < 16 years, pregnant Age (years), mean (SD): Men: 51.4 (13.8); women: 46.8 (14.4) Weight (kg), mean (SD): Men: 117.9 (22.4); women 97.2 (18.5) BMI (kg/m^2), mean (SD): Men: 37.8 (6.6); women: 36.7 (6.5) Baseline comparability: Men were older and slightly heavier with a higher BMI	Description of intervention: Primary care and NHS trust referral to commercial weight management provider (Slimming World). Participants issued 12-week voucher packs for Slimming World (funded by primary care/NHS trusts and subsidised by Slimming World). Vouchers could be used to attend local Slimming World group of choice. Participants treated and delivered the usual Slimming World programme in exactly the same way as private members (as described for Bye *et al.*[34]) Duration of active intervention: 12 weeks No. of times contacted: 12 No. allocated: Men: 3651; women: 30,620 No. completed: Men: 2329; women: 17,578 Dropout (%): Men: 36.2; women: 42.6 No. assessed: Men: 3651; women: 30,620	Length of follow-up: 12 weeks Outcomes by sex: Weight, BMI	

Study ID	Participants	Interventions	Outcomes	Notes
Stubbs 2012[157]	Study design: Retrospective cohort Location: 45 primary care or NHS trusts, UK Period of study: May 2004–November 2009 Inclusion criteria: Participants were offered subsequent referral at the referrer's discretion. Criteria for this varied between NHS trusts but included the selection of those who were deemed to be motivated by having a higher starting BMI, those making gradual progress towards their treatment objectives, those with comorbidities that would be improved by further weight loss and those unable to self-fund further attendance Exclusion criteria: Age < 16 years, pregnant women Age (years), mean (SD): Men: 53.9 (13.1); women: 49.2 (14.4) Weight kg: Mean (SD) Men: 119.9 (21.8); Women: 100.4 (19.4) BMI (kg/m2), mean (SD): Men: 38.4 (6.3); Women: 37.9 (6.8) Baseline comparability: Men were older and heavier than women	Description of intervention: As described in Stubbs *et al.*[36] except that some of the NHS trusts involved in the Stubbs 2011[36] audit offered a second, consecutive referral of 12 sessions Duration of active intervention: 24 weeks No. of times contacted: Up to 24 No. allocated: Men: 575; women: 4179 No. completed (attended at least 20/24 sessions): Men: 475; women: 3168 Dropout (%): Men: 17.4; women: 24.2 No. assessed: Men: 575; women: 4179	Length of follow-up: 24 weeks Outcomes by sex: Weight, BMI	

continued

TABLE 27 Characteristics of studies of men and women included in the review of UK interventions (*continued*)

Study ID	Participants	Interventions	Outcomes	Notes
Ahern 2011[37]	Study design: Retrospective cohort Location: NHS primary care trust communities, UK Period of study: 2 April–6 October 2009 Inclusion criterion: NHS referral to Weight Watchers Exclusion criteria: NR Age (years), median (IQR): Men + women: 49 (38 to 61) Weight (kg), median (IQR): Men + women: 94.3 (83.7 to 107.7) BMI (kg/m^2), median (IQR): Men + women: 35.1 (31.8 to 39.5) Baseline comparability: NR	Description of intervention: NHS-funded referral to commercial weight-loss programme. Participants received vouchers to attend 12 Weight Watchers group meetings. Participants followed the standard Weight Watchers ProPoints® Plan. The plan allows daily and weekly point allowances for food and drinks. Participants were also provided with information and tips for healthy eating/ lifestyle, menus and the ProPoints guide booklet. An online calculator and tools and mobile smart phone apps were also available. A ProPoints calculator and restaurant guide were available to buy at meetings. Social support was provided by attendance at group meetings and through Facebook, Twitter and YouTube Duration of active intervention: 12 sessions No. of times contacted: 12 No. allocated: Men: 3074; women: 26,252 No. completed: Men: 1274; women: 10,577 Dropout (%): Men: 58.6; women: 59.7 No. assessed: Men: 1274; women: 10,577	Length of follow-up: > 24 weeks Outcomes by sex: % weight change	

IQR, interquartile range; NR, not reported.

In terms of the interventions, three studies provided dietary advice only.[140,146,155] It was not clear whether or not any advice on behaviour change was given in these studies. All of the remaining studies discussed in this chapter provided dietary and exercise advice and behaviour change training, and four of these also provided an exercise programme to attend.[138,139,141,149] An exercise programme is also provided in the Rosemary Conley Diet and Fitness Clubs, which was one of the interventions evaluated by Dixon and colleagues.[150]

Characteristics of the men

A total of 11,426 men were allocated to an intervention and 8957 were included in the report analyses. Men represented 11.7% of the population of mixed-sex studies (*Table 28*). The youngest reported mean age for men was 39 years and the oldest was 61 years. The lowest reported mean BMI was 30.6 kg/m^2 and the highest was 39.0 kg/m^2. The lowest reported mean weight was 93.8 kg and the highest was 126.5 kg.

Overview of types of outcomes reported

All studies reported either baseline and end weights or changes in weight. Nine studies provided details of change in BMI[33,34,36,139,142,146–148,157] and four reported changes in waist circumference.[139,141,147,156] One study reported changes in total cholesterol and blood pressure[138] and one reported changes in total, LDL and HDL cholesterol and triglycerides.[146] Twelve studies gave details of percentage change in body weight.[34,36,138,140–142,147,151–154,156] Nine studies reported achieving 5 kg or 5% or 10% weight loss.[34,36,142,147,150–154]

Six reports[138,139,141,142,147,155] conducted a formal process evaluation.

TABLE 28 Percentage of men recruited to mixed-sex studies included in the review of UK interventions

Study ID	No. of participants			% men
	Men	Women	All	
Ross 2008[31] (Counterweight)	438	1468	1906	23.0
Dixon 2012[150]	150	907	1057	14.2
Kirk 2000[155]	6	16	22	27.3
Rolland 2013[156]	81	429	510	15.9
Johnson 2011[154] (Nutracheck)	642	2979	3621	17.7
Evans 2011[152] (ProHealth*Clinical*, Hertfordshire)[a]	298	846	1144	26.0
Evans 2011[151] (ProHealth*Clinical*, Cambridgeshire)[a]	43	179	222	19.4
Evans 2012[153] (ProHealth*Clinical*)[a]	118	294	412	28.6
Stubbs 2011[36] (Slimming World)	3651	30,620	34,271	10.7
Ahern 2011[37] (Weight Watchers)	3074	26,252	29,326	10.5
Total	8501	63,990	72,491	11.7

a Attending at least four ProHealth*Clinical* appointments.

Quality of the evidence

Risk of bias

The risk of bias assessment for the individual studies is shown in *Appendix 12* (see *Tables 60* and *61*). Only one full-text publication of an RCT[146] was identified; this study was judged to be at high risk of bias for the sequence generation, allocation concealment and blinding (participant and health-care provider) domains of The Cochrane Collaboration's risk of bias tool (see *Appendix 12*, *Table 60*).[57] It was unclear whether or not outcome assessors were blinded, all groups were treated identically and if the authors carried out intention-to-treat analyses. The trial was, however, judged to be at low risk of bias for incomplete data. The trial by Gray and colleagues[141] was excluded from the risk of bias assessment as outcome data were available only in abstract format.

The remaining 14 full-text publications were assessed using the ReBIP quality assessment tool for non-randomised comparative and case series studies (see *Appendix 12*, *Table 61*). *Figure 38* summarises the risk of bias assessment for these studies. Items in italics are valid for comparative studies only. The majority (57.1%) of studies included a representative participant sample. Rolland and colleagues[156] analysed data for participants who had baseline and 12-week weight data only and Kirk and colleagues[155] included only healthy overweight participants. Data were largely collected prospectively and interventions were delivered by appropriate people (71.4% and 64.3% of studies respectively). All studies used valid objective outcome measures but few (28.6%) included a sufficient follow-up time (here considered to be at least 1 year) to give meaningful information on the sustainability of weight loss. Just over half of the studies (57.1%) provided information on participant dropouts. Many items were unclear because of insufficient reporting by study authors and it is therefore not possible to summarise the impact of these biases on the overall body of evidence.

Assessment of equity and sustainability

We assessed 16 studies for equity and sustainability. Results for the individual studies are detailed in *Appendix 12* (see *Table 62*). Although the Football Fans in Training (FFIT) pilot RCT[141] was excluded from

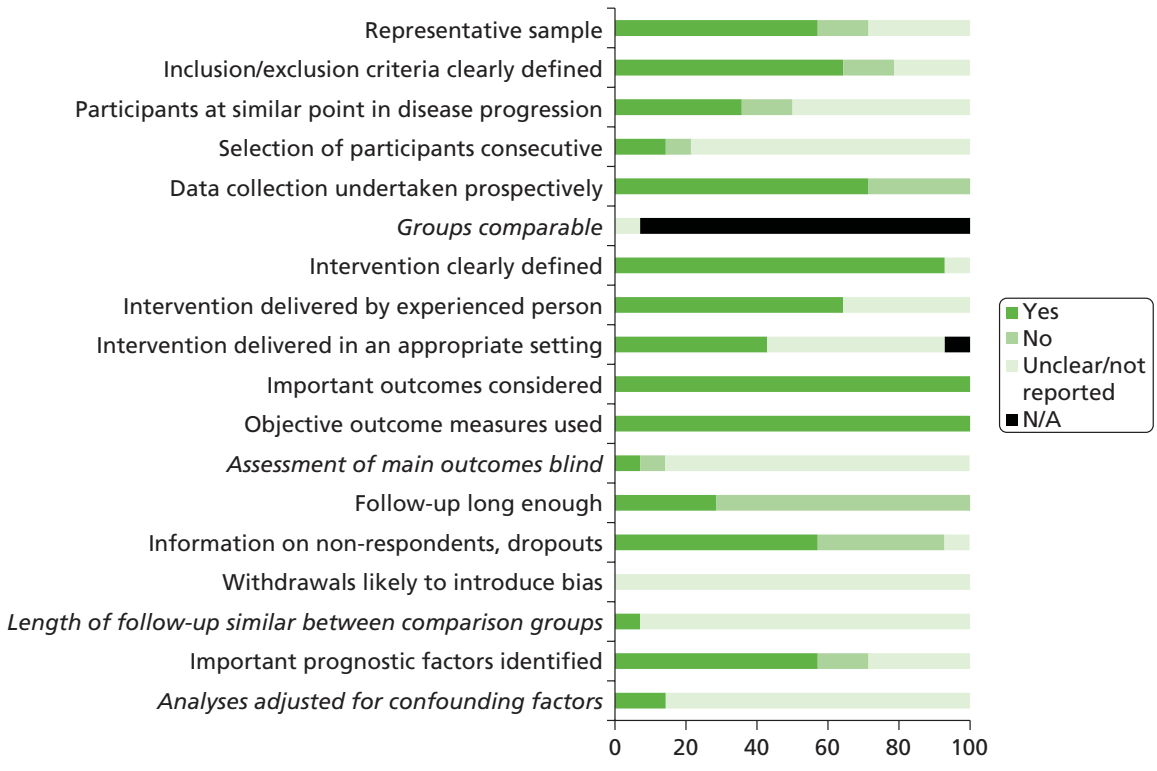

FIGURE 38 Summary of risk of bias assessment of non-RCT studies included in the review of UK interventions.

the risk of bias assessment, details of the intervention and intervention delivery were made available to us by the study authors (Kate Hunt, University of Glasgow, February 2012, personal communication). We therefore included this study in our assessment, summarised in *Figure 39*. Just over half (56.3%) of the studies were conducted in settings considered to target or exclude specific populations. Three studies targeted a male sports fan base[138,139,141,149] and two studies targeted participants in their workplace.[140,146] Three studies of commercial providers[34,154,156] were judged to have potentially excluded populations unable to afford their subscription charges. None of the studies reported on sociodemographic differences between participant dropouts and withdrawals, although many (56.3%) reported details for some PROGRESS categories at baseline. Few (25.0%) considered sustainability or discussed their interventions in political or other organisational contexts (31.2%). Four studies described partnerships between academic and sporting institutions and the NHS[138,139,141,149] and four described partnerships between commercial organisations and the NHS.[33,36,37,150]

None of the studies indicated whether participants had experienced adverse harms as a result of the interventions. The Slimming World studies[34,36] had potential conflicts of interest as the study authors are employed by Slimming World and the research was funded by the organisation. Conflict of interest was less clear for the Rolland and colleagues' LighterLife study,[156] with some of the authors acting as LighterLife consultants and research funding provided by LighterLife. Furthermore, although Johnson and colleagues[154] declared that they had no conflict of interest in their analysis of Nutracheck subscribers, the data were supplied by a company representative who also commented on the study analysis. Conflict of interest was also unclear in the study by Drummond and colleagues.[140] Although the authors were independent, the Carb Boosters snacks used in the study are manufactured by the study funder, the Sugar Bureau. Similarly, the study by Leslie and colleagues[146] included meat and no meat groups and was funded by the Meat and Livestock Commission, and the study by Kirk and colleagues[155] of breakfast cereal was supported by the Kellogg Company of Great Britain. Other items were largely unclear because of inadequate reporting issues.

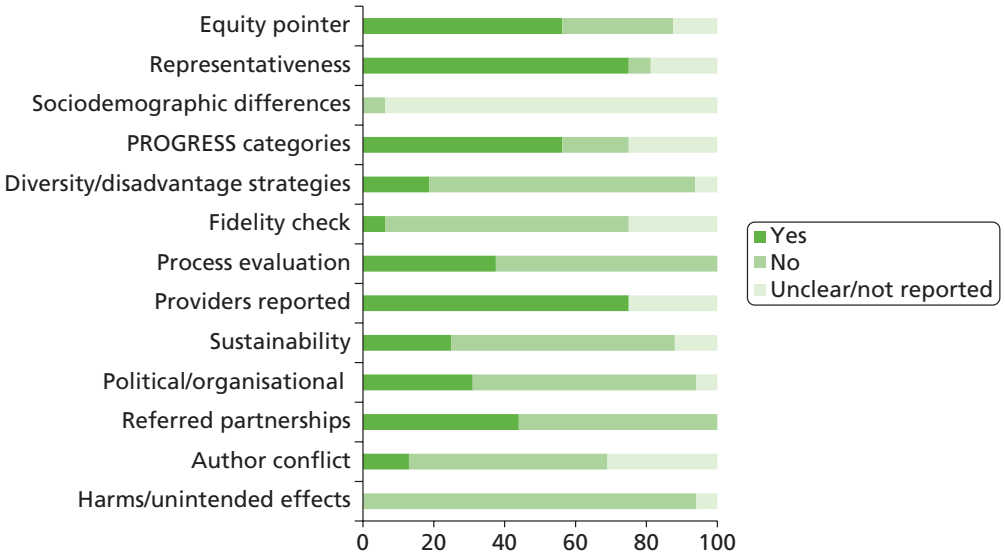

FIGURE 39 Summary of the equity and sustainability assessment of trials included in the review of UK interventions.

Assessment of effectiveness

Because of the heterogeneity of the included studies, we did not attempt any quantitative synthesis of the results. Instead, summary data from the included studies and a narrative overview of each study are presented.

Men-only programmes

Weight-loss programmes and the workplace

Two studies investigated the delivery of dietary interventions to promote weight loss in a male-orientated workplace setting. The first of these[146] was conducted in a single petrochemical worksite in Glasgow over a 24-week period. Men were randomised to receive either an individualised energy-deficient diet or a general low-calorie diet. Men in the energy-deficient diet group received individualised energy prescriptions calculated in accordance with their age, sex and body weight to produce a 600-kcal daily energy deficiency. Men in the general diet group consumed 1500 kcal per day. The weight-loss phase of the trial lasted 12 weeks. During weeks 12–24, diet and energy requirements were recalculated for weight maintenance rather than weight loss. Within each group, men were also randomised to consume meat or no meat. Men in the meat groups consumed red meat at least five times per week. Men in the non-meat groups substituted red meat with fish, eggs and cheese. Intention-to-treat analyses showed no significant difference in weight loss between the energy-deficient diet and the general low-calorie diet during the weight-loss phase [–3.7 kg (SD 3.4 kg) vs. –3.9 kg (SD 3.5 kg) respectively, $p = 0.78$]. Differences between groups for other risk factors were also non-significant (*Table 29*). For those who completed the programme, both groups significantly gained weight during the weight-maintenance phase but the difference between groups was not significant [+0.9 kg (SD 2.0 kg) vs. +1.4 kg (SD 1.6 kg), $p = 0.27$].

Data for meat/non-meat participants were not reported by the original diet group. Meat consumption did not significantly affect weight loss or biochemistry. Average weight loss during the weight-loss phase for those men who completed the meat and non-meat programmes was –4.2 kg (SD 3.7 kg) and –5.0 kg (SD 3.2 kg) respectively. Again, both groups gained weight during the weight-maintenance phase [+0.9 kg (SD 1.6 kg) vs. +1.4 kg (SD 2.0 kg)]. The study authors commented that weight loss was less than expected and the dropout rate was significantly greater in the general low-calorie diet group.

The study conducted by Drummond and colleagues[140] aimed to recruit male and female taxi drivers, but only men volunteered. Men followed a low-fat, high-carbohydrate (sugar-containing), energy-restricted diet that was tailored to produce a daily energy deficit of 600–700 kcal for each man over a 12-week period. Men were also advised to consume specialist sugar-containing Carb Boosters snacks to prevent a 'starve and binge' dieting pattern. The study was funded by the Sugar Bureau. By 12 weeks both BMI and weight were significantly reduced ($p < 0.05$). The average weight loss in completers was –5.5 kg,

TABLE 29 Mean (SD) change in risk factors at 12 weeks for those men who completed the energy-deficient and general low-calorie diets

Risk factor	Energy-deficient diet ($n = 49$)	General low-calorie diet ($n = 42$)
Weight loss (kg)	–4.3 (3.4)	–5.0 (3.5)
Waist circumference (cm)	–4.7 (3.4)	–5.2 (3.4)
Total cholesterol (mmol/l)	–0.20 (0.6)	–0.34 (0.5)
LDL cholesterol (mmol/l)	–0.09 (0.5)	–0.20 (0.2)
HDL cholesterol (mmol/l)	+0.005 (0.1)	–0.02 (0.2)
Triglycerides (mmol/l)	–0.2 (0.8)	–0.2 (0.8)

representing a 5.2% reduction in total body weight. The waist-to-hip ratio was reduced from 1.00 to 0.97. The men also perceived that their quality of life had increased over the 12-week period.

Men's health clinics

Two studies evaluated NHS-delivered, men-only weight management groups. The Bloke's Weigh programme[147] was jointly developed by the NHS Angus Weight Management Project Facilitator and the MACH4 (Male Checks for Health) Men's Health Project to provide a weight management group to the men of Arbroath, a town in Scotland that is recognised to have high levels of social deprivation. The men met in a local church hall and received advice for following a low-fat diet and increasing levels of physical activity over a 6-week period, extended to 10 weeks because of demand. Causes of weight gain, the role of alcohol, self-monitoring and the benefits of weight loss were also discussed. Four men also approached the Men's Health Project worker for a health check and advice outside the group environment; areas of concern were weight and diet related but mental health issues were also raised. Twenty-three of the 38 participants attended the sessions regularly. Of these, four men gained weight but the other men showed varying degrees of weight loss (15 men lost 1–6 kg and four men lost 7–11 kg). Reductions in BMI and waist circumference were also achieved (*Table 30*).

McFarlane and colleagues[147] conducted a process evaluation of the Bloke's Weigh programme. Ten men stated that they would have attended the programme in mixed-sex groups, nine stated that they would not or probably would not have attended and one man stated that he would possibly have attended. The authors reported that the majority of men enjoyed all sessions but that they would have preferred more meetings over a longer time period and the inclusion of an exercise class. Some men stated that a 19:00

TABLE 30 Bloke's Weigh programme: 10-week outcomes

Outcome	No. of men ($n = 23$)
Weight	
Gain	4
Lost 1–6 kg	15
Lost 7–11 kg	4
BMI	
Increase	5
Reduced by 2 kg/m^2	14
Reduced by up to 4 kg/m^2	4
% of baseline weight lost	
Increase	4
≤ 5	14
6–10	3
11–15	2
Waist circumference	
Increase	7
Lost ≤ 5 cm	7
Lost > 5 cm to ≤ 10 cm	8
Lost > 10 cm to ≤ 16 cm	1

start time would be more convenient than 18:00. Blood pressure measurements and relaxation/stress management techniques were also recommended for future programmes.

Gray and colleagues[142] evaluated a group-based weight management programme aimed at men in the Camelon and Grangemouth areas of Scotland. Twelve weekly group sessions were held in local community health clinics. The men were also given advice for following a low-fat reducing diet and increasing physical activity with the aim of losing 0.5–1 kg per week. The psychology of behaviour change and value of social support were also discussed. Men were also invited to join organised post-programme meetings to facilitate long-term weight management. Men with a BMI of ≥ 35 kg/m^2 were more likely to enrol in the programme than those with a BMI of < 30 kg/m^2. The majority of men who enrolled were married and employed (both 73.5%). Almost half (47.9%) of the men came from households classed as deprived according to the Scottish Index of Multiple Deprivation (see www.scotland.gov.uk/Topics/Statistics/SIMD), but none was from an area classified in the most deprived quintile. In total, 80 men completed the 12-week programme. The average weight loss was 5.0 kg (range –17.2 kg to +2.6 kg); the average reduction in BMI was 1.3 kg/m^2 (range –5.5 kg/m^2 to +2.2 kg/m^2); and the average reduction in waist circumference was 7.5 cm (range –27.5 cm to +3.0 cm). At 12 weeks, 35.4% of completers had lost ≥ 5% of their body weight and 8.9% had lost ≥ 10%. Following programme completion, weight-loss records were available for 20 men. These men were between 1 and 49 months post programme and had maintained an average 3.7% weight loss compared with their baseline weight (range –32.6% to +25.6%). In total, 14 men were lighter than their baseline weight, two were stable and four had gained weight compared with their original starting weight. The men's experiences of being in the programme were evaluated using focus group interviews. The results of this evaluation are discussed in *Chapter 6*.

Sports clubs

Four studies[138,139,141,149] investigated the use of male-orientated sports clubs to deliver nutritional advice and an exercise programme in men-only groups. The study by Brady and colleagues[138] included male season ticket holders at Glasgow Rangers and Celtic football clubs. Both clubs were part of the SPL at the time of the study. Interested men were asked to provide details of their height, weight, general fitness level and approximate level of general health. Men were graded according to their BMI measurement and those with the highest BMI were selected first. A total of 20 men were invited to each club for the first programme cycle. There were two early withdrawals before the initial assessment but these places were readily filled by others. The authors reported that almost all men underestimated their true weight and overestimated their height. The men attended 10 weekly sessions lasting 2 hours at their respective club stadiums. The first hour covered discussion of health issues, with health lectures delivered by a physician. Mediterranean-style low-fat dietary advice was delivered by research dietitians and nurses, with calorie restriction when required. Emphasis was placed on changing lifestyles and adopting healthy behaviours for the men and their families. The second hour consisted of exercise classes run by professional Rangers and Celtic coaching staff. Heart rate monitors were used and the men were instructed to exercise at an appropriate heart rate for 30 minutes three to four times a week. At the start of the programme only six men could jog round the stadium football pitch without stopping (distance of around 350 m). After the 10-week programme all of the men could complete one lap and some were able to complete multiple laps without stopping. The programme attracted 100% attendance. Furthermore, some of the men arranged to exercise in small groups after the programme finished. Others encouraged the setting up of exercise programmes at their workplace. Data for 36 out of 40 men were available 15 months after the programme finished (*Table 31*).

The study authors deliberately targeted their intervention at men who had a passion for their football club. Participants ranged from manual workers and office workers to a company director but all shared an enthusiasm for their club. The authors reported that every man considered their participation in the programme to be one of the most rewarding experiences of their lives.

Gray and colleagues[141] delivered a similar intervention at two SPL clubs (Hearts and Kilmarnock) as part of a pilot RCT lasting 12 weeks. Men were randomised either to receive the FFIT weight-loss programme or

TABLE 31 Mean change in outcomes at 15 months after programme cessation

Outcome	Baseline	Mean change at 10 weeks ($n = 40$)	Mean change at 15 months post baseline
Weight (kg)	95.0	–2.7	–3.8 ($n = 36$)
Total cholesterol (mmol/l)	5.66	–0.75	–0.49 (n = NR)
Systolic blood pressure (mmHg)	136.6	–2.5	NR
Diastolic blood pressure (mmHg)	NR	–1.0	NR

NR, not reported.

to a waiting list control group. The recruitment target ($n = 60$) was achieved in the larger city-based club (Hearts) but not in the smaller town-based club. As with the study by Brady and colleagues,[138] men in the FFIT programme attended 12 weekly sessions at their club training ground where they received personalised dietary and healthy eating and behaviour change advice followed by structured exercise classes. Men in the waiting list group were told that they would receive the FFIT programme 4 months later. The majority of men were white (99%), married (71.8%) and in full-time employment (76.7%). The authors reported that there were no baseline differences between the FFIT group and the waiting list group (Dr Cindy Gray, University of Glasgow, October 2012, personal communication).

The FFIT men achieved significant weight loss and a significant reduction in waist circumference compared with the waiting list men, who showed increases for both outcomes (*Table 32*). The FFIT men also reported significant improvements in self-esteem, quality of life (as measured by the SF-12) and physical activity and healthy eating. These changes were also significantly different from those in the waiting list group (reported $p = 0.001$ to 0.048).

The attrition rate was reported as low, with 83.5% of the men completing the FFIT programme. The authors reported that the men were very positive about their participation in the programme. The affiliation with the football clubs was highlighted as being the main incentive as many men indicated that they would not have attended a weight-loss programme in an alternative setting. The professional coaching staff also gave positive feedback about their involvement with the programme.

Similar weight-loss programmes have been aimed at men in the rugby league setting. The Tackling Men's Health (TMH) initiative was developed out of a partnership between the Department of Health, Leeds Rhinos Rugby League Club and Leeds Metropolitan University. The initiative was promoted in partnership

TABLE 32 Comparison of 12-week outcomes for the FFIT and comparison groups

	FFIT		Waiting list	
Outcome	Baseline ($n = 51$)	12 weeks ($n = 44$)	Baseline ($n = 52$)	12 weeks ($n = 42$)
Weight (kg), mean (SD)	107.6 (15.0)	101.6 (14.1)	107.5 (19.5)	106.2 (18.5)
% weight loss from baseline, mean (SD)[a]		–4.6 (2.8)		+0.6 (0.2)
Waist circumference (cm), median (IQR)[a]	115.5 (111.5 to 124.6)	112.9 (106.7 to 120.2)	115.1 (107.4 to 121.7)	116.6 (108.8 to 121.6)

IQR, interquartile range.
a Between-group difference significant (reported $p < 0.001$).

with male health-related projects, the Yorkshire Man Mini Manual (Men's Health Forum) and Change4Life (Cancer Research UK), and targeted men attending rugby matches at the Leeds Rhinos stadium with the aim of improving various areas of health and well-being (e.g. mental health, diet and nutrition, exercise and sexual health). TMH staff found it difficult to recruit men to the weight-loss group, highlighting difficulties in identifying men in a crowd of supporters as overweight without causing offence. The recruitment strategy was therefore altered for the weight-loss group: men were contacted by the Leeds Rhinos club through existing communication strategies and offered the opportunity to attend the weight-loss programme at the club training ground. Group sessions were split between discussing diet, physical activity and behaviour change and taking part in physical activity involving aerobic and muscle resistance training exercises. The programme was run over a 6-week period during the 2009 rugby league season for a group of seven men[149] and was repeated over an 8-week period during the 2010 season for a group of 12 men (10 completed the course).[139] The main facilitator for the theory sessions was male but the intervention was delivered by a mixed-sex team. The average weight loss for the 2009 and 2010 groups was –2.1 kg (SD 3.3 kg) and –2.4 kg (SD 1.4 kg) respectively. Furthermore, data for the 2010 group showed an average 4.3-cm (SD 2.3 cm) reduction in waist circumference and an average BMI reduction of 0.8 kg/m^2.

Men in the 2010 group[139] gave their evaluation of the course. The key reasons that the 12 men gave for joining the programme were the chance to use the club training facilities (five men); that the sessions were held in the evening (four men); the accessible location (three men); and the men-only group (two men). The men enjoyed the sessions, particularly the inclusion of physical activity exercises and the ability to discuss sensitive issues in a male-only environment. The initiative also provided the opportunity to refer the men to other local health initiatives and two men were referred to a specialist diabetes group.

Commercial weight-loss providers

We identified seven reports of men-only weight-loss groups provided by commercial organisations: Weight Watchers,[33] Slimming World[34] and LighterLife.[35,143–145,148] Both Weight Watchers and Slimming World delivered their standard programme in men-only groups. Men in the Weight Watchers report were referred by their NHS health-care provider. Weight Watchers provide a dietary plan that allocates points to certain foods whereas Slimming World allows unlimited consumption of low-calorie 'free foods' and a 'no hunger' diet plan. A 30-minute exercise add-on class was provided to two-thirds of the Weight Watchers groups. The Weight Watchers programme is designed to create a caloric deficit for a healthy weight-loss rate of up to 2 lb a week, taking into account an individual's sex, age, height and current weight. Slimming World does not differentiate by sex in its dietary prescription.

The LighterLife 'Man Plan' programme was aimed at men and participants were provided with a booklet using male-friendly language and humour, using a football team analogy to describe the benefits of the programme. The LighterLife men abstained from conventional food and alcohol for 8 weeks and consumed very low-calorie diet formula foods known as 'Man Plan' food packs (although the diet is the same for men and women, irrespective of body weight). Abstinence from conventional food is reported by the LighterLife authors as providing clarity around boundaries for food and drink consumption. Group behaviour change work is also used to explore reasons for overeating and develop practical and psychological strategies for future weight maintenance.

Men in the LighterLife, Weight Watchers and Slimming World reports were followed up for a period of 8, 12 and 24 weeks, respectively, although men in the Weight Watchers group were able to complete the 12 sessions over a longer time period if necessary. For the Slimming World programme, data were analysed for men who had attended for at least 8 weeks.

LighterLife data were available at 8 weeks from five reports.[35,143–145,148] Details are presented in *Table 33*.

The majority of men completed the Weight Watchers programme (63%, 39/62) and the majority achieved a weight loss of ≥ 5% [77% of programme completers (30/39) and 52% of all participants (32/62)].[33] Average weight loss for all men was –6.3 kg (SD 4.1 kg) and average BMI reduction was 2.1 kg/m^2. The

TABLE 33 Effect of the LighterLife diet on mean weight and BMI at 8 weeks

Study ID (number of men)	Mean start weight (kg)	Mean start BMI (kg/m²)	Mean weight change (kg)	Mean BMI change (kg/m²)	% weight loss
Holt 2007[145] (*n* = 1279)	121.5	38.5	–17.4	–5.5	14.3
Hallam Spencer 2008[143] (*n* = 1000)	121.3	38.0	–17.5	–5.5	14.5
Salsbury 2009[148] (*n* = 2200)	119.2	37.4	–14.8	–4.7	12.5
Hallam 2010[144] (*n* = 950)	123.2	38.6	–19.5	–6.1	15.8
Hallam 2011[35] (*n* = 1006)	124.0	39.0	–19.4	–6.1	15.6

authors reported that the men were positive about the Weight Watchers programme and unanimously preferred the men-only meetings.

Weight-loss data for the Slimming World programme for those men who had been members for at least 24 weeks were available for 16 men only.[34] These men lost an average of 13.2 kg (SD 3.6 kg) representing an 11.4% (SD 4.2%) change in weight (69% achieved 10% weight loss and 31% achieved at least 5% weight loss). At the point of data collection, the average BMI reduction was –3.4 kg/m². There were no significant differences in weight loss between men employed in shift work and men employed in non-shift work.

Mixed-sex programmes

NHS primary care setting

We identified four reports of weight-loss programmes delivered in the NHS primary care setting.[31,151–153] Three of these reports describe an evidence-based computer programme, ProHealth*Clinical*. The programme provides instant access to practical eating plans and strategies for increasing physical activity as well as motivational information, such as behaviour change techniques, and tools for tracking patient progress for health-care practitioners. The Counterweight programme offers patients a prescribed energy-deficient diet, behavioural therapy and advice for increasing physical activity.

*ProHealth*Clinical

ProHealth*Clinical is* a computer toolbox of weight and behaviour modification resources developed by KasTech Ltd. KasTech Ltd is a private, non-NHS company that sells its product and training to health-care professionals. ProHealth*Clinical* provides a range of evidence-based weight and behaviour tools that enhance the skills, knowledge and effectiveness of health-care and non-health-care practitioners providing weight-loss advice to patients (e.g. a lifestyle goal-setting database, meal and snack plans, activity energy expenditure information, progress graphs). Advice takes account of the age and sex of the patient. We identified three studies of GP practices that purchased the programme and training from KasTech Ltd. The first of these evaluated ProHealth*Clinical* in 26 GP practices and four leisure centres in NHS Hertfordshire Primary Care Trust.[152] Centres either offered dedicated weight-loss clinic sessions or integrated patients into existing chronic illness clinics over six appointment sessions. Practitioners were encouraged to discharge patients who were unmotivated to make lifestyle changes within the first 4 weeks. The number of men enrolling in the programme (26.7%) was reported to be higher than is usually seen for commercial weight-loss programmes (10%). Of those attending five or more appointments, 26.7% (*n* = 246) were male, the majority of whom lost weight (228/246, 92.7%). The average weight loss for men attending five or more appointments was 5.1 kg (average 4.4% change from baseline weight) and 102 (41.5%) men achieved weight loss of ≥ 5% of their baseline weight. For women attending five or more appointments, the average weight loss was 3.9 kg and the average percentage weight loss was 4%, with 245 (36.2%) losing ≥ 5% of their baseline weight.

A similar evaluation of the programme was conducted in 20 GP practices in NHS Cambridgeshire Primary Care Trust.[151] Eight fortnightly workshops were held over 3 months. Dietitians and physical activity instructors delivered four out of eight workshops to patients who worked together in small supportive teams. Participants were also given practical 2-week lifestyle challenges, for example eating only fruit or vegetable snacks. In total, 33 men and 123 women attended six or more workshops within 3 months. The mean reduction in weight was 5.2 kg for men (mean 4.6% of baseline weight) and 3 kg for women (mean 3.1% of baseline weight). The programme produced weight loss of ≥ 5% for 12/33 (36.4%) men and 28/123 (22.8%) women.

In the third study, ProHealth*Clinical* was used within a pilot weight management service, Weigh2Go, commissioned by the Cambridgeshire Association to Commission Health (CATCH).[153] Participants were invited to attend six appointments over a 3-month time frame. Of those attending at least five appointments, 118 (28.6%) were men and 112 (94.9%) lost weight. Mean weight loss was 5.4 kg and mean per cent weight change was 4.7% for men; the equivalent figures for women were 4.1 kg and 4.2%. In total, 52 men (44.1%) and 96 (32.7%) women achieved ≥ 5% weight loss.

Table 34 provides a summary of the data from the various programmes using ProHealth*Clinical*.

Counterweight

The Counterweight programme[31] was delivered by specially trained GP practice nurses and health-care assistants. Their role was to deliver education and advice through discussion and communication of information and through the transfer of behaviour change skills and strategies. Participants were prescribed a > 500 kcal per day energy-deficit low-fat diet plan and aimed to achieve a weight-loss goal of 5–10% through individual or group goal-setting behaviour. The GP exercise referral scheme was also offered to participants when this was available and appropriate for individuals. In total, 22 practices were located in deprived areas of the UK, a further 22 were from intermediately deprived areas and 12 were from affluent areas; these practices contributed 36.4%, 29.5% and 34.2% of the total study population respectively. The programme lasted twelve weeks. At 12 months, data for 171 (49%) men and 471 (32%) women were available. Mean weight loss was –3.4 kg (SD 7.31 kg) for men. There was no significant difference in weight loss between the sexes [mean weight loss for women –2.8 kg (SD 6.38 kg)].

Commercial weight-loss programmes

We identified two eligible studies of commercial weight-loss programmes: LighterLife[156] and Nutracheck.[154]

TABLE 34 Mean weight loss and per cent weight change for programmes using ProHealth*Clinical*

Outcome	Hertfordshire PCT	Cambridgeshire PCT	Weigh2Go
No. of appointments attended	≥ 5	≥ 6	≥ 5
Men			
n	246	33	118
Weight loss (kg), mean (range)	–5.1 (–17.3 to +4.1)	–5.2 (–17.7 to +3.1)	–5.4 (–18.4 to +2.7)
Weight change (%), mean (range)	–4.4 (–12.5 to +2.6)	–4.6 (–15.5 to +2.5)	–4.7 (–14.8 to +2.3)
Women			
n	677	123	294
Weight loss (kg), mean (range)	–3.9 (–23.2 to +5.5)	–3.0 (–19.7 to +1.6)	–4.1 (–16.5 to +2.1)
Weight change (%), mean (range)	–4.0 (–19.9 to +4.4)	–3.1 (–16.6 to +2.0)	–4.2 (–16.8 to +2.2)

PCT, primary care trust.

In the first of these reports, Rolland and colleagues[156] investigated whether or not British Asian men and women differed from a matched Caucasian group in their response to the LighterLife very low-calorie diet. The standard programme was delivered to participants in single-sex groups. Outcomes at 12 weeks are shown in *Table 35*. Asian men and Caucasian men lost a similar percentage of weight whereas Asian men showed a greater reduction in mean waist circumference per kg of weight loss.

Nutracheck is a commercial internet-based weight-loss programme offering reducing diet and exercise advice. Nutracheck offers personalised daily calorie and physical activity targets, online food and exercise diaries that calculate calorie intake and energy expenditure, and access to an online social community providing support and motivation. Johnson and Wardle[154] carried out a retrospective analysis of self-reported weight loss in men and women joining Nutracheck between July 2005 and November 2008. During the study period the Nutracheck Men service was launched (April 2007). Men registering from this time onwards were free to join either the male or the unisex version of the programme. Data were available for 642 men and 2979 women with a mean follow-up period of 186.7 days (SD 192.6 days). Average (mean) weight loss for the men was 5.6 kg (SD 6.5 kg), equivalent to 5.5% (SD 5.9%) of initial weight. Just under half of the overweight or obese men (47.6%) achieved > 5% weight loss. For women, average weight loss was less than for men [3.7 kg (SD 5.1 kg)], equivalent to 4.5% (SD 5.5%) of initial weight. A smaller percentage of overweight or obese women also achieved 5% weight loss (40.7%). Men remained registered for longer than women (187 vs. 170 days, reported $p < 0.05$) and made more frequent diary entries (56% vs. 52% of daily entries, reported $p < 0.05$). Women posted more messages on the online forum (35% vs. 19%, reported $p < 0.001$) although forum use was not a significant predictor of weight loss. It is unclear whether both the unisex and the Nutracheck Men forums were included in the analysis.

NHS referral to commercial weight-loss programmes

Four reports investigated NHS referral to commercial weight-loss programmes. Ahern and colleagues[37] conducted an independent analysis of referral to Weight Watchers and Dixon and colleagues[150] reported on referral to Weight Watchers, Slimming World or Rosemary Conley Diet and Fitness Clubs. Stubbs and colleagues[36,157] reported on referral to Slimming World, although the research team was not independent of the commercial provider. Participants in all studies were given vouchers for 12 free sessions with the commercial provider. Participants in the study by Dixon and colleagues[150] had a free choice of provider. Vouchers for Weight Watchers cost the NHS £45 per participant.[37] Vouchers for Slimming World were funded by the NHS and subsidised by the commercial company.[157]

In the study by Ahern and colleagues[37] some of the 12-week courses were repeat referrals for the same participant. For those completing a first referral course, median percentage weight change was greater in men than in women (difference between men and women –0.54%, 95% CI –0.81% to –0.27%, reported $p < 0.001$). For men and women completing their first referral course, median weight change was –5.4 kg [interquartile range (IQR) –7.8 to –3.1 kg)] representing 5.6% (IQR –8.1% to –3.2%) weight loss. Dixon

TABLE 35 Effect of the LighterLife very low-calorie diet on mean (SD) weight and waist circumference at 12 weeks in Asian and Caucasian men

Outcome	Asian men ($n = 36$)	Caucasian men ($n = 36$)	Asian women ($n = 166$)	Caucasian women ($n = 166$)
Weight loss (kg)	–21.4 (6.7)	–24.4 (8.2)	–14.5 (4.6)	–19.3 (4.2)
Weight loss (%)	18.1 (4.0)	18.6 (7.3)	15.9 (5.0)	28.1 (7.3)
Change in waist circumference (cm)	–20.6 (12.8)	–16.1 (6.7)	–15.9 (6.6)	18.9 (5.3)
Waist circumference change per kg of weight loss (cm)	–1.05 (0.7)	–0.71 (0.4)	–1.19 (0.74)	1.00 (0.3)

and colleagues[150] similarly reported that men were more likely to lose 5 kg than women (OR 0.66, 95% CI 0.46 to 0.96, reported $p = 0.03$). Fewer men in this report were referred by GPs to the scheme ($n = 265$, 18.5%). Men were also less likely to return their consent form and receive vouchers than women. There was no difference in attendance and completion rates between sexes.

Stubbs and colleagues[157] noted that men represented a greater proportion of their audit than the proportion in the standard commercial Slimming World population (11% ($n = 3651$) vs. 6%). The mean follow-up time was 9.2 weeks. Using the last observation carried forward, mean weight loss for men was 5.8 kg (SD 4.9 kg) or 4.9% (SD 4.0%) of initial weight, with a reduction in BMI of 1.8 kg/m^2 (SD 1.6 kg/m^2). Weight loss was less for women: 3.8 kg (SD 3.5 kg) or 3.9% (SD 3.5%) of initial weight, with a reduction in BMI of 1.4 kg/m^2 (SD 1.3 kg/m^2). Men did not attend a greater number of sessions but significantly more men than women were classed as completers (attended at least 10/12 sessions) (63.8% vs. 57.4%, reported $p < 0.001$). More men lost 5% (46.3%) and 10% (10.6%) of their initial weight than women (34.6% and 5.2% respectively) by the 12th session.

Some of the NHS trusts involved in the study by Stubbs and colleagues[36] offered a second referral, resulting in 4754 participants (575 men and 4179 women) having a 24-session referral period to Slimming World.[157] There was no significant difference between men and women in the percentage classed as completers (attended 20/24 sessions) (82.6% vs. 75.8% respectively). Men continued to lose significantly more weight than women (79.5% vs. 73.8% lost 5% of their weight at baseline and 44.3% vs. 36.4% lost 10% of their weight by the 24th session). In the regression model, male sex was the second greatest predictor of weight loss (reported $p = 0.013$) after percentage weight loss in the first week (reported $p < 0.001$). Men in both Slimming World studies were older (reported $p < 0.001$) and had a higher BMI ($p < 0.001$[36] and $p = 0.032$[157]) at baseline than women.

Weight maintenance

One study examined the promotion of dietary carbohydrate for weight maintenance following an initial energy reduction phase.[155] In total, 29 employees of Queen Margaret University College, Edinburgh, enrolled in the Kellogg's-funded study and, of these, six men and 16 women completed the full 6-week course. All were habitual breakfast eaters and four were regular smokers. For the first 2 weeks participants were asked to replace one main meal, lunch or dinner, with a 45-g serving of a Kellogg's breakfast cereal of the participant's choice with 125 ml semi-skimmed milk. Following the energy restriction phase, meal replacement ended but participants were encouraged to eat breakfast cereals as snacks if desired. Participants were also given individually tailored advice on increasing their carbohydrate intake and how to consume at least five portions of fruit and vegetables per day. A participation fee of £75 was paid to everyone completing the study. Of those completing the study, mean weight loss at 2 weeks was 1.6 kg for men and 2.1 kg for women. At 6 weeks, overall mean weight loss was 0.8 kg in men and 2.3 kg in women. It should be noted, however, that women had a slightly higher mean BMI than men at baseline and only six men completed the full regime. In total, 19 of the 22 completers responded to an acceptability feedback questionnaire administered at the end of the study, with 12 (63%) stating that they had found the 2-week meal replacement regime easy to follow and 16 (84%) stating that they would use this method for losing weight again. Only one woman who failed to maintain her initial weight loss gave a negative response.

Comparison between men-only and mixed-sex programmes

Few of the identified reports of men-only and mixed-sex weight management programmes included similar interventions or follow-up periods making comparisons between men-only and mixed-sex groups problematic. Interventions were comparable for two of the commercial providers, Slimming World and Weight Watchers, but differences in numbers of men recruited, follow-up and outcome reporting make comparisons difficult.

Discussion

We identified few studies for inclusion in the systematic review of studies of UK interventions with data for men or for men and women compared and found no eligible studies for inclusion in our review of interventions to promote male engagement with obesity services. The included studies were of moderate quality with limited follow-up and variable reporting of outcomes. Few studies identified were comparable in terms of interventions, timing of outcome assessment and participants recruited. Similarly, we were unable to make comparisons between the effectiveness of men-only and mixed-sex programmes from the available data. The results for this review should therefore be interpreted with caution because of the limited evidence base from which they are drawn.

Only seven reports[138,139,141,142,147–149] described tailoring intervention delivery to men. Strategies to promote engagement included using male-friendly language, male humour, men-only groups and venues that promoted camaraderie through shared sporting interests. These strategies were reported as being highly successful in attracting and engaging men with programmes, although it should be noted that very few men were recruited to these programmes and therefore robust conclusions cannot be drawn. Nevertheless, the men gave positive evaluations of these interventions, describing them as enjoyable and informative, and welcomed the opportunity to discuss sensitive issues in men-only groups. However, the men-only setting did not appear to be the most important reason for attracting men to join a weight-loss programme. Men particularly enjoyed interventions that were affiliated with their sports club, indicating that this is a potentially useful setting for attracting certain types of men. Indeed, enthusiasm for their chosen football or rugby team appeared to be the biggest driver for motivating men to join the weight-loss programme. These programmes included a structured exercise programme with healthy eating advice, which may suggest that men prefer to lose weight through exercise rather than through a programme requiring adherence to a strict dietary regime. Holding group sessions in the evening was also described as being useful for attendance.

Attrition rates for programmes designed for men tended to be low but programmes were short and numbers of men recruited were low, with the exception of the LighterLife study[148] (although the attrition rate for this study is unknown). All other studies were of standard unisex programmes delivered in either male-only groups[33,34,140,146] or mixed-sex groups.[31,36,37,150–157] As seen in our review of mixed-sex trials, fewer men joined these programmes than women but more men completed them and men tended to show a greater percentage weight loss than women. As some of the programmes required referral from health service staff, we do not know whether or not referral patterns differed for men and women.

It should be noted that studies did not often report adjusting energy allowances for men and women. However, Weight Watchers provide differing calorie allowances by sex[37,150] and Nutracheck[154] tailor daily calorie targets in accordance with individual participants' characteristics and chosen rate of weight loss.

Successful programmes generally included some element of individual tailoring, in the form of individualised dietary allowances,[33,37,140,154] exercise programmes[138,141] and/or personalised feedback on weight loss.[142,154] However, the only study in which an individualised energy-deficient diet and a general low-calorie diet were compared showed no difference in weight loss between the two types of dietary regime.[146] Weight loss for the general diet group was less than expected and the attrition rate was significantly higher in this group than in the individualised diet group, although there were no differences in reasons for withdrawal. This could indicate that men are more likely to adhere to a tailored diet even if it does not produce better weight-loss results. This study also found that diet plans high in red meat were no more beneficial than diets in which meat was excluded.

The LighterLife[148,156] very low-calorie formula food diet produced highly favourable results, especially in waist reduction for Asian men, although it should be noted that follow-up details for these participants were very limited. Longer-term results are required to understand whether or not weight loss achieved

through replacement food diets is sustainable following reintroduction of normal food during weight maintenance.

Programmes from commercial organisations[36,37,154,157] produced results that were as good as those from NHS programmes[31,151–153] when these were delivered in mixed-sex settings, whether this was for privately subscribing or NHS referral participants. When interventions were delivered in single-sex groups, however, commercial providers[33,34,148,150,156] outperformed NHS services, but data were very limited.[142,147] This is in keeping with the results of our reviews of RCTs, which highlighted the resource potential that commercial companies have, enabling them to offer flexible services to their participants compared with the NHS. In a single-sex setting, commercial companies have further opportunities to tailor services for men whilst offering them regular classes at times that can be compatible with work and family commitments. As previously shown, men are, however, less likely to choose a commercial provider than they are to choose a NHS programme. The NHS referral scheme may increase men's engagement with commercial providers.

Most of the interventions involved group meetings. We lack data within this review to be able to compare these interventions with interventions aimed at individuals but, in keeping with previous findings, it is suggested that men lose more weight in a group setting in which individual advice as well as support and motivation can be provided. As with our previous reviews, authors made little attempt to consult men in the design of the interventions and few were successful in recruiting substantial numbers of men. Men made up a very small proportion of participants recruited to mixed-sex studies, highlighting the problems of engaging men in weight-loss programmes compared with women. As seen in the results of our review of RCTs of men and women (*Chapter 3*), when men were recruited they were more likely than women to regularly attend and complete programmes. This highlights the importance of engaging men with weight-loss services. Future research should consult individual men or men's health representatives during intervention development with a view to improving male recruitment. Furthermore, outcome data should be collected at sufficient follow-up intervals to ensure that adequate information is obtained beyond the immediate weight-loss periods and through the difficult weight-maintenance phase. Study authors could also improve outcome reporting by adhering to the CONSORT[129] recommendations for scientific reporting and presenting baseline and outcome data consistently by sex and intervention group with clear reporting of numbers of participants enrolled, assigned, withdrawn (with reasons) and analysed. Weight-loss data should be provided for all participants enrolled, preferably using both baseline observation carried forward and last observation carried forward results for handling dropouts. Information concerning energy prescription by sex would also be useful, to allow a direct comparison of responses by sex.

Overall summary

We summarise below the main points that have arisen from the review in this chapter.

General issues relating to methodology

1. We found no studies specifically examining how to improve men's take-up of obesity services.
2. We identified very few randomised trials examining weight loss in men-only groups or weight loss by sex in the UK. Mixed-sex studies had much lower proportions of men than women, especially in commercial weight-loss programmes. Men were rarely consulted beforehand about the design of studies or asked their views on the programmes that they undertook.
3. Male study participants tended to be middle-aged, white and not morbidly obese. Relatively few interventions involved men who were obese and who were selected as a result of an existing health problem such as type 2 diabetes, cardiovascular disease or osteoarthritis. Very few studies presented data on changes in cardiovascular risk factors, clinical outcomes, quality of life or economic outcomes.
4. Most of the interventions were not described in sufficient detail such that they could be replicated. Few studies reported conducting fidelity checks for intervention delivery.

5. The sex of providers was not reported. It is unclear from the included studies whether or not the sex of the person providing a weight-loss intervention to men is an important factor in the effectiveness of that intervention.
6. Many studies were of short duration. Few authors presented data for the entire cohort (e.g. baseline observation carried forward, last entry carried forward), choosing instead to present data for completers only both at baseline and for final outcome measurement. It is therefore difficult to judge the level of attrition bias in these studies. Similarly, few studies reported details concerning the equity or sustainability of the considered interventions.

Pointers for effective interventions

Although few studies were available, there are some pointers for factors that may contribute to effective programmes for men:

1. Effective interventions in workplaces and with sports fans in sporting venues were able to recruit men, although the scale of these interventions was limited. Although a suitable place and time may aid recruitment, it may also exclude those for whom these are not relevant. Interventions with football fans have had low dropout rates and shown very positive responses from participants, with significant improvements in self-esteem and quality of life. The opportunity to improve physical fitness and discuss issues in a male-only environment was valued.
2. The type of reducing diet followed has not been shown so far to affect weight loss.[140,146]
3. Weight-loss programmes specifically for men delivered through the NHS[142,147] have so far been small, with limited follow-up. Feedback was generally positive; however, not all participants felt that men-only programmes were needed.
4. Weight Watchers, Slimming World and LighterLife have provided men-only weight-loss groups. LighterLife tailored its programme for men but the extent to which tailoring was carried out by Weight Watchers and Slimming World was unclear. For the Weight Watchers programme, men lost more weight in the men-only groups than in the mixed-sex groups. Short-term data show that all of these programmes were effective in terms of weight loss, and they were probably more effective than the men-only NHS programmes; however, data are very limited.
5. Short-term data also show that men do well in the mixed-sex LighterLife and Nutracheck online commercial programmes.
6. Data show that weight-loss programmes delivered in NHS primary care are also effective (ProHealth*Clinical* and Counterweight) and show that more men join these programmes than commercial mixed-sex weight-loss programmes. The Counterweight study provides much longer follow-up data than the ProHealth*Clinical* studies.
7. NHS referrals have been investigated in the trial by Jolly and colleagues and also for Weight Watchers, Slimming World and Rosemary Conley. The proportions of men attending such programmes are higher than for non-referral schemes.
8. It appears that men may lose more weight than women with the ProHealth*Clinical*, LighterLife, Nutracheck, Weight Watchers and Slimming World programmes. However, not all providers prescribed a calorie deficit that took account of sex.

Chapter 5 Systematic review of economic evaluations

This chapter, evaluating the cost-effectiveness of interventions for obesity in men, consists of three main sections, namely (1) a brief outline and explanation of the principles and methods of the economic evaluation of health-care programmes; (2) the methods of the systematic review process; and (3) the results of the systematic review, including summary results and quality assessment of the included studies. The chapter concludes with a discussion of the results, leading to broad conclusions and recommendations for the conduct of future economic evaluations of obesity interventions in a male subpopulation.

Principles of economic evaluation

The need for economic evaluation of health-care programmes (drugs, interventions, medical devices, diagnostic tools, etc.) is driven by the fact that national health budgets are a scarce resource. Budget limits mean that trade-offs between health-care interventions need to be made. The allocation of resources to one intervention or clinical area means that we are forgoing an opportunity to spend these resources on an alternative health-care programme. This economic concept is commonly referred to as opportunity cost, that is, the highest-valued alternative forgone as a result of a spending allocation decision. Economic evaluation is essentially the comparative analysis of alternative courses of action in terms of both their costs (resource use) and their effectiveness (health effects). It is a method of providing decision-makers with the tools and information necessary to make the allocation decision in a way that maximises benefit and reduces opportunity costs.

There are four main methods of economic evaluation, each of which is summarised briefly in *Table 36*. The measurement of costs is similar across all economic evaluation frameworks. Good studies would be expected to consider the direct costs of an intervention together with the costs of downstream complications, such as cardiovascular events, stroke, diabetes and other health conditions related to the clinical area of interest (in the context of this review we are interested in obesity-related complications). Of the four economic evaluation frameworks outlined, the most simplistic is cost-minimisation analysis, which would essentially lead a decision-maker to adopt the least costly intervention. Cost–benefit analysis could be considered the broadest measure of evaluation, accounting for individual preferences and broad outcomes measures that go beyond health outcomes. The wider the measure of benefit used, the more likely the analysis framework is to consider the effects that are of greatest importance to individuals. Cost–utility analysis [cost per quality-adjusted life-year (QALY) gained] and cost-effectiveness analysis (usually cost per life-year gained) are the most commonly used frameworks of economic evaluation. Cost–utility analysis is the approach to decision-making recommended by NICE.[161] QALYs represent a combination of the quality and length of additional life-years attributable to an intervention in one measure. For example, a value of 6 QALYs could mean 6 years in full health or 12 years in half of full health [i.e. 12 life-years gained (LYG) but with a quality of life of 0.5 on a scale from 0 to 1].

For the purposes of this review, the two frameworks used in the included studies are cost-effectiveness analysis and cost–utility analysis.

The concept of economic evaluation and specifically the comparative analysis of the differences between costs and benefits (incremental costs and incremental benefits) across treatment groups can be summarised on the cost-effectiveness plane (*Figure 40*).

TABLE 36 Methods of economic evaluation

Economic evaluation method	Outcomes measured as:
Cost-minimisation analysis	Not applicable; outcomes are assumed equal for all options, hence decisions are made based on the least costly intervention
Cost-effectiveness analysis	Outcomes are measured in their natural units (e.g. LYG or kg lost)
Cost–utility analysis	Outcomes are measured as QALYs
Cost–benefit analysis	Costs and outcomes are measured in monetary terms (benefit often measured as willingness to pay)

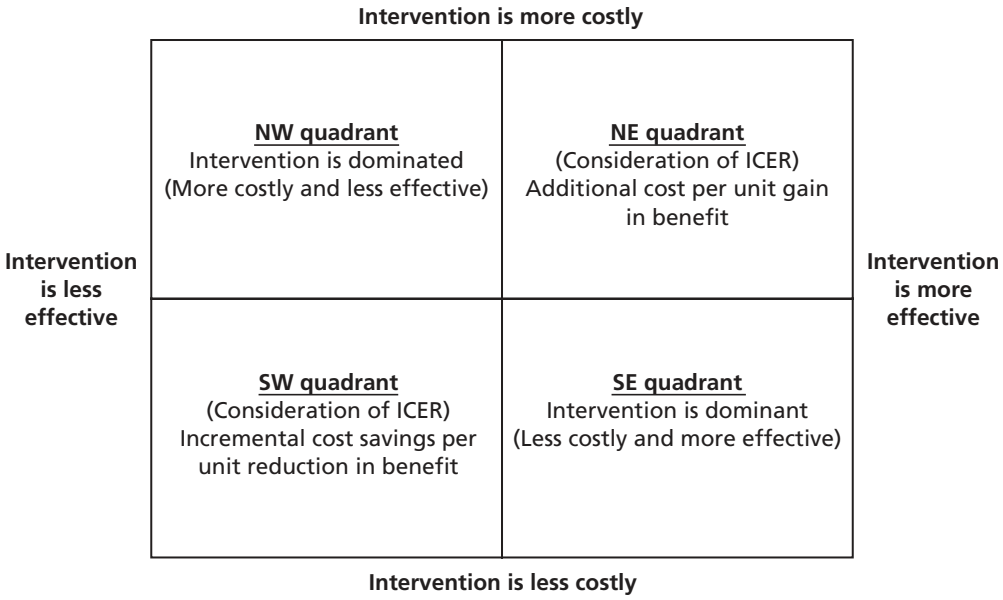

FIGURE 40 Cost-effectiveness plane of measures of economic costs and benefits. NE, north-east; NW, north-west; SE, south-east; SW, south-west.

The results of an analysis could be seen to fit onto one of four quadrants in the cost-effectiveness plane, namely:

1. North-west (NW) quadrant – the intervention under consideration is more costly and less effective than the comparator; therefore, the new intervention is dominated and should not be accepted.
2. South-east (SE) quadrant – the intervention under consideration is less costly and more effective than the comparator; therefore, the new intervention is dominant and should be accepted by a decision-maker.
3. South-west (SW) quadrant – the intervention is less costly but also less effective. In this case, a decision-maker would need to weigh up the potential cost savings against the loss in benefit, with a decision being required about the amount of savings that would be needed before a decision-maker could allow a unit loss of benefit to occur.
4. North-east (NE) quadrant – the intervention is more costly and more effective. A decision is required about how much we are willing to pay to achieve an additional single unit of benefit.

The decision rule for the NW and SE quadrants is clear because one treatment dominates (either the comparator or the experimental treatment is less costly and more effective). For the NE and SW quadrants a judgement is required whether the more effective treatment is worth the additional cost (or whether the cost savings are worth the potential loss in QALYs). To inform decision-making in these scenarios, information is provided in terms of the incremental cost-effectiveness ratio (ICER), which is essentially the

difference in costs between the two treatments under consideration divided by the difference in benefits. This allows us to calculate the cost per unit change in benefit. In the context of a cost–utility analysis, an intervention might typically be acceptable to a decision-maker if the additional cost of achieving an additional QALY is < £20,000–30,000 per QALY gained. Although NICE does not operate a threshold value of willingness to pay (WTP) for a QALY gain per se, it typically recommends interventions with a cost per QALY gained within this range. However, exceptions to this broad guideline exist. It is not clear what one might consider a typically acceptable value of WTP for a gain in life-years. However, generally speaking, the higher the ICER the greater the health-care expenditure required to achieve a unit gain in benefit and hence the less likely an intervention is to be considered cost-effective. Assuming that additional LYG are in full health, one could reasonably assume a similar decision rule to that mentioned for QALYs.

The results of the studies included in our systematic review will be described and discussed in the context of the cost-effectiveness plane and will include a discussion about which strategies for the management of obesity in men may be acceptable to health-care decision-makers. This process is, however, complicated by the heterogeneity of the included studies, the range of country settings and the uncertainty created through inflation and alternative values of currencies' purchasing power (purchasing power parity indices). The reader should therefore exercise caution in terms of any comparative conclusions across studies and should instead focus and assess each study on its own individual merits.

Systematic review of cost-effectiveness studies

Aims

To report the costs, outcomes and cost-effectiveness results of alternative strategies for the management of obesity in adult men.

Methods

Search strategy

Studies that reported both costs and outcomes of alternative strategies for weight loss, providing a distinct and interpretable focus on strategies for the management of male obesity, were identified. This included studies alongside RCTs as well as de novo decision-analytical models. An extensive electronic search was carried out to identify reports of relevant published and ongoing studies as well as grey literature. A highly sensitive search strategy using both appropriate subject headings and text word terms to identify reports on costs and weight-loss strategies for the management of male obesity was used (see *Appendix 1*).

The following databases were searched:

- MEDLINE (1946 to January 2012)
- MEDLINE-In-Process & Other Non-Indexed Citations (19 January 2012)
- EMBASE (1974 to January 2012)
- HMIC (1979 to January 2012)
- NHS EED
- CEA Registry
- RePEc.

No language restrictions were imposed on the search; however, the search was limited to studies published post 1990 in societies relevant to the UK setting.

Eligibility and inclusion criteria for studies

Studies that compared both costs and outcomes for interventions for the management of obesity in adult men were included. Studies were excluded if they did not attempt to relate cost to outcome data. Methodological papers, papers that review economic evaluations (although their reference lists were checked for additional papers to include), discursive analysis of costs/benefits, partial evaluation studies such as cost analysis, efficacy or effectiveness evaluations and cost of treatment/burden of illness papers were all excluded.

Studies included men with a mean or median age of ≥ 16 years, with no upper age limit. Studies particularly examining men with obesity related to psychotropic medication or a diagnosed eating disorder or with learning disabilities were excluded.

A range of interventions were deemed suitable for inclusion in our review, namely orlistat (but not sibutramine or rimonabant, which no longer have UK licences), diet, physical activity, behaviour change techniques or combinations of any of these. Complementary therapy (e.g. acupuncture), non-diet products promoted for weight loss available solely over the counter or bariatric surgery were not included for evaluation. Weight loss or weight gain prevention after weight loss needed to be explicitly stated as the main goal of the intervention undergoing economic evaluation. Studies examining a combination of interventions, for example smoking cessation and weight loss, at the same time were not included in the review.

Data extraction strategy

Data extraction was undertaken by the project health economist. Data extraction forms were checked by a second member of the review team for consistency and accuracy. The data extraction process focused on two key areas: (1) the results of the economic evaluations in terms of estimates of costs and effects and (2) the methods used to derive the results. Detailed data extraction forms for each study are reported in *Appendix 13*.

Data synthesis

Because of the heterogeneity of the studies retrieved, we did not attempt any quantitative synthesis of the included studies. Instead, summary data from the included studies and a narrative overview of each study are presented. When incremental costs, incremental effects or ICERs have not been reported, when possible we have undertaken these calculations, based on data included in the studies. The aim of the narrative is to identify common results across broad intervention groups. Common strengths and weaknesses across the studies are identified and used to develop recommendations for future economic evaluation studies of weight-loss interventions for men.

Results

Number of studies retrieved from the searches

Details of study identification are provided in *Figure 41*.

Using the search strategy outlined in *Appendix 1* a total of 1502 titles and abstracts were identified as being potentially relevant to our research question. These studies were screened by a project review team member to assess their relevance to the study question, focusing on economic evaluations of interventions for weight management in obese men. Of those initial 1502 screened titles and abstracts, a total of 79 were deemed potentially relevant and/or required further evaluation to assess their eligibility for inclusion and were read in full. On reading all full-text papers, a total of five studies[162–166] were deemed to fit with our inclusion criteria and were formally included in the review and quality assessment process. In addition, our searches retrieved one further methodological paper[167] reporting a value of information analysis alongside one of our included studies. We also retrieved one clinical guideline from NICE[53] that assessed the cost-effectiveness of orlistat for use in the UK. The guideline briefly discussed male-specific issues and conducted some brief modelling that showed potentially differential results for male and female subgroups. The additionally retrieved methodological study and clinical guideline have not been data

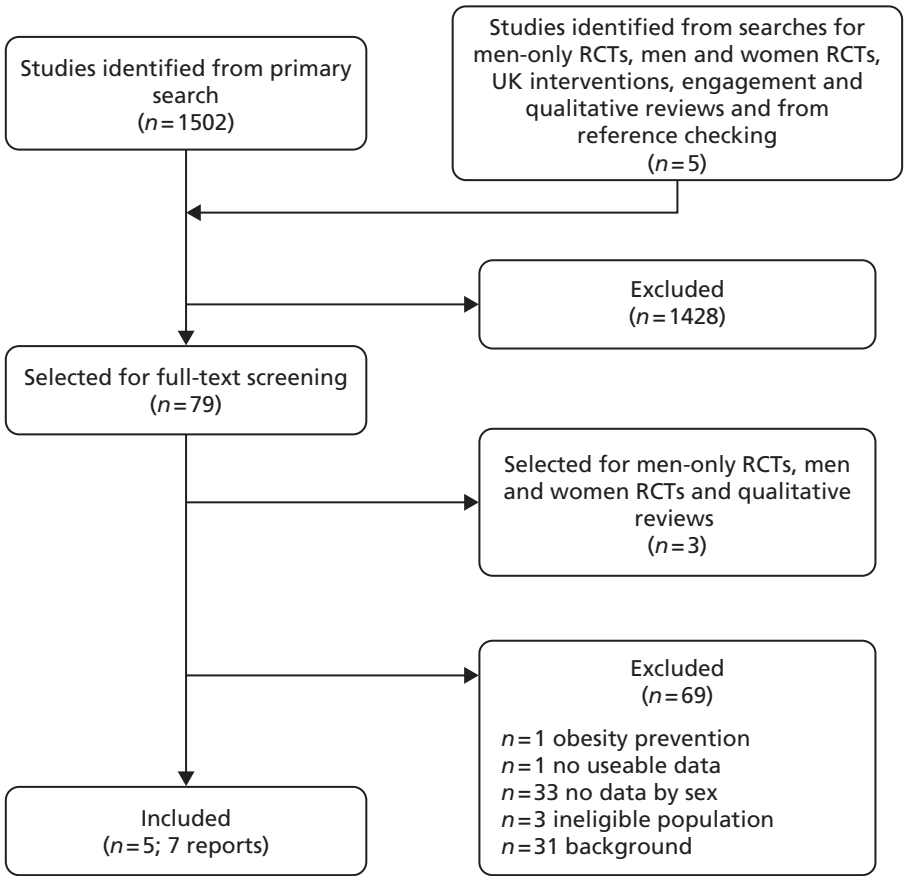

FIGURE 41 Flow chart for identification of studies.

extracted or formally quality assessed; however, they are discussed in the results section of this review as they address important policy and methodological questions, especially in relation to developing a future research agenda for obesity-related weight management.

Full and detailed data extraction forms for each included study as well as completed quality assessment checklists, based on Phillips and colleagues,[168] are presented in *Appendix 13*.

Description and characteristics of the included studies

Of the five studies that were deemed eligible for inclusion in the review, three[162,163,165] assessed lifestyle interventions including components of physical activity, dietary advice, professional counselling and group behavioural modifications. The remaining two studies[164,166] evaluated the cost-effectiveness of orlistat (a pharmaceutical agent to aid weight loss). The first evaluated orlistat in addition to standard diabetes management.[166] The second evaluated orlistat in addition to a lifestyle intervention.[164] The comparator group for both studies included a placebo drug, prescribed for the same frequency and duration as orlistat. All studies reported results for male subgroups; however, only one study[163] reported results for a wholly male group of participants. Another study[166] reported results for adults; however, because of the nature of the baseline data, it could be assumed that the results were most relevant to a very specific subgroup of the population (age 52 years, male).

Studies were conducted in a variety of countries, including Italy,[164] Switzerland,[162] Denmark,[165] Australia[163] and the USA.[166] None of the included studies was UK specific.

Description of the interventions included in the review

Lifestyle interventions

Of the five included studies, three[162,163,165] evaluated lifestyle interventions/behavioural modification interventions with the aim of reducing participant weight. Because of the heterogeneity of the interventions, it is not possible to make comparisons across the studies.

Segal and colleagues[163] evaluated a range of alternative programmes in different population groups in Australia for the prevention of type 2 diabetes. A total of six programmes were evaluated in different settings. For the purposes of this review, however, only one programme reported results for a male population. Programme IV consisted of a group behavioural modification for men based on an empowerment philosophy, involving five to six group sessions, with the aim of reducing waist size through dietary change and increased physical activity, with no further details reported. We were unable to retrieve additional information regarding the detailed methods and results for the male-specific programme IV. Alternative interventions evaluated ranged from diet and counselling to media campaigns to surgery. No results were presented for male-specific subgroups other than for programme IV detailed here.

Olsen and colleagues[165] assessed the role of alternative health-care professionals in the delivery of nutritional advice to obese patients, to stimulate weight loss and reduce the risks of ischaemic heart disease and death. The study compared two health professionals providing advice (GP or dietitian) with no active intervention. Although both interventions delivered dietary advice, there were important differences in the content of the interventions. GP counselling delivered over 12 months (one consultation for 30 minutes and a further five consultations of 12 minutes each) included the provision of general lifestyle advice, commercially available written information and leaflets on healthy diet. The dietitian-provided advice focused on the principles of good nutrition, including restricting total dietary energy, reducing fat intake and advice on a cholesterol-lowering diet. Six consultations were delivered over 12 months (one 60-minute consultation and five 30-minute consultations). Results were presented for male specific subgroups of the population.

Galani and colleagues[162] estimated the long-term health and economic consequences of preventing and treating obesity with lifestyle interventions in an overweight and obese population subgroup. The lifestyle intervention was the same for both overweight and obese subgroups and was compared against a standard of care deemed to be appropriate and reflective of participants' BMI. The intervention consisted of regular physical activity advice (to undertake at least 30 minutes of moderate physical activity daily) and detailed dietary recommendations (adapted from the FDPS).[132] Recommendations were to limit intake of fat to < 30% of energy consumed and of saturated fat to < 10% and to increase fibre to at least 15 g per 1000 kcal. Participants attended regular supervised exercise sessions and dietitian consultations over 3 years of follow-up. The intervention was compared with different standards of care for overweight and obese population groups. Overweight participants received no active intervention. Obese patients received basic dietary counselling and physical exercise sessions over the 3-year follow-up period. The study also evaluated cost-effectiveness for a borderline obese group to assess any important transitions to obesity and how these might impact on the cost-effectiveness outcomes.

Orlistat

A further two studies included in our review evaluated the use of orlistat in combination with lifestyle interventions for the prevention of type 2 diabetes.

Maetzel and colleagues[166] evaluated the cost-effectiveness of 120 mg of orlistat taken three times daily for 1 year in addition to standard treatment for type 2 diabetes, including pharmacotherapy (e.g. metformin) and weight management in the form of dietary and physical activity advice. This was compared over an 11-year time horizon with adherence to standard treatment guidelines alone. The evaluation thus compared an intervention group who received orlistat and adhered to treatment guidelines in year 1 followed by 10 years of adherence to guidelines with a comparator group who received 11 years of

adherence to treatment guidelines alone. The intervention was delivered in a US health-care setting. Detailed information on the components of standard treatment guidelines were not available by treatment group; however, it can be assumed that there are no incremental differences attributable to this.

The second orlistat study[164] involved a cost–utility analysis over a 10-year time horizon, which evaluated the longer-term economic impact of the use of orlistat plus a lifestyle intervention compared with a lifestyle intervention alone in Italian obese patients through the long-term projection of XENical in the Prevention of Diabetes in Obese Subjects (XENDOS) study results.[169] The intervention consisted of 120 mg of orlistat three times a day over 4 years in addition to the lifestyle intervention compared with the lifestyle intervention plus a similarly delivered placebo drug. The lifestyle intervention, common to both arms of the study, involved patients being prescribed a low-fat reducing diet and physical activity advice.

Both studies were quite similar in terms of the research question addressed (i.e. both evaluated the cost-effectiveness of orlistat over a similar time period); however, the baseline data sources were different. Maetzel and colleagues[166] relied on the UK Prospective Diabetes Study (UKPDS)[170] for input data and Iannazzo and colleagues[164] relied on the XENDOS RCT.[169] Both studies reported results for a male subgroup of the modelled population. However, in the study by Maetzel and colleagues[166] it was indirectly assumed that the results were most relevant to men because cardiovascular risk factors were calculated based on UKPDS data,[170] which references a 52-year-old man. The data from Iannazzo and colleagues,[164] on the other hand, are directly linked to the XENDOS trial data,[169] with extrapolations based on sex-specific data from the trial. There were key differences in the assumptions regarding maintenance of treatment effect and weight loss. Maetzel and colleagues[166] focused on HbA_{1c} levels, and tested two scenarios, one in which the treatment effect was maintained for only 1 year and the other in which the treatment effect persisted for 3 years. Iannazzo and colleagues[164] assumed, based on data from the XENDOS study,[169] that weight returned to baseline levels after 4 years of treatment. NICE has also issued guidance for the use of orlistat in the management of obesity.[53] The guidance issued by NICE is summarised in the following section.

Table 37 presents summary information with regard to the intervention type, reference population modelled and characteristics for all five of the included studies.

National Institute for Health and Care Excellence guidance

The National Institute for Health and Care Excellence in the UK has issued clinical guideline no. 43 (CG43) on obesity.[53] CG43 replaced previous NICE guidelines for individual therapies for the management of obesity, namely orlistat (technology appraisal no. 22, TA22),[172] sibutramine (TA31)[173] and surgery for morbid obesity (TA46).[174] The last TA is outwith the scope of our review and is not discussed further. In addition, following the suspension of the marketing authorisation for sibutramine (Reductil, Abbott Laboratories) by the Medicines and Healthcare products Regulatory Agency (MHRA) in January 2010,[170,175] NICE recommendations were updated to refer health-care professionals to the MHRA advice and its previous recommendation for the use of sibutramine was withdrawn.

The discussion in this section therefore focuses on NICE guidance for orlistat. The original guidance was developed in 2000 as part of TA22,[172] informed by an independent review group report.[176] However, this report did not present sex-specific results and so was not included in our review. Guidance was subsequently developed in 2006 (CG43), with the development of a comprehensive guideline document for the management of obesity.[53] The review was subsequently updated in December 2011.[177] In terms of the health economic content and cost-effectiveness case in the review, the guideline development team conducted a large systematic review of options for the treatment of obesity, which included orlistat and lifestyle interventions. However, few studies were found and none was reported to refer to a male subgroup of the population. Therefore, no sex-specific cost-effectiveness analyses were reported for orlistat or for lifestyle interventions for the management of male obesity.

TABLE 37 Summary of interventions evaluated in the economics studies included in the review

Study ID	Country	Population group evaluated	Male/female breakdown	Study setting	Description of intervention	Description of control/comparison
Galani 2007[162]	Switzerland	Overweight or obese adults (by Swiss standards), aged > 25 with a baseline BMI score of ≥ 27 kg/m^2 (overweight) or ≥ 33 kg/m^2 (obese)	Results reported for men and women together and for male and female subgroups separately	Primary care	Lifestyle intervention consisting of (1) regular physical activity, at least 30 minutes per day, plus detailed dietary advice on a low-fat, high-fibre reducing diet (based on FDPS[171]); (2) regular dietitian consultations and supervised exercise sessions over 3 years, frequency of classes unclear	Overweight: No active intervention Obese: Basic dietary counselling and physical exercise sessions delivered regularly over 3 years
Iannazzo 2008[164]	Italy	The population was based on the XENDOS study data[169] and the Italian obese population, with a BMI ≥ 30 kg/m^2. The model was analysed for the Italian obese population, age 30–60 years, base-case model age 35 years	47.7% male; 52.3% female Model inputs were sex specific	Not reported but assumed to be primary care	4 years of treatment with 120 mg of orlistat three times per day in combination with a low-fat reducing diet and physical activity advice	4 years of treatment with a placebo drug three times per day in combination with the same low-fat reducing diet and physical activity advice
Maetzel 2003[166]	USA	Overweight and obese adults with type 2 diabetes	Not reported; however, risk factors used for the model refer to a 52-year-old man, with data sourced from the UKPDS[170]	US health-care setting, assumed secondary care	Treatment over an 11-year time horizon: Year 1: orlistat + adherence to guideline therapy;[a] years 2–11: adherence to guideline therapy[a] only	Treatment over an 11-year time horizon with adherence to guidelines[a] only

Study ID	Country	Population group evaluated	Male/female breakdown	Study setting	Description of intervention	Description of control/comparison
Olsen 2005[165]	Denmark	Obese patients with at least one of the following: BMI $\geq 30 kg/m^2$, waist circumference > 102 cm (men) and > 88 cm (women), dyslipidaemia and type 2 diabetes	Not reported but results were presented based on sex-specific cardiovascular risk parameters, generated from weight loss in the study	Primary care (GP/ dietitian clinics)	GP nutritional counselling: General lifestyle and healthy diet advice, six counselling sessions over 12 months (one of 30 minutes and five of 12 minutes) Dietitian nutritional counselling: Detailed advice on principles of good nutrition (restricted total dietary energy, reduced-fat and cholesterol-lowering diet). Six consultations over 12 months (one of 60 minutes and five of 30 minutes)	Standard care – no active intervention
Segal 1998[163]	Australia	People with impaired glucose tolerance, overweight/obese men, seriously obese people, women with previous gestational diabetes and the general Australian population	Programme IV – men only[b]	Programme IV – primary care	Programme IV: Group behavioural modification for men based on empowerment philosophy (five to six group sessions). The aim was to reduce waist size through diet change and increased activity	Standard care – no active intervention

a Standard pharmacotherapy for type 2 diabetes (e.g. metformin) and weight management (diet and physical activity).
b A total of five alternative programmes were evaluated in the study; however, as only programme IV presented male-specific results, the others have not been included. Further information is available in the data extraction forms in *Appendix 13*.

Additional modelling work was therefore undertaken to estimate sex-specific quality-of-life weights to inform QALY calculations and for use in subsequent economic modelling exercises. Data from Macran[178] were used to estimate quality-of-life weights for five BMI ranges. Data from Ara and Brennan's submission to NICE,[179] quoted in CG43,[53] were used to estimate weight based on BMI for male and female subgroups, given the average height of a typical man and typical woman. Weight-loss figures were ascribed to central values of each range and a linear trend between midpoints was assumed. Taking this midpoint of each BMI range, weight loss and utility gain[178] were synthesised into utility gained per kg lost for men and women. Expected quality of life values were estimated for each 0.1 increment of BMI. A diabetes disutility value of 0.8661 was identified from the literature and assumed.[3] Sex-specific QALY and cost per QALY sensitivity analyses were presented based on available effectiveness (weight loss) and cost data for orlistat. Detailed costings were not presented within the analysis. The modelled sensitivity analysis presented indicates little or no sex-specific difference in cost-effectiveness of 12 months' treatment with orlistat, with ICERs for both male and female subgroups well below a commonly acceptable WTP of £20,000 per QALY gained.

Differences between male and female subgroups appear to be more pronounced when comparing longer-term treatment (48 months) with current practice of 12 months' treatment. The base-case analysis reports a higher cost per QALY for men (£29,089) than women (£26,917). Within this analysis, in a male subgroup, the data suggest that the greater the initial BMI, the more cost-effective orlistat is, with an ICER of £29,920 when BMI is 38 kg/m^2, increasing to £33,134 when initial BMI is 30 kg/m^2. The converse appears to be true for women, with an ICER of £30,155 for an initial BMI of 38 kg/m^2 and an ICER of £23,982 for an initial BMI of 30 kg/m^2. The results show that for the comparison between 48 months of treatment and 12 months of treatment, cost-effectiveness of orlistat is dependent on a number of factors, including sex, baseline BMI, weight trend without orlistat and weight regain after treatment discontinuation. The conclusion of the evaluation was that NICE could not recommend 48 months of treatment with orlistat, given the uncertainty in the ICER presented.

Work by Foxcroft[180] and referenced by NICE[53] evaluates both the European Medicines Agency (EMA)[181,182] and NICE guidelines[172] for the use of orlistat. These guidelines recommend different continuation rules for treatment with orlistat. The original NICE guidelines[172] (TA22, updated as part of CG43[53]) recommend continuation only if patients achieve 5% weight loss at 3 months and 10% weight loss at 6 months. The EMA criterion[181,182] is slightly more relaxed than that used by NICE, requiring only a minimum of 5% weight loss at 3 months to justify continuation of treatment. Results from the Foxcroft study[180] were not reported separately for male and female subgroups. However, for all adults, the results suggest that adoption of the EMA criterion for the continuation of orlistat would result in a lower ICER than that obtained using the NICE guideline criterion. The cost per QALY was £24,400 (range £10,900–77,200) and £19,000 (range £8800–57,800) for the NICE and EMA criteria respectively. The study recommended that future economic evaluations of the cost-effectiveness of orlistat should consider the use of the EMA criterion. The most recent review of the NICE guidelines[177] considered the Foxcroft analysis and the less restrictive EMA criterion. The NICE update to the guidance found that, although there was some evidence to support removal of the requirement that at least 10% of body weight is lost by 6 months for continuation of treatment, there are equally reasons for the criterion to remain unchanged. Methodological uncertainty in the estimation approach to QALY gains led NICE to conclude that adoption of wider EMA-based criterion was not recommended at this time.

Quality of the included studies

Model structure

All studies included in the review were based on models with a common goal of extrapolating short-term outcomes, such as weight loss, to longer-term health benefits, either in terms of survival (LYG) or a combination of survival and quality of life (QALYs). All studies reported incremental costs and incremental benefits, for which formal cost-effectiveness analyses were undertaken. For the purposes of assessing the quality of the modelling studies in this review, particular attention was given to model parameter

estimation and the methods by which short-term outcomes were extrapolated over a longer-term horizon, accounting for downstream health-care costs and patient health outcomes. Included studies were quality assessed using the criteria of Phillips and colleagues.[168] These criteria provide a platform to quality assess studies based on best practice methods for the conduct of decision modelling studies for use in health-care decision-making. Detailed quality assessment checklists for each of the included studies are presented in *Appendix 13* for information.

All included studies used modelling techniques of varying degrees of complexity and sophistication to synthesise cost and effectiveness outcomes. All studies measured cost-effectiveness using some form of extrapolation of lifetime mortality and disease risk. Four out of the five included studies estimated their results using Markov models to extrapolate weight loss and disease risk to longer-term outcomes.[162–164,166] Two out of the four Markov models measured outcomes in terms of incremental cost per QALY gained, combining measures of additional life-years with quality-of-life weights applied to disease states in the model.[162,164] The remaining two Markov models[163,166] did not report any utility values and hence outcomes were based on survival estimates alone, with the economic evaluation presented as cost per life-year gained[163] and cost per event-free/diabetes-free life-year gained.[166] The remaining study[165] was based on a Cox regression model using time to event modelling, adjusted for baseline risk factors, to estimate survival associated with treatment. The model predicted life-years and LYG without ischaemic heart disease. Given that the obesity-related health complications are likely to occur into the future, it is important that the dynamic nature of progression between disease states is adequately modelled. For this reason it could be argued that Markov modelling was the most appropriate method to synthesise the dynamic cost and effect relationships for obesity-related disease pathways. Further, Markov models, because of their design, are more appropriate to estimate the impact of more dynamic state transitions associated with alternative courses of disease progression. The models are, however, only as good as the data used to generate the state transitions and there is a trade-off between the level of sophistication of the models and the data available to populate them.

Selection of interventions considered

Only one of the included studies explicitly discussed or justified the intervention strategies compared.[163] However, given the wide variation in possible interventions (both pharmaceutical and lifestyle related), the interventions compared in each study appear to be appropriate, given the decision problem and stated objective of the respective analyses. Segal and colleagues[163] conducted a systematic review to determine the most appropriate programmes to compare in a cost-effectiveness framework. Although the review was systematic and six programmes were ultimately evaluated, it was difficult to draw comparisons across programmes given the heterogeneity of the populations and programmes evaluated. For the purposes of this review, our discussion pertaining to this study relates only to the male-specific group behavioural intervention (programme IV).[163]

Incorporation of data into economic models

All studies clearly described the methods used to incorporate data into their models and sources were mainly derived from the literature. Although a broad spectrum of literature appears to have been considered for the majority of included studies, literature searches were none the less ad hoc and there was no evidence of systematic literature searching to identify key model parameters. Justification for the use of data is generally poor with little discussion of choices between key data sources. When meta-analyses of treatment effects were carried out there was little information provided on the data synthesis methods used and so quality assessment was not possible. Only one study briefly described the model used to synthesise data as a random-effects meta-analysis.[162] Nevertheless, the data included in the studies were well referenced and data sources were clear for the most part.

Cost data in the models

Four[162–164,166] of the five studies considered costs over an extended time horizon. The remaining study[165] did not extrapolate costs beyond the cost of the intervention and so failed to account for any downstream costs associated with obesity-related complications. This is an important part of the disease process and limits the value of the study results. The costing perspective was described in all studies. Two studies stated that a societal perspective was used;[162,164] however, explicit data relating to a societal perspective, beyond health service resource use, were not detailed in the studies. It appears that, given the data included, these studies would more accurately be described as using a health services or health services and personal perspective. One explanation for this could be a lack of consistency in the definition of perspectives across countries. Some countries might consider publicly provided health care to be provided from a societal perspective. It is important that perspective is clearly defined for all studies. Intervention costs were included for all studies; however, detailed calculations were not presented in all studies, rendering it difficult to quality assess the costing methods in general. Costs were incorporated for downstream health events in all but one study;[165] however, again this information was reported with varying degrees of completeness and detail. It is imperative that economic evaluation studies include detailed unit costs of interventions, follow-up costs of obesity-related complications and a synthesis of these two cost aspects to generate total cost estimates. It should in theory be possible to reproduce results given the data provided in a study; however, this was not the case in the studies retrieved for this review.

The costing year was explicitly reported in four studies;[162,163,165,166] however, it was also possible to source the costing year indirectly for the fifth study through the appropriate references.[164] A range of currency data was reported, with only one study[163] converting currency to international dollars. Galani and colleagues[162] also converted data to study year euros. Many different currencies and costing years meant that a comparison of the results is subject to considerable uncertainty because of the wide variations in exchange and inflation rates over time. Discount rates applied to costs were clearly detailed for all studies that measured longer-term horizon costs (four[162–164,166] out of five included studies). The fifth study[165] considered costs over a 1-year time horizon only and thus discounting of costs was not necessary. The impact of uncertainty surrounding discount rates was tested in sensitivity analyses, with two[162,166] of the five studies reporting cost-effectiveness results associated with varying discount rates. Iannazzo and colleagues[164] reported discount rates but did not test assumptions regarding their impact in sensitivity analysis. As Olsen did not consider long-term costs, discounting was considered only for outcome data.[165] The final study did not report any sensitivity analyses for the male-specific programme within the study.[163]

Effectiveness, treatment outcomes and linking of evidence

Effectiveness data used for the studies relate to a linked evidence approach. For the majority of studies, the goal was weight loss. For the most part, however, model inputs were predicted based on clinical outcomes such as lipid levels, systolic blood pressure and HbA_{1c} levels and taken from published sources, with the link between weight loss and these outcomes less clear. One study[164] used Framingham risk equations[183] to determine relative risks of cardiovascular events. These were then linked, using a combination of the literature and modelling exercises, to final health outcomes and complications (e.g. diabetes, stroke, myocardial infarction). This has been completed to varying degrees of complexity and it is not always clear whether male-specific data are used for the model inputs. In terms of the effectiveness of the interventions for weight loss, only one[162] of the five studies explicitly reported weight-loss data, despite this being an outcome of importance to the study questions. Instead, studies relied on cardiovascular risk data at a population level, based on weight-loss data from randomised trials, as model inputs.

Galani and colleagues[162] estimated weight loss on the basis of a meta-analysis of randomised trials and used Framingham risk equations together with national Swiss data to estimate cardiovascular risk factors and mortality. Methods for the meta-analysis were not clearly reported and it was not possible to quality assess this aspect. Assumptions regarding weight loss were clearly documented and weight loss was maintained over 6 years, with linear regain over 4 years. Therefore, after 10 years it was assumed that weight had returned to baseline levels. This assumption was validated against the FDPS;[132] however,

alternative assumptions were not explored in sensitivity analysis. Although mortality and cardiovascular risk factors are based on sex-specific data and these are extrapolated to final outcomes, it is not clear whether these were applied to sex-specific weight-loss data or not.

The remaining studies did not report weight loss per se, despite this being an implied goal of the studies in all but one case.[165] Olsen and colleagues[165] used a combination of clinical data, including risk factors of age, sex and BMI score, to establish the lifetime mortality risk. It was assumed that the effects of the intervention would be continued over the lifetime of follow-up, an assumption that the authors acknowledge as a key limitation of the study. Despite this, no alternative sensitivity analyses were presented to test the impact of this assumption on cost-effectiveness outcomes.

The model developed by Iannazzo and colleagues[164] was based on the extrapolation of results from the XENDOS RCT.[169] Data from the trial were used to predict diabetes incidence and forecast blood pressure and cholesterol variation. The impact on cardiovascular disease was described using Framingham risk equations. Although no other studies were considered, and no data synthesis was undertaken, the randomised and blinded nature of the XENDOS data is likely to ensure that rigorous estimates were used in the model. Methods of data extrapolation were clearly described and were sex specific; however, the use of Framingham equations, which do not explicitly include BMI as a risk parameter, mean that the model was not sufficiently sensitive to changes in weight and BMI. However, data from the original XENDOS trial,[169] which did measure weight gain and maintenance, showed that weight returned to almost baseline levels at 4 years' follow-up.

Maetzel and colleagues[166] also did not directly report weight loss in their study. However, weight loss was an important goal of the study. Instead, weight loss impacted on HbA_{1c} scores, which were reported and linked to relative cardiovascular risk reductions. Data from four placebo-controlled trials were used to conduct meta-analyses to synthesise outcomes in terms of HbA_{1c} levels. However, details of the data synthesis methods used were not provided and the quality of the analysis methods was not critiqued within the study. Methods of extrapolation of treatment effects over an extended time horizon were clearly described and it was assumed that patients receiving orlistat would experience weight loss over 1 year of therapy, after which weight regain would be linear over 3 years and weight would then match that of the placebo group. This assumption was tested in sensitivity analysis and was found to have an impact on cost-effectiveness results.

In general, data syntheses for treatment effects were documented but methods were poorly reported. It was not clear whether or not separate weight-loss parameters were included for men and women; however, cardiovascular risk inputs to the model were sex specific. The link between weight loss and cardiovascular outcomes was poorly addressed and this adds uncertainty to the cost-effectiveness results. Although results were often clearly reported separately for male and female subgroups, it would also be useful to see input parameters (including weight-loss data, cardiovascular risks and health state utilities) reported by sex subgroup. This would give a clear picture of how sex-specific inputs were used in the model and would facilitate the hypothetical/theoretical reproduction of the results by sex subgroup. Assumptions regarding maintenance of weight loss were well described in the orlistat studies.[162,166] However, one of the lifestyle intervention studies[165] does not deal explicitly with this issue and appears to assume that the treatment effect is continuous based on initial or transient improvement in cardiovascular health parameters. This is a strong assumption and likely inappropriate in the context of the research question addressed. No sensitivity analyses were explored.

Utilities and quality-adjusted life-years

Only two studies reported results in terms of QALYs.[162,164] Although details of mortality risk and hence life-years were clearly described across the studies, methods of utility estimation were not. Utility estimates were taken from the literature, were sourced adequately and were clearly referenced. However, the methods used to derive those utilities were not clearly described (e.g. standard gamble, time trade-off, visual analogue scale or discrete choice experiments or other methods). The estimation method for utilities

is an important factor in determining their robustness and theoretical validity, and hence in the quality assessment of this part of the studies. However, neither of the two studies that estimated QALYs provided in-depth descriptions of the utility estimation methods. There was no discussion of different options for utility estimation or of any impact that these would have had on the overall results. This is a key methodological limitation of these otherwise well-conducted and methodologically appropriate studies.

Sensitivity analyses

All studies attempted some form of sensitivity analysis, mainly focusing on issues of parameter uncertainty. However, none addressed all four types of uncertainty (structural uncertainty, methodological uncertainty, heterogeneity and parameter uncertainty).

Two of the included studies addressed structural uncertainty. Segal and colleagues[163] calculated both gross costs (intervention programme delivery costs only) and net costs (programme delivery costs less any downstream future costs to health services) in their analysis. Maetzel and colleagues[166] explored the impact of alternative assumptions regarding weight regain and duration of treatment effect. This was the only study to consider this important issue and, as expected, the results were found to be sensitive to this assumption.

Methodological uncertainty was generally well addressed. However differences in results, arising from varying discount rates were explicitly presented in only two[162,166] of the five studies. Although Segal and colleagues[163] reported sensitivity analysis of discount rates for one individual programme, this was not differences in results for the male-specific programme, and so the impact of alternative discount rates on this programme was not clear. Iannazzo and colleagues[164] recalculated the cost-estimates assuming that the Italian NHS and not the patient paid for orlistat. Olsen and colleagues [165] addressed methodological uncertainty in terms of alternative costing assumptions and by inclusion of people's own use of time in sensitivity analysis.

Heterogeneity in the study results was well accounted for across studies, with four out of five studies reporting results for key subgroups (e.g. impaired glucose tolerance, age, sex). All studies apart from that by Maetzel and colleagues[166] reported male and female subgroup results separately; in the study by Maetzel and colleagues[166] the base-case model results were specific to a male subgroup. Subgroup analyses conducted were appropriate to the study question and were generally clearly reported and interpreted. When multivariable sensitivity analyses were conducted, the results were not always reported separately for male and female subgroups. Sensitivity analyses tended to focus on base-case results for all patients and not individual subgroups. This renders it difficult to interpret any impact that sensitivity analyses may have had on sex-specific cost-effectiveness estimates.

Parameter uncertainty was explored in four out of five studies, the exception being the study by Olsen and colleagues.[165] Most sensitivity analyses were conducted as simplistic one-way analyses (changing one parameter at a time); however, this does not account for the joint dependence of one parameter on another or, indeed, the dependence of one parameter on sex-specific subgroups. However, some two-way deterministic analyses (varying the values of two parameters at the same time) were conducted by Maetzel and colleagues[166] and Galani and colleagues.[162] Sensitivity analyses undertaken were clearly described and justified across the studies. Results were presented in a fair and balanced way and the impact of the sensitivity analyses was appropriately discussed. In one study,[163] comprehensive sensitivity analyses were presented for some programmes but not for the programme relevant to a male subgroup.

Three studies[162,164,166] conducted extensive probabilistic analysis. Results were presented in the form of cost-effectiveness acceptability curves (CEACs) and scatterplots to illustrate uncertainty. However, in only one of the studies were uncertainty illustrations presented separately for male and female subgroups.[162] Maetzel and colleagues[166] also conducted probabilistic sensitivity analysis with an extensive range of clinical outcome parameters. The inclusion of cost parameters was less clear. Results were again illustrated in the form of CEACs. Bootstrapping analyses were plotted on a comparative graph of costs and effects from the

Cox regression models used in the study by Olsen and colleagues[165] and these illustrated the uncertainty and wide variability in the ICERs presented.

Consistency and validation of the results

The mathematical logic behind the models was tested in only one study, that by Iannazzo and colleagues,[164] with the convergence and stability of the model being tested. Multiple chains were run and both visual and statistical tests were used to test the model's reliability. Counterintuitive results were found in one study,[162] with cost-effectiveness in a borderline obese group being greater than in an overweight group and poorer than in an obese group. These results were acknowledged and discussed, with justification provided in the article. Four[162,164–166] out of five studies discussed the results in the context of other literature in the field and comparisons were made with the results of similar studies when appropriate. No in-depth discussion of other studies was presented by Segal and colleagues.[163]

Summary

Studies were of variable methodological quality but many were appropriate to and compliant with best practice guidelines at the time of their publication. There are some common themes and issues that could be addressed to improve future economic evaluations of men's health interventions to induce weight loss:

1. Improving the reporting of sources used to inform utility weights and also the methods used within source studies to derive those weights (e.g. standard gamble, time trade-off, visual analogue scale or discrete choice experiments).
2. Reporting of costs (both intervention and subsequent costs of complications) in detail, with appropriate references, in a manner that would facilitate the theoretical reproduction of the study results.
3. Downstream costs to health services associated with the differential risk of significant health-care events should be incorporated in economic models as standard.
4. Assumptions should be clearly defined and highlighted in the published articles. It should be clear to the reader what assumptions have been used, especially regarding maintenance of weight loss and continuation of treatment effect. These should be comprehensively tested in structural sensitivity analyses.
5. Methods used to model the effect of weight loss on future obesity-related disease should be comprehensively explained. Where a number of potential data sources exists, choices regarding which source to use should be clearly outlined and any potential variation explored in deterministic or probabilistic sensitivity analysis.
6. Specifically for interventions relating to men, data inputs for the model should be clearly detailed on a sex-specific basis. When data for all sexes have been used and applied to male and female subgroups separately, this should be acknowledged and highlighted as a potential limitation.

By addressing these points it would be possible to greatly improve the quality of studies in the area of men's health in general and in the area of the treatment of male obesity in particular. These points are based on issues arising from the studies included in the review; however, it is acknowledged that the estimation of results separately for male and female subgroups was not the primary goal of the included studies and so sensitivity analyses were not all presented separately for sex-specific subgroups.

A summary of the quality assessment checklists is presented in *Table 38*. Detailed comments on individual studies are presented in the detailed quality assessment checklists in *Appendix 13*.

TABLE 38 Summary of the quality assessment of studies included in the review

Quality criterion	Dimension of quality	Question	Galani 2007[162]	Iannazzo 2008[164]	Maetzel 2003[166]	Olsen 2005[165]	Segal 1998[163]
Structure							
S1	Statement of decision problem/objective	Is there a clear statement of the decision problem?	Y	Y	Y	Y	Y
		Is the objective of the evaluation and model specified and consistent with the stated decision problem?	Y	Y	Y	Y	Y
		Is the primary decision-maker specified?	N	N	N	N	N
S2	Statement of scope/perspective	Is the perspective of the model clearly stated?	Y	Y	Y	?	Y
		Are the model inputs consistent with the stated perspective?	N	N	Y	N	Y
		Has the scope of the model been stated and justified?	Y	Y	N	N	Y
		Are the outcomes of the model consistent with the perspective, scope and overall objective of the model?	Y	Y	Y	?	?
S3	Rationale for structure	Is the structure of the model consistent with a coherent theory of the health condition under evaluation?	Y	Y	Y	N	Y
		Are the sources of data used to develop the structure of the model specified?	Y	Y	N	N	N
		Are the causal relationships described by the model structure justified appropriately?	Y	Y	Y	Y	N
S4	Structural assumptions	Are the structural assumptions transparent and justified?	Y	Y	Y	?	Y
		Are the structural assumptions reasonable given the overall objective, perspective and scope of the model?	Y	Y	Y	N	Y
S5	Strategies/comparators	Is there a clear definition of the options under evaluation?	Y	Y	Y	Y	?
		Have all feasible and practical options been evaluated?	Y	Y	Y	Y	Y
		Is there justification for the exclusion of feasible options?	NA	NA	NA	NA	Y
S6	Model type	Is the chosen model type appropriate given the decision problem and specified causal relationships within the model?	Y	Y	Y	N	Y

Quality criterion	Dimension of quality	Question	Galani 2007[162]	Iannazzo 2008[164]	Maetzel 2003[166]	Olsen 2005[165]	Segal 1998[163]
S7	Time horizon	Is the time horizon of the model sufficient to reflect all important differences between options?	Y	?	?	N	Y
		Are the time horizon of the model, the duration of treatment and the duration of treatment effect described and justified?	Y	Y	Y	Y/N	?
S8	Disease states/ pathways	Do the disease states (state transition model) or the pathways (decision tree model) reflect the underlying biological process of the disease in question and the impact of interventions?	Y	Y	Y	NA	Y
S9	Cycle length	Is the cycle length defined and justified in terms of the natural history of disease?	Y	Y	Y/N	NA	Y/N
Data							
D1	Data identification	Are the data identification methods transparent and appropriate given the objectives of the model?	Y/N	Y/N	Y	Y	?
		When choices have been made between data sources, are these justified appropriately?	N	?	N	?	?
		Has particular attention been paid to identifying data for the important parameters in the model?	Y	Y/N	Y	Y	Y
		Has the quality of the data been assessed appropriately?	Y	Y	?	N	N
		When expert opinion has been used, are the methods described and justified?	NA	NA	NA	NA	N
D2	Data modelling	Is the data modelling methodology based on justifiable statistical and epidemiological techniques?	Y	Y	Y	Y	Y
D2a	Baseline data	Is the choice of baseline data described and justified?	Y	Y	Y	Y	Y/N
		Are transition probabilities calculated appropriately?	?	Y	?	NA	?
		Has a half-cycle correction been applied to both costs and outcomes?	N/Y	N	N	NA	N
		If not, has this omission been justified?	NA	N	N	NA	N

continued

TABLE 38 Summary of the quality assessment of studies included in the review (*continued*)

Quality criterion	Dimension of quality	Question	Galani 2007[162]	Iannazzo 2008[164]	Maetzel 2003[166]	Olsen 2005[165]	Segal 1998[163]
D2b	Treatment effects	If relative treatment effects have been derived from the trial data, have they been synthesised using appropriate techniques?	Y	Y	?	?	?
		Have the methods and assumptions used to extrapolate short-term results to final outcomes been documented and justified?	Y	Y	Y	Y	Y
		Have alternative extrapolation assumptions been explored through sensitivity analysis?	N	N	Y	N	N
		Have assumptions regarding the continuing effect of treatment once treatment is complete been documented and justified?	Y	Y	Y	Y/N	Y
		Have alternative assumptions regarding the continuing effect of treatment been explored through sensitivity analysis?	N	N	Y	N	Y
D2c	Costs	Are the costs incorporated into the model justified?	Y	Y	Y	N	Y
		Have the sources for all costs been described?	Y	Y	Y	Y	Y
		Have discount rates been described and justified given the target decision-maker?	Y	Y	Y	Y	Y
D2d	Quality of life weights (utilities)	Are the utilities incorporated into the model appropriate?	?	Y	NA	NA	NA
		Is the source for the utility weights referenced?	Y	Y	NA	NA	NA
		Are the methods of derivation for the utility weights justified?	?	?	NA	NA	NA
D3	Data incorporation	Have all data incorporated into the model been described and referenced in sufficient detail?	Y	Y	Y	Y	Y/N
		Has the use of mutually inconsistent data been justified (i.e. are assumptions and choices appropriate)?	NA	NA	NA	NA	NA
		Is the process of data incorporation transparent?	Y	Y	Y	Y	N
		If data have been incorporated as distributions, has the choice of distribution for each parameter been described and justified?	Y	Y	NA	NA	NA
		If data have been incorporated as distributions, is it clear that second-order uncertainty is reflected?	Y	Y	Y	NA	NA

Quality criterion	Dimension of quality	Question	Galani 2007[162]	Iannazzo 2008[164]	Maetzel 2003[166]	Olsen 2005[165]	Segal 1998[163]
D4	Assessment of uncertainty	Have the four principal types of uncertainty been addressed?	N	N	N	N	N
		If not, has the omission of particular forms of uncertainty been justified?	N	N	Y	N	N
D4a	Methodological	Have methodological uncertainties been addressed by running alternative versions of the model with different methodological assumptions?	Y	Y	Y	Y	N
D4b	Structural	Is there evidence that structural uncertainties have been addressed through sensitivity analysis?	N	N	Y	N	Y
D4c	Heterogeneity	Has heterogeneity been dealt with by running the model separately for different subgroups?	Y	Y	N	Y	Y
D4d	Parameter	Are the methods of assessment of parameter uncertainty appropriate?	Y	Y	Y	Y	?
		If data are incorporated as point estimates, are the ranges used for sensitivity analysis stated clearly and justified?	N	Y	Y	NA	Y
Consistency							
C1	Internal consistency	Is there evidence that the mathematical logic of the model has been tested thoroughly before use?	N	Y	N	N	N
C2	External consistency	Are any counterintuitive results from the model explained and justified?	Y	NA	NA	NA	NA
		If the model has been calibrated against independent data, have any differences been explained and justified?	Y	Y	N	NA	N
		Have the results of the model been compared with those of previous models and any differences in results explained?	Y	Y	Y	Y	N

?, uncertain; N, criterion not met; NA, not applicable; N/Y, first part of criterion is not met but second is; Y, criterion met; Y/N, first part of criterion is met but second is not.
Based on the checklist of Phillips *et al.*[168]

Summary of the results of the included studies

As described in *Table 37*, three studies focused on lifestyle interventions and two on orlistat. The included studies were, in most cases, broadly similar in terms of patient populations; however, there was wide heterogeneity in terms of the concomitant lifestyle intervention and control group accompanying orlistat treatment. Data were not reported in sufficient detail across studies to assess common outcome measures and the study designs were not sufficiently homogeneous to draw any comparative conclusions across studies. When appropriate, incremental costs, incremental effects and ICERs have been calculated based on data provided within the studies. Because of the wide variation in reported currencies and costing years, we have inflated costs from the study publication dates to 2012 values using appropriate inflation indices for each individual country. Inflation rates were sourced from Eurostat[184] (EU and US data) and rate inflation sources[185] (Australian historical data). Costs were then converted to common 2012 UK pounds using purchasing power parity indices provided by the Organisation for Economic Co-operation and Development.[186] The purpose of this exercise is not to facilitate a direct comparison between studies but rather to assess them all in a common currency and year of valuation, to aide understanding of the results.

Despite the heterogeneity of the study results we can nonetheless comment on individual study results and interpret these in the context of the decision problem, the objective of the analysis, the structure of the model and the outcome measures reported. Summary cost-effectiveness results are presented in *Table 39*, with more detailed information on each study available from the data extraction forms included in *Appendix 13*. In this table the key base-case results are presented. In studies in which the base-case analysis was concluded using a cost–utility and cost-effectiveness analysis framework, the former is reported. Results refer to male-only subgroup analysis unless otherwise stated.

Lifestyle interventions

In relation to the lifestyle intervention studies, Segal and colleagues[163] found the group behavioural intervention for men to be cost-effective for both the mixed glucose tolerance subgroup (presumed to be a mix of normal glucose tolerance, impaired glucose tolerance and type 2 diabetes) and the impaired glucose tolerance subgroup. Although the intervention was found to be cost-effective for both groups, the estimates of ICER were slightly lower for the impaired glucose tolerance subgroup, indicating potentially greater value for money associated with intervening with those at greatest risk. The male-specific programme was on average less costly and more effective and was thus dominant over the comparator treatment of no routine intervention. The sensitivity analyses showed that the conclusions were robust to plausible variation in the treatment success rate. Despite a lack of detailed information available for the male-specific programme, the results indicated that a group behavioural modification intervention may be a cost-effective use of health-care resources. Preventative measures in type 2 diabetes thus showed the potential to be either cost saving or highly cost-effective. However, the authors flagged an urgent need for research in the area of diabetes prevention, especially in terms of quality-of-life outcomes. Despite this recommendation being made in 1998, there is still little robust evidence regarding the impact of weight loss on quality of life and cardiovascular risk events within an economic evaluation framework for overweight and obese men.

Olsen and colleagues[165] found that GP counselling was more cost-effective than dietitian counselling for encouraging weight loss. The authors concluded that GP counselling is cost-effective, but that the differences are probably the result of GPs offering extra advice beyond the dietary/nutritional counselling prescribed in the protocol. The authors concluded that, despite the lack of data from their study to support dietitian counselling, the role of the dietitian should not be discounted, especially given health-care provider constraints in practice.

Galani and colleagues[162] conducted a cost–utility analysis and found that a lifestyle intervention was highly cost-effective, with ICERs well below those typically considered good value for money for health gains. ICERs were dominant for a male subgroup including those who were borderline obese, with the intervention being less costly and more effective than the comparator. Results for other groups

TABLE 39 Detailed cost and outcome data from the studies

Study ID	Intervention	Comparator	Time horizon of model	Currency (year)	Base-case discount rates	Primary economic outcome measure	Incremental costs, study currency (2012 UK £)[a]	Incremental outcomes[a]	ICER, study currency (2012 UK £)[a]	ICER range from sensitivity analyses, study currency (2012 UK £)[a]	Results from probabilistic sensitivity analysis (if applicable)
Galani 2007[162]	Lifestyle intervention	OW group (standard care); OB group (lifestyle advice)	60 years or to max. age of 85 years	Swiss francs (2006)	Costs 3%; effects 3%	QALYs	OW: +405 (+196); BL: –6 (–3); OB: +127 (+61)	OW: +0.25; BL: +0.28; OB: +0.29	NR for all age groups; calculated as: OW: 1620 (784); BL: dominant; OB: 438 (212)[b]	Dominant to +2014 (974)	BL only presented[c] 57% (35-year-old man) to 72% (55-year-old man) probability of cost-effectiveness at a WTP of 0 CHF per QALY gained 92% (35-year-old man) to 98% (55-year-old man) probability of cost-effectiveness at a WTP of 1000 CHF per QALY gained
Iannazzo 2008[164]	Orlistat + lifestyle intervention	Placebo + lifestyle intervention	10 years	Euros (2007)[d]	Costs 3.5%; effects 3.5%	QALYs	+2931 (+2739)	+0.046	74,290 (69,427)	Men only: NR Men and women: 10,160 (9495)–79,110 (73,931)	Men only: NR Men and women: 15% probability of cost-effectiveness at a WTP of 45,000 per QALY gained (base-case analysis), increasing to 99% probability for a subgroup with IGT

continued

TABLE 39 Detailed cost and outcome data from the studies (*continued*)

Study ID	Intervention	Comparator	Time horizon of model	Currency (year)	Base-case discount rates	Primary economic outcome measure	Incremental costs, study currency (2012 UK £)[a]	Incremental outcomes[a]	ICER, study currency (2012 UK £)[a]	ICER range from sensitivity analyses, study currency (2012 UK £)[a]	Results from probabilistic sensitivity analysis (if applicable)
Maetzel 2003[166]	Orlistat in addition to standard treatment	Standard treatment guidelines alone	11 years	US dollars (2001)	Costs 3%; effects 3%	Event-free LYG	+1099 (+969)	+0.162	8327 (7258)	8327 (7258)–25,827 (22,511)	95% probability of cost-effectiveness at a WTP of US$20,000 (i.e. £17,431) per event-free life-year gained, assuming continuation of treatment effect over 3 years 95% probability of cost-effectiveness at a WTP of US$68,000 (£59,265) per event-free life-year gained, assuming continuation of treatment effect for 1 year only
Olsen 2005[165]	GP or dietitian counselling	Standard care	Costs: 1 year; effects: up to age 80 years	Danish kroner (2001)	Costs none; effects 5%	LYG	Diet: +1684 (+182); GP: +774 (+84)	Diet: +0.0002; GP: +0.1210	Diet: NR, calculated as 8.42 M (912,148); GP: 6399 (615)	Diet: 26,730 (2896)–6,155,000 (660,820); GP: 3240 (351)–24,037 (2604)	NA
Segal 1998[163,e]	Group behavioural modification	Standard care	25 years post intervention	Australian dollars (1997)	Costs 5%; effects 5%	LYG	Intervention cost 577 (365); total cost NR	Mixed:[f] +111;[9] IGT: +138[g]	(Net costs) Mixed:[f] dominant; IGT: Dominant	Dominant to 1600 (1013)	NA

BL, borderline obese; CHF, Swiss francs; F, female; IGT, impaired glucose tolerance; M, male; NA, not applicable; NR, not reported; OB, obese; OW, overweight.

a ICER may not always be equal to incremental costs/incremental outcomes. For full details and explanations of calculations for incremental costs, outcomes and ICERs see the data extraction forms in *Appendix 13*.

b Based on author calculations from included studies.

c Further probabilistic analyses are presented in Galani *et al.*[167]

d Year 2007 costing assumed based on reference lists for unit costs.

e Programme IV male results only.

f Presumed a mix of normal glucose tolerance, impaired glucose tolerance and type 2 diabetes.

g Cohort size of 100 patients.

(overweight and obese) were also associated with ICERs of < 2000 CHF (Swiss francs) or £1000 (year 2012) per QALY gained. Given usual values of WTP for a QALY gained considered by decision-makers, the intervention evaluated was highly cost-effective. The results remained robust to sensitivity analyses for the male population subgroup, adding strength to the cost-effectiveness conclusions drawn by the authors. The authors recommend that pan-European research in the area should be a priority.

In summary, based on the data presented in this review, there is some evidence to suggest that lifestyle interventions could be a highly cost-effective use of resources in terms of encouraging weight loss and improving health outcomes in overweight and obese men. However, because of the many assumptions made and the heterogeneity of the studies, it is not possible to synthesise a robust comparison of these interventions regarding cost-effectiveness.

Orlistat

Two studies evaluating orlistat for obesity presented data of relevance to a male subgroup of the population. The first[164] reported a cost–utility analysis of orlistat in combination with a lifestyle intervention compared with a lifestyle intervention alone. The base-case ICER was €74,290 (£69,427, year 2012), well above a level of WTP for a QALY gain that would typically be accepted as cost-effective. Although sensitivity analyses were not available for a male-specific subgroup, sensitivity analyses were conducted for the wider group of all sexes combined. There was significant uncertainty in the presented ICERs, with the results being particularly sensitive to the level of risk of developing diabetes. Therefore, the authors concluded that, if the drug was targeted at a high-risk group (i.e. impaired glucose tolerance), the treatment had an estimated ICER of €10,160 (year 2007) per QALY gained, equivalent to approximately £9500 (year 2012), indicating that the drug was likely to be cost-effective if targeted at the highest-risk subgroups of the population. Although data were not presented, it is likely that the conclusion on cost-effectiveness in those at greatest risk also holds true for men.

The second study,[166] carried out in the USA, reported costs per event-free LYG. In the base-case analysis it appeared that the drug was an appropriate addition to standard guideline treatment for diabetes, resulting in weight loss. The findings suggest that the use of orlistat was cost-effective in the management of overweight and obese patients with diabetes in the USA. The results of the study are not presented separately for male and female subgroups but could be considered representative of a 52-year-old man, based on the relative risk calculations for cardiovascular events used in the model. Although the authors suggested that the intervention may be cost-effective in a US setting, it was not clear whether results would be transferable to a UK setting. There was some uncertainty in the estimates of cost-effectiveness and the results were particularly sensitive to the assumed duration of treatment effect. The greater the duration of benefit, the more likely the drug was to be cost-effective. Observational data to support long-term use of orlistat in this population are needed to validate the results of the study and further studies are required to reproduce the results in male subgroups of different ages in the UK population.

In summary, there is some evidence to suggest that orlistat is a cost-effective add-on to lifestyle interventions in male overweight and obese patients, with a greater likelihood of cost-effectiveness if the drug is targeted towards those at greatest risk of diabetes.

Summary

There is evidence of mixed quality and strength which suggests that lifestyle interventions are cost-effective at reducing weight and improving future health gains. There is also some evidence that orlistat may be cost-effective as an add-on to lifestyle interventions if targeted at the subgroups at greatest risk. Despite these promising results, strong assumptions were made in the studies regarding the continuation of treatment effects and the similarity of weight-loss success across male and female subgroups. There were no clear indications of large differences in cost-effectiveness outputs across studies between male-specific subgroups and their female counterparts.

Discussion

We conducted a systematic search of the literature for studies that assessed the cost-effectiveness of a range of interventions for the treatment of male obesity. To our knowledge, this is the only systematic review of the cost-effectiveness of weight-loss interventions specific to a male subgroup of the population.

However, we were unable to find any studies that specifically set out to model the cost-effectiveness of obesity interventions in men. In total, five studies reporting male-specific subgroup analyses were deemed relevant for inclusion (three evaluating lifestyle interventions and two evaluating orlistat). Of the included studies, one described a male-specific intervention programme, among others;[163] however, only limited details of the particular intervention are provided. A second study[166] was modelled on risk factors for a 52-year-old man (from the UKPDS[170]); however, male-specific weight-loss data were not explicitly included in the model. The fact that only subgroup analyses are reported renders it difficult to quality assess the included studies in terms of sex-specific model inputs. The remaining three studies simply presented male subgroup analyses.

There is an indication in the included studies that lifestyle interventions appear to be highly cost-effective and that orlistat has the potential to be cost-effective when prescribed to those at greatest risk of complications of type 2 diabetes. However, it is important to interpret the studies in this review in light of their methodological quality and limitations.

First, as discussed, the studies were not designed to determine cost-effectiveness for a male-only subgroup of the population. The male-specific results presented were instead subgroup analyses of the main studies. It is unclear in a number of studies how sex-specific data were used to populate the economic models. Although results are presented for male subgroups, the use of non-sex-specific baseline data inputs for the models is likely to reduce the ability to show any male/female differences in the cost-effectiveness results.

Second, strong assumptions were made across the studies with regard to the continuation of treatment effects and weight-loss maintenance over time, with no clear consensus about how these assumptions have been incorporated into the economic models. Studies that assumed maintenance of incremental weight loss over time for the experimental group are likely to bias the analysis greatly in favour of the experimental intervention. There is great uncertainty, for example, with regard to the continuation of the treatment effect for orlistat. One study[166] investigated this and found substantial variation in the ICER depending on the assumptions used in the model. Although it is accepted that there is a lack of evidence with regard to the continuation of the treatment effect, it is imperative that this aspect is adequately and comprehensively tested in sensitivity analyses to explore the impact of uncertainty in the model parameters on the final results. This will allow decision-makers to decide what level of uncertainty they are willing to accept when making recommendations regarding the provision of various treatments or interventions.

Third, the models have been developed with varying degrees of modelling sophistication and complexity. Although four studies included Markov decision-analytic models, the level of complexity and the number of potentially important health states included varied greatly across the studies, from only three in one study to eight in another. It is important that best practice guidelines and detailed clinical expertise are sought when developing economic models for weight-loss interventions, both in men specifically and in all population groups more generally. The inconsistency across studies in terms of model structure and health states modelled means that results are likely to differ substantially across studies, and common comparisons cannot be made. For example, studies that consider downstream costs of diabetic complications are more likely to accurately reflect the dynamics of the disease pathway than those that do not. This coupled with the fact that outcome measures are not consistent across the studies (some reporting cost per life-year gained, others cost per event-free life-year gained and others QALYs) renders it difficult to disentangle any real trends across the studies.

Fourth, only two of the included models presented detailed cost–utility analyses with dynamic modelling of the treatment pathway and reported results in terms of costs per QALY gained. Cost–utility analyses are recommended by NICE for the evaluation of health-care interventions and have been used previously in numerous cardiovascular and diabetic modelling studies. The use of QALYs as the estimate of choice is important as QALYs measure both the mortality aspect and the quality-of-life aspect of the chronic complications of obesity. However, although methodologically robust, the two studies that reported costs per QALY gained were not designed to answer a male-specific question.

Fifth, broader measures of benefit, which go beyond the QALY measure and value attributes of an intervention beyond health outcomes, are more likely to capture issues of importance to the patients themselves. One suggestion for future health research in this area could be the use of cost–benefit analyses and discrete choice experiments to evaluate the processes and attributes of care that patients, and indeed taxpayers, feel are of greatest value. This would extend the measure of benefit considered beyond quality of life to include a range of attributes of importance.

Finally, the use of older studies with outdated unit costs across different countries and with different control treatments and subtle differences in the interventions delivered renders broad comparisons across studies difficult. The lack of evidence is further complicated by the lack of generalisability of the studies to the UK setting. Although we have endeavoured to generate UK estimates where possible based on inflationary and purchasing power parity assumptions, such an approach generates uncertainty in itself. It is therefore our conclusion that, on the basis of the retrieved literature, there is insufficient evidence available to make clear recommendations regarding the cost-effectiveness of interventions or treatments for male obesity. There is also insufficient evidence to recommend different treatment strategies for male and female subgroups on the grounds of cost-effectiveness.

Overall summary of the cost-effectiveness review

The key conclusions from the review of cost-effectiveness studies are summarised below:

1. There were no studies evaluating the cost-effectiveness of weight reduction interventions exclusively in an overweight and obese male population.
2. Five studies of weight-loss interventions for male and female participants evaluated the cost-effectiveness of the interventions in male subgroups.
3. The evidence suggests that lifestyle interventions combining low-fat, usually calorie-reducing dietary advice and physical activity are likely to be cost-effective; however, the interventions were poorly described in some studies.
4. There is some evidence suggesting that orlistat may be cost-effective in addition to lifestyle interventions, especially when targeted at those with or at greatest risk of developing type 2 diabetes (e.g. those individuals who have impaired glucose tolerance).
5. None of the studies presented clearly differing conclusions for male and female subgroups and there is insufficient evidence to say whether this is because of a real similarity in the groups or the result of methodological complications with regard to sex-specific inputs to the economic models.
6. Studies were of varying methodological quality, especially with regard to modelling methods and assumptions over the continuation of the treatment effect (i.e. the modelling of maintenance of weight loss over a longer time period) and the modelled link between weight loss and final health outcomes.
7. The methodological variability and study heterogeneity, with many key differences across studies, including differences in comparators, interventions, costing methodology, model sophistication, primary economic analysis outcomes and country of study, make it difficult to assess the factors that are of greatest importance in determining cost-effectiveness.
8. Therefore, on the basis of the evidence summarised in the review and the lack of generalisability to a UK setting, it is impossible to draw clear conclusions on the cost-effectiveness of alternative interventions for the treatment of male obesity.

Future research recommendations

There is an urgent need for UK male-specific economic evaluations to assess the value for money of alternative weight reduction strategies in a UK decision-making context. Such studies should systematically consider the available evidence on acceptability, effectiveness, costs and cost-effectiveness of alternative interventions. The following are key requirements for future research:

1. The development of decision-analytical models that model a dynamic disease pathway, using sex-specific model inputs to determine the key drivers of cost-effectiveness in weight-loss interventions for obese men and what, if any, differences exist in terms of cost-effectiveness across sex subgroups.
2. In terms of the parameters of greatest importance, a study conducted by Galani and colleagues[167] alongside one of our included studies[162] indicated that, based on expected value of information analysis, if further research were to be commissioned it should focus on the effectiveness of lifestyle interventions for cardiovascular risk factors and quality of life of overweight and obese people.
3. An important consideration for future research will be to explore and improve modelling methods to link the effect of weight loss to overall disease risk. Some of our included studies seemed to suggest that small and even transient weight loss may have an impact on future disease risk and therefore could have an important impact on long-term effectiveness and cost-effectiveness outcomes.
4. Future studies should focus on assumptions surrounding the maintenance of weight loss over time, rigorously testing the impact of assumptions on cost-effectiveness outcomes through comprehensive sensitivity analyses.
5. It is important for future research to use a broad measure of benefit and to involve service users in the decision-making process, focusing on the interventional processes and associated outcomes of care that are of greatest importance to individuals to effectively and cost-effectively moderate behaviour.

Chapter 6 Systematic review of qualitative research and mixed-method synthesis of data from men

This chapter is organised into themes based on a logic model (*Figure 42*) that emerged by applying a combined realist and socioecological approach (for methods see *Chapter 2*). *Study characteristics* presents a narrative description of the studies that were included in this review. *Social, cultural and environmental influences on obesity in men* highlights the wider social, cultural, economic and political macro-level themes that have been implicated as predisposing men to gain weight in the first place. *Engagement with weight management programmes* focuses on men's engagement with weight management programmes and implementing programme advice within their everyday lives. First, themes that relate to the role and influence of relationships and interactions with family, friends and peers, and various settings like the workplace, home and sports facilities are discussed. We focus on the time period *before* joining a formal weight management programme to understand factors that motivate men to want to lose weight and decide to engage. In *The weight management programme*, the themes that relate to men's perspectives of the relevance and utility of weight-loss programmes and their experiences acquired *during* their journey through the processes and components delivered as part of weight-loss interventions and how this relates to programme adherence are discussed. *The impact and consequences of weight-loss programmes* discusses men's perspectives on the outcomes achieved *after* they have completed a weight management programme and the consequences for men, their families and their friends. For each theme the qualitative findings are linked to randomised and non-randomised intervention studies aimed at obese men. These findings are then integrated with relevant quantitative systematic review findings (see *Chapters 3* and *4*). Finally, we draw on the wider qualitative literature on aspects of obesity in men. Our analysis is supported by first-order quotations from men with relevant characteristics included in the studies. Author interpretations of primary qualitative data have been described as second-order constructs or second-order themes[39] and, finally, third-order interpretations are made as a research team. The chapter finishes with the quality assessment carried out during the data extraction process (see *Quality assessment of qualitative studies linked to interventions*).

Study characteristics

The primary searches identified 5209 references of which 407 were selected for full-text screening. In addition, 29 studies were identified from other sources, such as commercial organisations and contact with experts. Of these 436 studies, 22 met the inclusion criteria.[44,46,49,89,142,149,187–202] *Figure 43* provides details of study identification (see *Appendix 15* for the data extraction form).

We included 13 studies linked to interventions[46,49,89,142,149,187–194] and nine studies not linked to interventions.[44,195–202] With regard to the studies linked to interventions, five studies[46,89,187–189] were linked to RCTs and the remaining eight[49,142,149,190–194] were linked to non-randomised studies.

Four of the included studies linked to interventions[46,142,149,189] were linked to studies included in the quantitative reviews in this report and these findings are reported in *Chapters 3* and *4*. Eight studies[46,49,89,142,149,189,191,193] were linked to interventions that were open to men only. Of these eight, the studies by Gray and colleagues[142] and Leishman[193] were linked to the same group-based programme (the Camelon model[147]), which was delivered in men's health clinics in Scotland, whereas the studies by White and colleagues[49] and Harrison[191] were linked to the Health of Men workplace-based weight management programme that was delivered in England in a group format. The study by Witty and White[149] was linked to a group-based intervention that was delivered at Leeds Rhinos Rugby League Club in England.[139] The studies by Morgan and colleagues[89,189] were linked to the SHED-IT trial,[189] which was an individual

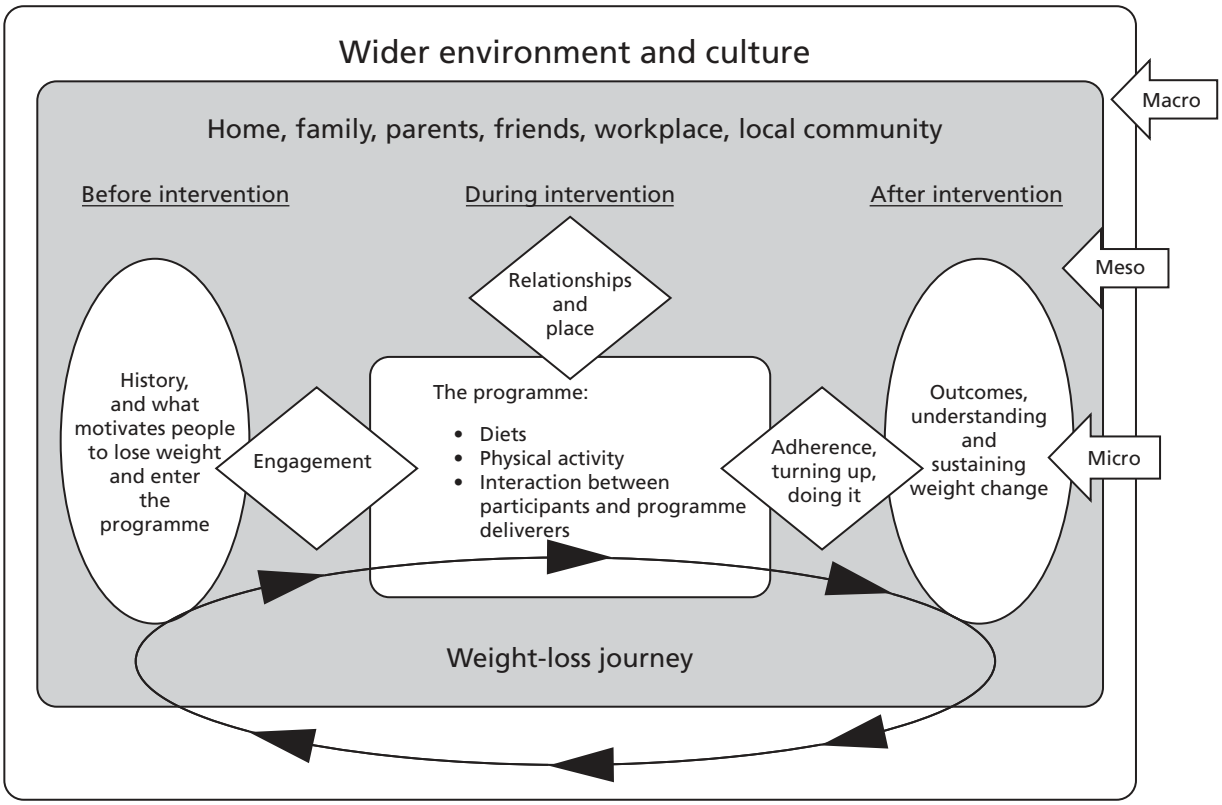

FIGURE 42 Review Of MEn and Obesity (ROMEO) evidence synthesis logic model.

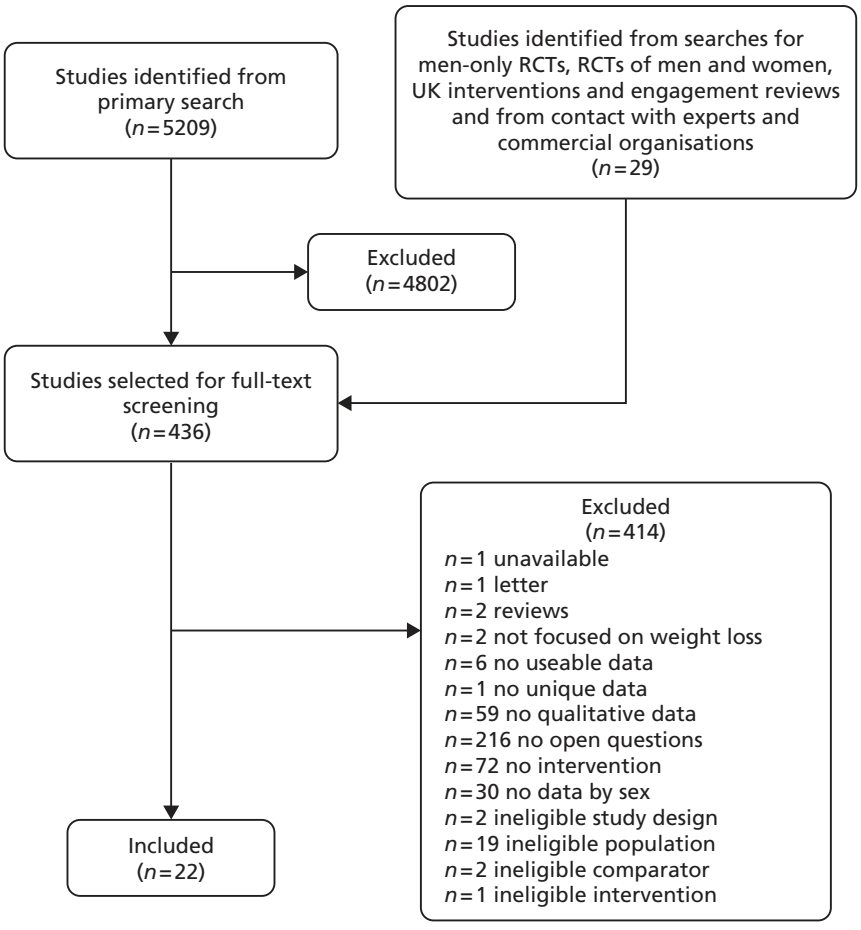

FIGURE 43 Flow chart for identification of studies.

website-based weight management programme delivered in Australia. The study by Hunt and colleagues[46] was linked to the group-based FFIT intervention delivered at senior Scottish football club stadiums.[141]

The remaining five studies were linked to interventions that were open to both men and women. The study by Gallagher and colleagues[187] was linked to a group-based intervention delivered in Australia,[203] that by Mallyon and colleagues[188] was linked to an individual-based intervention delivered in Australia,[204] and the study by Abildso and colleagues[190] was linked to a group-based insurance-sponsored weight management scheme delivered in the USA.[205] The study by Kim and colleagues[192] reported on a faith-based group weight management programme delivered within a rural African American community, whereas the study by Ogden and Sidhu[194] analysed the experiences of individuals taking the medication orlistat for weight loss in England.

Each of the nine studies not linked to interventions was UK based and collected primary data from a male-only sample. These studies drew on the views, attitudes and perceptions of men who taken part in formal weight management programmes and interventions or who had attempted to reduce or manage their weight in other ways. De Souza and Ciclitira[195] interviewed men to investigate their views on health and body image. In addition, Gillon[196] examined how men talk about body weight. The study by Gough and Conner[44] provided an account of meanings that men attach to food and the links between food and health. Gough and Flanders[197] conducted research with men who were active members of the gay 'bear' community, which is a homosexual subculture in which excess weight is considered sexually attractive. McCullagh[198] interviewed long-distance lorry drivers to inform the development of appropriate health education strategies to encourage them to be health aware, access services and attain a healthier lifestyle. One study by Monaghan[199] investigated attitudes to obesity and ill health, disease and disease risk and another study by Monaghan[200] discussed justifications for levels of body mass that are in the overweight or obese range. A third study by Monaghan[201] explored men's talk about physical activity, weight, health and slimming. Finally, the study by Weaver and colleagues[202] investigated how men understand obesity and its relation to the risk of diabetes.

Social, cultural and environmental influences on obesity in men

Most included studies took a predominantly individualistic approach to the factors that may influence weight gain, rather than a more ecological and environmental approach. References to issues in the wider environment that may act to increase the propensity for men to be obese were identified in four[45,48,141,148] of the 13 included studies linked to interventions and six[43,190,193,197,198,201] of the nine studies that were not linked to interventions.

Two distinct subthemes emerged from the data: *Sociostructural determinants of obesity* and *Obesity and deprivation*. No quantitative data from the other systematic reviews were found to support or disconfirm these themes.

Sociostructural determinants of obesity

White and colleagues[49] referred to structural changes in society that may predispose individuals to gain weight. They presented this in a second-order construct as a dichotomy between (1) the fecklessness of three-quarters of men in the UK, which the authors thought was unlikely, and (2) vulnerability because of structural changes in the wider society.

No participant quotes were found to indicate that men were thinking about wider society-level determinants of their behaviour when discussing factors that helped or hindered weight-loss attempts. Indeed, it is evident from the data presented in the remainder of this chapter that those issues were almost entirely absent from men's conceptualisation of the problem, with an emerging prevalent theme of personal responsibility more obviously apparent. White and colleagues[49] did not reference specific examples of sociostructural issues that may influence the increasing prevalence of obesity in the UK.

However, previous research[206] has demonstrated that individuals may interact with environments on many levels in activity-related settings such as the workplace, home, school and the neighbourhood that can be and are influenced by structural factors in the macro environment such as government policy, education and health systems.

Some studies in this review suggested that the role that environment plays in influencing behaviours helped some researchers decide where to locate the delivery of weight management programmes. For example, the Health of Men programme, as described by Harrison[191] and White and colleagues,[49] was located in the workplace, with the rationale that it was more convenient to access than non-workplace settings. Two other studies were located in sports facilities,[46,149] with the rationale that these environments were congruous to male identities and therefore more appealing to men than interventions in more formal clinical settings. Targeting a population through a special interest setting was apparent in the study by Kim and colleagues,[192] who located their faith-based weight management intervention in a (predominantly) African American church. The Camelon model[142,193] was located in a more formal health-care setting, namely a men's health clinic. However, in contrast to the other studies mentioned here, the authors emphasised the utility of a group-based setting for men (over the physical location of the intervention) in allowing men to raise sensitive issues that may otherwise be embarrassing to discuss.[142] The remaining studies[188,190,194] were not clear about the setting where the intervention took place.

Participants in two studies[191,194] made reference to environmental factors relating to work that they believed played a part in the onset of their obesity. A 43-year-old white participant in Ogden and Sidhu's study[194] on the experiences of taking orlistat for weight management stated that his static job played a part in his obesity. This man talked about knowing that he ate far too much of the wrong things, naming bacon, eggs, sausages, chips, meat and bread.

The repeated use of 'I' by this participant (in his account of this issue) suggested a strong sense of intrinsic personal responsibility with regard to his engagement in behaviours that he perceived had led to his obesity. Nevertheless, reference to external determinants of behaviour (considered beyond the control of the individual) that had contributed to a person's weight gain was observed in the study by Harrison,[191] linked to the Health of Men workplace-based intervention. Here a participant described how working irregular hours away from home played a role in his gaining weight:

> *When you work away from home you have no one to prepare nutritious food for you, you live off takeaways, kebabs, pub meals and have a few pints*
>
> *Mark, age 34 years, p.70*[191]

The reference to 'you' as opposed to 'I' may thus be viewed as absolving oneself from blame. Finally, a 47-year-old participant quoted by Ogden and Sidhu[194] attributed his obesity to his home environment, family behaviour in relation to food availability, finishing his children's food and his personal coping strategy of turning to food for comfort to improve his general sense of well-being.

These examples illustrate the complexity of the interactions between the individual men's intrinsic and extrinsic motivation to change and the environmental barriers to and facilitators of instigating and sustaining change. Such interactions, which operate between the macro, meso and micro levels described in ecological models of behaviour, pervade the themes that are presented in the subsequent sections of this chapter.

Referring to the wider qualitative literature on obesity in men, reference is made to the concept of the obesogenic environment. This has been defined as:

> *The sum of influences that the surroundings, opportunities, or conditions of life have on promoting obesity in individuals or populations*
>
> *p. 564*[65]

Rayner and Lang,[67] Hanlon and colleagues,[64] Butland and colleagues,[5] Swinburn and colleagues[65] and Leeder[207] have argued that sociostructural factors have played a very powerful role in creating toxic environmental conditions that make it very difficult for individuals to maintain a healthy weight. They point to relatively recent but radical changes in food supply (in terms of the price and availability of food), transport and urban design (especially walkability) as well as commercial pressures to overconsume food and engage in less than optimal levels of physical activity as key drivers of the obesity problem.

The importance of the sociostructural determinants of obesity as a theme that contrasts with the obesity as individual responsibility standpoint was supported in five of the studies not linked to weight management interventions.[44,197,198,201,202] For example, Weaver and colleagues[202] provided direct quotes from men regarding sociostructural determinants of keeping fit and eating healthily. These quotes, related to press and government health promotion messages, such as eating five portions of fruit or vegetables a day, and food labelling, indicated that some men were conscious of the sociocultural and economic aspects of their lives that encourage weight gain.[202]

However, government public health messages were described in another study[44] as an intrusive health lobby, which can prompt resistance and a will to reclaim eating as personal choice. A quote provided to support this referred to all enjoyable food being bad for you, something which the 47-year-old respondent argued was not the case two decades ago when you could eat what you liked.

Nevertheless, another participant, in the study by Weaver and colleagues,[202] appeared to show that government-driven health messages are heeded by some:

> *There is always fresh fruit in the house . . . I try and keep away from microwave meals . . . we don't eat a lot of fried food you know, if everything is done, it would be grilled or it would be boiled*
>
> *Jack, age 34 years, p. 4*[202]

The use of pronouns is interesting, as the impersonal 'there is always fresh fruit' represents a detachment from the actual buying or eating of the fruit but also a recognition of the importance of healthy food being always available as a facilitator to healthy behaviour.

The men in McCullagh's study[198] on long-distance lorry drivers also frequently attributed their self-perceived poor diet and low levels of exercise to their obesogenic work environment. They recognised that driving long hours leads to weight gain, with some expressing regrets about gaining a licence. In particular, the drivers lamented the lack of healthy food available at roadside catering establishments in the UK:

> *The food offered in transport cafes is appalling. The breakfasts have names like 'Belly Buster' or 'Heart Attack'*
>
> *No individual characteristics provided, p. 5*[198]

The theme pertaining to perceptions of obesogenic environments was also confirmed in Monaghan's[199] field diary, written when observing male members of a slimming club. One excerpt covered the difficulties that men encounter in resisting the temptations of the garage shop when filling up their cars, as well as vending machines at work, with a discussion of strategies of how to avoid these temptations.

Obesity and deprivation

Links between obesity and deprivation were highlighted in the Camelon men's health clinic group-based intervention of Gray and colleagues,[142] who stated in a second-order construct that obesity is linked to socioeconomic status through poorer men eating less well, with the incidence of obesity increasing with deprivation and lower levels of education.

This was supported by author text in five of the non-intervention studies,[193,197,198,201,202] in which the relationship between obesity and health inequalities was discussed. For example, Weaver and colleagues[202] investigated how men understand obesity and its relation to the risk of diabetes. They concluded that lower social class men were more at risk of obesity and its related diseases, but that they were also a hard-to-reach group for health promotion.

In addition, De Souza and Ciclitira[195] referenced findings from the literature which suggested that people with lower levels of education and wealth are at a greater risk of obesity and as a result have a lower life expectancy.[195,208] In addition, De Souza and Ciclitira state that, although people of higher socioeconomic status report higher levels of perceived overweight, they have been found to be more likely to monitor their weight closely, more likely to try to lose weight and more likely to report higher levels of physical activity.[195,209] Furthermore, De Souza and Ciclitira[195] cite evidence that men of lower socioeconomic status were less likely than women to have knowledge of healthy eating and that the lower a man's social class or education level the lower the level of such knowledge.

A debate emerges concerning the relative appropriateness of framing obesity discourses according to gender, health or wider macro sociostructural and socioeconomic perspectives. De Souza and Ciclitira[195] argue that an appreciation of socioeconomic factors and education, rather than gender differences, is important when investigating the causes of obesity.

However, Monaghan[199] argues that focusing the obesity debate on the perceived unhealthiest individuals occupying lower socioeconomic strata is unhelpful. Monaghan refers to victim blaming, a term generated by the orthodox medicalised view of obesity, whereby obese people from lower social class backgrounds are regarded as being in poor health because of their obesity. Moreover, they are forced into pursuing individualised solutions that, in themselves, may be physiologically or psychologically harmful. It is argued that one of the consequences of the focus on obesity is that it legitimates and perpetuates a society in which many people are dissatisfied with their bodies.

The study by Weaver and colleagues[202] also provided direct quotes from men indicating that economic factors constrained their choices for healthy eating and exercise. For example, men described the high cost of membership of clubs and gyms, or the fact that healthy food, especially fruit and vegetables, is more expensive than food high in sugar. Similar economic issues were raised by long-distance lorry drivers in the context of work, with an example given in the study by McCullagh[198] of a apple costing an expensive 60p.

Engagement with weight management programmes

Despite the increasing prevalence of male obesity in the UK, and the existence of well-established links between obesity and poor health, men are less likely than women to participate in weight-loss programmes.[142,210] The reasons for this lack of participation are not well understood as little research has been carried out to identify the barriers to and facilitators of the participation and engagement of men in weight-loss programmes.[189] This section discusses themes that have been found to affect men's engagement with programmes and programme advice, in particular considering the lead-up to participating in a weight-loss programme. These themes relate to the role and influence of programme settings and interactions with family, friends and peers and in particular refer to the initial motivation to lose weight, factors that attract men to participate in interventions, the importance of location and setting in acting as a 'hook' to engage men to join weight management programmes and the influence of partners, family and friends on men's engagement with weight management programmes.

Initial motivation to lose weight

Men may pay less attention to their weight than women and may therefore be less likely to attempt weight loss than women.[41,42] However, little is known about the types of issues that motivate men to either join a formal programme or try to lose weight independently. Leishman[193] reported that a diagnosis

and label of obesity came as a substantial jolt to men attending the group-based Camelon programme in Scotland, who had not previously thought of themselves as being problematically overweight. This realisation appeared to increase their motivation and commitment to embark on a process of trying to lose weight. For example, a 42-year-old man expected that tests would show that he was a bit overweight but finding out that he was obese hit him very hard. When the facts were staring him in the face he felt motivated to act.[193]

Another participant from the study by Leishman[193] referred to how men who are big can be normalised within some environmental settings such as the workplace. The authors suggested that presenting information on weight visually can potentially provide the jolt needed to increase motivation. The use of charts to display clinical measurements in relation to norms links to the theme discussed later around men's preference for more scientific and technological representations of obesity. One 38-year-old man was shocked to be labelled obese because in his workplace most of his colleagues were big, suggesting that obesity and being overweight was a previously unacknowledged social network norm for him:

> *My size just seemed normal. When the girl (assessing nurse) showed me the chart I was really shocked to see that I was clinically obese. If it had showed me as being fat it wouldn't have got to me as much and I probably wouldn't have done anything about it.*
>
> *p. 79*[193]

The obesity diagnosis bringing about the motivation to act (as opposed to being labelled fat) is also highlighted in the study by Gray and colleagues,[142] which was linked to the Camelon programme, delivered to men in groups in a health clinic setting in Scotland. In this study men experienced dissatisfaction with their body image only when they were labelled as obese. In contrast, it was reported that men whose BMI was in the overweight range (< 30 kg/m^2) were less likely to enrol in the Camelon model's weight management programme. Gray and colleagues[142] therefore contended that contemporary social norms that place emphasis on the idea that men should be bigger and stronger than women have perhaps influenced men's perceptions of an ideal weight as being in the overweight range.

Concerns regarding health issues that may be worsened by obesity and the concomitant fear and anxiety related to a medical diagnosis or event, or the realisation of how ageing with obesity affects health, can also motivate obese men to lose weight. For example, a 44-year-old participant in the study by Morgan and colleagues[89] reported having had a recent health scare and realising that he was not getting any younger, which motivated him to act.

Motivation seemed to increase particularly if a hospital admission was reported, with accounts of medical procedures interpreted as serious or life threatening involving mechanical deficiencies in the heart or breathing, as detailed by Ogden and Sidhu[194] investigating the experiences of individuals taking the medication orlistat for weight loss in England. Typically, men would attend their GP surgery and be referred for tests, which showed that their health was far worse than they had envisaged, and this diagnosis/realisation triggered them to do something. As one 43-year-old (of white ethnic origin) in the study explained:

> *It got to the stage that I knew I was going to die and that was the turning point. I knew I was going to die unless I did something about it. And then I just got into gear and it turned me right around*
>
> *p. 548*[194]

A similar picture was seen in the study by Gallagher and colleagues:

> *Having a heart attack really scared me. I just wanted to feel better, see my kids grow up, and be more in control. I had tried so many things, but being in hospital really brought me to my senses*
>
> *John, age 38 years*[187]

In addition, the study by White and colleagues[49] (which is linked to the Health of Men workplace-based weight management programme delivered in a group format in England) found that some overweight participants who felt unhealthy, as opposed to actually being diagnosed with a health problem, were motivated to lose weight.

A desire to improve personal health was also highlighted in the quantitative evidence base. In our review of men-only trials (see *Chapter 3*), emphasising the link between weight loss and improved erectile dysfunction[85,122] produced very favourable reductions in body weight. Similarly, men who participated in the Bloke's Weigh programme[147] expressed concerns over mental health issues in addition to concerns about weight and diet (see *Chapter 4*). The greater take-up of commercial weight-loss programmes by men referred from general practice than from self-referral, as seen in *Chapter 4*, also suggests the importance of health issues for motivation.

In the study by Morgan and colleagues[189] linked to the web-based SHED-IT trial, a concern over physical appearance was also described as a motivator to take part in a weight-loss programme for younger men in particular. However, the only quote provided to support this is from a middle-aged man who, whilst looking at himself in a mirror, compared his appearance unfavourably to that of his father.

These themes pertaining to the initial motivation to lose weight were largely supported in the studies not linked to weight management interventions. For example, the study by De Souza and Ciclitira[195] confirmed the theme that men were likely to be motivated to lose weight for health reasons, which they distinguish from their perceptions about why women attempt to lose weight (for appearances). One 54-year-old man reiterated that women were more likely to want to lose weight to fit into their clothes for reasons of vanity and that men were more likely to want to lose weight for medical reasons. Another 45-year-old man in the same study agreed that women's weight loss was driven by vanity.

Similarly, the study by Gough and Conner[44] reported that men were initially motivated to lose weight for health reasons, for example after being diagnosed with diabetes, or when health professionals advised a diet to lower cholesterol.

The study by De Souza and Ciclitira[195] also found that for gay men weight management was thought of as a way to improve appearance. For example, a 33-year-old participant talked about slimness as being something that was socially prized within the gay community and another man of the same age talked about withdrawing from the gay scene as he no longer thought himself attractive enough because of weight gain.

However, evidence from participants self-identifying as gay 'bears' in the study by Gough and Flanders[197] refuted the notion that being labelled as obese provides motivation to lose weight**.** In this particular gay subculture, obese bodies are the norm and are viewed as desirable and healthy. A 39-year-old man explains how the bear community encourages him to be 'meaty', with a BMI in the overweight to obese range. Moreover, the bear community had an immense appeal to him as he felt that he had gained more friends since increasing his BMI.

Factors that attract men to participate in interventions

It has been argued that the failure of programmes to recognise gender issues in weight management may have a part to play in the apparent lack of enthusiasm that men have for joining weight management programmes.[210] Several studies demonstrated how being able to undertake weight-loss activities in a male-only environment was appealing for some men. In the study from Australia by Morgan and colleagues[189] a 21-year-old participant explained that he was attracted to the male-only aspect of the programme.

This was also found in the study linked to the group-based Camelon programme, delivered in a health clinic setting in Scotland, with Gray and colleagues[142] quoting a man as saying that he would not attend any intervention with female participants.

However, other research[211] has found that male-only features of interventions were less important to most men. Instead, the opportunity to receive a second opinion was more important. In addition, a 19-year-old participant in the study by Morgan and colleagues[189] stated that the website-based programme with individual advice sounded achievable and this was more important than the male-only aspect of the intervention.

A non-intervention study[195] provided evidence to support the view that not all men prefer male-only weight management environments. One 40-year-old man, who was the only man in a slimming club, appreciated the support that he got from his fellow club members. He was also helped by the fact that he was the manager of 20 women, half of whom attended slimming clubs, leading to a competition at work to lose weight, with him reporting that he had beaten them all.

An example of how the delivery of an intervention can engage men is provided by several studies through the use of humour or banter.[46,49,142,149,189,191,193] For example, a nurse in Witty and White's study[149] noted the sensitive communication issues that arise in identifying obesity and inviting men to join a group. A light-hearted approach with the use of banter was important when attempting to approach and encourage overweight or obese men to take part in a study, to lessen the chance of causing offence.

Morgan and colleagues[189] explained how humour was deployed in the SHED-IT website-based weight management programme to aid participation and engagement. Comical language and imagery (such as the picture of a beer glass) were used in the programme's promotional materials to attract men and get across the message that the internet-based programme allowed treats such as beer. This was said to be particularly successful with regard to recruitment; a 29-year-old man said he saw the glass of beer and signed up immediately.[189]

A further reason why men were attracted to take part in the Camelon programme was the knowledge that the programme had been successful for other men. This is illustrated by one participant who had been persuaded to join because he had heard that the groups worked well and were a good laugh.[193]

The theme of humour is considered again in the following section (see *The weight management programme*) when the nature of the interactions within weight-loss programmes are reported.

Engagement is also influenced by perceptions of what the weight management programme will involve. Two of the included studies[141,192] indicated that men would be disinclined to undertake any forms of strict dieting. For example, a participant in Leishman's study[193] linked to the Camelon programme delivered in a group format in health clinics in Scotland, explained his feelings of apprehension at joining if strict dieting was involved, as a diet that makes one starve is not appealing. However, the man was pleasantly surprised that Camelon was more of an education programme about healthy eating and exercise not a strict diet. In fact, at first he thought that it would not work as he felt that he was eating the same volume of food, with just more vegetables and fruit.

The absence of an extreme dietary regime appeared to be instrumental in attracting men to participate in several studies.[142,189] Gray and colleagues[142] found that men had joined the group-based Camelon programme as it was marketed as not involving dieting. However, no participant quotations are given to support this finding.

The importance of location and setting as a 'hook' to engage men

The location and setting of certain programmes acted as an important element to attract men to participate in them. In the study by Hunt and colleagues[46] the intervention was located within SPL football club stadiums and targeted obese supporters. The aim of weight loss therefore becomes congruent

with a strong personal commitment to being a football supporter. Our interpretation is that associating long-standing loyalty, commitment and pleasure attained from collectively supporting a football team (still predominantly a male activity) with challenging men's lifestyles to encourage behaviour change, such as losing weight, could hypothetically increase the likelihood of 'contagious motivation' whereby motivation for turning up to support the team either consciously or subconsciously transfers to motivation to lose weight with fellow team supporters. To support this interpretation, a participant emphasised having been a lifelong football supporter and the status that being part of an intervention with his club gave him in his circle of friends and how this was an incentive to engage with the intervention and lose weight.[46]

Hunt and colleagues[46] contended that the setting acted as a 'hook' and an additional incentive to attract men to participate in weight-loss activities, which they had felt unable to do in other contexts. The football context confirmed the men's male identities and made them feel comfortable. Our interpretation is that the football club setting facilitated enrolment into a cohesive group of men with shared characteristics (overweight team supporters) who partook in a task-orientated group to lose weight according to key criteria for delivering health improvement groups.[212] Similarly, Witty and White[149] studied a weight-loss programme that was set in a rugby stadium. Certain men seemed more inclined to attend a weight management programme located in such a setting, which might be because of a reduction in men's anxiety in this setting. One respondent commented that he would recommend this programme to his friends and that he found it more comfortable than traditional health services, because some men still have:

> *Anxiety or apprehension about consulting a health professional in a building that is very clearly a health oriented building so I think that the opportunity to be able to access some form of health service in an environment that I would imagine feels far less threatening.*
>
> *Age 35–44 years, p. 25*[149]

The sense of well-being and pleasure associated with attending a football or rugby game contrasts with the anxiety and fear that can be experienced when attending a programme in a health setting. Indeed, a participant in the study by Gallagher and colleagues[187] appeared to display a degree of distrust towards health professionals and a lack of confidence that they could offer effective solutions for his problems.

It may be that juxtaposing a challenging task such as weight loss with an activity that increases well-being might help to overcome some of the emotional barriers such as anxiety and fear that could impact on enrolment and engagement with interventions delivered in a health setting.

In *Chapter 4* we discussed how Brady and colleagues[138] deliberately targeted men who had a shared passion for their football club. The trial attracted limited numbers of men from varying socioeconomic backgrounds but all stated that they found the experience highly rewarding.

White and colleagues[49] reported on men's experiences of a weight-loss intervention based in the workplace, which again appeared to act as an attractor for several of the men who took part. A 54-year-old participant stated that being able to attend an intervention during work hours provided the motivation to attempt weight loss, which is something he would not have attempted in the evening. White and colleagues[49] stated that the convenience of having the programme in the workplace played a key part in attracting men; however, they also highlighted that male participation in work-based programmes is to some extent dependent on the creation of a positive environment within the organisation to provide the right climate for the initiative to work. In addition, one aspect that links these three separate contexts (football stadium, rugby stadium, work environment) is that they fit well with masculine identities. Hunt and colleagues[46] noted that, when a context is congruent with masculine ideals and not challenging, attempts at engaging in weight loss and health improvement activities are more palatable for men.

Influence of partners, family and friends on men's participation with weight management programmes

The concept of hegemonic masculinity refers to a culturally normative ideal of male behaviour and is used by Mallyon and colleagues[188] to refer to the ways that men think about and do manliness, and specifically as a construct that is the opposite of femininity. In the study by Mallyon and colleagues,[188] which is linked to a RCT from Australia, men who engaged in hegemonic masculinity received appropriate dieting support from (female) partners in terms of the preparation of food, which helped them stick to a weight management programme, whereas those less engaged in hegemonic masculinity were more likely to take control of their own dieting practices. Mallyon and colleagues[188] explain that men who engage in hegemonic masculinity view dieting as a feminine activity that is about looking slim and pretty, which is linked to vanity. Thus, hegemonically masculine men will look for ways to distance themselves from dieting. For example, a participant who was described by the authors as being more engaged in hegemonic masculinity explained his female partner's role in his dieting. His wife cooked for him and he acknowledged that his wife did it all for him.[188]

The role that female partners play in the preparation of food is also evident in other studies. Leishman[193] provided an example in which a man undertaking the Camelon programme set a SMART goal (specific, measurable, achievable, realistic and time limited) for his weight loss in which the importance of his partner's cooking was illustrated. Instead of having biscuits whilst waiting for his partner to cook for him, he removed himself from that temptation by leaving the house to take the dog for a walk.

Contradictory results were found for the role of female partners in men's weight loss in our quantitative reviews of men and women[94,112,120] (see *Chapter 3*). It is not possible to comment on any causal link between quality of female partner support and weight loss for these studies, but differences could highlight the importance of positive and negative influences of significant others on weight-loss efforts.

The study by Mallyon and colleagues,[188] which was linked to a RCT of an intervention delivered individually in Australia, also provided an example of a family member having a negative effect on a man's engagement with a weight management programme. A quotation described how the man's mother thought that he was becoming gaunt and too skinny and his perception that her solution to everything was to provide excessive amounts of food, which he blamed for his obesity. Some men undertaking weight management programmes reported having difficulties if they needed to reject their mother's cooking (which might include large portions or high-calorie food) for dietary reasons, fearing that any rejection would be perceived as a form of insult, which would damage the mother–son relationship.[188]

Mallyon and colleagues[188] found that being less engaged in hegemonic masculinity could leave a man's adherence to dieting plans more vulnerable to social sabotage, which in turn could act as a deterrent to adherence. In particular, the encouragement of male peers who were not dieting was found to be an important issue in that, if male peers respond in a way that is perceived by the male dieter to be negative, motivation to stick to a programme may diminish. Choosing against the expected social norm is challenging, for example it was suggested that ordering a healthy meal at a restaurant would often be questioned by male friends.[188] Another participant's motivation to adhere to a diet was tested and reduced when he ate diet food while his friends ate normal food.[188]

Mallyon and colleagues[188] suggested that in this context the diet functions as a barrier to normal socialising with friends. Similar issues were presented by Kim and colleagues[192] (linked to a faith-based group weight management programme delivered within a rural African American community) with a

participant explaining that peer pressure to consume unhealthy food affected his ability to adhere to eating healthily, commenting on how strong you have to be to resist peer pressure:

> *'Man, you better get up from here – nobody want that food you're eating. You know, eat something that's good for you.' And it may, if you're not strong enough, you gonna say, 'Well, hey, maybe I'll try a piece'*
>
> *Age 45 years, p. 641*[192]

Unlike the facilitating influence of cohesive group settings such as sports clubs or the workplace on the engagement of men in weight management interventions, the influence of groups such as family and friends can serve as either a facilitator of or a barrier to engagement with weight management programmes and/or the prescribed advice forthcoming from such programmes. One of the studies not linked to a weight management intervention provided evidence to confirm the crucial role of partners in weight-loss attempts, suggesting that sudden jolts relating to opportune moments or particularly symbolic or important situations, as described earlier for health, can be the trigger for behaviour change for men:

> *I realized for some time that I was overweight, and I wasn't as fit as I should be, and the jolt was my wife saying she's not going on holiday sitting on a coach with a fat man on half a seat you know*
>
> *Age 52 years, p. 799*[195]

On the other hand, it was found that partners of the homosexual men in the study could be very unsupportive of weight-loss attempts, because weight loss made the man more attractive to others.[195]

Gough and Flanders[197] provided a new theme on the influence of families, partners and friends, demonstrating that the gay 'bear' community actively encourages men to reject established advice on appropriate BMI levels in order to remain obese, which is seen as sexually attractive. The bear community acts as a social milieu in which these men are empowered to reject the advice of health professionals and feel, comfortable and desired in their obese state. This acceptance (of their overweight status) was valued by some participants over and above the value they place on their personal physical health. A 39-year-old man weighing 20 stone who developed type 2 diabetes as a consequence of being obese downplayed obesity as being manageable and claimed to be more active, because of stopping smoking, than when he was lighter. He was more comfortable being obese.

The weight management programme

This section presents and discusses themes that influence and shape men's perspectives and experiences when participating in weight management programmes. The content, format and delivery processes of weight management programmes are considered, as well as how these relate to the individual, biological and social determinants of health and well-being. The following themes are presented: men and diets, alcohol and obesity, men and physical activity and understanding interactions within a weight management programme. It should be noted that a degree of overlap was observed with the themes relating to engagement described in the previous section. The demarcation of themes is presented here as a dynamic rather than categorical process.

Men and diets

As noted earlier, men may be more inclined to avoid what is perceived as the feminised realm of dieting, in which women are often viewed as the experts.[51] In addition, poor-tasting diets that emphasise smaller portions are also hypothesised as a reason why men may distance themselves from dieting.[44] However, little is known about the subjective experiences of dieting men[188] or the meanings that men attach to food,[51] or indeed their experiences and understanding of food.[44] The approach in the Camelon weight management programme was to de-emphasise the role of dieting and weight loss and emphasise a personalised approach that accounts for individual needs, to make men feel in control of their weight loss.

Gray and colleagues[142] reported that this personalised approach gained the approval of some participants who had taken part in the Camelon programme.

Evidence from Gallagher and colleagues[187] also appears to support the idea that a personalised approach is more appealing to men. Quotes from this study in which the intervention was delivered in a group format without an individualised component show that men can find a one size fits all approach confusing. Calorie counting was seen as needing time, which one 58-year-old man perceived as a barrier. Another found it hard to put all of the components of losing weight together – what to eat, how to exercise – and found that it could be too much, with a recommendation to break down the information, implying a need to simplify the messages and reduce the burden.

The finding that individualised programmes are preferable to men is substantiated from the quantitative evidence as successful programmes generally included some element of individual tailoring, either in the form of individualised dietary allowances or advice and/or personalised feedback or support (see *Chapter 3*).[88,90,96,99,100,106,110,142,154,213]

A similar de-emphasis on the role of extreme dieting was employed in the SHED-IT internet-based study,[189] which some men compared positively with imposed crash diets elsewhere.

The SHED-IT programme also encouraged participants to enjoy some treats in moderation, such as beer and junk food, which was welcomed by participants. One man (age 35 years) used a variant of the expression 'have one's cake and eat it' when referring to having your beer and losing weight. A 21-year-old highlighted that:

> *The most enjoyable aspect [of the SHED-IT programme] was the fact that it allows for those days where you know, if you have a **** day at work you can just go and have a few beers afterwards and not feel ****house for it*
>
> *p. E245, quote as in the original*[189]

A 50-year-old participant quoted by Morgan and colleagues[189] stated that an appealing aspect of the SHED-IT programme was that he did not have to make any significant alterations to his diet, whereas a 19-year-old participant in the same study welcomed the fact that SHED-IT gave him choices and thus facilitated personal control.

Therefore, men from three studies appeared to welcome aspects of programmes that placed less emphasis on strict dieting and emphasised personal control over which foods they consumed. This appears to support the notion that men are reluctant to diet and are attracted to engage in and adhere to programmes that appear realistic and can feasibly be assimilated into their lives.

Alcohol and obesity

According to Gray and colleagues[142] alcohol may pose a particular problem for men in relation to weight gain and thus alcohol intake should be managed when attempting weight loss. An alcohol awareness component was built into the Camelon programme, with the role of alcohol in weight gain considered and each participant setting SMART goals to decrease alcohol intake. However, there were no participant quotes in the study by Gray and colleagues[142] to shed light on any issues that men may have had with alcohol in relation to their weight. One other study[191] provided participant data on alcohol and obesity. Here, a causal link between alcohol consumption and increased appetite is proposed. For example, one 34-year-old man suggested that after a few beers he lowered his defences and ate more. He would have a few cans of beer most nights and put his feet up to watch television and he commented that with the drinking his diet also deteriorated.

Several of the non-intervention studies provided evidence to both confirm and (in one case) refute our other findings on diet and alcohol. For example, the study by De Souza and Ciclitira[195] confirmed that men

disliked the restrictiveness of strict dieting and having their alcohol intake limited, especially in social situations. This was argued by the authors rather than being obviously evident from the data presented from the men themselves. For example, the authors stated that a feature of maleness was avoiding activities that could be construed as feminine, such as having a soft drink or following a diet.[195]

However, De Souza and Ciclitira[195] also explained that the men in this study may have been atypical as they admitted after several interviews to multiple weight-loss attempts in the past, including crash diets such as the Cambridge diet or SlimFast, and described the difficulties that they had experienced in maintaining weight loss. The authors argued that this could be the primary reason why they finally decided to use a formal weight-loss programme, with the support of their partners, with it being perceived as including a legitimate and sensible diet.

The study by Monaghan[199] confirmed that men undertaking weight management programmes prefer a system in which they can still enjoy treats, which meet the programme goals but can undermine a healthy diet. One of the participants described a point-based system based on energy-dense foods used by a commercial slimming club. The man explained how he can still enjoy some chocolate, crisps and a bottle of vodka at the end of the working week, yet stay within his weekly maximum points.

Men and physical activity

The included qualitative studies contained very little on the views of men about physical activity. Most data were provided by just one of the included studies[46] linked to the group-based FFIT trial delivered in Scotland at the stadiums of Scottish football clubs.

It is suggested that men may view physical activity in different ways from women, especially with regard to using physical activity to become stronger, fitter and healthier,[47] and also in how they use pedometers for self-monitoring.[46] Men have also been posited to be more likely to use physical exercise than dieting to control their weight.[46,142]

The use of pedometers in the men-only FFIT programme appeared to act as a key motivator for many interviewees.[46] In particular, the pedometer appeared to be useful in encouraging men to meet prespecified individualised activity targets. One quote suggested that a man was competing with himself, for example to reach his daily target of recommended steps, and that he changed his perception of walking as a mode of travel:

> *I'm walking places I'd just never have dreamed of walking*
>
> *p. 61*[46]

In addition, a 72-year-old participant in the study by Gallagher and colleagues[187] (linked to a group-based RCT delivered in Australia) also felt that using a pedometer helped to facilitate weight loss by allowing him to keep track and understand how much physical activity he undertook each day.

However, the perception of walking as enjoyable was not universal amongst participants. For example, one man who wore his pedometer all the time still did not find walking as attractive as attending the gym,[46] and another participant in the same study had got bored with the lack of variety in walking routes.

That men like engaging in physical activity is supported by our review of the quantitative evidence (see *Chapter 4*). Men were also more likely to be successful in their weight-loss efforts if they included some element of physical activity in their weight-loss programme, but only if this was combined with some form of dietary regime[106,109] (see *Chapter 3*). In our review of men-only RCTs (*Chapter 3*), the trial by Patrick and colleagues[90] reported that pedometers were enjoyed by the men for their novelty and assistance with self-monitoring of their behaviour. The men in this trial were randomised to receive a low-fat diet with behavioural therapy and exercise advice or general health advice only. It should be noted that, although the intervention group initially lost more weight, by 12 months the differences were not

statistically significant, indicating that, although men may enjoy using pedometers, their usefulness in losing weight may vary depending on the overall weight-loss programme. Alternatively, it may be the case that the fun aspect of using pedometers declines with repeated use, which may negatively impact on walking behaviour.

With the above in mind, the studies not linked to weight management interventions also displayed limited data on men's physical activity preferences. The study by Weaver and colleagues[202] provided data that confirmed men's enjoyment of exercise; their participants spoke of experiencing various immediate benefits, such as being more alert or being less stiff.

Nevertheless, pain as a limiting factor for exercise was raised as a new theme by Weaver and colleagues.[202] Many men particularly described having knee pain, which had a debilitating effect on their ability to exercise. Interestingly, different causal relationships were proposed between knee pain, exercise and obesity. Some men thought that their exercise regime had caused the knee pain, which in turn resulted in weight gain. Weaver and colleagues[202] weighed up the available evidence and suggested that taking exercise is unlikely to cause osteoarthritis (unless perhaps in top footballers) and that obesity is clearly linked with long-term knee problems. They concluded that men need to be educated about the impact of weight on their knees and about weight loss as a means to prevent knee problems.

Understanding interactions within a weight management programme

The data pertaining to interactions within the weight management programme were diverse. Within this theme we provide five further subheadings: group-based programmes and social support, promoting engagement and the use of humour, scientific appeal, accountability and adherence, and goal setting.

Group-based programmes and social support

Several studies highlighted the importance of group-based weight management programmes. Proponents of this approach argued that it facilitated peer or social support amongst people with similar health problems. This was observed in the study by Leishman,[193] which was linked to the group-based Camelon programme, delivered in men's health clinics in Scotland. Here, men praised the support that they got from each other and valued the ability to talk to other men on a similar programme.

In addition, a 34-year-old participant in the study by Harrison[191] was surprised at how supportive his work colleagues were of him taking part in the Health of Men work-based programme, something he had not expected. Nevertheless, the study by Morgan and colleagues[89] found that men undertaking an individually based weight management programme that was internet based would have preferred more contact with the instructor as opposed to peer support, but no participant quotes were provided to support this assertion. However, it is difficult to know how generalisable this finding is to interventions not delivered over the internet.

Indeed, the study by Leishman[193] emphasised the importance of support offered by health professionals delivering weight management interventions to help men to stay confident about their ability to lose weight and to stay motivated to do so. Leishman[193] argued that men should be encouraged to focus less on ideal body weight, which if using the BMI classification would involve losing large (and unrealistic) amounts of weight. Leishman[193] argued that this would be unachievable for many men and instead recommended that men should be directed towards smaller, more realistic weight-loss goals of 5–10%, which still have many direct health benefits and seem more achievable.

Other authors suggested that group-based programmes can be logistically difficult with regard to scheduling meetings and are therefore impractical for time-poor men who already consider time a barrier to engagement with physical activity.[190]

Although our quantitative data[85,86,90,95,96] supported the assertion that group-based programmes produce beneficial results (see *Chapter 3*), men may be less inclined to join these types of programmes depending

on their perception of the weight-loss provider, setting or gender mix.[100] Group-based weight management programmes have been stated to produce more weight loss than individual programmes, even for those who expressed a preference for individual treatment.[121,214] Leishman's study[193] linked to the group-based Camelon programme delivered in a Scottish health-care setting[147] noted that factors such as group competitiveness and team spirit can motivate men to meet their goals, whereas the potential for group camaraderie to facilitate the sharing of information, tips and humorous banter can help men to meet weight-loss targets and reduce attrition.[215]

Promoting engagement and the use of humour

In *Engagement with weight management programmes*, describing the importance of location and setting as a 'hook' to engage men, the role of humour in attracting men to programmes was mentioned. The included studies also found that humour and banter had a valuable function in building positive relationships between group members and promoting adherence to a programme once engaged. For example, a participant quoted in the study by Gray and colleagues[142] (linked to the group-based Camelon programme delivered to men in health clinics in Scotland) explained how the camaraderie and enjoyable conversation in the group made men want to come back the following week. Similarly, a participant in the study by Leishman[193] enjoyed and was helped by the atmosphere, laughter and support from men who were all there for the same reason.

Of the non-intervention studies, Gillon[196] confirmed that humour was used by men when discussing issues related to weight and was often useful. One participant's quote discussed how being a rugby player in his youth and being very active had helped him maintain a steady body weight, despite the fact that he tended to eat lots.

The experience of a team atmosphere, with men in similar situations attempting to achieve similar goals, was also found to play a part in the perception that group-based programmes were preferred. This connects with the earlier discussion in which we identified the value of employing cohesive, task-oriented groups for men engaging in a process of weight management. For example, a participant in a study that was linked to the Camelon programme delivered to men in groups in a health clinic setting perceived that being with men who were in the same situation as himself made him realise that he was not alone.[142]

In addition, the importance of sharing commonalities (i.e. being a rugby fan and being overweight) with fellow participants was also valued by a participant in the group-based programme at a rugby club described in the study by Witty and White.[149]

However, in our quantitative review of UK studies, half of the men (10/20, 50%) attending the Bloke's Weigh programme[147] stated that they would have attended a mixed-gender programme and in the Leeds Rhinos study[139] the male-only environment was the least important reason for joining the programme (see *Chapter 4*).

Nevertheless, a participant in the study by Morgan and colleagues[189] explained that the male-only feature of the SHED-IT programme was important in that it helped to facilitate engagement in male-oriented banter that for him would have been curtailed in a mixed-sex environment.

Several authors offered views on why they believed that interventions for men should be different from those for women; however, these assertions were unsupported by participant quotes. For example, Gray and colleagues[142] argue in their study linked to the Camelon programme that the association between femininity and dieting may act as a major barrier for men:

> *However, the current evaluation suggests that the perceived focus on the 'feminine domain' of dieting within the commercial sector may also act as a significant barrier to men*
>
> *p. 78*

Mallyon and colleagues[188] also contended in their study linked to an individually delivered intervention in Australia that male weight management programmes should be framed in such a way that they do not threaten masculine identities, but also conceded that more research in this area was required.

Scientific appeal

Mallyon and colleagues[188] suggested that it might be possible to enhance the attractiveness of weight management programmes for men by emphasising their scientific appeal. This, they contended, can help to draw attention away from associations of dieting with feminine weakness. Furthermore, Mallyon and colleagues[188] stated that emphasis on the scientific nature of a weight management programme can empower dieting men to resist social sabotage by (often well-meaning) friends and family if they try and entice them to eat like a real man.

Accountability and adherence

Adherence is a decisive factor in predicting success for participants undertaking weight management programmes.[216] With this in mind, the included studies detailed various methods to help participants stick to the programmes in terms of being accountable to oneself and having to account for food choices to others within the programmes. One such method involved creating ways to promote self-monitoring and accountability for participants. For example, the study by Abildso and colleagues,[190] which was linked to a group-based insurance-sponsored weight management scheme delivered in the USA, encouraged participants to use a daily food log that was checked by programme staff. The accountability that came with staff reviewing the food logs was stated to be central to successful participant weight loss, and statistical analyses revealed that these food logs were more frequently completed by those who lost a large amount of weight than by those who lost a moderate amount of weight. The following participant extract supports this:

> *What really helped me was having somebody go over the food log every day. That was the big thing; just having staff talk about things I was eating, choices I was making, maybe making a few little suggestions – that was really very helpful.*
>
> *No individual characteristics provided, p. 286*[190]

Accountability for one's own actions whilst undertaking a weight-loss programme was also a factor that promoted adherence in the study linked to the SHED-IT website-based programme delivered in Australia.[189] Men felt accountable by keeping track through the weekly weigh-ins.

Morgan and colleagues[189] also reported a similar approach to awareness and self-monitoring of food intake to promote adherence. As outlined in *Chapter 3*, participants were randomised to either a weight-loss information-only group or to a group who received weight-loss information, use of a weight-loss website and individualised support from programme staff. Both groups received a weight-loss handbook that detailed a simple energy in/energy out equation, allowing participants to keep a record of their energy intake balance. Morgan and colleagues[189] stated that this was mentioned as a source of satisfaction and acted as a mechanism that participants used to control their weight. With this in mind, sticking to the mathematical equation was found to aid initial weight loss, which facilitated further adherence. For example, a 43-year-old man was quoted as noticing that his energy count was directly related to weight, with this knowledge acting as a motivating factor. Similarly, two younger participants preferred the regular counting routines in contrast to less concrete aspects of support. The 21-year old had used some support early on to get going and the 19-year-old seemed to prefer the calorie counting and spoke quite derogatively about the ineffective support.

That men welcome simple, fact-based instruction as part of their weight-loss programme is supported by the reported preferences of men who participated in focus groups during the intervention development stage of the trial conducted by Patrick and colleagues[90] (see *Chapter 3*).

The internet users in the programme reported by Morgan and colleagues[89] were also asked to submit food (and exercise) logs to receive feedback from programme staff, in a similar approach to that successfully employed in the study by Abildso and colleagues.[190] One man was quoted as saying that the website format alone was sufficient to maintain adherence and self-discipline. He described how he did not need or want someone telling him what to do; he had the knowledge and the website provided him with accountability.[89] This acknowledges the intrinsic motivation that is required to engage in such programmes.

In the Nutracheck study[154] (see *Chapter 4*) men made more frequent diary entries than women, suggesting that they prefer this type of self-monitoring activity. However, in the study by Morgan and colleagues,[89] non-compliers found that keeping a food diary was overly time-consuming and thus operated as a barrier to successful adherence:

> *It was just constantly having to get to a computer everyday and spend 10/20 min on there trying to plug in everything I ate was a bit tough*
>
> *No individual characteristics provided*[89]

A further complaint of non-adherers to this internet programme pertained to a lack of face-to-face contact with programme staff, which was stated to act as a barrier to adherence. Certain participants felt that small group meetings or lectures would have given a more human touch to the project, facilitated peer support and helped maintain focus and motivation.

Goal setting

A further way in which participants were encouraged to stick to programmes was by setting weight-loss goals. For example, a participant in the study by White and colleagues[49] linked to the Health of Men group-based programme delivered in the workplace described how setting easy weight-loss goals and anticipating the satisfaction of achieving the 1- or 2-stone weight loss 1 year later helped his adherence and motivation. However, this quote also highlights that there may be a mismatch between participants' expectations about goals and the targets that are found in the weight-loss literature. The published literature suggests goal-setting targets that are much lower than the targets stated by individuals wishing to lose weight. For example, the quantitative systematic reviews in this report have demonstrated that weight loss of 2 stone (13 kg) after 1 year was rarely achieved (see *Chapters 3* and *4*).

Other studies described the use of innovative methods to demonstrate achieved weight loss to men and to help men stick to a weight management programme. The study by Gray and colleagues[142] linked to the group-based Camelon programme delivered in Scotland explained how sandbags were used to give men tangible physical evidence of their weight loss at the midway point of the programme. A participant in the study by Leishman[193] (which also investigated men's experiences of the Camelon programme) explained how proud he was when he held the bag of sand and its weight and the motivational effect that this had on him at the half-way stage of the programme.

Mallyon and colleagues[188] examined before and after body scans of men who participated in their trial. The ability of men to compare scan images showing differences in body shape/weight was stated to help them stick to the diet and to be a motivational factor for losing weight.

The impact and consequences of weight-loss programmes

Several studies included data from participants reflecting retrospectively on their participation in weight management programmes and the consequences of participating. These reflections centred on the following issues: how programmes impact on partners and family members, the downside for men of losing weight, improvements in health and fears of relapse when programmes end.

How programmes impact on partners and family members

Within the included studies there were many reported reflections on how aspects of programme activities indirectly impacted on the family members of participants. For example, the Camelon group-based programme delivered in men's health clinics in Scotland[142,193] appeared to have a positive impact on the partners/family of participants. To investigate indirect effects of the programme on female partners, Gray and colleagues[142] conducted a focus group with female partners of men taking part in the programme. This focus group research indicated that many of the female partners had been influenced by the men's engagement with the programme. Indeed, some women had followed the programme alongside their male partner, whereas others stated that their family (including children) were snacking less, taking more exercise and eating more fruit and vegetables. Some women observed that their male partner's involvement in the Camelon programme had made them think more about what they were eating.[142]

In addition, a participant in the study by Leishman[193] suggested that the Camelon programme had a positive influence on both his own and his female partner's eating habits, for example they ate smaller portions and fewer unhealthy snacks. Similar indirect effects on close family members of the SHED-IT website programme were found in the study by Morgan and colleagues,[189] who described a 36-year-old speaking of his whole family now eating healthier home-cooked food and fewer takeaway meals. A 40-year-old man referred to his wife walking every morning, something she did not do before he got involved in the SHED-IT programme.

A further effect of weight management programmes on partners and family members was observed in the study by Gallagher and colleagues[187] that was linked to a group-based intervention in Australia. It was inferred that nutritional knowledge gained by men through undertaking a weight management programme can be passed on to their children. This was supported by a quote from a man who stated that he was actively teaching his 13-year-old son the right things to eat so that he could make informed choices regarding his weight.

The downside for men of losing weight

Gray and colleagues[142] found that men attending the Camelon group-based programme felt dissatisfied with their weight only when they were labelled as obese, for example one 15-stone man was quoted as saying that if he lost too much weight he would probably start looking ill. This sentiment regarding weight loss was found to be universal amongst the men interviewed by Gray and colleagues,[142] meaning that, for these men, being in the overweight range represented an ideal weight and they did not want to become too thin.

In a second-order construct, Gray and colleagues[142] suggested that this phenomenon arises from social norms with regard to the construction of the ideal male. This dictates that men should be bigger and stronger than women, referring to the ideal male bodybuilder's body. They concluded that such ideal overweight body images may render health promotion interventions to lose weight ineffective.

With regard to the non-intervention studies the study by Gough and Flanders,[197] which conducted research with men who were active members of the gay 'bear' community, confirmed the view that losing too much weight can result in a perceived unhealthy appearance. A 37-year-old man explained that losing weight as a gay man could be associated with being human immunodeficiency virus positive. When he lost weight he felt uncomfortable, lost confidence and stopped going out to meet people and he recalled how losing weight made him feel unhappy and lonely. Furthermore, Gough and Flanders[197] quoted a 44-year-old man who did not want to adhere to a perfect BMI because:

> *I want to be around 16 stone, my GP wants me to be 12.5 stone, if I was 12.5 stone, I'd look like I'd been incinerated, something out of Jason and the Argonauts, like the skeletons walking around*
>
> *p. 248*[197]

These statements suggest that men from a range of backgrounds are keen to avoid looking too thin. The study by De Souza and Ciclitira[195] also found that gay men may be put off losing too much weight in case it threatens their relationship with their partner. In addition, Monaghan[199] noted in his field diary that some men expressed anxieties about the potential adverse health impacts of rapid weight loss and crash diets, with some agreeing that men need to lose weight gradually to give their bodies a chance to adapt and to stabilise the effects on the heart, kidneys and muscles.

Improvements in health

The studies by Abildso and colleagues[190] (linked to a group-based insurance-sponsored weight management scheme delivered in the USA) and Hunt and colleagues[46] (linked to the group-based FFIT trial delivered at the stadiums of Scottish football clubs) reported that many participants experienced benefits to health beyond weight loss after participating in the programmes. Examples of such health benefits included improved sleep, decreased pain, improved blood pressure, improved cholesterol levels, loss of leg neuralgia and a decrease in headaches associated with coming off some of the medications taken for conditions related to obesity.[46,190]

In addition, there were accounts of how physical fitness had improved as a consequence of a weight-loss programme, with positive consequences for health, with some being quoted as having a more positive mindset, feeling younger or being able to walk up stairs again.[46] Feelings of subjective well-being induced by greater fitness levels were also found in the study by Harrison,[191] who quoted men who were proud of their physical achievements in the gym.

These accounts of improved perceptions of health and well-being are positively reinforcing for both adhering to the programme and sustaining behaviour change after the programme has ended. They illustrate the sense of achievement and motivation resulting from success.

Fears of relapse when programmes end

The study by White and colleagues,[49] which was linked to a workplace-based weight management programme delivered in England in a group format, described how concern was expressed that the group might gradually stop meeting after the programme ended, which would perhaps impact on adherence to the messages of the programme after it ended. In particular, a participant expressed doubts about group members continuing to walk without the group support, in the context of busy working lives. Three- to 6-monthly group reunions were seen as a good idea to review progress. Popping into a group to be weighed or have blood pressure checked was perceived as more likely.[49]

This notion that some men would like to continue meeting up with their group after the programme had finished is mentioned further in the study by White and colleagues.[49] A Health of Men support worker expressed surprise and noted that men had initiated a poster on a board to document participants' weights, with continued regular weighing perceived as important, particularly if the men did not have scales at home. Sustained access to equipment and a dietitian were also considered important; however, concern was expressed about the lack of capacity to sustain ongoing weekly meetings.

The need for more sustained interventions was therefore evident, but this received little attention in the studies that we identified.

Conclusions

The key findings from this chapter are detailed in the following sections.

Social, cultural and environmental influences on obesity in men

1. Men made very little reference to wider social determinants of their behaviour and instead focused on their motivation and own agency to overcome (or attempt to overcome) those secular macro-level changes that have encouraged the overconsumption of energy-dense foods and constrained or reduced opportunities to be physically active.
2. The role that the environment plays in influencing behaviours helped some researchers decide where to locate the delivery of weight management programmes. For example, the programme described by Harrison[191] and White and colleagues[49] was located in the workplace, with the rationale that it was more convenient to access than a programme in a non-workplace setting.
3. The importance of the theme of sociostructural determinants of obesity in contrast to the obesity as individual responsibility standpoint is supported in four of the studies not linked to weight management interventions.

Engagement with weight management programmes

1. The main reasons that men gave as their primary motivation for losing weight were a diagnosis of obesity, health scares, particularly if hospitalisation was involved, and a desire to improve personal appearance.
2. From the participant data available we did not establish whether or not male-only weight-loss environments were more attractive to men. Data were presented that did indicate that men felt more comfortable in these settings; however, we also observed that a male-only setting was not consistently considered to be an issue that would attract men to participate.
3. The use of humour in promotional materials for weight management programmes (e.g. comical language and imagery, such as a picture of a beer glass) attracted men. In addition, the knowledge that programmes had been successful for other men increased the likelihood that men would participate.
4. Men were reluctant to undertake any forms of strict dieting as part of a weight management programme.
5. Men appeared to prefer community or workplace settings for interventions over hospital or other health-care settings.
6. The pivotal role of female partners emerged as an important aspect of successful weight-loss attempts.
7. Motivation to stick to a programme may diminish if family members and male peers who are not dieting respond in a negative way to men who diet.
8. The included qualitative studies contained very little information on the views of men on physical activity. However, the data indicated that the use of pedometers appeared to act as a key motivator for men. In particular, pedometers appeared to be useful in encouraging men to meet prespecified individualised activity targets.

The weight management programme

1. Group-based weight management programmes were found to facilitate peer or social support amongst people with similar health problems, despite the fact that some men were initially reluctant to take part in a group programme.
2. However, group-based programmes can be logistically difficult with regard to scheduling meetings and therefore impractical for time-poor men who already consider time a barrier to engagement with physical activity.[190]
3. The included studies found that humour, banter and camaraderie had a valuable function in building positive relationships between group members and promoting adherence to programmes once engaged.
4. Men found that being accountable to themselves and having to account for food choices to others within the programme facilitated adherence.

5. A further way in which participants were encouraged to stick to programmes was by setting weight-loss goals.

The impact and consequences of weight-loss programmes

1. The weight management activities of men were found to have had an indirectly positive impact on family members in terms of improved nutrition and increased physical activity levels.
2. Men from a range of backgrounds were keen to avoid looking too thin.
3. Men experienced benefits to health beyond weight loss after participating in the programmes.
4. In the case of group-based programmes, concern was expressed that groups may gradually stop meeting after the programmes ended and this might impact negatively on adherence to the messages of the programmes. The need for more sustained interventions was evident.

What is missing from the qualitative data?

1. Experiences and perspectives of men from black or ethnic minority backgrounds, low-income or unemployed men and rural and/or remote-dwelling men.
2. Although we have a little insight into gay men's perspectives and experiences of weight-loss attempts from the non-intervention studies, these insights are missing from the intervention literature.
3. Qualitative studies that target mixed samples of men and women need to make gender evident in the reporting of data to provide a clearer gender picture in relation to the results.

Quality assessment of qualitative studies linked to interventions

Our quality assessment covered the following five items: aims and methods, sample details, reflexivity, ethics and general criteria.

Aims and methods

Seven studies[45,87,141,148,186,188,189] stated an explicit aim of the research with one stating a research objective.[49] Another stated both an explicit aim and an objective,[194] whereas four studies[188,191–193] did not state any explicit aim (or objective). In addition, just two studies[188,189] stated explicit research questions in the text and only three[188,192,194] were clear about the theoretical perspective underpinning the research. In terms of describing the theoretical perspective underpinning the intervention that the qualitative study was linked to, three studies[46,89,192] provided this information. All studies provided an account of the qualitative methods that were used to gather data and all but two studies[191,193] provided in-depth accounts of the chosen procedure for data analysis.

Sample details

Only two studies[149,193] failed to provide a clear statement pertaining to sample size. In terms of sample characteristics, just three[188,189,191] of the male-only studies provided this information. Of the mixed-sample studies, only that by Ogden and Sidhu[194] provided sample characteristics clearly by gender, with those by Abildso and colleagues,[190] Gallagher and colleagues[187] and Kim and colleagues[192] providing sample characteristics but not by gender. In addition, nine[46,89,142,187–190,192,194] of the studies provided a clear description of the sample selection process. Seven[46,89,142,187,189,190,192] of the 13 studies provided clear details of sample inclusion and exclusion criteria.

Reflexivity

Reflexivity is a credibility-adding concept that is central to robust qualitative research. It refers to the qualitative researcher's engagement with self-critique and self-appraisal throughout the research and explains how his or her own experience has or has not influenced the stages of the research process (Koch and Harrington[217] cited in Dowling[218]). We were therefore interested in investigating whether or not

any of the studies linked to interventions made reference to this concept. We found that, despite most of the included studies detailing the ways in which the work was limited, only the study by Morgan and colleagues[189] considered the role that the researchers may have played in influencing the findings. For example, they drew attention to the fact that, as the researchers and research staff conducted the interviews; this may have led to some socially desirable responses from respondents.

Ethics

We further assessed whether or not the studies linked to interventions provided any details regarding ethical issues such as obtaining approval for the study from an institutional ethics board. Only three[191,193,194] of the included studies did not refer to any ethical issues in the text.

General criteria

The final section of the quality assessment investigated more general aspects of quality in the studies linked to interventions. First, we asked whether or not the findings were adequately supported by the data. We found that six studies[49,89,188,189,192,194] stated second-order findings that were unsupported by participant data in the study text. However, it should be noted that this issue may occur because of stringent publication word limits. We further investigated whether or not there was the potential for charisma effects in the research regarding the influence of the study principal investigator or a member of the research team. We suggest that there may have been the potential for such a phenomenon to occur in the studies reporting qualitative data from the SHED-IT internet-based trial from Australia. How the intervention is delivered and the qualitative data are collected may influence how feedback on the programme was reported by certain participants, in that favourable responses may have been given. For example, in the study by Morgan and colleagues[89] the authors state that the men would have preferred more contact with the instructor rather than peer support (p. 147). However, it is unclear whether or not the principal investigator is the actor referred to by the term 'instructor'. This would seem to infer that the instructor has a positive motivational influence on the men, which will most probably affect the ability of the programme to be effectively replicated elsewhere if the same charismatic influence is absent.

Finally, we addressed any other issues relating to the quality of the studies that were not covered by the previous items of the quality appraisal tool. In total, five studies[89,187,189,190,192] had issues that we considered were important when interpreting the data. For example, the studies by Abildso and colleagues[190] and Gallagher and colleagues[187] did not address the possibility that men and women may require different things from a weight-loss programme to successfully lose weight. In addition, the faith-based programme detailed by Kim and colleagues[192] lasted for just 8 weeks, which may have been too short a time. Furthermore, the studies by Morgan and colleagues[89,189] linked to the internet-based SHED-IT trial are limited in that only the most successful participants in terms of losing weight were interviewed. Thus, the data presented suffer from bias as the less successful participants and those who may not have actually liked the programme were not interviewed.

Chapter 7 Discussion

In this chapter we very briefly summarise our findings and current policies and guidelines relating to men's health and obesity before discussing the findings from all of the reviews in detail, following our evidence synthesis logic model (see *Chapter 6*). Our findings should be interpreted with the knowledge that the evidence base, particularly in the UK setting, is currently limited in the quality and number of studies and mainly reflects white, middle-class, middle-aged men. Few UK studies had long-term data available. Our results may not necessarily be applicable to all men. Some of our findings may also be applicable to women, but our reviews were not designed to answer questions on weight-loss programmes for women. We had difficulties retrieving studies and it is possible that the studies that we found had more promising results than those we were not able to access.

Summary of findings and policy implications

There were some consistent findings across the systematic reviews that may help with the formation of policies to increase men's uptake of and continuation with weight-loss programmes. Health issues were important intrinsic (because of increased levels of concern) and extrinsic (prompting advice from others) motivators to engage in programmes and change behaviour. Although health service staff can help motivate change, setting programmes in the health service may be far less attractive than using settings, such as a football stadium, that provide long-term social support and an ambience (e.g. humour and banter) that appeals to men.

Physical activity has more appeal for men than women as a means of weight control (although physical activity on its own is unlikely to result in much weight loss). Dieting, particularly strict dieting, is seen as a feminine activity. Thus, although reducing diets are needed for greater weight loss, strict diets seem unpopular and terms such as 'healthier eating' (which allows for treats such as alcohol) and 'portion control' seem to be more appealing to men.

Men may have particular difficulties perceiving that they or others are overweight or obese, because of the desirability of muscularity and the masculinity of a large body size. Obesity can be conceptualised as a predominantly female issue around image, a viewpoint perhaps reinforced by the greater attendance of women at weight-loss programmes.

A consistent finding was the lack of consultation with men when developing or evaluating interventions, with very little qualitative research, which is surprising as men are under-represented in almost all weight-loss interventions. NICE[3] and SIGN[52] also have not provided specific guidance for men for the prevention and treatment of obesity. However, our data show that, once committed, men are less likely to withdraw from programmes and might experience relatively more weight loss than women. Therefore, a focus only on lack of engagement with programmes can underestimate the benefits of existing programmes.

The need for men's health strategies in member states has been highlighted by a European Commission report,[219] which called for policy, research and practice to be developed specifically for men, whose health may be even more disadvantaged by deprivation. The Republic of Ireland has a national men's health policy, which has increased the focus on men's health and community settings targeting disadvantaged men, but the countries of the UK do not.[220] In the UK the Equality Act 2010[221] (applicable to England, Scotland and Wales) has improved men's health.[222] The introduction of Gender Equality Duty in 2007 placed a legal obligation on the NHS and public bodies to take account of the specific needs of men and women in these countries.[222]

The Men's Health Forum in England and Wales has been given 'strategic partner' status by the Department of Health.[222] The Men's Health Forum in Scotland also works closely with the Scottish

government. For example, in 2005 the Scottish government provided funding to support community-based partnerships in developing Well Men's Services, funding 16 pilots across seven health boards in Scotland, targeting disadvantaged areas.[211] Northern Ireland bases its equality obligations upon Section 75 of the 1998 Northern Ireland Act.[223]

The Men's Health Forum in England and Wales convened a conference about men and weight issues in 2005 with 23 health and social policy researchers. The outcomes of this conference were subsequently published in a book entitled *Hazardous Waist: Tackling Male Weight Problems*.[54] The need to focus on male-sensitive approaches to weight-loss issues was apparent then and was encompassed by the publication of *The HGV Man Manual*,[224] designed in the format of the Haynes car maintenance manuals. However, in the UK, initiatives specifically to help obese men, particularly from disadvantaged groups, lose weight, both within the NHS and outside the NHS, are still relatively few in number, with few evaluations available. The NHS Health Trainer Service aims to promote behaviour change in socially disadvantaged people in England and Wales. The most recent study[225] showed that only 21% of clients were men, although 69% were from the two most deprived quintiles.

The findings from our systematic reviews were limited by the relatively low numbers of included studies. This was especially the case with regard to data from the UK. It is also important to consider that men are not a homogeneous group. We had even fewer data or no data at all on men from deprived, unemployed, ethnic minority, younger age, disabled, gay, bisexual, transgender, rural and other minority groups.

Discussion of the results from the systematic reviews

How are men motivated to lose weight and to participate in weight management programmes?

We found that men were significantly less likely to drop out of weight-loss programmes than women, and there was some evidence to suggest that they might lose relatively more weight than women. Morishko and colleagues[30] undertook a systematic review of predictors of dropout in weight-loss interventions and reported narrative findings that sex was not associated with attrition. However, their review did not focus on RCTs only and there was no statistical synthesis of the results. Our results suggest that men may be harder to engage than women, but then show great commitment, emphasising the need to improve engagement without diminishing commitment.

The evidence from the qualitative studies suggests that middle-aged men were attracted to lose weight once they perceived that they had a problem with their health (particularly a health scare or hospitalisation), and were diagnosed as obese by a health professional or labelled with the term 'obese', and/or their weight was shown to them on a chart by a health professional.[44,187,189,193–195] Feeling unhealthy was also a motivator.[49] These findings could reflect the predominantly white, middle-class and middle-aged men recruited, who were conscious of their mortality, or suffering from some form of chronic condition that they believed, or had been told, might be ameliorated by weight loss. GP referral to a commercial organisation increased the proportion of men taking part compared with self-referral, again suggesting that for some men concerns about their health and health professionals' advice acted as motivators to engage in a weight-loss programme. However, qualitative research in the UK reports that GPs think that obesity management is not within their professional domain, even if patients would like them to take responsibility for their weight problems.[226] Contacts with primary care can provide 'teachable moments',[227] which are opportunities to motivate people to change unhealthy behaviours and opportunities for referral or signposting to available services. 'Teachable moments' might be of particular benefit to men from disadvantaged backgrounds, providing that they are in contact with health services already. Offers of health screening, such as checking cholesterol or blood pressure, including checks provided outside health service premises, may also be a way of engaging with obese men. We also found that 'jolts' from a partner[195] and word of mouth recommendations[193] could also help with motivation to lose weight and engage with services.

Our systematic reviews of trials showed that weight-loss programmes could help with comorbidities in obese men. Programmes with low-fat reducing diets and/or physical activity, with or without behaviour change training, improved erectile dysfunction in men with and without type 2 diabetes[85,110,122] and prevented diabetes,[104] although in type 2 diabetes successful weight loss might increase the risk of osteoporosis.[124] These health benefits could also help motivate men, for example the potential benefit on erectile dysfunction is probably not well known to men. Qualitative research also showed benefits for men, including taking fewer medications, decreased morbidity, increased mobility, such as the ability to tie shoelaces,[190] increased physical fitness[46,191] and improvement in outcomes not traditionally associated with obesity, such as a reduction in headaches.

The desire to improve personal appearance was an important motivator to lose weight in men too, such as the recognition by one man that he was starting to look like his obese father.[189] However, male social norms and expectations about body size mean that men, in contrast to women, may express a desire to gain weight rather than lose it, as a means of living up to bodily ideals emphasising strength and size.[228] The term 'bigorexia' has been used to describe large muscular men who do not wish to look small.[195] It was clear from our review that men from a range of backgrounds were keen to avoid looking too thin.[142] The importance of appearance as a motivator was also evidenced from the very small gay sample. We also found evidence that the so-called gay 'bear' subculture celebrated and encouraged men to take on a large body size.[197]

We found that interventions in community (particularly associated with Premier League football or rugby clubs) or workplace settings were acceptable and attractive to male supporters and preferable to interventions in hospital or health-care settings. The sense of well-being and pleasure associated with attending a football or rugby game contrasts with the anxiety and fear[149] that can be experienced when attending a programme in a health-care setting.[187] Interventions situated in sporting contexts[46,138,149] may provide men with a strong sense of affiliation and belonging, bolstering male identities and masculine social capital. Our interpretation is that associating long-standing loyalty, commitment and pleasure attained from collectively supporting a football team (still predominantly a male activity) while challenging men's lifestyles to encourage behaviour change, such as losing weight, could hypothetically increase the likelihood of 'contagious motivation' amongst fans. The club setting for the programme, with the kudos of club privileges such as access to team coaches, changing facilities and club tops, seems to reinforce a connection between being a club supporter and losing weight, and appears to fit the theory of associative coherence.[229] The motivation for being a long-standing team supporter could either consciously or subconsciously become associated with the motivation to lose weight with fellow team supporters. The National Institute for Health Research-funded FFIT trial is evaluating the long-term weight outcomes in a weight-loss programme delivered through SPL football clubs.[230]

However, the reach of programmes delivered through sporting venues is not clear, both among the club supporters and among obese men generally. Sporting venues may not be the most promising point of contact for the majority of obese men. Workplaces offer another opportunity to engage men[49] and have the potential to influence productivity and absenteeism.[231] Clubs in workplaces and for supporters will not reach those who are unemployed or unable to afford the cost of attending sporting events. Venues that are associated with male identities outside the NHS need to be selected to deliver programmes that could reach and engage these disadvantaged groups, such as barbers, pubs and road service stations.[232,233]

Careful use of humour in promotional materials in weight management programmes, such as comical language and imagery (e.g. a picture of a beer glass[189]), attracted men. However, these should be piloted first as humour has the potential to backfire if issues are seen to be trivialised (Paula Carroll, Men's Health Forum Ireland, 4 December 2012, personal communication).

What makes weight-loss programmes more effective for men?

Reducing diets and alcohol

There was clear evidence from the randomised trials that reducing diets, particularly low-fat reducing diets, were effective for men and were the most important component of any weight-loss intervention. We were unable to establish that the nutrient (such as providing more protein) or calorie content (provided that there is a prescribed calorie deficit) of the reducing diets influenced the amount of weight lost long term by men.[83,87,91,107,113,140,146] Men did not want to undergo strict or extreme diets[142,189,193,195,199] and it may be that using 'healthier eating' terms can be used to promote reducing diets to men.[193] The ability to have some alcohol and food treats was also valued.[89,199] However, intermittent periods of very low-calorie dieting, as required, may be better than regular periods of such dieting.[103]

Men reported valuing the scientific appeal of the energy intake and calorie expenditure equation and liked having the ability to monitor their calorie intake.[188,189]

Physical activity interventions

Men do well if physical activity is part of a weight-loss programme and they may be more likely to respond to such a programme than women.[93,106,109] However, weight loss was better with a reducing diet than with physical activity alone, and better still if both were provided,[91,93,109] although one small trial did not find that a physical activity programme and reducing diet were better than the diet alone.[92] We found very little qualitative data from men themselves on physical activity interventions.

The success of the interventions in football clubs and rugby clubs, with their focus on physical activity, reinforces the importance of this aspect for men's weight-loss programmes. However, pain and comorbidities may be limitations.[202] Men reported that they liked using pedometers.[46,90,187] NICE[234] presently recommends that pedometers are used only as part of a package that includes monitoring, feedback and support to set realistic goals (whereby the number of steps taken is gradually increased). Walking as a means to exercise was not universally liked and some men preferred the gym.[46] A preference for the more technological aspects of diets and physical activity, both in the content of the interventions and in the monitoring processes, was evident.

Helping to change behaviour

There were few RCTs that specifically examined whether or which behaviour change strategies were effective for men; those that did demonstrated improved long-term weight loss and maintenance.[88,101] Descriptions of the interventions were often limited with regard to the techniques used. NICE[235] recommends that interventions at the individual level contain easy steps that can be taken over time such as learning coping strategies, goal setting and sharing these goals, and planning for social situations that might undermine changes. More recently, Greaves and colleagues[236] undertook a systematic review of reviews of intervention components that increased effectiveness for changing diet and levels of physical activity. They found that engaging social support, increased contact frequency and using a cluster of self-regulatory behaviour change techniques (e.g. goal setting, prompting self-monitoring, providing feedback, review of goals) increased effectiveness.

With regard to self-monitoring and feedback, the accountability that came with staff reviewing food logs was stated to be central to successful participant weight loss,[190] and statistical analyses revealed that these food logs were more frequently completed by those who lost a large amount of weight than by those who lost a moderate amount of weight. Morgan and colleagues[189] found that participants liked the accountability of weigh-ins. Computer-linked monitoring was reported to help but also to be time-consuming, with a lack of personal contact.[189] Men may prefer less monitoring than women.[96] Telephone and mail support could be useful.[99]

Goal setting and more sustained interventions were also identified as important for men.[49] Interventions delivered in UK health services were often of short, fixed duration, perhaps reflecting the constrained spending on health care.

Social support within the programme

Group and individual support

In a systematic review of male inclusion in RCTs, Pagoto and colleagues[29] found a trend towards lower representation of men in group (24%) than in individual (29%) or mail/e-mail/internet programmes (34%). The male/female mix of the groups was not specified. We also found that men were considerably under-represented in commercial weight-loss groups when both men and women were eligible to participate.

We found that men do well in groups of men but that individual tailoring of fact-based, simple-to-understand advice or counselling was wanted too.[49,85,90,95,96,142,187] Jeffery and colleagues[86] also found that group monetary contracts were more effective for weight loss than individual monetary contracts for men.

Some men clearly wished to attend a men-only group[142,189] whereas for others this was not considered important.[189,195] It could be deduced that being able to identify with the other individuals attending the programme, rather than just men only, is the issue (although these are more likely to be other men).[191,193] Group-based weight management programmes were found to facilitate peer or social support amongst people with similar health problems, despite the fact that some men were initially reluctant to take part in a group programme.

De Souza and Ciclitira[195] suggested that men were happy to attend mixed slimming classes as they received support and were 'cheered on' by their fellow female slimmers. The authors talked about the 'competitive' aspect of this being attractive to men.

Groups provided camaraderie, and the spontaneous humour and banter was important to men.[46,49,142,149,189,191,193,196] These features are used in the FFIT trial, in which the Facebook page is engaging participants in banter and support (Kate Hunt, University of Glasgow, 6 February 2012, personal communication). Men also reported that being accountable to themselves and having to account for food choices to others within a programme facilitated programme adherence.[190]

There are many factors to consider when designing group-based programmes.[212] Although groups may require fewer resources, group-based programmes can be logistically difficult with regard to scheduling meetings and may therefore be impractical for time-poor men, who already consider time a barrier to engagement with physical activity.[190]

In the case of group-based programmes, concern was expressed that groups may gradually stop meeting after programmes have ended and this may impact negatively on adherence to the messages of the programmes.[49] This anxiety has also been seen with smoking cessation groups (Flora Douglas, University of Aberdeen, 12 March 2013, personal communication). On the other hand, too many weight-loss group sessions may be counterproductive.[101]

Commercial organisations

Commercial weight-loss organisations[36,37,154,157] were effective at producing weight loss in men, producing results that were as good as those in NHS programmes[31,151–153] when delivered in mixed-sex settings. Men are much less likely to enrol in mixed-sex programmes run by these organisations than women,[100] but some men-only groups and websites are available. When interventions were delivered to single-sex groups,[33,34,148,150,156] commercial providers appeared to outperform single-sex NHS services,[142,147] but data were very limited. Referral by GPs to commercial providers can improve the low take-up by men, but

health service programmes appear to be favoured by men, despite the fact that we also found that health service settings appear to provoke fear and anxiety amongst men.[96,100] The comparative effectiveness of NHS and commercial weight-loss programmes for men in the long-term randomised UK trial by Jolly and colleagues[100] was unclear.

Family and friends

In the trials that we reviewed, the effect of support from partners to aid weight loss was inconsistent.[94,112,120] Partners can have a pivotal role in successful weight-loss attempts,[188,193] providing support for those choosing against the expected social norms.[188,192] However, the influence of family members and peers who respond in a negative way can be very detrimental to men's efforts to lose weight. Men reported not wishing to offend mothers and mothers-in-law intent on 'feeding them up'.[188] Gay partners may not be happy with their partners losing weight, which they can perceive as making them more attractive to others.[195] Conflict over attempts to lose weight arose especially when the giving and receiving of food was regarded as a means of maintaining communication and relationships with family members.[237,238] Comments from family and friends on weight, body size or image or programme participation can either motivate or demotivate behaviour change.

There were no family-based interventions that fit any of the inclusion criteria for our reviews, but there was good evidence that men's participation in weight-loss programmes had beneficial effects on the weight of other members of the family.[89,112,121,142,187,193] The Healthy Dads, Healthy Kids study from Australia evaluated the effect of primary school children attending some of the weight-loss sessions intended for adult men.[239] After 6 months men had an impressive weight loss of 7.6 kg (baseline observation carried forward), with a significant improvement in the physical activity levels and dietary intake of their children.

Orlistat

We found that men are less likely than women to do well using orlistat to help long-term weight-loss maintenance.[105] Again, this might reflect men's lesser interest in dieting.

There was some evidence to suggest that orlistat was a cost-effective add-on to lifestyle interventions in male overweight and obese patients, with a greater likelihood of cost-effectiveness if the drug was targeted towards those at greatest risk of diabetes.[164,166] NICE and EMA both recommend the use of orlistat for the treatment of obesity in the UK and Europe respectively. Thresholds of weight loss required to justify continued treatment with the drug differ across the regulatory bodies. The original NICE guidelines[172] recommend continuation of treatment only if subjects achieve 5% weight loss at 3 months and 10% at 6 months. The original[181] and updated[182] EMA criteria are slightly more relaxed than those used by NICE, requiring only a minimum of 5% weight loss at 3 months to justify continuation of treatment.

Innovations

There was some evidence that men found technology and innovations appealing in their weight-loss programmes, for example using sandbags to demonstrate the weight that had been lost[193] or using body scans to show changes in body composition.[188] These tangible props with objective measures to support programmes, for example pedometers, could reduce the need for men to discuss their feelings.

Do men state who they believe to be the best person/persons to deliver the intervention?

We found no clear evidence that the sex or profession of the person delivering the intervention affected men's outcomes. The only evidence came from an economic evaluation of a study from Denmark by Olsen and colleagues,[165] which was not eligible for any of our other reviews. This found that men did better with lifestyle counselling from their GP than with the same number of longer sessions with a dietitian who focused on nutritional counselling. The opposite was the case for women. The sex of the GPs and

dietitians was not given. These results could reflect men's lesser enthusiasm for dieting, rather than the influence of the person providing the counselling.

There is evidence that important differences in training, skills and the personal experience of weight-loss advisors may influence engagement with group-based programmes, although whether advisors were men or women was not examined.[240] In the UK, men appear to be more likely to raise weight problems with primary care nurses than with their GPs.[241]

Research by Dutton and colleagues[242,243] in the USA found that physicians had target BMIs that were significantly lower for obese women than for obese men. Obese women themselves were significantly more likely to endorse unrealistic weight-loss goals than obese men, but female physicians recommended more reasonable goals than male physicians for both male and female patients.

Social, cultural and environmental influences on obesity in men

Normative understandings of masculinity are often associated with risky behaviours (e.g. drinking, smoking, late health care seeking) even after social class is accounted for.[244] Men's reluctance to seek help is often explained through theories of masculinity.[245–247] Theories of masculinity rest on the concept of 'hegemonic' or dominant masculinity[248] and, in debates on health-related help-seeking, hegemonic masculinity is thought to create patterns of behaviour that are based on resisting contact with formal services to emphasise self-sufficiency and robustness. However, the notion of hegemonic masculinity as the dominant force in health-related decision-making has been criticised. Some have suggested that masculinity has become abstracted and consequently divorced from studying the actual practices of men.[249] Masculinity, it is argued, interconnects with other factors such as social class, age and ethnicity[245,246] and, accordingly, from this perspective, it is impossible to pull men out of the social structures in which they are located. Other factors such as social stratification or age are considered more important than gender.[250] One of the theoretical implications of envisaging masculinity as an external pressure is that men are conceptualised as 'slaves' to hegemonic discourses. Unfortunately, this perspective has led to 'men' being constructed as a universal category.[251]

The desire for muscularity could make it harder for men than women to identify that they are overweight.[2] Although BMI tends to be used more than waist circumference in risk prediction and the NHS, waist circumference might be a better measurement for raising awareness of weight issues amongst men, and less susceptible to conflicts over muscularity. There is continuing debate about the health risks of being overweight with a BMI of ≥ 25 kg/m^2 and < 30 kg/m^2 as opposed to being obese with a BMI of ≥ 30 kg/m^2.[15] An evidence synthesis of health risks according to BMI and waist circumference for men and women by age group would be useful to direct policy.

In our qualitative research synthesis men made very little reference to wider social determinants of their behaviour and instead focused on their motivation and own agency to overcome (or attempt to overcome) those secular macro-level changes that had encouraged the overconsumption of energy-dense foods and constrained or reduced opportunities to be physically active. This could reflect the influence of the intrusive health lobby.[44]

We would reiterate the importance of environmental influences on men's weight,[191,194,198,199] as exemplified by the Foresight report.[5] Egger and Swinburn[252] have long drawn attention to the environmental determinants of obesogenic behaviours. More recently, De Vogli and colleagues[253] have found a clear link between economic globalisation, income inequality and BMI in high-income countries.

The role that the environment plays in influencing behaviours helped some researchers to decide where to locate the delivery of weight management programmes. For example, the programme described by Harrison[191] and White and colleagues[49] was located in the workplace, with the rationale that it was more convenient to access than non-workplace settings, thus removing a barrier to engagement.

Finally, the cost of attending exercise facilities or purchasing healthier food is a deterrent to making lifestyle changes.[198,202]

Findings from the systematic review of economic evaluations

The review of cost-effectiveness studies has revealed a real paucity of evidence on the cost-effectiveness of interventions to tackle male obesity. No studies were conducted in a UK setting and there was much heterogeneity across the five studies included in our review, with studies being of variable methodological quality. The evidence suggested that GP counselling may be more cost-effective than dietitian counselling (although more detailed), again suggesting that an emphasis on diet is a turn-off for male participants.[165] It is interesting that this study showed that women tended to do better with the dietitian than their male counterparts. Segal and collegaues[163] investigated a group lifestyle intervention for men but reported only limited data and did not fully describe the intervention evaluated. Evidence suggested that this group intervention was cost-effective. Galani and colleagues[162] conducted a high-quality economic modelling study, showing that a lifestyle intervention was highly cost-effective, although further work would be required to demonstrate the viability of such an intervention in a UK male population. Orlistat was found to be a cost-effective addition to a lifestyle intervention, but only when targeted at those men with greatest risk of developing type 2 diabetes.

Further information is required to generate more specific evidence on the cost-effectiveness of orlistat in a UK context and also which prescribing guidelines (NICE or EMA) offer the greatest patient benefit and value for money to the NHS.

Although the studies included in our review provide information on the potential cost-effectiveness of different interventions for weight loss, the results should be interpreted in light of their variable methodological quality, their relevance to a UK health-care setting, the assumptions regarding maintenance of weight loss over time and the applicability of model inputs to a male subgroup of the population. We conclude that, on the basis of the retrieved literature, there is insufficient evidence available to make clear recommendations regarding the cost-effectiveness of interventions or treatments for male obesity, nor is there any evidence to recommend for or against different treatment strategies for male and female subgroups on the grounds of cost-effectiveness. It is imperative that future clinical studies should be accompanied by high-quality economic evaluations.

Limitations of our research

We had difficulty identifying the evidence bases for the reviews included here. Current indexing by databases makes searching for male-/female-related issues and qualitative research very challenging. Finding unpublished evaluations of UK studies was even more challenging. Thus, it is likely that we will have missed some of the evidence base. Evaluations with more favourable results are more likely to have been found. Only one of the long-term randomised trials[100] came from the UK, so the generalisability of the trial evidence could be limited. Furthermore, no long-term randomised trial provided qualitative and health economic data. In fact, qualitative and quantitative evidence often did not come from the same study. However, the findings were mostly consistent across the randomised trials, non-randomised interventions and qualitative evidence. If resources had allowed we would also have liked to explore the evidence from a systematic review of surveys of men's views on obesity and weight loss.

The evidence base for black or ethnic minority men, men with low incomes or who are unemployed, men living in rural and/or remote areas or men with a gay, bisexual or transgender background was almost completely absent. It will be important to study how programmes can be readily adapted to encompass these groups.

Our reviews focused on weight-loss interventions for men who were obese. Prevention of obesity in men should also be a focus for research and health care.

Other evidence and resources

One previous systematic review by Young and colleagues[56] has examined the effectiveness of male-only weight-loss and maintenance interventions. Included studies were of any duration or study design, and studies with men with comorbidities were excluded. There is little overlap between our reviews and Young's review. Young and colleagues[56] found that younger age, more frequent contact (three or more contacts per month), a prescribed energy restriction and group face-to-face delivery were associated with improved effectiveness. However, older men are more likely to have not been included in their review because of the presence of comorbidities. A systematic review of workplace physical activity interventions for men has also highlighted the need to specifically target men in the development of interventions.[254] Our findings would not disagree with these reviews.

There are resources available to help people to engage men and to design and provide services to help obese men lose weight.[54,224,255–260] These resources emphasise the need for commitment, training and adequate long-term resources for services.

There are also resources available to aid with the conduct and reporting of high-quality randomised trials and economic modelling exercises. Glick and colleagues[261] have published detailed guidelines that provide a step-by-step guide to carrying out pragmatic economic evaluations alongside randomised trials. Perhaps of more relevance to obesity-related conditions is the requirement for high-quality modelling studies projecting disease progress, costs and benefits over a longer time horizon, including the impact on patient health and risk of future obesity-related complications. A series of seven papers published by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) provides guidance on decision-analytical modelling in drug trials,[262–268] and Briggs and colleagues[269] provide a good grounding in and discussion of the methods of decision modelling and should be used to inform best practice methods for conducting cost-effectiveness analyses of obesity-related interventions.

Chapter 8 Conclusions

Implications for health care

1. Weight reduction for men is best achieved and maintained with the combination of a reducing diet, physical activity advice or a physical activity programme and behaviour change techniques (e.g. self-monitoring, goal setting, prompting self-monitoring, providing feedback, review of goals). These key components differ from those for women in that men prefer more factual information on how to lose weight and more emphasis on providing physical activity programmes. Weight-loss programmes can prevent type 2 diabetes and improve cardiovascular risk factors and erectile dysfunction, self-esteem and quality of life in men.
2. For some men the opportunity to attend men-only groups may enhance intervention effectiveness. Individual tailoring and feedback may also be features of more effective services.
3. Weight-loss programmes for men may be better provided in social settings, such as sports clubs and workplaces, which may be more successful at engaging men than health service settings. Innovative means of delivering services are needed for hard-to-reach groups, such as those men who do not see their weight status as a problem, younger men, unemployed men and those living in remote and rural locations.

Recommendations for research

General recommendations

1. Research is needed to examine the effectiveness and cost-effectiveness of new approaches to engaging men with weight-loss services and the best design for those services.
2. Men (and women) are a heterogeneous group. Rigorous methods are needed to test more complex interventions in recognition of the fact that simple interventions testing a few components are unlikely to motivate all men. Men should be consulted on how to optimise engagement and make interventions more user-friendly, and services need to be formally evaluated. The experiences and perspectives of men (and women) who are black and from ethnic minority backgrounds, who are unemployed and on low incomes, who are gay, bisexual and transgender and who are from rural and/or remote locations need to be addressed. Rigorous feasibility studies and piloting with service user input at all stages is required before undertaking definitive RCTs.
3. Health concerns, which may prompt contact with health service staff, motivate men to address their obesity. Research is required to examine the most effective brief interventions delivered at these pivotal health service encounters when an obesity-related diagnosis is made.
4. Although there are many published evaluations of weight-loss interventions, the lack of data on participation and outcome by sex and gender suggests that sex and gender are not considered important issues. It is essential to report these data in weight-loss programmes, including the proportions of disadvantaged and minority group participants.
5. The influence of the sex of providers and gatekeepers on engagement in, and outcomes from, weight-loss services should be examined. In addition, the importance of personal experience of weight problems in those delivering weight management programmes requires exploration.
6. Clearer reporting of all aspects of interventions, including psychological and ecological theories and behaviour change techniques, is needed to develop the evidence base and allow others to replicate interventions.
7. Systematic reviews should examine the quantitative and qualitative evidence base for the management of obesity in women, whose needs will differ from those of men.

8. Research is needed on programmes that aim to tackle more than one health-related behaviour at once (such as harmful drinking and obesity), the implementation of such services and their reach in underserved groups of men.

Quantitative research

1. We found relatively few long-term RCTs and there were even fewer UK studies that provided outcome data for men of more than a few months' follow-up. As was clear from our reviews, men would value longer-term support and there is a need to provide longer-term outcome data (at least 1 year of follow-up). There is also a need to look specifically at ways of enhancing the maintenance of long-term weight loss. The majority of the programmes did not make a distinction between support for the initial weight loss and a different or modified programme to help maintain that weight loss.
2. Although weight loss was the primary aim of the programmes that we reviewed, it is also essential to study the impact of weight-loss programmes, with adequate statistical power, on the prevention and treatment of comorbidities and on quality of life. We recommend that data are collected on cardiovascular risk factors to allow the modelling of impacts on cardiovascular disease, or that the direct effects of weight loss are presented for clinical conditions, for example type 2 diabetes and erectile dysfunction. Our data suggest that weight-loss programmes in the right social setting can improve well-being; thus, quality-of-life data should also be collected.
3. An evidence synthesis of health risks according to BMI and waist circumference by sex and age group is needed to direct policy.
4. Although the written reports of RCTs have improved over time, there is still a need for trials to improve the reporting of methods and reporting of the items recommended by the CONSORT statement (e.g. sequence generation, allocation concealment) and provide the items for the Campbell & Cochrane Equity Methods Group checklist, to assess the impact on disadvantaged groups and the sustainability of interventions. Intervention studies that are not RCTs also need to report these items when relevant. Process evaluations and fidelity checks are needed in trials.
5. Identifying reports of sex-specific studies, or reports in which data are reported separately for men and women, is challenging because of suboptimal indexing in databases. Sex-specific index terms are a feature of the controlled vocabularies of several major databases but they are underutilised. Consistent, reliable indexing is needed to facilitate more efficient literature searching.
6. Identifying studies in a UK setting is problematic. Within electronic databases, indexing with country names could be used more frequently to enable efficient identification of studies set in a particular country.
7. There is no consensus yet on reporting weight-loss results in intervention studies, in which dropouts almost inevitably occur. Providing data for completers only, as was the case in many of the studies reviewed here, will inevitably provide optimistic results. Similarly, using the last observation carried forward for dropouts is also likely to provide results indicating better than actually achieved weight loss. Baseline observation carried forward results are likely to provide the worst case scenario, with the last observation carried forward results between these and the complete case results. Researchers and programme providers should attempt to establish body weight at the end of follow-up, even if only self-reported. Complete case, baseline observation carried forward and last observation carried forward results should be provided to allow comparisons between weight-loss programmes.

Health economics

1. UK cost-effectiveness studies in men are needed.
2. Improvements are needed in the reporting of methods for the estimation of utility weights and the methods used to derive them (e.g. standard gamble, time trade-off, visual analogue scale or discrete choice experiments).
3. Costs (both intervention and subsequent costs of complications) should be reported in detail, with appropriate references, in a manner that would facilitate the theoretical reproduction of the study results.

4. Costs and outcomes should be measured over the appropriate time horizon to include the downstream impact on health service utilisation and quality of life. Best practice decision-analytical methods should be used to model the future impact of weight-loss interventions on disease areas such as diabetes and coronary heart disease. The time horizon of the model should be sufficient to capture all differences between study groups and future costs and outcomes should be discounted to present values using appropriate discount rates relative to the study country.
5. Assumptions used for modelling studies should be clearly defined and highlighted. It should be clear to the reader the assumptions that have been used, especially with regard to maintenance of weight loss and continuation of treatment effect. These assumptions should be comprehensively tested in structural sensitivity analyses.
6. Methods used to model the effect of weight loss on future obesity-related disease should be comprehensively explained, with choices for sources of data clearly outlined and any potential variation explored in deterministic or probabilistic sensitivity analysis.
7. Specifically for interventions relating to men, data inputs for models should be clearly detailed for men. When data for men and women have been assumed and applied to male and female subgroups separately, this should be acknowledged and highlighted as a potential limitation.

Qualitative and mixed-methods research

1. Qualitative research with men is needed to inform all aspects of intervention design, including the identification of new intervention settings, optimal recruitment processes, reasons for attrition and how processes might minimise attrition. Process evaluations of intervention studies are needed to seek feedback on the marketing, content and delivery of interventions and how the macro, meso and micro contexts interact with the intervention.
2. We require a better understanding of the barriers to, and facilitators of, the decision to lose weight and subsequent weight maintenance.
3. Integrating qualitative and quantitative research methods both in systematic reviews and in the design and delivery of complex intervention trials is needed to better understand how men can effectively lose weight and sustain weight loss and how the health service can best deliver services that help them to succeed.
4. There were indications in this research that men may be maintaining relationships with family members by accepting food offerings that may be contraindicated when following a weight-loss/weight-maintenance diet. In addition, given the finding about men's desire for flexibility and treats within weight-loss diets, more research is needed to understand men's personal food systems and values to understand how different groups of men value and act on the different dimensions that have been found to be instrumental in food choice decision-making. Having a better understanding of these issues may help with the design of future interventions that take account of, or help men find ways of dealing with unintended social sabotage that comes from not wanting to offend mothers, mothers-in-law, girlfriends or boyfriends, etc.
5. The feasibility and acceptability of interventions delivered to families should be explored.
6. There is a need to understand the public perceptions of men who are not yet overweight or obese (to the extent that they have taken action on it) or suffering from a weight-related health condition, to understand how men who have not yet 'problematised' obesity and overweight can be engaged in taking action to prevent their weight becoming a problem (i.e. needing medical intervention and incurring costs to the NHS).
7. With regard to qualitative research recommendations associated with qualitative evidence synthesis, in primary research papers there is a need to reduce the instances in papers in which second-order author interpretations are unsupported by first-order evidence. Participant details attached to quotes when reporting qualitative research should provide details of the sex of the respondent.
8. Reports of qualitative research are indexed inadequately in electronic databases. Despite the primary searches for the review of qualitative studies yielding a large number of results, only five studies were found from the databases for this review. Electronic databases need to index qualitative research as a publication type.

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Contributions of authors

Alison Avenell (Chief Investigator and Clinical Chair in Health Services Research) co-ordinated the design of the study, oversaw and co-ordinated all aspects of the study and wrote the first drafts of the background, discussion and conclusion chapters of the report.

Clare Robertson (Research Fellow) reviewed the evidence for clinical effectiveness and wrote the first drafts of the abstract, executive summary and *Chapters 3* and *4* of the report and the first draft of the methods chapter in conjunction with Daryll Archibald.

Daryll Archibald (Research Assistant) reviewed the qualitative evidence and wrote the first draft of *Chapter 6* of the report and the first draft of the methods chapter in conjunction with Clare Robertson.

Flora Douglas (Lecturer) led the supervision of the qualitative systematic review and the development and integration of the systematic review themes.

Pat Hoddinott (Professor of Primary Care) co-supervised the qualitative systematic review and the development and integration of the systematic review themes and led the development of the logic model.

Edwin van Teijlingen (Professor) co-supervised the qualitative systematic review and the development and integration of the systematic review themes.

Dwayne Boyers (Health Economist) reviewed the economic evidence and wrote the first draft of *Chapter 5*.

Fiona Stewart (Information Specialist) developed and ran the search strategies for all systematic reviews and was responsible for obtaining full-text papers and reference management and providing the flow charts from the searches.

Charles Boachie (Statistician) provided statistical advice and wrote the first draft of the statistical results.

Evie Fioratou (Research Fellow) carried out the literature screening for the qualitative systematic review and drafted an initial outline of the qualitative methods section.

David Wilkins, **Tim Street**, **Paula Carroll** and **Colin Fowler** (representatives from the Men's Health Forums covering England and Wales, Scotland and all of Ireland respectively) provided valuable consumer input and advice throughout the study.

All authors assisted in preparing the manuscript and commenting on drafts.

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Appendix 1 Search strategies

Clinical effectiveness searches

Review of men-only randomised controlled trials and review of randomised controlled trials of men and women

MEDLINE (1948 to 18 May 2012), MEDLINE In-Process & Other Non-Indexed Citations (18 May 2012) and EMBASE (1980 to 2012 Week 20)
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"

Cumulative Index to Nursing and Allied Health Literature (1981 to May 2012)

http://search.ebscohost.com

1. (MH "Obesity+")
2. (MH "Abdominal Fat")
3. (MH "Body Mass Index") OR (MH "Body Weight+")
4. TX Obes* n2 morbid*
5. TX Obes* n2 diabet*
6. TX overweight or obes*
7. TX obes* n3 abdom*
8. TX fat n3 abdom*
9. (S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8)
10. (MH "Weight Loss")
11. (MH "Diet, Reducing") OR (MH "Weight Control") OR (MH "Weight Reduction Programs") OR (MH "Diet, Fat-Restricted")
12. TX weight n1 los*
13. TX weight n1 reduc*
14. TX weight n1 maint*
15. TX weight n1 control*
16. TX weight n5 diet
17. TX diet n2 restrict*
18. TX calorie* n3 restrict*
19. TX low n1 calorie
20. (S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19)
21. (MH "Clinical Trials+")
22. PT randomized controlled trial OR PT clinical trial
23. TX trial* or random* or placebo*
24. S21 or S22 or S23
25. S9 and S20 and S24
26. (MH "Animals+")
27. S25 not S26
28. PT pamphlet or letter or comment or commentary or editorial
29. S27 not S28
30. S27 not S28 Limiters – Exclude MEDLINE records; Age Groups: Fetus, Conception to Birth, Infant, Newborn: birth-1 month, Infant: 1–23 months, Child, Preschool: 2–5 years, Child: 6–12 years, Adolescent: 13–18 years
31. S29 not S30 Limiters – Published Date from: 20010101–20121231; Exclude MEDLINE records

PsycINFO (1806 to May 2012)

http://search.ebscohost.com

1. DE "Obesity"
2. DE "Body Weight" OR DE "Overweight" OR DE "Obesity"
3. DE "Body Fat"
4. DE "Body Mass Index"
5. TX Obes* n2 morbid*
6. TX Obes* n2 diabet*
7. TX overweight or obes*
8. TX obes* n3 abdom*
9. TX fat n3 abdom*
10. S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9
11. DE "Weight Loss" OR DE "Weight Control"
12. DE "Dietary Restraint"

13. TX weight n1 los*
14. TX weight n1 reduc*
15. TX weight n1 maint*
16. TX weight n1 control*
17. TX weight n5 diet
18. TX diet n2 restrict*
19. TX calorie* n3 restrict*
20. S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19
21. DE "Clinical Trials"
22. TX trial* or random* or placebo*
23. S21 or S22
24. S10 and S20 and S23 Limiters – Age Groups: Childhood (birth–12 yrs), Neonatal (birth–1 mo), Infancy (2–23 mo), Preschool Age (2–5 yrs), School Age (6–12 yrs), Adolescence (13–17 yrs)
25. (S10 and S20 and S23) NOT S24
26. PZ pamphlet or letter or comment or commentary or editorial
27. S25 not S26 Limiters – Publication Year from: 2001–2012

Cochrane Central Register of Controlled Trials (The Cochrane Library, Issue 5, 2012)

www.thecochranelibrary.com

1. MeSH descriptor Obesity explode tree 3
2. MeSH descriptor Weight Loss, this term only
3. (obesity near/2 (morbid or diabet*)):ti or (obesity near/2 (morbid or diabet*)):ab
4. (overweight or obes*):ti or (overweight or obes*):ab
5. (#1 OR #2 OR #3 OR #4)
6. (#5), from 2001 to 2012

Cochrane Database of Systematic Reviews (The Cochrane Library, Issue 5, 2012)

www.thecochranelibrary.com

1. MeSH descriptor Obesity explode tree 3
2. MeSH descriptor Weight Loss, this term only
3. (obesity near/2 (morbid or diabet*)):ti or (obesity near/2 (morbid or diabet*)):ab
4. (overweight or obes*):ti or (overweight or obes*):ab
5. (#1 OR #2 OR #3 OR #4)
6. (#5), from 2001 to 2012

Database of Abstracts of Reviews of Effects, NHS Economic Evaluation Database and Health Technology Assessment database (May 2012)

Centre for Reviews and Dissemination: www.crd.york.ac.uk

1. MeSH DESCRIPTOR weight loss
2. MeSH DESCRIPTOR obesity
3. MeSH DESCRIPTOR obesity, morbid
4. (obesity adj2 (morbid or diabet*))
5. (overweight or obes*):TI
6. #1 OR #2 OR #3 OR #4 OR #5
7. FROM 2001 TO 2012
8. #6 AND #7

Trials

ClinicalTrials.gov
www.clinicaltrials.gov

CenterWatch
www.centerwatch.com

Controlled Trials
www.controlledtrials.com/mrct

International Clinical Trials Registry
http://apps.who.int/trialsearch/

Review of UK interventions

MEDLINE (1948 to 17 July 2012), MEDLINE In-Process & Other Non-Indexed Citations (17 July 2012) and EMBASE (1980 to 2012 Week 29)
Ovid multifile search: http://shibboleth.ovid.com/

1. *obesity/
2. obesity hypoventilation syndrome/
3. abdominal obesity/ use emez
4. morbid obesity/ use emez
5. diabetic obesity/ use emez
6. obesity, abdominal/ use prmz
7. obesity, morbid/ use prmz
8. (overweight or obes$).ti.
9. (obes$ adj1 (morbid or diabet$ or abdom$ or central)).tw.
10. or/1–9
11. *weight loss/ use prmz
12. *weight reduction/ use emez
13. (weight adj1 (los$ or reduc$ or maint$ or control or manag*)).tw.
14. (reduc$ adj2 (waist adj3 (ratio or circumference))).tw.
15. (reduc$ adj2 (bmi or body mass index)).tw.
16. (obesity adj1 manag*).tw.
17. (anti obesity or antiobesity).tw.
18. or/11–16
19. comparative study/ use prmz
20. follow-up studies/ use prmz
21. time factors/ use prmz
22. Treatment outcome/ use emez
23. major clinical study/ use emez
24. controlled study/ use emez
25. clinical trial/ use emez
26. (chang$ or evaluat$ or reviewed or baseline).tw.
27. ((prospective$ or retrospective$) adj1 (study or studies)).tw.
28. (cohort$ or case series).tw.
29. ((compare$ or compara$) adj1 (study or studies)).tw.
30. or/19–29
31. 10 and 18 and 30

32. limit 31 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)")
33. 31 not 32
34. limit 31 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>)
35. 31 not 34
36. 33 or 35
37. exp animals/ not humans/
38. exp nonhuman/ not human/
39. 37 or 38
40. 36 not 39
41. (letter or editorial or comment or note or review or Video-Audio Media).pt.
42. 40 not 41
43. exp great britain/ use prmz
44. united kingdom/ use emez
45. (united kingdom or uk or britain or scotland or england or wales or northern ireland or british or irish or scottish or welsh or english).tw.
46. (United kingdom or uk or Britain or scotland or England or wales or Ireland or London or Birmingham or Leeds or Glasgow or Sheffield or Bradford or Edinburgh or Liverpool or Manchester or Bristol or Wakefield or Cardiff or Coventry or Nottingham or Leicester or Sunderland or Belfast or Newcastle upon Tyne or Brighton or Hull or Plymouth or Stoke-on-Trent or Wolverhampton or Derby or Swansea or Southampton or Salford or Aberdeen or Westminster or Portsmouth or York or Peterborough or Dundee or Lancaster or Oxford or Newport or Preston or Norwich or Chester or Cambridge or Salisbury or Exeter or Gloucester or Lisburn or Chichester or Winchester or Londonderry or Carlisle or Worcester or Bath or Durham or Lincoln or Hereford or Armagh or Inverness or Stirling or Canterbury or Lichfield or Newry or Ripon or Bangor or Truro or Ely or Wells).ad.
47. (United kingdom or uk or Britain or scotland or England or wales or Ireland or London or Birmingham or Leeds or Glasgow or Sheffield or Bradford or Edinburgh or Liverpool or Manchester or Bristol or Wakefield or Cardiff or Coventry or Nottingham or Leicester or Sunderland or Belfast or Newcastle upon Tyne or Brighton or Hull or Plymouth or Stoke-on-Trent or Wolverhampton or Derby or Swansea or Southampton or Salford or Aberdeen or Westminster or Portsmouth or York or Peterborough or Dundee or Lancaster or Oxford or Newport or Preston or Norwich or Chester or Cambridge or Salisbury or Exeter or Gloucester or Lisburn or Chichester or Winchester or Londonderry or Carlisle or Worcester or Bath or Durham or Lincoln or Hereford or Armagh or Inverness or Stirling or Canterbury or Lichfield or Newry or Ripon or Bangor or Truro or Ely or Wells).in.
48. or/43–47
49. 42 and 48
50. male/
51. (men or male or males).tw.
52. or/50–51
53. 49 and 52
54. (female not male).tw.
55. (women not men).tw.
56. 53 not (54 or 55)

PsycINFO (1806 to July 2012)

http://search.ebscohost.com

1. DE "Obesity"
2. TX Obes* n2 morbid*
3. TX Obes* n2 diabet*
4. TX overweight or obes*
5. TX obes* n3 abdom*
6. TX central n3 obes*
7. S1 or S2 or S3 or S4 or S5 or S6
8. DE "Weight Loss"
9. DE "Weight Control"
10. TX weight n1 los*
11. TX weight n1 reduc*
12. TX weight n1 maint*
13. TX weight n1 control*
14. TX reduc* n2 bmi
15. TX reduc* n2 body mass index
16. TX reduc* n2 waist circumference
17. S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16
18. AF United kingdom or uk or Britain or scotland or England or wales or Ireland or London or Birmingham or Leeds or Glasgow or Sheffield or Bradford or Edinburgh or Liverpool or Manchester or Bristol or Wakefield or Cardiff or Coventry or Nottingham or Leicester or Sunderland or Belfast or Newcastle upon Tyne or Brighton or Hull or Plymouth or Stoke-on-Trent or Wolverhampton or Derby or Swansea or Southampton or Salford or Aberdeen or Westminster or Portsmouth or York or Peterborough or Dundee or Lancaster or Oxford or Newport or Preston or Norwich or Chester or Cambridge or Salisbury or Exeter or Gloucester or Lisburn or Chichester or Winchester or Londonderry or Carlisle or Worcester or Bath or Durham or Lincoln or Hereford or Armagh or Inverness or Stirling or Canterbury or Lichfield or Newry or Ripon or Bangor or Truro or Ely or Wells
19. TX women NOT TX men
20. TX female not TX male
21. (TX child* or TX adolescen*) NOT TX adult*

Social Sciences Citation Index (1970 to July 2012) and Conference Proceedings Citation Index – Social Science & Humanities (1990 to July 2012)

www.webofknowledge.com

1. TS=(obes* or overweight)
2. TS=(obes* near/2 morbid*)
3. TS=(obes* near/2 diabet*)
4. TS=(obes* near/2 central)
5. TS=(obes* near/2 abdom*)
6. #5 OR #4 OR #3 OR #2 OR #1
7. TS=(weight near/1 los*)
8. TS=(weight near/1 reduc*)
9. TS=(weight near/1 maint*)
10. TS=(weight near/1 control*)
11. TS=(weight near/1 manag*)
12. TS=(reduc* near/2 bmi)
13. TS=(reduc* SAME (body mass index))
14. TS=(reduc* SAME (waist circumference))
15. TS= (obesity near/1 manag*)
16. TS=(antiobesity or anti obesity or anti-obesity)

17. #16 OR #15 OR 14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7
18. AD=(United kingdom or uk or Britain or scotland or England or wales or Ireland or London or Birmingham or Leeds or Glasgow or Sheffield or Bradford or Edinburgh or Liverpool or Manchester or Bristol or Wakefield or Cardiff or Coventry or Nottingham or Leicester or Sunderland or Belfast or Newcastle upon Tyne or Brighton or Hull or Plymouth or Stoke-on-Trent or Wolverhampton or Derby or Swansea or Southampton or Salford or Aberdeen or Westminster or Portsmouth or York or Peterborough or Dundee or Lancaster or Oxford or Newport or Preston or Norwich or Chester or Cambridge or Salisbury or Exeter or Gloucester or Lisburn or Chichester or Winchester or Londonderry or Carlisle or Worcester or Bath or Durham or Lincoln or Hereford or Armagh or Inverness or Stirling or Canterbury or Lichfield or Newry or Ripon or Bangor or Truro or Ely or Wells)
19. #6 and #14 and #15
20. TS=(female not male)
21. TS=(women not men)
22. TS=((child* or adolescen* or teenage* or infant*) not adult*)
23. #16 NOT #17
24. #20 NOT #18
25. #21 NOT #19

Review of engagement

MEDLINE (1948 to 25 July 2012), MEDLINE In-Process & Other Non-Indexed Citations (25 July 2012) and EMBASE (1980 to 2012 Week 30)

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

1. *obesity/
2. obesity hypoventilation syndrome/
3. abdominal obesity/ use emez
4. morbid obesity/ use emez
5. diabetic obesity/ use emez
6. obesity, abdominal/ use prmz
7. obesity, morbid/ use prmz
8. (overweight or obes$).ti.
9. (obes$ adj1 (morbid or diabet$ or abdom$ or central)).tw.
10. *weight loss/
11. *weight reduction/ use emez
12. (weight adj1 (los$ or reduc$ or maint$ or control or manag$)).tw.
13. (reduc$ adj2 (waist adj3 (ratio or circumference))).tw.
14. (reduc$ adj2 (bmi or body mass index)).tw.
15. (anti obesity or antiobesity).tw.
16. (obesity adj1 manag$).tw.
17. or/1–16
18. *"patient acceptance of health care"/ or *patient compliance/ or *medication adherence/ or *patient participation/ or exp *patient satisfaction/ or treatment refusal/
19. exp health promotion/
20. exp patient attitude/
21. *patient dropouts/ use prmz
22. exp patient compliance/
23. exp Consumer Participation/
24. (uptake or retention or retain or engag$ or particip$ or motivat$ or encourag$ or attrition or dropout or promot$ or recruit$ or involv$).tw.
25. or/18-24
26. ((male or men?) adj3 (uptake or retention or retain or engag$ or particip$ or motivat$ or encourag$ or attrition or dropout or promot$ or recruit$ or involv$)).tw.

27. ((service$ or program$ or scheme$ or initiative$ or intervention$ or diet$) adj3 ((uptake or retention or retain or engag$ or particip$ or motivat$ or encourag$ or attrition or dropout or promot$ or recruit$ or involv$) adj3 (male or men?))).tw.
28. ((uptake or retention or retain or engag$ or particip$ or motivat$ or encourag$ or attrition or dropout or promot$ or recruit$ or involv$) adj3 (men? or male) adj3 ((obesity adj1 manag$) or (weight adj1 (los$ or reduc$ or maint$ or control or manag$)) or (overweight or obes$))).tw.
29. 25 and 28
30. 17 and 26
31. 17 and 27
32. or/29–31
33. limit 32 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>)
34. 32 not 33
35. limit 32 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)")
36. 32 not 35
37. 34 or 36
38. exp animals/ not humans/
39. 37 not 38
40. (female not male).tw.
41. (women not men).tw.
42. 39 not (40 or 41)

PsycINFO (1806 to July 2012)

http://search.ebscohost.com

1. DE "Obesity"
2. DE "Overweight"
3. DE "Weight Loss"
4. DE "Weight Control"
5. TX Obes* n2 morbid*
6. TX Obes* n2 diabet*
7. TX overweight or obes*
8. TX obes* n3 abdom*
9. TX central n3 obes*
10. TX weight n1 los*
11. TX weight n1 reduc*
12. TX weight n1 maint*
13. TX weight n1 control*
14. TX reduc* n2 bmi
15. TX reduc* n2 body mass index
16. TX reduc* n2 waist circumference
17. TX obesity n1 manag*
18. TX anti#obesity
19. (S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18)
20. DE "Treatment Compliance" OR DE "Client Participation" OR DE "Treatment Barriers" OR DE "Treatment Dropouts" OR DE "Treatment Refusal"
21. DE "Client Attitudes" OR DE "Client Satisfaction"
22. TX (uptake or retention or retain or engag* or particip* or motivat* or encourag* or attrition or dropout* or promot* or recruit* or involv*)
23. S20 or S21 or S22

24. (TX (uptake or retention or retain or engag* or particip* or motivat* or encourag* or attrition or dropout* or promot* or recruit* or involv*)) N3 (TX (male or men#))
25. (TX (uptake or retention or retain or engag* or particip* or motivat* or encourag* or attrition or dropout* or promot* or recruit* or involv*)) N3 (TX (male or men#)) N3 (TX (service* or program* or scheme* or initiative* or intervention* or diet*))
26. (TX (uptake or retention or retain or engag* or particip* or motivat* or encourag* or attrition or dropout* or promot* or recruit* or involv*)) N3 (TX (male or men#)) N3 (S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18)
27. S23 and S26
28. S19 and S25
29. S19 and S24
30. S27 or S28 or S29
31. TX women NOT TX men
32. TX female not TX male
33. S30 NOT S31
34. S33 NOT S32
35. (TX child* or TX adolescen*) NOT TX adult*
36. S34 NOT S35

Cumulative Index to Nursing and Allied Health Literature (1981 to July 2012)

http://search.ebscohost.com

1. (MH "Obesity+")
2. (MH "Body Mass Index") OR (MH "Body Weight+")
3. TX Obes* n2 morbid*
4. TX Obes* n2 diabet*
5. TX overweight or obes*
6. TX obes* n3 abdom*
7. TX fat n3 abdom*
8. (MH "Weight Loss")
9. TX weight n1 los*
10. TX weight n1 reduc*
11. TX weight n1 maint*
12. TX weight n1 control*
13. TX weight n1 manag*
14. TX reduc* n2 bmi
15. TX reduc* n2 body mass index
16. TX reduc* n2 waist circumference
17. TX obesity n1 manag*
18. TX anti#obesity
19. S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18
20. (MH "Patient Compliance+") OR (MH "Treatment Refusal")
21. (MH "Research Dropouts") OR (MH "Patient Dropouts")
22. (MH "Consumer Participation")
23. (MH "Patient Attitudes")
24. TX (uptake or retention or retain or engag* or particip* or motivat* or encourag* or attrition or dropout* or promot* or recruit* or involv*)
25. S20 or S21 or S22 or S23 or S24
26. (TX (uptake or retention or retain or engag* or particip* or motivat* or encourag* or attrition or dropout* or promot* or recruit* or involv*)) N3 (TX (male or men#))

27. (TX (uptake or retention or retain or engag* or particip* or motivat* or encourag* or attrition or dropout* or promot* or recruit* or involv*)) N3 (TX (male or men#)) N3 (TX (service* or program* or scheme* or initiative* or intervention* or diet*))
28. (TX (uptake or retention or retain or engag* or particip* or motivat* or encourag* or attrition or dropout* or promot* or recruit* or involv*)) N3 (TX (male or men#)) N3 S19
29. S25 and S28
30. S19 and S27
31. S19 and S26
32. S29 or S30 or S31
33. TX women NOT TX men
34. TX female not TX male
35. S32 not S33
36. S35 not S34
37. (TX child* or TX adolescen*) NOT TX adult*
38. S36 NOT S37

Applied Social Sciences Index and Abstracts (1987 to July 2012)

http://www.csa.com/

(((uptake or retention or retain or engag* or particip* or motivat* or encourag* or attrition or dropout* or promot* or recruit* or involv*) within 3 (male or males or men or men's)) within 3 ((obes* or overweight or (obes* within 2 control*)) or ((obes* within 2 central) or (obes* within 2 abdom) or (obes* within 2 manag*)) or ((weight within 2 manag*) or (weight within 1 control*) or (weight within 1 los*)) or ((weight within 1 reduc*) or (weight within 1 maint*) or (reduc* within 2 bmi)) or ((reduc* within 2 body mass index) or (reduc* within 5 circumference))))

Or

(((obes* or overweight or (obes* within 2 control*)) or ((obes* within 2 central) or (obes* within 2 abdom) or (obes* within 2 manag*)) or ((weight within 2 manag*) or (weight within 1 control*) or (weight within 1 los*)) or ((weight within 1 reduc*) or (weight within 1 maint*) or (reduc* within 2 bmi)) or ((reduc* within 2 body mass index) or (reduc* within 5 circumference))) And ((uptake or retention or retain or engag* or particip* or motivat* or encourag* or attrition or dropout* or promot* or recruit* or involv*) within 3 (male or males or men or men's)))

Or

(((obes* or overweight or (obes* within 2 control*)) or ((obes* within 2 central) or (obes* within 2 abdom) or (obes* within 2 manag*)) or ((weight within 2 manag*) or (weight within 1 control*) or (weight within 1 los*)) or ((weight within 1 reduc*) or (weight within 1 maint*) or (reduc* within 2 bmi)) or ((reduc* within 2 body mass index) or (reduc* within 5 circumference))) And (((uptake or retention or retain or engag* or particip* or motivat* or encourag* or attrition or dropout* or promot* or recruit* or involv*) within 3 (male or males or men or men's)) within 3 (service* or program* or scheme* or initiative* or intervention* or diet*)))

Review of qualitative evidence

MEDLINE (1948 to 30 July 2012), MEDLINE In-Process & Other Non-Indexed Citations (30 July 2012) and EMBASE (1980 to 2012 Week 31)

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

1. qualitative research/
2. exp questionnaires/ use prmz
3. exp questionnaire/ use oemezd
4. exp interviews as topic/ use prmz
5. exp interview/ use oemezd
6. (qualitative or interview$ or focus group$ or questionnaire$ or survey$).tw.
7. (ethno$ or grounded or thematic or interpretive or narrative or realist$ or meta stud$ or experience?).tw.
8. or/1-7
9. *obesity/
10. obesity hypoventilation syndrome/
11. abdominal obesity/ use oemezd
12. morbid obesity/ use oemezd
13. diabetic obesity/ use oemezd
14. obesity, abdominal/ use prmz
15. obesity, morbid/ use prmz
16. (overweight or obes$).ti.
17. (obes$ adj1 (morbid or diabet$ or abdom$ or central)).tw.
18. or/9–17
19. *weight loss/
20. *weight reduction/ use oemezd
21. (weight adj1 (los$ or reduc$ or maint$ or control or manag$)).tw.
22. (reduc$ adj2 (waist adj3 (ratio or circumference))).tw.
23. (reduc$ adj2 (bmi or body mass index)).tw.
24. anti obesity.tw.
25. (obesity adj1 manag$).tw.
26. or/19–25
27. 8 and 18 and 26
28. limit 27 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)")
29. 27 not 28
30. limit 27 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. 27 not 30
32. 29 or 31
33. (female not male).tw.
34. (women not men).tw.
35. 33 or 34
36. 32 not 35
37. or/19-21,24-25
38. 8 and 37
39. (men or male or males).tw.
40. 38 and 39
41. 36 not 40
42. exp animals/ not humans/
43. remove duplicates from 36

44. limit 43 to yr="2012 -Current"
45. (20111$ or 2012$).ed. use prmz
46. (20114$ or 20115$ or 2012$).em. use oemezd
47. 43 and 45
48. 43 and 46
49. 44 or 47 or 48

Cumulative Index to Nursing and Allied Health Literature (1981 to July 2012)

http://search.ebscohost.com

Search 1:

1. (MH "Obesity") OR (MH "Obesity, Morbid")
2. TX Obes* n2 morbid*
3. TX Obes* n2 diabet*
4. TX overweight or obes*
5. TX obes* n3 abdom*
6. TX central n3 obes*
7. S1 or S2 or S3 or S4 or S5 or S6
8. (MH "Weight Loss")
9. (MH "Weight Control")
10. TX weight n1 los*
11. TX weight n1 reduc*
12. TX weight n1 maint*
13. TX weight n1 control*
14. TX reduc* n2 bmi
15. TX reduc* n2 body mass index
16. TX reduc* n2 waist circumference
17. S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16
18. (MH "Qualitative Studies+")
19. (MH "Interviews+")
20. (MH "Narratives")
21. (MH "Projective Techniques+")
22. (MH "Questionnaires+")
23. (MH "Focus Groups")
24. TX qualitative or interview* or focus group* or questionnaire* or survey* or ethno* or grounded or thematic or interpretive or narrative or realist* or meta stud*
25. S18 or S19 or S20 or S21 or S22 or S23 or S24
26. S7 and S17 and S25
27. TX female not male
28. TX women not men
29. S27 or S28
30. S26 not S29
31. ((MH "Child+") OR (MH "Infant+")) NOT (MH "Adult+")
32. S30 not S31

Search 2:

1. (MH "Qualitative Studies+")
2. (MH "Interviews+")
3. (MH "Narratives")
4. (MH "Projective Techniques+")
5. (MH "Questionnaires+")

6. (MH "Focus Groups")
7. TX qualitative or interview* or focus group* or questionnaire* or survey* or ethno* or grounded or thematic or interpretive or narrative or realist* or meta stud*
8. S1 or S2 or S3 or S4 or S5 or S6 or S7
9. (MH "Weight Loss")
10. (MH "Weight Control")
11. TX weight n1 los*
12. TX weight n1 reduc*
13. TX weight n1 maint*
14. TX weight n1 control*
15. TX weight n1 manag*
16. TX obesity n1 manag*
17. TX anti#obesity
18. S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17
19. TX men or male or males
20. S8 and S18 and S19
21. ((MH "Child+") OR (MH "Infant+")) NOT (MH "Adult+")
22. S20 not S21 Exclude MEDLINE records Published Date from: 19900101-20121231

Social Sciences Citation Index (1970 to July 2012) and Conference Proceedings Citation Index – Social Science & Humanities (1990 to July 2012)

www.webofknowledge.com

Search 1:

1. TS=(obes* or overweight)
2. TS=(obes* near/2 morbid*)
3. TS=(obes* near/2 diabet*)
4. TS=(obes* near/2 central)
5. TS=(obes* near/2 abdom*)
6. #5 OR #4 OR #3 OR #2 OR #1
7. TS=(weight near/1 los*)
8. TS=(weight near/1 reduc*)
9. TS=(weight near/1 maint*)
10. TS=(weight near/1 control*)
11. TS=(reduc* near/2 bmi)
12. TS=(reduc* SAME (body mass index))
13. TS=(reduc* SAME (waist circumference))
14. #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7
15. TS=(qualitative or survey* or questionnaire* or focus group* or interview* or ethno* or grounded theory or interpretive or narrative or realist* or meta stud*)
16. #15 AND #14 AND #6
17. TS=(female not male)
18. TS=(women not men)
19. #18 OR #17
20. #16 not #19
21. TS=((child* or adolescen* or teenage* or infant*) not adult*)
22. #20 not #21

Search 2:

1. TS=(qualitative or survey* or questionnaire* or focus group* or interview* or ethno* or grounded theory or interpretive or narrative or realist* or meta stud*)
2. TS=(weight near/1 los*)
3. TS=(weight near/1 reduc*)
4. TS=(weight near/1 maint*)
5. TS=(weight near/1 control*)
6. TS=(weight near/1 manag*)
7. TS=(anti-obesity or anti obesity or antiobesity)
8. TS=(obesity near/1 manag*)
9. #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2
10. TS=(male or males or men)
11. #10 AND #9 AND #1

PsycINFO (1806 to July 2012)

http://search.ebscohost.com

Search 1:

1. DE "Obesity"
2. TX Obes* n2 morbid*
3. TX Obes* n2 diabet*
4. TX overweight or obes*
5. TX obes* n3 abdom*
6. TX central n3 obes*
7. S6 or S5 or S4 or S3 or S2 or S1
8. DE "Weight Loss"
9. DE "Weight Control"
10. TX weight n1 los*
11. TX weight n1 reduc*
12. TX weight n1 maint*
13. TX weight n1 control*
14. TX reduc* n2 bmi
15. TX reduc* n2 body mass index
16. TX reduc* n2 waist circumference
17. S16 or S15 or S14 or S13 or S12 or S11 or S10 or S9 or S8
18. TX qualitative or interview* or focus group* or questionnaire* or survey* or ethno* or grounded or thematic or interpretive or narrative or realist* or meta stud*
19. DE "Questionnaires" OR DE "Surveys" OR DE "Consumer Surveys" OR DE "Mail Surveys" OR DE "Telephone Surveys" OR DE "Questionnaires" OR DE "General Health Questionnaire" OR DE "Qualitative Research" OR DE "Grounded Theory" OR DE "Ethnography" OR DE "Narratives" OR DE "Projective Techniques" OR DE "Holtzman Inkblot Technique" OR DE "Projective Personality Measures"
20. S19 or S19
21. S7 and S17 and S20
22. TX female NOT TX male
23. TX women NOT TX men
24. S21 not S22
25. S24 not S23
26. (TX child* or TX adolescen*) NOT TX adult*
27. S25 NOT S26

Search 2:

1. DE "Questionnaires" OR DE "Surveys" OR DE "Consumer Surveys" OR DE "Mail Surveys" OR DE "Telephone Surveys" OR DE "Questionnaires" OR DE "General Health Questionnaire" OR DE "Qualitative Research" OR DE "Grounded Theory" OR DE "Ethnography" OR DE "Narratives" OR DE "Projective Techniques" OR DE "Holtzman Inkblot Technique" OR DE "Projective Personality Measures"
2. TX qualitative or interview* or focus group* or questionnaire* or survey* or ethno* or grounded or thematic or interpretive or narrative or realist* or meta stud*
3. S1 or S2
4. DE "Weight Loss"
5. DE "Weight Control"
6. TX weight n1 los*
7. TX weight n1 reduc*
8. TX weight n1 maint*
9. TX weight n1 control*
10. TX weight n1 manag*
11. TX obesity n1 manag*
12. TX anti#obesity
13. S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12
14. TX men or male or males
15. S3 and S13 and S14 Publication Year from: 1990-2012

Education Resources Information Center (1966 to July 2012)

http://search.proquest.com

(((cabs(weight near/1 los*)) OR (cabs(weight near/1 reduc*) or cabs(weight near/1 maint*))) OR (cabs (weight near/1 control*) or cabs(reduc* near/2 bmi))) OR ((cabs(reduc* near/2 body mass index) or cabs (reduc* near/2 waist circumference))) AND (((cabs(obes*)) OR (cabs(overweight) or cabs(obes* near/2 morbid*))) OR (cabs(obes* near/2 diabet*) or cabs(obes* near/2 central))) OR ((cabs(obes* near/2 abdom*) or cabs(fat near/2 abdom)))

Education Resources Information Center (1966 to July 2012)

http://www.csa.com/

((DE=((qualitative research) or (qualitative methods) or interviews) or DE=((cognitive interviews) or (exit interviews) or (fitness for interview)) or DE=((focus group interviews) or (semistructured interviews) or (structured interviews)) or DE=((structured behavioural interviews) or (structured clinical interviews) or (videotaped interviews)) or DE=(questionnaires or (mail surveys) or (multiple choice questionnaires)) or DE=(polls or (exit polls) or (opinion polls)) or DE=(semistructured questionnaires)) or((qualitative or interview* or questionnaire*) or (survey* or ethno* or grounded) or (thematic or interpretive or narrative) or (realist* or (meta stud*)))) and (((weight within 1 los*) or (weight within 1 control*) or (weight within 1 reduc*)) or ((weight within 1 maint*) or (weight within 1 manag*) or (obesity within 1 manag*) or (anti*obesity))) and(men or males or male)
1990–2012

Applied Social Sciences Index and Abstracts (1987 to July 2012)

http://www.csa.com/

Search 1:

1. obes* or overweight
2. ((obes* within 2 morbid*) or (obes* within 2 diabet*) or (obes* within 2 control*)) or ((obes* within 2 central) or (obes* within 2 abdom))
3. #1 or #2
4. ((weight within 1 los*) or (weight within 1 control*) or (weight within 1 reduc*)) or ((weight within 1 maint*) or (reduc* within 2 bmi) or (reduc* within 2 body mass index)) or (reduc* within 5 circumference))
5. (DE=((qualitative research) or (qualitative methods) or interviews) or DE=((cognitive interviews) or (exit interviews) or (fitness for interview)) or DE=((focus group interviews) or (semistructured interviews) or (structured interviews)) or DE=((structured behavioural interviews) or (structured clinical interviews) or (videotaped interviews)) or DE=(questionnaires or (mail surveys) or (multiple choice questionnaires)) or DE=(polls or (exit polls) or (opinion polls)) or DE=(semistructured questionnaires)) or((qualitative or interview* or questionnaire*) or (survey* or ethno* or grounded) or (thematic or interpretive or narrative) or (realist* or (meta stud*)))
6. #3 and #4 and #5

Search 2:

((DE=((qualitative research) or (qualitative methods) or interviews) or DE=((cognitive interviews) or (exit interviews) or (fitness for interview)) or DE=((focus group interviews) or (semistructured interviews) or (structured interviews)) or DE=((structured behavioural interviews) or (structured clinical interviews) or (videotaped interviews)) or DE=(questionnaires or (mail surveys) or (multiple choice questionnaires)) or DE=(polls or (exit polls) or (opinion polls)) or DE=(semistructured questionnaires)) or((qualitative or interview* or questionnaire*) or (survey* or ethno* or grounded) or (thematic or interpretive or narrative) or (realist* or (meta stud*)))) and(((weight within 1 los*) or (weight within 1 control*) or (weight within 1 reduc*)) or ((weight within 1 maint*) or (weight within 1 manag*) or (obesity within 1 manag*) or (anti*obesity))) and(men or males or male)
1990–2012

Anthropology Plus (1957 to July 2012)

http://firstsearch.oclc.org

Search 1:

(kw: overweight or kw: obes*) or (kw: obes* n2 morbid*) or (kw: obes* n2 abdomin*) or (kw: obes* n2 diabet*) or (kw: obes* n2 central) and ((kw: weight n2 los*) or (kw: weight n2 reduc*) or (kw: weight n2 control*))

Search 2:

(kw: weight n2 los*) or (kw: weight n2 reduc*) or (kw: weight n2 control*) or (kw: weight n2 manag*) or (kw: obesity n2 manag*) or (kw: anti and kw: obesity) or (kw: anti-obesity) or (kw: antiobesity)

British Nursing Index (1994 to July 2012)
Ovid multifile search: http://shibboleth.ovid.com/

1. obesity/
2. (overweight or obes$).ti.
3. (obes$ adj1 (morbid or diabet$ or abdom$ or central)).tw.
4. or/1-3
5. research methods/ or "interviews and interviewing"/
6. (qualitative or interview$ or focus group$ or questionnaire$ or survey$).tw.
7. (ethno$ or grounded or thematic or interpretive or narrative or realist$ or meta stud$ or experience$).tw.
8. or/5–7
9. (female not male).tw.
10. (women not men).tw.
11. 9 or 10
12. (child$ or adolescent$ or infant$).tw,hw.
13. 4 and 8
14. 13 not 11
15. 14 not 12

Websites consulted

Picker Institute
http://pickerinstitute.org

Joanna Briggs Institute
www.joannabriggs.edu.au/

Men's Health Forum
www.menshealthforum.org.uk/

Association for the Study of Obesity
www.aso.org.uk/

fatmanslim.com
www.fatmanslim.com

Cost-effectiveness searches

MEDLINE (1946 to 19 January 2012), MEDLINE In-Process & Other Non-Indexed Citations (19 January 2012) and EMBASE (1974 to 2012 Week 02)

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

1. exp "costs and cost analysis"/
2. cost-benefit analysis/
3. quality-adjusted life years/
4. economics,pharmaceutical/
5. exp budgets/
6. exp models, economic/
7. exp decision theory/
8. monte carlo method/

9. markov chains/
10. exp health status indicators/
11. cost$.ti.
12. (cost$ adj2 (effective$ or utilit$ or benefit$ or minimis$)).ab.
13. economic$ model$.tw.
14. (economic$ or pharmacoeconomic$ or pharmaco-economic$).tw.
15. (price$ or pricing).tw.
16. (financial or finance or finances or financed).tw.
17. ((value adj2 money) or monetary).tw.
18. markov$.tw.
19. monte carlo.tw.
20. (decision$ adj2 (tree? or analy$ or model$)).tw.
21. (standard adj1 gamble).tw.
22. trade off.tw.
23. or/1–22
24. *obesity/
25. *overweight/
26. obesity, morbid/ use prmz
27. morbid obesity/ use oemez
28. (obes$ or overweight).tw.
29. weight loss/ use prmz
30. weight reduction/ use oemez
31. (weight adj1 (los$ or reduc$ or maint$ or control or manag$)).tw.
32. (obesity adj1 management).tw.
33. (anti obesity or antiobesity).tw.
34. or/24–32
35. (men or male or males).tw.
36. *obesity/ec
37. *overweight/ec
38. or/36-37
39. (women not men).tw.
40. (female not male).tw.
41. 38 not (39 or 40)
42. 23 and 34 and 35
43. 41 or 42
44. exp animals/ not humans/
45. 43 not 44
46. (rat or rats).tw.
47. 45 not 46
48. limit 47 to ("all infant (birth to 23 months)" or "all child (0 to 18 years)" or "all adult (19 plus 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)")
49. limit 47 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>)
50. 47 not 48
51. 47 not 49
52. 50 or 51
53. limit 52 to yr="2009 -Current"
54. remove duplicates from 53
55. (letter or editorial or comment or note).pt.
56. 54 not 55

NHS Economic Evaluation Database (January 2012)

Centre for Reviews and Dissemination: www.crd.york.ac.uk

1. MeSH DESCRIPTOR Obesity EXPLODE ALL TREES
2. MeSH DESCRIPTOR weight loss
3. MeSH DESCRIPTOR obesity
4. MeSH DESCRIPTOR obesity, morbid
5. (obesity adj2 (morbid or diabet*))
6. (overweight or obes*):TI
7. #2 OR #3 OR #4 OR #5 OR #6
8. IN NHSEED FROM 1990 TO 2012
9. #7 AND #8

Health Management Information Consortium (1979 to November 2011)

http://ovidsp.uk.ovid.com/

1. exp obesity/
2. weight loss/
3. (overweight or obes$).tw.
4. (weight adj1 (los$ or reduc$ or maint$ or control or manag$)).tw.
5. (obesity adj1 management).tw.
6. (anti obesity or antiobesity).tw.
7. or/1-6
8. exp "cost effectiveness"/
9. exp economic evaluation/
10. "cost benefit analysis"/
11. monte carlo methods/
12. cost$.tw.
13. ((value adj2 money) or monetary).tw.
14. quality adjusted life years/
15. economic$ model$.tw.
16. (decision$ adj2 (tree? or analy$ or model$)).tw.
17. (standard adj1 gamble).tw.
18. trade off.tw.
19. or/8–18
20. 7 and 19
21. limit 20 to yr="1990 -Current"
22. (female not male).tw
23. (women not men).tw
24. 21 not (22 or 23)

Cost-Effectiveness Analysis Registry (January 2012)

https://research.tufts-nemc.org/cear4/SearchingtheCEARegistry/SearchtheCEARegistry.aspx

obesity OR weight loss OR overweight

Research Papers in Economics (January 2012)

http://ideas.repec.org/

obesity or overweight or weight loss

List of professional and commercial organisations contacted

Association for the Study of Obesity
Boots Pharmacy
British Dietetic Association
Cambridge Weight Plan
Counterweight
Diet Chef
Dietitians in Obesity Management
fatmanslim
Go Lower
Jenny Craig
LighterLife
Men's Health Forums of England and Wales, Scotland, and Ireland
Motivation
Nestlé
Online Slimming Club
ProHealth*Clinical*
Rosemary Conley
Rotherham Institute for Obesity
Scottish Slimmers
Slimming World
Sure Slim
The Lose-It Coach
Trim Up Shape Down
Weight Care
Weight Medics
Weight Watchers

Appendix 2 Data extraction form (reviews of clinical effectiveness)

Version 2 October 2011

Included in systematic review number

Trial author and date

First author institution

Study ID of any linked reports

Reference Manager number

Extracted by

Checked by

Location/setting

Period of study and duration of follow-up

Method of recruitment and sampling

	Yes	No	Details (include whether single or multicentre, prospective/retrospective, etc.)
RCT design?			
	Yes	No	Details (include whether single or multicentre, prospective/retrospective, etc.)
Quasi-RCT design?			
	Yes	No	Details (include whether single or multicentre, prospective/retrospective, etc.)
Other study design?			
	Yes	No	Details
Pretreatment phase?			
	Yes	No	Details
Subgroup analysis?			
	Yes	No	Details

Groups comparable at baseline?

Participants' general description (e.g. cardiac risk factors, etc.):

Targeted particularly at: men Y/N, diabetics Y/N, impaired glucose tolerance Y/N, impaired fasting glucose Y/N, glycaemia Y/N, hypertensive Y/N, hyperlipidaemia Y/N

Inclusion criteria

Exclusion criteria

Notes

TABLE 40 Details of interventions

	Control group	Treatment 1	Treatment 2	Treatment 3	Treatment 4
Type of intervention					
Individual/group/both					
Couple/family					
Lifestyle/drug/both					
Behaviour change (and underlying theory)					
Description of intervention (include length of meeting, duration, etc.)					
Timing of active intervention					
Duration					
Number of times contacted					
Frequency of contact					
Maximum length of follow-up					
Health professional involvement (role, timing)					
Other details of care					

TABLE 41 Study population baseline characteristics: men (record details for female participants on a separate page)

Baseline characteristics	Control	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Overall
Number of men enrolled						
Number randomised (RCTs only)						
Age (mean/median, SD/range)						
Social class						
Ethnic group						
Smoking status						
Weight (kg)						
Height (m)						
Reported BMI (kg/m^2) (mean/median, SD/range)						
Calculated BMI (kg/m^2)						
Waist circumference (give units)						

TABLE 42 Study population baseline characteristics: men (record details for female participants on a separate page)

Baseline characteristics	Control	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Overall
Total cholesterol (give units)						
LDL cholesterol (give units)						
HDL cholesterol (give units)						
Triglycerides (give units)						
Systolic blood pressure (mmHg)						
Diastolic blood pressure (mmHg)						
HbA_{1c} (%)						
Fasting plasma glucose (give units)						
Erectile dysfunction (specify measure and whether validated or not)						
Quality of life						
Generic (specify measure)						
Disease specific (specify measure)						
Other (specify)						

TABLE 43 Participant flow for weight data only: men (record details for female participants on a separate page)

	Control	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Overall
Number eligible						
Number assigned/selected to each group						
Number withdrawn/lost to follow-up (with reasons)						
Number present for weight at time =						
Number withdrawn/lost to follow-up (with reasons)						
Number present for weight at time =						
Number withdrawn/lost to follow-up (with reasons)						
Number present for weight at time =						
Number withdrawn/lost to follow-up (with reasons)						
Number assessed at end of study, with details						
Number completed at end of study						
% dropout at end of study						
Number dead at end of study						
Period of active intervention						
Maximum period of follow-up						

TABLE 44 Outcomes: men (record details for female participants on a separate page)

Outcome	Statistics	Timing (e.g. 1 year, 18 months, 2 years)	Control (*n*/*N* =)	Treatment 1 (*n*/*N* =)	Treatment 2 (*n*/*N* =)	Treatment 3 (*n*/*N* =)	Treatment 4 (*n*/*N* =)
Weight (kg)							
Height (m)							
BMI (kg/m^2)							
% ideal body weight							
Waist circumference (give units)							
Total cholesterol (give units)							
LDL cholesterol (give units)							
HDL cholesterol (give units)							

TABLE 45 Outcomes: men (record details for female participants on a separate page)

Outcome	Statistics	Timing (e.g. 1 year, 18 months, 2 years)	Control (*n*/*N* =)	Treatment 1 (*n*/*N* =)	Treatment 2 (*n*/*N* =)	Treatment 3 (*n*/*N* =)	Treatment 4 (*n*/*N* =)
Triglycerides (give units)							
Systolic blood pressure (mmHg)							
Diastolic blood pressure (mmHg)							
HbA_{1c} (%)							
Fasting plasma glucose (give units)							
Erectile dysfunction (specify measure and whether validated or not)							

TABLE 46 Outcomes: men (record details for female participants on a separate page)

Outcome	Statistics	Timing (e.g. 1 year, 18 months, 2 years)	Control (*n*/*N* =)	Treatment 1 (*n*/*N* =)	Treatment 2 (*n*/*N* =)	Treatment 3 (*n*/*N* =)	Treatment 4 (*n*/*N* =)
Quality of life							
Generic (specify measure)							
Disease specific (specify measure)							
Other (specify)							
Deaths							
Morbidity							
Adverse events							
Compliance							

TABLE 47 Study population baseline characteristics: women

Baseline characteristics	Control	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Overall
Number of women enrolled						
Number randomised (RCTs only)						
Age (mean/median, SD/range)						
Social class						
Ethnic group						
Smoking status						
Weight (kg)						
Height (m)						
Reported BMI (kg/m^2) (mean/median, SD/range)						
Calculated BMI (kg/m^2)						
Waist circumference (give units)						

TABLE 48 Study population baseline characteristics: women

Baseline characteristics	Control	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Overall
Total cholesterol (give units)						
LDL cholesterol (give units)						
HDL cholesterol (give units)						
Triglycerides (give units)						
Systolic blood pressure (mmHg)						
Diastolic blood pressure (mmHg)						
HbA_{1c} (%)						
Fasting plasma glucose (give units)						
Quality of life						
Generic (specify measure)						
Disease specific (specify measure)						
Other (specify)						

TABLE 49 Participant flow for weight data only: women

Baseline characteristics	Control	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Overall
Number eligible						
Number assigned/selected to each group						
Number withdrawn/lost to follow-up (with reasons)						
Number present for weight at time =						
Number withdrawn/lost to follow-up (with reasons)						
Number present for weight at time =						
Number withdrawn/lost to follow-up (with reasons)						
Number present for weight at time =						
Number withdrawn/lost to follow-up (with reasons)						
Number assessed at end of study, with details						
Number completed at end of study						
% dropout at end of study						
Number dead at end of study						
Period of active intervention						
Maximum period of follow-up						

TABLE 50 Outcomes: women

Outcome	Statistics and who measured	Timing (e.g. 1 year, 18 months, 2 years)	Control (*n*/*N* =)	Treatment 1 (*n*/*N* =)	Treatment 2 (*n*/*N* =)	Treatment 3 (*n*/*N* =)	Treatment 4 (*n*/*N* =)
Weight (kg)							
Height (m)							
BMI (kg/m^2)							
% ideal body weight							
Waist circumference (give units)							
Total cholesterol (give units)							
LDL cholesterol (give units)							
HDL cholesterol (give units)							

TABLE 51 Outcomes: women

Outcome	Statistics and who measured	Timing (e.g. 1 year, 18 months, 2 years)	Control (*n*/*N* =)	Treatment 1 (*n*/*N* =)	Treatment 2 (*n*/*N* =)	Treatment 3 (*n*/*N* =)	Treatment 4 (*n*/*N* =)
Triglycerides (give units)							
Systolic blood pressure (mmHg)							
Diastolic blood pressure (mmHg)							
HbA_{1c} (%)							
Fasting plasma glucose (give units)							

TABLE 52 Outcomes: women

Outcome	Statistics and who measured	Timing (e.g. 1 year, 18 months, 2 years)	Control (*n*/*N* =)	Treatment 1 (*n*/*N* =)	Treatment 2 (*n*/*N* =)	Treatment 3 (*n*/*N* =)	Treatment 4 (*n*/*N* =)
Quality of life							
Generic (specify measure)							
Disease specific (specify measure)							
Other (specify)							
Deaths							
Morbidity							
Adverse events							
Compliance							

TABLE 53 Economic analysis

	Timing (e.g. 1 year, 18 months, 2 years)	Control	Treatment 1	Treatment 2	Treatment 3	Treatment 4
Measure of health benefits used in the economic analysis						
Direct costs						
Indirect costs						
Currency						
Statistical analysis of quantities/costs						
Sensitivity analysis						
Estimated benefits used in the economic evaluation						
Costs results						
Synthesis of costs and benefits						
Authors' conclusions						

TABLE 54 Engagement

	Formally evaluated (Y/N)	Control	Treatment 1	Treatment 2	Treatment 3	Treatment 4
Explicit strategies used to promote recruitment						
Explicit strategies used to promote attendance/ compliance or weight loss						
Explicit strategies used to promote attendance/ compliance/weight maintenance						
Sex of programme facilitator and health-care professionals reported (give details)						
Programme environment						
Use of technology						

Appendix 3 Risk of bias form (review of men-only randomised controlled trials and randomised controlled trials of men and women compared)

RCT quality assessment form, version 1, January 2012

Study ID: Reviewer initials: Date:

Question	Judgement (L = low, U = unclear, H = high) L	U	H	A description that explains how the judgement was reached
Potential for selection bias at trial entry (quality of random allocation concealment)				
1. Was allocation adequately concealed? • Low = good attempt at concealment; method should not allow disclosure of assignment (telephone randomisation, third-party involvement in allocation procedure, etc.) • Unclear = states concealment but no description given • High = concealed (open random numbers tables or quasi-randomised, e.g. day of week, date of birth, alternation) or an attempt at concealment but real chance of disclosure of assignment before formal entry (envelopes without third-party involvement, random numbers table but procedures not described)				
2. Was random sequence generation adequately generated? (selection bias) • Low = adequate, e.g. random numbers table, use of computer random number generator, shuffling cards or envelopes • Unclear = insufficient information to permit judgement of low or high • High = inadequate, e.g. use of alternation, case record numbers, birth dates, date of admission				
Potential for bias around time of treatment or during outcome assessment (blinding) (performance and detection bias)				
3. Were participants 'blind' to treatment status? • Low = action taken to blind participants to treatment likely to be effective (e.g. placebo) • Unclear = blinding stated but no description given • High = attempt at blinding participants to intervention but reason to think it may not have been successful (e.g. placebo smells different), no mention of blinding or not blinded				
4. Were health-care providers 'blind' to treatment status? (performance bias) • Low, unclear or high as in Q3				
5. Were outcome assessors 'blind' to treatment status? (detection bias) • Low, unclear or high as in Q3				
6. Were the groups treated identically other than for the named interventions? (performance bias)				

Question	Judgement (L = low, U = unclear, H = high) L	U	H	A description that explains how the judgement was reached
Incomplete outcome data: potential for selection bias in analysis (attrition bias)				
7. Was there a description of withdrawals, dropouts and those lost to follow-up? • Low = states numbers and reasons for withdrawals, no missing data, missing data balanced across intervention groups, missing data unlikely to impact on important effect size, appropriate imputation methods used • Unclear = states numbers of withdrawals only (no reason given) or insufficient reporting • High = states withdrawals but no number given or not mentioned, missing data unbalanced, missing data likely to be clinically relevant, inappropriate imputation used				
8. Was the analysis on an intention-to-treat basis (or is it possible to do so on available data)? i.e. (A) Are results reported for everyone who entered the trial?, (B) are participants analysed in the groups they were originally allocated to? If low for both, intention-to-treat analysis has been performed				
9. Are reports of the study free of the suggestion of selective outcome reporting? • Low = the study protocol is available and all prespecified outcomes have been reported; or the study protocol is not available but it is clear that the published report includes all of the study's prespecified outcomes and all expected outcomes • Unclear = insufficient information • High = not all of the study's prespecified primary outcomes have been reported; one or more primary outcome is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not prespecified; one or more reported primary outcome was not prespecified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); one or more outcome of interest in the review is reported incompletely so that it cannot be entered in a meta-analysis; the study report fails to include results for a key outcome that would be expected to have been reported for such a study				
10. Was the study apparently free of other bias that could put it at a high risk of bias? (validity, topic/design specific) • Low = appears to be free of other bias • Unclear = insufficient information • High = the study had a potential source of bias relating to the specific study design used; the study stopped early because of some data-dependent process; or the study had an extreme baseline imbalance in any factor that is strongly related to the outcome, etc.				

Appendix 4 Review Body for Interventional Procedures quality assessment form (review of UK interventions and engagement)

Checklist for quality assessment of non-randomised studies (comparative and cohort studies)

Version 1, August 2012

Items specific to comparative studies are in italics

Assessor initial: Date evaluated: Study ID:

Criteria	Yes	No	Unclear	Comments
1. Were participants a representative sample selected from a relevant patient population, e.g. randomly selected from those seeking treatment despite age, duration of disease, primary or secondary disease and severity of disease?				
2. Were the inclusion/exclusion criteria for participants clearly described?				
3. Were participants entering the study at a similar point in their disease progression, i.e. severity of disease?				
4. Was the selection of patients consecutive?				
5. Was data collection undertaken prospectively?				
6. *Were the groups comparable on demographic characteristics and clinical features?*				
7. Was the intervention (and comparison) clearly defined?				
8. Was the intervention undertaken by someone experienced at performing the procedure?[a]				
9. Were the staff, place and facilities where the patients were treated appropriate for performing the procedure? (e.g. access to back-up facilities in hospital or special clinic)				
10. Were any of the important outcomes considered, i.e. weight, clinical effectiveness, cost-effectiveness?				
11. Were objective (valid and reliable) outcome measures used, including satisfaction scale?				
12. *Was the assessment of the main outcomes blind?*				
13. Was follow-up long enough (≥ 1 year) to detect important effects on outcomes of interest?				
14. Was information provided on non-respondents, dropouts?[b]				
15. Did the withdrawals/dropouts have similar characteristics to those of participants who completed the study and were they therefore unlikely to cause bias?[c]				

Criteria	Yes	No	Unclear	Comments
16. *Was the length of follow-up similar between comparison groups?*				
17. Were the important prognostic factors identified, e.g. age, duration of disease, disease severity?[d]				
18. *Were the analyses adjusted for confounding factors?*				

The same form was adapted to assess the quality of case series by removing questions 6, 12, 16 and 18.

a 'Yes' if the practitioner had received training on conducting the procedure or had conducted the same kind of procedure before, i.e. no learning curve.

b 'No' if participants were selected from those whose follow-up records were available (retrospective).

c 'Yes' if no withdrawals/dropouts; 'no' if dropout rate was = 30% or there was differential dropout, e.g. those having the most severe disease died during follow-up but the death was not due to the treatment.

d 'Yes' if two or more than two factors were identified.

Appendix 5 Campbell & Cochrane Equity Methods Group equity checklist (reviews of clinical effectiveness)

Item	Yes	No	Unclear	Not reported	Notes
Equity pointer: social context of the study, e.g. was the study conducted in a particular setting that might target/exclude specific populations?					
Representativeness of sample: are participants in the study likely to be representative of the target population?					
Sociodemographic differences between withdrawals and exclusions?					
PROGRESS categories reported at baseline (indicate letters of those reported: place of residence, race, occupation, gender, religion, education and literacy, socioeconomic status, social capital)					
Did the intervention include strategies to address diversity/disadvantage?					
Was there a fidelity check?					
Were process measures taken?					
Providers (who, number, education/training in intervention delivery, ethnicity, etc., if potentially relevant to acceptance and uptake by participants)					
Was sustainability discussed by the authors? Was it a consideration in study development?					
Do the authors describe any political or organisational context?					
Were any partnerships described?					
Potential for author conflict, i.e. evidence that author or data collectors would benefit if results favoured the intervention under study or the control?					
Were outcomes relating to harms/unintended effects of the intervention described?					

Appendix 6 Statistical methods for the reviews of clinical effectiveness

Introduction

The following provides an equation for deriving the SD for the change in weight from baseline given the absolute value of the mean change in weight from baseline, as used in our previous systematic review.[23]

Method

Summary statistics were provided from a series of trials representing 62 trial–treatment combinations of which four had no data. A linear regression was made of the SD of the mean change on the absolute mean change for weight.

Results

Of the 58 trial–treatment combinations, 43 reported both the mean change and the standard error of the mean change in body weight from baseline to the end of the first treatment phase whereas eight reported only the mean and seven reported neither. The plot of SD by the absolute value of the mean change (*Figure 44*) shows two points for which both the absolute mean and the SD of the mean are close to zero; both were excluded from the linear regression, giving $n = 41$. The linear regression was also repeated with observation 13, which was influential, excluded, to see whether or not the regression coefficients changed (*Table 55*).

Discussion

The results from the two linear regressions were similar. Diagnostic plots (not shown) suggested that the regression could be improved by allowing for the increase in variation of the SD with increasing mean; however, this is unlikely to change the results.

Conclusion

When the mean change in weight from baseline (mean) is known but its SD is unknown then the SD of the mean change can be derived using the following equation:

$$\text{SD in kg} = 5.915 + 0.283 \times \text{absolute (mean) in kg} \quad (1)$$

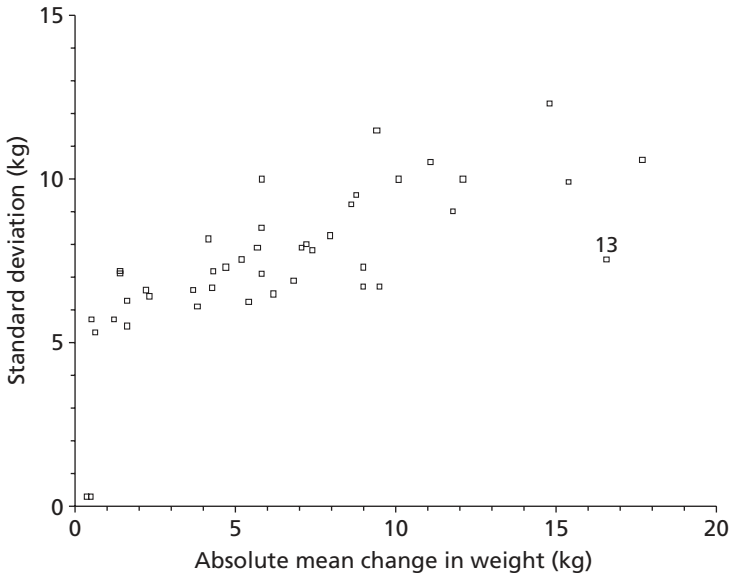

FIGURE 44 Scatterplot of the SD of the mean change in weight by the absolute mean change in weight. Observation 13 is labelled.

TABLE 55 Summary statistics and the equations for the predicted values of the SDs of the two linear regressions

n	R^2			Constant		Slope	
41	53.7%	SD	=	5.915	+	0.283	× abs(mean)
40	63.4%	SD	=	5.694	+	0.328	× abs(mean)

Appendix 7 List of included studies: review of men-only randomised controlled trials

Benassi-Evans 2010

Benassi-Evans B, Clifton PM, Noakes M, Keogh JB, Fenech M. High protein–high red meat versus high carbohydrate weight loss diets do not differ in effect on genome stability and cell death in lymphocytes of overweight men. *Mutagenesis* 2009;**24**:271–7.

Borg 2002

Borg P, Kukkonen-Harjula K, Fogelholm M, Pasanen M. Effects of walking or resistance training on weight loss maintenance in obese, middle-aged men: a randomized trial. *Int J Obes* 2002;**26**:676–83.

Secondary publication

Kukkonen-Harjula KT, Borg PT, Nenonen AM, Fogelholm MG. Effects of a weight maintenance program with or without exercise on the metabolic syndrome: a randomized trial in obese men. *Prev Med* 2005;**41**:784–90.

Esposito 2004

Esposito K, Giugliano F, Di Palo C, Giugliano G, Marfella R, D'Andrea F, *et al.* Effect of lifestyle changes on erectile dysfunction in obese men. *JAMA* 2004;**291**:2978–84.

Jeffery 1983

Jeffery RW, Gerber WM, Rosenthal BS, Lindquist RA. Monetary contracts in weight control: effectiveness of group and individual contracts of varying size. *J Consult Clin Psychol* 1983;**51**:242–8.

Secondary publications

Jeffery RW, Bjornson-Benson WM, Rosenthal BS, Lindquist RA, Johnson SL. Behavioral treatment of obesity with monetary contracting: two-year follow-up. *Addict Behav* 1984;**9**:311–13.

Multiple risk factor intervention trial. Risk factor changes and mortality results. Multiple Risk Factor Intervention Trial Research Group. *JAMA* 1982;**248**:1465–77.

Khoo 2011

Khoo J, Piantadosi C, Duncan R, Worthley SG, Jenkins A, Noakes M, *et al.* Comparing effects of a low-energy diet and a high-protein low-fat diet on sexual and endothelial function, urinary tract symptoms, and inflammation in obese diabetic men. *J Sex Med* 2011;**8**:2868–75.

King 1989

King AC, Frey-Hewitt B, Dreon DM, Wood PD. Diet vs exercise in weight maintenance. The effects of minimal intervention strategies on long-term outcomes in men. *Arch Intern Med* 1989;**149**:2741–6.

Morgan 2011

Morgan PJ, Lubans DR, Collins CE, Warren JM, Callister R. 12-Month outcomes and process evaluation of the SHED-IT RCT: an internet-based weight loss program targeting men. *Obesity* 2011;**19**:142–51.

Patrick 2011

Patrick K, Calfas KJ, Norman GJ, Rosenberg D, Zabinski MF, Sallis JF, *et al.* Outcomes of a 12-month web-based intervention for overweight and obese men. *Ann Behav Med* 2011;**42**:391–401.

Pavlou 1989

Pavlou KN, Krey S, Steffee WP. Exercise as an adjunct to weight loss and maintenance in moderately obese subjects. *Am J Clin Nutr* 1989;**49**:1115–23.

van Aggel-Leijssen 2001

van Aggel-Leijssen DPC, Saris WHM, Hul GB, van Baak MA. Short-term effects of weight loss with or without low-intensity exercise training on fat metabolism in obese men. *Am J Clin Nutr* 2001;**73**:523–31.

Secondary publications

van Aggel-Leijssen DP, Saris WH, Hul GB, van Baak MA. Long-term effects of low-intensity exercise training on fat metabolism in weight-reduced obese men. *Metabolism* 2002;**51**:1003–10.

Lejeune MPGM, van Aggel-Leijssen DPC, van Baak MA, Westerterp-Plantenga MS. Effects of dietary restraint vs exercise during weight maintenance in obese men. *Eur J Clin Nutr* 2003;**57**:1388–44.

Wood 1988

Wood PD, Stefanick ML, Dreon DM, Frey-Hewitt B, Garay SC, Williams PT, *et al.* Changes in plasma lipids and lipoproteins in overweight men during weight loss through dieting as compared with exercise. *N Engl J Med* 1988;**319**:1173–9.

Secondary publication

Fortmann SP, Haskell WL, Wood PD. Effects of weight loss on clinic and ambulatory blood pressure in normotensive men. *Am J Cardiol* 1988;**62**:89–93.

Appendix 8 Detailed quality assessment for individual studies: review of men-only randomised controlled trials

TABLE 56 Risk of bias assessment for individual studies included in the review of men-only RCTs

Item	Benassi-Evans 2009[83]	Borg 2002[84]	Esposito 2004[85]	Jeffrey 1983[86]	King 1989[88a]	Khoo 2011[87]	Morgan 2011[89]	Patrick 2011[90]	Pavlou 1989[91]	van Aggel-Leijssen 2001[92]	Wood 1988[93]
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.
a Continuation of Wood *et al.*[93]

TABLE 57 Equity and sustainability assessment for individual studies included in the review of men-only RCTs

Item	Benassi-Evans 2009[83]	Borg 2002[84]	Esposito 2004[85]	Jeffrey 1983[86]	King 1989[88a]	Khoo 2011[87]	Morgan 2011[89]	Patrick 2011[90]	Pavlou 1989[91]	van Aggel-Leijssen 2001[92]	Wood 1988[93]
Equity pointer: social context of the study, e.g. was the study conducted in a particular setting that might target/exclude specific populations?	?	✗	✗	✓	✗	✗	✓	✓	✗	✗	✗
Representativeness of the sample: are participants in the study likely to be representative of the target population?	✓	✓	✗	?	✗	✓	✗	?	✗	✓	✗
Sociodemographic differences between withdrawals and exclusions?	?	?	?	?	?	✗	?	✓	?	?	?
PROGRESS categories reported at baseline (indicate letters of those reported: place of residence, race, occupation, gender, religion, education and literacy, socioeconomic status, social capital)	✗	✗	?	✓	✗	✗	✓	✓	?	?	✗
Did the intervention include strategies to address diversity/disadvantage?	✗	✗	✗	✗	✗	✗	✗	?	✗	✗	✗
Was there a fidelity check?	✗	✓	✗	✗	✗	✗	✗	✗	✓	✓	✓
Were process measures taken?	✗	✓	✗	✗	✓	✗	✓	✗	✗	✗	✗
Providers (who, number, education/training in intervention delivery, ethnicity, etc. if potentially relevant to acceptance and uptake by participants)	✓	?	✓	?	?	✗	✓	✓	?	✓	✓
Was sustainability discussed by the authors? Was it a consideration in study development?	✗	✗	✗	?	✗	✗	✗	✗	✗	✗	✗

continued

TABLE 57 Equity and sustainability assessment for individual studies included in the review of men-only RCTs (*continued*)

Item	Benassi-Evans 2009[83]	Borg 2002[84]	Esposito 2004[85]	Jeffrey 1983[86]	King 1989[88a]	Khoo 2011[87]	Morgan 2011[89]	Patrick 2011[90]	Pavlou 1989[91]	van Aggel-Leijssen 2001[92]	Wood 1988[93]
Do the authors describe any political or organisational context?	✗	✗	✗	?	✗	✗	✗	✗	✗	✗	✗
Were any partnerships described?	✗	✗	✗	?	✗	✗	✗	✗	✗	✗	✗
Potential for author conflict, i.e. evidence that author or data collectors would benefit if results favoured the intervention under study or the control?	?	?	?	✗	?	✗	✗	✓	?	?	?
Were outcomes relating to harms/unintended effects of the intervention described?	?	✓	?	✗	?	✓	✗	✗	?	✓	?

✓, yes; ✗, no; ?, unclear/not reported.
a Continuation of Wood *et al.*[93]

Appendix 9 List of included studies: review of randomised controlled trials of men and women compared

Gorin 2013

Gorin AA, Raynor HA, Fava J, Maguire K, Robichaud E, Trautvetter J, *et al.* Randomized controlled trial of a comprehensive home environment-focused weight-loss program for adults. *Health Psychol* 2013;**32**:128–37.

Hakala 1993

Hakala P, Karvetti RL, Ronnemaa T. Group vs. individual weight reduction programmes in the treatment of severe obesity – a five year follow-up study. *Int J Obes Relat Metab Disord* 1993;**17**:97–102.

Hakala 1994

Hakala P. Weight reduction programmes at a rehabilitation centre and a health centre based on group counselling and individual support: short- and long-term follow-up study. *Int J Obes* 1994;**18**:483–9.

Heitzmann 1987

Heitzmann CA, Kaplan RM, Wilson DK, Sandler J. Sex differences in weight loss among adults with type II diabetes mellitus. *J Behav Med* 1987;**10**:197–211.

Jeffery 1984

Jeffery RW, Bjornson-Benson WM, Rosenthal BS, Kurth CL, Dunn MM. Effectiveness of monetary contracts with two repayment schedules of weight reduction in men and women from self-referred and population samples. *Behav Ther* 1984;**15**:273–9.

Jeffery 2003

Jeffery RW, Sherwood NE, Brelje K, Pronk NP, Boyle R, Boucher JL, *et al.* Mail and phone interventions for weight loss in a managed-care setting: Weigh-To-Be one-year outcomes. *Int J Obes* 2003;**27**:1584–92.

Jolly 2011

Jolly K, Lewis A, Beach J, Denley J, Adab P, Deeks JJ, *et al.* Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: Lighten Up randomised controlled trial. *BMJ* 2011;**343**:d6500.

Karvetti 1992

Karvetti RL, Hakala P. A seven-year follow-up of a weight reduction programme in Finnish primary health care. *Eur J Clin Nutr* 1992;**46**:743–52.

Korhonen 1987

Korhonen T, Uusitupa M, Aro A, Kumpulainen T, Siitonen O, Voutilainen E, *et al.* Efficacy of dietary instructions in newly diagnosed non-insulin-dependent diabetic patients. Comparison of two different patient education regimens. *Acta Med Scand* 1987;**222**:323–31.

Lantz 2003

Lantz H, Peltonen M, Agren L, Torgerson JS. Intermittent versus on-demand use of a very low calorie diet: a randomized 2-year clinical trial. *J Intern Med* 2003;**253**:463–71.

Lindstrom 2008

Lindstrom J, Peltonen M, Eriksson JG, Aunola S, Hamalainen H, Ilanne PP, *et al.* Determinants for the effectiveness of lifestyle intervention in the Finnish Diabetes Prevention Study. *Diabetes Care* 2008;**31**:857–62.

Richelsen 2007

Richelsen B, Tonstad S, Rossner S, Toubro S, Niskanen L, Madsbad S, *et al.* Effect of orlistat on weight regain and cardiovascular risk factors following a very-low-energy diet in abdominally obese patients: a 3-year randomized, placebo-controlled study. *Diabetes Care* 2007;**30**:27–32.

Ross 2012

Ross R, Lam M, Blair SN, Church TS, Godwin M, Hotz SB, *et al.* Trial of prevention and reduction of obesity through active living in clinical settings: a randomized controlled trial. *Arch Intern Med* 2012;**172**:414–24.

Shai 2008

Shai I, Schwarzfuchs D, Henkin Y, Shahar DR, Witkow S, Greenberg I, *et al.* Weight loss with a low-carbohydrate, Mediterranean, or low-fat diet. *N Engl J Med* 2008;**359**:229–41.

Secondary publication

Golan R, Schwarzfuchs D, Stampfer MJ, Shai I, DIRECT Group. Halo effect of a weight-loss trial on spouses: the DIRECT-Spouse study. *Public Health Nutr* 2010;**13**:544–9.

Vanninen 1992

Vanninen E, Uusitupa M, Siitonen O, Laitinen J, Lansimies E. Habitual physical activity, aerobic capacity and metabolic control in patients with newly-diagnosed type 2 (non-insulin-dependent) diabetes mellitus: effect of 1-year diet and exercise intervention. *Diabetologia* 1992;**35**:340–6.

Secondary publication

Vanninen E, Uusitupa M, Lansimies E, Siitonen O, Laitinen J. Effect of metabolic control on autonomic function in obese patients with newly diagnosed Type 2 diabetes. *Diabet Med* 1993;**10**:66–73.

Volpe 2008

Volpe SL, Kobusingye H, Bailur S, Stanck E. Effect of diet and exercise on body composition, energy intake and leptin levels in overweight women and men. *J Am Coll Nutr* 2008;**27**:195–208.

Wadden 2011

Wadden TA, Neiberg RH, Wing RR, Clark JM, Delahanty LM, Hill JO, *et al.* Four-year weight losses in the Look AHEAD study: factors associated with long-term success. *Obesity* 2011;**19**:1987–98.

Secondary publications

Gorin AA, Wing RR, Fava JL, Jakicic JM, Jeffery R, West DS, *et al.* Weight loss treatment influences untreated spouses and the home environment: evidence of a ripple effect. *Int J Obes* 2008;**32**:1678–84.

Schwartz AV, Johnson KC, Kahn SE, Shepherd JA, Nevitt MC, Peters AL, *et al.* Effect of 1 year of an intentional weight loss intervention on bone mineral density in type 2 diabetes: results from the Look AHEAD randomized trial. *J Bone Miner Res* 2012;**27**:619–27.

Stewart TM, Bachand AR, Han H, Ryan DH, Bray GA, Williamson DA. Body image changes associated with participation in an intensive lifestyle weight loss intervention. *Obesity* 2011;**19**:1290–5.

Wing RR, Rosen RC, Fava JL, Bahnson J, Brancati F, Gendrano I, *et al.* Effects of weight loss intervention on erectile function in older men with type 2 diabetes in the Look AHEAD trial. *J Sex Med* 2010;**7**:156–65.

West 2008

West DS, Prewitt TE, Bursac Z, Felix HC. Weight loss of black, white, and Hispanic men and women in the Diabetes Prevention Program. *Obesity* 2008;**16**:1413–20.

Wing 1991

Wing RR, Marcus MD, Epstein LH, Jawad A. A 'family-based' approach to the treatment of obese type II diabetic patients. *J Consult Clin Psychol* 1991;**59**:156–62.

Wing 1994

Wing RR, Blair E, Marcus M, Epstein LH, Harvey J. Year-long weight loss treatment for obese patients with type II diabetes: does including an intermittent very-low-calorie diet improve outcome? *Am J Med* 1994;**97**:354–62.

Appendix 10 Detailed risk of bias assessment for individual studies: review of randomised controlled trials of men and women compared

TABLE 58 Risk of bias assessment for individual studies included in the review of RCTs of men and women compared

Item	Gorin 2013[94]	Hakala 1993[95]	Hakala 1994[96]	Heitzmann 1987[97]	Jeffery 1984[98]	Jeffery 2003[99]	Jolly 2011[100]	Karvetti 1992[101]	Korhonen 1987[102]
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.

Lantz 2003[103]	Lindstrom 2008[104]	Richelsen 2007[105]	Ross 2012[106]	Shai 2008[107]	Vannine *n* 1992[108]	Volpe 2008[109]	Wadden 2011[110]	West 2008[111]	Wing 1991[112]	Wing 1994[113]
?	✓	✓	✓	?	?	?	?	?	?	?
?	✓	?	✓	?	?	?	?	?	?	?
✗	✗	✓	✗	✗	✗	✗	✗	✗	✗	✗
✗	✗	?	✗	✗	✗	✗	✗	✗	✗	✗
?	✓	?	?	✓	?	?	?	✓	?	?
✓	✓	✓	✓	✗	✓	✓	✓	✗	✓	✗
?	✓	?	✓	✓	?	?	✓	✗	✓	?
✗	✓	✗	✓	✓	✗	?	✓	✗	✗	✗
✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
?	✓	?	✓	?	✓	✓	✓	✓	?	✓

TABLE 59 Equity and sustainability assessment for individual studies included in the review of RCTs of men and women compared

Item	Gorin 2013[94]	Hakala 1993[95]	Hakala 1994[96]	Heitzman 1987[97]	Jeffery 1984[98]	Jeffery 2003[99]	Jolly 2011[100]	Karvetti 1992[101]	Korhonen 1987[102]
Equity pointer: social context of the study, e.g. was the study conducted in a particular setting that might target/exclude specific populations?	✗	?	?	✗	✓	✓	✗	?	✗
Representativeness of the sample: are participants in the study likely to be representative of the target population?	✗	?	✓	✓	✗	✓	✓	✗	✓
Sociodemographic differences between withdrawals and exclusions?	✓	?	?	?	?	?	?	?	?
PROGRESS categories reported at baseline (indicate letters of those reported: place of residence, race, occupation, gender, religion, education and literacy, socioeconomic status, social capital)	✓	?	?	✓	?	✓	✓	✓	✓
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 described?	✗	✗	✗	?	?	?	✓	✗	?
Was there potential for author conflict	✗	?	?	?	?	?	✗	?	?
Harms/unintended effects of the intervention described?	?	✗	✗	?	?	?	✓	✗	?

✓ =, yes; ✗ =, no; ? =, unclear/not reported.

Lindstrom 2008[104]	Lantz 2003[103]	Richelsen 2007[105]	Ross 2012[106]	Shai 2008[107]	Vannine *n* 1992[108]	Volpe 2008[109]	Wadden 2011[110]	West 2008[111]	Wing 1991[112]	Wing 1994[113]
?	✗	✗	✗	✓	✗	✗	✗	✗	✓	?
✓	✓	?	✓	✓	✓	✗	✓	✓	✓	✓
?	?	?	?	?	?	?	✗	?	?	?
✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
✗	✗	✗	✗	✗	✗	✗	✓	?	✗	✗
✗	✗	?	✗	✗	?	?	✓	?	?	✗
✗	✗	?	✗	✗	?	?	✗	?	?	✗
✓	✓	✓	✓	✓	✓	✓	✓	✓	?	✓
?	?	?	?	?	?	?	?	?	?	✗
?	?	?	✗	?	?	?	?	?	?	✗
?	?	?	✗	?	?	?	?	?	?	✗
?	?	?	?	✗	✗	✗	✗	?	?	?
✗	?	✓	✓	?	✗	?	?	?	?	?

Appendix 11 List of included studies: review of UK interventions

Ahern 2011

Ahern AL, Olson AD, Aston LM, Jebb SA. Weight Watchers on prescription: an observational study of weight change among adults referred to Weight Watchers by the NHS. *BMC Public Health* 2011;**11**:434.

Brady 2010

Brady AJ, Perry C, Murdoch DL, McKay G. Sustained benefits of a health project for middle-aged football supporters, at Glasgow Celtic and Glasgow Rangers Football Clubs. *Eur Heart J* 2010;**31**:2696–8.

Bye 2005

Bye C, Avery A, Lavin J. Tackling obesity in men – preliminary evaluation of men-only groups within a commercial slimming organization. *J Hum Nutr Diet* 2005;**18**:391–4.

Department of Health and Leeds Metropolitan University 2010

Department of Health and Leeds Metropolitan University. *Tackling Men's Health. Men Only Weight Management Group: NHS Leeds and Leeds Rhinos, 2010 Season.* Leeds: Public Health and Social Care Group Yorkshire and the Humber and NHS Leeds; 2010.

Dixon 2012

Dixon KJ, Shcherba S, Kipping RR. Weight loss from three commercial providers of NHS primary care slimming on referral in North Somerset: service evaluation. *J Public Health* 2012;**34**:555–61.

Drummond 2004

Drummond S, Dixon K, Griffin J, De Looy A. Weight loss on an energy-restricted, low-fat, sugar-containing diet in overweight sedentary men. *Int J Food Sci Nutr* 2004;**55**:279–90.

Evans 2011a

Evans S. Primary care weight management in Hertfordshire using ProHealthClinical. National Obesity Forum (NOF) Eastern Regional Obesity Network meeting, December 2011.

Evans 2011b

Evans S. Community health improvement programme. Cambridgeshire Countywide Joint Obesity Strategy meeting, April 2011.

Evans 2012

Evans S. Evans S. Weigh2Go: a peripatetic level 1 weight management service in Cambridge City and South, interim report 2012. Treatment of Obesity Conference, Birmingham, June 2012.

Gray 2009

Gray CM, Anderson AS, Clarke AM, Dalziel A, Hunt K, Leishman J, *et al.* Addressing male obesity: an evaluation of a group-based weight management intervention for Scottish men. *J Mens Health* 2009;**6**:70–81.

Gray 2011

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Appendix 12 Detailed quality assessment for individual studies: review of UK interventions

TABLE 60 Risk of bias assessment for individual RCTs included in the review of UK interventions

Item	Leslie 2002[146]
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 61 Quality assessment for individual non-randomised studies included in the review of UK interventions

	Ahern 2011[37]	Brady 2010[138]	Bye 2005[34]	Department of Health 2010[139]	Dixon 2012[150]	Drummond 2004[140]	Gray 2009[142]	Johnson 2011[154]	Kirk 2000[155]	McFarlane 2006[147]	Rolland 2013[156]	Ross 2008[31]	Stubbs 2011[36]	Witty 2010[149]
Representative sample	✓	✓	?	?	✓	✓	✓	✓	✗	✓	✗	✓	?	?
Inclusion/exclusion criteria clearly defined	✓	✓	✓	?	✓	✓	?	✓	✓	✗	✗	✓	✓	?
Participants at similar point in disease progression	?	✓	?	?	✗	✓	✓	?	✗	?	✓	✓	?	?
Selection of participants consecutive	?	?	?	?	?	?	?	✗	?	✓	?	✓	?	?
Data collection undertaken prospectively	✗	✓	✗	✓	✓	✓	✓	✗	✓	✓	✓	✓	✗	✓
Groups comparable	NA	NA	NA	NA	?	NA	NA	NA	NA	NA	NA	NA	NA	NA
Intervention clearly defined	✓	✓	?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Intervention delivered by an experienced person	✓	✓	✓	✓	?	?	✓	✓	?	?	✓	✓	✓	?
Intervention delivered in an appropriate setting	?	✓	?	✓	?	?	✓	NA	✓	?	?	✓	?	✓
Important outcomes considered	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Objective outcome measures used	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

	Ahern 2011[37]	Brady 2010[138]	Bye 2005[34]	Department of Health 2010[139]	Dixon 2012[150]	Drummond 2004[140]	Gray 2009[142]	Johnson 2011[154]	Kirk 2000[155]	McFarlane 2006[147]	Rolland 2013[156]	Ross 2008[31]	Stubbs 2011[36]	Witty 2010[149]
Assessment of main outcomes blind	NA	NA	NA	NA	✗	NA	NA	✓	NA	NA	NA	NA	NA	NA
Follow-up long enough	✗	✓	✗	✗	✗	✗	✓	✗	✗	✗	✗	✓	✗	✓
Information on non-respondents, dropouts	✗	✓	✓	✗	✓	✓	?	✗	✗	✓	✗	✗	✓	✓
Withdrawals likely to introduce bias	?	?	?	?	?	?	?	?	✓	?	?	?	?	?
Length of follow-up similar between comparison groups	NA	NA	NA	NA	✓	NA	NA	NA	NA	NA	NA	NA	NA	NA
Important prognostic factors identified	?	✓	?	?	✓	✓	✓	✓	✗	✓	✗	✓	✓	?
Analyses adjusted for confounding factors	NA	NA	NA	NA	✓	NA	NA	NA	NA	NA	NA	NA	✓	NA

✓, yes; ✗, no; ?, unclear/not reported; NA, not applicable.

TABLE 62 Equity and sustainability assessment of individual studies included in the review of UK interventions

	Ahern 2011[37]	Brady 2012[138]	Bye 2005[34]	Department of Health 2010[139]	Dixon 2012[150]	Drummond 2004[140]	Gray 2009[142]	Gray 2011[141]	Johnson 2011[154]	Kirk 2000[87]	Leslie 2002[146]	McFarlane 2006[147]	Rolland 2013[156]	Ross 2008[31]	Stubbs 2011[36]	Witty 2010[149]
Equity pointer: social context of the study, e.g. was the study conducted in a particular setting that might target/ exclude specific populations?	✗	✓	✓	✓	✗	✓	✗	✓	✓	✓	✓	✗	?	✗	?	✓
Representativeness of the sample: are participants in the study likely to be representative of the target population?	✓	✓	?	✓	✓	✓	✓	✓	✓	✗	✓	?	✓	✓	?	✓
Sociodemographic differences between withdrawals and exclusions?	?	?	?	?	?	?	?	?	✗	?	?	?	?	?	?	?
PROGRESS categories reported at baseline (indicate letters of those reported: place of residence, race, occupation, gender, religion, education and literacy, socioeconomic status, social capital)	?	✗	✓	✗	✓	?	✓	✓	✓	✓	?	?	✓	✓	✓	✗

	Ahern 2011[37]	Brady 2012[138]	Bye 2005[34]	Department of Health 2010[139]	Dixon 2012[150]	Drummond 2004[140]	Gray 2009[142]	Gray 2011[141]	Johnson 2011[154]	Kirk 2000[87]	Leslie 2002[146]	McFarlane 2006[147]	Rolland 2013[156]	Ross 2008[31]	Stubbs 2011[36]	Witty 2010[149]
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?	?	✗	✗	✓	✗	✗	✗	?	✗	✗	✗	✗	✗	✓	✓	✓
Do the authors describe any political or organisational context?	✓	✗	✗	✓	✗	✗	✗	?	✗	✗	✗	✗	✗	✓	✓	✓
Were any partnerships described?	✗	✓	✗	✓	✓	✗	✗	✓	✗	✗	✗	✗	✗	✓	✓	✓
Was there potential for author conflict	✗	✗	✓	✗	✗	?	✗	✗	?	?	?	✗	?	✗	✓	✗
Harms/unintended effects of the intervention described?	✗	✗	✗	✗	?	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗

✓, yes; ✗, no; ?, unclear/not reported.

Appendix 13 Supplementary material for the review of cost-effectiveness

Quality assessment checklists for included economic evaluations

Galani 2007[162]

Quality criterion	Dimension of quality	Question	Response	Comments
Structure				
S1	Statement of decision problem/objective	Is there a clear statement of the decision problem?	Y	The decision problem was to quantify the lifetime health and economic consequences of preventing and treating obesity with lifestyle interventions in Switzerland
		Is the objective of the evaluation and model specified and consistent with the stated decision problem?	Y	The objective of the model was to measure the lifetime effects of a 3-year lifestyle intervention compared with standard care in an overweight and obese Swiss population using a Markov decision-analytic model. This was consistent with the decision problem
		Is the primary decision-maker specified?	N	None stated; however, given that the project was funded by the Swiss Federal Office of Health, it might be assumed that Swiss health-care decision-making bodies would be the primary decision-makers using the results of this study
S2	Statement of scope/ perspective	Is the perspective of the model clearly stated?	Y	Perspective of the model is stated as societal
		Are the model inputs consistent with the stated perspective?	N	It is not clear how society's wider costs have been included. Given the parameters detailed in the analysis, it would appear that costs are measured from a health services provider's perspective
		Has the scope of the model been stated and justified?	Y	The scope of the model is not explicitly discussed; however, it is clear from the objectives detailed
		Are the outcomes of the model consistent with the perspective, scope and overall objective of the model?	Y	Outcomes are measured as LYG and QALYs gained. The economic evaluation is reported as incremental cost per life-year gained and cost per QALY gained and is appropriate to the decision problem and objectives
S3	Rationale for structure	Is the structure of the model consistent with a coherent theory of the health condition under evaluation?	Y	A comprehensive model structure has been described detailing the progression through key health states linked to obesity
		Are the sources of data used to develop the structure of the model specified?	Y	The model structure is based on key health states linked to obesity, which were chosen based on published data. A detailed diagram of the model structure is also provided
		Are the causal relationships described by the model structure justified appropriately?	Y	Causal relationships and methods to derive links between treatment effects, cardiovascular risks, etc., are clearly outlined and discussed

Quality criterion	Dimension of quality	Question	Response	Comments
S4	Structural assumptions	Are the structural assumptions transparent and justified?	Y	Structural assumptions are acknowledged and discussed. It is assumed that patients enter a state and remain in that state unless they develop cardiovascular disease or die
		Are the structural assumptions reasonable given the overall objective, perspective and scope of the model?	Y	The structural assumptions of the model are clearly acknowledged and justified in the context of the complexity of the decision problem (e.g. comorbidities have not been modelled because of a lack of Swiss prevalence data to inform the model)
S5	Strategies/comparators	Is there a clear definition of the options under evaluation?	Y	Interventions that are considered are clearly detailed
		Have all feasible and practical options been evaluated?	Y	All practical options are considered given the decision problem and scope of the analysis. The authors clearly discuss their reasons for including standard care as the comparator, most notably because it is current practice in Switzerland
		Is there justification for the exclusion of feasible options?	NA	See above
S6	Model type	Is the chosen model type appropriate given the decision problem and specified causal relationships within the model?	Y	The Markov decision model with a lifetime horizon is appropriate to link intermediate outcomes to longer-term health outcomes and costs. The choice of model structure and health states is appropriate
S7	Time horizon	Is the time horizon of the model sufficient to reflect all important differences between options?	Y	A lifetime model horizon of 60 years' duration (up to age 85 years) is appropriate to measure all potential differences between modelled interventions over a patient's lifetime
		Are the time horizon of the model, the duration of treatment and the duration of treatment effect described and justified?	Y	Time horizon, treatment effect and duration of effect are all clearly described. It is assumed that weight lost as a result of the intervention is maintained up to 6 years, with a linear weight regain each year thereafter for 4 years. The assumption was sustained by data from the FDPS[171]
S8	Disease states/ pathways	Do the disease states (state transition model) or the pathways (decision tree model) reflect the underlying biological process of the disease in question and the impact of interventions?	Y	A total of five key health states related to obesity are included in the Markov model. The authors also acknowledge and justify the omission of a number of other health states for which the link between obesity and health state is less clear/less data rich
S9	Cycle length	Is the cycle length defined and justified in terms of the natural history of disease?	Y	A cycle length of 1 year is described and is appropriate to the decision problem

Quality criterion	Dimension of quality	Question	Response	Comments
Data				
D1	Data identification	Are the data identification methods transparent and appropriate given the objectives of the model?	Y/N	All data included in the model are clearly identified and sources are clearly referenced throughout. To estimate the efficacy of the intervention, a random-effects meta-analysis of a range of trials was carried out. However, it is not clear how the trials used for the meta-analysis were identified (e.g. whether or not a systematic literature search was carried out). Sources of utility data are clearly reported; however, identification methods and methods used to measure the utility weights in the source studies are not discussed or justified
		When choices have been made between data sources, are these justified appropriately?	N	Alternative sources of data are not systematically explored in the study; however, a meta-analysis of treatment effectiveness is carried out
		Has particular attention been paid to identifying data for the important parameters in the model?	Y	Disease-related mortality used in the model is age and sex specific and meta-analyses are conducted for treatment effectiveness
		Has the quality of the data been assessed appropriately?	Y	Limitations of the data are discussed and, when appropriate, they are tested in comprehensive probabilistic sensitivity analysis
		When expert opinion has been used, are the methods described and justified?	NA	No expert opinion has been referred to in the study
D2	Data modelling	Is the data modelling methodology based on justifiable statistical and epidemiological techniques?	Y	Modelling methodology follows well-known best practice Markov modelling methodology
D2a	Baseline data	Is the choice of baseline data described and justified?	Y	There is a clear description and justification of all baseline data used for the model. Sources are clearly referenced. Baseline data, cardiovascular risk and transition probabilities between health states are estimated using sex-specific data; however, data for inputs are not presented for male and female subgroups separately
		Are transition probabilities calculated appropriately?	?	Not clear – transition probabilities are calculated based on two large American prospective epidemiological studies. Detailed calculation methods are not provided, neither are the transition probabilities themselves
		Has a half-cycle correction been applied to both costs and outcomes?	N/Y	A half-cycle correction has not been applied to costs but has been applied to life expectancy data assuming transition midway through the cycle
		If not, has this omission been justified?	NA	

Quality criterion	Dimension of quality	Question	Response	Comments
D2b	Treatment effects	If relative treatment effects have been derived from the trial data, have they been synthesised using appropriate techniques?	Y	A random-effects meta-analysis of a range of studies has been used to estimate treatment effect. A large number of studies have been included in the meta-analysis for the estimation of both BMI and other key clinical outcome data
		Have the methods and assumptions used to extrapolate short-term results to final outcomes been documented and justified?	Y	Methods and assumptions for extrapolation are clearly described and justified
		Have alternative extrapolation assumptions been explored through sensitivity analysis?	N	No alternative extrapolation assumptions have been explored
		Have assumptions regarding the continuing effect of treatment once treatment is complete been documented and justified?	Y	Assumptions regarding maintenance of weight loss are clearly described
		Have alternative assumptions regarding the continuing effect of treatment been explored through sensitivity analysis?	N	None detailed
D2c	Costs	Are the costs incorporated into the model justified?	Y	Costs incorporated into the model appear to be appropriate. In general, the reporting of cost data is lacking in detail and it is unclear which, if any, indirect costs are included. The perspective is stated as societal but it appears more like a health services provider perspective, given the data included
		Have the sources for all costs been described?	Y	Sources are reported in the study although details are limited. Both direct costs and indirect costs of complications were obtained from published literature
		Have discount rates been described and justified given the target decision-maker?	Y	Discount rates for costs and QALYs are 3% and are appropriate. Discount rates are varied in sensitivity analysis
D2d	Quality of life weights (utilities)	Are the utilities incorporated into the model appropriate?	?	Unclear as methods of utility estimation are not clearly described in the study, although references for the source studies are provided
		Is the source for the utility weights referenced?	Y	References for utility weights are provided throughout
		Are the methods of derivation for the utility weights justified?	?	Not clear as no details of the methods for calculation of utility weights are provided

Quality criterion	Dimension of quality	Question	Response	Comments
D3	Data incorporation	Have all data incorporated into the model been described and referenced in sufficient detail?	Y	Data incorporated in the model are described and referenced throughout. Greater detail for unit costs and utility data would have been helpful
		Has the use of mutually inconsistent data been justified (i.e. are assumptions and choices appropriate)?	NA	No mutually inconsistent data presented
		Is the process of data incorporation transparent?	Y	Data incorporation is clearly explained
		If data have been incorporated as distributions, has the choice of distribution for each parameter been described and justified?	Y	Distributions are detailed for key model parameters. No justifications are provided; however, the distributions used are standard practice for probabilistic sensitivity analysis
		If data have been incorporated as distributions, is it clear that second-order uncertainty is reflected?	Y	Monte Carlo simulations were used
D4	Assessment of uncertainty	Have the four principal types of uncertainty been addressed?	N	Structural uncertainty has not been accounted for. The model has not been rerun to test the impact of structural assumptions
		If not, has the omission of particular forms of uncertainty been justified?	N	No discussion of structural uncertainty is provided
D4a	Methodological	Have methodological uncertainties been addressed by running alternative versions of the model with different methodological assumptions?	Y	Discount rate varied between 0% and 3% for the base case and all subgroup analyses
D4b	Structural	Is there evidence that structural uncertainties have been addressed through sensitivity analysis?	N	No structural uncertainty addressed in sensitivity analysis
D4c	Heterogeneity	Has heterogeneity been dealt with by running the model separately for different subgroups?	Y	Model has been rerun for a number of subgroups, including age- and sex-specific results
D4d	Parameter	Are the methods of assessment of parameter uncertainty appropriate?	Y	Probabilistic sensitivity analysis has been undertaken
		If data are incorporated as point estimates, are the ranges used for sensitivity analysis stated clearly and justified?	N	Ranges for potential parameter values are not reported. Extended details of inputs for distributions for the probabilistic sensitivity analysis are reported in a subsequent study[167]

Quality criterion	Dimension of quality	Question	Response	Comments
Consistency				
C1	Internal consistency	Is there evidence that the mathematical logic of the model has been tested thoroughly before use?	N	There are no details of piloting/validation or testing of the model; however, it would appear that the model is logical and generates results which have good face validity. The modelling method used is well established in the economic evaluation field
C2	External consistency	Are any counterintuitive results from the model explained and justified?	Y	Counterintuitive results for the borderline obese group compared with the obese group are discussed and justified with discussion of the possible reasons for the dominant ICERs in the borderline obese group. This is because lifestyle intervention costs are offset by longer-term treatment outcomes and reduced costs associated with treating cardiovascular disease in later life from obesity complications
		If the model has been calibrated against independent data, have any differences been explained and justified?	Y	Data from the model have been compared against and justified with independent data whenever possible
		Have the results of the model been compared with those of previous models and any differences in results explained?	Y	A comprehensive literature search was conducted for other economic models in this clinical area and the results of these models were compared with those of the present study. Anomalies and inconsistencies are explored and reasons for differences discussed

?, uncertain; N, criterion not met; NA, not applicable; N/Y, first part of criterion is not met but second is; Y, criterion met; Y/N, first part of criterion is met but second is not.

Iannazzo 2008[164]

Quality criterion	Dimension of quality	Question	Response	Comments
Structure				
S1	Statement of decision problem/objective	Is there a clear statement of the decision problem?	Y	The decision problem was to evaluate the economic impact of the use of orlistat plus a lifestyle intervention compared with the lifestyle intervention alone in an Italian obese population
		Is the objective of the evaluation and model specified and consistent with the stated decision problem?	Y	The model simulated clinical and economic outcomes in a representative Italian obese cohort using a Bayesian probabilistic Markov model to extrapolate the clinical results from the XENDOS double-blind RCT[169] in terms of diabetes progression and associated mortality
		Is the primary decision-maker specified?	N	The primary decision-maker is not explicitly specified; however, the study was funded by a grant from Roche. Publication of the study results was not dependant on agreement or input from the funders and the authors' results were independent of the company funding the study
S2	Statement of scope/ perspective	Is the perspective of the model clearly stated?	Y	A societal perspective is stated
		Are the model inputs consistent with the stated perspective?	N	The authors state that a societal perspective was considered. However, costs considered appear only to be applicable to a health services and patient perspective (assuming patients pay for orlistat directly in Italy). Indirect costs (e.g. productivity losses) associated with a typical analysis from a societal perspective to not appear to have been considered
		Has the scope of the model been stated and justified?	Y	The scope of the model is clear from the information included in the objective and methods
		Are the outcomes of the model consistent with the perspective, scope and overall objective of the model?	Y	Outcomes are measured as QALYs and are consistent with the perspective, scope and objectives of the model

Quality criterion	Dimension of quality	Question	Response	Comments
S3	Rationale for structure	Is the structure of the model consistent with a coherent theory of the health condition under evaluation?	Y	The structure is consistent with the development of diabetes from weight gain and associated risk factors. A more dynamic model may have presented a better picture of diabetes disease progression and this is acknowledged by the study authors
		Are the sources of data used to develop the structure of the model specified?	Y	The model is broadly structured around the extrapolation of the XENDOS study results.[169] There is no evidence of any structured literature searching to inform the model structure
		Are the causal relationships described by the model structure justified appropriately?	Y	Data are sourced from the XENDOS study[169] and are used to estimate risks of cardiovascular disease/stroke, etc. Risks and data were age and sex specific and the key clinical end point was transition from obese health state to diabetes. Data are clearly linked from weight loss to cardiovascular risk outcomes and hence mortality and QALYs gained. The authors acknowledge the limitations of the modelling processes that were used to model long-term outcomes, and in particular that the model was insensitive to changes in weight-loss data
S4	Structural assumptions	Are the structural assumptions transparent and justified?	Y	Structural assumptions are clear; however, a comprehensive list of all model assumptions would have been helpful
		Are the structural assumptions reasonable given the overall objective, perspective and scope of the model?	Y	The model structure used appears to be appropriate
S5	Strategies/comparators	Is there a clear definition of the options under evaluation?	Y	Options evaluated are clearly defined and comprehensive data on the content of the interventions are provided
		Have all feasible and practical options been evaluated?	Y	Given that the model evaluates the long-term costs and economic consequences of the interventions in the XENDOS trial,[169] the use of these options for evaluation is appropriate
		Is there justification for the exclusion of feasible options?	NA	No details of exclusions presented
S6	Model type	Is the chosen model type appropriate given the decision problem and specified causal relationships within the model?	Y	The analysis was based on best practice modelling techniques and a Bayesian probabilistic Markov decision model was used to answer the decision problem. This modelling approach is appropriate in the context of the decision problem and is a key strength of the analysis

Quality criterion	Dimension of quality	Question	Response	Comments
S7	Time horizon	Is the time horizon of the model sufficient to reflect all important differences between options?	?	The time horizon of the model is 10 years (4 years of treatment plus 6 years of follow-up). Although it is likely that this is sufficient to establish the cost-effectiveness of the intervention, a longer time horizon might have been appropriate to estimate lifetime diabetes-related outcomes. The choice of a 10-year time horizon is not discussed; however, the authors acknowledge that a more dynamic model of diabetes might generate more relevant results. A longer time horizon would rely on stronger assumptions about weight-loss maintenance in the long term, for which data are sparse
		Are the time horizon of the model, the duration of treatment and the duration of treatment effect described and justified?	Y	The time horizon is clearly described, as is treatment duration. The duration of treatment effect is based on the XENDOS follow-up results at 4 years.[169] The weight reduction trend was stronger in the orlistat group at 2 years but weight returned almost entirely to baseline levels at 4 years' follow-up. The lack of sufficient modelling sensitivity to weight changes is discussed as a limitation of the analysis
S8	Disease states/ pathways	Do the disease states (state transition model) or the pathways (decision tree model) reflect the underlying biological process of the disease in question and the impact of interventions?	Y	The disease states broadly fit with the decision problem; however, the authors acknowledge a key limitation, the inadequately modelled relationship between weight loss and cardiovascular risk. Further, a more dynamic modelling of health states would be helpful; however, this is subject to data availability to inform such a process
S9	Cycle length	Is the cycle length defined and justified in terms of the natural history of disease?	Y	The cycle length is 1 year and is appropriate to the decision problem and the history of diabetic disease

Quality criterion	Dimension of quality	Question	Response	Comments
Data				
D1	Data identification	Are the data identification methods transparent and appropriate given the objectives of the model?	Y/N	Data identification methods are clear in terms of cardiovascular risk, cost inputs and mortality calculations. However, there is little information on the methods used to identify appropriate utility weights for the model
		When choices have been made between data sources, are these justified appropriately?	?	Unclear – alternative data sources for populating the model are not discussed and there is no evidence of systematic literature searches to populate the model. However, the data that have been included appear appropriate to the decision problem
		Has particular attention been paid to identifying data for the important parameters in the model?	Y/N	Adequate attention is given to the identification of data for the key model parameters (mortality, cardiovascular risks, costs, etc.). However, more information could have been supplied on the identification of utility weights for QALY calculations. When weights are sourced from the literature, a brief critical appraisal of calculation methods would have been beneficial
		Has the quality of the data been assessed appropriately?	Y	Although there is no systematic critique of the data used in the model, the limitations of the data are clearly outlined and discussed in the discussion section of the paper
		When expert opinion has been used, are the methods described and justified?	NA	There is no evidence that expert opinion has been used to inform the model structure and design or parameter inputs
D2	Data modelling	Is the data modelling methodology based on justifiable statistical and epidemiological techniques?	Y	A Bayesian probabilistic Markov model is used and this is a key strength of the analysis. The Markov model included two Bayesian statistical models fitted on the trial data, to predict diabetes incidence and cardiovascular disease risk factors. Parameters were drawn directly from their posterior distributions. Risk and mortality inputs are age and sex specific. The comprehensiveness of the model used is a key strength of the study

Quality criterion	Dimension of quality	Question	Response	Comments
D2a	Baseline data	Is the choice of baseline data described and justified?	Y	The main data source to populate the model was the XENDOS study.[169] This is appropriate and justified given the double-blind randomised nature of the study. Other secondary data sources are used and justified appropriately
		Are transition probabilities calculated appropriately?	Y	Transition probabilities between the three key health states are clearly described and justified, including detailed information on their calculations
		Has a half-cycle correction been applied to both costs and outcomes?	N	No half-cycle correction has been included
		If not, has this omission been justified?	N	No justification given
D2b	Treatment effects	If relative treatment effects have been derived from the trial data, have they been synthesised using appropriate techniques?	Y	Treatment effects and clinical input data are derived from a range of sources, most notably the XENDOS trial,[169] which ensures the use of rigorous data because of the blinded randomised approach. No detailed data syntheses are reported in the study
		Have the methods and assumptions used to extrapolate short-term results to final outcomes been documented and justified?	Y	Methods of extrapolation are clearly described in the study for each relevant parameter (e.g. cardiovascular risk, mortality, QALYs)
		Have alternative extrapolation assumptions been explored through sensitivity analysis?	N	None documented – it would have been helpful to explore a lifetime model horizon
		Have assumptions regarding the continuing effect of treatment once treatment is complete been documented and justified?	Y	It appears that no continuing effect is assumed beyond the pivotal trial follow-up period, with weight seen to return to baseline levels at 4 years
		Have alternative assumptions regarding the continuing effect of treatment been explored through sensitivity analysis?	N	Assessments of alternative treatment effects have not been explicitly modelled
D2c	Costs	Are the costs incorporated into the model justified?	Y	Costs are appropriate to the decision model. Costs of the lifestyle intervention are not included; however, the authors point out that there would be little or no difference in costs between the intervention group and the control group as all study participants received the lifestyle intervention. Diabetes costs are incorporated and referenced but are not broken down into specific components of cost. The authors acknowledge this as a limitation of their analysis

Quality criterion	Dimension of quality	Question	Response	Comments
		Have the sources for all costs been described?	Y	Sources are clearly referenced throughout
		Have discount rates been described and justified given the target decision-maker?	Y	Discount rates for costs and QALYs are 3.5% per annum and are appropriate given best practice guidelines for discounting
D2d	Quality of life weights (utilities)	Are the utilities incorporated into the model appropriate?	Y	Utility weights used appear to be appropriate and are taken from published literature; however, methods of utility estimation are not clearly described
		Is the source for the utility weights referenced?	Y	Sources are clearly referenced
		Are the methods of derivation for the utility weights justified?	?	Not clear – methods of utility estimation from the source studies are not described in detail
D3	Data incorporation	Have all data incorporated into the model been described and referenced in sufficient detail?	Y	All important data sources are sufficiently referenced
		Has the use of mutually inconsistent data been justified (i.e. are assumptions and choices appropriate)?	NA	There do not appear to be any mutually inconsistent data in the study
		Is the process of data incorporation transparent?	Y	Data incorporation is clearly explained and transparent. It is clear that sex-specific inputs run throughout the model from input to risk calculation to final mortality rate estimation. Sex-specific utilities are also used
		If data have been incorporated as distributions, has the choice of distribution for each parameter been described and justified?	Y	Choices of distributions are clearly presented and are appropriate
		If data have been incorporated as distributions, is it clear that second-order uncertainty is reflected?	Y	Monte Carlo simulation of the Markov model is clearly undertaken
D4	Assessment of uncertainty	Have the four principal types of uncertainty been addressed?	N	Structural uncertainties are not considered in the sensitivity analysis
		If not, has the omission of particular forms of uncertainty been justified?	N	None reported
D4a	Methodological	Have methodological uncertainties been addressed by running alternative versions of the model with different methodological assumptions?	Y	The model has been rerun on the basis of alternative payers for orlistat [Italian patients – base case; Italian NHS – sensitivity (scenario) analysis]. No sensitivity analysis was carried out around the discount rate used in the model

Quality criterion	Dimension of quality	Question	Response	Comments
D4b	Structural	Is there evidence that structural uncertainties have been addressed through sensitivity analysis?	N	No structural sensitivity analyses were undertaken
D4c	Heterogeneity	Has heterogeneity been dealt with by running the model separately for different subgroups?	Y	The model is rerun for age- and sex-specific subgroups. Data inputs are age and sex specific and risks, etc., flow the whole way from model input to final output analysis. A separate model is run for an impaired glucose tolerance subgroup
D4d	Parameter	Are the methods of assessment of parameter uncertainty appropriate?	Y	Comprehensive probabilistic analyses are undertaken to investigate parameter uncertainty
		If data are incorporated as point estimates, are the ranges used for sensitivity analysis stated clearly and justified?	Y	Ranges are sampled from the appropriate distributions for the probabilistic sensitivity analysis
Consistency				
C1	Internal consistency	Is there evidence that the mathematical logic of the model has been tested thoroughly before use?	Y	Convergence and overall stability of the model have been thoroughly checked. Multiple chains were run and both visual and Gelman–Rubin–Brooks diagnostics were performed
C2	External consistency	Are any counterintuitive results from the model explained and justified?	NA	Results do not appear to be counterintuitive and have good face validity
		If the model has been calibrated against independent data, have any differences been explained and justified?	Y	All data are incorporated into the model and are in broad agreement with similar independent data sources
		Have the results of the model been compared with those of previous models and any differences in results explained?	Y	A comprehensive comparison with other similar models is carried out and hypotheses drawn up as to why differences may exist across the studies considered

?, uncertain; N, criterion not met; NA, not applicable; Y, criterion met; Y/N, first part of criterion is met but second is not.

Maetzel 2003[166]

Quality criterion	Dimension of quality	Question	Response	Comments
Structure				
S1	Statement of decision problem/objective	Is there a clear statement of the decision problem?	Y	The decision problem was to evaluate the economic value of pharmacological treatment of type 2 diabetes mellitus in overweight and obese patients using orlistat in conjunction with standard diabetes therapies and weight-loss management, compared with standard therapy and weight-loss management alone
		Is the objective of the evaluation and model specified and consistent with the stated decision problem?	Y	The objective of the model was to evaluate the cost-effectiveness of orlistat in addition to standard diabetes treatment (including sulphonylureas, metformin or insulin plus diet and physical activity). The model objective is thus consistent with the decision problem
		Is the primary decision-maker specified?	N	Not explicitly stated; however, the study was funded by Roche pharmaceuticals and two of the authors are employees of the company
S2	Statement of scope/ perspective	Is the perspective of the model clearly stated?	Y	Perspective was that of a US health-care provider
		Are the model inputs consistent with the stated perspective?	Y	Costs are included that are relevant to a health-care provider in the US setting (both drug and secondary care costs) and consistent with the perspective stated. Indirect costs for a range of health states are also included
		Has the scope of the model been stated and justified?	N	Not explicitly stated; however, this is clear from the objectives
		Are the outcomes of the model consistent with the perspective, scope and overall objective of the model?	Y	Outcomes are measured as event-free LYG. Outcomes in the form of QALYs may have been preferable; however, the authors address this in the limitations section
S3	Rationale for structure	Is the structure of the model consistent with a coherent theory of the health condition under evaluation?	Y	A range of health states linked to diabetes are included and are relevant given the decision problem
		Are the sources of data used to develop the structure of the model specified?	N	The comparators for the model are clearly explained and referenced. There is, however, no evidence of systematic searching to inform the most important health states for the model
		Are the causal relationships described by the model structure justified appropriately?	Y	Causal relationships between weight loss, HbA_{1c} level and risk of developing complications are clearly described, as is the link to health states

Quality criterion	Dimension of quality	Question	Response	Comments
S4	Structural assumptions	Are the structural assumptions transparent and justified?	Y	Structural assumptions are clearly outlined and justified in a separate section of the article
		Are the structural assumptions reasonable given the overall objective, perspective and scope of the model?	Y	Given the data availability, the structural assumptions are clear and valid. When assumptions have been made, these are discussed in detail in the discussion with clear acknowledgement of the likely negative implications for the study results of simplifying assumptions
S5	Strategies/comparators	Is there a clear definition of the options under evaluation?	Y	Intervention and comparator are broadly described. Specific details of the exercise and diet advice are not provided; however, given that these are the same across groups, there is no impact on cost-effectiveness results
		Have all feasible and practical options been evaluated?	Y	Given the decision problem to evaluate orlistat, all practical options are considered
		Is there justification for the exclusion of feasible options?	NA	
S6	Model type	Is the chosen model type appropriate given the decision problem and specified causal relationships within the model?	Y	A Markov state transition model is appropriate for the evaluation and modelling of complications and dynamics of a chronic disease such as diabetes
S7	Time horizon	Is the time horizon of the model sufficient to reflect all important differences between options?	?	Probably, although it is not clear whether the 11-year time horizon for the model is sufficient to capture all of the health-related effects of diabetes linked to improving HbA_{1c} levels and weight loss
		Are the time horizon of the model, the duration of treatment and the duration of treatment effect described and justified?	Y	All are clearly described and justified. Limitations are acknowledged because of uncertainties of weight regain and duration of treatment effect, including transient weight loss and its impact on longer-term health outcomes. The choice of time horizon is justified on the basis of a single study which found that intensive blood glucose control for 10 years substantially reduced diabetes-related complications
S8	Disease states/ pathways	Do the disease states (state transition model) or the pathways (decision tree model) reflect the underlying biological process of the disease in question and the impact of interventions?	Y	The states modelled appear to be appropriate for the condition that the model has been developed for
S9	Cycle length	Is the cycle length defined and justified in terms of the natural history of disease?	Y/N	Cycle length of 1 year is clearly defined; however, no explicit justification is given. A cycle length of 1 year is probably sufficient to capture the dynamics of a disease such as diabetes and the annualised risks of developing complications related to diabetes

Quality criterion	Dimension of quality	Question	Response	Comments
Data				
D1	Data identification	Are the data identification methods transparent and appropriate given the objectives of the model?	Y	All data used in the model are clearly defined. Although there is no evidence of systematic searching of the literature, the effectiveness of the drug was estimated using a meta-analysis of key RCTs and risks of complications adapted from the well-known UKPDS[170]
		When choices have been made between data sources, are these justified appropriately?	N	Choices between alternative data sources have not been discussed in the paper, although it would appear that the data used are appropriate to the objective of the model. It is not clear why the UKPDS data are specific only to a 52-year-old man. There is no discussion presented around this assumption/interpretation of the results from the UKPDS[170]
		Has particular attention been paid to identifying data for the important parameters in the model?	Y	A meta-analysis was undertaken of four placebo-controlled RCTs in overweight or obese adults to measure the effectiveness of orlistat in terms of reduced HbA_{1c} levels. Reduced HbA_{1c} levels were used to derive the reduction in diabetes incidence attributable to treatment, using the UKPDS[170]
		Has the quality of the data been assessed appropriately?	?	It is not clear how the quality of the data inputs was assessed
		When expert opinion has been used, are the methods described and justified?	NA	There is no reference to the use of expert opinion in the study, although one would assume that expert opinion might have been sought to inform some of the key model assumptions, including the health states included
D2	Data modelling	Is the data modelling methodology based on justifiable statistical and epidemiological techniques?	Y	Markov modelling is used and is appropriate given the decision problem and objective of the evaluation
D2a	Baseline data	Is the choice of baseline data described and justified?	Y	Baseline relative risk data are taken from the UKPDS[170] and are appropriate to the study decision problem
		Are transition probabilities calculated appropriately?	?	The calculation of transition probabilities is not explicitly addressed. Risk data are taken from the UKPDS[170] and are based on a selective demographic of the population. Alternative methods of selecting risks were not addressed
		Has a half-cycle correction been applied to both costs and outcomes?	N	No half-cycle correction is mentioned
		If not, has this omission been justified?	N	No justification given

Quality criterion	Dimension of quality	Question	Response	Comments
D2b	Treatment effects	If relative treatment effects have been derived from the trial data, have they been synthesised using appropriate techniques?	?	Treatment effects have been synthesised using meta-analysis; however, details of the methods of the data synthesis are not clearly described. Methods are not described in sufficient detail to quality assess the meta-analysis used
		Have the methods and assumptions used to extrapolate short-term results to final outcomes been documented and justified?	Y	Methods of extrapolation are detailed in the study and these are justified in the text. Alternative assumptions regarding the maintenance of treatment effect are explored in sensitivity analysis
		Have alternative extrapolation assumptions been explored through sensitivity analysis?	Y	Alternative assumptions around the duration of treatment effect and the length of continued weight loss resulting from orlistat treatment are explored in sensitivity analysis and are found to have an impact on the cost-effectiveness results
		Have assumptions regarding the continuing effect of treatment once treatment is complete been documented and justified?	Y	Uncertainty surrounding the continued effect of orlistat on blood glucose levels and thus risk of complications related to diabetes is discussed
		Have alternative assumptions regarding the continuing effect of treatment been explored through sensitivity analysis?	Y	Key assumptions are described and tested in sensitivity analysis when appropriate. The authors explore a 1-year vs. a 3-year continuation of response based on alternative methods of calculating HbA_{1c} data outcomes
D2c	Costs	Are the costs incorporated into the model justified?	Y	All costs included in the model are justified. It appears that given the perspective of the analysis all relevant costs have been included
		Have the sources for all costs been described?	Y	All sources for costs are clearly referenced and individual cost elements for each diabetic complication were taken into account
		Have discount rates been described and justified given the target decision-maker?	Y	Discount rates are 3% as appropriate
D2d	Quality of life weights (utilities)	Are the utilities incorporated into the model appropriate?	NA	Utilities were not considered as part of this model. This is a shortcoming of the analysis, which is acknowledged in the limitations section. No attempt was made to estimate utility weights for the various disease health states, at least some of which could have been retrieved from the literature and supplemented with author assumptions to obtain a broad idea of QALY outcomes
		Is the source for the utility weights referenced?	NA	
		Are the methods of derivation for the utility weights justified?	NA	

Quality criterion	Dimension of quality	Question	Response	Comments
D3	Data incorporation	Have all data incorporated into the model been described and referenced in sufficient detail?	Y	All data sources are clearly described and referenced throughout
		Has the use of mutually inconsistent data been justified (i.e. are assumptions and choices appropriate)?	NA	There are no mutually inconsistent data
		Is the process of data incorporation transparent?	Y	Data are all incorporated clearly into the model, with clear links between source studies and final model outcomes. Understanding is aided by the diagram of the decision tree
		If data have been incorporated as distributions, has the choice of distribution for each parameter been described and justified?	NA	Distributions were not explicitly assigned to individual parameters. Instead, sampling was conducted with 1000 estimates taken from CIs and focused around the mean estimate
		If data have been incorporated as distributions, is it clear that second-order uncertainty is reflected?	Y	Yes, through Monte Carlo simulation with sampling from the reported CIs, with more sampling from around the mean of the distributions
D4	Assessment of uncertainty	Have the four principal types of uncertainty been addressed?	N	Heterogeneity has not been accounted for, given that the results are applicable only to 52-year-old men, reflective of the results of the UKPDS.[170] These limitations are acknowledged by the authors
		If not, has the omission of particular forms of uncertainty been justified?	Y	Justification is provided based on the data availability from the source study; however, the results could have been rerun for other hypothetical inputs into the model and based on other published literature discussed by the authors
D4a	Methodological	Have methodological uncertainties been addressed by running alternative versions of the model with different methodological assumptions?	Y	A range of alternative discounting rates is explored. Other methodoligical uncertainties are not considered in the sensitivity analyses
D4b	Structural	Is there evidence that structural uncertainties have been addressed through sensitivity analysis?	Y	Alternative assumptions surrounding the continued effect of treatment are explored in sensitivity analysis
D4c	Heterogeneity	Has heterogeneity been dealt with by running the model separately for different subgroups?	N	Heterogeneity has not been addressed (see above)

Quality criterion	Dimension of quality	Question	Response	Comments
D4d	Parameter	Are the methods of assessment of parameter uncertainty appropriate?	Y	Probabilistic sensitivity analysis is conducted. The inclusion of parameters is extensive in terms of effectiveness data. Parameter uncertainty is reflected through sampling from CIs of the key clinical outcome parameters. It is stated that cost data are also included in the probabilistic sensitivity analysis, although ranges/CIs are not included. It would appear that sampling may have been conducted around total cost estimates although this is not explicitly clear from the article
		If data are incorporated as point estimates, are the ranges used for sensitivity analysis stated clearly and justified?	Y	CIs for distributions are provided. No other analyses focused on ranges apart from those considered in the probabilistic sensitivity analysis
Consistency				
C1	Internal consistency	Is there evidence that the mathematical logic of the model has been tested thoroughly before use?	N	No evidence of validation of the mathematical logic of the model was provided; however, the modelling process used is well known and widely validated in the health economics field
C2	External consistency	Are any counterintuitive results from the model explained and justified?	NA	Counterintuitive results did not emerge from the model. A detailed discussion of the model results is given in the discussion section
		If the model has been calibrated against independent data, have any differences been explained and justified?	N	No evidence of model calibration
		Have the results of the model been compared with those of previous models and any differences in results explained?	Y	The authors engage in a detailed comparison of their results with the results of similar studies. Differences between the results of this study and those of a previously published model were discussed. Problems associated with generalisability (especially to a female group of the population) were addressed and limitations appropriately acknowledged

?, uncertain; N, criterion not met; NA, not applicable; Y, criterion met; Y/N, first part of criterion is met but second is not.

Olsen 2005[165]

Quality criterion	Dimension of quality	Question	Response	Comments
Structure				
S1	Statement of decision problem/objective	Is there a clear statement of the decision problem?	Y	The decision problem is to determine the costs and effects in terms of LYG of providing nutritional counselling by a GP or dietitian
		Is the objective of the evaluation and model specified and consistent with the stated decision problem?	Y	The objective of the valuation is to compare nutritional counselling by a GP with that provided by a dietitian to patients with obesity and a high risk of ischaemic heart disease. The objective of the model was to measure LYG and LYG without IHD, accounting for a range of risk factors
		Is the primary decision-maker specified?	N	It is not clear who funded the study; however, it is stated that the study was supposed to form the basis for future decisions on the organisation of nutritional counselling in primary care
S2	Statement of scope/ perspective	Is the perspective of the model clearly stated?	?	The perspective of the model is not explicitly stated, although a patient, health services and even a societal perspective appear to be considered. The final results appear to be from a health services perspective
		Are the model inputs consistent with the stated perspective?	N	Although the perspective is not explicitly stated, it appears that the costing data used refer to a health services perspective for the base-case analysis. Patients' use of time was identified in the methods and reported in the sensitivity analysis results. It was also stated that production losses were considered, although the model inputs and results were not reported for this perspective
		Has the scope of the model been stated and justified?	N	Not explicitly stated but appears to be clear from the objective of the study and model
		Are the outcomes of the model consistent with the perspective, scope and overall objective of the model?	?	Given the lack of clarity regarding the perspective, outlined above, it is not clear whether or not costs are consistent with the analysis perspective. For example, productivity costs and the methods to derive their estimates are not clearly stated

Quality criterion	Dimension of quality	Question	Response	Comments
S3	Rationale for structure	Is the structure of the model consistent with a coherent theory of the health condition under evaluation?	N	The modelling of life-years is appropriate; however, costs are considered only over a short time horizon, which is insufficient to measure the impact of future obesity-related health events. The use of QALYs would provide a more robust analysis for decision-makers
		Are the sources of data used to develop the structure of the model specified?	N	The model was developed by the authors and no data have been identified to inform the model structure specifically. No explicit justification was given for the chosen model structure over any plausible alternatives. There is no evidence of any systematic approach to deciding on the most appropriate model structure
		Are the causal relationships described by the model structure justified appropriately?	Y	Causal relationships within the model appear justified and appropriate, given the model design and decision problem. Mathematical models are clearly defined and explained. There is no clear link specified between weight loss and final outcomes. Weight-loss data are not reported
S4	Structural assumptions	Are the structural assumptions transparent and justified?	?	There is no clear list of assumptions. It is assumed that the effect of the lifestyle intervention is maintained throughout the study period
		Are the structural assumptions reasonable given the overall objective, perspective and scope of the model?	N	Structural assumptions are not clear. The assumption of maintenance of effect is unreasonable and likely introduces bias to the study results in favour of the intervention being evaluated
S5	Strategies/comparators	Is there a clear definition of the options under evaluation?	Y	GP or dietitian advice compared with no routine advice
		Have all feasible and practical options been evaluated?	Y	Other options may be of relevance but, given the scope and objective of the model, the interventions included could be deemed appropriate. No other plausible interventions have been explored for inclusion
		Is there justification for the exclusion of feasible options?	NA	None reported
S6	Model type	Is the chosen model type appropriate given the decision problem and specified causal relationships within the model?	N	The decision problem is to estimate the costs and effects; however, lifelong costs are omitted. The model is inadequate to fully capture the long-term dynamics of a lifestyle intervention

Quality criterion	Dimension of quality	Question	Response	Comments
S7	Time horizon	Is the time horizon of the model sufficient to reflect all important differences between options?	N	The time horizon is appropriate for estimation of differences in life-years; however, it is inappropriate for the long-term cost implications in terms of reduced cardiovascular events
		Are the time horizon of the model, the duration of treatment and the duration of treatment effect described and justified?	Y/N	The time horizon of the model is clearly described, as is the duration of treatment. The assumption that treatment effect is sustained for the duration of the study is not appropriate. This is acknowledged as a limitation; however, no attempt was made to remedy this or investigate its impact through sensitivity analysis
S8	Disease states/ pathways	Do the disease states (state transition model) or the pathways (decision tree model) reflect the underlying biological process of the disease in question and the impact of interventions?	NA	Dynamic state transition models were not considered
S9	Cycle length	Is the cycle length defined and justified in terms of the natural history of disease?	NA	The model did not contain cycles
Data				
D1	Data identification	Are the data identification methods transparent and appropriate given the objectives of the model?	Y	Baseline risk scores are taken from two Danish population studies. Effects were estimated from a meta-analysis of nine RCTs. References are clear throughout. Costing of the intervention is clearly described
		When choices have been made between data sources, are these justified appropriately?	?	It is not clear what other choices for data sources were available. There is no clear systematic discussion of the available evidence so it is not possible to assess the appropriateness of any choices that were made
		Has particular attention been paid to identifying data for the important parameters in the model?	Y	Key baseline data and data used in the model are clearly described and referenced
		Has the quality of the data been assessed appropriately?	N	The authors do not present a comprehensive discussion of all of the shortcomings of their data, despite acknowledging some of the limitations
		When expert opinion has been used, are the methods described and justified?	NA	No expert opinion is referred to in the study
D2	Data modelling	Is the data modelling methodology based on justifiable statistical and epidemiological techniques?	Y	The methods used to develop the model appear to be appropriate given the model structure chosen; however, this form of model is not ideal to measure the lifetime cost and effect dynamics of a lifestyle intervention to encourage weight loss

Quality criterion	Dimension of quality	Question	Response	Comments
D2a	Baseline data	Is the choice of baseline data described and justified?	Y	Baseline data are clearly identified and are appropriate inputs for the model used. Further details on the methods used for the meta-analysis of treatment effect would have improved the study
		Are transition probabilities calculated appropriately?	NA	
		Has a half-cycle correction been applied to both costs and outcomes?	NA	
		If not, has this omission been justified?	NA	
D2b	Treatment effects	If relative treatment effects have been derived from the trial data, have they been synthesised using appropriate techniques?	?	It is not clear whether or not the synthesis of treatment effects from the nine RCTs meta-analysed was appropriate as details of the methods used in the meta-analysis are not reported
		Have the methods and assumptions used to extrapolate short-term results to final outcomes been documented and justified?	Y	Extrapolation of risk factors to LYG is appropriate given the model used to answer this decision problem. However, alternative models may have been more appropriate for the disease pathway
		Have alternative extrapolation assumptions been explored through sensitivity analysis?	N	The model for extrapolation to LYG was not explored in sensitivity analysis
		Have assumptions regarding the continuing effect of treatment once treatment is complete been documented and justified?	Y/N	It is assumed that the effects of the lifestyle intervention will be maintained over a lifetime. This is acknowledged by the authors as a key limitation of the study. Although the assumption is documented, it is not necessarily justified and is inappropriate given the disease pathway and known poor maintenance of treatment effect once support is removed
		Have alternative assumptions regarding the continuing effect of treatment been explored through sensitivity analysis?	N	No alternative sensitivity analyses have been presented for assumptions relating to the continuation of treatment effects
D2c	Costs	Are the costs incorporated into the model justified?	N	Costs were described and included for the intervention only. Longer-term cost implications have not been explored. It is not clear how productivity costs and/or patient-related costs are incorporated
		Have the sources for all costs been described?	Y	The sources for all costs that were included in the model are clearly referenced and described; however, detailed unit costs are not presented, rendering a theoretical reproduction of the study results difficult

Quality criterion	Dimension of quality	Question	Response	Comments
		Have discount rates been described and justified given the target decision-maker?	Y	Discount rates of 5% were applied to life-years only. This may be appropriate but was not tested in sensitivity analysis. Costs were not discounted as all costs considered occurred within a 1-year time frame
D2d	Quality of life weights (utilities)	Are the utilities incorporated into the model appropriate?	NA	No utilities were incorporated into the model
		Is the source for the utility weights referenced?	NA	
		Are the methods of derivation for the utility weights justified?	NA	
D3	Data incorporation	Have all data incorporated into the model been described and referenced in sufficient detail?	Y	All data are referenced and described appropriately
		Has the use of mutually inconsistent data been justified (i.e. are assumptions and choices appropriate)?	NA	No mutually inconsistent data
		Is the process of data incorporation transparent?	Y	Data are clearly incorporated
		If data have been incorporated as distributions, has the choice of distribution for each parameter been described and justified?	NA	Data are not incorporated as distributions
		If data have been incorporated as distributions, is it clear that second-order uncertainty is reflected?	NA	Data are not incorporated as distributions
D4	Assessment of uncertainty	Have the four principal types of uncertainty been addressed?	N	No structural uncertainty was addressed
		If not, has the omission of particular forms of uncertainty been justified?	N	No justification given
D4a	Methodological	Have methodological uncertainties been addressed by running alternative versions of the model with different methodological assumptions?	Y	A range of methodological uncertainties was explored in the analysis. Sensitivity analysis, including a value for patients' own use of time, was considered. Outcomes were presented in terms of LYG without ischaemic heart disease as well as the base case of LYG. Calculations were rerun based on interchanging GP and dietitian costs of delivering the respective interventions

Quality criterion	Dimension of quality	Question	Response	Comments
D4b	Structural	Is there evidence that structural uncertainties have been addressed through sensitivity analysis?	N	The model has not been revised to use any alternatively plausible structures, such as a Markov model structure
D4c	Heterogeneity	Has heterogeneity been dealt with by running the model separately for different subgroups?	Y	Heterogeneity is addressed and results are reported for male/female subgroups
D4d	Parameter	Are the methods of assessment of parameter uncertainty appropriate?	Y	Uncertainty in costs and effects is addressed using bootstrapping of cost and effect differences to determine the precision of the ICERs and to calculate CIs. No alternative values of input parameters were explored in the model
		If data are incorporated as point estimates, are the ranges used for sensitivity analysis stated clearly and justified?	NA	Point estimates are presented alongside CIs of cost and effect outcomes. The impact of uncertainty was not included in a sensitivity analysis
Consistency				
C1	Internal consistency	Is there evidence that the mathematical logic of the model has been tested thoroughly before use?	N	The model structure and mathematical equations were not tested for consistency within the study; however, the model used is a common approach adopted for survival analysis
C2	External consistency	Are any counterintuitive results from the model explained and justified?	NA	No counterintuitive results have been reported
		If the model has been calibrated against independent data, have any differences been explained and justified?	NA	No calibration undertaken
		Have the results of the model been compared with those of previous models and any differences in results explained?	Y	The model results are compared with those of a range of other similar studies. However, no comparison is made to sex-specific subgroups from other studies in the literature. The study results appear to be broadly aligned with the literature for both sexes together, considering the differing assumptions in some of the models

?, uncertain; N, criterion not met; NA, not applicable; Y, criterion met; Y/N, first part of criterion is met but second is not.

Segal 1998[163]

Quality criterion	Dimension of quality	Question	Response	Comments
Structure				
S1	Statement of decision problem/objective	Is there a clear statement of the decision problem?	Y	The decision problem is to determine the cost-effectiveness of methods for the prevention of type 2 diabetes and to determine if some approaches are more cost-effective than other uses of health-care resources
		Is the objective of the evaluation and model specified and consistent with the stated decision problem?	Y	The key objective of the evaluation is to use cost-effectiveness analysis to determine the role of type 2 diabetes prevention and to ascertain whether or not programmes for primary prevention are cost-effective and whether or not certain programmes are more cost-effective than others. The model objective was to track states of impaired glucose tolerance/normal glucose tolerance/type 2 diabetes for intervention and control cohorts
		Is the primary decision-maker specified?	N	None stated; however, the project was funded by the Department of Human Services, Victoria, Australia. It could be assumed that the target audience for the article is an Australian decision-making body
S2	Statement of scope/ perspective	Is the perspective of the model clearly stated?	Y	Although not explicitly stated, the perspective is clearly that of the health services provider
		Are the model inputs consistent with the stated perspective?	Y	Costs relate to intervention cost and downstream cost savings associated with each intervention group and are thus consistent with the assumed perspective
		Has the scope of the model been stated and justified?	Y	The scope of the model is to evaluate life-years, diabetic state and short- and long-term costs of a range of interventions
		Are the outcomes of the model consistent with the perspective, scope and overall objective of the model?	?	Yes; however, not all results and outcomes were comprehensively reported for each individual programme considered. Outcomes would be better reported as QALYs although this was not possible because of a lack of information on utility weights for the health states

Quality criterion	Dimension of quality	Question	Response	Comments
S3	Rationale for structure	Is the structure of the model consistent with a coherent theory of the health condition under evaluation?	Y	Given the objective to look at only diabetes as a health condition, the structure of the model is appropriate. However, a more dynamic model of diabetes may be required to fully address progression between diabetes health states
		Are the sources of data used to develop the structure of the model specified?	N	It is not clear what, if any, data sources were used to develop the structure of the model
		Are the causal relationships described by the model structure justified appropriately?	N	Causal relationships are not clearly presented for each individual programme. There are inadequate data specific to each programme to make a judgement on how causal relationships are generated. Further data have been requested from the study authors but were not available at the time of publication
S4	Structural assumptions	Are the structural assumptions transparent and justified?	Y	Key assumptions are noted in the methods section, especially with regard to the definition of success or not in terms of continuation of weight loss within the model. The authors acknowledge that a more dynamic structure would have been better; however, because of a lack of data this was not possible
		Are the structural assumptions reasonable given the overall objective, perspective and scope of the model?	Y	The assumptions stated are reasonable; however, it was not possible to assess the appropriateness of all assumptions and their application to each individual programme
S5	Strategies/comparators	Is there a clear definition of the options under evaluation?	?	There is mixed information available for each of the six programmes and further systematic information is required for all six interventions in terms of who delivered the intervention, how long it was delivered for, in what setting, the frequency of classes, etc. Information summarising key trials for each programme are available from the authors on request; details were requested but were not available at the time of publication
		Have all feasible and practical options been evaluated?	Y	Interventions were included based on a systematic review of the literature and a detailed process of selection of the most appropriate interventions
		Is there justification for the exclusion of feasible options?	Y	Diabetes drug therapies were excluded as they refer to management of disease rather than prevention
S6	Model type	Is the chosen model type appropriate given the decision problem and specified causal relationships within the model?	Y	The broad model type is appropriate for measuring longer-term costs and outcomes of the disease pathway

Quality criterion	Dimension of quality	Question	Response	Comments
S7	Time horizon	Is the time horizon of the model sufficient to reflect all important differences between options?	Y	A time horizon of 25 years post intervention seems appropriate to capture relevant cost and mortality differences
		Are the time horizon of the model, the duration of treatment and the duration of treatment effect described and justified?	?	The time horizon is described clearly but not justified. The duration of treatment is clear for programme IV but is not justified explicitly. Assumptions regarding the duration of treatment effect are clear and tested in sensitivity analysis through the use of alternative success rates
S8	Disease states/ pathways	Do the disease states (state transition model) or the pathways (decision tree model) reflect the underlying biological process of the disease in question and the impact of interventions?	Y	States of impaired glucose tolerance and normal glucose tolerance are appropriate given the decision problem and objective of the model; however, the inclusion of other states could have improved the relevance of the model, were the data available
S9	Cycle length	Is the cycle length defined and justified in terms of the natural history of disease?	Y/N	Cycle length is defined as 5-yearly but this appears to be an arbitrary choice with no clear justification given
Data				
D1	Data identification	Are the data identification methods transparent and appropriate given the objectives of the model?	?	Transparent for some but not all programmes. Data were well defined for the men-only programme
		When choices have been made between data sources, are these justified appropriately?	?	No clear evidence of systematic searches for data and evidence and no documentation of key choices that were made nor any justification for such choices. However, the choice of some data inputs was validated against peer-reviewed studies (e.g. the impact of weight loss on type 2 diabetes incidence)
		Has particular attention been paid to identifying data for the important parameters in the model?	Y	A range of sources is referenced for key data inputs, especially in relation to mortality estimates. Details of downstream costs are clearly referenced. Although systematic searches are not described, it appears as if the most relevant data are included
		Has the quality of the data been assessed appropriately?	N	There is no critical assessment/critique/quality assessment of the data used to inform the model beyond implied quality as data are from RCTs
		When expert opinion has been used, are the methods described and justified?	N	It is stated that expert clinical advice is used in combination with studies from the literature to inform the process of identifying transition matrices; however, no further details are provided. It is not clear where model inputs (e.g. transition probabilities) are sourced from (e.g. published literature or clinical expert opinion, nor is it clear if model inputs are programme specific or if similar input data were used for all programmes

Quality criterion	Dimension of quality	Question	Response	Comments
D2	Data modelling	Is the data modelling methodology based on justifiable statistical and epidemiological techniques?	Y	Extrapolation methodology is broadly appropriate and appears justifiable and to reflect best practice at the time that the study was conducted
D2a	Baseline data	Is the choice of baseline data described and justified?	Y/N	Baseline data are described but not clearly justified
		Are transition probabilities calculated appropriately?	?	Unclear. Expert opinion was used to inform transition matrices; however, it is unclear how this was used
		Has a half-cycle correction been applied to both costs and outcomes?	N	No half-cycle correction reported
		If not, has this omission been justified?	N	No justification or mention of half-cycle correction being omitted
D2b	Treatment effects	If relative treatment effects have been derived from the trial data, have they been synthesised using appropriate techniques?	?	Not clear – insufficient information provided for each individual programme with regard to baseline trial data. No syntheses of outcome data were reported and it is assumed that no such meta-analyses were conducted
		Have the methods and assumptions used to extrapolate short-term results to final outcomes been documented and justified?	Y	The method of extrapolation uses 5-yearly transitions between impaired glucose tolerance and normal glucose tolerance and appears appropriate given the decision problem. A comprehensive list of references for mortality estimation, including national sources, is provided
		Have alternative extrapolation assumptions been explored through sensitivity analysis?	N	No alternative extrapolation approaches are considered
		Have assumptions regarding the continuing effect of treatment once treatment is complete been documented and justified?	Y	Model assumptions have been clearly documented. There were no data on continued treatment effect over time, which limits the usefulness of the cost-effectiveness conclusions
		Have alternative assumptions regarding the continuing effect of treatment been explored through sensitivity analysis?	Y	Sensitivity analyses are conducted for programme IV based on altering success rates and hence mortality vectors within the model. A range of other sensitivity analyses was undertaken and reported only for another programme, for which data were not male specific
D2c	Costs	Are the costs incorporated into the model justified?	Y	Cost data are included. There is no detail of how the costs of each individual intervention are calculated and unit costs are not presented. Total net costs over follow-up are not presented for each intervention
		Have the sources for all costs been described?	Y	Sources are described although details are not thoroughly reported
		Have discount rates been described and justified given the target decision-maker?	Y	5% discount rate used for costs and life-years

Quality criterion	Dimension of quality	Question	Response	Comments
D2d	Quality of life weights (utilities)	Are the utilities incorporated into the model appropriate?	NA	Utilities were not included in the model. The authors acknowledge the value of QALYs; however, information to inform such a calculation was not available at the time of the study
		Is the source for the utility weights referenced?	NA	
		Are the methods of derivation for the utility weights justified?	NA	
D3	Data incorporation	Have all data incorporated into the model been described and referenced in sufficient detail?	Y/N	Data sources are referenced although it is not clear how each source is applied to each programme. Further details are required to adequately quality assess this point
		Has the use of mutually inconsistent data been justified (i.e. are assumptions and choices appropriate)?	NA	No mutually inconsistent data
		Is the process of data incorporation transparent?	N	Because of the large number of programmes considered, it is not clear how data are incorporated on a programme-specific basis. Details are, however, provided for programme IV (men-only group)
		If data have been incorporated as distributions, has the choice of distribution for each parameter been described and justified?	NA	Data were not incorporated as distributions
		If data have been incorporated as distributions, is it clear that second-order uncertainty is reflected?	NA	
D4	Assessment of uncertainty	Have the four principal types of uncertainty been addressed?	N	Uncertainty was addressed through extensive sensitivity analysis only for one programme; this was not related to the men-only intervention (programme IV)
		If not, has the omission of particular forms of uncertainty been justified?	N	Only one of the programmes evaluated report sensitivity analyses in detail. No sensitivity analyses are reported for the male-specific programme. There is no justification given as to why this programme was selected as the only one on which to report sensitivity analyses. A sensitivity analysis of treatment success rate was carried out for all programmes
D4a	Methodological	Have methodological uncertainties been addressed by running alternative versions of the model with different methodological assumptions?	N	Not for all programmes – methodological uncertainty was investigated for the behavioural programme for the seriously obese only, in terms of adjusting the discount rate. Details and results were not presented for the male-specific programme IV

Quality criterion	Dimension of quality	Question	Response	Comments
D4b	Structural	Is there evidence that structural uncertainties have been addressed through sensitivity analysis?	Y	Gross costs (intervention costs only) and net costs (intervention delivery and downstream costs) were provided
D4c	Heterogeneity	Has heterogeneity been dealt with by running the model separately for different subgroups?	Y	Analyses were rerun for impaired glucose tolerance only and mixed glucose tolerance subgroups for all programmes
D4d	Parameter	Are the methods of assessment of parameter uncertainty appropriate?	?	Assumed patient success is varied within a sensible range of values; however, no other results were reported for other parameters specific to programme IV
		If data are incorporated as point estimates, are the ranges used for sensitivity analysis stated clearly and justified?	Y	Ranges are based on arbitrary numbers but are clear in their objective of characterising the uncertainty in the results
Consistency				
C1	Internal consistency	Is there evidence that the mathematical logic of the model has been tested thoroughly before use?	N	There are no reports of mathematical consistency checks applied to the model
C2	External consistency	Are any counterintuitive results from the model explained and justified?	NA	Results do not appear counterintuitive and no such results were identified in the study
		If the model has been calibrated against independent data, have any differences been explained and justified?	N	No discussion of any attempt to calibrate the results against independent data
		Have the results of the model been compared with those of previous models and any differences in results explained?	N	Results of the overall study of six interventions were compared against other those of studies in the field and cost-effectiveness estimates were found to compare favourably with those in other studies. A detailed comparative discussion of the methods and associated results is not undertaken for programme IV

?, uncertain; N, criterion not met; NA, not applicable; Y, criterion met; Y/N, first part of criterion is met but second is not.

Individual study data extraction forms

Galani 2007[162]

Title: Modelling the lifetime costs and health effects of lifestyle intervention in the prevention and treatment of obesity in Switzerland

Study charateristics	
Country of study	Switzerland
Setting	Primary care
Research question/objective	To quantify the lifetime health and economic consequences of preventing and treating obesity with a lifestyle intervention in Switzerland
Study design (model/RCT)	Markov model
Inclusion criteria	For the economic model inclusion criteria were overweight and obese by Swiss standards; minimum age 25 years; ages modelled 25, 35, 45 and 55 years. In the economic model, subjects have a BMI of 27 kg/m^2 (overweight group) or 33 kg/m^2 (obese group)
Exclusion criteria	None specified
Intervention	Overweight and obese subjects received the same lifestyle intervention of regular physical activity and low-fat reducing diet, including diets rich in fruit and vegetables (adapted from the FDPS[171]). Detailed dietary recommendations, including limiting intake of fat to < 30% of energy consumed and saturated fat to < 10% and increasing fibre to at least 15 g per 1000 kcal as well as advice about specific food types. Also asked to undertake moderate exercise for at least 30 minutes per day. Participants attended dietitian and supervised exercise sessions over the 3 years: seven dietitian visits in the first year with four visits per year thereafter over the remaining 2 years; four exercise sessions per month in the first year and two sessions per month thereafter in each subsequent year for a total of 3 years
Control/comparison	Overweight subjects: no active intervention. Obese subjects: basic dietary counselling (three visits to the dietitian in year 1 and one visit per year thereafter) and physical exercise sessions (two sessions per month for the first year and one session per month thereafter)
Methods: costing	
Perspective	Societal perspective stated
Currency	Swiss francs, converted to euros in the analysis
Currency year of reporting	All costs were updated to year 2006 using the consumer price index
Discount rate for costs	3%
Other costing information	The inclusion of indirect costs was not entirely clear, except that they were derived from the literature
Methods: outcome measures	
Primary economic evaluation outcome	LYG and QALYs
Discount rate for outcomes	3%
Time horizon over which outcomes were assessed	60 years, to a maximum age of 85 years

Methods: modelling	
Type of model used	Markov decision model
Size of model cohort	10,000
Model time horizon	60 years (for a 25-year-old) or to a maximum age of 85 years
Health states modelled	A total of seven health states were modelled: (1) overweight/obese (overweight or obese and free of complications); (2) hypertension (overweight or obese and BP > 140/90 mmHg); (3) hypercholesterolaemia (overweight or obese and total serum cholesterol ≥ 6.2 mmol/l); (4) diabetes (overweight or obese and type 2 diabetes: fasting glucose at least 7.8 mmol/l or 2-hour glucose at least 11.1 mmol/l); (5) stroke (overweight or obese and developed stroke); (6) coronary heart disease (overweight or obese and developed coronary heart disease); (7) death
Methods: economic evaluations alongside RCTs	
Age group	NA
Sex breakdown	NA
Period of intervention	NA
Period of follow-up	NA
n randomised to intervention	NA
n randomised to control	NA
Data completeness intervention	NA
Data completeness control	NA
Results, base-case costs: deterministic model analysis results	
Intervention costs (male only)	Total cost data from the base-case model were not reported in detail. Unit costs (CHF) included were:

Lifestyle intervention	1268
Standard care obese	573
Hypertension	1653
Type 2 diabetes	2890
Hypercholesterolaemia	1245
Coronary heart disease	6242
Stroke	11,495

Comparator group costs (male only)	Cost of delivering the control arm of the study estimated as 573 CHF. No further details regarding total comparative costs reported
Incremental costs (male only)	Total incremental costs (CHF) were reported as follows (Incremental data refer to long-term costs and effects per person per year.):

Weight category	0% discounting	3% discounting
Overweight	+156	+405
Borderline obese	–260	–6
Obese	–70	+127

Results, base-case primary economic outcome: deterministic model analysis results

Intervention group outcomes (male only): NR

Comparator group outcomes (male only): Individual results by intervention/control group not explicitly reported

Incremental outcomes (male only):

Weight category	0% discounting	3% discounting
Life-years (intervention – control)		
Overweight	+0.03	+0.01
Borderline obese	+0.03	+0.01
Obese	+0.02	+0.01
QALYs (intervention – control)		
Overweight	+0.29	+0.25
Borderline obese	+0.32	+0.28
Obese	+0.33	+0.29

Results, primary economic analysis

Incremental results are as follows (all of these results are based on probabilistic analysis)

Weight category	Age (years)	0% discounting	3% discounting
ICERs (cost per life-year gained) (costs reported in CHF)			
Overweight	25	–2840 (D)	34,291
	35	3006	30,934
	45	3054	24,473
	55	2787	17,149
Borderline obese	25	–19,496 (D)	–14,886 (D)
	35	–14,196 (D)	–52,927 (D)
	45	–14,158 (D)	–9595 (D)
	55	–13,282 (D)	–10,417 (D)
Obese	25	–12,657 (D)	58
	35	–7373 (D)	5580
	45	–8912 (D)	185
	55	–8048 (D)	–1745 (D)
ICERs (cost per QALY gained) (costs reported in CHF)			
Overweight	25	–374 (D)	1854
	35	395	2014
	45	324	1457
	55	237	914
Borderline obese	25	–2560 (D)	–781 (D)
	35	–283 (D)	–331 (D)
	45	–1373 (D)	–523 (D)
	55	–1027 (D)	–508 (D)
Obese	25	–1453 (D)	3
	35	395	276
	45	–741 (D)	9
	55	–502 (D)	–69 (D)

Results, secondary analysis (1)	
No other secondary analyses reported	
Results, sensitivity analysis (1)	
No other deterministic sensitivity analyses reported	
Results, subgroup analyses (1)	
No other subgroup analyses reported beyond those reported in the tables above	
Uncertainty	
Probabilistic analysis undertaken?	Yes
Results reported for male subgroup?	Yes
Distribution for costs	Normal (intervention costs); gamma (costs of obesity complications)
Parameter a	NR
Parameter b	NR
Distribution for utilities	Beta
Parameter a	NR
Parameter b	NR
Distribution for other	Normal (cardiovascular risk scores)
Parameter a	NR
Parameter b	NR
Results illustrated using (e.g. CEAC, scatter plot)	CEACs and scatter plots of the cost-effectiveness plane; scatter plot of cost-effectiveness results was not presented for a male-only subgroup
Key results of PSA (mean estimates of ICER)	See above
Probability of cost-effectiveness	Men and women together: Overweight 5%, borderline obese 78%, obese 47% at WTP = 0 CHF; overweight 35%, borderline obese 99%, obese 92% at WTP = 1000 CHF Men only, borderline obese patients reported only (estimated from the graphs presented): Male age 25 years 70%, male age 35 years 57%, male age 45 years 68%, male age 55 years 72% at WTP = 0 CHF; male age 25 years 93%, male age 35 years 92%, male age 45 years 96%, male age 55 years 98% at WTP = 1000 CHF Results are on average (according to the graph) better for men than for women in terms of cost-effectiveness, especially for young men compared with young women. Results for borderline obese male and female subgroups, 3% discount rate
Other methodological issues	
Expected value of perfect information (EVPI) analysis undertaken?	No – a related study provides value of information analysis[167]
Type	NA
Results	NA
Conclusions of EVPI analysis/recommendations for future research	NA – no EVPI analysis conducted as part of this study
Study strengths	The separate analysis of the borderline obese group allows the researchers to study the transition from overweight to obesity

Study limitations (as identified by authors)	(1) The availability of additional Swiss-specific data would have improved the model (e.g. epidemiological data such as the correlation between BMI and risk of complications, obesity-related mortality and changes in utility for weight loss have not been recorded for Swiss populations); (2) future work should account for other complications of obesity such as metabolic syndrome, colorectal cancer, gall bladder disease, sleep apnoea and depression; (3) this study does not account for the impact of smoking as a risk factor for disease, although it has been documented that obese smokers have an increased risk of mortality; (4) the costs of obesity are estimated using secondary sources (the cost of stroke in this study is very high, although this was confirmed through a number of cost-of-illness studies)

Conclusions

Key issues noted with regard to sex: (1) the average LYG using the lifestyle intervention compared with standard care in overweight, borderline obese and moderately obese patients were between 0.02 and 0.05 for men and women; (2) the average QALYs gained using the lifestyle intervention compared with usual care are greater for men than for women: 0.29 vs. 0.27 (overweight); 0.32 vs. 0.29 (borderline obese); 0.33 vs. 0.29 (morbidly obese) respectively; (3) incremental costs tended to be slightly lower for men than for women; (4) for overweight subjects, the ICER tended to favour younger (age 25 years) and older (age 85 years) men, with ICERs consistently but only marginally favourable in comparison to the female group (this was consistent across weight groups); (5) the intervention is highly cost-effective for all subgroups of age and sex with ICERs often dominant and always falling below 2014 CHF per QALY (men) and 6286 CHF per QALY (women)

The key study conclusion was that lifestyle interventions are cost-effective for the long-term prevention and treatment of obesity

Recommendations for future research

There is a need for pan-European research into the cost-effectiveness of interventions to tackle obesity

D, dominant; NA, not applicable; NR, not reported; PSA, probabilistic sensitivity analysis.

Iannazzo 2008[164]

Title: Economic evaluation of treatment with orlistat in Italian obese patients	
Study characteristics	
Country of study	Italy
Study setting	Not reported, presumably primary care
Research question/objective	To evaluate the economic impact of the use of orlistat plus a lifestyle intervention compared with the lifestyle intervention alone in Italian obese patients through the long-term projection of XENDOS study results[169]
Study design (model/RCT)	Bayesian probabilistic Markov model extrapolating the findings of the XENDOS study[169]
Inclusion criteria	XENDOS study: BMI $\geq$ 30 kg/m^2; Italian obese patients, age 30–60 years (modelled cohort age $\geq$ 35 years) Age (SD): 57.5 (13.3) years (men only); 47.7% male, 52.3% female (Institute for Statistics data)
Exclusion criteria	None explicitly reported in this study, although the main study report will include exclusion criteria
Intervention	Orlistat (120 mg three times a day over 4 years) + lifestyle intervention. The lifestyle intervention consisted of a prescribed calorie-lowering diet with 30% of calories from fat and no more than 300 mg of cholesterol per day. Also encouraged to walk at least an extra 1 km per day
Control/comparison	Lifestyle intervention as described above in combination with a placebo drug given three times per day over 4 years
Methods: costing	
Perspective	Societal perspective considered as orlistat is not available on the Italian NHS
Currency	Euros
Currency year of reporting	Not reported although assumed to be 2007 from reference list
Discount rate for costs	3.5%
Methods: outcome measures	
Primary economic evaluation outcome	QALYs
Discount rate for outcomes	3.5%
Time horizon over which outcomes were assessed	10 years (4 years of treatment and 6 years of follow-up); cycle length was 1 year
Methods: modelling	
Type of model used	Bayesian probabilistic Markov model derived using random distributions from a Monte Carlo simulation
Size of model cohort	30,000 iterations and excluding the first 15,000 to ensure the convergence of the two Bayesian fitting models.
Model time horizon	10 years

Health states modelled/model description	Health states modelled: (1) obese; (2) diabetes; (3) death. The Markov model included two Bayesian statistical models fitted to the outcomes from the XENDOS data:[169] (1) to predict diabetes incidence; (2) to forecast blood pressure and cholesterol changes from baseline (cardiovascular risk parameters). Mortality – transition to the death state in the model estimated using cardiovascular disease mortality Framingham risk equations and non-cardiovascular disease mortality. Utility for obese state extrapolated from the literature. Disutilities were associated with the risk of major cardiovascular events
Methods, economic evaluations alongside RCTs: XENDOS RCT data[169] (baseline data for model)	
Age group	30–60 years, mean 43 years
Sex breakdown	XENDOS: NR; Italian population: 47.7% (men), 52.3% (women)
Period of intervention	4 years
Period of follow-up	4 years only (no additional follow-up in the RCT, hence the need for a model)
n randomised to intervention	NR in the modelling study
n randomised to control	NR in the modelling study
n randomised total	NR in the modelling study
Data completeness intervention	NR in the modelling study
Data completeness control	NR in the modelling study
Results, base-case costs	
Intervention group costs (95% CI)	Men only: NR; men and women: €15,530 (€3342 to €117,000)
Comparator group costs (95% CI)	Men only: NR; men and women: €12,580 (€51 to €116,600)
Incremental costs (95% CI)	Men only: +€2931 (€383 to €3351); men and women: +€2948 (€369 to €3353)
Results, base-case primary economic outcome (QALYs)	
Intervention group outcomes (95% CI)	Men only: NR; men and women: 6.13 (2.44 to 8.718)
Comparator group outcomes (95% CI)	Men only: NR; men and women: 6.084 (2.417 to 8.666)
Incremental outcomes (95% CI)	Men only: +0.046 (0.018 to 0.074); men and women: +0.046 (0.017 to 0.076)
Results, base-case results	
Incremental costs (95% CI)	Men only: +€2931 (€383 to €3351); men and women: +€2948 (€369 to €3353)
Incremental outcomes (95% CI)	Men only: +0.046 (0.018 to 0.074); men and women: +0.046 (0.017 to 0.076)
ICER (95% CI)	Men only: €74,290 (€8408 to €179,600); men and women: €75,310 (€7613 to €180,600)
Results, subgroup analysis (1): impaired glucose tolerance	
Incremental costs (95% CI)	Men only: NR; men and women: +€2237 (–€5601 to €3239)
Incremental outcomes (95% CI)	Men only: NR; men and women: +0.123 (0.048 to 0.199)
ICER (95% CI)	Men only: NR; men and women: €21,230 (dominant to €62,050)
Results, subgroup analysis (2): age < 60 years	
Incremental costs (95% CI)	Men only: NR; men and women: +€2933 (–€312 to €3355)
Incremental outcomes (95% CI)	Men only: NR; men and women: +0.043 (0.017 to 0.072)
ICER (95% CI)	Men only: NR; men and women: €79,110 (dominant to €194,500)

Results, subgroup analysis (3): age ≥ 60 years	
Incremental costs (95% CI)	Men only: NR; men and women: +€2918 (€895 to €3327)
Incremental outcomes (95% CI)	Men only: NR; men and women: +0.048 (0.019 to 0.077)
ICER (95% CI)	Men only: NR; men and women: €70,720 (€18,090 to €162,900)
Results, sensitivity analysis (1): orlistat is given to every obese patient and the NHS pays an estimated ex-factory price for it	
Incremental costs (95% CI)	Men only: NR; men and women: NR
Incremental outcomes (95% CI)	Men only: NR; men and women: NR
ICER (95% CI)	Men only: NR; men and women: €42,300 (dominant to €108,700)
Results, sensitivity analysis (2): orlistat is given only to obese patients with impaired glucose tolerance	
Incremental costs (95% CI)	Men only: NR; men and women: NR
Incremental outcomes (95% CI)	Men only: NR; men and women: NR
ICER (95% CI)	Men only: NR; men and women: €10,160 (dominant to €38,760)
Uncertainty	
Probabilistic analysis undertaken?	Yes
Results reported for male subgroup?	No – results reported only for men and women together
Probabilistic distributions used in the model:	

Distribution for	Distribution
Costs per patient per year (DIA)	Gamma
Cost per case (diabetes)	Normal
Cost per case (control)	Normal
Utilities, obese state (male)	Beta
Disutilities (DIA)	Beta
Disutilities (myocardial infarction)	Beta
Disutilities (stroke)	Beta
Non-cardiovascular disease mortality OB (male)	Gamma
Non-cardiovascular disease mortality DIA (male)	Gamma

DIA, obese patients with diabetes; OB, obese patients without diabetes.

Results illustrated using (e.g. CEAC, scatter plot)	CEACs and scatter plots used to illustrate the data; however, none of the illustrations are presented separately for a male subgroup
Key results of PSA (mean estimates of ICER)	NR
Probability of cost-effectiveness	Base case: ~15% at €45,000 per QALY gained; scenario 2 (impaired glucose tolerance only subgroup): 99.2% at €45,000 per QALY gained
Other methodological issues	
Expected value of perfect information (EVPI) analysis undertaken?	No
Type	NA
Results:	NA
Conclusions of EVPI analysis/recommendations for future research	NA

Study strengths	(1) The authors use a novel modelling approach, based on detailed clinical data from the XENDOS trial;[169] (2) the modelling includes Monte Carlo simulation within a probabilistic sensitivity analysis to address uncertainty; (3) integrated WinBUGS modelling – linking posterior distributions of each modelled parameter within a probabilistic framework; (4) the modelling process follows best practice ISPOR guidelines
Study limitations	(1) The cost of diabetes – to make a more accurate estimate a submodel to represent the dynamics of diabetes progression, complications and related costs would probably have been necessary; (2) the costs of the lifestyle intervention have not been included; this would impact on the budget but not on the incremental results for the economic evaluation given that the resource use was assumed to be equal across the randomised groups; (3) the model has a lack of predictive power for estimating cardiovascular risk impacts based on weight loss – the effects of orlistat were therefore lower than initially expected; (4) the model simulates cardiovascular disease risk parameters independently (e.g. blood pressure and cholesterol risk); however, these risk parameters could be cross-linked, resulting in a higher overall risk than that modelled; (5) Framingham equations are intrinsically conservative for the estimation of cardiovascular risks and the relationships between risk and weight reduction
Conclusions	
If orlistat treatment is targeted at patients at high risk of developing diabetes, this treatment has an estimated cost–utility ratio of about €10,160 per QALY and is therefore highly cost-effective at usual threshold values of the maximum WTP for a QALY gain. There appears to be little or no difference between a male-only subgroup and both sexes (men and women considered together). However, this could be because the model is insensitive to links between weight loss and cardiovascular disease outcomes and therefore any potential differences by sex at the weight-loss stage might be missed using the model	
Recommendations for future research	
None explicitly made	

DIA, obese patients with diabetes; OB, obese patients without diabetes; NA, not applicable; NR, not reported; PSA, probabilistic sensitivity analysis.

Maetzel 2003[166]

Title: Economic evaluation of orlistat in overweight and obese patients with type 2 diabetes mellitus

Study characteristics	
Country of study	USA
Research question/objective	To evaluate the cost-effectiveness of orlistat in addition to standard type 2 diabetes treatment in the treatment of overweight and obese people with diabetes (type 2) in a US-based health-care setting
Study design (model/RCT)	Markov state transition model
Inclusion criteria	Not specifically stated but the model refers to overweight and obese patients with type 2 diabetes mellitus
Exclusion criteria	None stated
Study setting	US health-care setting. Not explicitly stated whether secondary or primary care delivery
Intervention	11 years of standard diabetes therapy (ATG) + treatment with orlistat (120 mg three times per day for the first year), i.e. year 1 (orlistat + ATG), years 2–11 (ATG only). ATG = standard pharmacotherapy for type 2 diabetes (e.g. metformin) and weight management (diet and physical activity)
Control/comparison	11 years of therapy with ATG
Methods: costing	
Perspective	US health-care provider
Currency	US dollars
Currency year of reporting	All costs inflated to 2001 US dollars using appropriate component of the consumer price index
Discount rate for costs	3%
Other costing information	Costs included in the analysis were for (1) study drugs (orlistat, metformin, sulphonylurea and insulin) and (2) management of complications (included a variety of cost categories depending on the complication). Drug costs came from the National Prescription Audit. Costs were reported as costs for one-time treatment and follow-up for the specific complication considered in the model. Assumptions are described and justified
Methods: outcome measures	
Primary economic evaluation outcome	Incremental cost per event-free life-year gained
Discount rate for outcomes	3%
Time horizon over which outcomes were assessed	11 years

ATG, adherence to guidelines.

Methods: modelling	
Type of model used	Markov state transition model
Size of model cohort	100,000 were simulated and run through the model
Model time horizon	11 years
Health states modelled	(1) fatal or non-fatal myocardial infarction; (2) fatal or non-fatal stroke; (3) fatal or non-fatal microvascular disease; (4) amputation or death from peripheral vascular disease; (5) heart failure; (6) cataract extraction; (7) no complication
Methods: economic evaluations alongside RCTs	
Age group:	NA
Sex breakdown	NA
Period of intervention	NA
Period of follow-up	NA
n randomised to intervention	NA
n randomised to control	NA
Data completeness intervention	NA
Data completeness control	NA

Results, primary economic analysis and sensitivity analysis

	Discount rate (%)	Incremental costs [(ATG + orlistat) vs. ATG] (US$)[a]	Incremental outcome [(ATG + orlistat) vs. ATG][a]	ICER (US$)[a]
Mean updated HbA_{1c} (3-year persistence of effect)[b]	**3**	**+1122**	**+0.135**	**8327**
	0	+1099	+0.162	6791
	5	+1136	+0.12	9462
Raw annual HbA_{1c} (1-year persistence of effect)[c]	**3**	**+1352**	**+0.057**	**23,574**
	0	+1365	+0.065	20,899
	5	+1348	+0.052	25,827

Uncertainty	
Probabilistic analysis undertaken?	Yes. PSA was applied by sampling from the CIs for clinical and cost outcomes ($n = 1000$ samples). Distributions were not specified for the parameters but sampling was more frequent around mean estimates
Results reported for male subgroup?	Results are based on the UKPDS[170] and are therefore based on specific risk factors for a 52-year-old male referent group
Distribution for costs	Not specified
Parameter a	Not specified
Parameter b	Not specified
Distribution for utilities	Not specified
Parameter a	Not specified
Parameter b	Not specified
Distribution for other	Not specified
Parameter a	Not specified
Parameter b	Not specified
Results illustrated using (e.g. CEAC, scatterplot)	CEACs
Key results of PSA (including probability of cost-effectiveness)	Sensitivity analysis for the base case (i.e. mean imputed HbA_{1c} – 3-year persistence of effect) showed that 95% of cost-effectiveness ratios fell under a threshold of slightly less than US$20 000 per event-free life-year gained. For the raw annual HbA_{1c} (1-year persistence scenario), 95% of the cost-effectiveness ratios fell below a threshold of US$68,000 per event-free life-year gained. By studying graphically presented data it appears that the probability of cost-effectiveness is ~30% for a 1-year persistence of effect and > 95% for a 3-year persistence of effect at a WTP of US$20,000 per event-free life-year gained; and ~80–90% for a 1-year persistence of effect and > 95% for a 3-year persistence of effect at a WTP of US$50,000 per event-free life-year gained. Overall, it is clear that less benefit is achieved with a shorter persistence of orlistat effect (maintenance of weight-loss effect)
Conclusions of sensitivity analysis	Use of raw annual HbA_{1c} but 3-year persistence of effect led to an ICER of US$21,962 per event-free life-year gained, which is higher than the ICER observed using mean updated HbA_{1c}. The assumption of 0% and 5% discounting led to ICERs of US$6791 and US$9462 per event-free life-year gained respectively
Conclusions of subgroup analysis	Main subgroup analysis undertaken was based on raw/imputed (1–3-year persistence) HbA_{1c} levels, showing as expected that a longer persistence of effect yields greater benefits and is more cost-effective
Conclusions drawn from PSA	Longer persistence of effect (mean imputed HbA_{1c}) is more likely to be cost-effective than 1-year persistence of effect (raw data)
Other methodological issues	
Expected value of perfect information (EVPI) analysis undertaken?	No
Type	NA
Results	NA
Conclusions of EVPI analysis/recommendations for future research	NA
Study strengths (as identified by authors)	Results were based on the combined experience of orlistat from four RCTs of 1 years' duration in obese adult patients with type 2 diabetes

Study limitations (as identified by authors)	(1) The results are likely to be conservative as the authors did not account for a reduction in lipid parameters or blood pressure and their effect on other known conditions that were not modelled; (2) the costs included for treating congestive heart failure were likely too low, representing only one episode of inpatient care; (3) the results are limited by the short-term nature of the supporting clinical trials; (4) there is limited evidence supporting the efficacy of orlistat beyond treatment duration; (5) it is not known how long it takes for body weight to return to baseline levels; (6) the long-term clinical impact of even a transient reduction in HbA_{1c} or body weight is unknown; (7) relative risk reductions used in the model are sourced from the UKPDS[170] and as such are applicable to a cohort of 52-year-old men only; (8) quality of life measures were not reported in the supporting clinical trials, preventing a full-scale cost–utility (cost per QALY) analysis
Key author conclusions	
Orlistat complements traditional type 2 diabetes medication by causing weight loss. The findings suggest that orlistat is a cost-effective therapy in the management of overweight and obese patients with type 2 diabetes in the USA	
Recommendations for future research	
Observational data to support long-term use of orlistat in this population are needed to validate the results of the study	

NA, not applicable; PSA, probabilistic sensitivity analysis.

Bold text indicates base-case rate of discounting.

a ICER values reported directly from the study; incremental data are calculated based on available study data and are subject to rounding errors.

b Mean updated HbA_{1c}: average annual HbA_{1c} of the patient over all years in the UKPDS.[170]

c Raw annual HbA_{1c}: raw data taken directly from the UKPDS,[170] representing a 1-year snapshot in time.

Olsen 2005[165]

Title: Cost-effectiveness of nutritional counseling for obese patients and patients at risk of ischemic heart disease	
Study characteristics	
Country of study	Denmark (not directly stated but assumed)
Study setting	Primary care (GP/dietitian clinics)
Research question/objective	To compare the costs and effects (in terms of LYG) of nutritional counselling provided by a GP or a dietitian
Study design (model/RCT)	Randomised study used to inform costs and a Cox regression model used to estimate LYG
Inclusion criteria	RCT inclusion criteria included BMI $\geq$ 30 kg/m^2, waist circumference > 102 cm (male) or > 88 cm (female), dyslipidaemia, type 2 diabetes
Exclusion criteria	None reported
Intervention	GPs were randomised to deliver nutritional counselling or to refer to a dietitian GP counselling: Initial counselling session of 30 minutes plus five follow-on sessions of 12 minutes each over a 12-month period. Counselling consisted of general lifestyle advice and the delivery of commercially available information on a healthy diet Dietitian referrals: Dietitian provided individual counselling based on indication from referral, dietary history and routine. Focus was on principles of good nutrition, food shopping, cooking methods, meal planning and exercise. Recommendations included reduction of fat component of diet and/or a cholesterol-lowering diet. Initial counseling session of 1 hour plus five follow-up sessions of 30 minutes each
Control/comparison	Both interventions (GP and dietitian) were compared against 'do nothing' (no active intervention). This was based on assumption, rather than a randomised 'do nothing' arm
Methods: costing	
Perspective	Health services perspective. Patient perspective considered as a sensitivity analysis. Article methods section indicates a societal perspective may also have been considered but no results are reported
Currency	Danish kroner
Currency year of reporting	2001
Discount rate for costs	No discounting as time horizon was 1 year
Other costing information	Direct intervention costs (time spent with dietitian and GP), patients' use of time and potential changed consumption of medicine because of intervention were all considered. Long-term costs were not considered
Methods: outcome measures	
Primary economic outcome measure	LYG and LYG without ischaemic heart disease
Discount rate for outcomes	5%
Time horizon for outcomes	Time to event of death, model run up to 80 years of age. Time horizon was therefore 80 years minus current age

Methods: modelling	
Type of model used	Cox regression model for LYG/survival; non-parametric bootstrapping used to estimate CIs
Size of model cohort	NA
Model time horizon	80 years of age – current age of the modelled participant
Health states modelled/model description	Primary modelled outcomes were LYG and LYG without ischaemic heart disease, so the main health states modelled were survival and death. The risk factors included in the model were sex, cholesterol (including HDL), systolic blood pressure, smoking, BMI, diabetes, familial predisposition and previous heart disease. Two Danish population studies ($n = 11,765$) were used to estimate the risk scores in the model and nine RCTs were used to estimate the effect of the intervention. The Cox regressions described time to event (i.e. death) based on these risk factors and an underlying survival function, adjusting for current age. For each included patient, the prognostic index, absolute risk of dying by the 80th year and absolute risk of ischaemic heart disease and survival were estimated before and after the intervention to estimate LYG. Therefore, the comparator group was essentially no intervention as it was assumed that the prognostic index remained unchanged without intervention
Methods: economic evaluations alongside RCTs	
Age group	NR
Sex breakdown	Results available for men = 121/401 (70/243 dietitian, 51/158 GP)
Period of intervention	1 year
Period of follow-up	Costs over 1 year, life-years long term using Cox regression model
n randomised to intervention 1 (dietitian)	Total randomised: $n = 503$; $n = 312$ randomised to dietitian, full data available for $n = 243$ ($n = 70$ male)
n randomised to intervention 2 (GP)	Total randomised: $n = 503$; $n = 191$ randomised to GP, full data available for $n = 158$ ($n = 51$ male)
Data completeness intervention 1 (dietitian)	Life-years estimated for men: 243/312
Data completeness intervention 2 (GP)	Life-years estimated for men: 158/191
Results, base-case costs (results based on LYG)	
Intervention group costs (men only) (range)	Dietitian: 1684 DKK (720–2971 DKK); GP: 774 DKK (416–818 DKK)
Comparator group costs (men only)	Essentially do nothing, cost 0 DKK
Incremental costs (men only) (range)	Dietitian: 1684 DKK (720–2971 DKK); GP: 774 DKK (416–818 DKK)
Results, base-case primary economic outcome	
Outcomes measure used	LYG
Discount rate used	5%
Intervention group outcomes (men only) (95% CI)	Dietitian: ΔLYG: 0.0002 (–0.053 to 0.0531); GP: ΔLYG: 0.1210 (0.0424 to 0.1997)
Comparator group outcomes (men only)	Essentially do nothing (ΔLYG = 0)
Incremental outcomes (men only) (95% CI)	Dietitian: ΔLYG: 0.0002 (–0.053 to 0.0531); GP: ΔLYG: 0.1210 (0.0424 to 0.1997)
Results, base-case analysis (LYG)	
Incremental costs (men only) (range)	Dietitian: 1684 DKK (720–2971 DKK); GP: 774 DKK (416–818 DKK)
Incremental outcomes (men only) (95% CI)	Diet: ΔLYG: 0.0002 (–0.053 to 0.0531); GP: ΔLYG: 0.1210 (0.0424 to 0.1997)
ICER (men only) (95% CI)	Dietitian: NR, calculated as 8,420,000 DKK (NR); GP: 6399 DKK (bias-corrected 95% CI 3911 DKK to 16,787 DKK)

Results, secondary analysis (1): outcomes measured as LYG without ischaemic heart disease	
Incremental costs (men only) (range)	Dietitian: 1684 DKK (720–2971 DKK); GP: 770 DKK (416–818 DKK)
Incremental outcomes (men only) (95% CI)	Dietitian: 0.0630 (–0.0140 to 0.1400); GP: 0.2376 (0.1015 to 0.3737)
ICER (men only)	Dietitian: NR, calculated as 26,730 DKK (bias-corrected 95% CI NR); GP: 3240 DKK (bias-corrected 95% CI 2069 DKK to 6841 DKK)
Results, sensitivity analysis (1): costs and ICERs calculated based on the estimated use of GP time (identical time estimates for dietitians and GPs)	
Incremental costs (men only) (95% CI)	Dietitian: 541 DKK (NR); GP: 774 DKK (NR)
Incremental outcomes (men only) (95% CI)	Dietitian: 0.0002 (–0.0530 to 0.0531); GP: 0.1210 (0.0424 to 0.1997)
ICER (men only) (95% CI)	Dietitian: 2,705,000 DKK (NR); GP: 6399 DKK (NR)
Results, sensitivity analysis (2): costs and ICERs calculated based on registered use of dietitian time (identical time estimates for dietitians and GPs)	
Incremental costs (men only) (95% CI)	Dietitian: 1231 DKK (NR); GP: 2278 DKK (NR)
Incremental outcomes (men only) (95% CI)	Dietitian: 0.0002 (–0.0530 to 0.0531); GP: 0.1210 (0.0424 to 0.1997)
ICER (men only) (95% CI)	Dietitian: NR, calculated as 6,155,000 DKK (NR); GP: 18,821 DKK (NR)
Results, sensitivity analysis (3): base-case analysis – outcomes measured as LYG and reported for men and women together	
Incremental costs (men and women) (range)	Dietitian: 1642 DKK (720–3204 DKK); GP: 755 DKK (416–818 DKK)
Incremental outcomes (men and women) (95% CI)	Dietitian: 0.0274 (0.0013 to 0.0534); GP: 0.0919 (0.0569 to 0.1269)
ICER (men and women)	Dietitian: 59,987 DKK (bias-corrected 95% CI 30,545 DKK to 996,368 DKK); GP: 8213 DKK (bias-corrected 95% CI 5910 DKK to 12,850 DKK)
Results, sensitivity analysis (4): outcomes measured as LYG without ischaemic heart disease and reported for men and women together	
Incremental costs (men and women) (range)	Dietitian: 1642 DKK (720–3204 DKK); GP: 751 DKK (416–818 DKK)
Incremental outcomes (men and women) (95% CI)	Dietitian: 0.0700 (0.0388 to 0.1011); GP: 0.1608 (0.1054 to 0.2162)
ICER (men and women)	Dietitian: 23,469 DKK (bias-corrected 95% CI 16,223 DKK to 41,912 DKK); GP: 4670 DKK (bias-corrected 95% CI 3480 DKK to 6905 DKK)
Results, sensitivity analysis (5): costs and ICERs calculated based on the estimated use of GP time (identical time estimates for dietitians and GPs); outcomes measured as LYG and reported for men and women together	
Incremental costs (men and women) (range)	Dietitian: 533 DKK (NR); GP: 755 DKK (NR)
Incremental outcomes (men and women) (95% CI)	Dietitian: 0.0274 (0.0013 to 0.0534); GP: 0.0919 (0.0569 to 0.1269)
ICER (men and women) (95% CI)	Dietitian: 19,472 DKK (NR); GP: 8213 DKK (NR)
Results, sensitivity analysis (6): costs and ICERs calculated based on the estimated use of dietitian time (identical time estimates for dietitians and GPs); outcomes measured as LYG and reported for men and women together	
Incremental costs (men and women) (range)	Dietitian: 1204 DKK (NR); GP: 2209 DKK (NR)
Incremental outcomes (men and women) (95% CI)	Dietitian: 0.0274 (0.0013 to 0.0534); GP: 0.0919 (0.0569 to 0.1269)
ICER (men and women)	Dietitian: 43,987 DKK (NR); GP: 24,037 DKK (NR)

Uncertainty	
Probabilistic analysis undertaken?	NA – bootstrapped estimates used to describe uncertainty in the cost–effect pairs
Results reported for male subgroup?	No
Distribution for costs	NA
Parameter a	NA
Parameter b	NA
Distribution for utilities	NA
Parameter a	NA
Parameter b	NA
Distribution for other	NA
Parameter a	NA
Parameter b	NA
Results illustrated using (e.g. CEAC, scatterplot)	CEACs and scatterplots of 10,000 bootstrapped iterations
Key results of PSA	Probability of cost-effectiveness: Dietitian ~0% and GP ~100% at a WTP of 25,000 DKK per life-year gained; dietitian ~80% and GP ~100% at a WTP of 100,000 DKK per life-year gained
Conclusions of sensitivity analysis	GP counselling tends to be more cost-effective. Using identical time estimates for dietitian and GP counselling services resulted in lower intervention costs for the dietitian group; however, GP counselling was still more cost-effective. Male participants tended to have a lower ICER for GP counselling and female participants tended to have a lower ICER for dietitian counselling
Conclusions of subgroup analysis	Information based on subgroups showed that, in general, ICERs were lower when the outcome measured was LYG without ischaemic heart disease, that is, the cost of gaining 1 extra life-year without ischaemic heart disease was lower than the cost of gaining 1 extra life-year. The GP group tended to be more cost-effective here also, especially for the male subgroup
Conclusions drawn from PSA	The probability of acceptance of GP counselling would be much greater than the probability of acceptance of dietitian counselling. Further, there was much greater statistical uncertainty for the dietitian group than the GP group
Other methodological issues	
Expected value of perfect information (EVPI) analysis undertaken?	No
Type	NA
Results	NA
Conclusions of EVPI analysis/recommendations for future research	NA
Study strengths (as identified by authors)	None explicitly referenced in the text
Study limitations (as identified by authors)	(1) Simplifying model assumptions are in their own right a potential limitation (e.g. it was assumed that the improvement in lifestyle was maintained beyond the intervention period); (2) it should be noted that the greater effect in the GP group could be caused by other factors, for example GPs may give wider lifestyle advice than dietitians (e.g. on smoking cessation); (3) the applied costing method can give rise to methodological concerns because time estimates are compared with standard agreed salaries; transferability of results may thus be limited; (4) the GPs that partook in the study may not be representative as they may have an unrepresentative interest in preventative care

Key author conclusions
GP counselling appears more cost-effective than dietitian counselling. Both dietitian- and GP-provided interventions were considered potentially cost-effective. The results were not so clear for the male-only group with some ICERs excessively high because of small outcome differences. For all age groups the base-case analysis showed both counselling strategies to be cost-effective. Although GP counselling was more cost-effective and had a lower ICER than the dietitian intervention, the dietitian intervention could also be considered potentially cost-effective, costing an additional 59,987 DKK per life-year gained. Basing conclusions on the assumption that the WTP for a life-year and a QALY gained is similar, then both GP and dietician advice could offer good value for money, given that society typically places the WTP for a QALY gain at 88,000 DKK
Recommendations for future research
The results indicate that nutritional counselling should be combined with advice regarding other lifestyle changes. No sex-specific recommendations were made

DKK, Danish kroner; NA, not applicable; NR, not reported; PSA, probabilistic sensitivity analysis.

Segal 1998[163]

Title: Cost-effectiveness of the primary prevention of non-insulin dependent diabetes mellitus

Study characteristics	
Country of study	Australia
Study setting	Hospital, community and primary care, depending on programme delivered; programme IV appears to be delivered in a primary care/community setting
Research question/objective	To investigate whether the prevention of NIDDM is cost-effective compared with other possible uses of health-care resources and whether some approaches to NIDDM prevention are more cost-effective than others
Study design (model/RCT)	Markov model (specific Markov submodel for each of the six programmes considered)
Inclusion criteria	Those with IGT, overweight/obese men, seriously obese people, women with previous gestational diabetes and the general Australian population. Detailed inclusion criteria for each programme are not reported. For programme IV the target was obese and overweight men, a mixed group (10% impaired glucose tolerance, 90% normal glucose tolerance) and those with impaired glucose tolerance only
Exclusion criteria	Not reported. The use of antidiabetic drugs was not included as a programme for evaluation as this was deemed management rather than prevention of diabetes and was outwith the scope of the study
Intervention	A total of six programmes were considered of which only one was male specific. Programme IV was a group behavioural modification for men (five to six group sessions; aim to reduce waist size through diet change and increased activity; empowerment philosophy). Information regarding potentially relevant male-specific data from other programmes was not available
Control/comparison	Standard care – no active intervention in the control cohort of the models/submodels
Methods: costing	
Perspective	Health-care providers
Currency	Australian dollar. Conversion to US dollars was carried out using a median exchange rate for August/September/October 1997 of AUS $1 = US$0.72
Currency year of reporting	1997
Discount rate for costs	5%, applied to downstream costs
Other information on costing	Average programme costs were reported; however, individual cost components or detailed resource use was not. Costs were reported in the study results as gross costs (i.e. programme costs) and net costs (i.e. programme/intervention delivery costs less any downstream cost savings from the treatment of diabetes). The cost of managing NIDDM was AUS$1800 per diabetic per year in the model
Methods: outcome measures	
Primary economic outcome measures	LYG, reduction in diabetes years
Discount rate for outcomes	5%
Time horizon for outcomes	Mortality vectors applied to intervention and control cohorts for 25 years post intervention. Remaining life expectancy calculated by adjusting the population life expectancy for the diabetic state and whether or not weight loss was achieved

Methods: modelling	
Type of model used	Markov models (a set of sub Markov models for each individual programme)
Size of model cohort	NR
Model time horizon	25 years post intervention
Health states modelled/model description	NIDDM, normal glucose tolerance, impaired glucose tolerance
Methods: economic evaluations alongside RCTs	
Age group	NA
Sex breakdown	NA
Period of intervention	NA
Period of follow-up	NA
n randomised to intervention	NA
n randomised to control	NA
Data completeness intervention	NA
Data completeness control	NA
Results, base-case costs	
Intervention group programme IV (men only)	Gross cost: AUS$577 (AUS$195 excluding screening cost per case detected); net cost: NR
Comparator group programme IV (men only)	Assumed AUS$0
Incremental costs	Final discounted incremental costs were not directly reported; therefore, incremental gross cost for programme IV can only be extracted as AUS$577 (AUS$195 excluding screening cost per case detected)
Results, base-case primary economic outcome	
Programme IV (per 100)	

Group	Diabetes years prevented	LYG
Intervention group		
Mixed	135	3016
IGT	484	2750
Comparator group		
Mixed	172	2905
IGT	639	2888
Incremental outcomes		
Mixed	37	111
IGT	155	138

Results, primary economic analysis (base-case results)

Incremental costs (programme IV): Gross cost: AUS$577 (AUS$195 excluding screening cost per case detected); net cost: NR

Incremental outcomes (programme IV, per 100)

Group	Diabetes years prevented	LYG
Mixed	37	111
IGT	155	138

ICER, reported only as incremental cost per life-year gained

Group	Gross cost per life-year gained	Net cost per life-year gained
IGT	500	NS
IGT[a]	1600	NS
Mixed	700	NS

Results, secondary analysis

None applicable to programme IV

Results, sensitivity analysis (1): the impact of a change in the programme success rate on cost-effectiveness (programme IV, men only)

Incremental net cost per life-year saved:

Programme type	Analysis	Assumed success rate (%)	Net cost per life-year saved
IV (men only)	Low	20	100
	Base case[b]	**33**	**NS**
	High	45	NS

Results, sensitivity analysis (2)

A range of other sensitivity analyses was carried out on various programmes but none of those reported was for the male-specific programme IV. Additional male-specific data from other programmes were requested from the study authors but were not available at the time of publication

Uncertainty

Probabilistic analysis undertaken?	No
Results reported for male subgroup?	NA
Distribution for costs	NA
Parameter a	NA
Parameter b	NA

Distribution for utilities	NA
Parameter a	NA
Parameter b	NA
Distribution for other	NA
Parameter a	NA
Parameter b	NA
Results illustrated using (e.g. CEAC, scatterplot)	NA
Key results of PSA	NA
Conclusion of sensitivity analysis	Net cost per life-year gained is sensitive to the rate of programme success. However, despite varying the success rate of the male-only programme IV, the intervention remained highly cost-effective and there was a net saving for all but the lowest success rate considered
Conclusions of subgroup analysis	The group behavioural programme was cost-effective for both the impaired glucose tolerance subgroup and the mixed levels of glucose tolerance subgroup of men. Cost-effectiveness appeared even more definitive in those with impaired glucose tolerance
Conclusions drawn from PSA	NA
Other methodological issues	
Expected value of perfect information (EVPI) analysis undertaken?	None
Type	NA
Results	NA
Conclusions of EVPI analysis/recommendations for future research	NA
Study strengths (as identified by authors)	NR
Study limitations (as identified by authors)	(1) A single transition matrix for most programmes has been used to progress each cohort between diabetic states; a more dynamic model of progression between diabetic states might have been preferred; (2) a further simplification is the selection of a single target age group; (3) costs have been limited to direct costs; no account is taken of other programme costs (e.g. time commitment of participants); (4) the results do not account for quality of life; the authors state that this was not possible given the poor evidence base at the time of the study
Key author conclusions	
For the prevention of NIDDM, the interventions considered may be cost saving or highly cost-effective relative to other possible uses of health-care resources. The behavioural diet programmes for high-risk groups were found to be highly cost-effective relative to other health-care programmes. The male-specific group behavioural programme was particularly cost-effective or cost saving when accounting for downstream cost savings associated with the prevention of and lesser need for costly management of NIDDM	
Recommendations for future research	
(1) There is a need to focus on NIDDM prevention; if the incidence of NIDDM is not contained, the cost to the community in terms of illness, loss of quality of life, premature death and allocation of scarce health-care resources will be an ever-increasing burden; (2) broader population-based programmes targeting high-risk groups; (3) the application of studies to a more international context; (4) the pilot introduction of programmes is recommended	

NA, not applicable; NR, not reported; NS, net saving.
a Based on the cost of a new case of diabetes found through the screening programme.
b Parameter value for the base-case analysis shown in bold.
Gross cost-effectiveness is the quotient of programme cost and diabetes years avoided or life-years saved. Net cost is calculated by subtracting the discounted future health service costs avoided through the prevention of NIDDM from the cost of programme implementation. Net costs are not directly reported.

Appendix 14 List of included studies: qualitative review

Abildso 2010

Abildso C, Zizzi S, Gilleland D, Thomas J, Bonner D. A mixed methods evaluation of a 12-week insurance-sponsored weight management program incorporating cognitive-behavioral counseling. *J Mix Methods Res* 2010;**4**:278–94.

De Souza 2005

De Souza P, Ciclitira KE. Men and dieting: a qualitative analysis. *J Health Psychol* 2005;**10**:793–804.

Gallagher 2012

Gallagher R, Kirkness A, Armari E, Davidson PM. Weight management issues and strategies for people with high cardiovascular risk undertaking an Australian weight loss program: a focus group study. *Nurs Health Sci* 2012;**14**:18–24.

Gillon 2003

Gillon E. Can men talk about problems with weight? The therapeutic implications of a discourse analytic study. *Counsell Psychother Res* 2003;**3**:25–32.

Gough 2006

Gough B, Conner MT. Barriers to healthy eating amongst men: a qualitative analysis. *Soc Sci Med* 2006;**62**:387–95.

Gough 2009

Gough B, Flanders G. Celebrating 'obese' bodies: Gay 'bears' talk about weight, body image and health. *Int J Mens Health* 2009;**8**:235–53.

Gray 2009

Gray CM, Anderson AS, Clarke AM, Dalziel A, Hunt K, Leishman J, *et al.* Addressing male obesity: an evaluation of a group-based weight management intervention for Scottish men. *J Mens Health* 2009;**6**:70–81.

Harrison 2007

Harrison A. Weight management in the workplace. In Conrad D, White A, editors. *Men's Health: How To Do It*. Oxford: Radcliffe Publishing; 2007. pp. 59–72.

Hunt 2013

Hunt K, McCann C, Gray CM, Mutrie N, Wyke S. 'You've got to walk before you run': positive evaluations of a walking program as part of a gender-sensitized, weight-management program delivered to men through professional football clubs. *Health Psychol* 2013;**32**:57–65.

Kim 2008

Kim KH, Linnan L, Campbell MK, Brooks C, Koenig HG, Wiesen C. The WORD (Wholeness, Oneness, Righteousness, Deliverance): a faith-based weight-loss program utilizing a community-based participatory research approach. *Health Educ Behav* 2008;**35**:634–50.

Leishman 2007

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Monaghan 2007b

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Monaghan LF. Men, physical activity, and the obesity discourse: critical understandings from a qualitative study. *Sociol Sport J* 2008;**25**:97–129.

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Morgan PJ, Lubans DR, Collins CE, Warren JM, Callister R. 12-Month outcomes and process evaluation of the SHED-IT RCT: an internet-based weight loss program targeting men. *Obesity* 2011;**19**:142–51.

Morgan 2011b

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White 2008

White A, Conrad D, Branney P. Targeting men's weight in the workplace. *J Mens Health* 2008;**5**:133–40.

Witty 2010

Witty K, White A. *The Tackling Men's Health Evaluation Study: Final Report.* Leeds: Leeds Metropolitan University, Centre for Men's Health; 2010. URL: www.leedsmet.ac.uk/hss/docs/Tackling_Men_Health_Final_Report.pdf (accessed November 2011).

Appendix 15 Data extraction form: qualitative review

1. Bibliographic information

Article title:

Extracted by:

Checked by:

Type of publication, date and page numbers (if journal article also give title of the journal):

Linked to RCT or non-randomised intervention:

Country of setting:

2. Researcher details

Authors and affiliations (list as presented on paper):

Gender of researchers who collect the qualitative data:

Academic discipline of authors:

3. Aims and methods

Study aims:

Research questions – Stated explicitly or implicit within the general text/topic guide? In what section(s) of the paper are questions mentioned? Are they prospective or retrospective?

Theoretical and epistemological perspective underpinning the qualitative research (if not explicitly stated the extractor should offer an interpretation):

Theoretical perspective underpinning the intervention:

Qualitative methods used:

Data analysis technique and procedure:

4. Findings

(a) Themes

Which key themes are stated to have emerged from the qualitative research?

(b) Engagement

How are men attracted to taking part in the trial/intervention?	Notes: Summary (third order): Participant quotes (first order): Author statements (second order):
How are men motivated to lose weight?	Notes: Summary (third order): Participant quotes (first order): Author statements (second order):

(c) Intervention	
Characteristics of the intervention:	
Timing of the intervention (when, how often, for how long):	
Who delivers the intervention? (discipline, gender)	
Focus of the programme (i.e. diet, exercise, behavioural counselling):	
Results:	
Demographic information:	
Dropout rate:	
Sex breakdown (if programme not for men only):	
(d) Intervention (communication) process	
Are communication processes referred to in the protocol?	Notes:
Any specific training provided as part of the intervention? (e.g. psychological behaviour change techniques). If so, are certain features of behaviour change found to be more attractive for obese men? How and why are these features more attractive?	Notes: Summary (third order): Participant quotes (first order): Author statements (second order):
Is fidelity to protocol mentioned?	
What are men's perceptions of the communication process?	Notes: Participant quotes (first order): Author statements (second order): Summary (third order):
(e) Central research questions derived from quantitative review to guide data extraction	
How are men consulted in the design of the intervention (if they are)? Should also include which literature is consulted to aid conception of the design. Was the literature gender specific?	Notes: Summary (third order): Participant quotes (first order): Author statements (second order):
If it is found that interventions for men should be different from those for women, how should they be different and why?	Notes: Summary (third order): Participant quotes (first order): Author statements (second order):
Are group-based interventions for men found to be more effective for weight loss than interventions delivered to individual men? How and why are they more effective?	Notes: Summary (third order): Participant quotes (first order): Author statements (second order):
Are certain features of diets found to be more attractive for obese men? How and why are these features more attractive?	Notes: Summary (third order): Participant quotes (first order): Author statements (second order):
Are certain features of physical activity stated to be more attractive for obese men? How and why are these features more attractive?	Notes: Summary (third order): Participant quotes (first order): Author statements (second order):

What is stated with regard to participant attrition and what efforts are made to help men continue with the programme?	Notes: Summary (third order): Participant quotes (first order): Author statements (second order):
Do men state who they believe to be the best person/persons to deliver the intervention? If so, why are they preferred?	Notes: Summary (third order): Participant quotes (first order): Author statements (second order):
Are programmes deliberately involving partners/families more effective? How, why and at what stage?	Notes: Summary (third order): Participant quotes (first order): Author statements (second order):
Were there any other emergent themes or gaps/omissions not covered by the above?	Notes: Summary (third order): Participant quotes (first order): Author statements (second order):
5. Area and context (micro, meso and macro levels)	
Rationale for setting choice (for intervention and where qualitative research is conducted):	
Meaning attributed to where the intervention is delivered:	
Perceptions about the venue (micro) and area of setting (meso):	
What else is going on at the time of the intervention (e.g. clinic appointment) (meso):	
Does the setting potentially exclude/target populations? (meso)	
Are there any wider media, cultural, political or contextual factors that might be influencing the intervention? (macro)	
6. Quality	
(a) Sample	
Sample size:	
Sample characteristics:	
Sample selection process:	
Sample inclusion and exclusion criteria:	
(b) Reflexivity	
Evidence of researcher reflexivity:	
(c) Ethics	
Evidence of attention to ethical issues:	
(d) General	
Are the findings adequately supported by the data presented?	
Is there potential for a 'charisma effect' in this study? (this relates to the potential influence of the principal investigator)	
Any other quality issues not covered above?	

Appendix 16 List of excluded studies

Reviews of men-only randomised controlled trials and randomised controlled trials of men and women compared

Abstracts, commentaries, errata, evidence summaries, protocols, recommendations and news articles

First year of Look AHEAD trial yields encouraging results. *Diabetes Dateline* spring/summer 2008, pp. 7–8.

Collins CE, Morgan PJ, Jones P, Fletcher K, Martin J, Aguiar EJ, *et al.* Evaluation of a commercial web-based weight loss and weight loss maintenance program in overweight and obese adults: a randomized controlled trial. *BMC Public Health* 2010;**10**:669.

Cudjoe S, Moss S, Nguyen L. How do exercise and diet compare for weight loss? *J Fam Pract* 2007;**56**:841–4.

Donaldson E, Fallows S. A text message-based weight management intervention for overweight adults. *J Hum Nutr Diet* 2011;**24**:385–6.

Donnelly JE, Blair SN, Jakicic JM, Manore MM, Rankin JW, Smith BK; American College of Sports Medicine. Appropriate physical activity intervention strategies for weight loss and prevention of weight regain in adults. *Med Sci Sports Exerc* 2009;**41**:459–71.

Gordon J, Dibble T, Adams C, McGee E. An evaluation of the long-term effectiveness of two adult community-based group weight management interventions. *J Hum Nutr Diet* 2011;**24**:388.

Kumanyika SK, Shults J, Fassbender J, Whitt MC, Brake V, Kallan MJ, *et al.* Corrigendum to 'Outpatient weight management in African-Americans: the Healthy Eating and Lifestyle Program (HELP) study'. *Prev Med* 2006;**42**:1

Miyachi M, Ohmori Y, Morita A, Aiba N. Effects of pedometer-based physical activity intervention on abdominal fat and blood pressure: Saku community-based randomized crossover intervention study. *J Clin Hypertens* 2010;**12**:A14.

Morgan PJ, Collins CE, Plotnikoff RC, McElduff P, Burrows T, Warren JM, *et al.* The SHED-IT community trial study protocol: a randomised controlled trial of weight loss programs for overweight and obese men. *BMC Public Health* 2010;**10**:701.

Resch KL. Dietary Intervention Randomized Controlled Trial (DIRECT) group: weight loss with a low-carbohydrate, Mediterranean, or low-fat diet. *Forsch Komplementmed* 2008;**15**:351–2.

Rossner S. Atkins – the superior slimming diet? *Scand J Food Nutr* 2007;**51**:4.

Wycherley TP, Brinkworth GD, Clifton PM, Noakes M. A one year high protein, low fat weight loss diet improves body composition and cardiometabolic risk factors in overweight males with features of the metabolic syndrome. *Australas Med J* 2011;**4**:731.

Different inclusion criteria for men and women

Kiernan M, King AC, Stefanick ML, Killen JD. Men gain additional psychological benefits by adding exercise to a weight-loss program. *Obes Res* 2001;**9**:770–7.

Torgerson JS, Lissner L, Lindroos AK, Kruijer H, Sjostrom L. VLCD plus dietary and behavioural support versus support alone in the treatment of severe obesity. A randomised two-year clinical trial. *Int J Obes* 1997;**21**:987–94.

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Cost-effectiveness reviews

Bogers RP, Barte JC, Schipper CM, Vijgen SM, de Hollander EL, Tariq L, *et al.* Relationship between costs of lifestyle interventions and weight loss in overweight adults. *Obes Rev* 2010;**11**:51–61.

Cecchini M, Sassi F, Lauer JA, Lee YY, Guajardo-Barron V, Chisholm D. Tackling of unhealthy diets, physical inactivity, and obesity: health effects and cost-effectiveness. *Lancet* 2010;**376**:1775–84.

Cobiac L, Vos T, Veerman L. Cost-effectiveness of Weight Watchers and the Lighten Up to a Healthy Lifestyle program. *Aust N Z J Public Health* 2010;**34**:240–7.

Joo NS, Park YW, Park KH, Kim CW, Kim BT. Cost-effectiveness of a community-based obesity control programme. *J Telemed Telecare* 2010;**16**:63–7.

Follow-up < 12 months

Apekey T, Morris A, Fagbemi S, Griffiths G. Benefits of moderate-intensity exercise during a calorie-restricted low-fat diet. *Health Educ J* 2012;**71**:154–64.

Azadbakht L, Parvin M, Ahmad E, Tohid A, Fereidoun A. Beneficial effects of a Dietary Approaches to Stop Hypertension eating plan on features of the metabolic syndrome. *Diabetes Care* 2005;**28**:2823–31.

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Kamioka H, Nakamura Y, Okada S, Kitayuguchi J, Kamada M, Honda T, *et al.* Effectiveness of comprehensive health education combining lifestyle education and hot spa bathing for male white-collar employees: a randomized controlled trial with 1-year follow-up. *J Epidemiol* 2009;**19**:219–30.

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ter Bogt NC, Milder IE, Bemelmans WJ, Beltman FW, Broer J, Smit AJ, *et al.* Changes in lifestyle habits after counselling by nurse practitioners: 1-year results of the Groningen Overweight and Lifestyle study. *Public Health Nutr* 2011;**14**:995–1000.

van Wier MF, Dekkers JC, Hendriksen IJ, Heymans MW, Ariëns GA, Pronk NP, *et al.* Effectiveness of phone and e-mail lifestyle counseling for long term weight control among overweight employees. *J Occup Environ Med* 2011;**53**:680–6.

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Atlantis E, Barnes EH, Ball K. Weight status and perception barriers to healthy physical activity and diet behavior. *Int J Obes* 2008;**32**:343–52.

Clifford PA, Tan SY, Gorsuch RL. Efficacy of a self-directed behavioral health change program: weight, body composition, cardiovascular fitness, blood pressure, health risk, and psychosocial mediating variables. *J Behav Med* 1991;**14**:303–23.

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No comparator

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