

# The clinical effectiveness and cost-effectiveness of long-term weight management schemes for adults: a systematic review

E Loveman, GK Frampton, J Shepherd, J Picot, K Cooper, J Bryant, K Welch and A Clegg



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# The clinical effectiveness and cost-effectiveness of long-term weight management schemes for adults: a systematic review

E Loveman,\* GK Frampton, J Shepherd, J Picot, K Cooper, J Bryant, K Welch and A Clegg

Southampton Health Technology Assessments Centre, Southampton, UK

\*Corresponding author

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 08/49/01. The contractual start date was in July 2009. The draft report began editorial review in February 2010 and was accepted for publication in June 2010. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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## Abstract

### The clinical effectiveness and cost-effectiveness of long-term weight management schemes for adults: a systematic review

E Loveman,\* GK Frampton, J Shepherd, J Picot, K Cooper, J Bryant, K Welch and A Clegg

Southampton Health Technology Assessments Centre, Southampton, UK

\*Corresponding author

**Objective:** To assess the long-term clinical effectiveness and cost-effectiveness of multicomponent weight management schemes for adults in terms of weight loss and maintenance of weight loss.

**Data sources:** Bibliographic databases were searched from inception to December 2009, including the Cochrane Library, MEDLINE (Ovid), EMBASE (Ovid), and MEDLINE In-Process & Other Non-Indexed Citations. Bibliographies of related papers were screened, key conferences and symposia were searched and experts were contacted to identify additional published and unpublished references.

**Review methods:** For the clinical effectiveness review, two reviewers independently screened titles and abstracts for eligibility. Inclusion criteria were applied to the full text of retrieved papers by one reviewer and checked by a second reviewer using a pre-piloted inclusion flow chart. The studies were long-term randomised controlled trials (RCTs) of adult participants who were classified by body mass index as overweight or obese. Interventions were multicomponent weight management programmes (including diet, physical activity and behaviour change strategies) that assessed weight measures. Programmes that involved the use of over-the-counter medicines licensed in the UK were also eligible. For the cost-effectiveness review two reviewers independently screened studies for inclusion. Cost-effectiveness, cost-utility, cost-benefit or cost-consequence analyses were eligible. Data were extracted using a standardised and pre-piloted data extraction form. The quality of included studies was assessed using standard criteria. Studies were synthesised through a narrative review with full tabulation of results.

**Results:** A total of 3358 references were identified, of which 12 were included in the clinical effectiveness review. Five RCTs compared multicomponent interventions with non-active comparator groups. In general, weight loss appeared to be greater in the intervention groups than in the comparator groups. Two RCTs compared multicomponent interventions that focused on the diet component. In these studies there were no statistically significant differences in weight loss between interventions. Four RCTs compared multicomponent interventions that focused on the physical activity component. There was little consistency in the pattern of results seen, in part owing to the differences in the interventions. In one RCT the intervention focused on the goal-setting interval and it appeared that weight loss was greatest in those given daily goals compared with weekly goals. Overall, where measured, it appeared that most groups began to regain weight at further follow-up. Of the 419 studies identified in the cost-effectiveness searches, none met the full inclusion criteria. Two economic evaluations are described in our review; however, caution is required

in their interpretation, as they did not meet all inclusion criteria. Lifetime chronic disease models were used in these studies and the models included the costs and benefits of avoiding chronic illness. Both studies found the interventions to be cost-effective, with estimates varying between –£473 and £7200 (US\$12,640) per quality-adjusted life-year gained; methodological omissions from these studies were apparent and caution is therefore required in the interpretation of these results.

**Conclusions:** Long-term multicomponent weight management interventions were generally shown to promote weight loss in overweight or obese adults. Weight changes were small however and weight regain was common. There were few similarities between the included studies; consequently an overall interpretation of the results was difficult to make. There is some evidence that weight management interventions are likely to be cost-effective, although caution is required as there were some limitations in the two cost-evaluation studies described.

**Funding:** The National Institute for Health Research Health Technology Assessment programme.

# Contents

<b>List of abbreviations</b>	<b>vii</b>
<b>Executive summary</b>	<b>ix</b>
<b>1. Background</b>	<b>1</b>
Description of the underlying health problem	1
Current service provision	5
Description of technology under assessment	10
Overall aims of this assessment	12
<b>2. Methods</b>	<b>13</b>
Search strategy	13
Inclusion process	13
Data extraction and quality assessment strategy	15
Data synthesis	16
<b>3. Clinical effectiveness</b>	<b>17</b>
Quantity and quality of research available	17
Assessment of effectiveness of multicomponent interventions versus non-active intervention comparators	22
Assessment of effectiveness for multicomponent interventions with a focus on diet	31
Assessment of effectiveness for multicomponent interventions with a focus on exercise	36
Assessment of effectiveness for multicomponent interventions where the focus was on other variables	44
Ongoing studies	48
<b>4. Cost-effectiveness</b>	<b>51</b>
Quantity and quality of published research	51
Description and results of the published economic evaluations	54
Comparison of cost-effectiveness analyses	60
Summary of cost-effectiveness studies	62
<b>5. Discussion</b>	<b>63</b>
Statement of principal findings	63
General discussion	64
Comparison to existing systematic reviews	66
Other issues and methodological concerns	66
Strengths and limitations	68
Need for further research	69
<b>6. Conclusions</b>	<b>71</b>
<b>Acknowledgements</b>	<b>73</b>
<b>References</b>	<b>75</b>

<b>Appendix 1</b> Methods from the research protocol and commissioning brief (scope) for project	<b>83</b>
<b>Appendix 2</b> Sources of information and search terms	<b>87</b>
<b>Appendix 3</b> Inclusion criteria worksheet for full papers	<b>91</b>
<b>Appendix 4</b> Quality assessment criteria	<b>93</b>
<b>Appendix 5</b> Data from included studies	<b>95</b>
<b>Appendix 6</b> Excluded studies	<b>147</b>
<b>Appendix 7</b> Unclear studies	<b>157</b>
<b>Appendix 8</b> Informal assessment of key attributes of included studies	<b>159</b>
<b>Appendix 9</b> Data extractions for full papers for included studies in cost-effectiveness review	<b>161</b>
<b>Health Technology Assessment programme</b>	<b>177</b>



## List of abbreviations

BMI	body mass index (kg/m <sup>2</sup> )
BP	blood pressure
CRD	Centre for Reviews and Dissemination
CHD	coronary heart disease
CI	confidence interval
EQ-5D	European Quality of Life-5 Dimensions
FP	food provision
GP	general practitioner
HR	hazard ratio
HRQoL	health-related quality of life
HSE	<i>Health Survey for England</i>
HYHEP	Help Your Heart Eating Plan
HPA	high physical activity
ICER	incremental cost-effectiveness ratio
ITT	intention to treat
LDL	low-density lipoprotein
LI	lifestyle intervention
LOV-D	lacto-ovo-vegetarian diet
LYG	life-year gained
NICE	National Institute for Health and Clinical Excellence
NS	not statistically significant
NSF	National Service Framework
OTC	over-the-counter
PCT	primary care trust
QALY	quality-adjusted life-year
QoL	quality of life
RCT	randomised controlled trial
RD	registered dietitian
REE	resting energy expenditure
RR	relative risk
SBT	standard behavioural therapy/treatment
SBTE	standard behavioural therapy and exercise
SBTT	standard behavioural therapy and trainer
SBTI	standard behavioural therapy and incentive
SBTTI	standard behavioural therapy and trainer and incentive
SD	standard deviation
SE	standard error
SOC	stages of change
SS	social support
STD-D	standard diet

TOHP	Trials of Hypertension Prevention
UC	usual care
USDA	US Department of Agriculture
VLCD	very-low-calorie diet
WHO	World Health Organization

---

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

# Executive summary

## Background

The number of people who are overweight or obese in the UK is increasing and overweight and obesity is a significant public health problem. The impact to the individual and on health-care resources can be considerable because overweight and obesity are associated with a range of comorbidities, such as cardiovascular disease, Type 2 diabetes and many cancers. Weight loss can reduce the risk factors for these conditions. Weight management schemes consisting of diet, exercise and behaviour therapy have been developed to help people lose weight; however, after initial weight loss, many people regain weight in the long term. Recently, over-the-counter (OTC) weight loss medications have become available and these treatments may be used in some weight management schemes.

## Objectives

The aim of this systematic review is to assess the clinical effectiveness and cost-effectiveness of multicomponent weight management programmes in overweight and obese adults. Multicomponent weight management programmes include diet, exercise and behaviour therapy elements.

## Methods

### *Data sources*

A sensitive search strategy was designed and applied to 10 electronic bibliographic databases (including MEDLINE, EMBASE and the Cochrane Library) from inception to December 2009. Bibliographies of related papers were screened, key conferences and symposia were searched and experts were contacted to identify additional published and unpublished references.

### *Study selection*

Independently, two reviewers screened titles and abstracts for eligibility. Inclusion criteria were defined a priori and applied to the full text of retrieved papers by two reviewers using a standard form. Clinical effectiveness studies were included if participants were adults with a body mass index  $> 25 \text{ kg/m}^2$ ; if the interventions were well-described multicomponent (diet, exercise and behaviour therapy) weight management approaches with a weight loss outcome; and if the studies were randomised controlled trials (RCTs) with at least 18 months' follow-up. Studies were required to be cost-effectiveness analyses in the systematic review of cost-effectiveness.

### *Data extraction and quality assessment*

Data extraction and assessment of methodological quality was undertaken by one reviewer and checked by a second. Differences in opinion were resolved through discussion or recourse to a third reviewer at each stage.

### *Data synthesis*

The trials were reviewed in a narrative synthesis with full tabulation of the results of all included studies. Meta-analysis was not undertaken due to clinical heterogeneity in the participant groups and comparator treatments.

## Results

A total of 3358 references were identified for the review of clinical effectiveness. Following screening, 22 publications describing 12 RCTs were included.

Five RCTs compared multicomponent interventions with non-active comparator groups. In general weight change appeared to be greater in the intervention groups than the comparator groups. In those studies that measured it, most groups began to regain weight at further follow-up, although a statistically significant difference in weight loss in favour of the intervention group was maintained in some studies at up to 36 months' follow-up. Two RCTs compared multicomponent interventions that focused on the diet component. In these studies there were no statistically significant differences in weight loss between interventions and again participants regained weight over time. Four RCTs compared multicomponent interventions that focused on the physical activity component. The first study, a high physical activity intervention, led to more weight loss than a standard behavioural therapy approach at 18 months, but by 30 months the difference was not statistically significant. The second study described a standard behavioural therapy intervention that led to greater weight loss when compared with the same intervention plus supervised exercise. In the third study a diet and physical activity intervention led to similar weight losses as a diet alone intervention or an exercise alone intervention. Data were only presented for a subgroup of those participating in the remaining study, and not by study arm. One RCT compared a multicomponent intervention that focused on the goal-setting interval and it appeared that weight loss was greatest in those given daily dietary and exercise goals compared with those given weekly goals. However, there were no statistical analyses presented to support this observation and the study suffered from additional methodological limitations. No studies were identified which included the use of OTC weight loss medications.

In these 12 included studies any weight lost was generally small and may not reflect a clinically significant reduction in weight. Despite attempts to ensure the data included were as meaningful as possible there were few similarities between the studies, their interventions, or their lengths of follow-up and, as a result, conclusions are difficult to make.

For the review of cost-effectiveness, 419 references were identified. No studies met the full inclusion criteria. Two economic evaluations met many of the core criteria and a pragmatic decision was taken to describe these studies. However, caution is required in their interpretation as one study used prescription antiobesity drugs in some participants, and the other had a follow-up of less than 18 months. Each study used a lifetime chronic disease model to evaluate the effect of changes in an individual's weight. The models included the costs and benefits from avoiding chronic illnesses such as coronary heart disease and diabetes. Both studies found the interventions to be cost-effective, with estimates varying between –£473 and £7200 (US\$12,640) per quality-adjusted life-year gained. Omissions in reporting details of the modelling methodology and data inputs reduced transparency making it difficult to draw conclusions about the results; however, the results and methodology of the studies seemed reasonable. There were limitations to each study. One study was conducted in North America, and one in the UK. In the North American study, the costs were much higher than for the UK and non-medical costs have been included. In the UK study, the intervention effect is not based upon an RCT, and the costs are likely to be underestimated.

## Conclusions

Long-term multicomponent weight management interventions were generally shown to promote weight loss in overweight or obese adults. However, weight changes were small and weight regain was common in those studies that measured it. There were few similarities between the included studies; consequently interpretation of the results was difficult to make overall. In addition, it is not clear what degree of weight loss is deemed to be clinically meaningful. The cost-effectiveness studies offer some evidence that weight management interventions are likely to be cost-effective, although caution is required as there were a number of limitations to the two cost evaluation studies described. There were no UK-based RCTs included in the review and as such there is a research need to evaluate the effects of long-term multicomponent weight management interventions in a UK setting.

## Funding

The National Institute for Health Research Health Technology Assessment programme.



# Chapter 1

## Background

Overweight and obesity are defined as abnormal or excessive fat accumulation that may impair health. A complex relationship between genetic,<sup>1</sup> biochemical, neural and psychological factors, and environmental aspects<sup>2</sup> can come into play in the development of overweight and obesity. Studies have shown that age, gender and ethnicity are key risk factors for weight gain.<sup>3-5</sup> Without intervention, reversal of overweight and obesity is uncommon.<sup>4</sup>

The most commonly used measure for classifying overweight and obesity is the body mass index (BMI). This is a simple ratio that is defined as the weight in kilograms divided by the square of the height in metres (kg/m<sup>2</sup>). Overweight in adults is most commonly defined as a BMI of 25 kg/m<sup>2</sup> or over, and obesity as a BMI of 30 kg/m<sup>2</sup> or over (Table 1).

### Description of the underlying health problem

It has been estimated that globally, in 2005, approximately 1.6 billion adults (aged 15 years and over) were overweight and at least 400 million adults were obese.<sup>7</sup> A recent systematic review estimated that across European countries the prevalence of obesity (BMI > 30 kg/m<sup>2</sup>) ranged from 4% to 28.3% in men, and 6.2% to 36.5% in women.<sup>8</sup> A 2009 NHS Information Centre report,<sup>9</sup> drawing on data from the *Health survey for England 2007* (HSE)<sup>10</sup> states that in England in 2007, 65% of men and 56% of women were overweight or obese. In Wales in 2007, 57% of adults were classified as overweight or obese, including 21% obese.<sup>11</sup> In 2008, 68.5% of men and 61.8% of women aged 16 years or over in Scotland were overweight or obese.<sup>12</sup> Data from Northern Ireland in 2005/6 show that 59% of adults were either overweight (35%) or obese (24%), and rates were similar across genders.<sup>13</sup>

Prevalence of obesity varies by age as well as by gender. In the 2009 NHS Information Centre report<sup>9</sup> prevalence of overweight and obesity varied by age, with high rates in older age groups (Table 2). In the *Northern Ireland health and social wellbeing survey 2005/06*, obesity (BMI > 30 kg/m<sup>2</sup>) was most prominent among those aged between 35 and 64 years.<sup>13</sup>

**TABLE 1** The international classification of adult underweight, overweight and obesity according to BMI<sup>6</sup>

Classification	BMI (kg/m <sup>2</sup> )
Underweight	< 18.50
Normal range	18.50–24.99
<b>Overweight</b>	≥ 25.00
Pre-obese	25.00–29.99
<b>Obese</b>	≥ 30.00
Obese class I	30.00–34.99
Obese class II	35.00–39.99
Obese class III (morbid obesity)	≥ 40.00

**TABLE 2** Proportion of overweight or obesity among adults by age and gender in England 2007<sup>9</sup>

Overweight or obese	Age (%)							All ages
	16–24 years	25–34 years	35–44 years	45–54 years	55–64 years	65–74 years	75+ years	
All adults	33	49	65	68	74	73	69	61
Men	33	54	71	75	79	77	71	65
Women	32	44	58	62	68	69	67	56

Overweight or obesity in women is more common in lower income households (defined using equivalised household income which takes account of the number of people in the household) than in women in the highest income households.<sup>9</sup> In men this pattern is not seen. Other demographic characteristics potentially associated with overweight and obesity include urbanisation, marital status and ethnicity. Available data for rates of obesity from the HSE 2004 report showed that men from Bangladeshi and Chinese minority ethnic groups had the lowest prevalence (both 6%) while Black Caribbean and Irish men had the highest prevalence (both 25%).<sup>9</sup> There are also regional differences in England in the prevalence of overweight and obesity, with generally higher levels in the North.<sup>14</sup> Estimates from survey data also suggest these geographical differences are widening in women but not in males (based on Health Survey data from 1993 and 2004).<sup>14</sup>

The prevalence of obesity (BMI > 30 kg/m<sup>2</sup>) among adults is increasing. Estimates from England in 2007 reported obesity prevalence was 24% for both men and women. This shows a clear increase from the figures shown in 1993, which were 13% for men and 16% for women.<sup>9</sup> In Wales there has also been an upward trend in obesity over time among people aged over 16 years.<sup>10</sup> Data from Scotland also show that there has been a steady upward trend (data is for overweight and obesity) in adults since 1995 (55.6% of men and 47.2% of women aged 16–64 years in 1995 compared with 66.3% and 59.6%, respectively in 2008).<sup>12</sup>

The prevalence of obesity is predicted to rise in the future. The World Health Organization (WHO) has projected that by 2015 more than 700 million adults worldwide will be obese. A projection of the UK prevalence of obesity (BMI > 30 kg/m<sup>2</sup>) extrapolating data from 1993 to 2004 onto 2012, showed that the prevalence would be 32.1% in men and 31.0% in women, suggesting nearly 13 million people will be obese by 2012.<sup>15</sup> The projected prevalence for adults was higher for those in manual social classes (48%) than non-manual social classes (35%). Another estimate of obesity prevalence, modelled in the UK's Foresight project '*Tackling obesity: future choices*', showed that if current trends persist, 36% of men and 28% of women aged 21–60 years will be obese in 2015.<sup>16</sup>

### Health consequences of overweight or obesity

Obesity can cause a variety of adverse health consequences. An increased risk of health problems starts when someone is only very slightly overweight; this risk increases as someone becomes more and more overweight.<sup>7,17</sup> The predominant serious health consequences associated with overweight and obesity include Type 2 diabetes, cardiovascular disease, musculoskeletal disorders such as osteoarthritis, and many cancers (*Table 3*).

A recent systematic review and meta-analysis of 89 studies reporting incidence of comorbidities related to obesity and overweight found statistically significant associations for multiple comorbidities.<sup>18</sup> Being overweight (BMI 25.00–29.99 kg/m<sup>2</sup>) was associated with the increased incidence of Type 2 diabetes, most cancers (except oesophageal in females, pancreatic and



**TABLE 3** Health problems associated with obesity. Reproduced with permission from the World Health Organization<sup>6</sup>

Greatly increased risk (relative risk > 3) <sup>a</sup>	Moderately increased risk (relative risk 2–3) <sup>a</sup>	Slightly increased risk (relative risk 1–2) <sup>a</sup>
Type 2 diabetes	Coronary heart disease	Cancer (breast cancer in postmenopausal women, endometrial cancer, colon cancer)
Gallbladder disease	Hypertension	Reproductive hormone abnormalities
Dyslipidaemia	Osteoarthritis (knees)	Polycystic ovary syndrome
Insulin resistance	Hyperuricaemia and gout	Impaired fertility
Breathlessness		Low back pain due to obesity
Sleep apnoea		Increased risk of anaesthesia complications
		Fetal defects associated with maternal obesity

a Relative risk values are approximate.

prostate cancer), all cardiovascular diseases, asthma, gallbladder disease, osteoarthritis and chronic back pain. Being obese (BMI  $\geq 30$  kg/m<sup>2</sup>) was associated with an increased incidence of Type 2 diabetes, all cancers (except oesophageal and prostate), all cardiovascular diseases, asthma, gallbladder disease, osteoarthritis and chronic back pain. The associations were most strongly observed for the incidence in Type 2 diabetes in females, for those overweight and those obese.

A recent meta-analysis of prospective observational studies<sup>19</sup> assessed the association between increases in BMI and the incidence of common adult cancers. Positive and strong associations with a 5 kg/m<sup>2</sup> increase in BMI in men were identified for cancer of the oesophagus [relative risk (RR) 1.52], thyroid cancer (RR 1.33), colon cancer (RR 1.24) and renal cancer (RR 1.24). In women, positive and strong associations with a 5 kg/m<sup>2</sup> increase in BMI were seen for endometrial cancer (RR 1.59), gallbladder cancer (RR 1.59), oesophageal cancer (RR 1.51) and renal cancer (RR 1.34). Weaker positive associations were identified for rectal cancer and malignant melanoma in men, postmenopausal breast cancer, pancreatic, thyroid, and colon cancers in women, and leukaemia, multiple myeloma and non-Hodgkin's lymphoma in both sexes. These findings are similarly reflected in a recently published report on the relationship between food, nutrition, and physical activity and the prevention of cancer by the World Cancer Research Fund.<sup>20</sup> Based on a series of systematic reviews this report shows evidence of a convincing risk of oesophageal, pancreatic, colorectal, breast, endometrial and kidney cancers with increased body fatness. The association with oesophageal cancer noted in these latter studies is in contrast to that of the systematic review noted above and may reflect differences in the analysis.

The relationship between BMI and mortality has also recently been investigated in an analysis of 57 prospective studies.<sup>17</sup> Deaths of known cause during a mean of 8 years of follow-up (adjusted for age, gender, smoking status and study) showed that in both sexes and at all ages, mortality was lowest in people with a BMI of about 22.5–25 kg/m<sup>2</sup>. A progressive excess mortality above this range was shown, with each 5 kg/m<sup>2</sup> higher BMI being associated with approximately 30% higher overall mortality {hazard ratio [HR] per 5 kg/m<sup>2</sup> 1.29 [95% confidence interval (CI) 1.27 to 1.32]}. For vascular mortality, diabetic, renal and hepatic mortality the HRs were 1.41 (95% CI 1.37 to 1.45), 2.16 (95% CI 1.89 to 2.46), 1.59 (95% CI 1.27 to 1.99) and 1.82 (95% CI 1.59 to 2.09), respectively (ranging from 40% to 120% higher mortality). There were no specific causes of death that were inversely associated with a BMI above the range 22.5–25 kg/m<sup>2</sup>. This study showed that mortality from cancer was 10% higher with each 5 kg/m<sup>2</sup> higher BMI [HR 1.10 (95% CI 1.06 to 1.15)].<sup>17</sup> In this study there was a greater proportional increase in the risk of mortality at younger ages (35–59 years) with each 5 kg/m<sup>2</sup> increase in BMI, but the trend for higher overall mortality

per increment in BMI was still seen in the older age groups. This is different to the findings of an earlier systematic review<sup>21</sup> of elevated BMI in those aged 65 years or over. The conclusions of this latter study suggested that a BMI in the overweight range was not associated with a significantly increased risk of mortality.<sup>21</sup>

### **Psychosocial consequences of overweight and obesity**

Alongside the health consequences of overweight and obesity a number of self-perceived problems such as low self-esteem and disturbance of body image can also affect an individual. Socially, obese people often encounter discrimination and prejudice at work and in public.<sup>22</sup> This can lead to negative economic and social consequences such as low educational attainment and lower income.<sup>23,24</sup> In general, quality of life (QoL), whether physical, psychological or social, is lower in those who are overweight or obese.<sup>23</sup> There is growing evidence to show that there is a strong negative correlation between degree of overweight and QoL; greater impairments in QoL are associated with greater degrees of weight increase.<sup>22,23</sup> One recent analysis based on surveillance data<sup>25</sup> found that being obese was associated with a significant deterioration in health-related quality of life (HRQoL) but being overweight was not. Reduced physical health and QoL associated with obesity can contribute to impaired mental well being.<sup>25</sup> This may also be influenced by gender as excess weight among women has been shown to be associated with an increased risk of depression, suicidal thoughts and suicide attempts, whereas this is less common in males.<sup>24</sup> A recent large population study ( $n = 43,534$ )<sup>26</sup> investigated the relationship between depression and BMI. This study noted that there was a significant U-shaped association between BMI categories and depression such that being obese and being underweight were associated with depression.

### **Benefits of weight loss**

Overweight and obesity together are the second leading cause of preventable death, primarily through effects on cardiovascular disease risk factors (hypertension, dyslipidaemia and Type 2 diabetes).<sup>27</sup> Weight loss improves these risk factors, and some evidence suggests that benefits can persist as long as weight loss is maintained.<sup>28,29</sup> A systematic review<sup>30</sup> found that weight loss from various interventions was associated with decreased risk of development of diabetes, and a reduction in low-density lipoprotein cholesterol, total cholesterol and blood pressure (BP) in the long term. The results of weight loss on mortality are however less certain. One systematic review<sup>31</sup> undertaken in 2007 suggests that weight loss has long-term benefits on all-cause mortality, particularly for women and for those with diabetes. However, a recent (2009) meta-analysis<sup>32</sup> showed that weight loss had a neutral effect on all-cause mortality. This study did find evidence of benefit in terms of mortality in those classified as 'unhealthy and obese'. A recent evidence synthesis of surgery for obesity compared with non-surgical options found that weight loss in the longer term reduced the incidence of risk factors such as metabolic syndrome, hypertriglyceridaemia and hyperuricaemia, and increased the proportion of people with remission from Type 2 diabetes.<sup>33</sup>

After weight loss, HRQoL has also been shown to be improved, even when weight loss has been small to moderate.<sup>23,24</sup> Participants in one cohort study showed improved HRQoL after a 1-year weight loss programme, and a strong relationship between the amount of weight lost and the change in QoL was also seen. This suggests that greater weight loss leads to greater improvement in HRQoL.<sup>34</sup>

In addition to health benefits resulting from weight loss there are cost implications to the health service. As many of the factors making up this cost are attributable to comorbidities [such as stroke, coronary heart disease (CHD), hypertension and diabetes mellitus], any reduction in the incidence of these conditions as a consequence of weight loss is likely to produce a cost saving to the health service.

However, for many people the lifestyle factors that have contributed to weight gain are difficult to change in order to lose weight. Although attempts at weight loss are often successful in the short term, sustaining the weight loss can be difficult.

## Current service provision

### Management of disease

Overweight and obesity are initially managed within the general practice setting. The recommendation within the clinical section of the National Institute for Health and Clinical Excellence (NICE) obesity guideline<sup>35</sup> is that the level of intervention discussed with patients should be based on patient BMI, waist circumference measurement, and presence of comorbidities (*Table 4*).

Non-surgical interventions based on a combination of diet and physical activity, accompanied by strategies to support behavioural (lifestyle) changes, form the cornerstone of overweight and obesity treatment. Recommendations regarding lifestyle interventions (LIs) for overweight and obesity have been provided within the clinical section of recommendations within the NICE guideline.<sup>35</sup> These recommendations state that ‘Multicomponent interventions are the treatment of choice. Weight management programmes should include behaviour change strategies to increase people’s physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person’s diet and reduce energy intake.’<sup>35</sup> It is also recommended that treatments should be individualised, both in terms of the type of treatment suggested and the level of support provided.

The guidelines give some indication of the information or content within a multicomponent intervention that should be provided for the weight loss, behavioural and physical activity aspects. For weight loss, adults should be informed that a realistic maximum weekly weight loss target is 0.5–1 kg (1–2 lb), and the overall aim should be to lose 5–10% of original weight. Diets that have a 600 kcal/day deficit (that is, they contain 600 kcal fewer than the person needs to stay the same weight) or that reduce calories by lowering the fat content (low-fat diets), in combination with expert support and intensive follow-up, are recommended for sustainable weight loss. The guidance states that low-calorie diets (1000–1600 kcal/day) may be considered, but are less likely to be nutritionally complete. Very-low-calorie diets (VLCD) (< 1000 kcal/day) may be used for a maximum of 12 weeks continuously, or intermittently with a low-calorie diet (for example, for 2–4 days per week), by people who are obese and have reached a plateau in weight loss. There should be clinical supervision of any diet of < 600 kcal/day.

**TABLE 4** Level of intervention based on BMI, waist circumference and presence of comorbidities<sup>35</sup>

BMI classification	Waist circumference			Comorbidities present
	Low	High	Very high	
Overweight (BMI 25.00–29.99 kg/m <sup>2</sup> )	General advice on healthy weight and lifestyle	Diet and physical activity <sup>a</sup>		Diet and physical activity; consider drugs
Obesity I (BMI 30.00–34.99 kg/m <sup>2</sup> )				
Obesity II (BMI 35.00–39.99 kg/m <sup>2</sup> )	Diet and physical activity; consider drugs			
Obesity III (BMI 40 kg/m <sup>2</sup> and above)	Diet and physical activity; consider drugs; consider surgery			

<sup>a</sup> Although not explicitly stated in the NICE guideline it is assumed that all diet and physical interventions will also include behavioural change strategies.

Behavioural therapy interventions should be delivered with the support of an appropriately trained professional. The strategies included in behavioural therapy interventions need to be appropriate for the person, and can include:

- self-monitoring of behaviour and progress
- stimulus control
- goal-setting
- slowing rate of eating
- ensuring social support
- problem solving
- assertiveness
- cognitive restructuring (modifying thoughts)
- reinforcement of changes
- relapse prevention
- strategies for dealing with weight regain.

The physical activity recommendation is for at least 30 minutes of moderate-intensity physical activity on 5 days or more a week. To prevent obesity, people may need to do 45–60 minutes of moderate-intensity activity a day, particularly if they do not reduce their energy intake.

The NICE guideline<sup>35</sup> also states that the distinction between losing weight and maintaining weight loss should be explained and stresses the importance of developing skills for both phases. The change from losing weight to maintenance typically happens after 6–9 months. In the longer term, people should move towards eating a balanced diet, consistent with other healthy eating advice and continue with regular physical activity to avoid regaining weight.

In addition to the clinical recommendations the NICE guideline<sup>35</sup> also provides recommendations for the wider public health setting. In this section the guideline states that weight loss programmes (including commercial or self-help groups, slimming books or websites) are recommended only if they are based on a balanced healthy diet, encourage regular physical activity, and expect people to lose no more than 0.5–1 kg (1–2 lb) a week. The guidance indicates that programmes that do not meet these criteria are unlikely to help people maintain a healthy weight in the long term and that people with certain medical conditions – such as Type 2 diabetes, heart failure or uncontrolled hypertension or angina – should check with their general practitioner (GP) or hospital specialist before starting a weight loss programme.

In some people who are overweight or obese, in particular those with other comorbidities or class I obesity, a prescription for weight control drugs can be considered. Surgery is usually only considered as a last resort if a number of criteria are fulfilled (e.g. BMI  $\geq 40$  kg/m<sup>2</sup> or between 35 kg/m<sup>2</sup> and 40 kg/m<sup>2</sup> with other significant disease and all appropriate non-surgical measures have been tried previously).

### **Current service cost**

Estimating the costs of overweight and obesity has been approached in different ways. The impact of BMI on prescribing costs in the UK has been recently reported.<sup>36</sup> This study found that the attributable cost of overweight and obesity accounted for 23% of spending on all drugs, with 16% attributable to obesity. The minimum annual cost of any drug prescriptions at BMI 20 kg/m<sup>2</sup> rose from £50.71 for men and £62.59 for women by £5.27 and £4.20, respectively, for each unit increase in BMI to a BMI of 25 kg/m<sup>2</sup>. Increases for each BMI unit were greater to BMI 30 kg/m<sup>2</sup>, and greater still, £8.27 (men) and £4.95 (women) to BMI 40 kg/m<sup>2</sup>, giving total annual prescribing costs at this level of obesity of £63.59 (men) and £27.16 (women).

A House of Commons Health Committee report<sup>37</sup> included an update of the National Audit Office estimate of obesity costs for England in 1998 using cost data for 2002 (Table 5). This update estimated that the direct treatment costs of obesity for 2002 were between £46M and £49M. The costs included in calculating this estimate were those for GP consultations, ordinary admissions, day cases, outpatient attendances and prescriptions. The costs of treating the consequences of obesity (comorbidities) lay between £945M and £1075M. Combining the total costs of treating obesity with the total costs of treating the consequences of obesity results in total direct costs of £990–1225M (2.3%–2.6% of net NHS expenditure in 2001–2). When indirect costs are also included the costs of obesity rise further.

These figures were based on people with a BMI of 25 kg/m<sup>2</sup> and over and the Health Committee report stresses that these figures are likely to underestimate the true cost of treating obesity and its consequences. A more recent study, which included a wider range of costs, estimated the direct cost of overweight and obesity to the UK NHS at £3.2B per year.<sup>38</sup> The majority of the costs attributable to overweight and obesity were from treating stroke, CHD, hypertensive disease and diabetes mellitus. The cost estimate from this study may be higher than those of other published sources because cost estimates are sensitive to the chosen cut-off point for BMI. In this case people with a BMI of 22 kg/m<sup>2</sup> and above were included, whereas some other studies have taken a BMI cut-off of 25 kg/m<sup>2</sup>.

The UK's Foresight project '*Tackling obesity: future choices*'<sup>16</sup> estimated that in 2007, overweight and obesity would account for £4.2B of the overall £17.4B estimated total annual cost to the NHS of diseases for which elevated BMI is a risk factor. The only factor considered in the model used to provide these estimates was BMI.

It has not been possible to determine the costs of adult weight management schemes within a primary care trust (PCT). There are a number of reasons for this but chiefly a lack of any centralised reporting of such information. When cost information for individual PCTs is found,

**TABLE 5** Estimated cost of obesity in England in 2002<sup>37</sup>

Included costs	2002 (£M)
GP consultations	12–15
Ordinary admissions	1.9
Day cases	0.1
Outpatient attendances	0.5–0.7
Prescriptions	31.3
<i>Total cost of treating obesity</i>	<i>45.8–49.0</i>
<b>Consequences of obesity</b>	
GP consultations	90–105
Ordinary admissions	210–250
Day cases	10–15
Outpatient attendances	60–90
Prescriptions	575–625
<i>Total cost of treating the consequences of obesity</i>	<i>945–1075</i>
Lost earnings due to attributable mortality	1050–1150
Lost earnings due to attributable sickness	1300–1450
<i>Total indirect costs</i>	<i>2350–2600</i>
<i>Total cost of obesity</i>	<i>3340–3724</i>

for example on PCT websites or within press releases, the costs quoted are very variable. This variation in costs is because of factors that include:

- Differences between PCTs in the proportion of adult weight management schemes provided within different settings such as leisure centres, primary care, pharmacies and schemes delivered in partnership with commercial weight loss organisations.
- Costs for adult weight management services may be reported within an overall value that includes adult, child, and family-centred weight management services.
- Differences in the target adult population: some schemes are only available to those who are obese, others are available to the overweight and the obese.

In general it appears that these weight management schemes are provided by PCTs to eligible adults who are not charged for using the service.

### **Variation in services**

The large numbers of people in the population who are overweight and/or obese place a high demand on services from primary care. However, at the same time many practices have limited capacity to manage these people, and few evidence-based interventions to choose from. This has led to variation across the UK in the service offered to overweight and obese people. In 2001 a National Audit Office report<sup>39</sup> concluded that approaches to weight management were inconsistent and that effective strategies for weight management were needed. This view was similarly echoed in a report of the House of Commons Health Committee in 2004.<sup>37</sup> More recently a survey by the Dr Foster organisation published in 2005<sup>40</sup> showed that primary care organisations employ a number of innovative approaches to the management of obesity; however, there is considerable national and regional variation in the service provided. The survey also showed that while more organisations had established weight management clinics than in their previous survey in 2003 (up by 5%), in the majority of general practices (69%) there was still no organised weight-management clinic.

### **Relevant national guidelines**

The most comprehensive guideline for the prevention and management of obesity in adults in England and Wales is the NICE guideline.<sup>35</sup> This guideline, referred to in detail above, covers both primary and secondary care. Other guidelines which are relevant to the prevention and management of obesity in adult populations in the UK have been produced by the National Obesity Forum<sup>41</sup> and the Northern Ireland Clinical Resource Efficiency Support Team.<sup>42</sup> They are consistent with the NICE guideline<sup>35</sup> but focus on either primary care<sup>41</sup> or secondary care.<sup>42</sup> Several UK guidelines are also available on the prevention and management of obesity in children and young people [e.g. the Scottish Intercollegiate Guidelines Network guideline<sup>43</sup> (currently being updated; spring 2010)], and on the management of obesity using pharmacological and surgical approaches. However, these populations and interventions are outside the scope of the current assessment (see *Chapter 2*).

There are currently no National Service Frameworks (NSFs) that specifically focus on overweight or obesity. Guidance on avoiding obesity, with a focus on healthy diet and exercise, is included in the current NSF for CHD.<sup>44</sup>

### **Existing systematic reviews**

Weight management interventions have been the focus of a number of systematic reviews in recent years. Ten systematic reviews, published between 1997 and 2009, have included studies with weight management or weight maintenance interventions that comprised diet, exercise and/or behavioural components and reported weight outcomes for adults, and are summarised in



**TABLE 6** Systematic reviews of weight management studies in overweight or obese adults

Authors and date	Goal	Principal inclusion criteria		
		Design and intervention	Population	Follow-up
Glenny <i>et al.</i> 1997 <sup>51</sup>	Determine effectiveness of interventions for obesity prevention and treatment, weight loss and weight maintenance	RCTs (other study designs accepted for prevention goal)	Overweight and obese adults and/or children	≥ 12 months
McLean <i>et al.</i> 2003 <sup>45</sup>	Evaluate family involvement in weight control or weight loss	RCTs with at least one family-based intervention	Adults and/or children	≥ 12 months
McTigue <i>et al.</i> 2003 <sup>47</sup>	Determine effectiveness of adult obesity screening and treatment	RCTs of fair or good quality	BMI ≥ 25 kg/m <sup>2</sup>	≥ 12 months
Avenell <i>et al.</i> 2004 <sup>46</sup>	Systematically review effectiveness of exercise ± diet ± and behaviour therapy for weight loss and other outcomes	RCTs; specific details of interventions required; weight change an explicit outcome	Adults with minimum, mean or median BMI 28 kg/m <sup>2</sup>	≥ 12 months from randomisation
Avenell <i>et al.</i> 2004 <sup>30</sup>	Systematically review obesity treatments in adults to identify therapies that achieve weight reduction, risk factor modification or improved clinical outcomes	RCTs; sufficient details of interventions required	Adults with minimum, mean or median BMI 28 kg/m <sup>2</sup>	≥ 12 months from randomisation
Franz 2004 <sup>48</sup>	Not clearly stated but focus on weight management interventions targeting women	RCTs of weight loss and maintenance	Women, BMI > 25 kg/m <sup>2</sup>	≥ 12 months
Tsai <i>et al.</i> 2005 <sup>53</sup>	Describe major commercial and self-help weight loss programmes in the USA that provide structured in-person or online counselling	RCTs (other designs permitted); ≥ 10 participants; assessed intervention under same conditions as offered to public	Adults	≥ 12 weeks
Söderlund <i>et al.</i> 2009 <sup>49</sup>	Determine effectiveness of exercise ± diet ± behaviour therapy in overweight and obese healthy adults	RCTs; minimum <i>n</i> = 15 per intervention	Overweight or obese otherwise healthy adults	≥ 12 months (or intervention ≥ 12 months)
Turk <i>et al.</i> 2009 <sup>50</sup>	Summarise findings of RCTs that tested strategies for weight loss	RCTs with weight maintenance intervention after initial weight loss	Adults	Follow-up not stated
Brown <i>et al.</i> 2009 <sup>52</sup>	Determine the effectiveness of long-term lifestyle interventions for the prevention of adult weight gain and morbidity	RCTs and controlled before-after studies	Adults, BMI < 35 kg/m <sup>2</sup>	Weight reported ≥ 24 months after randomisation

*Table 6.*<sup>30,45–53</sup> Seven of these systematic reviews were restricted to randomised controlled trials (RCTs)<sup>30,45–50</sup> and three focused on RCTs but also permitted inclusion of other study designs.<sup>51–53</sup> The minimum follow-up for weight management outcomes required for studies to be included in the systematic reviews was 12 months in the majority (*n* = 7), 12 weeks (*n* = 1), 24 months (*n* = 1) or was not specified (*n* = 1) (*Table 6*).

Eligible interventions varied between these systematic reviews. Their inclusion criteria required interventions to comprise diet, exercise and/or behavioural components, but not necessarily all three together. None of the systematic reviews precisely matched the ‘multicomponent’ approach supported in the NICE guidelines. The goal of the systematic review by Söderlund and colleagues<sup>49</sup> appears the most similar, but this review did not formally require interventions to include diet or behavioural components. The remaining nine systematic reviews also included some interventions with diet, exercise and/or behavioural components but the reviews all had different goals (*Table 6*) from assessing multicomponent approaches per se. For example, the systematic review by Avenell and colleagues<sup>46</sup> focused on interventions that included

exercise, behaviour therapy and/or drugs and was not limited to those that also contained a diet component. In addition, many of their included studies provided limited details of their interventions and many were of relatively short-term follow-up.

The conclusions of the 10 systematic reviews were mixed, which in part reflects their differing objectives and inclusion criteria. Some reviews (including Söderlund and colleagues<sup>49</sup>) suggested that the most effective weight loss interventions are those that combine diet, exercise and behaviour components to achieve weight loss.<sup>30,49,51</sup> There was also some support for interventions that contained only one or two of these three elements.<sup>30,48,52</sup> However, it is difficult to draw any firm conclusions regarding the long-term benefits of multicomponent weight management approaches from these systematic reviews due to their different objectives and inclusion criteria.

There is therefore a need to systematically synthesise all relevant evidence from good-quality studies that report long-term results, in order to compare the effectiveness and cost-effectiveness of different weight management programmes in delivering sustained weight loss.

## Description of technology under assessment

Weight management programmes aim to improve the eating behaviour and the quality of a person's diet, to reduce energy intake, and to also increase people's physical activity levels or decrease inactivity.<sup>35</sup> A multicomponent intervention is defined as one which combines more than one mutually reinforcing strategy to achieve a common outcome. It is thought that addressing multiple influences on overweight and obesity will be an effective way to reduce and maintain healthy weight. The components may be distinguished from each other in terms of setting, location, provider, format, media and content. As previously stated, good practice guidelines promote weight management programmes that are multicomponent interventions that usually involve a combination of diet, exercise and behavioural therapy with ongoing support. In this sense the components differ primarily in terms of content (i.e. focus on diet or physical activity), but may also differ, to varying extents, in terms of setting (e.g. clinics, leisure centres), provider (e.g. dietitians, behavioural therapists) and other attributes. They work towards the common goal of encouraging weight loss and maintenance.

Dietary approaches incorporated in weight management programmes used in the UK may involve strategies such as calorie restriction, VLCDs, low fat, low carbohydrate, high fibre, meal replacement, food combining, or low glycaemic index foods. As described above (see *Current service provision*), dietary goals, in terms of the number of kilocalories per day permitted, may be set according to the type of diet followed. Nutritionists, dietitians or trained nurses may deliver dietary interventions. Broader lifestyle approaches may also accompany dietary goals, including education around food labelling, cookery skills and identifying where healthier foods can be purchased.

Physical activity elements of weight management programmes include exercise training and endurance exercises (e.g. running, swimming) and resistance training (e.g. use of weights). Physiotherapists, specially trained staff or fitness coaches may deliver physical activity sessions to individuals or groups with differing degrees of supervision in settings such as leisure centres or community centres. Physical activity may also be self-supervised, with participants given exercise goals to be reached through activities of their own choosing, for example daily living activities, walking or cycling.

Behavioural therapy may include a number of specific techniques including: self-monitoring (e.g. systematically observing and recording one's own behaviour); problem analysis (e.g. dealing with



situations that might interfere with reaching dietary or exercise goals); alteration of cognitive patterns such as cognitive reframing and coping imagery; cognitive strategies for replacing negative thinking with positive statements (e.g. modifying self-defeating thoughts about dieting, constructive self-statements); relapse prevention (e.g. identifying when lapses might occur in diet or physical activity and how to deal with high-risk situations); goal-setting; menu planning; stimulus control (e.g. avoiding stimuli that might encourage eating, such as reducing the visibility of food in the home, slowing the pace of eating, avoiding fast food restaurants); and may be delivered by psychologists, trained interventionists and counsellors. Ongoing support may take the form of personal contact, meetings, telephone calls and internet technology, and be individual, group or family based. Therapy may be theoretically based, for example drawing on the stages of change (SOC) approach of the Transtheoretical Model, or Social Cognitive Theory.<sup>54-56</sup> However, it is recognised that definitions of behavioural techniques are not always standardised, or explicitly linked to a theoretical model of behaviour change.<sup>57</sup>

Multicomponent interventions may also include surgery and prescribed or over-the-counter (OTC) weight loss drugs, although this is more often as a second-line treatment if weight loss goals have not been attained through diet, physical activity and behavioural therapy strategies. There has been recent interest in the use of OTC drugs for obesity and their place within multicomponent approaches to weight management. In 2009 the European Union approved the use of 60 mg orlistat per day (Alli™, GlaxoSmithKline) for purchase following consultation with a pharmacist for people with a BMI over 28 kg/m<sup>2</sup>. It is possible that people participating in multicomponent interventions may use OTC orlistat as an additional weight loss strategy, though it has been suggested that some may use it in place of diet and exercise. Research is needed to establish how it might be best used in practice.<sup>58</sup>

Weight management programmes may be delivered in the primary care setting, by GPs supported by specialists as mentioned above, and tutors trained specifically to deliver such programmes, or through professionals in specialist hospital clinics. For example, the Counterweight Programme<sup>54</sup> is a primary care-based programme in the UK that aims to help obese people to achieve weight loss (e.g. 5%–10% over 3–6 months) and weight maintenance through changes in diet and exercise. In addition to NHS-based programmes, commercial and self-help programmes are available such as Weight Watchers®, Slimming World, Rosemary Conley™, LighterLife™ and others. LIs in overweight working populations are also available.<sup>59</sup>

Weight management programmes vary in terms of their duration. Generally there will be an initial period where the aim is to achieve a desired weight loss goal (e.g. 6–12 months). Thereafter there may be a weight maintenance phase where the aim is to sustain weight lost in the first stage. There is some evidence to suggest that weight is lost rapidly at first, and the point of greatest loss occurs 6 months after beginning treatment; weight is then slowly regained and often reaches near the original level.<sup>60</sup> For example, approximately a third of lost weight may be regained in the first year after treatment and often continues with the average loss of about 1.8 kg remaining at 4 years after treatment.<sup>60</sup> Therefore, it is important that any weight management scheme facilitates weight maintenance after the target weight has been reached. Resulting changes to lifestyle must become part of everyday life for long-term health benefits to be realised.<sup>35</sup> It is important to acknowledge, however, that weight gain in the general population may occur throughout life and therefore people who have participated in a weight loss intervention may still be at lower weight than if they have not participated.

Well-managed, multicomponent weight management schemes are not thought to lead to any specific adverse events for participants;<sup>35</sup> however, there are some suggestion that negative outcomes for some participants may occur from weight management programmes. This appears to be largely based on 'dieting' in general, where evidence suggests that for some people dieting

can lead to eating disorders, negative psychological and emotional effects and increased social stigma.<sup>61</sup>

### **Overall aims of this assessment**

The aim of this review was to assess the long-term clinical effectiveness and cost-effectiveness of multicomponent weight management schemes for adults in terms of weight loss and maintenance of weight loss.

## Chapter 2

### Methods

The a priori methods for systematically reviewing the evidence of clinical effectiveness and cost-effectiveness are described in the research protocol (see *Appendix 1*), which underwent comment by our expert advisory group. Although helpful comments were received relating to the general content of the research protocol, there were none that identified specific problems with the methods of the review. The methods outlined in the protocol are briefly summarised below.

#### Search strategy

The search strategy was developed, tested and refined by an experienced information scientist. Separate searches were conducted to identify studies of clinical effectiveness, cost-effectiveness and epidemiology. Sources of information and search terms are provided in *Appendix 2* and a flow chart of identification of studies can be seen in *Figure 1*.

Searches for clinical effectiveness and cost-effectiveness literature were undertaken from database inception to December 2009. Electronic databases searched included: MEDLINE; EMBASE; MEDLINE In-Process & Other Non-Indexed Citations; The Cochrane Library including the Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Database of Abstracts of Reviews of Effects, NHS Economic Evaluation Database and HTA databases; Web of Science; PsycINFO; BIOSIS; and databases listing ongoing clinical trials.

Searches were restricted to the English language. Bibliographies of related papers were screened for relevant studies, the expert advisory group were also contacted for advice and peer review and to identify additional published and unpublished references.

#### Inclusion process

Titles and abstracts identified by the search strategy for the clinical effectiveness section of the review were assessed for possible eligibility by two reviewers independently. The full texts of relevant papers were then obtained and inclusion criteria were applied by one reviewer and checked by a second reviewer using a previously piloted inclusion flow chart (see *Appendix 3*). Any disagreements over eligibility were resolved by discussion or by recourse to a third reviewer.

Titles and abstracts identified by the search strategy for the systematic review of cost-effectiveness were assessed for potential eligibility by two reviewers independently. Economic evaluations were considered for inclusion if they reported both health service costs and effectiveness of multicomponent adult weight management programmes, or presented a systematic review of such evaluations. Two reviewers formally assessed full papers independently, with respect to their potential relevance to the research question. Any differences in judgement were resolved through discussion.

## Inclusion criteria

### Population

- Adults ( $\geq 18$  years) classified as overweight or obese, i.e. people with a BMI of  $\geq 25$  kg/m<sup>2</sup> and  $\geq 30$  kg/m<sup>2</sup>, respectively.
- Studies in children and people with eating disorders were not included, nor were studies specifically in people with a pre-existing medical condition such as diabetes, heart failure, uncontrolled hypertension or angina.

### Intervention

- Structured, sustained multicomponent weight management programmes (i.e. the intervention had to be a combination of diet and physical activity with a behaviour change strategy to influence lifestyle).
- Components of the programme had to be clearly specified (i.e. details provided of the diet, behavioural definition, and exercise components; see below).
- Programmes that included a long-term follow-up of more than 18 months.
- The programme was delivered by the health sector, in the community or commercially.
- Multicomponent programmes that involved the use of OTC medicines that are licensed in the UK for overweight or obesity were also included. Programmes that involved non-OTC drug therapies or surgery for obesity were not included.
- Interventions incorporating other lifestyle changes such as efforts at smoking cessation or reduction of alcohol intake were not included.

### Comparators

- Normal practice (as defined by the study).
- Single-component weight management strategies.
- Other structured multicomponent weight management programmes.

### Outcomes

- Studies were required to include a measure of weight loss.
- Data on the following outcomes were also eligible for extraction where reported in the included studies: study-defined success rates at more than 18 months, attrition rates at more than 18 months, barriers and facilitators of weight loss and maintenance of weight loss.
- Outcomes of cost-effectiveness studies were costs, benefits in terms of weight loss and cost-effectiveness.

### Types of studies

- For the systematic review of clinical effectiveness RCTs were included.
- For the systematic review of cost-effectiveness eligible study types were full cost-effectiveness analyses, cost–utility analyses, cost–benefit analyses and cost–consequence analyses.
- Studies published as abstracts or conference presentations were only included if sufficient details were presented to allow an appraisal of the methodology and the assessment of results to be undertaken.
- Case series, case studies, cohort studies, narrative reviews, feasibility studies, editorials and opinions were not included.
- Systematic reviews were used as a source of references.
- Non-English language studies were excluded.

As stated above, all three components of the intervention had to be clearly specified for a trial to meet the inclusion criteria. This was firstly to ensure that interventions were ‘multicomponent’ (providing evidence of the three components rather than simply reporting that an intervention had a diet, exercise and behavioural component) and secondly to ensure that included interventions were, as far as possible, reproducible. It has been proposed that interventions

that include a behaviour change element should clearly describe the content, the characteristics of the providers, the setting, the mode of delivery, the intensity, the duration and adherence to protocols.<sup>62</sup> There have also been calls for greater standardisation of specific behavioural techniques used, including explicit links to guiding theory.<sup>57</sup> Where details of these attributes of the included interventions were available these have been reported.

In many cases discussion as regards study selection were straightforward as one or more of the components were absent or no details whatsoever were provided for one or more of the components. In other cases a decision had to be made whether the level of detail about the component was sufficient. In these cases the following criteria were looked for in each of the three components:

- diet
  - type of diet
  - calories
  - proportion of diet (e.g. proportion of diet made up of fats, protein, carbohydrate)
  - monitoring
- exercise
  - mode
  - type
  - frequency/length sessions
  - delivered by
  - level of supervision
  - monitoring
- behaviour modification
  - mode
  - type
  - content
  - frequency/length sessions
  - delivered by.

Using these criteria any studies that provided detail on only one aspect of one (or more) of the three main components were excluded (e.g. only the type of diet, but no detail of calorie goals, proportions of diets, or how the diet was monitored), and studies which referred to a secondary source for the description of their interventions were marked as unclear and authors were contacted for further information.

## Data extraction and quality assessment strategy

Data were extracted by one reviewer using a standardised and pre-piloted data extraction form and checked by a second reviewer. Any disagreements were resolved by discussion, if necessary involving a third reviewer.

Within the clinical effectiveness review the quality of included studies was assessed using criteria based on those recommended by the Centre for Reviews and Dissemination (CRD)<sup>63</sup> (see *Appendix 4*). Each RCT was assessed by one reviewer and checked by a second reviewer. Any disagreements were resolved by discussion, if necessary involving a third reviewer. The reviewers assessed the adequacy of reporting; randomisation; allocation concealment; population baseline characteristics; blinding of assessors, care providers and participants; imbalances in attrition; outcomes; intention-to-treat (ITT) analyses; and analyses of missing data. For ease of presentation and interpretation of the quality assessment of RCTs the responses were then

translated into judgements of 'high', 'low' or 'uncertain' risk of bias based on the Cochrane risk of bias criteria.<sup>64</sup> For example, where a positive response to a question indicated an adequate procedure to minimise bias (e.g. 'was the allocation adequately concealed?') this was translated into a 'low' risk of bias. Similarly, where a positive response to a question indicated an inadequate procedure to minimise bias (e.g. 'is there any evidence to suggest that the authors measured more outcomes than they reported?') this was translated into a 'high' risk of bias.

For the systematic review of cost-effectiveness, the methodological quality of the cost-effectiveness studies was assessed using a critical appraisal checklist based on that by Philips and colleagues,<sup>65</sup> Drummond and Jefferson<sup>66</sup> and the NICE reference case requirements.<sup>67</sup> These checklists were combined to include the key elements that were relevant to internal and external validity, and the generalisability of the studies to the UK NHS.

## Data synthesis

Data were synthesised through a narrative review with tabulation of results of all included studies. Full data extraction forms for the clinical effectiveness review are presented in *Appendix 5*. Within the clinical effectiveness section studies using similar interventions were grouped together to aid interpretation. Studies were categorised according to which of the intervention components (diet, exercise, and/or behaviour modification) were of primary interest and how they differed from the comparator intervention. This led to four groups: studies in which the comparator was a non-intervention group; studies in which the intervention focused on the diet aspect versus another active comparison; studies in which the intervention focused on the exercise aspect versus another active comparison; and studies where other variables were the focus of the study.

Where trials reported several interventions, decisions were made by consensus among the review group as to which was the 'key' intervention of relevance to the scope of this review (as noted above, these are multicomponent interventions involving a combination of diet, exercise and behavioural therapy) and which comparators were relevant. For some trials there was little discernible difference between the interventions tested and as such the focus of our report is limited to those which appeared to be the most relevant to our research protocol, with complete details of all interventions reported (see *Appendix 5*).

Our pre-defined inclusion criteria excluded studies with < 18 months' follow-up from randomisation, in order to focus the review on long-term weight loss and maintenance of weight loss given that weight regain in the long term is an intractable problem. Therefore, where included studies report interim data before 18 months' follow-up these have not been included. However, we do provide comment in the text where these data are available in the primary studies.

It was considered inappropriate to combine the results of the studies in a meta-analysis due to differences in the interventions, comparators and populations in the included studies.

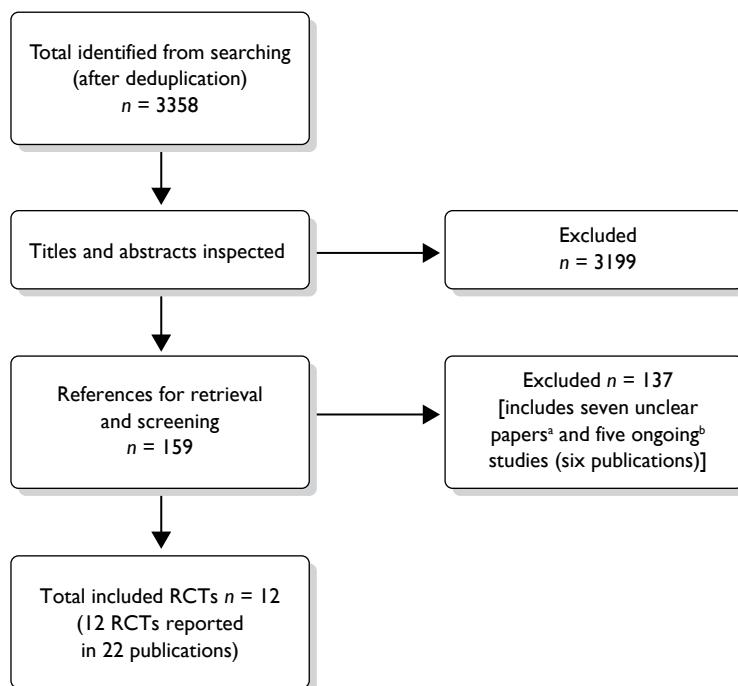
## Chapter 3

# Clinical effectiveness

### Quantity and quality of research available

Searching identified 3358 references after deduplication. After initial screening of titles and abstracts, 159 references were retrieved for further inspection. The total number of published papers included at each stage of the systematic review is shown in the flow chart in *Figure 1*. References to the studies retrieved for further inspection but subsequently excluded can be seen in *Appendix 6*. The most common reason for exclusion was the inadequate length of follow-up (54 studies); lack of, or only minimal, detail reported on one or more of the components of the intervention (see *Chapter 2*) led to 20 studies being excluded; another 21 were not deemed to be multicomponent interventions, and 19 were not RCTs. In addition, one study did not have an appropriate comparator; two studies did not report weight loss outcomes and the participants in seven studies did not meet the inclusion criteria. The level of agreement between reviewers assessing study eligibility was generally good although this was not formally measured.

Six RCTs (seven publications) appeared to meet all of the inclusion criteria except that the details of the multicomponent interventions were judged to be below our threshold (see *Chapter 2*). Authors of these six studies were contacted for further detail. A response from one author was received; however, the information provided did not clarify any further whether the interventions did indeed meet our criteria. These studies were undertaken between 2 and 15 years ago, which



**FIGURE 1** Flow chart of identification of studies for inclusion in the review. (a) Details of the interventions in six RCTs (seven publications) nearly met our threshold of containing enough detail (see *Methods*). (b) Five studies (six publications) were assessed as ongoing and are described as such in *Assessment of effectiveness of multicomponent interventions versus non-active intervention comparators*.

may explain the poor response from the authors. As such there were six studies that we were unable to identify whether they met the inclusion criteria of the review. These studies can be seen in *Appendix 7*.

Twelve RCTs met all of the inclusion criteria,<sup>68–79</sup> of which five had two intervention arms, one had three arms, four had four arms and two had five arms (*Table 7*). In many of these RCTs data were reported in multiple publications; for ease of presentation the primary reference is used here, with full details of all secondary publications given in *Appendix 5*. Not all of the intervention arms were considered relevant to the scope of the current review; this is outlined in the subsequent sections where this is the case. The key methodological attributes of these trials are summarised in *Table 8*, with full details of the interventions, outcomes and quality assessments provided in *Appendix 5*. All included trials were individual-level interventions; no community-level interventions met the inclusion criteria.

All RCTs that met the inclusion criteria were conducted in the USA. Most (83%) of these were published between 1993 and 2008, with two older RCTs, published in 1984<sup>68</sup> and 1988.<sup>69</sup> The total number of participants randomised ranged from 59<sup>69</sup> to 1191,<sup>70</sup> while the number of participants per intervention group ranged from 18<sup>69</sup> to 596.<sup>70</sup> Only four of the 12 RCTs had sample sizes > 100 participants per intervention group.<sup>70,72–74</sup> The earliest of the RCTs<sup>68</sup> did not report the number of participants randomised. Power analyses to calculate the necessary sample sizes were reported in only five trials.<sup>70–74</sup>

In all but one<sup>73</sup> of the 12 RCTs the target population was stated as being overweight. The RCT by Simkin-Silverman and colleagues<sup>73</sup> enrolled middle-aged women and aimed to prevent the rise in weight and low-density lipoprotein (LDL) cholesterol observed during the menopause. The baseline weight, however, indicated that participants were overweight (mean BMIs > 25 kg/m<sup>2</sup>). The two trials reported by Stevens and colleagues<sup>70,74</sup> were conducted as part of a larger study of risk factors for hypertension [Trials of Hypertension Prevention (TOHP)] and included overweight participants.

Nine of the 12 RCTs reported the starting BMI of their participants.<sup>70–78</sup> According to the international classification of overweight or obesity,<sup>6</sup> participants would be considered overweight (pre-obese) in two RCTs,<sup>73,74</sup> class I obese in five RCTs,<sup>70,71,75–77</sup> and class II obese in one RCT.<sup>78</sup> The remaining RCT<sup>72</sup> contained a mixture of pre-obese (18%–22%), class I obese (32%–36%), class II obese (21%–24%) and class III obese (22%–24%) participants (see *Appendix 5*). Seven of the 12 RCTs specified that their participants, aside from being overweight, were in good health.<sup>68,70,73–77</sup> One RCT, by Weinstock and colleagues,<sup>78</sup> excluded women with bulimia but not those with binge eating disorder. The remaining four RCTs<sup>69,71,72,79</sup> did not include health status as an inclusion criterion.

Three studies did not mention age among their inclusion criteria (however participants were all adults).<sup>68,69,78</sup> The upper age limit specified for inclusion of participants was 45 years in two RCTs,<sup>75,79</sup> 50 years in two RCTs,<sup>73,77</sup> 54 years in two RCTs,<sup>70,74</sup> 55 years in two RCTs,<sup>71,76</sup> and 69 years in the remaining RCT.<sup>72</sup> None of the trials specifically included elderly populations.

Descriptions of the baseline characteristics of the populations included in the RCTs varied considerably in their detail (see *Table 7*). In eight (67%) of the RCTs the mean age of participants within each intervention group was in the range 35.7–47.0 years.<sup>69–71,73–76,78</sup> Two RCTs did not report the age by intervention group but stated that the overall mean age was 42.2 years<sup>77</sup> or that most participants (≥ 80%) were aged 40–59 years.<sup>72</sup> The remaining two RCTs did not report the age of their participants.<sup>68,79</sup> In two of the RCTs the participants were all female,<sup>73,78</sup> in five RCTs they were mostly (67%–91%) female,<sup>68,69,71,72,76</sup> in two RCTs they were mostly (63%–73%) male,<sup>70,74</sup>



and in two RCTs the gender balance was nearly equal (42%–53% male).<sup>77,79</sup> One RCT<sup>75</sup> did not report the gender balance of its participants.

Weight change from baseline was reported as a primary outcome in 11 RCTs<sup>68–77,79</sup> and as a secondary outcome in one RCT.<sup>78</sup> Two RCTs also reported changes in BMI, either as a primary outcome<sup>75</sup> or as a secondary outcome.<sup>71</sup> The proportion of participants maintaining weight loss was also a primary outcome in one RCT<sup>69</sup> (see *Table 7*).

In one study the setting of the intervention was reported to be in primary care.<sup>72</sup> Six studies<sup>70,71,73,74,76,78</sup> reported that their study was clinic based; in some cases these were clinical practice-based research units within universities. Five studies<sup>68,69,75,77,79</sup> did not report the setting of their intervention.

The duration of follow-up (post randomisation) ranged from 18 to 54 months. Eight<sup>68,69,71,72,74,76,78,79</sup> of the 12 RCTs provided weight outcome follow-up data for a single time point after randomisation, three RCTs<sup>70,75,77</sup> provided follow-up data for two time points, and one RCT<sup>70</sup> provided follow-up data for four time points. Six<sup>68–70,73,75,77</sup> of the RCTs included follow-up beyond 2 years (see *Table 7*). The duration of interventions is discussed more fully in the following three sections.

The methodological detail reported varied considerably among the RCTs. As an indication of methodological rigour, the risk of bias was assessed for each of the 10 methodological criteria (see *Table 8*). Quality assessment of each individual trial can be seen in *Appendix 5*.

Trials that do not properly randomise their participants or conceal the allocation of interventions could be at risk of selection bias. Trials were assessed according to whether they used an adequate method to generate random allocations and to conceal their intervention allocations. Four trials provided information on their randomisation sequence<sup>70,72,73,79</sup> and three described their allocation concealment,<sup>70,73,74</sup> and all of these were judged to have a low risk of selection bias (see *Table 8*). For the remaining trials there is an uncertain risk of bias as there was either inadequate or no information reported from which this could be assessed.

Blinding of participants, care providers and outcome assessors can help to reduce the risk that participants and trial personnel become aware of intervention assignment, so potentially influencing their performance in the trial (detection bias). None of the trials clearly reported blinding of their participants or care providers, so it is unknown whether blinding occurred. It seems unlikely that care providers and participants would have been blinded as it would have been difficult to conceal the identity of the weight loss interventions without substantial spatial and/or temporal separation of the care providers and participant groups that were allocated to different interventions. Blinding of outcome assessors, however, is more feasible but was only reported in two trials.<sup>70,73</sup> In both of these the method of blinding was judged as adequate, with a low risk of bias (see *Table 8*).

Sources of measurement bias in clinical trials include losses of participants to follow-up, unequal dropout rates between interventions, selective reporting of outcomes (missing outcomes) and failure to explain why participants are missing (e.g. whether they are missing at random). Six RCTs were judged to have low risk of bias from dropout (no dropout imbalance);<sup>69,73,78</sup> five, however, provided inadequate or no information to assess risk of bias from dropout,<sup>68,74–77</sup> and one had unequal dropout between interventions, indicating a high risk of bias.<sup>79</sup> All 12 trials provided sufficient information to permit an evaluation of reporting bias,<sup>68–79</sup> of which three had a high risk of bias (some outcomes not reported)<sup>71,72,75</sup> and nine had a low risk of bias (all outcomes were adequately reported).<sup>68–70,73,74,76–78,79</sup> Four trials were judged to have a high risk

**TABLE 7** Overview of study characteristics of multicomponent interventions for weight management

Study details	Study arms <sup>a</sup>	Target population and selected baseline characteristics
Burke <i>et al.</i> 2008 <sup>71</sup> Country: USA Design: RCT Follow-up: 18 months	Preference for standard diet (pref STD-D), <i>n</i> = 48 Preference for lacto-ovo-vegetarian diet (pref LOV-D), <i>n</i> = 35 No preference for standard diet (no pref STD-D), <i>n</i> = 48 No preference for lacto-ovo-vegetarian diet (no pref LOV-D), <i>n</i> = 45 Total <i>n</i> = 176 <sup>b</sup>	<i>Target population:</i> overweight men and women aged 18–55 years Mean age (years): pref STD-D 43.2; pref LOV-D 44.3; no pref STD-D 43.2; no pref LOV-D 43.2 Sex (% M:F): pref STD-D 12.5 : 87.5; pref LOV-D 20 : 80; no pref STD-D 12.5 : 87.5; no pref LOV-D 9 : 91 Mean BMI (kg/m <sup>2</sup> ): pref STD-D 34.5; pref LOV-D 34.1; no pref STD-D 32.9; no pref LOV-D 33.7 Mean weight (kg): pref STD-D 97.2; pref LOV-D 96.7; no pref STD-D 92.4; no pref LOV-D 91.8
Tate <i>et al.</i> 2007 <sup>77</sup> Country: USA Design: RCT Follow-up: 30 months	High physical activity (HPA), <i>n</i> = 109 Standard behavioural treatment (SBT), <i>n</i> = 93 Total <i>n</i> = 202	<i>Target population:</i> overweight men and women aged 25–50 years Mean age (years): overall 42.2 Sex (% M:F): overall 42 : 58 Mean BMI (kg/m <sup>2</sup> ): overall 31.7 Mean weight (kg): approximately 90.5 for both interventions
Logue <i>et al.</i> 2005 <sup>72</sup> Country: USA Design: RCT Follow-up: 24 months	Transtheoretical model and chronic disease paradigm (TM-CD), <i>n</i> = 329 Augmented usual care (AUC), <i>n</i> = 336 Total <i>n</i> = 665	<i>Target population:</i> overweight men and women aged 40–69 years Age (years): mean not reported. In both arms ≥80% aged 40–59 years Sex (% M:F): TM-CD 29 : 71; AUC 33 : 67 BMI (kg/m <sup>2</sup> ): not reported Weight: not reported
Stevens <i>et al.</i> 2001 <sup>70</sup> Country: USA Design: RCT Follow-up: 36 months	Weight loss (WL), <i>n</i> = 595 Usual-care control group (C), <i>n</i> = 596 Total <i>n</i> = 1191	<i>Target population:</i> overweight men and women with non-medicated diastolic blood pressure (BP) of 83–89 mmHg and systolic BP < 140 mmHg and aged 30–54 years Mean age (years): WL 43.4; C 43.2 Sex (% M:F): WL 63 : 37; C 68 : 32 Mean BMI (kg/m <sup>2</sup> ): men: WL 31.0; C 31.0; women: WL 31.0; C 30.8 Mean weight (kg): WL 93.4; C 93.6
Jeffery <i>et al.</i> 1998 <sup>76</sup> Country: USA Design: RCT Follow-up: 18 months	Standard behavioural therapy (SBT), <i>n</i> = 40 SBT + supervised exercise (SBTE), <i>n</i> = 41 SBT + trainer (SBTT), <i>n</i> = 42 SBT + incentive (SBTI), <i>n</i> = 37 SBT + trainer + incentive (SBTTI), <i>n</i> = 36 Total <i>n</i> = 196	<i>Target population:</i> overweight men and women aged 25–55 years Mean age (years): SBT 40.0; SBTE 41.5; SBTT 41.0; SBTI 42.6; SBTTI 40.7 Sex (% M:F): SBT 18 : 82; SBTE 17 : 83; SBTT 21 : 79; SBTI 14 : 86; SBTTI 14 : 86 Mean BMI (kg/m <sup>2</sup> ): SBT 31.4; SBTE 31.5; SBTT 31.4; SBTI 31.5; SBTTI 30.6 Mean weight (kg): SBT 85.6; SBTE 87.1; SBTT 84.7; SBTI 87.7; SBTTI 85.7
Simkin-Silverman <i>et al.</i> 1998 <sup>73</sup> Country: USA Design: RCT Follow-up: 54 months	Lifestyle intervention (LI), <i>n</i> = 260 Assessment-only control group (C), <i>n</i> = 275 Total <i>n</i> = 535	<i>Target population:</i> perimenopausal women, aged 44–50 years, of whom a subgroup were overweight Mean age (years): LI 47; C 47 Sex (% M:F): LI 0 : 100; C 0 : 100 Mean BMI (kg/m <sup>2</sup> ): LI 25; C 25 Mean weight, lb (kg) <sup>c</sup> : LI 148.0 (67.1); C 147.6 (67.0)
Weinstock <i>et al.</i> 1998 <sup>78</sup> Country: USA Design: RCT Follow-up: 96 weeks	Diet plus combined strength and aerobic training (DSA), <i>n</i> = 29 <sup>d</sup> Diet plus strength training (DS), <i>n</i> = 31 <sup>d</sup> Diet plus aerobic training (DA), <i>n</i> = 31 <sup>d</sup> Diet alone (D), <i>n</i> = 29 <sup>d</sup> Total <i>n</i> = 120 <sup>d</sup>	<i>Target population:</i> overweight women Mean age (years): DSA 42.8; DS 40.0; DA 40.8; D 41.0 Sex (% M:F): 0 : 100 in all arms Mean BMI (kg/m <sup>2</sup> ): DSA 35.3; DS 36.5; DA 37.3; D 36.4 Mean weight (kg): DSA 92.4; DS 96.8; DA 98.7; D 96.3

**TABLE 7** Overview of study characteristics of multicomponent interventions for weight management (*continued*)

Study details	Study arms <sup>a</sup>	Target population and selected baseline characteristics
Skender <i>et al.</i> 1996 <sup>79</sup> Country: USA Design: RCT Follow-up: 2 years	Diet + exercise (D + E), <i>n</i> = 42 Diet (D), <i>n</i> = 42 Exercise (E), <i>n</i> = 43 Waiting list ( <i>n</i> = 38; data not reported) Total <i>n</i> = 127 (165)	<i>Target population:</i> overweight men and women aged 25–45 years Age (years): not reported Sex (% M:F): D + E 50:50; D 52:48; E 53:47 BMI (kg/m <sup>2</sup> ): not reported Mean weight (kg): D + E 97.60; D 97.65; E: 93.92
Jeffery and Wing 1995 <sup>75</sup> Country: USA Design: RCT Follow-up: 30 months	Standard behavioural treatment (SBT), <i>n</i> = 40 SBT + food provision (SBT + FP), <i>n</i> = 40 SBT + incentives (SBT + I), <i>n</i> = 41 Combined intervention (SBT + FP + I), <i>n</i> = 41 Control group (no intervention) (C), <i>n</i> = 40 Total <i>n</i> = 202	<i>Target population:</i> overweight men and women aged 25–45 years Mean age (years): SBT 37.5; SBT + FP 38.5; SBT + I 38.1; SBT + FP + I 37.6; C 35.7 Sex (% M:F): Not reported by intervention group BMI <sup>e</sup> (kg/m <sup>2</sup> ): SBT 30.9; SBT + FP 30.8; SBT + I 31.1; SBT + FP + I 31.1; C 31.1 Weight <sup>e</sup> (kg): SBT 89.4; SBT + FP 88.1; SBT + I 92.3; SBT + FP + I 91.1; C 88.2
Stevens <i>et al.</i> 1993 <sup>74</sup> Country: USA Design: RCT Follow-up: 18 months	Weight loss (WL), <i>n</i> = 308 Usual-care control group (C), <i>n</i> = 256 Total <i>n</i> = 564	<i>Target population:</i> overweight men and women, average diastolic BP of 80–89 mmHg and aged 30–54 years Mean age (years): WL 43.1; C 42.4 Sex (% M:F): WL 73:27; C 63:37 Mean BMI (kg/m <sup>2</sup> ): WL 29.5; C 29.5 Mean weight (kg): WL 90.2; C 89.3
Wadden <i>et al.</i> 1988 <sup>69</sup> Country: USA Design: RCT Follow-up: 3 years	Behaviour therapy (BT), <i>n</i> = 18 Combined treatment (BT + VLCD), <i>n</i> = 23 Very-low-calorie diet (VLCD), <i>n</i> = 18 Total <i>n</i> = 59	<i>Target population:</i> overweight men and women Mean age (years): BT 44.3; BT + VLCD 43.6; VLCD 44.3 Sex (% M:F): BT 19:81; BT + VLCD 11:89; VLCD 13:87 BMI (kg/m <sup>2</sup> ): not reported Weight <sup>f</sup> (kg): BT 112.2; BT + VLCD 108.0; VLCD 106.4
Dubbert and Wilson 1984 <sup>68</sup> Country: USA Design: RCT Follow-up: 30 months after end of intervention (circa 34 months after randomisation)	Individual treatment with weekly (distal) goals <sup>f</sup> Individual treatment with daily (proximal) goals <sup>f</sup> Couples' treatment with weekly (distal) goals <sup>f</sup> Couples' treatment with daily (proximal) goals <sup>f</sup> Total <i>n</i> = 62	<i>Target population:</i> overweight married men and women currently living with spouse; spouse willing to attend sessions Age (years): not reported Sex (M:F): overall 23:77 BMI (kg/m <sup>2</sup> ): not reported Weight <sup>f</sup> lb (kg): individual, distal 207.7 (94.2); individual, proximal 208.9 (94.8); couples, distal 190.4 (86.4); couples, proximal 195.0 (88.5)

a Not all intervention arms are relevant to this systematic review; further details are given in the sections below.

b Of which 24 were excluded after randomisation.

c Reported in lb; conversion to kg provided by reviewers.

d Number randomised to each intervention not reported; these are baseline sample sizes excluding eight subjects.

e Values are assumed to be means (not stated in the publications).

f Number randomised to each intervention not reported.

Studies are listed chronologically (most recent first) and then alphabetically. Note that percentages are rounded. More detailed information is given in *Appendix 5*.

**TABLE 8** Risk of bias in RCTs of multicomponent interventions for weight management

Study	Randomisation sequence	Allocation concealment	Similarity of groups	Blinding of assessors	Blinding of care providers	Participant blinding	Dropout imbalance	Missing outcomes	ITT analysis	Missing data explained
Burke <i>et al.</i> 2008 <sup>71</sup>	?	?	High	?	?	?	Low	High	High	High
Tate <i>et al.</i> 2007 <sup>77</sup>	?	?	Low	?	?	?	?	Low	?	?
Logue <i>et al.</i> 2005 <sup>72</sup>	Low	?	Low	?	?	?	Low	High	Low	Low
Stevens <i>et al.</i> 2001 <sup>70</sup>	Low	Low	Low	Low	?	?	Low	Low	High	?
Jeffery <i>et al.</i> 1998 <sup>76</sup>	?	?	Low	?	?	?	?	Low	High	High
Simkin-Silverman <i>et al.</i> 1998 <sup>73</sup>	Low	Low	Low	Low	?	?	Low	Low	Low	High
Weinstock <i>et al.</i> 1998 <sup>78</sup>	?	?	Low	?	?	?	Low	Low	High	High
Skender <i>et al.</i> 1996 <sup>79</sup>	Low	?	?	?	?	?	High	Low	?	High
Jeffery and Wing 1995 <sup>75</sup>	?	?	Low	?	?	?	?	High	?	?
Stevens <i>et al.</i> 1993 <sup>74</sup>	?	Low	Low	?	?	?	?	Low	?	?
Wadden <i>et al.</i> 1988 <sup>69</sup>	?	?	?	?	?	?	Low	Low	?	High
Dubbert and Wilson 1984 <sup>68</sup>	?	?	Low	?	?	?	?	Low	?	High

?, uncertain risk of bias; High, high risk of bias; Low, low risk of bias.

of bias because they did not report an ITT analysis,<sup>70,71,76,78</sup> and seven trials were judged to have a high risk of bias because their analysis and interpretation did not account for missing data<sup>68,69,71,73,76,78,79</sup> (see *Table 8*).

Given the lack of methodological information reported it was not possible to rank the RCTs according to their methodological rigour or risk of bias. The extent to which methodological criteria were reported did not appear to show any patterns in relation to the publication date, suggesting there has not been an obvious improvement or deterioration in rigour through time. Where appropriate, the implications of risk of bias are considered in more detail for specific trials in the following three sections of this report.

The 12 RCTs varied considerably in the structure and content of their interventions and comparators and were consequently grouped into four categories (see *Chapter 2*). The four categories are: trials in which the comparator was a non-active intervention group, for example described as usual care (five trials);<sup>70,72–75</sup> trials where the focus of the study was predominantly on diet (two trials);<sup>69,71</sup> trials where the focus of the study was predominantly on exercise (four trials);<sup>76–79</sup> trials where the focus was on other factors (one trial).<sup>68</sup> Studies are reported in the following sections grouped in these four categories. In these subsequent sections of the report we describe the key aspects of the interventions and results of the studies. As described above there were differences between studies in terms of quality, follow-up, participant characteristics and sample sizes that are referred to where relevant in the subsequent sections. Studies were statistically powered to detect a difference between groups unless stated.

## Assessment of effectiveness of multicomponent interventions versus non-active intervention comparators

Five trials<sup>70,72–75</sup> compared multicomponent interventions against a non-active intervention comparator group, and can be seen in *Table 9*. The nature of the comparator differed slightly between these studies. In two of the RCTs, reported by Stevens and colleagues,<sup>70,74</sup> the comparator

was described only as a usual-care control group, with no further details provided. In one RCT, reported by Jeffery and Wing,<sup>75</sup> the comparator was a control group whose participants received no instruction or guidance and were free to act independently to achieve weight loss. The remaining two RCTs, reported by Logue and colleagues<sup>72</sup> and Simkin-Silverman and colleagues,<sup>73</sup> provided participants in their comparator group with limited general guidance on improving diet<sup>72</sup> or reducing cardiovascular risk factors<sup>73</sup> (see *Table 9*). The trial by Jeffery and Wing<sup>75</sup> differed in that it had five arms (four active interventions and one non-active comparator), with only 40 or 41 participants randomised per arm. The four active intervention arms reported by Jeffery and Wing<sup>75</sup> were standard behavioural therapy/treatment (SBT) alone, or SBT in combination with food provision (FP) and/or incentives (see *Table 7*). For the purpose of this review we consider SBT as the multicomponent intervention of most relevance. Details of the other interventions can be found in *Appendix 5*.

One trial did not explicitly report an aim.<sup>72</sup> The trial reported by Simkin-Silverman and colleagues<sup>73</sup> was restricted to premenopausal women and aimed to prevent the natural gain in weight and adverse changes in lipid profiles that occur during the menopause. The remaining three trials stated that they aimed to achieve specific weight loss goals, which were to lose 4.5 kg during the first 6 months,<sup>70,74</sup> or to achieve participants' self-selected weight loss goals of 14, 18, or 23 kg together with an exercise energy expenditure goal of 1000 kcal/week by the final week.<sup>75</sup> Three of the RCTs also included weight maintenance in their aim (see below).<sup>70,73,74</sup>

Only Logue and colleagues<sup>72</sup> explicitly stated that their intervention was based on a theoretical model (the Transtheoretical Model). Their intervention was from the Reasonable Eating and Activity to Change Health (REACH) trial (not included in this systematic review) and the diet component was based on the US Department of Agriculture (USDA) Food Guide Pyramid *Dietary Guidelines for Americans*. The intervention for perimenopausal women reported by Simkin-Silverman and colleagues<sup>73</sup> was described as an LI (the Women's Healthy Lifestyle Project). Jeffery and Wing<sup>75</sup> reported interventions that they described as standard behaviour

**TABLE 9** Details of the multicomponent interventions for those studies that included a non-active intervention (e.g. usual care) as the comparator

<i>Logue et al. 2005</i> <sup>72</sup>	
Length of intervention: 24 months, follow-up immediate	
<b>Transtheoretical model applied to chronic disease</b>	<b>Augmented usual care</b>
<i>Diet:</i>	<i>Diet:</i>
Calorie goal: reduce calories	Calorie goal: reduce calories
Proportions diet: increase fruit and vegetables, and reduce fat	Proportions diet: increase fruit and vegetables, and reduce fat
<i>Exercise:</i>	<i>Exercise:</i>
Energy expenditure goal: increase activity and exercise but no details provided	Energy expenditure goal: not reported
Type: not reported	Type: not reported
<i>Behaviour modification:</i>	<i>Behaviour modification:</i>
Mode: not reported explicitly but assume individual	Mode: not reported
Frequency: face-to-face counselling once every 6 months. Telephone counselling every month	Frequency: counselling once every 6 months
Content – see <i>Table 10</i>	<i>Delivered by:</i>
<i>Delivered by:</i>	Registered dietitian
Registered dietitian and weight loss advisor	<i>Ongoing support:</i>
<i>Ongoing support:</i>	None reported
Written materials mailed on request	

*continued*

**TABLE 9** Details of the multicomponent interventions for those studies that included a non-active intervention (e.g. usual care) as the comparator (*continued*)

<b>Stevens et al. 2001<sup>70</sup></b>	
<b>Length of intervention:</b> intensive phase – 14 weeks; transitional phase – 16–18 months; follow-up 36 months	
<b>Weight loss intervention</b>	<b>Usual-care control</b>
<i>Diet:</i> Calorie goal: men: < 1500 kcal/day. Women: < 1200 kcal/day Proportions diet: decreasing consumption of excess fat, sugar and alcohol	No description provided
<i>Exercise:</i> Energy expenditure goal: approximately 40%–55% of heart rate reserve. From initially 10–15 minutes at least 3 days per week to 30–45 minutes per day, 4–5 days per week Type: primarily brisk walking (moderate intensity)	
<i>Behaviour modification:</i> Mode: individual then groups of 11–34 Frequency: weekly for 14 weeks (intensive phase) then six biweekly meetings and then monthly meetings for additional 3–4 months (transitional phase) Content – see Table 10	
<i>Delivered by:</i> Dietitians and health educators and some psychologists	
<i>Ongoing support:</i> Variety of options including refreshing or redelivering the intervention content. Biweekly contacts for three to six sessions, offered six times a year (participants expected to attend at least three)	
<b>Simkin-Silverman et al. 1998<sup>73</sup></b>	
<b>Length of intervention:</b> phase 1 – 20 weeks; phase 2 – 6–54 months; follow-up 54 months	
<b>Lifestyle intervention</b>	<b>Control</b>
<i>Phase 1:</i> <i>Diet:</i> Calorie goal: 1300–1500 kcal/day meal plan in the first month. When weight goal met, intake increased gradually until weight stabilised Proportions diet: for the first month dietary fat reduced to 25%, saturated fat to 7% of daily calories, and cholesterol to 100 mg/day	Assessment only (received a health education pamphlet on reducing cardiovascular risk factors and for those who were smokers, advice to quit)
<i>Exercise:</i> Energy expenditure goal: expend 1000 kcal per week from week 3. Already active women to expend 1500 kcal per week, those already expending 1500 kcal per week encouraged to maintain this	
<i>Behaviour modification:</i> Mode: group, size ≈ 20 Frequency: weekly for 10 weeks, biweekly for 10 weeks Content – see Table 10	
<i>Delivered by:</i> Behavioural psychologists and nutritionists	
<i>Ongoing support</i> <i>Phase 2:</i> Meetings in months 6, 7, 8, 10, 12 and 14. After month 14 participants offered refresher programmes to help with maintenance of behaviour change	

**TABLE 9** Details of the multicomponent interventions for those studies that included a non-active intervention (e.g. usual care) as the comparator (*continued*)

<b>Jeffery and Wing 1995<sup>25</sup></b>	
<b>Length of intervention:</b> 18 months; follow-up 30 months	
<b>Standard behavioural treatment</b>	<b>Control</b>
<i>Diet:</i>	No intervention. Participants could do whatever they wished to lose weight on their own
Calorie goal: 1000 or 1500 kcal per day on the basis of baseline body weight to produce an estimated weight loss of about 1 kg per week	
Proportions diet: not stated	
<i>Exercise:</i>	
Energy expenditure goal: 50 kcal per day for 5 days a week to increase to a final goal of 1000 kcal per week	
Type:	
Walking or cycling	
<i>Behaviour modification:</i>	
Mode: group, size ≈ 20	
Frequency: weekly for first 20 weeks and then once a month	
Content – see <i>Table 10</i>	
<i>Delivered by:</i>	
Trained interventionists with advanced degrees in nutrition or behavioural science	
<i>Ongoing support:</i>	
Not specifically mentioned but content of monthly group meetings noted above may fill this role	
<b>Stevens et al. 1993<sup>24</sup></b>	
<b>Length of intervention:</b> phase 1 – 6 months; phase 2 – 12 months; follow-up 18 months	
<b>Weight loss intervention</b>	<b>Usual-care control</b>
<i>Phase 1:</i>	No description provided
<i>Diet:</i>	
Calorie goal: not to fall below 1200 kcal/day, no upper limit reported	
Proportions diet: not stated (optional method of counting fat intake noted)	
<i>Exercise:</i>	
Energy expenditure goal: 4–5 days per week with between 30 and 45 minutes of exercise per session, at an intensity of 40%–55% of heart rate reserve	
Type:	
Principally walking	
<i>Behaviour modification:</i>	
Mode: group 7–20, plus occasional friends or family members	
Frequency: 14 weekly meetings	
Content – see <i>Table 10</i>	
<i>Delivered by:</i>	
Dietitian and a psychologist or exercise physiologist	
<i>Phase 2:</i>	
<i>Ongoing support:</i>	
Continued monitoring of weight and exercise encouraged. Goal of at least one contact per month for the remainder of the trial. The type and exact number of contacts varied monthly according to individual needs	



treatment. The two remaining interventions by Stevens and colleagues<sup>70,74</sup> were referred to as weight loss interventions (see *Table 9*) which were from the TOHP study.

The RCTs ranged in duration from 18 to 54 months. In the three trials that specifically referred to weight maintenance, the weight maintenance phase was assisted with ongoing support (details are given below). The RCTs reported by Stevens and colleagues<sup>70,74</sup> consisted of a 6-month weight loss phase followed by a weight maintenance phase of 12 months<sup>74</sup> or 36 months (up to 48 months for some data).<sup>70</sup> The trial reported by Simkin-Silverman and colleagues<sup>73</sup> consisted of a 20-week initial phase of weight stabilisation followed by a maintenance phase up to 54 months.

Four of the RCTs specified quantitative calorie goals in the diet component of their interventions.<sup>70,73–75</sup> These were daily limits of: < 1500 kcal for men or < 1200 kcal for women;<sup>70</sup> 1000 or 1500 kcal according to body weight;<sup>75</sup>  $\geq$  1200 kcal (no upper limit specified);<sup>74</sup> or 1300–1500 kcal, gradually increased until weight stabilised.<sup>73</sup> Three RCTs specified dietary composition,<sup>70,72,73</sup> but only one, by Simkin-Silverman and colleagues,<sup>73</sup> mentioned quantities (dietary fat reduced to 25%, saturated fat to 7% and cholesterol to 100 mg/day). The remaining two trials specified an increase in fruit and vegetables, and reduction in fat,<sup>72</sup> or decreased consumption of excess fat, sugar and alcohol<sup>70</sup> (see *Table 9*).

The same four RCTs that specified quantitative calorie goals also provided quantitative exercise goals.<sup>70,73–75</sup> In two of these, exercise intensity was expressed as approximately 40%–55% of the heart rate reserve, achieved principally by increasing the frequency and duration of walking.<sup>70,74</sup> In one trial, exercise energy expenditure was specified as 1000 or 1500 kcal week, depending on participants' initial activity levels, with maintenance of 1500 kcal/week encouraged, but the mode of exercise was not specified.<sup>73</sup> The remaining trial specified an exercise energy expenditure goal of 50 kcal/day for 5 days/week, increasing to 1000 kcal/week, achieved by walking or cycling.<sup>75</sup> Two of the RCTs<sup>72,73</sup> did not specify the mode of exercise (such as walking or cycling) (see *Table 9*).

Four RCTs reported that the mode of behavioural therapy involved group delivery of the intervention.<sup>70,73–75</sup> Group sizes were 7–20,<sup>74</sup> approximately 20,<sup>73,75</sup> or 11–34 participants.<sup>70</sup> The frequency of group meetings was initially weekly for the first 10 weeks,<sup>73</sup> 14 weeks,<sup>70,74</sup> or 20 weeks.<sup>75</sup> Subsequent meetings were then fortnightly for 10 weeks,<sup>73</sup> fortnightly for 12 weeks, then monthly for 3–4 months,<sup>70</sup> or monthly.<sup>75</sup> The behavioural therapy intervention reported by Logue and colleagues<sup>72</sup> was not described in detail but appeared to involve an individual mode of delivery, as telephone counselling was provided every month (see *Table 9*).

The personnel who delivered the behavioural therapy interventions were described only briefly. Behaviour therapy in the trial by Logue and colleagues<sup>72</sup> was delivered by a registered dietitian and a weight loss advisor, but it is unclear how many people delivered these two roles. None of the other RCTs specified the number of people who delivered the intervention. In four RCTs the behavioural therapy interventions were delivered partly by dietitians,<sup>70,72,74</sup> or nutritionists.<sup>73</sup> These RCTs also included delivery by a weight loss advisor,<sup>72</sup> a health educator and psychologist,<sup>70</sup> behavioural psychologists,<sup>73</sup> or a psychologist or exercise physiologist.<sup>72</sup> The remaining trial used trained interventionists with advanced degrees in nutrition or behavioural science to deliver the intervention<sup>75</sup> (see *Table 9*). None of the studies reported where the behaviour therapy was undertaken.

At least 10 different components of behaviour therapy were identifiable among descriptions provided in the RCTs and are summarised in *Table 10*. As mentioned above, Logue and colleagues<sup>72</sup> did not specify which components they included, but instead reported the



behavioural model they used. The model employed is widely documented and accessible, and five individual target behaviours for change were specified for the intervention. Among the remaining four RCTs, the behavioural components represented most commonly were goal-setting or action plans (four studies),<sup>70,73–75</sup> relapse prevention (four studies),<sup>70,73–75</sup> problem solving (three studies),<sup>73–75</sup> self-monitoring (three studies),<sup>70,73,74</sup> and social support (three studies).<sup>70,74,75</sup> Two RCTs included cognitive restructuring,<sup>73,75</sup> motivation enhancing, and stimulus control, whereas only one trial included behaviour modelling and none explicitly included self-reinforcement or skill development (see *Table 10*).

Ongoing support for participants in the intervention group was reported in four RCTs and varied in its type and frequency.<sup>70,72–74</sup> Logue and colleagues<sup>72</sup> provided written materials, which were mailed to participants on request. Stevens and colleagues<sup>70,74</sup> provided a variety of options, including refreshing or redelivering the intervention content and encouraging a number of participant contacts, the type and number of which varied according to the needs of individual participants. Simkin-Silverman and colleagues<sup>73</sup> provided five meetings for participants during months 7–14, after which they were offered refresher programmes to assist maintenance of behaviour change (see *Table 9*).

The population characteristics of these RCTs limit the generalisability of their findings. The RCT by Simkin-Silverman and colleagues<sup>73</sup> is relevant only to perimenopausal women and based on a subgroup of the total population who were mildly overweight (total population mean BMI 20–34 kg/m<sup>2</sup>; aged 44–50 years). The remaining RCTs were mostly limited to people with an upper BMI of approximately 34–37 kg/m<sup>2</sup>, with an upper age limit of 45–54 years. This precludes generalising the findings to very obese and/or older people. In contrast, the trial by Logue and colleagues<sup>72</sup> represented overweight participants whose BMI was  $\geq 40$  kg/m<sup>2</sup> and included people aged up to 69 years. The trials, which were all conducted in the USA, recruited predominantly white volunteers who responded to media advertisements and, who apart from being overweight, were free from serious disease. Such people are unlikely to be representative of the UK overweight population. Where reported, participants were relatively well educated and employed. Three of the trials used incentives to enhance participation, which could also influence their generalisability.<sup>72,73,79</sup>

The starting weight and BMI of the trial participants were reported for four of the five trials (excluding Logue and colleagues<sup>72</sup>) (see *Table 7*). The participants would be classed as pre-obese in two RCTs<sup>73,74</sup> and class I obese in two RCTs.<sup>70,75</sup>

The appraisal of methodological quality (see *Quantity and quality of research available*) does not enable any of these five RCTs to be considered 'best' or 'worst' in terms of risk of bias. This mainly reflects the lack of, or unclear, reporting of the methodological variables. However, for three<sup>70,72,73</sup> of these studies the overall risk of bias is generally low, with many key attributes required to reduce potential bias present, while for the remaining two studies<sup>74,75</sup> the risk of bias remains uncertain.

## Clinical effectiveness

### Weight loss

Logue and colleagues<sup>72</sup> used three statistical analysis approaches which indicated that at 24 months' follow-up the Transtheoretical Model-based intervention yielded weight losses of 0.21–0.23 kg relative to the augmented usual-care comparator group (whose participants had received limited general guidance on improving diet). This difference was not statistically significant (NS) ( $p=0.50$ , reported only for an unadjusted analysis) (*Table 11*). In this study,<sup>72</sup> attrition ranged from 31% to 46% depending upon the study arm and time of follow-up.

**TABLE 10** Components of the behavioural aspects of multicomponent weight management studies that included a non-active intervention (e.g. usual care) as the comparator

	Cognitive restructuring	Goal-setting/action plans	Modelling	Motivation enhancing	Problem solving	Relapse prevention	Self-monitoring	Self-reinforcement	Skill development	Social assertion (SA)/social support (SS)	Stimulus control	Theoretical model	Others (n)
Logue <i>et al.</i> 2005 <sup>72</sup>												✓	
Stevens <i>et al.</i> 2001 <sup>70</sup>		✓				✓	✓			SS			1
Simkin-Silverman <i>et al.</i> 1998 <sup>73</sup>	✓	✓	✓	✓	✓	✓	✓			SA	✓		1
Jeffery and Wing 1995 <sup>75</sup>	✓	✓		✓	✓	✓				SA and SS	✓		
Stevens <i>et al.</i> 1993 <sup>74</sup>		✓			✓	✓	✓			SS			

Attrition was 9% higher in the usual-care control arm than in the intervention arm at 18 months' follow-up, and 7% higher in the control arm at 30 months' follow-up. The analysis was undertaken using an ITT analysis however.

Stevens and colleagues<sup>70</sup> weight loss intervention yielded a weight loss relative to the control group of 2.7 kg at 18 months' follow-up and 2.0 kg at 36 months' follow-up. These intervention-comparator differences were both statistically significant ( $p < 0.001$ ). The attrition rates in this study were reported to be similar between groups at approximately 7%–9%.<sup>70</sup> The earlier RCT by Stevens and colleagues,<sup>74</sup> which also compared a weight loss intervention against a control group, also reported a statistically significant intervention-comparator difference in weight loss ( $p < 0.001$ ). However, Stevens and colleagues<sup>74</sup> did not specify the amount of weight lost in kg for the intervention and comparator groups as a whole group (see *Table 11*). In this study the attrition rate was unclear.<sup>74</sup> It was also not reported for either RCT<sup>70,74</sup> whether their statistical analyses were powered for testing differences in weight change (tests were powered for the primary outcome, BP).

Simkin-Silverman and colleagues<sup>73</sup> demonstrated that their LI for perimenopausal women resulted in large initial weight losses relative to their control group (which had received limited general guidance on reducing cardiovascular risk factors). However, their results were presented for posthoc subgroups of participants who were overweight or obese at baseline. It is unclear whether the study was powered for this analysis and the results should therefore be interpreted cautiously. At 18 months' follow-up, weight losses were 3.6 kg more in the intervention overweight subgroup than in the comparator overweight subgroup, and 6.1 kg more in the intervention obese subgroup than in the comparator obese subgroup. For the overweight subgroups, weight-change differences in the intervention group at 30, 42 and 54 months exceeded those in the comparator group by 3 kg, 2.7 kg and 1.4 kg, respectively. For the obese subgroups, the corresponding differences at these follow-up times were 7.2 kg, 3.9 kg and 3.3 kg. For each subgroup, the differences at 18, 30 and 42 months' follow-up were reported to be statistically significant, but at 54 months' follow-up the differences were stated to be not statistically significant. Participant attrition was 4%–6% in both intervention groups.<sup>73</sup> Full details are given in *Table 11*.

Jeffery and Wing<sup>75</sup> reported large initial weight losses for their standard behaviour treatment interventions compared with the control group. At 18 months' follow-up, the standard behaviour

**TABLE 11** Weight change outcomes for those multicomponent weight management studies that included a non-active intervention (e.g. usual care) as the comparator

Study	Treatment arms		Difference (95% CI); <i>p</i> -value between groups
<b>Logue <i>et al.</i> 2005<sup>72</sup></b>	<b>Transtheoretical model (n=271)</b>	<b>Augmented usual care (n=266)</b>	
<i>Mean ± SE weight change, kg (95% CI) 0–24 months</i>			
Unadjusted	−0.39 ± 0.38 (−1.1 to 0.4)	−0.16 ± 0.42 (−1.0 to 0.7)	0.23 (−1.4 to 0.9); <i>p</i> = 0.50 (NS)
Adjusted for baseline weight and other covariates	Not reported	Not reported	0.22 (CI and <i>p</i> -value not reported)
Adjusted for participants with missing final weight	Not reported	Not reported	0.21 (CI and <i>p</i> -value not reported)
<b>Stevens <i>et al.</i> 2001<sup>70</sup></b>	<b>Weight loss intervention (1) n=545; (2) n=547</b>	<b>Usual care (1) n=551; (2) n=554</b>	
<i>Mean ± SD weight change, kg (95% CI)</i>			
0–18 months	−2.0 ± 5.8 (−2.5 to −1.5)	0.7 ± 4.2 (0.4 to 1.6)	−2.7 ± 0.3 (−3.3 to −2.1); <i>p</i> < 0.001
0–36 months	−0.2 ± 5.9 (−0.7 to 0.3)	1.8 ± 5.3 (1.3 to 2.2)	−2.0 ± 0.2 (−2.6 to −1.3); <i>p</i> < 0.001
<b>Simkin-Silverman <i>et al.</i> 1998<sup>73</sup></b>	<b>Lifestyle intervention (n=260)</b>	<b>Control (n=275)</b>	
<i>Mean ± SD weight change, kg (% of initial weight lost)</i>			
Subgroup 1: overweight at baseline (BMI: 25–29.9 kg/m <sup>2</sup> )	Subgroup 1 (n=95):	Subgroup 1 (n=95):	Subgroup 1:
18 months	−3.5 ± 5.8 (−4.6)	0.1 ± 4.0 (0.07)	<i>p</i> < 0.001
30 months	−2.7 ± 5.4 (−3.5)	0.3 ± 5.1 (0.41)	<i>p</i> < 0.001
42 months	−1.4 ± 5.7 (−1.7)	1.3 ± 5.5 (1.9)	<i>p</i> < 0.001
54 months	0.1 ± 6.1 (0.31)	1.5 ± 5.2 (2.2)	Stated NS (no <i>p</i> -value)
Subgroup 2: obese at baseline (BMI ≥ 30 kg/m <sup>2</sup> )	Subgroup 2 (n=22):	Subgroup 2 (n=36):	Subgroup 2:
18 months	−6.6 ± 8.4 (−7.7)	−0.5 ± 4.5 (−0.36)	<i>p</i> < 0.01
30 months	−4.3 ± 6.7 (−5.0)	2.9 ± 5.4 (3.5)	<i>p</i> < 0.01
42 months	−2.0 ± 6.4 (−2.3)	1.9 ± 5.7 (2.5)	<i>p</i> < 0.05
54 months	−0.2 ± 6.9 (−0.17)	3.1 ± 7.7 (3.7)	Stated NS (no <i>p</i> -value)
<b>Jeffery and Wing 1995<sup>75</sup></b>	<b>Standard behavioural therapy (n=40)</b>	<b>Control (n=40)</b>	
<i>Mean ± SD<sup>a</sup> weight change, kg</i>			
0–18 months	−4.6 (n=26) <sup>b</sup>	0.0 (n=34) <sup>b</sup>	Reported for any differences between groups only (see Appendix 5)
0–30 months	−1.4 ± 7.2 (n=40)	0.6 ± 5.3 (n=40)	
<b>Stevens <i>et al.</i> 1993<sup>74</sup></b>	<b>Weight loss intervention (n=308)<sup>c</sup></b>	<b>Control (n=256)<sup>c</sup></b>	
<i>Mean weight change, kg</i>			
0–18 months	Men −4.7 <sup>c</sup> Women −1.6 <sup>c</sup>	Men: stated no change (no data reported) Women 0.2 <sup>c</sup>	<i>p</i> < 0.001 <sup>c</sup>

SD, standard deviation; SE, standard error.

a Reported only for 30 months.

b Sample sizes estimated from chart by reviewer.

c Sample sizes and analysis not reported separately by gender subgroups.

Some of the RCTs reported weight loss or weight gain. To assist interpretation this has been standardised across all studies to weight change (− indicates loss; + indicates gain).

treatment alone resulted in 4.6 kg weight loss compared with no weight change in the control group. At 30 months' follow-up, weight loss in the standard behaviour treatment group was 2.0 kg more than in the control group. For the results of the other interventions in this trial see *Appendix 5*. Pair-wise statistical comparisons of differences relative to the control group at 30 months were not reported for individual interventions. Instead, statistical tests were conducted to detect any differences between the groups. These differences were not statistically significant (overall test for differences among groups  $p > 0.45$ ; post hoc test for differences between any interventions and comparator  $p < 0.08$ ). Statistical power calculations for this analysis were not reported (for full details see *Appendix 5*). Attrition rates were not reported by study arm but were reported to be 12% overall.

Although it is possible that their starting weight and BMI may have influenced participants' desire or likelihood of achieving weight loss, none of the studies stratified populations by weight or BMI at entry, and the results show no consistent pattern with regard to whether pre-obese or class I obese participants lost more weight.

All of the active interventions resulted in weight change relative to baseline, and in all cases where follow-up was assessed at multiple time points, the amount of weight lost relative to baseline decreased with increasing time after randomisation (see *Table 11*). While not directly tested, three studies offer data that suggest that long-term weight regain occurred following the end of the active interventions.<sup>70,73,75</sup> Stevens and colleagues<sup>70</sup> show that the difference between the weight loss group and control group at the end of the 18-month intervention was similar to the difference at the 36-month end point (2.7 kg and 2.0 kg, respectively). However, comparison of weight loss from baseline to 18 months and from baseline to 36 months (see *Table 11*) suggests that weight was gained in both the intervention and control arms during 18–36 months, despite participants in the weight loss arm receiving ongoing support for weight maintenance. This finding is difficult to interpret in detail as Stevens and colleagues<sup>70</sup> did not explicitly report weight maintenance or weight regain for any time periods of their study. The study by Jeffery and Wing<sup>75</sup> appears to show a similar pattern, based on observation of differences between weight changes from baseline to 18 months and from baseline to 30 months, although their study differed from that by Stevens and colleagues<sup>70</sup> in that it did not provide ongoing support for the participants after 18 months (note that weight maintenance or regain were not explicitly reported as outcomes; not all randomised participants were followed up to 30 months; and no statistical analyses were presented for this comparison). Similar patterns were seen in the study by Simkin-Silverman and colleagues<sup>73</sup> in that despite ongoing maintenance participants appeared to regain weight over the duration of the study. Similar caveats apply as per the discussion of the two studies above, but also because these results are based on subgroups of the overall study population.

### Barriers and facilitators

Only one of the five RCTs, by Jeffery and Wing,<sup>75</sup> considered participants' perceived barriers to behaviour change. These were assessed by self-report using a 15-item questionnaire with items scored on a 1–5 scale. The barriers were not reported as outcomes, although the authors stated that at the 30-month follow-up there were no significant differences between the groups in perceived barriers.

### Other outcomes reported in the trials (not evaluated here)

The most frequently-reported outcomes other than weight change that were reported in the RCTs were: physical activity,<sup>70,72–75</sup> dietary intake,<sup>70,72–75</sup> BP,<sup>70,72–74</sup> and blood lipids.<sup>72,73</sup> The number of other outcomes reported in addition to weight change ranged from two (BP and attendance)<sup>74</sup> to 10 (including various psychosocial, mental and physical health assessments).<sup>72</sup> Adherence to the interventions was assessed and reported in three of the five RCTs, by Stevens and colleagues,<sup>70</sup> Simkin-Silverman and colleagues,<sup>73</sup> and Jeffery and Wing.<sup>75</sup>

### Summary of effectiveness

Five RCTs compared multicomponent interventions to non-active intervention groups.<sup>70,72–75</sup> One of these RCTs provided evidence that longer term (up to 42 months) weight change in the intervention group was significantly different from that of the control group, although much of the weight lost had been regained.<sup>73</sup> However, these long-term benefits are relevant only to perimenopausal women and the analyses were based on posthoc subgroups which may not have been statistically powered. One trial with a 24 month duration found no statistically significant differences in weight loss between the two study arms although it should be noted that attrition was relatively high in this study and appeared to differ between the study arms.<sup>72</sup> One RCT did not directly test for statistical significance between the intervention and the control, although data were available for 30 months' follow-up and did appear to show greater weight loss in the intervention group than in the control group.<sup>75</sup> Two trials, by Stevens and colleagues, showed statistically significant difference in weight loss (using similar weight loss interventions) at 18 months<sup>74</sup> or 36 months.<sup>70</sup> The results of the Stevens and colleagues<sup>70</sup> study provide the opportunity to assess weight change 18 months after the intervention had finished. This trial was also among those that would be judged overall to have the lowest risk of bias. Issues over differences in the interventions and differences in the duration of follow-up, and issues around the generalisability of the studies and their risk of bias make comparisons across these studies difficult. However, the weight loss interventions used in the Stevens and colleagues<sup>70,74</sup> studies may offer a model that could be tested with relevant UK overweight populations. These trials are from the TOHP study group.

## Assessment of effectiveness for multicomponent interventions with a focus on diet

Two<sup>69,71</sup> included studies compared a multicomponent intervention which had a focus on the dietary component compared with another active comparator. The two studies are briefly described below and the main components are summarised in *Table 12*.

Burke and colleagues<sup>71</sup> hypothesised that choice of either a standard calorie and fat-restricted diet (standard diet, STD-D) or a calorie- and fat- restricted vegetarian diet (lacto-ovo-vegetarian diet, LOV-D) would result in greater weight loss than having one of these diets randomly assigned. The authors' secondary hypothesis was that LOV-D would result in greater weight loss than STD-D. There were four arms to the trial but for the purpose of this review we consider just two of these arms to be the most relevant, those where participants were randomised to either the intervention with STD-D or LOV-D and therefore had no choice regarding the type of diet they received. Wadden and colleagues<sup>69</sup> compared three active interventions. For our review we consider the SBT the intervention of relevance to the scope. The other two groups were SBT and VLCD, and VLCD alone.

In the Burke and colleagues<sup>71</sup> study the interventions only differed in the type of diet participants were asked to adhere to. For the duration of the 12-month interventions participants in both groups who weighed < 90.5 kg at baseline aimed to reduce their maximum daily calorie intake to 1200 kcal (women) or 1500 kcal (men). Those who weighed over 90.5 kg at baseline had goals of 1500 kcal (women) and 1800 kcal (men). Participants were advised to maintain a minimum daily intake of at least 1000 kcal. All participants also aimed to reduce their fat intake to 25% of total kilocalorie intake, but were advised not to consume < 10% of total kilocalorie intake as fat. The only difference between the two groups was that the LOV-D group eliminated meat, poultry and fish first from breakfast, then lunch, and then dinner so that by the sixth week they had eliminated these foods from their diet. In the Wadden and colleagues study<sup>69</sup> participants in the SBT group consumed a 1000–1200 kcal/day 'balanced' diet of their choosing for the 6-month

**TABLE 12** Details of multicomponent interventions with a focus on diet

<b>Burke et al. 2008<sup>71</sup></b>		
<b>Length of intervention:</b> 12 months; follow-up 18 months		
<b>STD-D (no preference group)</b>		<b>LOV-D (no preference group)</b>
<i>Diet:</i>		<i>Diet:</i>
Calorie goal: reduce maximum daily calorie intake to 1200 kcal (women) 1500 kcal (men) for those weighing <90.5 kg at baseline; 1500 kcal (women) 1800 kcal (men) for those weighing >90.5 kg at baseline. Minimum daily intake was 1000 kcal		Calorie goal: reduce maximum daily calorie intake to 1200 kcal (women) 1500 kcal (men) for those weighing <90.5 kg at baseline; 1500 kcal (women) 1800 kcal (men) for those weighing >90.5 kg at baseline. Minimum daily intake was 1000 kcal
Proportions diet: reduce fat intake to 25% of total kilocalorie intake, but $\leq$ 10% fat		Proportions diet: reduce fat intake to 25% of total kilocalorie intake, but $\leq$ 10% fat. The diet was lacto-ovo-vegetarian (meat, poultry and fish eliminated)
<i>Exercise:</i>		<i>Exercise:</i>
Energy expenditure goal: participants encouraged to walk at least 50 minutes per week initially, gradually increasing to at least 150 minutes per week by week 6		Energy expenditure goal: participants encouraged to walk at least 50 minutes per week initially, gradually increasing to at least 150 minutes per week by week 6
Type: mostly walking		Type: mostly walking
<i>Behaviour modification:</i>		<i>Behaviour modification:</i>
Mode: group, size 10–20 participants		Mode: group, size 10–20 participants
Frequency: 32 treatment sessions (lasting 60 minutes) over 12 months. Sessions held in the evening weekly for first 6 months, then every 2 weeks for months 7–9 and monthly for months 10–12		Frequency: 32 treatment sessions (lasting 60 minutes) over 12 months. Sessions held in the evening weekly for first 6 months, then every 2 weeks for months 7–9 and monthly for months 10–12
Content – see Table 13		Content – see Table 13
<i>Delivered by:</i>		<i>Delivered by:</i>
Dietitian with masters degree, exercise physiologist, or nurse behavioural scientist		Dietitian with masters degree, exercise physiologist, or nurse behavioural scientist. Also vegetarian nutritionist
<i>Ongoing support:</i>		<i>Ongoing support:</i>
None. After 12 months the maintenance phase began and no further contact was made with participants until the final 18 month assessment		None. After 12 months the maintenance phase began and no further contact was made with participants until the final 18 month assessment
<b>Wadden et al. 1988<sup>69</sup></b>		
<b>Length of intervention:</b> 4 months (VLCD arm); 6 months (SBT and SBT and VLCD arm); follow-up 3 years		
<b>SBT</b>	<b>SBT and VLCD</b>	<b>VLCD only</b>
<i>Diet:</i>	<i>Diet:</i>	<i>Diet:</i>
Calorie goal: 1000–1200 kcal/day	Calorie goal (kcal/day): month 1, 1000–1200; months 2–3, 400–500; months 4–6, 1000–1200	Calorie goal (kcal/day): month 1, 1000–1200; months 2–3, 400–500; month 4, 1000–1200
Proportions diet: ‘balanced’ diet of participants choosing	Proportions diet: month 1: ‘balanced’ diet; months 2–3: meat, fish, fowl, plus daily supplements of 3 g each of potassium and sodium chloride and 800 mg of calcium; month 4: conventional food, with introduction of fruits, vegetables, breads, cereals, and fats; months 5–6: chosen by participants	Proportions diet: month 1: ‘balanced’ diet; months 2–3: meat, fish, fowl, plus daily supplements of 3 g each of potassium and sodium chloride and 800 mg of calcium; month 4: conventional food, with introduction of fruits, vegetables, breads, cereals, and fats
<i>Exercise:</i>	<i>Exercise:</i>	<i>Exercise:</i>
Energy expenditure goal: not reported	Energy expenditure goal: not reported	Energy expenditure goal: not reported
Type: involved walking and using stairs	Type: involved walking and using stairs	Type: not reported
<i>Behaviour modification:</i>	<i>Behaviour modification:</i>	<i>Behaviour modification:</i>
Mode: group, size 4–7 participants	Mode: group, size 4–7 participants	No behaviour modification.
Frequency: weekly 90-minute sessions	Frequency: weekly 90-min sessions	<i>Delivered by:</i>
Content – see Table 13	Content – see Table 13	Doctoral-level clinical psychologists
<i>Delivered by:</i>	<i>Delivered by:</i>	<i>Ongoing support:</i>
Doctoral-level clinical psychologists	Doctoral-level clinical psychologists	Six scheduled follow-up meetings at 1, 2, 3, 6, 9, 12 months post-treatment. No other details reported
<i>Ongoing support:</i>	<i>Ongoing support:</i>	
11 scheduled follow-up meetings: fortnightly for 2 months post-treatment, then monthly for 4 months then at 2-month intervals for 6 months. No other details reported	11 scheduled follow-up meetings: fortnightly for 2 months post-treatment, then monthly for 4 months then at 2-month intervals for 6 months. No other details reported	



intervention period. The mean [standard deviation, (SD)] baseline weight of participants in this study was 112.2 kg (21.5kg) in the SBT group, 108.0 kg (21.5kg) in the SBT and VLCD group, and 106.4 kg (18.4kg) in the VLCD alone group. So for participants over 90.5 kg the weekly calorie goal was lower than in the Burke and colleagues study.<sup>71</sup> Participants in the SBT and VLCD, and VLCD only groups consumed a 1000–1200 kcal/day ‘balanced’ diet of their choosing for the first month of intervention, then they began a 2-month VLCD protein-sparing modified fast of only 400–500 kcal/day. This diet consisted of lean meat, fish and fowl plus potassium, sodium chloride and calcium supplements. In the fourth month fruits and vegetables, breads and cereals, and finally fats were reintroduced to the diet, in that order, to return to a more conventional diet. The VLCD intervention ended at this point (4 months), whereas the SBT and VLCD group continued at 1000–1200 kcal/day diet for a further 2 months (months 5 and 6).

All participants engaged in physical activity for the duration of the Burke and colleagues<sup>71</sup> study. Participants were encouraged to walk at least 50 minutes per week initially, gradually increasing this to at least 150 minutes per week, by week 6. In the Wadden and colleagues study<sup>69</sup> only two of the three groups had an exercise component. The SBT and SBT and VLCD groups each received the same instruction on increasing lifestyle activity by walking and using the stairs. However, unlike the study by Burke and colleagues,<sup>71</sup> it does not appear that there was a specific activity goal.

For the first 6 months of the Burke and colleagues<sup>71</sup> study participants attended weekly 60-minute sessions in groups of about 10–20 participants. Sessions were held in the evenings biweekly for months 7–9 and then monthly for the final 3 months of the intervention period. Dietitians, exercise physiologists and nurse behavioural scientists were involved in delivering the sessions, with the LOV-D group also receiving advice from a vegetarian nutritionist for four sessions on how to adopt the eating plan. The behavioural aspect of the intervention was based on several models of motivation and behavioural change such as Social Cognitive Theory. The range of features and strategies included in the behavioural component of the interventions are summarised in *Table 13*. It is not reported in the study where the behaviour therapy was undertaken. At the end of the 12-month intervention participants had no further contact with the interventionists until the final 18-month assessment. In the Wadden and colleagues study<sup>69</sup> the intervention periods of 4 months for VLCD alone, and 6 months for the SBT and SBT and VLCD groups were all shorter than for the Burke and colleagues<sup>71</sup> study. All participants were treated weekly for 90 minutes during the intervention period in groups of four to seven participants, a smaller group number than in the Burke and colleagues<sup>71</sup> study. A doctoral-level clinical psychologist led the groups. Only two groups, SBT and SBT and VLCD, were taught traditional behavioural methods of weight control following a published manual, although it was not clear whether this was based on a particular behavioural theory. The range of features and strategies included in the behavioural component of the intervention can be seen in *Table 13*. The setting for the behaviour therapy was not reported. The SBT and VLCD group received additional instruction in the final 3 months of the intervention on maintenance of the weight loss achieved with the VLCD, including relapse prevention training and strategies for handling weight regain. The VLCD alone group did not receive any formal instruction about modifying their eating and exercise habits, and did not receive any behaviour therapy. Following the intervention period participants in the SBT group and SBT and VLCD group attended 11 follow-up meetings in the year after treatment. The timing of these meetings was not reported. Participants in the VLCD only group attended six follow-up meetings at 1, 2, 3, 6, 9 and 12 months post treatment. There was then no further contact with participants in any of the groups until the 3-year follow-up.

The Burke and colleagues<sup>71</sup> study enrolled a much higher proportion of women than men, and the majority of participants (about 70%) were white with average socioeconomic status. The majority of the participants recruited by Wadden and colleagues<sup>69</sup> were women, but the ethnicity

**TABLE 13** Components of behavioural aspects of multicomponent weight management studies with a focus on diet

	Cognitive restructuring	Goal-setting/action plans	Modelling	Motivation enhancing	Problem solving	Relapse prevention	Self-monitoring	Self-reinforcement	Skill development	Social assertion (SA)/social support (SS)	Stimulus control	Theoretical model	Others (n)
Burke <i>et al.</i> 2008 <sup>71</sup>	✓	✓	✓		✓	✓	✓	✓	✓	SA	✓	✓	1
Wadden <i>et al.</i> 1988 <sup>69</sup>	✓						✓	✓		SS	✓		1

of participants was not reported. The generalisability of the results to men and people of different ethnicities is therefore unknown. The mean ages of the participants in both trials were similar, at approximately 43 years. Wadden and colleagues<sup>69</sup> charged a fee to cover medical tests and all other expenses, and in addition participants had to pay a deposit which was refundable after the first year of follow-up. This may have affected the type of people willing to be recruited into the trial.

The starting weight of the trial participants was reported by both trials<sup>69,71</sup> and Burke and colleagues<sup>71</sup> also reported starting BMI. In the Burke and colleagues study<sup>71</sup> starting weight was slightly over 90 kg in both groups (*Table 7*) and participants would be categorised as having class I obesity according to their starting BMIs. Participants in the Wadden and colleagues study<sup>69</sup> were heavier than those in the Burke and colleagues study with baseline weights over 100 kg in each group. Although BMI was not reported, if height is assumed to be 170 cm, then these participants would be categorised as having class II obesity.

Details of the methods of the Burke and colleagues<sup>71</sup> trial either were not reported or were unclear (see *Quantity and quality of research available*). In the Wadden and colleagues<sup>69</sup> study the majority of items contributing to the assessment of study quality were not reported. This may be a reflection of the age of the study, which was undertaken over 20 years ago. Therefore, when interpreting the results of these studies the likelihood that they may be associated with a high risk of bias should be borne in mind (see *Table 8*).

## Clinical effectiveness

### Weight loss

*Table 14* shows the results of the two included studies on measures of weight loss.<sup>69,71</sup> In the Burke and colleagues<sup>71</sup> study, by the 18-month assessment attrition from the STD-D group was 29% (14 of 48 participants) and from the LOV-D group was 24% (11 of 45 participants). It is therefore important that the outcome analyses study were conducted on an ITT basis (although nine participants who were randomised between all four arms of the study were excluded because they were found to be ineligible to take part). The primary outcome of the Burke and colleagues<sup>71</sup> study was percentage change in body weight from baseline to 18 months. Participants in the STD-D group had a mean ( $\pm$ SD) loss of 8.0% ( $\pm$ 7.8%) of their baseline body weight, which was not statistically different from the mean loss reported for the LOV-D group (7.9%  $\pm$  8.1%,  $p=0.30$ ). The percentage BMI change from baseline to 18 months also appears similar between the groups although a  $p$ -value for the between group comparison was not reported [mean (SD)% BMI change STD-D -7.8 (7.9) vs LOV-D -7.9 (8.2)]. Burke and colleagues<sup>71</sup> provide data on weight change at 6-, 12-, and 18-month follow-ups. Weight loss occurred during the 12-month intervention period (mean 9.7 kg loss in STD-D and LOV-D groups) but between the end of the intervention and the 18-month follow-up participants had already begun to regain weight (mean weight regain between 12 and 18 months of 2.4 kg in the STD-D group and 1 kg in the LOV-D



**TABLE 14** Weight change outcomes for studies with a focus on diet

Study	Treatment arms			<i>p</i> -value between groups
	STD-D ( <i>n</i> =48)	LOV-D ( <i>n</i> =45)		
<b>Burke <i>et al.</i> 2008<sup>71</sup></b>				
% weight change, baseline to 18 months (mean SD)	-8.0 (7.8)	-7.9 (8.1)		0.30
Weight change, baseline to 12 months, mean kg <sup>a</sup>	-9.7	-9.7		
Weight change, 12–18 months maintenance phase, mean kg <sup>a</sup>	2.4	1		
% BMI (kg/m <sup>2</sup> ) change, baseline to 18 months, mean (SD)	-7.8 (7.9)	-7.9 (8.2)		
<b>Wadden <i>et al.</i> 1998<sup>69</sup></b>	<b>SBT (<i>n</i>=14)</b>	<b>SBT and VLCD (<i>n</i>=16)</b>	<b>VLCD (<i>n</i>=15)</b>	
Weight loss at 3 years, mean ± SD (kg)				
Uncorrected analysis <sup>b</sup>	4.76 ± 6.56	6.53 ± 9.50	3.76 ± 8.85	Stated NS; no <i>p</i> -values reported
Corrected analysis <sup>a</sup>	3.54 ± 6.26	5.11 ± 8.28	2.20 ± 8.50	<i>p</i> -values reported
Mean proportion (%) of participants who equalled or exceeded their pre-treatment weight <sup>c,d</sup>	38	47	43	Stated NS; no <i>p</i> -values reported
Mean proportion (%) of participants who maintained weight loss within 2 kg of their end-of-treatment weight <sup>d</sup>	19	13	7	Not reported
Mean proportion (%) of participants who maintained weight loss <sup>c,d</sup>				
5 kg or greater	44	33	29	Stated NS; no <i>p</i> -values reported
10 kg or greater	31	27	7	<i>p</i> -values reported

a Calculated by reviewer. Not possible to calculate SDs from information provided.

b Some participants in each intervention group received additional external therapy 1–3 years after the end of treatment (VLCD: *n*=8; SBT: *n*=5; SBT and VLCD: *n*=6). These participants lost on average 3.42 kg during additional therapy before participating in the 3-year follow-up. The uncorrected analysis includes these participants but does not take into account the effect of additional therapy on their weight. The corrected analysis includes these participants but accounts for the effect of additional therapy by subtracting their self-reported weight at the time they received additional therapy from their pre-treatment weight.

c Stated that the per cent are approximate.

d Based on corrected analyses.

group). As this study did not report beyond 18 months of follow-up it was not clear whether weight regain continued at the same rate over time.

Wadden and colleagues<sup>69</sup> followed participants at 3 years but at the 3-year assessment attrition, which was only reported for the whole study population, was 24% (14 of 59 participants). Therefore results were only available for 45 of the 59 participants who had been randomised between the three groups. Furthermore, in the period since the end of the intervention some participants had received additional weight loss therapy. Therefore Wadden and colleagues<sup>69</sup> included a correction for this (see Table 14) and presented the results of both the uncorrected and corrected analyses. There were no statistically significant differences between the three groups in mean (kg) weight loss at 3 years' follow-up [corrected analysis: SBT 3.54 (SD 6.26); SBT and VLCD 5.11 (SD 8.28); VLCD 2.20 (SD 8.50), stated not significant, *p*-value not reported] and less than a fifth of participants in each group had maintained their weight loss to within 2 kg of their end-of-treatment weight (SBT 19%; SBT and VLCD 13%; VLCD 7%; no *p*-value reported). There were no statistically significant differences between the groups in the proportion of participants who equalled or exceeded their pre-treatment weight (SBT 38%; SBT and VLCD 47%; VLCD 43%; no *p*-value reported). Less than half the participants followed up at 3 years had maintained a 5 kg or greater weight loss; proportions for the three groups ranged from 29% to 44% with no significant differences between the groups (*p*-value not reported). The proportion maintaining a ≥10 kg weight loss was less than a third, ranging from 7% to 31%. Again there were no significant

differences between the groups ( $p$ -values not reported). No analysis of the statistical power to detect a difference between groups was reported for this study.

As the follow-up periods differed between the studies it was not possible to determine whether participants in the Burke and colleagues<sup>71</sup> trial who had class I obesity lost more or less weight than the participants in the Wadden and colleagues<sup>69</sup> trial who were heavier (and likely to have class II obesity).

### Barriers and facilitators

Neither study reported on potential barriers or facilitators.

### Other outcomes reported in the trials (not evaluated here)

Burke and colleagues<sup>71</sup> also presented results for changes in cholesterol, glucose levels, insulin levels, kilocalorie consumption, fat consumption, carbohydrate consumption, animal protein consumption, vegetable protein consumption, and fibre consumption. Wadden and colleagues<sup>69</sup> reported on outcomes at 1 year in an earlier publication but due to the short follow-up this did not meet the inclusion criteria of this review. Wadden and colleagues<sup>69</sup> did not report whether they measured participants' attendance at sessions, whereas Burke and colleagues<sup>71</sup> did measure this.

### Summary of effectiveness

Two studies<sup>69,71</sup> assessed multicomponent interventions that differed only in terms of the dietary component. One of these studies<sup>69</sup> also had a third arm to investigate the dietary component VLCD alone. Participants in both studies lost weight but there were no statistically significant differences in weight loss between study groups. After completing the intervention participants from both studies regained weight over time. The two studies were not directly comparable owing to different interventions, duration of the interventions, and duration of follow-up. The generalisability of these findings to participants in the UK is not clear.

## Assessment of effectiveness for multicomponent interventions with a focus on exercise

Four<sup>76-79</sup> of the included studies compared a multicomponent intervention to an active comparator in which the focus of the study in general was on exercise. The four studies are briefly described below and the main components are summarised in *Tables 15* and *16*.

Of the four studies, those by Tate and colleagues<sup>77</sup> and Jeffery and colleagues<sup>76</sup> were the most similar in terms of intervention characteristics and design, having been conducted by some of the same investigators (these are therefore discussed first in this subsection, with the characteristics of the remaining two studies presented afterwards). Both studies evaluated an 18-month-long 'SBT intervention' comprising similar behavioural change techniques, alongside exercise and diet components. The most intensive phase in both studies appeared to be the first 6 months with weekly meetings to encourage weight loss, followed by biweekly or monthly meetings to promote weight maintenance. Final outcomes were measured at the end of the 18-month period in the study by Jeffery and colleagues<sup>76</sup>, but in the Tate and colleagues<sup>77</sup> study they were measured 1 year following the end of the intervention (i.e. at 30 months).

The Tate and colleagues<sup>77</sup> study compared SBT with a 'high physical activity (HPA)' arm, identical to the SBT group but with higher weekly energy expenditure goals and a greater level of supervision and social support (see *Appendix 5*). The aim of the study was to determine whether higher levels of energy expenditure (2500 kcal/week) would result in greater weight loss

**TABLE 15** Details of multicomponent interventions with a focus on exercise

<b>Tate et al. 2007<sup>77</sup></b>	
<b>Length of intervention:</b> 18 months; follow-up 30 months	
<b>SBT</b>	<b>HPA</b>
<i>Diet:</i>	<i>Diet:</i>
Calorie goal: to reduce daily energy intake to 1000–1500 kcal depending on initial body weight. Proportions diet: consume < 20% of energy as fat	Calorie goal: to reduce daily energy intake to 1000–1500 kcal depending on initial body weight. Proportions diet: consume < 20% of energy as fat
<i>Exercise:</i>	<i>Exercise:</i>
Energy expenditure goal: to build up from energy expenditure of 250 kcal/week, increasing by 250 kcal/week, to energy expenditure of 1000 kcal/week (roughly equivalent to walking for 30 minutes/day)	Energy expenditure goal: to build up to an energy expenditure of 2500 kcal/week by the end of the first 6 months of the intervention (roughly equivalent to walking < 75 minutes/day)
<i>Type:</i>	<i>Type:</i>
Not reported	Not reported
<i>Behaviour modification:</i>	<i>Behaviour modification:</i>
Mode: group, size 10–20	Mode: group, size 10–20
Frequency: weekly meetings for first 6 months, biweekly from 6 to 12 months, then monthly from 12 to 18 months	Frequency: weekly meetings for first 6 months, biweekly from 6 to 12 months, then monthly from 12 to 18 months
Content – see <i>Table 16</i>	Content – see <i>Table 16</i>
<i>Delivered by:</i>	<i>Delivered by:</i>
Trained interventionists (nutritionists, exercise physiologists, or psychologists) with expertise in both content areas (i.e. physical activity and nutrition) and behavioural therapy	Trained interventionists (nutritionists, exercise physiologists, or psychologists) with expertise in both content areas (i.e. physical activity and nutrition) and behavioural therapy
<i>Ongoing support:</i>	<i>Ongoing support:</i>
None	None
<b>Jeffery et al. 1998<sup>76</sup></b>	
<b>Length of intervention:</b> 18 months; follow-up 18 months	
<b>SBT</b>	<b>SBTE</b>
<i>Diet:</i>	<i>Diet:</i>
Calorie goal: 1000 kcal/day if weight was < 91 kg and 1500 kcal/day if weight was ≥ 91 kg	Calorie goal: 1000 kcal/day if weight was < 91 kg and 1500 kcal/day if weight was ≥ 91 kg
Proportions diet: restrict fat to 20% or less of calories (22 g/day for 1000 kcal and 33 g/day for 1500 kcal)	Proportions diet: restrict fat to 20% or less of calories (22 g/day for 1000 kcal and 33 g/day for 1500 kcal)
<i>Exercise:</i>	<i>Exercise:</i>
Energy expenditure goal: to exercise to the equivalent of 250 kcal/week and to gradually increase to a minimum of 1000 kcal/week	Energy expenditure goal: to exercise to at least 1000 kcal/week. Regular attendance at supervised sessions would produce approximately 750 kcal/week
<i>Type:</i>	<i>Type:</i>
Primarily walking or cycling	Primarily walking or cycling
<i>Behaviour modification:</i>	<i>Behaviour modification:</i>
Mode: group, size ~ 20	Mode: group, size ~ 20
Frequency: weekly for 24 weeks and once per month thereafter	Frequency: weekly for 24 weeks and once per month thereafter
Content – see <i>Table 16</i>	Content – see <i>Table 16</i>
<i>Delivered by:</i>	<i>Delivered by:</i>
Trained interventionists with advanced degrees in nutrition or behavioural sciences	Trained interventionists with advanced degrees in nutrition or behavioural sciences
<i>Ongoing support:</i>	<i>Ongoing support:</i>
Not stated except for as part of the programme described above (monthly meetings after first 24 weeks)	Not stated except for as part of the programme described above (monthly meetings after first 24 weeks)

continued

**TABLE 15** Details of multicomponent interventions with a focus on exercise (*continued*)

<b>Skender et al. 1996<sup>79</sup></b>		
<b>Length of intervention:</b> 1 year; follow-up 2 years		
<b>Combination intervention (diet and exercise)</b>		
<b>Diet:</b>	<b>Exercise intervention</b>	<b>Diet intervention</b>
Calorie goal: adjust caloric intake so weight loss not more than 1 kg/week	<b>Diet:</b>	<b>Diet:</b>
Proportions diet: 30% of calories as fat, 50% as carbohydrate and 20% as protein	Calorie goal: not reported. Participants were asked to maintain their current eating habits and nutrition was not discussed	Calorie goal and proportions diet: as reported for the combination intervention
<b>Exercise:</b>	Proportions diet: not applicable	<b>Exercise:</b>
Energy expenditure goal: based on heart rate, breathing difficulty, and perceived effort to be 'vigorous' but never 'strenuous'. Goal was three to five sessions per week of 45 minutes or more per session	<b>Exercise:</b>	Energy expenditure goal: none
<b>Type:</b>	Energy expenditure goal: based on heart rate, breathing difficulty, and perceived effort to be 'vigorous' but never 'strenuous'. Goal was three to five sessions per week of 45 minutes or more per session	<b>Type:</b>
Brisk walking	<b>Type:</b>	Normal physical activity only (no new exercise programmes)
<b>Behaviour modification:</b>	Brisk walking	<b>Behaviour modification:</b>
Mode: group, size ≈ 15	<b>Behaviour modification:</b>	Mode: group, size ≈ 15
Frequency: 12 weekly 60 minute group instructional sessions, then three biweekly sessions, then eight monthly maintenance sessions (total 1 year)	Mode: group, size ≈ 15	Frequency: 12 weekly 60 minute group instructional sessions, then three biweekly sessions, then eight monthly maintenance sessions (total 1 year)
Content – see <i>Table 16</i>	Frequency: 12 weekly 60 minute group instructional sessions, then three biweekly sessions, then eight monthly maintenance sessions (total 1 year)	Content – as reported for 'combination' intervention
<b>Delivered by:</b>	Content – as reported for 'combination' intervention	<b>Delivered by:</b>
By registered dietitians who were trained and experienced in behaviour modification	<b>Delivered by:</b>	By registered dietitians who were trained and experienced in behaviour modification
<b>Ongoing support:</b>	By registered dietitians who were trained and experienced in behaviour modification	<b>Ongoing support:</b>
Only as part of maintenance sessions reported above. No ongoing support following the end of the intervention	<b>Ongoing support:</b>	Only as part of maintenance sessions reported above. No ongoing support following the end of the intervention
	Only as part of maintenance sessions reported above. No ongoing support following the end of the intervention	
<b>Weinstock et al. 1998<sup>78</sup></b>		
<b>Length of intervention:</b> 48 weeks; follow-up 96 weeks		
<b>Diet and aerobic training</b>		
<b>Diet:</b>	<b>Diet alone</b>	
Calorie goal: 900–925 kcal/day (weeks 2–17). Increasing to 1250 kcal/day (week 18–20); 1500 kcal/day (weeks 22–48)	<b>Diet:</b>	
Proportions diet: 150 kcal, 15 g protein, 11.2 g carbohydrate, 5 g fat (per serving of a liquid meal replacement four times per day, weeks 2–17); 280–300 kcal, 20 g protein, 35–40 g carbohydrate, 7 g fat (per dinner entrée, weeks 2–17); 12–15% calories from protein, 55–60% from carbohydrate, and 15–30% from fat (weeks 22–48)	Calorie goal: 900–925 kcal/day (weeks 2–17). Increasing to 1250 kcal/day (week 18–20); 1500 kcal/day (weeks 22–48)	
<b>Exercise:</b>	Proportions diet: 150 kcal, 15 g protein, 11.2 g carbohydrate, 5 g fat (per serving of a liquid meal replacement four times per day, weeks 2–17); 280–300 kcal, 20 g protein, 35–40 g carbohydrate, 7 g fat (per dinner entrée, weeks 2–17); 12–15% calories from protein, 55–60% from carbohydrate, and 15–30% from fat (weeks 22–48)	
Energy expenditure goal: three sessions per week for 28 weeks, two per week during weeks 29–48. 12 minutes at week 1, additional 2 minutes to routine each week, by week 14 performed 40 minutes of stepping	<b>Exercise:</b>	
<b>Type:</b>	None. Participants agreed not to engage during the study in any programme of regular activity that resembled the aerobic or strength training conditions (but they were allowed to maintain lifestyle activities such as occasionally playing tennis, bowling or lunchtime walks)	
Step aerobics	<b>Behaviour modification:</b>	
<b>Behaviour modification:</b>	Mode: group, size 7–10 participants	
Mode: group, size 7–10 participants	Frequency: 28 weekly 90 minute sessions, followed by biweekly maintenance programme sessions (weeks 29–48)	
Frequency: 28 weekly 90 minute sessions, followed by biweekly maintenance programme sessions (weeks 29 to 48)	Content – see <i>Table 16</i>	
Content – see <i>Table 16</i>	<b>Delivered by:</b>	
<b>Delivered by:</b>	Clinical psychologists, dietitian and graduate students in exercise physiology	
Clinical psychologists, dietitian and graduate students in exercise physiology	<b>Ongoing support:</b>	
<b>Ongoing support:</b>	Mentions only that participants attended group sessions once every 3 months in the year following treatment	
Participants attended group sessions once every 3 months in the year following treatment. Between weeks 48 and 96 the women were encouraged to continue exercising unsupervised		

**TABLE 16** Components of the behavioural aspects of multicomponent weight management studies with a focus on exercise

	Cognitive restructuring	Goal-setting/action plans	Modelling	Motivation enhancing	Problem solving	Relapse prevention	Self-monitoring	Self-reinforcement	Skill development	Social assertion (SA)/social support (SS)	Stimulus control	Theoretical model	Others (n)
Tate <i>et al.</i> 2007 <sup>77,a</sup>		✓		✓	✓	✓			?	SS	✓		0
Jeffery <i>et al.</i> 1998 <sup>76</sup>	✓	✓		✓	✓	✓				SA and SS	✓		0
Skender <i>et al.</i> 1996 <sup>79</sup>		✓				✓	✓				✓	? <sup>b</sup>	3
Weinstock <i>et al.</i> 1998 <sup>78,c</sup>									✓			? <sup>b</sup>	

a Content was adapted from prior research.

b Unclear if the programme used in this study was based on a theoretical model of behaviour change or not.

c Manuals that summarised the material from each phase of the study were provided.

compared with SBT (1000 kcal/week). In contrast, Jeffery and colleagues<sup>76</sup> compared SBT with four other arms including SBT plus supervised exercise (SBTE), SBT and supervised exercise plus a personal trainer (SBTT), SBT and supervised exercise plus incentives to exercise (SBTI), and SBT and supervised exercise plus both personal trainer and incentives to exercise (SBTTI). The hypothesis was that a greater number of exercise sessions would be attended by those receiving support from a personal trainer or financial incentives than SBT alone, and that a combination of trainer and incentives would result in greater exercise adherence and therefore greater energy expenditure in exercise and greater weight loss.

For both studies we considered the SBT arm as being the multicomponent intervention of most relevance to the scope of this review. In the Jeffery and colleagues<sup>76</sup> study we have compared SBT with SBTE only, hence the characteristics and results of the other three arms are not reported here (for further details of these see *Appendix 5*).

The diet component, which was the same in both arms in each study, was similar between the two studies, with an emphasis on calorie restriction to between 1000 and 1500 kcal per day, with  $\leq 20\%$  of calories from fat. Both studies encouraged a gradual increase in exercise (e.g. walking, cycling) to build up energy expenditure to at least 1000 kcal per week (or, as mentioned, to 2500 kcal in the HPA arm of the Tate and colleagues study<sup>77</sup>). Exercise activities were conducted either individually or as part of group sessions.

Likewise, the behavioural component, which was the same in both arms in each study, was similar between the two studies, with therapy delivered in small groups (10–20 participants) on a weekly basis for the first 6 months, then biweekly or monthly thereafter until the end of the 18-month intervention. The sessions were led by interventionists trained in exercise, nutrition or the behavioural sciences and incorporated motivation enhancement, problem solving, stimulus control (e.g. reducing the visibility of food in the home), and relapse prevention techniques (e.g. recognising precursors and consequences of dietary lapses) (see *Table 16*).

The third study in this subsection was a trial of a cognitive behavioural weight control intervention by Skender and colleagues<sup>79</sup>. The trial compared a multicomponent ‘combination’ intervention comprising diet, exercise and behaviour therapy with an intervention focused on

exercise, and with another intervention focused on diet (a waiting list control group was also included, but no outcome data were reported for this group so it is not mentioned any further in this subsection). All three interventions included the same behavioural component. The aim was to assess whether the addition of exercise to diet would lead to greater weight loss. For the purpose of this review the 'combination' intervention was considered to be most relevant to the scope.

The interventions took place over 1 year with weekly 1-hour meetings over a 12-week period, then three biweekly sessions followed by the maintenance phase comprising eight monthly meetings. Final outcomes were measured at 2 years from baseline (i.e. a year after the end of the intervention). The dietary component featured in the combination intervention and the diet-focused intervention encouraged a caloric intake to attain weight loss of up to 1 kg per week, with 30% of calories to come from fat, 50% from carbohydrate and 20% from protein. Participants were instructed to plan their meals based on the Help Your Heart Eating Plan (HYHEP) low-cholesterol diet. In the exercise focus group participants were asked to maintain their current eating habits and nutrition was not discussed.

The exercise component featured in the combination intervention and the exercise-focused intervention. Information was provided on the benefits of exercise and instruction was given on correct methods of walking. Participants were instructed to self-regulate the intensity of brisk walking based on heart rate, breathing difficulty, and perceived effort. They were instructed to exercise at a level that felt 'vigorous' but never 'strenuous', and were encouraged to exercise for three to five sessions per week for 45 minutes or more per session. Those in the diet-focused intervention were asked to maintain their relatively sedentary lifestyles and not to begin any new exercise programme.

The behavioural therapy component (common to all three interventions) involved the use of self-monitoring contracts to reward behaviour change (contingency contracting), stress management, stimulus control, goal-setting and maintenance techniques (see *Table 16*). The behavioural component followed the principles outlined in the LEARN<sup>®</sup> programme for weight control. This is a 12-week educational lifestyle weight management programme ('Lifestyle, Exercise, Attitudes, Relationships and Nutrition'). It aims to enable people to lose between 1 and 2 lb per week through a decrease in dietary caloric intake and an increase in exercise to burn stored calories. The interventions were delivered by registered dietitians who were trained and experienced in behaviour modification.

The fourth study, a 48-week trial by Weinstock and colleagues,<sup>78</sup> randomised participants to either a diet only intervention or one of three exercise interventions, diet with aerobic training, diet with strength training and diet with aerobic and strength training. In the exercise interventions the diet and behaviour components were the same across the arms. For the purpose of this review we considered that the diet and aerobic training intervention was the multicomponent intervention of most relevance to the scope. In this intervention the exercise type was 'step' aerobics. Details of the other exercise interventions can be seen in *Appendix 5*. An increasing daily kilocalorie goal was used through the 48-week intervention, increasing to 1500 kcal by week 22 which remained then until week 48. In the first 17 weeks a 900–925 kcal/day goal was used and this was as a liquid meal replacement. For the rest of the duration of the study participants were advised on the proportions of their diet to be made up from protein, carbohydrate and fat (see *Table 15*). Participants maintained weekly diet diaries.

Participants met weekly in groups of 7–10 people until week 28 for their behavioural therapy and biweekly thereafter. The components of the behavioural aspect of the intervention were poorly described (see *Table 15*). The features and strategies covered appeared to be centred on skill



development. The intervention was delivered by clinical psychologists, a dietitian and graduate students in exercise physiology. For the first 28 weeks participants exercised with members of their behavioural treatment groups by step aerobics. They were required to participate in three sessions per week for 28 weeks and then two sessions per week during weeks 29–48. The time spent undertaking the step aerobics increased from 12 minutes at week 1 to 40 minutes by week 14. In the diet alone arm no prescribed exercise was undertaken, although the participants were allowed to maintain any lifestyle activities as normal. After the 48-week intervention participants were followed up at week 96. In the interim, group sessions occurred every 3 months as a form of ongoing support.

The multicomponent interventions included in the four studies appear to be similar in terms of content and structure. All studies encouraged participants to choose low-calorie diets and to reduce the proportion of calories from fat. They were also supported to take regular exercise, primarily through walking and cycling, according to set weekly goals. Behavioural techniques such as stimulus control, self-monitoring and goal-setting were also common aspects of the interventions, typically led by trained interventionists in small groups of < 20 participants. None of the studies reported where the behaviour therapy was undertaken. The level of detail in which the interventions were reported precludes a full assessment of generalisability. However, all studies were conducted in the USA with mostly white, educated populations who were paid monetary incentives to participate. The mean ages of participants were between 40 and 42 years for three studies,<sup>76–78</sup> but in one study were not reported.<sup>79</sup> With the exception of Tate and colleagues,<sup>77</sup> the interventions were delivered in the early to mid-1990s. It is not clear whether the LEARN<sup>®</sup> programme or the HYHEP diet are necessarily representative of current UK practice.

The value of the Weinstock and colleagues<sup>78</sup> study to this systematic review is limited for a number of reasons. The trial predominantly reported changes in body composition and resting energy expenditure (REE), appetite and mood, and the long-term weight loss outcomes reported in the study were from a subgroup of the overall trial population. In addition, the number of participants randomised to each intervention was not explicitly reported (but has been estimated by our reviewers to be between 29 and 31 per intervention group) and the results presented were for three of the groups combined rather than for all randomised interventions.

In terms of starting weight, two of the studies included participants classified as BMI obesity I,<sup>76,77</sup> and in a third study<sup>78</sup> the participants were classified as BMI obesity II. The fourth study<sup>79</sup> did not report baseline BMI; however, it did report weight in terms of kg that appeared to be reasonably similar to the other studies.

Poor reporting of methodological details of the studies hampers an informed judgement regarding potential risks of bias (see *Quantity and quality of research available*) and therefore these risks are generally regarded as uncertain, which needs to be considered when interpreting results presented below.

## Clinical effectiveness

### Weight loss

Table 17 reports the results of the four studies in terms of weight loss.<sup>76–79</sup> More weight in kilograms was lost by participants in the HPA intervention than by participants in the SBT group in the study by Tate and colleagues<sup>77</sup> at both 18 months ( $6.7 \pm 8.1$  vs  $4.1 \pm 8.3$ , respectively,  $p = 0.04$ ) and 30 months ( $2.86 \pm 8.6$  vs  $0.9 \pm 8.9$ , respectively,  $p = 0.16$ ), though the difference was only statistically significant at the end of the 18-month intervention. In contrast, more weight was lost by those receiving SBT than those undergoing SBT plus supervised exercise at 18 months in the study by Jeffery and colleagues<sup>76</sup> [ $-7.6$  kg (standard error, SE 1.1) vs  $-3.8$  kg (SE 1.3), respectively,  $p = 0.03$ ]. Statistical power calculations were not reported for either of

**TABLE 17** Weight change outcomes for multicomponent weight management studies with a focus on exercise

Study	Treatment arms			<i>p</i> -value between groups
<b>Tate <i>et al.</i> 2007<sup>77</sup></b>	<b>SBT (<i>n</i>=109)</b>	<b>HPA (<i>n</i>=93)</b>		
Weight change kg, baseline to 18 months	-4.1 ± 8.3 ( <i>n</i> =80) <sup>a</sup>	-6.7 ± 8.1 ( <i>n</i> =87) <sup>a</sup>		<i>p</i> =0.04
Weight change kg, baseline to 30 months <sup>b</sup>	-0.9 ± 8.9 ( <i>n</i> =74) <sup>a</sup>	-2.86 ± 8.6 ( <i>n</i> =84) <sup>a</sup>		<i>p</i> =0.16
Weight loss (%) of initial body weight, baseline to 30 months <sup>b</sup>	1	3		States no significant difference, <i>p</i> -value not reported
Success at 30 months	Total weight loss ≥ 5% achieved by 26% Total weight loss ≥ 10% achieved by 12%			States no significant difference, <i>p</i> -value not reported
<b>Jeffery <i>et al.</i> 1998<sup>76</sup></b>	<b>SBT (<i>n</i>=40)<sup>c</sup></b>	<b>SBTE (<i>n</i>=41)<sup>c</sup></b>		
Weight change in kg at 18 months <sup>f</sup> follow-up, mean (SE)	-7.6 (1.1)	-3.8 (1.3)		<i>p</i> =0.03 <sup>d</sup>
<b>Skender <i>et al.</i> 1996<sup>79</sup></b>	<b>Combination intervention (<i>n</i>=21)</b>	<b>Diet-focused intervention (<i>n</i>=15)</b>	<b>Exercise-focused intervention (<i>n</i>=25)</b>	
Mean ± SD weight change (kg) from baseline (0–2 years) <sup>e</sup>	-2.2 ± 6.7	+0.9 ± 7.7	-2.7 ± 9.2	<i>p</i> =0.36
Number (%) of participants with clinical success (weight loss > 4.5 kg)	8 (38%)	2 (13%)	6 (24%)	<i>p</i> =0.36
Number (%) of participants with no weight change (within ± 4.5 kg) <sup>f</sup>	10 (48%)	9 (60%)	18 (72%)	Not reported
<b>Weinstock <i>et al.</i> 1998<sup>78</sup></b>	<b>Diet and aerobic exercise (<i>n</i>=29)</b>	<b>Diet only (<i>n</i>=29)</b>		
Maintenance of weight loss at week 96	Not reported	Not reported		

a Variance estimate not defined.

b Unclear whether this is an ITT analysis.

c Number randomised. Number of participants remaining at 18 months not reported.

d Adjusted analysis for baseline weight, gender and centre. There is a discrepancy in the study report with the *p*-value reported to be *p*<0.03 and also *p*=0.03. The difference was reported to be attributed to the greater weight losses in the SBT group compared with the other four groups.

e Calculated from baseline weight for those attending follow-up at 24 months only.

f Percentages calculated by reviewer based on the total number of participants who completed the 2-year follow-up.

these two studies.<sup>76,77</sup> By the 30-month follow-up between 21% and 23% of participants across the study groups had dropped out of the study by Tate and colleagues<sup>77</sup> An ITT analysis was conducted, and participants with missing data at any time point were assumed not to have lost any weight and their baseline weight was carried forward. In the study by Jeffery and colleagues<sup>76</sup> by 18 months 22% of participants had dropped out. This figure was for the study population in general, so it is not known whether the rate of dropout varied between study groups. It was not reported whether an ITT analysis had been conducted and hence whether dropouts had been included in the analysis, so caution is advised in the interpretation of the results.

In the study by Skender and colleagues,<sup>79</sup> the greatest amount of weight was lost by the exercise-focused intervention (-2.7 kg ± 9.2), followed by the combination intervention (-2.2 kg ± 6.7) over the 2-year follow-up period. During this time the mean weight in the diet-focused intervention increased to +0.9 kg (± 7.7). The differences between the three groups were not statistically significant (*p*=0.36). However, the proportion of participants classified as achieving clinical success (defined as weight loss > 4.5 kg) was highest in the combination group (38%), followed by the exercise-focused group (24%) and the diet-focused group (13%). Again, this difference



was not statistically significant ( $p = 0.36$ ). The proportion of participants classified as having no weight change was lowest in the combination group (48%), followed by the diet-focused group (60%) and then the exercise-focused group (72%), ( $p$ -value not reported). Caution is advised in the interpretation of these results as outcomes at the 2-year follow-up were based only on those participants who returned for assessment [61 (48%) of the 127 randomised to the three active interventions]. Also, no statistical power analysis was reported for this study.

Weinstock and colleagues<sup>78</sup> did not report outcomes for the 96-week evaluation between intervention arms; rather they reported outcomes as the change from baseline for more than one group combined. Data presented were also from a subgroup of the original population. Therefore there is little in the way of useful data from this study (see *Appendix 5* for full details).

No clear pattern was evident from the results in the trials in terms of the degree of weight lost according to the starting weight (e.g. whether those who were more obese at baseline lost more weight).

### Weight regain

*Table 18* reports data on weight regain or gain from the two studies that report this outcome. In the study by Tate and colleagues<sup>77</sup> mean weight regain in each group between the end of the intervention at the 18- and the 30-month follow-up appeared generally similar (around 5–6 kg), with a non-statistically significant difference between groups ( $p$ -value not reported). Skender and colleagues<sup>79</sup> reported the proportion of participants who gained in excess of 4.5 kg of weight from baseline to the 2-year follow-up. This category was distinct from the mutually exclusive categories of participants whose weight did not change and those with clinical success (both of which are reported in *Table 17*). Less than a third of participants came under this category, with the highest proportion in the diet-focused intervention (27%), followed by the combination intervention (14%) and the exercise-focused intervention (4%). No statistical tests were reported for this outcome. As mentioned above, caution is required when interpreting results of the Skender and colleagues<sup>79</sup> study as they are based on less than half of those originally randomised.

Data from these two studies can be used to assess weight regain following the end of the active interventions. In the Tate and colleagues<sup>77</sup> study results suggest a lack of long-term success after the end of the intervention (at 18 months). In the Skender and colleagues<sup>79</sup> study, interim data were presented for weight loss at the end of the 12-month intervention (Note: 12-month data do not meet the inclusion criteria for our review as the inclusion criteria state that studies had to

**TABLE 18** Weight gain or regain for studies with a focus on exercise

Study	Treatment arms			$p$ -value between groups
<b>Tate <i>et al.</i> 2007<sup>77</sup></b>	<b>SBT (<math>n=109</math>)</b>		<b>HPA (<math>n=93</math>)</b>	
Weight regain kg, 18–30 months <sup>a</sup>	5.3±7.0 ( $n$ not reported) <sup>b</sup>		5.9±5.9 ( $n$ not reported) <sup>b</sup>	States no significant difference, $p$ -value not reported
<b>Skender <i>et al.</i> 1996<sup>79</sup></b>	<b>Combination intervention (<math>n=21</math>)</b>	<b>Diet-focused intervention (<math>n=15</math>)</b>	<b>Exercise-focused intervention (<math>n=25</math>)</b>	
Number (%) of participants with weight gain > 4.5 kg <sup>c</sup>	3 (14)	4 (27)	1 (4)	Not reported

a Variance estimate not defined.

b Unclear whether this is an ITT analysis.

c Percentages calculated by reviewer based on the total number of participants who completed the 2-year follow-up.

report follow-up data at 18 months or longer – see *Chapter 2, Data synthesis*). These data appear to show a similar pattern, with the greatest weight loss at the end of the intervention and then a gradual increase in weight again prior to the 24-month follow-up.

### Barriers and facilitators

Only one of the studies mentioned measuring barriers and facilitators.<sup>76</sup> Jeffery and colleagues<sup>76</sup> used a 15-item questionnaire to assess participants' perceptions of practical, social and interpersonal barriers to successful behaviour change. However, no results were reported.

### Other outcomes reported in the trials (not evaluated here)

Physical activity was a primary outcome measure in the study by Jeffery and colleagues<sup>76</sup>. A variety of secondary outcome measures were reported including physical activity or exercise,<sup>76,77,79</sup> dietary intake,<sup>76,77</sup> attitudes to diet and exercise,<sup>79</sup> cardiorespiratory fitness,<sup>79</sup> percentage body fat,<sup>79</sup> depression,<sup>76</sup> binge eating<sup>76</sup> and adverse effects.<sup>77</sup> Weinstock and colleagues<sup>78</sup> also reported body composition, REE, appetite, mood, insulin resistance, glucose tolerance and BP as outcome measures. The four studies measured adherence to the intervention, but in varying ways.<sup>76–79</sup> Skender and colleagues<sup>79</sup> measured self-reported adherence to diet and exercise which participants recorded in questionnaires, whilst Jeffery and colleagues<sup>76</sup> and Weinstock and colleagues<sup>78</sup> measured attendance at the group sessions. Tate and colleagues<sup>77</sup> report outcomes for a selected 'high-adherence' exercise group.

### Summary of effectiveness

Four studies in which a multicomponent intervention was compared with another active comparator (in which the focus of the study was generally about physical activity) have been presented in terms of changes in weight up to 30 months. Most of the interventions were associated with weight loss at the 18-month to 2-year follow-up time points, with losses of up to 7.6 kg. However, mean weight loss had diminished at 30 months in the one study that reported outcomes at this time point, suggesting a lack of longer-term weight maintenance. There was no consistent pattern in terms of comparative effectiveness between the SBT intervention and the SBTE or HPA variants. In one study the HPA participants lost significantly more weight than the SBT participants (but by 30 months the difference was no longer statistically significant). Conversely, in another study SBT participants lost significantly more weight than participants who received SBTE. There were no statistically significant differences when comparing the combination of diet and physical activity with these two components separately (all of which included a behavioural therapy component).<sup>79</sup> The results of this study are difficult to interpret given the high loss to follow-up rates. Lack of details in the publications precludes full judgements of risk of bias and generalisability.

## Assessment of effectiveness for multicomponent interventions where the focus was on other variables

One included study by Dubbert and Wilson<sup>68</sup> did not appear to fit into the categories of active intervention versus no-active comparator, focusing on the dietary component, or focusing on the exercise component. This study is therefore considered separately in this section. The trial tested two variables – goal-setting (daily or weekly), and spouse involvement (or not) – in their multicomponent approach to weight loss. The intervention is briefly described here and in *Table 19*. BMI at baseline was not reported in this study (see *Table 7*); however, the participants were required to be at least 15 lb (approximately 7 kg) overweight and participants in both of these groups had mean weights around 208 lb (~94 kg). If height is assumed to be 170 cm, then these participants would be categorised as having class I obesity.

**TABLE 19** Details of multicomponent interventions in the studies where the focus was on other variables

<i>Dubbert and Wilson 1984<sup>68</sup></i>	
<b>Length of intervention:</b> 19 weeks; follow-up 34 months	
<b>Treatment with daily goals</b>	<b>Treatment with weekly goals</b>
<i>Diet:</i>	<i>Diet:</i>
Calorie goal: from week 5 recommended 1215 kcal/day for women or 1525 kcal/day for men. Participants were encouraged to set daily calorie goals and to divide these into subgoals for portions of the day	Calorie goal: participants were encouraged to set weekly calorie goals of 8500 kcal for women or 10,675 kcal for men
Proportions diet: not reported	Proportions diet: not reported
<i>Exercise:</i>	<i>Exercise:</i>
Energy expenditure goal: states individual-based goal-setting to meet a daily goal. From week 5 minimal caloric-expenditure goals were recommended, starting at 145 cal/day above initial baseline. Goals were increased each week by 25 cal/day if previous week's goals were met on at least 4 days	Energy expenditure goal: states individual-based goal-setting to meet a weekly goal
<i>Type:</i>	<i>Type:</i>
Aerobic exercise walking programme	Aerobic exercise walking programme
<i>Behaviour modification:</i>	<i>Behaviour modification:</i>
Mode: group, size not reported	Mode: group, size not reported
Frequency: weeks 1–4: 2-hour lectures and small group discussion meetings; week 5: individual sessions of 15–20 minutes duration commenced (one per week during weeks 5–7); fortnightly thereafter	Frequency: weeks 1–4: 2-hour lectures and small group discussion meetings; week 5: individual sessions of 15–20 minutes duration commenced (one per week during weeks 5–7); fortnightly thereafter
Content – see <i>Table 20</i>	Content – see <i>Table 20</i>
<i>Delivered by:</i>	<i>Delivered by:</i>
Clinical psychology graduate student therapists (one experienced in behavioural weight-control treatment)	Clinical psychology graduate student therapists (one experienced in behavioural weight-control treatment)
<i>Ongoing support:</i>	<i>Ongoing support:</i>
None reported	None reported

In the trial<sup>68</sup> the interventions lasted for 19 weeks, with follow-up 30 months later. Participants were randomised to essentially the same multicomponent intervention undertaken either as an individual or with a spouse, and with the calorie and exercise goals set either daily or weekly. For the purpose of this review we consider the interventions with individuals and with daily goals as the multicomponent intervention of most relevance to the scope. The individual treatment with weekly goals is treated as the comparator intervention. The details of the couples' interventions can be seen in *Appendix 5*. Multicomponent interventions often involve family members; however, in this study the spouse monitored adherence and progress with the weight loss programme and was involved in the problem solving and goal-setting.

In the daily goal-setting treatment group participants were recommended to set a goal of 1215 kcal per day (females) or 1525 kcal per day (males) from week 5. Participants were encouraged to divide the daily goals into subgoals for portions of the day. No detail was given for the proportions of the diet but participants were encouraged to record their weight daily as a form of monitoring. The exercise component of this intervention also set daily goals for energy expenditure from an aerobic exercise and walking programme. Participants started at an initial 145 kcal per day (equivalent to a 1.5-mile walk or 1.5 hours of active housework) above their initial baseline of activity and this increased by 25 kcal/day if the previous week's goals had been met on at least 4 days. In addition, participants were instructed to walk for at least 30 minutes on 5 days each week and to monitor their heart rate to ensure that they were exercising within a 70%–80% range of their age-predicted heart rate (see *Appendix 5*). The participants recorded daily records of activities. The behavioural modification element of the interventions was

undertaken in groups (size not reported) and included lectures and small group discussions in weeks 1–4; weekly 15- to 20-minute individual sessions in weeks 5–7; and then fortnightly sessions thereafter. The setting for the behaviour therapy was not reported. *Table 20* describes the range of features and strategies covered in the behavioural treatment component of the study. These appeared to centre on goal-setting, cognitive restructuring and problem-solving skills. Clinical psychology graduate students delivered the sessions. The intervention with weekly goal-setting was very similar to the daily goal-setting intervention, with a few exceptions. The participants were encouraged to set weekly calorie goals of 8500 kcal for women and 10,675 kcal for men and the exercise component was to meet a weekly exercise goal equivalent to the sum of the same number of days for those in the daily goal-setting intervention (1000 kcal in the first week) (see *Appendix 5*). Participants were instructed to weigh themselves only once per week.

There are questions over the generalisability of the findings of this study to UK practice. Participants in this study had answered a media advertisement and paid a refundable fee to take part in the study, which may have affected the types of people taking part. The number of participants allocated to each treatment arm was not explicitly reported in the study report, and there was no report of results of any statistical significance testing of the data. The mean age of the participants in the study was not reported. Another factor that needs to be considered when interpreting results of this study is that the daily goal-setting for the diet component was likely to be more detailed than common practice. Also, the exercise component used a daily goal. The study was also undertaken some 25 years ago, before the advent of standards for reporting of RCTs, and this is reflected in the assessment of the trial quality that suggests an uncertain risk of bias (see *Table 8*).

## Clinical effectiveness

### Weight loss

Dubbert and Wilson<sup>68</sup> reported weight change as their primary outcome. At 34 months (30 months after the end of treatment) weight was similar in the daily goal-setting group (194 lb) and the weekly goal-setting group (200 lb) (see *Table 21*). No statistical significance testing was reported, there was no information that the analysis was statistically powered and no data on drop-out rates within the individual study arms were provided. Mean weight change from baseline was –14.9 lb in the daily goal-setting group and –7.7 lb in the weekly goal-setting group, again with no test for statistical significance reported. Participants were likely to be class I obese (estimated from mean weight at baseline).

In the Dubbert and Wilson study<sup>68</sup> interim data were presented for weight loss at the end of the 19-week intervention (note: the 19-week data do not meet the inclusion criteria for our review as the inclusion criteria state that studies had to report follow-up data at 18 months or longer – see *Chapter 2, Inclusion criteria*). Although not formally assessed, these data show that for those in the daily goal group at 19 weeks there was a loss of 20.2 lb (9.1 kg) compared with a loss of

**TABLE 20** Components of the behavioural aspects of studies where the focus was on other variables

	Cognitive restructuring	Goal-setting/action plans	Modelling	Motivation enhancing	Problem solving	Relapse prevention	Self-monitoring	Self-reinforcement	Skill development	Social assertion (SA)/social support (SS)	Stimulus control	Theoretical model	Others (n)
<sup>a</sup> Dubbert and Wilson 1984 <sup>68</sup>	✓	✓			✓		✓			SA	?		

<sup>a</sup> Some eating behaviour change suggestions were based on existing manuals.

**TABLE 21** Weight change outcomes for multicomponent weight management studies where the focus was on other variables

Study	Treatment arms		<i>p</i> -value, 95% CI between groups
	Individual; daily goals ( <i>n</i> not reported)	Individual; weekly goals ( <i>n</i> not reported)	
Dubbert and Wilson, 1984 <sup>68</sup>			
Weight, lb (kg) <sup>b</sup> at 30 months <sup>a</sup>	194 (88)	200 (91)	Not reported
Weight change from baseline lb (kg) <sup>b</sup> at 30 months <sup>a</sup>	-14.9 (6.7)	-7.7 (3.5)	Not reported

a Estimated by reviewer from graph (quantitative data not reported).

b reported in lb; conversion to kg provided by reviewers.

16.6lb (7.5 kg) in the weekly goal group. Over time it would therefore appear (when informally comparing 19-week weight change with 30-month weight change) that there was weight regain over the longer term.

### Barriers and facilitators

Dubbert and Wilson<sup>68</sup> did not report potential barriers or facilitators.

### Other outcomes reported in the trials (not evaluated here)

Dubbert and Wilson<sup>68</sup> also reported cardiovascular fitness, BP, marital satisfaction, spouse weight, spouse co-operation, body image, satisfaction, depression, aerobic fitness, and binge eating and measured attendance at sessions.

### Summary of effectiveness

One multicomponent approach to weight loss that did not fit the other categories used in the present review was included. This study tested both goal-setting and spouse involvement.<sup>68</sup> The study suffered from considerable methodological shortcomings. Participants in the two goal-setting arms lost weight and it appeared that weight loss was greatest in those given daily goals, but there were no statistical analyses presented to support this observation.

### Overall comments on clinical effectiveness of multicomponent weight management interventions

As noted in the methods section, and demonstrated in the above sections, studies using similar goals were grouped together to aid interpretation of their results. To attempt to summarise the results of these studies across the four categories would therefore be unproductive. However, in order to attempt to inform future policy as to what might be the most effective intervention we have considered all of the included studies in terms of their length of follow-up ( $\geq 2$  years), sample size ( $\geq 100$  participants per arm), any methodological limitations, reproducibility, generalisability and overall effect size. While not a formal analysis (therefore caution is required) this has enabled us to make suggestions as to which studies may be the most relevant to informing policy. We focused our assessment on those studies that tested against a control/usual care arm (see *Appendix 8*). From this, speculatively, the Stevens and colleagues<sup>70</sup> study appears to be the most robust, although it should be stressed that the US setting (different health system and population) places a restriction on its generalisability. This study is discussed more fully in the *Discussion*.

## Ongoing studies

The following studies, which may meet the review eligibility criteria, were identified in searches and are currently ongoing:

Ross and colleagues<sup>80</sup> *Prevention and Reduction of Obesity through Active Living (PROACTIVE)*. This is a Canadian RCT of 491 adults with BMI 25–39.9 kg/m<sup>2</sup>. The goal of the study is to reduce abdominal adiposity, increase physical activity, and maintain and improve diet quality. Participants are randomised to the intervention group or a usual-care control group. Trial outcomes were unpublished as of December 2009.

Stolley and colleagues<sup>81</sup> *Obesity Reduction Black Intervention Trial (ORBIT)*. This is a US RCT of a culturally proficient weight loss intervention compared with a general health control group in 213 obese black women. Short-term (6-month) outcomes were published in January 2009.

van Weir and colleagues<sup>82</sup> *ALIFE@work trial aims to evaluate a lifestyle intervention among a Dutch overweight working population*. Participants (BMI > 25 kg/m<sup>2</sup>) ( $n = 1386$ ) were randomised to either the LI via the telephone, the internet or to a control group. Trial outcomes were unpublished as of December 2009.

Williams and colleagues<sup>83</sup> *Work, Weight, and Wellness: The 3W program*. This is a worksite obesity prevention and intervention trial being conducted on 11,559 employees on the island of Oahu in Hawaii, USA. Work sites are randomised to either a minimal intervention or an intensive intervention. Trial outcomes were unpublished as of December 2009.

Østbye and colleagues<sup>84,85</sup> *Active Mothers Postpartum*. This is a trial being undertaken in the USA of women with a BMI > 25 kg/m<sup>2</sup> post partum. A total of 450 women were randomly assigned to either an intervention group (healthy eating classes, physical activity classes, telephone counselling) or a control group. Short-term (12-month) outcomes were published in 2009.

Modifying Obesogenic Homes: Impact on Weight Maintenance, is an RCT which aims to deliver 18 months of SBT or 18 months of SBT plus direct modifications to the home environment (SBT + Home) to people who are BMI > 25. The study of approximately 200 participants is currently recorded as ongoing, but no longer recruiting participants and is funded by the National Heart, Lung and Blood Institute in the USA.

Internet Assisted Obesity Treatment (iReach) is an RCT comparing three weight loss interventions: internet alone, internet and periodic in-person support, and in-person support alone. A US study this is funded by the National Institute of Diabetes and Digestive and Kidney Diseases. The study aims to follow-up participants with a BMI > 25 kg/m<sup>2</sup> at baseline for up to 18 months. This study is recorded as ongoing but no longer recruiting participants.

The Take HEED (Healthy Eating and Exercise Decisions) RCT is a US study which aims to examine the effect of a culturally-adapted weight loss programme in African American females aged 40–65 years. Take HEED is a combination of two active interventions, Therapeutic Lifestyle Changes diet and the 'change' exercise programme. The study is ongoing but no longer recruiting and is funded by Kaiser Permanente and the Garfield Memorial Foundation.

Maintenance-Tailored Obesity Treatment is an RCT comparing state-of-the-art, SBT for weight loss with a maintenance tailored treatment and will follow participants until 30 months. Participants are required to be BMI between 30.0 and 37.0 kg/m<sup>2</sup> to be included in this study which is ongoing but no longer recruiting participants. The study is a US study funded by the National Institute of Diabetes and Digestive and Kidney Diseases.

Participants in an 18-month study funded by the National Heart, Lung and Blood Institute will be randomly assigned to either a standard behavioral weight loss programme or a stepped-care weight loss programme. The study is currently recruiting participants with a BMI between 25.0 and 39.9 kg/m<sup>2</sup> to the 'Step-up Study' which is expected to complete in January 2012.

Another ongoing study is comparing a wellness-centred intervention with a weight-centred intervention (LEARN<sup>®</sup> programme) in people with a BMI between 30 and 45 kg/m<sup>2</sup>. The interventions are delivered over 6 months with follow-up at 18 months. The study is active but no longer recruiting participants and is funded by The Reading Hospital and Medical Center and The Edna G. Kynett Memorial Foundation in the USA.





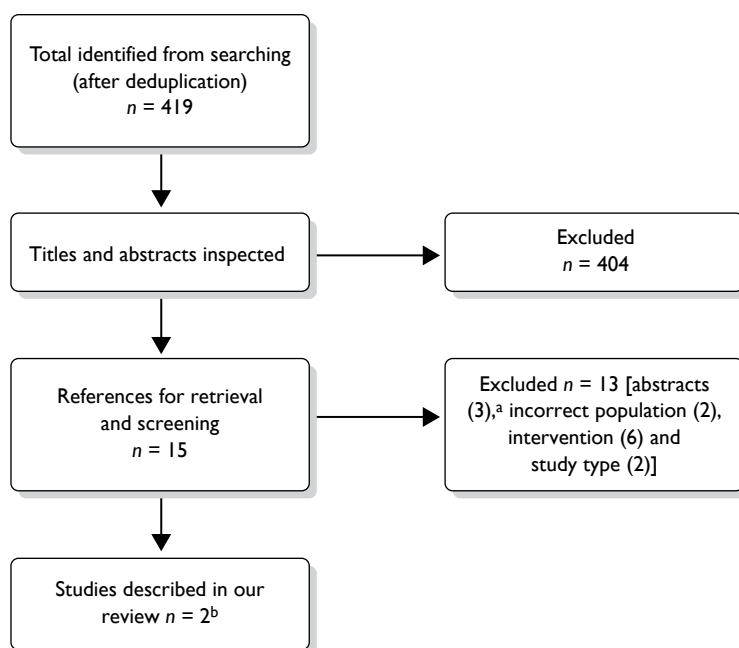
## Chapter 4

### Cost-effectiveness

The aim of this section is to assess the cost-effectiveness of multicomponent adult weight management programmes compared with standard care or other weight management programmes through a systematic review of the literature. The methods used for the search strategy are described in *Chapter 2*, and inclusion criteria are shown in *Chapter 2, Inclusion criteria*. Data from the studies were extracted and evaluated for their quality and generalisability to the UK, using a critical appraisal checklist.<sup>65</sup> The studies are then described in more detail, together with a discussion of the key issues arising from each of the studies, and an exploratory sensitivity analysis around the programme costs presented. The full data extraction forms for both of the studies are shown in *Appendix 9*.

#### Quantity and quality of published research

A total of 419 potentially relevant references were identified in the cost-effectiveness searches. Of these, the full texts of 15 papers were retrieved but no studies met all of the a priori inclusion criteria. A summary of the selection process and the reasons for exclusion are presented in *Figure 2* and a list of excluded studies in *Appendix 6*. Two studies<sup>86,87</sup> met the core criteria of evaluating diet, exercise and behaviour interventions in overweight or obese populations using a lifetime economic model. However, one of these included the use of prescription antiobesity drugs in a small number of participants<sup>87</sup> and the length of follow-up in the other study was < 18 months (12 months). In the absence of any other evidence a pragmatic decision was taken to describe these two studies in the review of cost-effectiveness, as these studies were considered



**FIGURE 2** Flow chart of identification of studies for inclusion in the review of cost-effectiveness. a, The abstracts provided insufficient details of methods and results to allow inclusion in the systematic review; b, a pragmatic decision was taken to describe these studies despite them not fully meeting the a priori inclusion criteria.

relevant and useful to the research question. However, caution is required in their interpretation. Characteristics of the studies are shown in *Table 22*.

### Critical appraisal of economic evaluations

The cost-effectiveness studies were assessed against a critical appraisal checklist (*Table 23*). This checklist assessed the quality of the studies and their generalisability to the UK and was adapted by the review authors from checklists by Philips and colleagues,<sup>65</sup> Drummond and colleagues<sup>66</sup> and the NICE reference case requirements.<sup>67</sup> More details of the studies are given in *Chapter 4, Description and results of the published economic evaluations*.

Both economic evaluations involved complex models. Although descriptions of the model structures are given and these reflect the natural history and disease progression associated with obesity, omissions in reporting details of the modelling methodology and data inputs reduce transparency and make it difficult to draw conclusions about the results.

**TABLE 22** Characteristics of economic evaluations

Characteristics	Author	
	Counterweight Programme study <sup>87</sup>	Roux <i>et al.</i> <sup>86</sup>
Publication year	2010	2006
Country	UK	USA
Funding source	Roche Products Ltd	Not stated
Study type	Cost–utility analysis	Cost–utility analysis
Perspective	UK NHS	Societal
Study population	Obese adults (BMI > 30 kg/m <sup>2</sup> ) or adults with BMI > 28 kg/m <sup>2</sup> with comorbidities	Overweight and obese women (BMI > 24.9 kg/m <sup>2</sup> ) free from known CHD
Intervention(s)	Diet, exercise and behaviour intervention vs no treatment. About 10%–20% of participants received pharmacotherapy	Routine care Diet Diet and exercise Diet and pharmacotherapy Diet, exercise and behaviour modification
Intervention effect	Mean weight change at 12 months, for those still attending, was –3.0 kg (95% CI –3.5 to –2.4) and at 24 months was –2.3 kg (95% CI –3.2 to –1.4) Mean change in BMI kg/m <sup>2</sup> at 12 months: –1.1 (95% CI –1.3 to –0.89)	Change in BMI kg/m <sup>2</sup> : Routine care 0.26 Diet –1.98 Diet and exercise –2.55 Diet and pharmacotherapy –4.55 Diet, exercise and behaviour modification –3.11
Intervention cost	£60 per participant	Direct medical costs per participant were US\$3040 for diet, exercise and behavioural modification
Currency base	UK£ (2001–3)	US\$ (2001)
Model type, health states	Patient level simulation model, with health states for CHD, diabetes and colon cancer	Monte Carlo simulation with health states for CHD
Time horizon	Lifetime	Lifetime
Baseline cohort	UK adult population	Hypothetical cohort of 10,000 healthy, non-pregnant 35-year-old overweight and obese women with original BMI > 24.9 kg/m <sup>2</sup> and free from known CHD
Base case results	For no active intervention, lifetime quality-adjusted life-years (QALYs) are 28.32, for baseline intervention lifetime QALYs are 28.38. The lifetime QALY gain is 0.056 with a cost saving of £27. The incremental cost-effectiveness ratio (ICER) is –£473 per QALY gained (cost saving)	Diet, exercise and behaviour modification was the dominant strategy The lifetime QALY gain is 0.24 compared with routine care at an extra cost of US\$3080. The ICER is US\$60,390 (£36,000) per life-year gained (LYG) and US\$12,640 (£7600) per QALY when compared with routine care

Neither study described the transition probabilities in sufficient detail although, some parameters are listed and sources for values given. In one study<sup>87</sup> the effectiveness of the intervention was not based on a systematic review of the literature. In the other study<sup>86</sup> a 'comprehensive' review was undertaken but no details are provided on the studies identified and then selected as evidence of effectiveness. In spite of these limitations the effectiveness data used in the models seem consistent with the effect size in the studies in our systematic review of clinical effectiveness (see *Chapter 3, Quantity and quality of research available*).

The quality of the methodology used for estimating quality-adjusted life-years (QALYs) was mixed. One study<sup>86</sup> used utilities that were rescaled from data from a longitudinal study; but it was not reported how this was done. The other study<sup>87</sup> used appropriate methodology to derive utility estimates stratified by BMI, age and gender.

Methods for estimating costs were also variable across the studies. The Counterweight Programme study,<sup>87</sup> while describing and justifying the resource costs, appears to have miscalculations and may not include all relevant costs needed for an accurate estimation of total programme costs. The other study<sup>86</sup> reports cost per participant in the weight loss programme, but details of all the elements that contribute to this are not provided so it is difficult to comment on costs. Both studies applied discounting to costs and benefits.

One study assessed uncertainty through sensitivity analyses<sup>86</sup> while the other study only conducted five alternative scenario analyses.<sup>87</sup> Finally, no details have been given on validation of the models in either studies.

In summary, the cost-effectiveness studies lack detail on some aspects of methodology so it was not possible to assess individual components and interpretation of the results was difficult. However, the studies appear credible and the results are consistent between them. The Counterweight Programme study<sup>87</sup> is of most relevance to the UK as the health-care system in the study was the NHS and the study was conducted from the perspective of the UK NHS.

**TABLE 23** Critical appraisal checklist of economic evaluation

Item	Counterweight Programme study 2010 <sup>87</sup>	Roux <i>et al.</i> 2006 <sup>86</sup>	
1	Is there a clear statement of the decision problem?	Y	Y
2	Is the comparator routinely used in UK NHS?	Y	Y
3	Is the participant group in the study similar to those of interest in UK NHS?	Y	Y
4	Is the health care system or setting comparable to UK?	Y	?
5	Is the perspective of the model clearly stated?	Y	Y
6	Is the study type and modelling methodology reasonable?	Y	Y
7	Is the model structure described and does it reflect the disease process?	Y	Y
8	Are assumptions about model structure listed and justified?	Y	Y
9	Are the data inputs for the model described and justified?	?	?
10	Is the effectiveness of the intervention established based on a systematic review?	N	?
11	Are health benefits measured in QALYs?	Y	Y
12	Are health benefits measured using a standardised and validated generic instrument?	Y	?
13	Are the resource costs described and justified?	Y	?
14	Have the costs and outcomes been discounted?	Y	Y
15	Has uncertainty been assessed?	?	Y
16	Has the model been validated?	N	?

N, no; Y, yes; ?, unclear/incomplete.

## Description and results of the published economic evaluations

### The Counterweight Programme

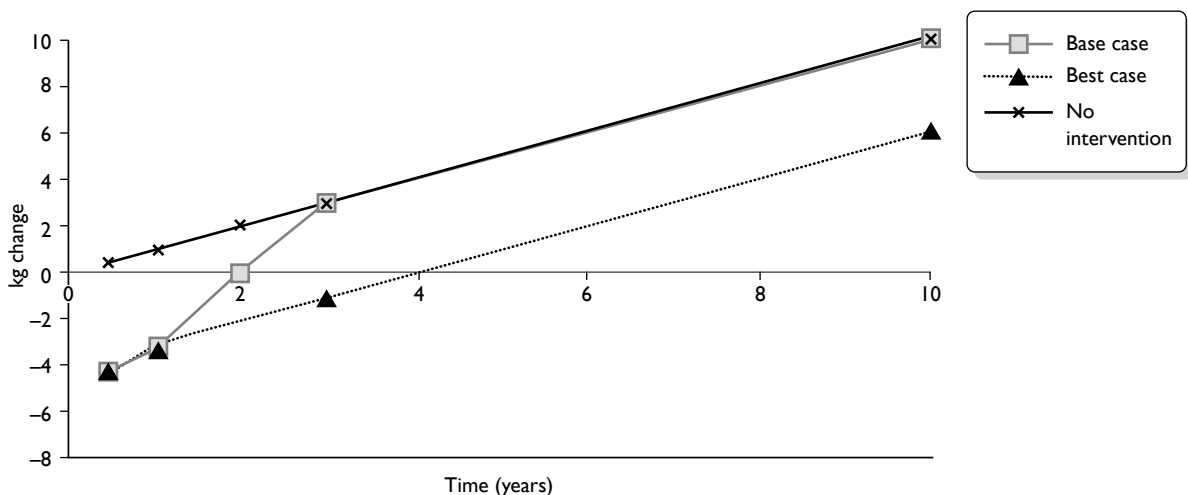
The Counterweight Programme is a weight management programme in primary care in the UK.<sup>87</sup> An economic evaluation was undertaken using an existing model developed for the NICE clinical guidelines on obesity.<sup>35</sup> The evaluation examines the impact of weight loss interventions on health outcomes and costs. The model incorporates the relationship between weight gain and the increased risk of developing a range of associated conditions. The analysis compared the costs and outcomes of the Counterweight Programme with no active intervention. The cost per patient of the Counterweight Programme was derived from an analysis of the budgetary impact of implementing the programme.<sup>54</sup> The analysis was conducted from the perspective of the UK NHS.

#### Modelling approach

A patient-level simulation model was used which had previously been developed to provide input to the UK national guidance on obesity.<sup>35</sup> The model works by randomly selecting an individual whose characteristics are based on those of the UK adult population (for example, BMI, age and gender) and following their health-care costs and outcomes until death. The model assesses people over 6-month cycles. During each cycle, individuals may experience a change in BMI (increase or decrease) or no change. Based on their characteristics, individuals can develop diabetes, CHD, or colon cancer depending on the prevalence of each disease at the BMI they are currently experiencing. There is a utility score associated with each health state. Patients are at increased risk of death if they experience one of these conditions. To determine whether the individual is experiencing each particular health state at any one time, the incidence of the chronic health states was calculated, based upon the prevalence of the condition for that individual's characteristics. The model was run for a cohort of 10,000 people.

#### Assumptions

In the base-case analysis, patients are assumed to regain all the weight lost in 2 years following removal of the programme while those obese adults not on the programme are assumed to gain a background rate of 1 kg per year (Figure 3).<sup>87</sup> Those patients who were not attending at 12 months were assumed to gain weight at the same rate as those not on the programme.



**FIGURE 3** Assumptions of weight change for the economic evaluation of the Counterweight Programme.

### Effectiveness of intervention

The estimates of the effectiveness of the Counterweight Programme were based on a prospective evaluation of 1906 obese adults in 65 UK general practices.<sup>54</sup> These patients had a mean age of 49.4 years, a mean BMI of 37.1 kg/m<sup>2</sup> and were mostly female (77%). All patients received the intervention, as the study was not a controlled trial, and the results are compared with weight gain in observational studies of obese adults. The intervention consisted of diet, exercise and behaviour modification components. First-line interventions were a prescribed eating plan, using a goal-setting approach, or a group intervention. These were all aimed at achieving an energy deficit of more than 500 kcal/day. Patients were asked to commit to nine appointments in 12 months, including six individual appointments (10–30 minutes) or six group sessions (1 hour each) over a 3-month period and then follow-up appointments at 6, 9, 12 and 24 months. Mean weight change at 12 months ( $n=642$ ) was  $-3.0$  kg (95% CI  $-3.5$  to  $-2.4$  kg) and at 24 months ( $n=357$ ) was  $-2.3$  kg (95% CI  $-3.2$  to  $-1.4$  kg) compared with original weight. Mean change in BMI was  $-1.1$  kg/m<sup>2</sup> (95% CI  $-1.3$  to  $-0.9$  kg/m<sup>2</sup>) at 12 months. Untreated patients are assumed to gain 1 kg weight per year. There were a large number of dropouts from the programme. Of 1419 attendees, 54% of patients (761) provided data at or beyond 12 months. These dropouts are likely to have incurred additional costs to the programme.

Caution is required in the interpretation of the evidence of effectiveness from the Counterweight Programme study. The effect of the intervention is not based on evidence from an RCT or a study with a concurrent control group and as such there is a higher risk of bias than there would be with a study using a more rigorous design.

### Estimation of QALYs

The Counterweight Programme economic evaluation uses QoL utility values stratified for BMI levels, age and gender based on a discussion paper by Macran<sup>88</sup> which estimated HRQoL based on European Quality of Life-5 Dimensions (EQ-5D) scores in the HSE, 1996 (Table 24). The utility values were for the general population that included individuals with CHD, diabetes and cancer. These values were adjusted to derive utility values for the general population without these chronic health states for different BMI scores. For a person with a relevant comorbidity, multipliers were applied to these utility scores to obtain their individual utility estimate. The multipliers for diabetes and CHD (0.8661 and 0.867, respectively) were from a manufacturer submission to NICE for the cost-effectiveness of sibutramine (Meridia®, Abbott Laboratories), published in NICE guidance for obesity.<sup>89</sup> Individuals with colon cancer had their utility score reduced by 5%. The utility values for the different health states do not appear to have been derived from a systematic search.

### Estimation of costs

The cost of the Counterweight Programme was based on participants from the evaluation of the weight management programme and scaled up to the national population. The costs used in the economic evaluation were the actual costs observed and recorded, and they were limited to the services actually provided. Costs included remuneration for all clinicians' time required for

**TABLE 24** Quality of life utility scores by BMI and gender

BMI (kg/m <sup>2</sup> )	Male	Female
<21	0.86	0.85
21–25	0.87	0.87
26–30	0.86	0.82
31–39	0.82	0.78
>39	0.88	0.75

the intervention – training, GPs' time for clinical and motivational assessment, practice nurse time for assessment, motivation, delivery of advice and review. Costs for the Counterweight Programme project team, training resources and patient information materials were also included in the analysis. Costs for the intervention were based on the optimal attendance rate of at least six visits in 12 months. In addition, the costs of weight management medications prescribed according to protocol were incorporated. Around 20% of patients followed up at 12 months or around 9% of the total intervention group were prescribed weight management drugs. The scaled-up national costs, assuming that the programme was available in all practices in the UK and would be taken up by 20% of eligible obese patients, included the following: (i) initial staff recruitment and training (£2M); (ii) weight management advisor team and support staff (£8.5M/year); and (iii) resources and practice staff time for meetings, GP discussion, intervention, equipment, medication, exercise referral and secondary care referral (£16M/year). After the initial year, each cohort was assumed to require 50% of year 1 costs. The total 5-year UK costs were about £200M for 3.3 million patients, which equates to about £60 per patient.

This is a very low intervention cost. Looking at the costs in more detail, they appear to have been calculated incorrectly. The cost for the intervention is £5707 per one GP practice for 92 patients for the first year. The authors assume the follow-up for the second year is one-half of the rate in the first year (e.g. three individual contacts instead of six). Management costs for the scheme are about £15.25 per person. Thus the cost per patient would be about £108.30. This is still a low estimate for the programme, as there does not appear to be any time allocated for administration by the practice nurse or the GP and the time in practice to run the programme may be considerably more than allocated. In the study, patients attended GP appointments for other clinical matters and as part of this the GP suggested practice nurse appointments to discuss weight management. In this way there is no cost allocated for this GP appointment. There is also no time allocated to specialist advisors such as dietitians, cognitive behavioural therapy counsellors or health trainers, except as part of the initial nurse training. There are also no costs included for the fitness programme, such as leisure centre costs. We suggest that the NHS or other government departments pay for part or all of exercise referral schemes. We suggest that the resource costs are more likely to be similar to those used by a recent NICE report for bariatric surgery.<sup>33</sup> This suggested that for a diet-only programme there would be four contacts with a GP per year and two additional contacts per year with a community dietitian, practice nurse and district nurse at a total cost of £282 per year.

As mentioned above, the practice nurse is expected to run almost the entire Counterweight Programme. The practice nurse only receives one full day of training before the start of the course but is expected to gain extensive competencies, in order to run diet, exercise and behavioural components. This training was provided by registered dietitians, who also provided subsequent peer support for about 6 months. It is likely to be the case that GP practices require more than one practice nurse to run the scheme and that they need more support from specialist health professionals and hence the cost incurred will be substantially higher.

The costs of the chronic conditions were based upon previous studies and converted to 2005 prices. Yearly costs included medical conditions such as CHD (£1637), diabetes (£653) and colon cancer (£7320).

Follow-up data were available for only 642 of 1419 participants at 12 months, with the remainder not reaching these data collection points. The costs and effect size have been estimated for these 642 participants. It is unclear what the costs and effect size are for these dropouts, and the weight loss may be lower for these individuals while they will still have incurred the intervention cost.

### Cost-effectiveness results

The model considers the impact of the 12-month observed outcomes of the Counterweight Programme. For the non-active intervention, lifetime QALYs are 28.32. For the baseline intervention, lifetime QALYs are 28.38, i.e. a QALY gain of 0.056 for the intervention. The lifetime cost to the NHS of the non-active intervention is £1884 and for the baseline intervention is £1857. The incremental cost-effectiveness ratio (ICER) is –£473 per QALY gained, i.e. it is cost saving. No sensitivity analyses were conducted for structural, methodological or parameter uncertainty. Scenario analyses were conducted for background weight change for the untreated population. For background weight change of 0.5 kg/year and 0.3 kg/year the ICER was £2017 and £2651, respectively.

### Summary of key issues

- The study has evaluated a diet, exercise and behavioural programme for obese people in the UK, using the actual costs observed in the Counterweight Programme.
- There appear to be some miscalculations in the intervention costs used and the costs recorded are lower than reported in other studies.
- The intervention effects are based upon a single observational study, rather than a controlled trial or systematic review.
- There are high dropout rates in this study that will have an added cost.
- The methodology of the model and the derivation of the QoL utility values seem reasonable.

Roux and colleagues<sup>86</sup> conducted an economic evaluation of outpatient weight loss strategies in overweight and obese women in North America. Each weight loss intervention consisted of a 6-month intervention followed by a 6-month maintenance programme. The strategies were: routine care; diet only; diet and exercise; diet and pharmacotherapy; and diet, exercise and behavioural modification. In all strategies women who successfully completed the 6-month weight loss intervention were modelled to enter the 6-month maintenance phase. Women who were unable to lose weight or maintain weight loss were assumed to remain at their age-adjusted original BMI. The base case simulated the natural history of a hypothetical cohort of healthy, non-pregnant 35-year-old overweight and obese women with original BMI > 25 kg/m<sup>2</sup> and free from known CHD. The model was used to project lifetime costs and gains in life-years and QALYs, and the analysis was from a societal perspective. Costs were in US\$ and the price year was 2001. The study used benefits from published RCTs and costs were derived from published data, Medicare reimbursement rates and primary data for indirect costs.

### Modelling approach

A first-order Monte Carlo simulation model was developed to simulate the natural history of a hypothetical cohort of otherwise healthy, non-pregnant 35-year-old overweight and obese women. The model uses a state-transition framework, where the natural history of obesity in the hypothetical cohort is characterised as a sequence of annual transitions from one health state to another. Women enter the model aged 35 years, free from known CHD, and their BMI is randomly chosen from a uniform distribution of BMIs > 24.9 kg/m<sup>2</sup>. Each year a woman's BMI is adjusted for age-related increases and predicts the risk of developing hypertension, Type 2 diabetes or hypercholesterolaemia that in turn predicts her risk of CHD and CHD death. Each woman's clinical course was tracked until death, when summary statistics such as quality-adjusted survival and total lifetime costs were recorded. The sample size was 10,000 women, for whom average life expectancy, QALYs and costs were calculated. Significant intervention-attributable weight loss was defined as a 10% BMI reduction after completion of the 6-month weight loss intervention. Short-term success was defined as maintenance of a reduced BMI post intervention for at least 6 months. Long-term success was defined as maintenance of a reduced BMI for at least 5 years after the weight loss intervention.



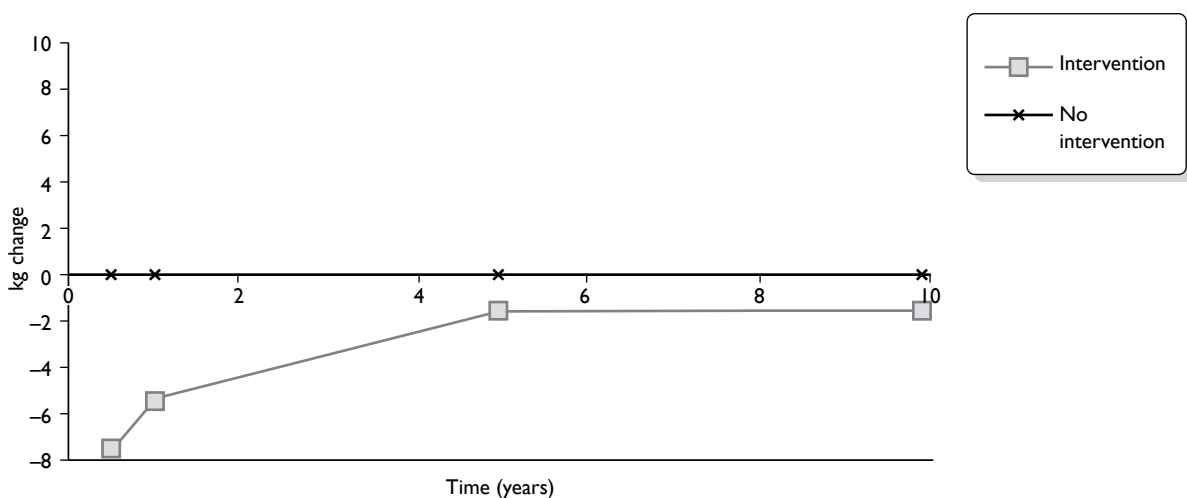
### Assumptions

It was assumed that the probability of long-term weight maintenance was 20% with lifestyle modification programmes and 10% without lifestyle modifications based on published literature. Women who successfully maintained their weight loss for at least 5 years were assumed to remain at their postintervention BMI for the remainder of their lifetime. *Figure 4* shows the assumptions used in the model for weight change for the intervention versus routine care (no intervention), although the study did not clearly describe how weight changed over time in the routine care group. Age- and BMI-specific obesity-related disease complications were assumed to be lifelong. It was assumed that a woman who achieves only short-term success accrues the clinical benefit associated with a lower BMI until she regains weight. Women who do not lose weight or who lose weight but do not maintain the weight loss are subject to age-adjusted cardiovascular disease risks based on their original BMI.

### Effectiveness of intervention

The dietary component in all modelled strategies, except routine care, was defined as the reduction in caloric intake necessary to achieve a 10% weight loss under the supervision of a dietitian, in accordance with the American Heart Association guidelines. For strategies incorporating exercise, the exercise protocol consisted of three 45-minute structured exercise sessions per week of moderate intensity, led by a certified instructor, and two sessions per month to review clinical progress with an exercise therapist. The strategy that incorporated pharmacotherapy was modelled to consist of 120 mg orlistat three times a day for 6 months, then half this dose per day during the 6-month maintenance phase. The behavioural modification strategy was modelled to consist of a 1-hour cognitive therapy counselling session led by a psychologist every other week.

The estimates of the effectiveness of the weight loss interventions were based on a 'comprehensive review' of the published literature from which four studies were selected on the basis of their methodological quality. However, no details are given and the study references are reported to be in an online appendix that is not available. The probability of weight loss for each strategy was estimated using bootstrapping methods by sampling random numbers to predict the change in BMI for 1000 representative women. Thus, the size of the treatment effect used in the evaluation was a change in BMI post intervention of 0.26 kg/m<sup>2</sup> for routine care, -1.98 kg/m<sup>2</sup> for diet only, -2.55 kg/m<sup>2</sup> for diet and exercise, -4.55 kg/m<sup>2</sup> for diet and pharmacotherapy, and -3.11 kg/m<sup>2</sup> for



**FIGURE 4** Assumptions of weight change for the economic evaluation by Roux and colleagues<sup>86</sup> Weight change derived by assuming average height in cohort of women of 1.63 m and those who do not maintain weight loss return to original weight.



diet, exercise and behavioural modification. The estimates of weight loss for the diet, exercise and behavioural modification strategy are higher than seen in our systematic review (see *Chapter 3, Quantity and quality of research available*).

### Estimation of QALYs

General age-specific quality weights were derived from the Beaver Dam Health Outcomes Study<sup>90</sup> (referenced but no details given). These were applied to women more than 45 years of age and adjusted to reflect weight loss and comorbid diseases using a multiplicative function. The quality weights for weight loss were obtained using primary data from a survey of 100 weight management programme participants. The average per cent reduction in life expectancy that participants were willing to give up to achieve weight loss was elicited, through a hypothetical treatment (a single pill, free of charge and side effects but which would not prevent or cure health problems or incur survival benefit). This was scaled to give utility scores for a sustained BMI reduction to the average weight for their height (0.87) and for a 10% reduction in BMI (0.93). A disease-specific quality weight of 0.75 (age-adjusted) was used for CHD and Type 2 diabetes.

Temporary decrements in utility attributable to the interventions were found from primary data analysis to be related to the intensity of effort required to participate in a particular programme. For routine care that required minimal effort, there was no utility decrement, whereas for the diet, exercise and behavioural modification programme there was a decrement, of 0.09 for a 6-month period. Other programmes of intermediate intensity were assigned decrement values between 0 and 0.09. Thus, for this 6-month period, the utility decrement cancelled out any gain in utility for a reduction in BMI. The derivation of this utility decrement has not been described and it is unclear why such a short period has been chosen.

### Estimation of costs

Micro costing techniques were used to estimate resource use associated with each weight loss intervention. Direct medical costs were based on published data and valued using average Medicare reimbursement rates. Drug costs were obtained from the 2001 pharmaceutical pricing index, based on average wholesale prices. Direct medical costs associated with obesity-related morbidity and mortality included annual age- and sex-specific treatment-related costs for hypertension, Type 2 diabetes and cardiovascular disease. The source of costs was reported but individual elements were not noted and so their unit costs and the quantities used were not reported. The costs were reported as the average cost per patient. Direct medical costs per patient were US\$700 for routine care, US\$2150 for diet only, US\$2750 for diet and exercise, US\$2820 for diet and pharmacotherapy and US\$3040 for diet, exercise and behavioural modification. The programme costs appear to be based upon those from a weight management programme at the Brigham and Women's Hospital in Boston, MA, USA, but the numbers of consultations and other resources used for the programme have not been described. However, the strategies appear to include consultations with a physician, nutritionist, exercise therapist and psychologist and included other investigations such as laboratory tests, X-ray, electrocardiogram and exercise stress test.

Direct non-medical costs (e.g. fitness attire, travel costs, diet-related costs) were estimated using primary self-reported cost and quantity data derived from the community sample of 100 participants. The study was from a societal perspective. As such, productivity costs are included, which are not included in studies taking an NHS perspective. Time-cost was estimated directly from the sample of 100 women by applying wage rates specific to their occupation. The analysis was repeated using 2001 US national-level average wage rate data to value time lost from work or leisure activity. Time lost from performing household duties was valued using wage rates for domestic child care and light duty cleaning services. The costs and quantities were not reported separately.

### Cost-effectiveness results

The most cost-effective and efficient strategy was the three component intervention of diet, exercise and behavioural modification with a discounted quality-adjusted life expectancy of 18.43 years and discounted lifetime costs of US\$124,200. The lifetime QALY gain is 0.24 compared with routine care, at an extra cost of \$3080. This had a cost per QALY gained of US\$12,640 compared with routine care or a cost per life-year saved of US\$60,390. The diet-only strategy was less effective and more costly than routine care (strongly dominated), the diet and pharmacotherapy and diet and exercise strategies were less effective and less costly and had a higher ICER versus routine care (weakly dominated) than with the diet, exercise and behaviour modification strategy.

Sensitivity analyses showed that the results were most influenced by the QoL utility values for obesity and the probabilities of weight loss maintenance. No probabilistic sensitivity analyses were included.

### Summary of key issues

- It is unclear how generalisable the model parameters and results are to the UK as the study is conducted in North America and from a societal perspective. In particular the health-care costs are much higher than the UK, non-medical costs are included, and it is unclear what the results would be if the study were adapted for the UK.
- The study was conducted for overweight and obese women.
- Adequate details are provided on the model structure and assumptions and the methodology used and results obtained seem credible.
- There are some methodological limitations and uncertainties such as no details about the source of clinical effectiveness data, an intervention effect which may be optimistic in terms of change in BMI, extrapolation of long-term maintenance of weight loss based on authors' assumptions and use of aggregated costs.

### Comparison of cost-effectiveness analyses

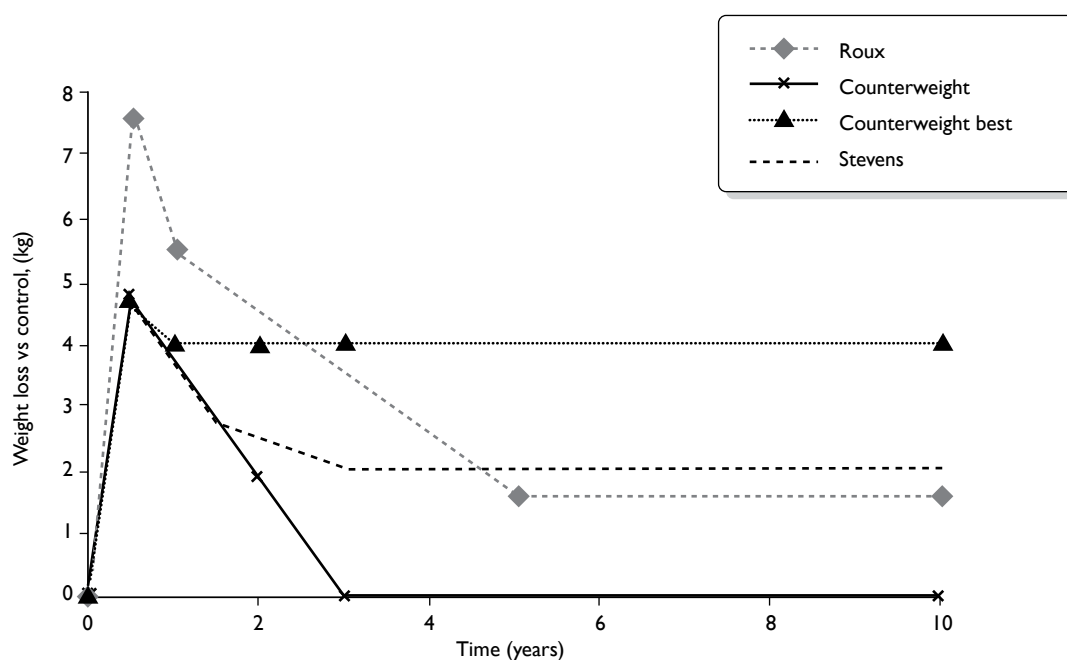
The intervention effect varied between the evaluations. The mean weight change was  $-3.0$  kg at 12 months ( $-1.1$  BMI kg/m<sup>2</sup> at 12 months) and  $-2.3$  kg at 24 months for the Counterweight Programme.<sup>87</sup> Roux and colleagues<sup>86</sup> reported weight change of  $-3.11$  kg/m<sup>2</sup> change after 6 months intervention and thereafter the probability of maintaining a 10% weight loss was 67% at 1 year and 20% at 5 years. The weight loss from the Counterweight Programme<sup>87</sup> seems consistent with that seen in the trials in our clinical effectiveness systematic review (see *Chapter 3*), while the weight loss from Roux and colleagues<sup>86</sup> appears optimistic.

There was a range of assumptions used to extrapolate weight change beyond the follow-up period of the intervention. These are shown graphically in *Figure 5*. Roux and colleagues<sup>86</sup> assumed that after 5 years, 20% of women on the diet, exercise and behaviour programme would maintain weight loss and that they would remain at their postintervention weight or maintain their weight loss post intervention for the remainder of their lifetime. In the base case, the Counterweight Programme<sup>87</sup> assumed that those on the programme return to the same weight as the control population within 2 years of finishing the programme. In a 'best-case' scenario, they assumed that individuals remain at a lower weight than the control population lifelong. From the evidence presented in our systematic review of clinical effectiveness, we suggest that the control group are likely to gain weight but at less than 1 kg/year, perhaps in the region of 0.3–0.5 kg/year. Individuals finishing the weight loss programme would be likely to regain weight within 2–4 years after the end of the intervention, and thereafter gain weight at a similar rate to the control group. *Figure 5* shows the weight loss of the intervention group compared with the control groups in the two economic analyses and one of the studies from the systematic

review of clinical effectiveness that seemed the most robust (Stevens and colleagues<sup>70</sup>). It is likely that although people may regain lost weight eventually, because the population gains weight throughout life, people may still be at a lower weight than those who never received a weight loss intervention. Compared with the Stevens and colleagues study,<sup>70</sup> the assumptions used to extrapolate beyond the follow-up period of the intervention seem reasonable for Roux and colleagues,<sup>86</sup> but for the Counterweight Programme study<sup>87</sup> seem pessimistic, as they do not assume any long-term difference between the intervention and control groups. On the other hand, in the best-case scenario of the Counterweight Programme<sup>87</sup> the long-term weight difference between the intervention and control group seems optimistic.

The gain in QALY compared with routine care varies between 0.06 and 0.243 for the two studies. These differences are mainly due to the differences in the assumptions for long-term weight loss maintenance and the utility values chosen for weight change. Neither study provided a clear explanation of the derivation of HRQoL values or was based upon a review of QoL literature. The studies adopt very different estimates for the effect on QoL of a reduction in weight. Roux and colleagues<sup>86</sup> use a HRQoL value of 0.93 for individuals with obesity and 0.87 for those who achieved a 10% weight loss, i.e. a change in BMI of roughly 3 kg/m<sup>2</sup>. The Counterweight Programme study<sup>87</sup> used values shown in *Table 24*, for example females have a utility of 0.82 and 0.78 for BMI between 26 and 30 and between 31 and 39 kg/m<sup>2</sup>, respectively. The change in utility values associated with a unit change in BMI varied between about 0.006 for the Counterweight Programme<sup>87</sup> and 0.02 for Roux and colleagues.<sup>86</sup>

The cost of the intervention varies between around £60 per patient in the Counterweight Programme study<sup>87</sup> and US\$3040 (£1820) for the diet, exercise and behaviour programme in the Roux and colleagues study.<sup>86</sup> Roux and colleagues<sup>86</sup> itemised the costs included in their programme and costs are included that would not be included in UK economic evaluations, for example non-medical and time per patient costs. There is also a large difference between the costs due to the personnel used to deliver the programmes. For example, Roux and colleagues<sup>86</sup> state



**FIGURE 5** Assumptions of weight loss difference between the intervention group and control group for the economic evaluations. Weight change derived for Roux and colleagues<sup>86</sup> by assuming average height in cohort of women of 1.63 metres and those who do not maintain weight loss return to original weight.

that the medical cost of the programme includes consultation costs for physician, nutritionist, exercise therapist and psychologist while the Counterweight Programme used six 20-minute consultations with a practice nurse to cover diet, exercise and behavioural components (total cost £43). Furthermore, the Roux and colleagues<sup>86</sup> programme included other investigations such as laboratory tests, X-ray, electrocardiogram and exercise stress test which were not included in the Counterweight Programme.<sup>87</sup>

### **Sensitivity analysis**

The Counterweight Programme study did not include sensitivity analyses and Roux and colleagues<sup>86</sup> did not include a sensitivity analysis relevant to the likely UK programme costs. We conducted a simple sensitivity analysis using both of the studies to show the effect of changes to the results using different programme costs. This is an exploratory analysis based on the published estimates.

Based on a previous review of the literature,<sup>35</sup> we estimate that the cost of diet, exercise and behavioural modification programme may be in the range £500–1000 per participant. Using a programme cost of £750 per participant, the ICER of the Counterweight Programme study<sup>87</sup> changes from –£473 to £11,600 per QALY gained and the ICER for the study by Roux and colleagues<sup>86</sup> changes from £7600 to £3200 per QALY gained. These exploratory analyses demonstrate that the results are sensitive to the programme costs and that the diet, exercise and behavioural modification programme remains cost-effective, at commonly used thresholds of £20,000–30,000 per QALY gained, for both models if the cost of the intervention is £750 per participant.

### **Summary of cost-effectiveness studies**

- Two cost-effectiveness studies were described in our review of economic evaluations.
- Each study used a lifetime chronic disease model to evaluate the effect of changes in individuals' weight. The models included the costs and benefits from avoiding chronic illnesses such as CHD and diabetes.
- Omissions in reporting details of the modelling methodology and data inputs reduced transparency and make it difficult to draw conclusions about the results; however, the results and methodology of the studies seemed reasonable.
- The Counterweight Programme study<sup>87</sup> is of most relevance to the UK as the health-care system in the study was the NHS and the study was conducted from the perspective of the UK NHS.
- There were limitations to each study. For the Roux and colleagues North American study,<sup>86</sup> the costs were much higher than for the UK NHS perspective as non-medical costs have been included. For the UK study,<sup>87</sup> the intervention effect is not based upon an RCT, and there is a likely underestimate of the actual costs for the intervention. Neither study has fully explored the uncertainty around the results.
- Both studies found the interventions to be cost-effective, with estimates varying between –£473 and £7200 (\$12,640) per QALY gained.
- One study compared<sup>86</sup> a diet, exercise and behavioural modification strategy with strategies for routine care, diet only, diet and exercise, and diet and pharmacotherapy, and found diet, exercise and behavioural modification to be the most effective and efficient strategy.
- Sensitivity analyses conducted in one of the studies<sup>86</sup> showed that the results were most influenced by the probability of weight loss maintenance and utility values for obesity.

# Chapter 5

## Discussion

### Statement of principal findings

#### *Clinical effectiveness*

Twelve RCTs<sup>68–79</sup> that compared multicomponent interventions with another weight loss intervention or control and which reported results on weight loss in their overweight or obese populations were included. In order to inform practice we attempted to minimise potential differences between studies given the complexity of these types of interventions. A prerequisite for including trials in this review was a minimum length of follow-up of 18 months. This was considered important to enable an assessment to be made of the impact of interventions on sustained weight loss, as weight regain is a known problem associated with weight loss treatment. Another requirement was that studies included in the systematic review needed to have reported their interventions in sufficient detail for them to be reproducible and hence useful to practice. This criterion was also included to allow identification of which, if any, aspects of the components appeared to relate to differences in outcome. However, in practice there were few similarities between the included studies; consequently, the number of meaningful conclusions that can be drawn from the range of studies included is limited (discussed in more detail below).

Five RCTs<sup>70,72–75</sup> compared multicomponent interventions with non-active comparator groups. In general, weight loss did appear to be greater in the intervention groups than in the comparator groups, although weight losses were relatively small and their clinical meaningfulness is unclear. Where studies measured outcomes at a time point after the active intervention phase, it was seen that the intervention groups began to regain the weight they had lost. Despite this a statistically significant difference in weight loss in favour of the intervention group was maintained in two studies up to 36 months of follow-up.

Two RCTs<sup>69,71</sup> compared multicomponent interventions that we classed as having the diet component as their focus. Participants in both studies lost weight, but there were no statistically significant differences in weight loss between study groups. After completing the intervention participants from both studies regained weight over time.

Four RCTs<sup>76–79</sup> compared multicomponent interventions in which the focus was on the physical activity component. In one study<sup>77</sup> participants assigned to the HPA intervention lost more weight at 18 months than those assigned to a SBT intervention, which also included physical activity but with a lower caloric expenditure goal. By 30 months the difference was not statistically significant (the trend remained however). In another study<sup>76</sup> weight loss was greater in those in a SBT group than in those in a SBTE group. In the third study<sup>79</sup> weight loss was similar between those allocated to a diet and physical activity combined group and those allocated to a diet alone or exercise alone group. In these physical activity focused studies any weight lost was generally small. Data were presented for a subgroup of participants only in the fourth study,<sup>78</sup> limiting its value to this review.

One RCT<sup>68</sup> compared multicomponent weight loss interventions but the study focus was not on diet or exercise but on other variables. It appeared that weight loss was greatest in participants given daily dietary and exercise goals compared with those given weekly goals. However,

no statistical analyses were presented to support this observation. This study suffered from additional methodological limitations.

No studies were identified which used OTC weight loss medications.

In general, weight changes across the included studies were small. The degree of weight loss achieved, however, may be meaningful depending on what threshold is considered a marker of success and from whose perspective it is taken. People who are overweight or obese, and the health professionals involved in their care, may differ in the degree of weight loss they see as 'significant'. There does not appear to be a consensus as to what would constitute a clinically meaningful weight loss. It is difficult to establish clinical significance because trends in the weight of the general population, the starting weight of individual participants, and the time over which the weight loss is measured would all need to be taken into account. In the studies we included there was a range in the starting weight and BMI of participants (discussed within each section). This might have led to variation in: the ease with which participants lost weight; their perceptions of the importance of losing weight; and their perceptions of meaningful weight loss. If we assume that a 5-kg threshold for the degree of weight loss is meaningful then participants in six<sup>68,69,71,73,76,77</sup> of the 12 studies would be considered to have received clinical benefit from their weight loss. An alternative assumption could be that for participants to benefit meaningfully from an intervention any weight loss at the end of the intervention followed by longer-term weight stability would be acceptable. Based on this criterion none of the five studies that presented weight change results at more than one time point would be considered to have demonstrated acceptable weight loss. As there is a natural tendency for weight gain over time in the general population, a further, alternative, assumption could be that no weight regain beyond baseline may be of importance. In this instance all four included studies presenting outcomes over more than one time period would be considered to have shown clinical benefit.<sup>70,73,75,77</sup>

### Cost-effectiveness

Two cost-effectiveness studies that used lifetime chronic disease models to evaluate the diet, exercise and behavioural interventions for overweight and obese people were described.<sup>86,87</sup> The models included the costs and benefits, in terms of HRQoL, from avoiding chronic illnesses such as CHD and diabetes. One study was conducted from the perspective of the UK NHS, the Counterweight Programme study,<sup>87</sup> and the other was conducted for a societal perspective for a North America health setting.<sup>86</sup> There were limitations to both studies and there were omissions in reporting details of the modelling methodology and data inputs which made it more difficult to draw conclusions about the results. The UK study was not based upon an RCT or a systematic review, and so caution is advised in the interpretation of the effectiveness of the intervention. In addition, the costs of the intervention appeared to be underestimated. The Roux and colleagues<sup>86</sup> North American study was conducted for overweight and obese women and the intervention costs were much higher than would be expected in the UK. Furthermore, non-medical costs, such as patient time, have been included. Despite the limitations of the studies, the results and methodology of the studies seemed reasonable. Both studies found the interventions to be cost-effective compared with a commonly used threshold of £20,000–30,000 per QALY gained, with estimates varying between –£473 and £7200 (\$12,640) per QALY gained.

### General discussion

Even though studies in the review of clinical effectiveness were grouped to try to keep the most similar studies together, the studies were still rarely comparable. Differences in the types and durations of interventions, and any subsequent weight maintenance strategies, the length of follow-up, issues around generalisability to the UK and the risk of bias of the studies



mean that it is difficult to draw robust conclusions as to the effectiveness of multicomponent weight management programmes. It is also difficult to establish what the core components of such programmes may need to be to maximise and sustain weight loss. With such complex interventions it is difficult to establish with any precision what the 'active ingredient(s)' causing any demonstrated effect is. It may be that there are necessary elements to successful weight loss, but with so few data, and so few similarities between interventions, it is difficult to draw any conclusions on this.

As noted earlier we informally assessed all of the studies included in this evaluation in terms of their length of follow-up, sample size, risk of bias, degree of reproducibility of components of the interventions, generalisability and overall effect size (see *Appendix 8*). Speculatively, the weight loss interventions evaluated by the Stevens and colleagues<sup>70,74</sup> studies may offer a useful model for long-term weight management. In particular the Stevens and colleagues<sup>70</sup> TOHP-II study, which has a large sample size, reported a statistically significant effect on weight loss at least 24 months after the active intervention, and the intervention appears to be reproducible. In terms of overall methodological rigour, the study was judged to have a generally low risk of bias. It is unclear whether the study was statistically powered to detect an effect of weight change (because the study was powered for reduction in BP); however, the large sample size provides no reason to suspect that the weight change outcome would not have been adequately powered. Its generalisability to the UK is uncertain. Although this study, based on the Trials of Hypertension, had some shortcomings it appears on balance to be best placed among those included in this systematic review to provide a model for further exploration and testing with overweight populations in the UK.

This study had two main phases: an intensive phase (14 weeks) and a maintenance phase (16–18 months), with some maintenance continuing until follow-up at 36 months. The participants' goals were to lose at least 4.5 kg during the first 6 months of the intervention and to maintain that weight loss for the remainder of the trial (participants did regain weight over time but their weight at 36 months remained just lower than at baseline). Key features of the intervention were a calorie-controlled diet with a focus on decreasing consumption of excess fat, sugar and alcohol, a gradual increase in walking, monitoring through self-report (diaries) and at group sessions, and a relatively simple behavioural therapy intervention. This comprised goal-setting or action plans, relapse prevention, self-monitoring and social support. These components appear consistent with recent NICE obesity guideline advice. The extended support and relatively straightforward goals for diet and exercise may be contributing factors to the weight change results shown in the intervention group compared with the usual-care control group but we are unable to test this. However, the resource requirements to deliver an intervention such as this are unclear at the present time as few details were reported in the study publication.

In the studies included in our review the interventions varied in terms of their length, their components, the personnel involved and the ongoing maintenance/support mechanisms involved. For example, if we look at the number of contacts with participants, personnel involved in the interventions saw or had contact with participants weekly for at least 14 weeks in most of the included studies. It is unclear whether this is realistic in terms of the likely resource availability or as an expectation of the participants. In the intervention that we feel may have the most potential for testing in a UK setting<sup>70</sup> the intervention was delivered by dietitians and health educators with some input from psychologists. It included 14 weekly sessions, then six biweekly sessions and then three to four monthly sessions during the 18-month intervention and then at least three contacts during the 18-month ongoing support phase. Weight change was generally positive and dropout rates were around 10% in both the intervention and a usual-care control group.



Throughout our report we have commented on issues of generalisability of the populations where appropriate. For example, where the populations are of a certain age or gender, have answered media advertisements for entry into the studies and/or paid deposits to do so and the fact that none of the studies were carried out in a UK setting and so may have different health systems and populations. A potential example of a more generalisable intervention is the Counterweight Programme.<sup>87</sup> This is currently being rolled out in primary care in many areas of the UK. However, the evaluation of the Counterweight Programme<sup>87</sup> intervention was based on a non-randomised study and thus did not meet the inclusion criteria for our systematic review of clinical effectiveness. We are therefore unable to ascertain whether the intervention is clinically effective. The economic evaluation of the Counterweight Programme<sup>87</sup> was summarised in our systematic review of cost-effectiveness studies and appeared to be cost saving. However, caution in interpretation is required as the study did not meet the inclusion criteria for this review and there were uncertainties around estimates of the costs of the programme and around assumptions about the extrapolation of effectiveness estimates over time.

## Comparison to existing systematic reviews

We have identified 10 existing systematic reviews that focused on weight management interventions for adults (see *Table 6*). All of these systematic reviews had included studies of interventions comprising diet, exercise and/or behavioural components, but none specifically included only studies with all three components as recommended in the NICE obesity guideline. There appeared to be a consensus from these systematic reviews that the most effective weight loss interventions were those that were multicomponent. Only one of these existing systematic reviews looked specifically at long-term evidence of the interventions, but its aims and inclusion criteria were different to those of our systematic review, precluding comparisons.

## Other issues and methodological concerns

The scope of this review was to focus on studies that would be of most use to policy and practice. We therefore sought studies with long-term follow-up and in which the interventions were clearly described (to enable replicability). Despite this, we identified evaluations of a range of different multicomponent interventions, making it difficult to compare results and to make meaningful conclusions. There are a number of other factors that should also be considered in the interpretation of the studies.

Weight regain was common among participants in the included interventions, even in studies with extended ongoing support. Unfortunately, the data available do not allow us the opportunity to offer any inference as to what might be causing this and it is unclear whether this is clinically meaningful in some way.

Incentives to recruit people to participate were used in three of the included studies.<sup>72,73,79</sup> Although not directly tested it does not appear that there was any relationship between using incentives and the likelihood of weight change.

Our review aimed to comment on any particular barriers to or facilitators of weight loss that may help to establish what the key components of these types of interventions should be, but the evidence we reviewed offers no insights into this. From the available data it is not possible to determine whether the weight loss interventions had any negative effects on participants.

Weight loss success may depend on whether trial participants have previously attempted weight loss or how long they have experienced overweight or obesity. Data on these factors could potentially be used to target interventions to certain populations. We attempted to capture these data; however, treatment history was only reported in three<sup>72,75,76</sup> of the included studies and the duration that participants had been overweight or obese was not reported in any study. As such there are not enough data for us to reflect on any patterns in the results seen.

Even in those studies with a non-active comparator (e.g. usual care) it was difficult to establish the true estimate of the effects of an intervention as very few studies adequately described their non-active comparator. It seems likely that participants assigned to control arms would still have received some contact with health-care professionals, which may have the potential to underestimate the treatment effect.

The methodological quality of the included studies varied. None of the studies reported all the details necessary to assess all 10 of the quality assessment criteria that we used. In most studies fewer than half of the criteria could be adequately assessed. Similarly, between the included studies there were no individual quality assessment criteria that were reported by all of the studies. A recent systematic review<sup>91</sup> of 63 RCTs of any intervention for weight loss found that while reporting seemed to have improved since the publication of the revised consolidated standards of reporting trials (CONSORT) statement in 2001, reporting of some key aspects was still poor. In the review, 60% of the overall CONSORT criteria were satisfied by the RCTs, but the reporting of criteria relating to the methods varied, with just 19% of studies satisfying the reporting criteria relating to treatment allocation. The authors of that systematic review suggest that there is considerable room for improvement in the adherence to the CONSORT reporting criteria.

Many studies included in our evaluation were undertaken more than 10 years ago. It is likely that this would have had a bearing on the reporting of methods used in the studies and the interpretation of results. For example, the general population today is more exposed (e.g. by mass media) to the issue of overweight and obesity and, as a result, likely to be more aware of healthy eating and physical activity messages. It is therefore possible that the effect of interventions conducted a decade or more ago might not be so large in the present day. Over time the roles of health professionals may also have changed, so the types of people delivering weight management interventions today may be different from those who would have delivered such interventions in the past. Practice may also vary geographically, including within countries. The studies in our review provided little detail on the process of training providers.

In the two studies<sup>86,87</sup> that were described in our cost-effectiveness review the costs of the multicomponent weight loss programme varied between £60 and US\$3040 (£1820) per participant. The costs reported in the other reviews for weight programmes appear also to be within this range. A NICE guidance report<sup>35</sup> for the management of obesity included a review of diet, exercise and behavioural treatment and the resource costs for these components. In the NICE report, physical activity interventions cost between £532 and £737; diet interventions cost between £103 and £621; and a diet and behavioural intervention cost £672 per patient. One study included in the NICE review of a pharmacological trial for sibutramine included diet and exercise advice as the control arm with a cost of £243.48 per person.<sup>92</sup> Avenell and colleagues<sup>30</sup> reviewed treatment for obesity and constructed an economic model for a diet and exercise intervention for individuals with impaired glucose tolerance. The total estimated cost for the LI was £324 per person in the first year and £178 per person for subsequent years. The resource costs reported for other weight loss interventions seem to concur with our conclusion that the costs in the Counterweight Programme study<sup>87</sup> are too low, and those from the Roux and colleagues North American study<sup>86</sup> do not reflect UK costs.

The gain in QALY compared with routine care varies considerably between the two studies<sup>86,87</sup> due to the differences in the assumptions for long-term weight loss maintenance and the utility values chosen for weight change. The change in utility values associated with a unit change in BMI varied between about 0.006 for the Counterweight Programme<sup>87</sup> and 0.02 for Roux and colleagues.<sup>86</sup> Neither study based these utility estimates upon a review of the QoL literature. A recent *Health Technology Assessment* report<sup>33</sup> on the clinical effectiveness and cost-effectiveness of bariatric surgery for obesity conducted a targeted search to identify published utility estimates for BMI values relevant to obese adults. The authors of this study stated that the values from the study by Hakim and colleagues<sup>93</sup> represented the most methodologically sound estimates derived. Hakim and colleagues<sup>93</sup> found that a one-unit decrease in BMI in obese individuals without diabetes was associated with a gain of 0.017, which was independent of age or gender. The utilities values from this study are consistent with those chosen by Roux and colleagues,<sup>86</sup> but much higher than those used by the Counterweight Programme study, suggesting that the Counterweight Programme study may be underestimating some of the health gain associated with weight loss. However, although the QALY gains are small in these studies, the interventions are still cost-effective by generally accepted thresholds, because the interventions have such low costs.

One of the studies discussed in our review (Roux and colleagues<sup>86</sup>) included a utility decrement associated with the effort involved with participating in a weight management scheme. This resulted in the situation where participants of a diet-only strategy had lower lifetime QALY than those having routine care. As the primary data analysis to derive these data was not reported, it is unclear how these data were derived and whether the assumptions are valid. Removing this assumption would result in a more favourable cost-effectiveness estimate.

The cost-effectiveness results in the two studies described in our cost-effectiveness review are consistent with other cost-effectiveness studies for diet and exercise interventions (but without a behavioural component). Gallani and colleagues<sup>94,95</sup> described a Markov model for a diet and exercise intervention in Switzerland in overweight and obese people. In their analysis the diet and exercise intervention was cost-effective for all subgroups with an ICER < £5000 per QALY. Bemelmans and colleagues<sup>96</sup> described a cost-utility study in the Netherlands in overweight and obese people. The ICER for the diet and exercise intervention was €7400 (£6700) per QALY saved. Furthermore, a NICE review<sup>35</sup> for diet, exercise and behavioural treatments concluded that 'the cost per QALY in the best-performing non-pharmacological studies ranges from £174 to £9971'. This suggests that even though there were limitations to each of the studies in our cost-effectiveness review, the results appear to be consistent with other studies.

## Strengths and limitations

This review has the following strengths:

- It is independent of any vested interest.
- It has been undertaken following the principles for conducting a systematic review. The methods were set out in a research protocol (see *Appendix 1*), which defined the research question, inclusion criteria, quality criteria, data extraction process and methods to be employed at different stages of the review.
- An advisory group has informed the review from its initiation. The research protocol was informed by comments received from the advisory group and the advisory group has reviewed and commented on the final report.

- The review brings together the evidence for the clinical effectiveness and cost-effectiveness of long-term weight management schemes for adults who are overweight or obese. This evidence has been critically appraised and presented in a consistent and transparent manner.

In contrast, this review also has certain limitations:

- Synthesis of the included studies was through narrative review. Although 12 studies were included in the review of clinical effectiveness, differences in the interventions meant that meta-analysis was inappropriate.
- No cost effectiveness or cost-effectiveness studies were found which met our full inclusion criteria and we therefore took a pragmatic approach to discuss two studies that met many of the attributes our review was looking for. Caution is therefore required in the interpretation of our results in terms of cost-effectiveness.
- Searches were limited to the English language. Therefore, we may have omitted non-English language, but otherwise includable, studies from our review.
- Many studies were excluded from our review because they either did not include a behavioural therapy element or they reported that there was a behavioural element but did not provide any details of how this was implemented. Although we attempted to contact authors of a number of studies to try to ascertain further details, this was unproductive. It may be that there are other studies with a long-term view of a weight management intervention that we were therefore unable to include. However, it is also apparent that the term 'behavioural' appears to be used in many situations to mean that a study aimed to change behaviours, but that this was as a result of the diet and/or exercise intervention components rather than of a specific behavioural therapy. It is unclear whether this is the case in any of these situations.

## Need for further research

There have been a number of RCTs of multicomponent weight management interventions, and despite a number of differences between the many studies, there does appear to be some degree of success in general. It is uncertain whether any one particular intervention is best; however, the results of our review suggest that the TOHP intervention<sup>70,74</sup> may be useful for testing further in a UK population. If any future RCT takes place, then replicating the intervention used in the TOHP study should be considered.

As most interventions succeeded in short-term weight loss, more research into the most appropriate long-term support to improve long-term maintenance of weight loss is required. Researchers should consider the Medical Research Council framework for developing evaluations of complex interventions<sup>97</sup> and the National Obesity Observatory standard evaluation framework for weight management interventions<sup>98</sup> when they design their studies.

There is a need for information on barriers to and facilitators of weight change in weight management interventions to be reported and, if possible, evaluated in clinical trials. As well as providing useful evidence on individual factors associated with greater or lesser weight change, such information could assist understanding of which of its components a multicomponent intervention should focus on.

There is a need for better reporting of behaviour therapy interventions, in terms of clear details of the techniques used, theoretical model, the format, setting and provider.<sup>62</sup> Authors of studies should more critically consider the reproducibility of their interventions. A taxonomy of a variety of behaviour change techniques has been devised and tested, to facilitate a common classification

by intervention providers and researchers.<sup>57</sup> It would be advantageous for future evaluations to employ such a system in the reporting of interventions to facilitate a greater understanding of the specific components of interventions associated with effective health-related behaviour change.

An economic model for weight management interventions is needed for the UK NHS that includes a complete explanation of model structure, assumptions and data inputs. This model should be based upon evidence of the intervention effect, from an RCT or systematic review, with UK-relevant data inputs, particularly with regard to costs.

## Chapter 6

### Conclusions

Weight management interventions were generally shown to promote weight loss in overweight or obese adults. Weight changes were small, however, and weight regain was common in those studies that measured it longer term. There were few similarities between the included studies that mean that interpretation of the results is difficult to make overall. Weight management interventions appear to be a cost-effective option, although caution is required as there were a number of limitations to the two cost-evaluation studies described here, not least that neither study met the full inclusion criteria of our review in terms of length of follow-up. There were no UK-based RCTs included in the review and as such there is a research need to evaluate the effects of long-term multicomponent weight management interventions in a UK setting.





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### Contributions of authors

E Loveman (Senior Research Fellow) developed the research protocol, drafted the background section, assisted in the development of the search strategy, assessed studies for inclusion, extracted data from and quality assessed included studies, synthesised evidence, drafted and edited the final report, and project managed the study; G Frampton (Research Fellow) drafted the background section, assessed studies for inclusion, extracted data from and quality assessed included studies, synthesised evidence, drafted the final report; J Shepherd (Principal Research Fellow) drafted the background section, assessed studies for inclusion, extracted data from and quality assessed included studies, synthesised evidence, drafted the final report; J Picot (Research Fellow) drafted the background section, assessed studies for inclusion, extracted data from and quality assessed included studies, synthesised evidence, drafted the final report; K Cooper (Senior Research Fellow), assessed studies for inclusion, extracted data from and quality assessed included studies, synthesised evidence, drafted the report; J Bryant (Principal Research Fellow) developed the research protocol, assessed studies for inclusion, extracted data from and quality assessed included studies, synthesised evidence, drafted the report; K Welch developed the search strategy, undertook literature searches and edited the final report; and A Clegg (Professor/Director of SHTAC) developed the research protocol, drafted and edited the final report and acted as guarantor.



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## Appendix 1

# Methods from the research protocol and commissioning brief (scope) for project

### **Report methods for the synthesis of clinical- and cost-effectiveness evidence**

A review of the evidence for clinical effectiveness and cost-effectiveness will be undertaken systematically following the general principles outlined in CRD Report Number 4 (2nd Edition) *Undertaking Systematic Reviews of Research on Effectiveness*.<sup>99</sup>

### **Search strategy**

The search strategies will be devised and tested by an experienced information scientist. The strategies will be designed to identify (i) clinical effectiveness studies reporting on comparisons between different adult weight management schemes, and comparisons between adult weight management schemes and normal practice; and (ii) studies reporting on the costs and cost-effectiveness of different adult weight management schemes.

The following electronic databases will be searched: MEDLINE; EMBASE; PREMEDLINE In-Process & Other Non-Indexed Citations; the Cochrane Library including the Cochrane Systematic Reviews Database, Cochrane Controlled Trials Register, DARE, NHS EED and HTA databases; Web of Knowledge Science Citation Index; Web of Knowledge ISI Proceedings; PsycINFO; CRD; BIOSIS.

Searches will be carried from database inception to current date and will be limited to the English language. All searches will be updated when the draft report is under review, prior to submission of the final report.

Bibliographies of related papers will be assessed for relevant studies where possible.

Members of an expert advisory group will be asked to review the adequacy of the searches and to indicate whether they are aware of any additional published or unpublished evidence.

### **Inclusion and exclusion criteria**

#### **Population**

- Adults ( $\geq 18$  years) classified as overweight or obese, i.e. people with a BMI of  $\geq 25$  kg/m<sup>2</sup> and  $\geq 30$  kg/m<sup>2</sup>, respectively.
- Studies in children and people with eating disorders will not be included, nor will studies specifically in people with a pre-existing medical condition such as diabetes, heart failure, uncontrolled hypertension or angina.

#### **Intervention**

- Structured, sustained multicomponent weight management programmes (i.e. the intervention must be a combination of diet and physical activity with a behaviour change strategy to influence lifestyle).

- Components of the programme have to be clearly specified (i.e. details of the diet, behavioural definition, exercise component details).
- Programmes include a long-term follow up of more than 18 months.
- The programme may be delivered by the health sector, in the community or commercially.
- Multicomponent programmes that involve the use of OTC medicines that are licensed in the UK for overweight or obesity will be included. Programmes that involve non-OTC drug therapies or surgery for obesity will not be included.
- Interventions incorporating other lifestyle changes such as efforts at smoking cessation or reduction of alcohol intake will not be included.

### Comparators

- Normal practice (defined).
- Single component weight management strategies.
- Other structured multicomponent weight management programme.

### Outcomes

- The main outcome of included studies must be explicitly stated as a measure of weight loss. Initial weight loss and maintenance of weight loss will be expressed as weight change (e.g. kilograms, BMI kg/m<sup>2</sup>) either reported or calculated from reported baseline weight.
- Studies must report more than 18 months' follow-up to be included.
- Data will also be extracted on the following outcomes where reported in the included studies: success rates at more than 18 months' attrition rates at more than 18 months, barriers and facilitators of weight loss and maintenance of weight loss.
- Outcomes of cost-effectiveness studies will be costs, benefits in terms of weight loss and cost-effectiveness.

### Types of studies

- For the systematic review of clinical effectiveness RCTs will be included.
- For the systematic review of cost-effectiveness study types will include full cost-effectiveness analyses, cost–utility analyses, cost–benefit analyses and cost–consequence analyses.
- Studies published as abstracts or conference presentations will only be included if sufficient details are presented to allow an appraisal of the methodology and the assessment of results to be undertaken.
- Case series, case studies, cohort studies, narrative reviews, feasibility studies, editorials and opinions will not be included.
- Systematic reviews will be used as a source of references.
- Non-English language studies will be excluded.

## **Reference screening, data extraction, and quality assessment process**

### Reference screening strategy

The titles and abstracts of studies identified by the search strategy will be assessed for potential eligibility using the inclusion/exclusion criteria detailed above. This will be performed by two reviewers. Full papers of studies that appear potentially relevant will be requested for further assessment. These will be screened by two reviewers and a final decision regarding inclusion will be agreed. At each stage, any disagreements will be resolved by discussion, with involvement of a third reviewer where necessary.

### Data extraction strategy

Data will be extracted by one reviewer using a standardised data extraction form. A second reviewer will independently check extracted data. Discrepancies will be resolved by discussion, with involvement of another reviewer when necessary.

### Quality assessment strategy

The quality of the clinical effectiveness studies will be assessed according to criteria based on CRD (University of York) criteria.<sup>99</sup> Economic evaluations will be assessed using criteria recommended by Drummond and colleagues,<sup>66</sup> and/or the format recommended and applied in the CRD NHS Economic Evaluation Database (using principles outlined in the NHS EED Handbook<sup>100</sup>). For any studies based on decision models the checklist for assessing good practice in decision analytic modelling will be used (Philips and colleagues<sup>65</sup>).

The quality of the individual studies will be assessed by one reviewer, and independently checked by a second reviewer. Any disagreements will be resolved by consensus, and if necessary a third reviewer will be consulted.

### Methods of data analysis/synthesis

Studies will be synthesised through a narrative review with tabulation of results of included studies. Where possible the results from individual studies will be synthesised through meta-analysis, with causes of heterogeneity of results examined. The specific methods for meta-analysis and for the detection and investigation of heterogeneity will depend upon the summary measure selected. When head-to-head randomised evidence is limited or unavailable, mixed-treatment comparison (MTC) is increasingly being used to inform clinical decision making.<sup>101,102</sup> MTC is an extension of traditional, pair-wise, meta-analysis.<sup>103</sup> A statistical analysis of the network of trial evidence is used to produce comparable estimates of effectiveness for a range of treatments. Where limited or no direct evidence of the relative effectiveness of the interventions is identified, a MTC will be considered. This will consider RCTs of weight management programmes that include a common comparator. Data on weight loss will be extracted from the clinical trials and a network of evidence constructed. Heterogeneity and consistency between included trials will be assessed before conducting the analysis. Fixed and random treatment effects will be considered. Sensitivity and subgroup analyses will be undertaken where appropriate.

Information on barriers and facilitators to weight loss will be summarised through narrative overview only.

### Commissioning brief: the effectiveness and cost-effectiveness of weight management schemes for adults

Research question:

- What is the comparative effectiveness and cost-effectiveness of different weight management schemes for adults?
  - *Technology*: weight management schemes that combine dietary and other approaches (whether delivered by the health sector or commercially).
  - *Population group*: overweight or obese adults.
  - *Setting*: OECD countries or settings with relevance to the UK.
  - *Control or comparator treatment*: normal practice.
  - *Design*: evidence synthesis, to include: (1) systematic review of the effectiveness of individual programmes' approaches to losing weight; (2) systematic review of direct comparisons of their effectiveness with statistical modelling for indirect comparisons; (3) researchers should explore the effects of barriers and facilitators to weight management (e.g. determinants of compliance); and (4) researchers should identify the key recommendations for future primary evaluation research. The HTA programme is also interested in longer-term QoL and health outcomes and would welcome ideas on exploring the feasibility of modelling these.

- *Outcomes*: both weight loss and maintenance of weight loss are of interest. Other outcomes to consider include duration of follow-up; attrition/success rates at 1 year or longer; cost of the intervention per unit of weight lost.

#### **Background to commissioning brief:**

Obesity affects at least 300 million people worldwide. In the UK, levels of obesity have trebled in the past 20 years to 25% of adults. Projections suggest that unless urgent and effective action is taken, by 2010 almost 30% of UK adults will be obese.

A huge amount of time and effort is spent on a variety of programmes to help people lose weight and maintain weight loss. Evidence about the effectiveness and cost-effectiveness of the approaches underpinning such programmes is lacking.

The Department of Health has an interest and has requested this piece of work from the HTA programme. Research is therefore required, in the form of evidence synthesis, comparing different weight management approaches to identify the most effective way of losing weight and maintaining weight loss. (The place of drugs in helping people lose weight is not part of this vignette.)



## Appendix 2

# Sources of information and search terms

A list of all databases searched for the systematic review, as well as searches for ongoing trials is presented below.

Database searched	Clinical effectiveness searches	Cost-effectiveness searches
BIOSIS (via Web of Science)	All available years	All available years
Cochrane	Searched 8 December 2009	Searched 22 December 2009
Centre for Reviews and Dissemination	Searched 8 December 2009	Searched 22 December 2009
EMBASE	All available years	All available years
MEDLINE	1950–2009	1950–2009
MEDLINE In-Process & Other Non-Indexed Citations	Searched 8 December 2009	Searched 22 December 2009
NHS Economic Evaluation Database	N/A	Searched 22 December 2009
PsychINFO	All available years	N/A
Web of Science: Conference Proceedings Citation Index	1990–2009	1970–2009
Web of Science: Science Citation Index	1990–2009	1970–2009

N/A, not applicable.

### Searched for ongoing trials

UK Clinical Research Network portfolio; controlled-trials multiple register (includes the International Standard Randomised Controlled Trial Number Register, National Institutes of Health, ClinicalTrials.gov, Action Medical Research, Medical Research Council, NHS Health Technology Assessment, Wellcome Trust, UK Clinical Trials Gateway); World Health Organization, International Clinical Trials Registry Platform; Australian New Zealand Clinical Trials Registry; GSK Clinical Trial Register.

### Clinical effectiveness

The MEDLINE search strategy for the clinical effectiveness section was adjusted as necessary for cost-effectiveness searches and other electronic database searches. Search strategies for the systematic review are available from the authors on request.

### MEDLINE search strategy

1. exp Obesity/or exp Obesity, Morbid/ (90,428)
2. exp weight gain/ (15,851)
3. Overweight/ (3101)
4. (overweight or over weight or overeat\* or over eat\* or overfeed\* or over feed\*).ti,ab. (19924)
5. (weight adj1 gain\*).ti,ab. (31,017)
6. obes\*.ti,ab. (96,808)
7. or/1-6 (162,369)
8. (modific\* or therap\* or intervention\* or strateg\* or program\* or management or scheme\* or group\* or pathway\*).ti,ab. (3,985,663)
9. (weight adj1 los\*).ti,ab. (36,353)
10. (weight adj1 reduc\*).ti,ab. (6674)

11. exp weight loss/ (18,198)
12. 8 and (9 or 10 or 11) (24,208)
13. Obesity/dh, pc, th [Diet Therapy, Prevention & Control, Therapy] (17,839)
14. Obesity, Morbid/pc, dh, th [Prevention & Control, Diet Therapy, Therapy] (630)
15. 8 and (13 or 14) (8782)
16. Diet Therapy/ (8676)
17. Diet, Fat-Restricted/ (1984)
18. Diet, Reducing/ (7805)
19. Dietetics/ed, mt (1228)
20. (diet or diets or dieting).ti,ab. (170,996)
21. (low calorie or hypocaloric or calorie control\*).ti,ab. (2549)
22. (health\* adj1 eating).ti,ab. (1335)
23. (diet\* adj2 (modific\* or therapy or intervention\* or strateg\* or program\* or management or scheme\*)).ti,ab. (10,919)
24. (nutrition adj2 (modific\* or therapy or intervention\* or strateg\* or program\* or management or scheme\*)).ti,ab. (3939)
25. Weight Watchers.ti,ab. (46)
26. slimming world.ti,ab. (2)
27. "lighterlife".ti,ab. (0)
28. or/16-27 (191,002)
29. 8 and 28 (88,245)
30. exp exercise/ (46,280)
31. exercise therapy/ (18,044)
32. (exercise and (therapy or activity or class\* or program\* or group\* or session\* or scheme\*)).ti,ab. (62,959)
33. (Gym and (trainer\* or therap\* or activit\* or class\* or program\* or group\* or session\* or scheme\* or club\*)).ti,ab. (157)
34. (walk\* or step\* or jog\* or run\*).ti,ab. (391,392)
35. (aerobic\* or physical therap\* or physical activit\*).ti,ab. (74,788)
36. (fitness adj (class or regime\* or program\* or group\* or session\* or scheme\*)).ti,ab. (522)
37. (reduc\* adj2 sedentary behavio?r).ti,ab. (33)
38. (dance and (therap\* or activit\* or class\* or program\* or group\* or session\* or scheme\*)).ti,ab. (615)
39. personal trainer\*.ti,ab. (27)
40. gym.mp. or gyms.ti,ab. [mp = title, original title, abstract, name of substance word, subject heading word] (321)
41. or/30-40 (533,389)
42. 8 and (30 or 31 or 34 or 35) (199,653)
43. 32 or 33 or 36 or 37 or 38 or 39 or 40 or 42 (238,474)
44. cognitive therapy/ (8971)
45. Counseling/ (22,190)
46. behavior therapy/ (19,855)
47. cognitive therapy/ (8971)
48. behavio?ral intervention\*.ti,ab. (2688)
49. (change\* adj2 lifestyle\*).ti,ab. (3214)
50. (changing adj2 lifestyle\*).ti,ab. (169)
51. (lifestyle adj2 modif\*).ti,ab. (1993)
52. Hypnosis/ (7452)
53. Counseling/ (22,190)
54. (counseling or counselling).ti,ab. (11,969)
55. or/44-54 (72,017)
56. Randomised Controlled Trials as Topic/ (59,060)

57. randomised controlled trial.pt. (266,956)
58. controlled clinical trial.pt. (78,767)
59. Controlled Clinical Trial/ (78,767)
60. placebos/ (27,688)
61. random allocation/ (63,466)
62. Double-Blind Method/ (100,248)
63. Single-Blind Method/ (12,666)
64. (random\* adj2 allocat\*).tw. (14,022)
65. placebo\*.tw. (114,670)
66. ((singl\* or doubl\* or trebl\* or tripl\*) adj (blind\* or mask\*)).tw. (97,304)
67. Research Design/ (55,162)
68. ((random\* or control\*) adj5 (trial\* or stud\*)).tw. (340,615)
69. Clinical Trials as Topic/ (141,960)
70. randomly.ab. (128,769)
71. (randomised or randomised).ab. (211,527)
72. Evaluation studies as topic/ (118,080)
73. comparative study/ (1,422,290)
74. (matched communities or matched populations).mp. (105)
75. (control\* adj (trial\* or stud\* or evaluation\*)).mp. (474,265)
76. (comparison group\* or control\* group\*).mp. (192,124)
77. Matched-Pair Analysis/ (3158)
78. matched pair\*.ti,ab. (3780)
79. Meta-Analysis/ (20,524)
80. meta analy\*.ti,ab. (23,386)
81. "Outcome Assessment (Health Care)"/ (31,921)
82. outcome stud\*.ti,ab. (4109)
83. intervention studies/ (3959)
84. follow up studies/ (377,220)
85. (systematic\* adj (review\* or methodolog\* or research\* or search\*)).ti,ab. (20,137)
86. ((hand or manual or computer or electronic or database) and search\*).ti,ab. (27,863)
87. (hand adj search\*).ti,ab. (2016)
88. (medline or embase or Cochrane or cinahl or psychlit or psychinfo or scisearch or pubmed).  
ab. (34,073)
89. Health technology assessment\*.ab,in. (801)
90. (pooled adj analys\*).ti,ab. (1661)
91. (electronic\* adj search\*).ti,ab. (1108)
92. (synthes\* adj5 (literature\* or research\* or studies or data)).ti,ab. (18,568)
93. or/56-92 (2,647,287)
94. 12 or 15 (28,964)
95. 7 and 93 and 94 (6560)
96. 7 and 28 and 93 (9785)
97. 7 and 29 and 93 (6480)
98. 7 and 41 and 93 (5762)
99. 7 and 43 and 93 (4440)
100. 7 and 55 and 93 (1554)
101. 96 or 98 or 100 (14,089)
102. 97 or 99 or 100 (9844)
103. 96 and 98 and 100 (395)
104. 96 and 98 (2040)
105. 96 and 100 (677)
106. 98 and 100 (690)
107. 104 or 105 or 106 (2617)

108. 97 and 99 (1728)
109. 97 and 100 (628)
110. 99 and 100 (654)
111. 108 or 109 or 110 (2250)
112. 103 or 107 or 111 (2617)
113. Anti-Obesity Agents/ (1742)
114. (sibutramine or orlistat or rimonabant).ti,ab,nm. (2771)
115. exp Bariatric Surgery/ (7820)
116. exp obesity/su (5586)
117. 113 or 114 or 115 or 116 (13,194)
118. 112 not 117 (2410)
119. limit 118 to (english language and humans) (2137)
120. limit 119 to (“all infant (birth to 23 months)” 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)”) (360)
121. 119 not 120 (1777)
122. (editorial or comment or letter).pt. (936,062)
123. 121 not 122 (1766)
124. from 123 keep 1-1000 (1000)
125. from 123 keep 1001-1766 (766)

### **Reference lists**

Reference lists of retrieved articles and reviews were hand searched for additional references.

### **Other searches**

Where possible, authors and relevant experts were contacted in order to obtain information about further references, missing data and any ongoing trials.

## **Appendix 3**

### **Inclusion criteria worksheet for full papers**

First author and reference ID:				Comments/flags
<b>Participants</b>				
Participants classified as overweight or obese (BMI $\geq 25$ or $\geq 30$ kg/m <sup>2</sup> )?	Yes ↓ Next question	Unclear ↓ Next question	No → EXCLUDE	
<i>Note: exclude eating disorders, focus on pre-existing medical condition</i>				
Participants described as 'adults'	Yes ↓ Next question	Unclear ↓ Next question	No → EXCLUDE	Note if mixture children/adults
<i>Note: exclude those &lt; 18 years</i>				
<b>Design</b>				
RCT or systematic review/meta-analysis?	Yes ↓ Next question	Unclear ↓ Next question	No → EXCLUDE	Abstract? Any cost-effectiveness studies? Systematic review?
If abstract only needs to have sufficient information				
<b>Outcomes</b>				
Report one or more of <i>primary outcomes</i> : weight loss, weight change, BMI change from reported baseline weight?	Yes ↓ Next question	Unclear ↓ Next question	No → EXCLUDE	Any cost outcomes?
<i>Note: other outcomes will also be included if primary outcomes reported</i>				
<b>Intervention</b>				
Multicomponent programme?	Yes ↓ Next question	Unclear ↓ Next question	No → EXCLUDE	
<i>Note: must contain a diet, physical activity, or behaviour change strategy.<sup>a</sup> Over the counter drug therapy acceptable. Other drug treatments, surgery, or other lifestyle changes exclude</i>				
Comparator of normal practice (defined), single component programme or other structural multicomponent programme?	Yes ↓ Next question	Unclear ↓ Next question	No → EXCLUDE	
Components clearly specified?				
Diet	Yes ↓ Next question	Unclear ↓ Next question	No	Any linked references with likely detail of intervention:
Exercise	Yes ↓ Next question	Unclear ↓ Next question	No	
Behavioural	Yes ↓ Next question	Unclear ↓ Next question	No	
Follow-up for > 18 months from point of randomisation?	Yes ↓ Next question	Unclear ↓ Next question	No → EXCLUDE	Length of follow-up?
Final decision	INCLUDE	UNCLEAR (Discuss)	EXCLUDE	Results of discussion:

a The behavioural change element may be difficult to establish, the default option if unclear is to discuss. Types of interventions may include self-monitoring approaches, problem analysis approaches, alteration of behaviour and/or cognition from 'behavioural therapy', or 'cognitive behavioural therapy' (such as cognitive reframing, coping imagery, use of positive statements, approaches to prevent relapse, goal-setting, menu planning, stimulus control, diary use, self-monitoring, motivation building, reinforcement, self-control, behavioural modification). We're not looking at psychotherapy, psychodynamic therapy, or counselling (although dietary or exercise 'counselling' may fulfil the criteria for the other components).

## Appendix 4

### Quality assessment criteria

**Quality criteria** – modified from the Centre for Reviews and Dissemination (CRD) report 4<sup>99</sup>

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1. Was the method used to generate random allocations adequate?
  2. Was the allocation adequately concealed?
  3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?
  4. Were outcome assessors blinded to the treatment allocation?
  5. Was the care provider blinded?
  6. Was the participant blinded?
  7. (i) Were there any unexpected imbalances in dropouts between groups?  
(ii) If so, were they explained or adjusted for?
  8. Is there any evidence to suggest that the authors measured more outcomes than they reported?
  9. (i) Did the analysis include an intention to treat analysis?  
(ii) If so, was this defined?
  10. (i) Did the analysis account for missing data?  
(ii) If so, were the methods appropriate?
- 

Answer yes/no/not reported/unclear.

Note: only answer part (ii) of a question if the answer to part (i) is yes.





# Appendix 5

## Data from included studies

Studies are listed alphabetically.

### Burke et al.

Study details	Participants	Outcome measures
<p>Author: Burke <i>et al.</i><sup>71</sup> (Burke <i>et al.</i><sup>104</sup>)</p> <p>Year: 2008</p> <p>Country: USA</p> <p>Study design: RCT</p> <p>Number of centres: one</p> <p>Funding: National Institutes of Health, Center for Research in Chronic Disorders, Obesity and Nutrition Research Center, Heinz Nutrition Laboratory, General Clinical Research Center, University of Pittsburgh</p> <p>Recruitment dates: three cohorts recruited between September 2002 and May 2004</p> <p>Setting: university</p> <p>Length of follow-up: 18 months</p>	<p>Number of participants randomised: 200</p> <p>Intervention 1 – preference for standard diet (pref STD-D) (<math>n=48</math>)</p> <p>Intervention 2 – preference for lacto-ovo-vegetarian diet (pref LOV-D) (<math>n=35</math>)</p> <p>Intervention 3 – no preference for standard diet (no pref STD-D) (<math>n=48</math>)</p> <p>Intervention 4 – no preference for lacto-ovo-vegetarian diet (no pref LOV-D) (<math>n=45</math>)</p> <p>Sample attrition/dropout: 44 were lost to follow-up or dropped out of the groups as follows:</p> <p>pref STD-D – 12</p> <p>pref LOV-D – 7</p> <p>no pref STD-D – 14</p> <p>no pref LOV-D – 11</p> <p>Plus 15 ‘discarded’ from intervention one, and nine excluded after becoming ineligible following randomisation. Total attrition rate was 68 (34%)</p> <p>Attendance at sessions measured: yes</p> <p>Other measures of adherence: yes</p> <p>Sample crossovers: none</p> <p>Inclusion criteria for study entry:</p> <p>Age 18–55 years, BMI of 27–43 kg/m<sup>2</sup>, willingness to be randomised to one of two treatment preference conditions and one of two dietary conditions, successful completion of a 5-day food diary, willingness and ability to provide informed consent</p> <p>Exclusion criteria for study entry: current medical condition requiring physician supervision of diet or physical activity, physical limitation restricting exercise ability, pregnancy or intention to become pregnant during the study, current treatment with a medication that might affect weight, alcohol intake &gt; 4 drinks/day, participation in a weight loss programme or use of weight loss medication in past 6 months, abstinence from eating meat, poultry or fish in the past month</p> <p>Characteristics of participants:</p> <p>Gender, M:F, <math>n</math> (%): pref STD-D – 6 (12.5): 42 (87.5); pref LOV-D – 7 (20): 28 (80); no pref STD-D – 6 (12.5): 42 (87.5); no pref LOV-D – 4 (9): 41 (91)</p> <p>Age (years), mean (SD): pref STD-D – 43.2 (9.4); pref LOV-D – 44.3 (8.4); no pref STD-D – 43.2 (8.4); no pref LOV-D – 43.2 (8.6)</p> <p>Ethnicity – white:non-white, <math>n</math> (%): pref STD-D – 34 (71): 14 (29); pref LOV-D – 25 (71): 10 (29); no pref STD-D – 34 (71): 14 (29); no pref LOV-D – 31 (69): 14 (31)</p> <p>Paffenbarger Activity Questionnaire (kilocalories expended/week), mean (SD) 1942.20 (2291.78)<sup>a</sup></p> <p>BMI kg/m<sup>2</sup>, mean (SD): pref STD-D – 34.5 (3.9); pref LOV-D – 34.1 (3.5); no pref STD-D – 32.9 (4.1); no pref LOV-D – 33.7 (4.3)</p> <p>Weight (kg), mean (SD): pref STD-D – 97.2 (12.9); pref LOV-D – 96.7 (12.1); no pref STD-D – 92.4 (16.1); no pref LOV-D – 91.8 (15.4)</p>	<p>Primary outcomes: change in body weight from baseline to 18 months</p> <p>Secondary outcomes: BMI, high- and low-density lipoprotein cholesterol, triglycerides, glucose levels, insulin levels, BP, waist circumference</p> <p>Facilitators and barriers: Barriers to Healthy Eating Scale (22-item questionnaire), Correlates of Maintenance to a Low-Fat Diet (25-item scale), Hunger Satiety Scale (6-item), Self-Efficacy in Weight Management (measures of adherence)</p> <p>Methods of assessing outcomes: weight measured on the Tanita Digital Scale. Height measured on a wall mounted stadiometer</p>

Baseline data are provided for the following factors, but have not been extracted here: low- and high-density lipoprotein cholesterol, triglycerides, glucose levels, insulin levels, BP, waist circumference, Beck Depression Inventory-II scores, physical and psychological function scores, hunger satiety, weight efficacy lifestyle scores, employment status, educational attainment, marital status, total energy, total fat, carbohydrates, animal protein, vegetable protein and fibre

Comorbid conditions, *n* (%):<sup>b</sup> coronary heart disease – 2 (1.0); hypertension – 48 (26.4); elevated cholesterol – 35 (19.2); history of emotional/psychological problems – 11 (6.0)

% weight lost before starting: not reported

### The PREFER study

Aim or goal: weight loss phase (up to 12 months) based on standard weight loss treatment goal of 1–2 lb per week. Weight maintenance phase (months 13–18)

Study hypothesis is that choice of either a standard calorie and fat-restricted diet (STD-D) or a calorie- and fat-restricted (LOV-D) would result in greater weight loss compared with having one of these diets randomly assigned. Secondary hypothesis is LOV-D results in greater weight loss than STD-D

### Intervention details

#### Randomised group 1 – dietary preference

##### Participants choose between STD-D and LOV-D

##### No pref STD-D

(*n* = 48)

*Diet:*

*Details, type of diet:* calorie and fat restriction

*Calories:* reduce maximum daily calorie intake to 1200 kcal (women) 1500 kcal (men) for those weighing < 90.5 kg at baseline; 1500 kcal (women) 1800 kcal (men) for those weighing > 90.5 kg at baseline. Minimum daily intake was 1000 kcal

*Proportions of diet:*

Reduce fat intake to 25% of total kilocalorie intake, but not less than 10% fat

*Monitoring:* participants recorded their calorie and fat content of foods eaten in a weekly diary. At each session a new diary was provided and completed diaries were collected and returned at the next session after interventionists reviewed and annotated the diaries

*Exercise:*

*Mode:* instruction to exercise given during group meetings, with the actual exercise to be done individually

*Type:* mostly walking

*Frequency and length of each session and total number sessions:* participants encouraged to walk at least 50 minutes per week initially, gradually increasing to at least 150 minutes per week by week 6

##### No pref LOV-D

(*n* = 45)

*Diet:*

*Details, type of diet:* calorie and fat restriction, and elimination of meat, poultry and fish consumption by the sixth week. Participants were instructed to eliminate these foods at breakfast, then lunch, then dinner and to record in their diaries when they ate meals containing these foods. Four sessions by a vegetarian nutritionist who advised participants on how to adopt the eating plan as well as including family members. Otherwise the content and behavioural strategies taught were the same as intervention 1

#### Randomised group 2 – no dietary preference

##### Participants randomised to STD-D and LOV-D

##### STD-D

(*n* = 48)

*Diet:*

As intervention 1

*Exercise:*

As intervention 1

*Behaviour modification:*

As intervention 1

*Ongoing support:*

As intervention 1

##### LOV-D

(*n* = 35)

*Diet:*

As intervention 2

*Exercise:*

As intervention 1

*Behaviour modification:*

As intervention 1

*Ongoing support:*

As intervention 1

<p><i>Delivered:</i> exercise physiologist</p> <p><i>Level of supervision:</i> not reported</p> <p><i>Monitoring:</i> daily recording of exercise in diaries, as above under 'diet'</p> <p><i>Behaviour modification:</i></p> <p><i>Mode:</i> group, 10–20 participants</p> <p><i>Type:</i> standard cognitive behaviour therapy. Based on several models of motivation and behavioural change, such as Social Cognitive Theory</p> <p><i>Content:</i> environmental modification, problem solving, modelling, relapse prevention, goal-setting, self-monitoring, self-reinforcement, cognitive restructuring, stimulus control, social assertion, and skill development. A cooking class and shopping tour was also given</p> <p><i>Frequency and length of each session and total number sessions:</i> 32 treatment sessions (lasting 60 minutes) over 12 months. Sessions held in the evening weekly for first 6 months, then every 2 weeks for months 7–9 and monthly for months 10–12</p> <p><i>Delivered:</i> master's prepared dietitian, exercise physiologist, or nurse behavioural scientist. Intervention manuals provided to ensure integrity of protocol</p> <p><i>Ongoing support:</i></p> <p>None. After 12 months the maintenance phase began and no further contact was made with participants until the final 18 month assessment</p> <p><i>Other details:</i></p> <p>Participants received <i>Cooking Light</i> magazine as an incentive</p>	<p><i>Calories:</i> as intervention 1</p> <p><i>Proportions of diet:</i> as intervention 1</p> <p><i>Monitoring:</i> as intervention 1</p> <p><i>Exercise:</i></p> <p>As intervention 1</p> <p><i>Behaviour modification:</i></p> <p>As intervention 1</p> <p><i>Ongoing support:</i></p> <p>As intervention 1</p> <p><i>Other details:</i></p> <p>Participants received <i>Vegetarian Times</i> magazine as an incentive</p>
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- a Only mentioned in relation to food diary data entered into the Nutrition Data System-Research software as a measure of adherence.
- b Based on a baseline sample of 182 participants (all randomised groups combined) as reported in Burke and colleagues.<sup>105</sup> (Note: this is a different denominator to the  $n=176$  for whom baseline data were presented in Burke and colleagues.<sup>71</sup>)

## Results

Outcomes	Pref STD-D ( $n=48$ )	Pref LOV-D ( $n=35$ )	No pref STD-D ( $n=48$ )	No pref LOV-D ( $n=45$ )	$p$ -value, 95% CI
% weight change (baseline to 18 months), mean (SD)	-3.9 (6.1)	-5.3 (6.2)	-8.0 (7.8)	-7.9 (8.1)	0.30
Maintenance of weight loss					
Weight change (baseline to 12 months), kg <sup>a</sup>	-7.6	-7.9	-9.7	-9.7	
Weight change (12–18 months maintenance phase), kg <sup>a</sup>	+2.9	+3.3	+2.4	+1	
% change in BMI kg/m <sup>2</sup> , mean (SD)	-3.9 (5.9)	-4.5 (7.4)	-7.8 (7.9)	-7.9 (8.2)	Not reported for between group comparisons
Other intermediate outcomes	<p>Between months 6 and 18 there was a significant difference in weight regain between preference groups. Participants who chose their diet (i.e. pref STD-D or pref LOV-D) regained 4.5% (95% CI -5.8 to -3.2), while those with assigned diets (i.e. no pref STD-D or no pref LOV-D) regained 2.1% (95% CI -3.4 to -0.8), <math>p&lt;0.001</math></p> <p>Over time there was no preference <math>\times</math> diet interaction, <math>p=0.34</math></p> <p>Comments: results also presented for changes in cholesterol, glucose levels, insulin levels, kilocalorie consumption, fat consumption, carbohydrate consumption, animal protein consumption, vegetable protein consumption, and fibre consumption but not extracted here</p>				

- a Calculated by reviewer.

## Methodological comments/notes

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- Allocation to treatment groups: no information is given on the methods of the randomisation procedure. Two-stage randomisation process after stratification on basis of gender, ethnicity and diet preference: (i) participants were randomised to the dietary preference and no dietary preference groups in a 3:2 ratio. The choice of ratio as based on a pilot study in which 29%–34% of the participants selected the vegetarian diet. It was projected that the ratio of participants who would prefer the STD-D to the LOV-D diet would therefore be 2:1. To ensure an adequate number of participants who preferred the LOV-D in the dietary preference group a 3:2 ratio was therefore used. Those in the dietary preference group who preferred the LOV-D received this option; those who preferred the STD-D underwent a random selection process with 50% probability of being included in the study (done to obtain a fair balance in size across the four groups). This resulted in 15 randomised participants being excluded from the study due to the STD-D being oversubscribed. (ii) Participants randomised to the no preference diet group were then further randomised between the LOV-D and STD-D on a 1:1 ratio. Therefore in terms of randomised comparison of weight loss interventions only the preference groups were randomised
- Blinding: not reported except in relation to food diary data entered into the Nutrition Data System-Research software as a measure of adherence
- Comparability of treatment groups: statistically significant differences between the dietary preference and no dietary preference conditions at baseline on mean weight [98.14 kg (SD 12.7) vs 93.64 kg (SD 16.4) respectively,  $p=0.01$ ]. It is also mentioned that cholesterol differed between preference groups. Both weight and cholesterol were included in the mixed model as a covariate (see below). No significant differences were reported for demographic variables
- Method of data analysis: outcomes were assessed at 6, 12 and 18 months. Analysis of variance (ANOVA), Kruskal–Wallis test, chi-square analysis and Fisher's exact test were used to compare preference groups (yes/no), diet groups and their combinations on participant characteristics and response variables at baseline. Mixed models were estimated for each outcome using the restricted maximum likelihood method. The effects included in the mixed model included fixed effects for diet, preference, time and their interactions and a random effect for participant and cohort
- ITT analysis: states that an ITT analysis was to be conducted which would include all randomised participants. In actuality the analysis excludes 24 of the randomised population (15 who were excluded from the STD-D subgroup of the dietary preference intervention, and nine who were excluded because they no longer met the eligibility criteria). Participants who dropped out over the course of the intervention were retained in the analysis. Mentions that missing data were handled through maximum likelihood estimation using all available data
- Sample size/power calculation: fixed effects ANOVA indicated that 33 participants in each of the four groups would provide 80% power to detect a modest effect size for the interaction between diet and preference at a significance level of 0.05. To test the main effects of diet and preference using two-sided sample  $t$ -tests with a significance level of 0.05, 66 participants in both diet groups and both preference groups would provide 80% power to detect a 2.2 kg difference between the groups assuming a common SD of 4.4 kg
- Attrition/dropout: reasons given. No statistically significant difference among the groups in attrition rates ( $p=0.82$ ). Nine participants were excluded on the grounds of ineligibility postrandomisation that may introduce a bias

### General comments

- Generalisability: participants recruited through database of individuals seeking weight loss treatment at the Obesity Nutrition Research Centre at the University of Pittsburgh, the university and medical centre audio announcement system and direct mailing from purchased mailing lists. The results are generalisable to predominantly white, obese but otherwise healthy middle-aged women of reasonable socioeconomic status (in terms of employment, education and household income)
  - Outcome measures: none
  - Facilitators/barriers not reported as outcomes: not reported. Eligible individuals were asked their preference for the two dietary interventions prior to randomisation. For those not in their preferred intervention this may have affected their adherence to the diet (as noted by the reviewers, not the authors)
  - Intercentre variability: not applicable
  - Conflict of interests: none reported
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### Quality criteria for assessment

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1. Was the method used to generate random allocations adequate?	Unclear
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	No
4. Were outcome assessors blinded to the treatment allocation?	Unclear
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	No
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	Yes
9. (i) Did the analysis include an intention to treat analysis?	No
(ii) If so, was this defined?	
10. (i) Did the analysis account for missing data?	No
(ii) If so, were the methods appropriate?	

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**Dubbert and Wilson**

Study details	Participants	Outcome measures			
Author: Dubbert and Wilson <sup>68</sup>	Number of participants:	Primary outcomes: weight; percentage of participants overweight; percentage of body fat			
Year: 1984	Individual treatment with weekly (distal) goals: number not reported	Secondary outcomes: reported, but not stated explicitly that these were secondary outcomes; data not extracted			
Country: USA	Individual treatment with daily (proximal) goals: number not reported	Cardiovascular fitness; BP; marital satisfaction; spouse weight; spouse co-operation; body image; satisfaction; depression; aerobic fitness; binge eating			
Study design: RCT	Couples' treatment with weekly (distal) goals: number not reported	Facilitators and barriers: none reported			
Number of centres: not reported	Couples' treatment with daily (proximal) goals: number not reported	Methods of assessing outcomes: weight measured using a balance beam scale. Per cent overweight calculated from Metropolitan Life Insurance Company norms for medium frame men or women of the participants' height (reference cited). Per cent body fat estimated from skinfold sums (reference cited)			
Funding: not reported. The research was based on the first author's doctoral dissertation	Total randomised: 62	Subgroup analyses: none reported			
Recruitment dates: not reported	Sample attrition/dropout:				
Setting: not reported	Not reported separately by intervention but stated that attrition was spread evenly across the interventions				
Length of follow-up: 30 months after end of treatment (~ 34 months after randomisation)	Completed treatment: overall 47 (75.8%)				
	Completed 30-month follow-up: overall 45 (72.6%)				
	Attendance at sessions measured: yes				
	Other measures of adherence: yes				
	Sample crossovers: none reported. However, the authors observed from questionnaire responses that some participants assigned daily goals reported that they were actually setting weekly goals, and vice versa (sample sizes not reported)				
	Inclusion/exclusion criteria for study entry:				
	<i>Inclusion:</i> responders to newspaper advertisements and public service announcements on local radio; married and currently living with spouse; at least 15 lb overweight (Metropolitan Life Insurance norms, US Department of Health, Education and Welfare); not more than 100% overweight; no medical problems other than obesity; not taking medications affecting appetite or weight; spouse willing to attend at least eight sessions, including four group sessions; physician consultation indicating diet, exercise and step testing were not contraindicated				
	<i>Exclusion:</i> failure to meet the above inclusion criteria; schedule conflicts (assumed to mean participants unable to attend sessions as scheduled because of other commitments); failure to complete the application				
	Characteristics of participants (sample sizes, parameter and variance estimates not reported):				
	<i>Risk factors noted:</i> none reported				
		1. Individual/distal	2. Individual/proximal	3. Group/distal	4. Group/proximal
	Weight (units not stated, assumed lb):	207.7 <sup>a</sup>	208.9 <sup>a</sup>	190.4 <sup>a</sup>	195.0 <sup>a</sup>
	Per cent overweight:	53.6 <sup>a</sup>	51.4 <sup>a</sup>	47.9 <sup>a</sup>	39.6 <sup>a</sup>
	Estimated per cent body fat:	41.2 <sup>a</sup>	42.7 <sup>a</sup>	44.0 <sup>a</sup>	41.3 <sup>a</sup>
	Age (years), mean ± SD:	Not reported	Not reported	Not reported	Not reported
	Gender, M:F (% M:F):	Overall 14:48 (23:77) (not reported separately by intervention)			
	BMI kg/m <sup>2</sup> , n (%):	Not reported	Not reported	Not reported	Not reported
	% weight lost before starting:	Not reported	Not reported	Not reported	Not reported
	Duration of overweight/obesity:	Not reported	Not reported	Not reported	Not reported
	Previous weight loss attempts:	Not reported	Not reported	Not reported	Not reported
	Physical activity level:	Not reported	Not reported	Not reported	Not reported
	Ethnicity:	Not reported	Not reported	Not reported	Not reported
	Socioeconomic position:	Not reported	Not reported	Not reported	Not reported

**Intervention details****1. Individual treatment with weekly (distal) goals: *n* not reported**

*Aim or goal:* participants to lose 1 lb weight per week and change selected eating and exercise behaviours (individually set)

*Diet:*

*Type of diet:* calorie restriction in which participants monitored, modelled and reinforced improved eating habits, adherence to self-monitoring and adherence to calorie restriction

*Frequency and length of each session and total number sessions:* as reported below for behaviour modification. Specific weekly (distal) calorie-counting prescriptions given to participants at first individual session (week 5)

*Level of supervision:* small groups supervised by 1–4 therapists but numbers of participants and therapists/group not stated

*Calories:* as for intervention 3

*Proportions of diet:* not reported

*Monitoring:* as for intervention 3

*Exercise:*

*Mode:* small groups (size not reported). Individual-based goal-setting

*Type:* as for intervention 3

*Frequency and length of each session and total number sessions:* as reported below for behaviour modification.

Prescription for exercise programme given in week 5

*Delivered:* as reported below

*Level of supervision:* as reported above for diet

*Monitoring:* weekly records of activities including type, duration and exercise heart rate

*Behaviour modification:*

*Mode:* small groups (size not reported)

*Type:* individual-based problem solving and goal-setting for weight management. No specific instructions for spouse co-operative behaviours were provided (participants attended intervention sessions alone; spouses were involved only in assessment sessions)

**2. Individual treatment with daily (proximal) goals: *n* not reported**

*Aim or goal:* same as intervention 1

*Diet:*

*Type of diet:* same as intervention 1

*Frequency and length of each session and total number sessions:* as reported below for behaviour modification. Specific daily (proximal) calorie-counting prescriptions given to participants at first individual session (week 5)

*Level of supervision:* same as intervention 1

*Calories:* as for intervention 4

*Proportions of diet:* not reported

*Monitoring:* as for intervention 4

*Exercise:*

*Mode:* as for intervention 1

*Type:* as for intervention 4

*Frequency and length of each session and total number sessions:* as for intervention 1

*Delivered:* as for intervention 1

*Level of supervision:* as for intervention 1

*Monitoring:* daily records of activities including type, duration and exercise heart rate

*Behaviour modification:*

*Mode:* same as intervention 1

**3. Couples' treatment with weekly (distal) goals: *n* not reported**

*Aim or goal:* same as intervention 1 but goals set by participant and their spouse

*Diet:*

*Type of diet:* same as intervention 4

*Frequency and length of each session and total number sessions:* as reported below for behaviour modification.

Specific weekly (distal) calorie-counting prescriptions given to participants at first couple session (week 5)

*Level of supervision:* same as intervention 1

*Calories:* participants were encouraged to set weekly calorie goals, equivalent to the weekly sums of the same number of days' calories for the proximal goal (intervention 4) (i.e. 8500 kcal for women or 10,675 kcal for men)

*Proportions of diet:* not reported

*Monitoring:* participants recorded their weight weekly; more frequent weighing was discouraged

*Exercise:*

*Mode:* As for intervention 4

*Type:* as for intervention 4 except that the flexibility of arranging activities to meet a weekly goal was emphasised instead of a daily expenditure goal

*Frequency and length of each session and total number sessions:* as for intervention 1

*Delivered:* as for intervention 1

*Level of supervision:* as for intervention 1

**4. Couples' treatment with daily (proximal) goals: *n* not reported**

*Aim or goal:* same as intervention 3

*Diet:*

*Type of diet:* calorie restriction in which spouses monitored, modelled and reinforced improved eating habits, adherence to self-monitoring and adherence to calorie restriction

*Frequency and length of each session and total number sessions:* as reported below for behaviour modification. Specific daily (proximal) calorie-counting prescriptions given to participants at first couple session (week 5)

*Level of supervision:* same as intervention 1

*Calories:* from week 5 recommended 1215 kcal/day for women or 1525 kcal/day for men. Participants were encouraged to set daily calorie goals and to divide these into subgoals for portions of the day (calorie recording forms were designed to assist this)

*Proportions of diet:* not reported

*Monitoring:* participants recorded their weight daily

*Exercise:*

*Mode:* small groups. Exercise goals were set by the participant and their spouse

*Type:* aerobic exercise walking programme with calorie monitoring in which participants monitored, modelled and reinforced improved adherence to exercise. From week 5, daily minimal caloric-expenditure goals were recommended, starting at 145 kcal/day above initial baseline (equivalent to 1.5 mile walk or 1.5 hours active housework). Goals were increased each week by 25 kcal/day (equivalent to walking 5–10 extra minutes), but only if participants met the previous week's goals on at least 4 days. In addition to calorie expenditure goals, participants were instructed to walk for at least 30 minutes on 5 days/week and to monitor their heart rate so they could exercise in the recommended range for improving fitness (70%–80% of their age-predicted heart rate) (reference cited). Adherence to the walking programme enabled participants to meet  $\geq 50\%$  of their daily caloric expenditure requirements

<p><i>Content:</i> facts about weight reduction; basic nutrition; techniques for controlling eating; safely increasing exercise; coping with negative emotions and self-defeating cognitions; asserting oneself to obtain necessary support from significant others; importance of keeping records and setting goals. Some of eating behaviour change suggestions based on existing manuals (references cited)</p> <p><i>Weeks 1–4:</i> education and goal-setting. Participants instructed to identify 1–2 eating and exercise behaviours they wanted to change, and to set goals to accomplish this. Also advised to reduce calorie intake while increasing daily activity</p> <p><i>Weeks 5–16:</i> implementation of diet, exercise and behaviour goal prescriptions. Participants received an individualised computer printout showing their progress at weeks 5, 10 and post-treatment</p> <p><i>Frequency and length of each session and total number sessions:</i></p> <p><i>Weeks 1–4:</i> 2-hour lectures and small-group discussion meetings</p> <p><i>Week 5:</i> individual sessions of 15–20 minutes duration commenced, with one/week during weeks 5–7 then fortnightly thereafter. In alternate weeks participants weighed in and their calorie records were collected</p> <p><i>Delivered:</i> by four (two male, two female) clinical psychology graduate student therapists (one experienced in behavioural weight-control treatment; three had been or were overweight)</p> <p><i>Monitoring:</i> not reported specifically for behaviour modification component</p> <p>All sessions comprised weigh-in by research assistant, review of previous week's records, new information or treatment prescriptions, problem-solving discussion concerning actual or anticipated difficulties with meeting calorie intake or expenditure goals, and distribution of new self-monitoring forms</p> <p><i>Ongoing support:</i> None reported</p>	<p><i>Type:</i> individual-based problem solving and goal-setting for weight management with limited spouse support. Same as intervention 1, except that participants were told to solicit support from their spouses and other significant others. With the exception of a brief discussion of assertiveness, no explicit directions were given as to how to get spouse support (participants attended intervention sessions alone; spouses were involved only in assessment sessions)</p> <p><i>Content:</i> same as intervention 1</p> <p><i>Frequency and length of each session and total number sessions:</i> same as intervention 1</p> <p><i>Delivered:</i> as for intervention 1</p> <p><i>Monitoring:</i> same as intervention 1</p> <p><i>Ongoing support:</i> None reported</p>	<p><i>Monitoring:</i> same as intervention 1</p> <p><i>Behaviour modification:</i></p> <p><i>Mode:</i> same as intervention 1</p> <p><i>Type:</i> same as intervention 4</p> <p><i>Content:</i> same as intervention 1</p> <p><i>Frequency and length of each session and total number sessions:</i> same as intervention 1</p> <p><i>Delivered:</i> as for intervention 1</p> <p><i>Monitoring:</i> same as intervention 4</p> <p><i>Ongoing support:</i> None reported</p>	<p><i>Frequency and length of each session and total number sessions:</i> same as intervention 1</p> <p><i>Delivered:</i> as for intervention 1</p> <p><i>Level of supervision:</i> as for intervention 1</p> <p><i>Monitoring:</i> same as intervention 2</p> <p><i>Behaviour modification:</i></p> <p><i>Mode:</i> same as intervention 1</p> <p><i>Type:</i> spouse-assisted problem solving and goal-setting for weight management. Participants and their spouses were encouraged to be inventive in applying the techniques discussed during the educational phase to meet their goals. Spouses were instructed to praise their weight-reducing partner for goal attainment and day-to-day adherence to the calorie plan and expenditure. In the presence of the participant, therapists instructed spouses to try to follow the same eating and exercise habit changes prescribed for their partner; educational materials were also provided to spouses. In the first 4 weeks spouses were asked to keep records of their own and of their weight-reducing partner's adherence. From week 5 onwards couples were asked to identify specific spouse behaviour changes which would assist the weight-reducing partner's effort</p> <p><i>Content:</i> same as intervention 1</p> <p><i>Frequency and length of each session and total number sessions:</i> same as intervention 1</p> <p><i>Delivered:</i> as for intervention 1</p> <p><i>Monitoring:</i> as for intervention 1. In addition a simple contract form was provided and spouses were encouraged to make a written as well as verbal commitment to the specified behaviour changes</p> <p><i>Ongoing support:</i> None reported</p>
<p><b>Other details</b></p> <p><i>Financial deposits/fees/incentives:</i> non-refundable US\$15 registration fee. Refundable US\$50 deposit with partial or full refunds contingent on the number of sessions and assessments attended</p> <p><i>Training/supervision of trainers:</i> therapists received 2 hours of training in behavioural weight-control techniques, including role playing interactions with participants and spouses. Throughout the programme they had regular meetings with clinical psychology faculty supervisors (timing not stated). Therapist sessions did not deviate from the treatment protocol (checked by audio-taping sessions)</p>			

a Stated differences between interventions not statistically significant; no *p*-values reported.

## Results

Outcomes (n=47)	1. Individual; distal goals (n not reported)	2. Individual; proximal goals (n not reported)	3. Couples; distal goals (n not reported)	4. Couples; proximal goals (n not reported)	p-value, 95% CI
Weight (lb) at 30 months <sup>a</sup>	200	194	176	185	Not reported
Weight (lb) change from baseline <sup>a</sup>	-7.7	-14.9	-14.4	-10	Not reported
Facilitators	None reported	None reported	None reported	None reported	None reported
Barriers	None reported	None reported	None reported	None reported	None reported
Other intermediate outcomes: not reported for 30 months	<p><i>Attendance at sessions:</i> after excluding dropouts, individual-treatment participants attended on average 16.5 (97%) of the sessions while couples-treatment participants attended 15.5 (91%) of the sessions (<i>t</i>-test, <math>p &lt; 0.05</math>). Spouses in the couples' treatment attended on average 11.9 sessions (70%)</p> <p><i>Other measures of adherence:</i> food and exercise calorie self-monitoring records (including records for dropouts) were not reported separately by intervention but indicated</p> <p>Adherence to record keeping was best during week 2 then declined and stabilised for several weeks and then declined rapidly after about week 9. Seventy-five per cent of participants in both spouse-involvement conditions reported adherence to aerobic exercise programmes during the first week but adherence declined thereafter. At 6-month follow-up only half of participants reported at least three exercise sessions/week and at 12-month follow-up exercise adherence was only slightly above pre-treatment level</p> <p>On average calorie records were kept for 10.5 of the 16 weeks</p> <p>29% of participants followed instructions to record their heart rate during exercise</p> <p>57.1% of spouses were willing to make written behaviour change contracts (i.e. a notable proportion failed to adhere formally to the goal-setting and contracting components of the couples treatment package)</p> <p>The total numbers of days for which participants recorded calorie intake and output were each significantly associated with weight change during treatment (<math>p &lt; 0.05</math>)</p>				

a Estimated by reviewer from graph (quantitative data not reported).

## Methodological comments/notes

- Allocation to treatment groups: subjects were assigned to the four interventions and to four therapists by a stratified randomisation procedure. Stated that the participants were first ranked in order of per cent overweight and that with the exception of a few (unexplained) scheduling restrictions assignments were random from each same-sex set of four individuals or couples. There were seven couples with both husband and wife participating and these were distributed among the four interventions. Also stated that subjects were then randomly assigned to four therapists. Overall, it is difficult from these descriptions to follow exactly how the randomisation process worked. No sample sizes per intervention were provided to assist interpretation
- Blinding: not reported
- Comparability of treatment groups: the groups did not differ in initial weight, proportion overweight, % body fat, or age. No other baseline characteristics were reported
- Method of data analysis: repeated measures ANOVA. Stated that analyses were performed including those who failed to complete the treatment programme (using last available weights) then with dropouts excluded, but not reported for 30 months' follow-up. The results were reported for 47 participants who completed the research requirements
- ITT analysis: not reported
- Sample size/power calculation: not reported. Small sample size (mean of approximately 15 participants per intervention, of which only one to two per intervention were husband and wife couples)
- Attrition/dropout: not reported separately by intervention but stated that attrition was spread evenly across the interventions. Reasons for dropout not fully reported. Stated that there were no significant differences between the dropouts and those who completed the programme for pre-treatment weight, per cent body fat, age, reported age of obesity onset, or weight loss goal

### General comments

- Generalisability: predominantly (77%) female population. Participants had answered a newspaper or local radio advertisement and paid a US\$15 non-refundable registration fee and a US\$50 refundable deposit. This may have had an impact on those taking part
- Outcome measures: reported only graphically for 30 months' follow-up
- Facilitators/barriers not reported as outcomes: none reported
- Intercentre variability: not reported
- Conflict of interests: none reported

### Quality criteria for assessment

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1. Was the method used to generate random allocations adequate?	Unclear
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups? (ii) If so, were they explained or adjusted for?	Unclear
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis? (ii) If so, was this defined?	Not reported
10. (i) Did the analysis account for missing data? (ii) If so, were the methods appropriate?	No

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Jeffery *et al.*

Study details	Participants	Outcome measures
<p>Author: Jeffery <i>et al.</i><sup>76</sup></p> <p>Year: 1998</p> <p>Country: USA</p> <p>Study design: RCT</p> <p>Number of centres: two</p> <p>Funding: National Heart, Lung and Blood Institute</p> <p>Recruitment dates: not given</p> <p>Setting: clinic, possibly university</p> <p>Length of follow-up: 18 months</p>	<p>Number of participants: abstract states 193, but <i>n</i>'s per group = 196 and description of participants states 196</p> <p>Standard behavioural therapy (SBT): <i>n</i> = 40</p> <p>SBT + supervised exercise (SBTE): <i>n</i> = 41</p> <p>SBT + trainer (SBTT): <i>n</i> = 42</p> <p>SBT + incentive (SBTI): <i>n</i> = 37</p> <p>SBT + trainer + incentive (SBTTI): <i>n</i> = 36</p> <p>Sample attrition/dropout: states that 78% completed the 18-month evaluation, no details of dropout by intervention group</p> <p>Attendance at sessions measured: yes</p> <p>Other measures of adherence: no</p> <p>Sample crossovers: none reported</p> <p>Inclusion/exclusion criteria for study entry:</p> <p>Between 14 and 32 kg overweight according to 1983 insurance industry standards, 25–55 years of age, free of serious diseases, able to walk for exercise and willing to be randomised</p> <p>Characteristics of participants:</p> <p>Any risk factors noted: none reported</p> <p>Gender (M:F), <i>n</i> (%): SBT 7:33 (18:82); SBTE 7:34 (17:83); SBTT 9:33 (21:79); SBTI 5:32 (14:86); SBTTI 5:31(14/86)</p> <p>Age (years), mean (SE): SBT 40.0 (1.3); SBTE 41.5 (1.3); SBTT 41.0 (1.3); SBTI 42.6 (1.4); SBTTI 40.7 (1.4)</p> <p>BMI, kg/m<sup>2</sup>, mean (SE): SBT 31.4 (0.3); SBTE 31.5 (0.3); SBTT 31.4 (0.3); SBTI 31.5 (0.4); SBTTI 30.6 (0.4)</p> <p>Body weight (kg), mean (SE): SBT 85.6 (1.7); SBTE 87.1 (1.6); SBTT 84.7 (1.6); SBTI 87.7 (1.7); SBTTI 85.7 (1.7)</p> <p>Ever in a weight programme (%): SBT 45; SBTE 71; SBTT 62; SBTI 68; SBTTI 58</p> <p>Exercise (kcal/week) mean (SE): SBT 681 (103); SBTE 725 (113); SBTT 699 (108); SBTI 768 (128); SBTTI 628 (99)</p> <p>Ethnicity (% white): SBT 82; SBTE 71; SBTT 88; SBTI 73; SBTTI 86</p> <p>% weight lost before starting: not reported</p> <p>Duration of overweight/obesity: not reported</p> <p>Also reports baseline education status, marital status, energy intake, fat intake, Beck Depression Inventory score, Gormally Binge Eating Questionnaire eating score and perceived barriers to adherence</p>	<p>Primary outcomes: exercise behaviours (Paffenbarger Physical Activity Questionnaire not extracted here), weight</p> <p>Secondary outcomes: also attendance at walks (where relevant by intervention); habitual energy and fat intake (by Block Food Frequency questionnaire), depression (by Beck Depression Inventory), and binge eating (by Gormally Binge Eating Questionnaire) but these were not data extracted here</p> <p>Facilitators and barriers: perceived barriers to adherence</p> <p>Methods of assessing outcomes:</p> <p>Weight measured on a balance beam scale with participant wearing light clothing without shoes</p> <p>Barriers to adherence were assessed by a 15-item questionnaire devised to assess participants' perceptions of practical, social, and interpersonal barriers to successful behaviour change. Reference to authors' own work, unclear if validated in any way</p>

**Intervention details**

<b>1. SBT (n=40)</b>	<b>2. SBTE (n=41)</b>	<b>3. SBTT (n=42)</b>	<b>4. SBTI (n=37)</b>	<b>5. SBTTI (n=36)</b>
Aim or goal: not stated	Aim or goal: not stated	Aim or goal: not stated	Aim or goal: not stated	Aim or goal: not stated
<i>Diet:</i>	<i>Diet:</i>	<i>Diet:</i>	<i>Diet:</i>	<i>Diet:</i>
<i>Details: type of diet:</i> not defined	As SBT intervention	As SBT intervention	As SBT intervention	As SBT intervention
<i>Calories:</i> 1000 kcal/day if weight was <91kg and 1500 kcal/day if weight was ≥91 kg	<i>Exercise:</i>	<i>Exercise</i>	<i>Exercise</i>	<i>Exercise</i>
<i>Proportions of diet:</i> restrict fat to 20% or less of calories (22 g/day for 1000 kcal and 33g/day for 1500 kcal). Given menus for five breakfasts and dinners per week along with grocery shopping lists	<i>Mode:</i> group and individual	<i>Mode:</i> group and individual	<i>Mode:</i> group and individual	<i>Mode:</i> group and individual
<i>Monitoring:</i> recorded calorie and fat intake every day for the first 24 weeks and 1 week per month thereafter	<i>Type:</i> primarily walking or cycling. Supervised walking (see below) initially 0.5 miles (0.8 km), increased over first 3 months to 2.5 miles (4.0 km)	<i>Type:</i> primarily walking or cycling. Supervised walking as per SBTE	<i>Type:</i> primarily walking or cycling. Supervised walking as per SBTE	<i>Type:</i> primarily walking or cycling. Supervised walking as per SBTE
<i>Exercise:</i>	<i>Frequency and length of each session and total number sessions:</i> to exercise to at least 1000 kcal/week. Regular attendance at supervised sessions would produce approximately 750 kcal/week	<i>Frequency and length of each session and total number sessions:</i> assume as per SBTE	<i>Frequency and length of each session and total number sessions:</i> assume as per SBTE	<i>Frequency and length of each session and total number sessions:</i> assume as per SBTE
<i>Mode:</i> assume individual	<i>Delivered:</i> by same group leaders as noted below	<i>Delivered:</i> personal trainer (student or staff assistant) assigned to work with three or four participants	<i>Delivered:</i> assume as per SBTE	<i>Delivered:</i> personal trainer as per SBTT
<i>Type:</i> primarily walking or cycling	<i>Level of supervision:</i> mixture of supervised and unsupervised – three supervised walking sessions per week. One at same time and day as group session, two on other days but at the same time of day and location	<i>Level of supervision:</i> The personal trainer walked with the participants, made reminder telephone calls, and scheduled walking sessions to accommodate participants' own schedules	Level of supervision: assume as per SBTE. Also financial award based on the number of walks attended at the end of each month. These were modest and increased in value with increments in cumulative attendance. Participants were paid per walk: US\$1 for their first 25 walks, US\$1.50 for the next 50 walks, US\$2 for the next 50 walks, and US\$3 for any remaining walks	<i>Level of supervision:</i> as per SBTT and SBTI
<i>Frequency and length of each session and total number sessions:</i> to exercise to the equivalent of 250 kcal/week and to gradually increase to a minimum of 1000 kcal/week	<i>Monitoring:</i> recorded distances walked in the daily food record	<i>Monitoring:</i> assume as per SBT	Monitoring: assume as per SBTE	<i>Monitoring:</i> assume as per SBTE
<i>Delivered:</i> by same group leaders as noted below	<i>Behaviour modification:</i>	<i>Behaviour modification:</i>	Monitoring: assume as per SBTE	<i>Behaviour modification:</i>
<i>Level of supervision:</i> none specifically	<i>Mode:</i> group (approximately 20)	As SBT intervention	Monitoring: assume as per SBTE	As SBT intervention
<i>Monitoring:</i> recorded distances walked in the daily food record	<i>Type:</i> not stated	<i>Ongoing support:</i>	<i>Behaviour modification:</i>	<i>Ongoing support:</i>
<i>Behaviour modification:</i>	<i>Content:</i> stimulus control techniques, problem solving strategies, social assertion, short-term goal-setting and techniques for enhancing motivation, cognitive strategies for altering self-defeating thoughts, relapse prevention, and social support	As per SBT	As SBT intervention	As per SBT
<i>Mode:</i> group (approximately 20)	<i>Frequency and length of each session and total number sessions:</i> weekly for 24 weeks and once per month thereafter		<i>Ongoing support:</i>	
<i>Type:</i> not stated	<i>Delivered:</i> led by trained interventionists with advanced degrees in nutrition or behavioural sciences		As per SBT	
<i>Ongoing support:</i>				
Not stated except for as part of the programme described above (monthly meetings after first 24 weeks)				



## Results

Outcomes	SBT ( <i>n</i> = 40 at baseline)	SBTE ( <i>n</i> = 41 at baseline)	SBTT ( <i>n</i> = 42 at baseline)	SBTI ( <i>n</i> = 37 at baseline)	SBTTI ( <i>n</i> = 36 at baseline)	<i>p</i> -value
Weight change in kg, mean (SE)	-7.6 (1.1)	-3.8 (1.3)	-2.9 (1.1)	-4.5 (1.2)	-5.1 (1.3)	<i>p</i> =0.03 <sup>a</sup>
Perceived barriers	Data not reported	Data not reported	Data not reported	Data not reported	Data not reported	Not significant <sup>b</sup>

a Adjusted analysis for baseline weight, gender and centre. Reports  $p < 0.03$  in the text but  $p = 0.03$  in the table. The difference was reported to be attributed to the greater weight losses in the SBT group compared with the other four groups. There was also a main effect for centre ( $p < 0.03$ ) where those in Minneapolis lost more weight than those in Pittsburgh but no treatment by centre interaction effect.

b Based on the text that states that two analyses of secondary outcomes were significant and perceived barriers were not the two reported.

## Methodological comments/notes

- Allocation to treatment groups: states participants were randomised within each centre to one of five treatment groups
- Blinding: no details
- Comparability of treatment groups: states treatment groups did not differ significantly on any of the baseline variables, no description of any significance testing undertaken is provided
- Method of data analysis: analyses conducted to assess changes from baseline to 18 months using general linear modelling to include baseline values, treatment group, centre, and gender as factors in the model. To try to maximise completeness of follow-up at 18 months, participants who were unwilling to attend clinic visits were asked to report their weight by telephone, of which 15 did. Analyses with and without these 15 is reported to have been undertaken which ascertained no differences in the pattern of the results and thus the analyses presented in the paper were for those attending clinic only
- ITT analysis: not reported
- Sample size/power calculation: not reported
- Attrition/dropout: reasons were not provided for the dropouts, and no numbers given by treatment group. Merely states attrition did not differ by treatment group

### General comments

- Generalisability: participants recruited through a media advertisement. Came from two urban communities in the USA. Were mostly white, educated and had been in weight control programmes previously. Study primarily set up to assess the effect on exercise level achieved
- Outcome measures: weight changes also reported at 6 months' follow-up. Adherence to walking sessions reported for four study groups (not SBT) over different time periods and showed a decrease in all groups ( $p < 0.001$ ) with differences between the groups also reported. Suggests moderately correlated with overall weight change ( $r = -0.35$ ,  $p < 0.0001$ ). Also reports average level of total exercise achieved by each treatment group at 6 and 18 months
- Facilitators/barriers not reported as outcomes: none
- Intercentre variability: not reported as such, centre was a factor within the analysis of study outcomes which showed that there was an effect of centre which suggests there probably was intercentre variability
- Conflict of interests: none reported

## Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Unclear
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	Unclear
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis?	No
(ii) If so, was this defined?	
10. (i) Did the analysis account for missing data?	No
(ii) If so, were the methods appropriate?	

**Jeffery and Wing**

Study details	Participants	Outcome measures
<p>Author: Jeffery and Wing;<sup>75</sup> Jeffery <i>et al.</i><sup>106</sup></p> <p>Country: USA</p> <p>Study design: RCT</p> <p>Number of centres: two</p> <p>Funding: National Institutes of Health grants HL41332 and HL41330</p> <p>Recruitment dates: not reported</p> <p>Setting: not reported</p> <p>Length of follow-up: 30 months</p>	<p>Number of participants: 202 (equal numbers of men and women), randomised to five groups:</p> <p>Control (C): <math>n=40</math></p> <p>Standard behavioural treatment (SBT): <math>n=40</math></p> <p>SBT + food provision (SBT + FP): <math>n=40</math></p> <p>SBT + incentives (SBT + I): <math>n=41</math></p> <p>SBT + FP + I: <math>n=41</math></p> <p>Sample attrition/dropout: 177 (88%) completed the 30-month follow-up evaluation. No differences among treatment groups, centres, or sex in the per cent of participants lost to follow-up. Number by treatment group not reported. 85% (172, calculated by reviewer) completed the 18-month follow-up. Overall attrition at 6 and 12 months also reported</p> <p>Attendance at sessions measured: yes</p> <p>Other measures of adherence: yes</p> <p>Sample crossovers: not reported</p> <p>Inclusion/exclusion criteria for study entry: between 14 kg and 32 kg overweight according to 1983 insurance industry standards, 25–45 years of age, non-smokers, drank fewer than three alcoholic drinks per day, not on a special diet or allergic to any foods, able to exercise, free of current serious disease, not taking prescription medications including oral contraceptives, and agreeable to conditions of participation</p> <p>Characteristics of participants:</p> <p>Any risk factors noted: no</p> <p>Paper does not indicate if data reported are means, and no measures of variance reported</p> <p>Gender (M:F), <math>n</math> (%): not reported by group</p> <p>Age (years): C 35.7; SBT 37.5; SBT + FP 38.5; SBT + I 38.1; SBT + FP + I 37.6</p> <p>BMI (<math>\text{kg}/\text{m}^2</math>): C 31.1; SBT 30.9; SBT + FP 30.8; SBT + I 31.1; SBT + FP + I 31.1</p> <p>Mean weight (kg): C 88.2; SBT 89.4; SBT + FP 88.1; SBT + I 92.3; SBT + FP + I 91.1</p> <p>% weight lost before starting: not reported</p> <p>Duration of overweight/obesity: not reported</p> <p>Previous weight loss attempts (%): C 50.0; SBT 57.5; SBT + FP 62.5; SBT + I 63.4; SBT + FP + I 58.5</p> <p>Physical activity level (kcal/week): C 1032.4; SBT 1445; SBT + FP 820; SBT + I 1,103; SBT + FP + I 1039</p> <p>Ethnicity white (%): C 92.5; SBT 87.5; SBT + FP 97.5; SBT + I 90.2; SBT + FP + I 92.7</p> <p>Socioeconomic position: not reported</p> <p>Pre-existing medical condition: not reported</p> <p><math>p</math>-values reported, all not statistically significant</p> <p>Baseline data for each group also reported on: non-college graduate; married, weight, nutrient intake (kcal/day; calories from fat); total barriers to adherence; eating behaviours inventory; knowledge (15-item test; calorie estimates)</p>	<p>Primary outcomes: change in obesity (weight and BMI)</p> <p>Secondary outcomes: nutrient intake (total energy intake, % of energy from fat); exercise – not data extracted</p> <p>Facilitators and barriers: process measures (potential mediators of weight change) were assessed – attendance at treatment sessions and weigh-ins; adherence; perceived barriers to adherence; adherence to behavioural weight control strategies; nutritional knowledge</p> <p>Methods of assessing outcomes:</p> <p>Adherence: calculated from completion of the 7-day food diaries that were requested at each group treatment session. The number of completed days was divided by the number of assigned days. No indication that this measure was validated in any way</p> <p>Perceived barriers to adherence: derived from a 15-item questionnaire designed specifically for this study. Covered practical and motivational barriers rated on a 5-point scale from 'not at all a problem for me (1)' to 'a very important problem for me (5)'</p> <p>Adherence to behavioural weight control strategies: the 26-item eating behaviours inventory of weight control practices (reference provided)</p> <p>Nutritional knowledge: a 15-item multiple-choice true–false test, and a test to estimate the caloric content of 22 food items</p>
<p><b>Intervention details:</b> study reports a weight management (weight loss) intervention (duration of intervention 18 months) with participants followed up for a further year after the end of the intervention (to determine how well weight loss maintained, but no intervention or contact with study staff in this period)</p>		

**Intervention details****SBT  
(n=40)**

Aim or goal: subjects selected a weight loss goal (14, 18 or 23 kg) to try to achieve during the programme. Exercise goals increased to a final goal of 1000 calories a week

*Diet:*

*Details, type of diet:* emphasised the importance of remaining below caloric goals, but restriction of fat and increasing consumption of complex carbohydrates also stressed

*Calories:* either 1000 or 1500 calories per day on the basis of baseline body weight. Goal derived by multiplying baseline body weight by 12, subtracting 1000 calories per day, and rounding to the closest caloric goal to produce an estimated weight loss of about 1 kg per week

*Proportions of diet:* not stated

*Monitoring:* recorded caloric intake in daily food records for the first 20 weeks and for 1 week each month thereafter

Subjects who reached their weight loss goal during treatment had their caloric goals adjusted upward to a level estimated to maintain this body weight

*Exercise:*

*Mode:* individual (not explicitly stated)

*Type:* based on walking or cycling

*Frequency and length of each session and total number sessions:* an amount equivalent to 50 calories per day for 5 days a week

*Delivered:* self-directed (not explicitly stated)

*Level of supervision:* none (not explicitly stated)

*Monitoring:* recorded distances walked or duration of bicycling

*Behaviour modification:*

*Mode:* group of about 20

*Type:* not stated

*Content:* included stimulus control techniques, problem solving strategies, social assertion, short-term goal-setting and reinforcement techniques for enhancing motivation, cognitive strategies for replacing negative thinking, relapse prevention, social support

*Frequency and length of each session and total number sessions:* met weekly for first 20 weeks and then once a month

*Delivered:* trained interventionists with advanced degrees in nutrition or the behavioural sciences

*Ongoing support:*

Not specifically mentioned but content of group meetings seem to fill this role

*Mode:* group of about 20

*Type:* behavioural counselling. Included a weigh-in, presentations of information by the interventionist, group discussion and a review of progress. During the period of monthly group sessions, participants were also encouraged to attend weekly weigh-in session to monitor progress

*Frequency and length of each session and total number sessions:* met weekly for first 20 weeks and then once a month

Other details

None

**Control  
(n=40)**

No intervention. Participants could do whatever they wished to lose weight on their own

**SBT + FP + I  
(n=41)**

Aim or goal: as described for SBT group

*Diet:* as described for SBT group

*Exercise:* as described for SBT group

*Behaviour modification:* as described for SBT group

*Ongoing support:* as described for SBT group

*Other details*

*Food provision:* food provided for five breakfasts and five dinners a week. Pre-packaged breakfasts consisted of cereal, milk, juice, and fruit. Dinners typically consisted of lean meat, potato or rice, and vegetable. For 1 or 2 days a week, a frozen dinner, such as a Weight Watchers® or Lean Cuisine meal, was provided. A meal plan outlined what foods were to be eaten for which meals. Recipes were provided to guide food preparation. Recommendations for lunches were provided

*Incentives:* cash payments received based on the amount of weight lost each week in relation to the weight loss goal. Minimum payment of US\$2.50 if participants did not gain weight; US\$12.50 if weight loss was 50% of goal. Maximum of US\$25 if goal reached and maintained. Incentives paid weekly by cheque at time of weigh-in

**SBT + FP  
(n=40)**

Aim or goal: unclear if meeting same goals as other group.

*Diet:* as described for SBT group

*Exercise:* as described for SBT group

*Behaviour modification:* as described for SBT group

*Ongoing support:* as described for SBT group

*Other details:*

*Food provision:* as described for SBT + FP + I group

**SBT + I  
(n=41)**

Aim or goal: weight loss goals as SBT + FP + I. Unclear if had the same exercise goal

*Diet:* identical to SBT but without any FP

*Exercise:* as described for SBT group

*Behaviour modification:* as described for SBT group

*Ongoing support:* as described for SBT group

*Other details*

*Incentives:* as described for SBT + FP + I group

## Results

Outcomes	SBT + FP + I (n = 41)	SBT+I (n = 41)	SBT + FP (n = 40)	SBT (n = 40)	Control (n = 40)	p-value, 95% CI
Weight change, baseline to 18 months, mean kg, n contributing data (data estimated from figure and n contributing data calculated by reviewer)	-6.4, n=34	-4.0, n=35	-6.6, n=36	-4.6, n=26	0.0, n=28	Not reported
Weight loss, baseline to 30 months, mean <sup>a</sup> kg (SD)	1.6 (6.3)	1.6 (5.5)	2.2 (6.6)	1.4 (7.2)	Gain 0.6 (5.3)	No overall difference between treatment groups ANOVA $p > 0.45$
Loss of $\geq 9$ kg from baseline to 30 months, % of participants	Ranged from 8% to 17% in the active treatment groups No detail by group reported.				0%	Not tested
BMI kg/m <sup>2</sup> – baseline, n	31.26, n=41	30.77, n=41	30.66, n=40	30.85, n=40	30.88, n=40	Not reported
18 months, n (calculated by reviewer)	28.95, n=34	29.28, n=35	28.17, n=36	29.10, n=26	30.67, n=28	
Maintenance of weight loss	The proportion maintaining some weight loss ranged from 51% to 73%				53%	Not tested
Other intermediate outcomes:	The post hoc planned contrast analyses indicated an effect, comparing all treatment groups with the no-treatment group, which approached conventional levels of statistical significance, ( $F_{1, 157} = 3.14$ , $p < 0.08$ ). No adjustment of p-value for significance due to multiple comparisons however. Mean weight losses of the SBT groups (all SBT groups) were 4.1 kg at 18 months; in the groups provided with food, mean weight losses increased to 6.4 kg at 18 months. For 18 months, data are based on the analysis restricted to subjects who attended all assessment sessions. The percentage of participants who completed all three follow-ups to provide 18 month data differed by treatment group ( $p = 0.03$ )					

ANOVA, analysis of variance.

a Paper does not state mean value, just says average. But as standard deviation is also presented, the average given is most likely to be the mean value.

## Methodological comments/notes

- Allocation to treatment groups: states randomised but details not reported. But note that randomisation was within centre and gender
- Blinding: not reported
- Comparability of treatment groups: states preliminary analysis found no significant differences between groups for any of the dependent variables, indicating that randomisation was effective in producing comparable treatment groups. For 30-month follow-up, also states there were no differences among treatment groups, centres or genders in the per cent of participants lost to follow-up
- Method of data analysis: dependent variables were assessed using a repeated measures ANOVA. Factors included in the analysis were gender, centre, treatment group, time and their interactions. Treatment effects due to FP, incentives, the interaction between FP and incentives, and all active treatments versus the control were specifically tested for
- ITT analysis: not reported for 30-month follow-up. Analysis for an 18-month follow-up explored two approaches for dealing with missing data, neither were ITT
- Sample size/power calculation: not reported
- Attrition/dropout: reasons not provided

### General comments

- Generalisability: subjects described as relatively well educated, and predominantly white. May not be representative of the obese population in the UK
- Outcome measures: no detailed results at 30 months for other outcomes. States at 30 months there were no significant differences between groups in dietary intake, exercise, or nutrition knowledge. At 18 months data reported on possible mechanisms for observed treatment effects: attendance at treatment sessions; completion of food records; effect of provision of food on percentage of calories from fat and total calorific intake; increases in nutritional knowledge, exercise, perception of barriers. These outcomes were not reported in detail or separately for each study group
- Facilitators/barriers not reported as outcomes: states at 30 months there were no significant differences between groups in perceived barriers
- Intercentre variability: to ensure standardisation across treatment groups and centres interventionists attended a 2-day training session. Identical instructional materials and identical leader guidelines for interventionists were used at each centre. Interventionists conferred by conference call approximately once per week to co-ordinate activities
- Conflict of interests: not reported. All meals in the FP group prepared by Nutrition Inc. but assume no sponsorship of the trial

## Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Not reported
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups? (ii) If so, were they explained or adjusted for?	Not reported
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	Yes – some outcomes reported at 18 months, not reported on at 30 months
9. (i) Did the analysis include an intention to treat analysis? (ii) If so, was this defined?	Not reported
10. (i) Did the analysis account for missing data? (ii) If so, were the methods appropriate?	Not reported

## Logue et al.

Study details	Participants	Outcome measures		
Author: Logue <i>et al.</i> <sup>72</sup>	Number of participants:	Primary outcome:		
Year: 2005	Transtheoretical Model and Chronic Disease Paradigm (TM-CD): 329	Change in body weight		
Country: USA	Augmented usual care (AUC): 336	Secondary outcomes (data not extracted):		
Study design: RCT	Total randomised: 665	Waist girth; blood lipids; BP; behavioural and cognitive-based estimates of daily energy intake and total energy expenditure; psychosocial assessments including self-efficacy, social support, decisional balance for healthy eating and exercise; general physical and mental health; social desirability; anxiety, depression; binge-eating disorder; stages of change.		
Number of centres: 15 primary-care practices	Sample attrition/dropout:	Facilitators and barriers: none explicitly assessed		
Funding: study supported by Agency for Healthcare Research and Quality and the National Institute of Diabetes, Digestive, and Kidney Diseases grants and by Nutrition and Exercise grants from the Summa Health System Foundation	<i>Attrition, n (%) 18 months:</i> TM-CD: 123 (37); AUC: 155 (46)	Methods of assessing outcomes:		
	<i>Attrition, n (%) 24 months:</i> TM-CD: 103 (31); AUC: 127 (38)	Weight measured using a standardised calibrated scale		
Recruitment dates: not reported; study conducted July 1998 to December 2002	Attendance at sessions measured: not reported	<i>Subgroup analyses:</i> none		
Setting: primary care	Other measures of adherence: not reported			
Length of follow-up: 18 and 24 months after randomisation	Sample crossovers: none reported			
	Inclusion/exclusion criteria for study entry:			
	<i>Inclusion:</i>			
	Participants of one of the primary-care practices affiliated with the study; had to provide written informed consent; men and women, 40–69 years of age; elevated BMI (> 27 kg/m <sup>2</sup> ) or elevated waist-to-hip ratio (> 0.95 for men or > 0.8 for women)			
	<i>Exclusion:</i>			
	No access to a telephone; difficulty understanding eight-grade spoken or written English; pregnancy, lactation, or < 6 months post partum; use of a wheelchair for mobility; high-risk participants with severe heart or lung disease			
	Characteristics of participants:			
	<i>Risk factors noted:</i> none			
		TM-CD (n=329)	AUC (n=336)	95% CI of difference
	Gender (M:F) (%):	97:232 (29:71) <sup>a</sup>	110:226 (33:67)	-3.8 to 10 (for number of men)
	Age group (years), n (%)			
	40–49:	139 (42)	129 (38)	-11 to 3.6
	50–59:	138 (42)	141 (42)	-7.5 to 7.5
	60–69:	52 (16)	66 (20)	-2.0 to 9.6
	Weight (kg), mean ± SD	Not reported	Not reported	Not reported
	Total number of minutes exercised	Not reported	Not reported	Not reported
	Energy expenditure	Not reported	Not reported	Not reported
	BMI kg/m <sup>2</sup> , n (%)			
	25–29.9	59 (18)	73 (22)	-2.3 to 9.8
	30–34.9	119 (36) <sup>a</sup>	107 (32)	-12 to 2.9
	35–39.9	69 (21)	82 (24)	-2.9 to 9.8
	40.0+	79 (24)	74 (22)	-8.4 to 4.4
	% weight lost before starting	Not reported	Not reported	Not reported
	Duration of overweight/obesity	Not reported	Not reported	Not reported
	Previous weight loss attempts n (%)	306 (93) <sup>a</sup>	303 (90) <sup>a</sup>	-7.0 to 1.4

Previous commercial weight loss programmes, <i>n</i> (%)	147 (45) <sup>a</sup>	155 (46) <sup>a</sup>	-6.1 to 9.0
Physician said to lose weight, <i>n</i> (%)	246 (75) <sup>a</sup>	262 (78) <sup>a</sup>	-3.3 to 9.7
Ethnicity: <i>n</i> (%) African American	88 (27) <sup>a</sup>	87 (26) <sup>a</sup>	-7.5 to 5.8
Socioeconomic position	Not reported	Not reported	Not reported
Prior/current psychotropic medicine, <i>n</i> (%)	85 (26)	79 (24)	-8.9 to 4.2
Hypertension, <i>n</i> (%)	138 (42) <sup>a</sup>	151 (45) <sup>a</sup>	-4.5 to 11
Elevated blood cholesterol, <i>n</i> (%)	107 (33) <sup>a</sup>	115 (34) <sup>a</sup>	-5.5 to 8.9
Diabetes, <i>n</i> (%)	41 (12) <sup>a</sup>	51 (15) <sup>a</sup>	-2.5 to 8.0

### Intervention details

#### 1. TM-CD

(*n*=329)

Aim or goal: not explicitly reported

##### Diet:

*Type of diet:* based on either the United States Department of Agriculture (USDA) Food Guide Pyramid (*Dietary Guidelines for Americans*) or a standard prescription to reduce calories, increase fruit and vegetables, and reduce fat

*Frequency and length of each session and total number sessions:* 10 minutes of in-person counselling (not stated whether group or individual) once every 6 months and mean of 15 minutes telephone counselling every month

*Level of supervision:* no further details reported

*Calories:* not reported (consult the materials referred to above)

*Proportions of diet:* not reported (references given; see above)

*Monitoring:* participants were asked to provide dietary data every 6 months and other information as reported below for behaviour modification

##### Exercise:

*Mode:* not reported whether individual or group contact

*Type:* included a standard prescription to increase activity and exercise but no details provided

*Frequency and length of each session and total number sessions:* as reported above for diet

*Delivered:* by registered dietician (RD) and weight loss advisor (WLA). The RD prepared written exercise prescriptions based on the information from dietary recalls. The WLA provided phone counselling

*Level of supervision:* no further details reported

*Monitoring:* participants were asked to provide exercise data every 6 months and other information as reported below for behaviour modification

##### Behaviour modification:

*Mode:* not reported, however, assume from description of telephone calls that is individual

*Type:* behavioural techniques based on TM-CD were taught consistent with Prochaska's description of the relationship between the processes of change and the stages of change (SOC) for increasing five target behaviours (exercise, usual activity, dietary portion control, dietary fat control, fruit and vegetable intake)

*Content:* participants were mailed stage- and behaviour-matched workbooks that corresponded to their most recent SOC profile as identified by monitoring. Content of WLA telephone contacts not reported

#### 2. AUC:

(*n*=336)

Aim or goal: not explicitly reported

##### Diet:

*Type of diet:* based on either the USDA Food Guide Pyramid (*Dietary Guidelines for Americans*) or a Soul Food Guide Pyramid. Included a standard prescription to reduce calories, increase fruit and vegetables, and reduce fat

*Frequency and length of each session and total number sessions:* 10 minutes of counselling once every 6 months

*Level of supervision:* no further details reported

*Calories:* not reported (references given)

*Proportions of diet:* not reported (references given)

Noted that participants were advised to discuss their lipid and BP values with their primary care physician, but not stated whether or how the results of such discussions influenced the diet

*Monitoring:* participants were asked to provide anthropometric and dietary data every 6 months

##### Exercise:

*Mode:* not reported whether individual or group contact

*Type:* not reported

*Frequency and length of each session and total number sessions:* as reported above for diet

*Delivered:* by a registered dietitian who prepared written exercise prescriptions based on the information from the exercise recalls

*Level of supervision:* no further details reported

*Monitoring:* participants were asked to provide exercise data every 6 months

##### Behaviour modification:

*Mode:* not reported whether individual or group contact

*Type:* not reported

*Content:* counselling based on 6-monthly review of diet, exercise and anthropometric monitoring, consistent with behavioural self-monitoring principles



*Frequency and length of each session and total number sessions:* as reported above for diet

*Delivered:* by a RD and a WLA trained to apply the processes of change that corresponded to a participant's SOC profile. The RD prepared written dietary prescriptions based on the information from dietary recalls. The primary-care physicians were expected to counsel participants on obesity issues but only when issues were raised by participants or at infrequent (one to three times/year) chronic disease visits (diabetes check-ups). Overall, physicians had little involvement (6% of participants) in dietary, exercise or weight issues

*Monitoring:* formal evaluation for anxiety, depression and binge eating disorder every 6 months. A SOC assessment for five behaviours was completed every 2 months (references cited). Self-monitoring by participants was recommended but self-monitoring records were not reviewed by the physician or the WLA

*Ongoing support:*

Upon request, the WLA mailed participants with public domain handouts and other materials (menu suggestions, mall walking impacts, descriptions of local walking trails)

Other details:

*Financial incentives:* participants were paid US\$25 for completing each postbaseline assessment (6, 12, 18 and 24 months)

*Training/supervision of trainers:* a part-time pharmaceutical representative was trained to provide academic detailing to physicians on the use of the SOC profiles, the processes of change, and how to use a SOC flip chart when counselling participants in the examination room. The project psychologist (KS) monitored implementation of the WLA telephone protocol and periodically debriefed the WLAs and advised WLAs how to interact with problematic participants

*Frequency and length of each session and total number sessions:* as reported above for diet

*Delivered:* as reported above for exercise

*Monitoring:* as reported for diet and exercise. (No evaluation was carried out for anxiety, depression and binge eating disorder as it was considered unethical to do this without informing the primary care physicians)

*Ongoing support:*

None reported

*Other details*

*Financial incentives:* participants were paid US\$25 for completing each postbaseline assessment (6, 12, 18 and 24 months)

a Calculated by reviewer; slight discrepancy with reported value.

## Results

Outcomes	1. TM-CD: <i>n</i> = 226 unless stated	2. AUC: <i>n</i> = 209 unless stated	Difference (TM-CD – AUC) 95% CI, <i>p</i> -value
Mean (SE), 95% CI weight change (kg) from baseline to 24 months <sup>a</sup>	–0.39 (0.38), –1.1 to 0.4 For adjusted difference <sup>b</sup> <i>n</i> = 271	–0.16 (0.42), –1.0 to 0.7 For adjusted difference <sup>b</sup> <i>n</i> = 266	Unadjusted difference 0.23 kg –1.4 to 0.9, <i>p</i> = 0.50 (NS) Adjusted difference <sup>c</sup> 0.22 kg (CI and <i>p</i> -value not reported) Adjusted difference <sup>b</sup> 0.21 kg (CI and <i>p</i> -value not reported)
Facilitators	None explicitly reported	None explicitly reported	
Barriers	None explicitly reported	None explicitly reported	

AUC, augmented usual care; NS, not statistically significant; TM-CD, Transtheoretical Model and Chronic Disease paradigm.

a Chart weights were substituted for measured weights where the latter were missing. Seventy per cent of participants had a measured weight at 18 and 24 months. Pearson correlation coefficients between measured and chart weights averaged 0.99 (over repeated measurements). At month 18 there were significantly more weight measurements available for TM-CD (85%) than AUC (78%) ( $\chi^2 = 5.6$ ; *p*-value not reported). At month 24 weight data (measurement or chart) were equally available from both treatment groups.

b After substituting baseline weight (i.e. no weight change) for final weight for the 12% of participants with missing final weight data.

c After adjustment for baseline weight and other (unspecified) covariates.



## Methodological comments/notes

- Allocation to treatment groups: participants were randomised by opening an envelope with a set of ordered tickets indicating Transtheoretical Model and Chronic Disease (TM-CD) paradigm or 'Traditional Care'. The order of randomisation tickets was prepared using permuted blocks of 10 by the Office of Biostatistics. A separate randomisation sequence was used for each primary-care practice
- Blinding: reported that participants and research staff at each practice were blind to the assignment of participants while obtaining baseline measures, because assignment envelopes were not opened until the end of the visit
- Comparability of treatment groups: no major differences in baseline characteristics noted (the 95% CI for all reported baseline variables included zero)
- Method of data analysis: the primary hypothesis test focused on the final weight change from baseline to month 24 (or month 18 if the month 24 value was missing). Analysis was based on linear models and linear mixed (repeated measures) models
- ITT analysis: stated yes. Analysis included all randomised participants using linear models and linear mixed (repeated measures) models that included baseline variables, unstructured covariance matrices, and a missing at random (MAR) assumption. Sensitivity analysis considered the 12% of participants who had missing 18- or 24-month data, using baseline weight as a substitute
- Sample size/power calculation: clearly reported for both primary (weight loss) and secondary outcomes. Power 0.9 to detect a difference of 4.5 kg (about 5% weight loss difference) between TM-CD and AUC with  $\alpha=0.05$  and assuming 20% attrition
- Attrition/dropout: reasons for attrition reported (primarily because participants declined further participation when an effort was made to schedule a follow-up appointment) but not separated for the intervention groups. Attrition was defined imprecisely as participants who did not have 'a measured weight and other information'

### General comments

- Generalisability: stated that the original design called for equal numbers of male and female participants and African American participants to be in proportion to their local and national representation (12%) but supplemental funds secured in the second year of the trial allowed African American enrolment to double. Results indicate approximately 27% African American, 25% were on or had received psychotropic medicine, and the majority ( $\geq 90\%$ ) had made previous weight loss attempts. Participants were recruited when they inquired about the study after either talking to their physician or reading study brochures, posters, or letters that were mailed to potential participants identified by primary care physicians. Participants also responded to waiting room brochures and posters, general newspaper articles (no details given) and announcements at churches with African American congregations, which may affect generalisability. Also, participants were paid US\$25 for completing each postbaseline assessment
- Outcome measures: psychosocial assessments including self-efficacy, social support, decisional balance for healthy eating and exercise, general physical and mental health, and social desirability were stated as secondary outcomes but no quantitative or narrative results were provided for these. Other intermediate outcomes (no quantitative data reported) were: waist girth at 24 months [difference between interventions stated not statistically significant (NS);  $p=0.57$ ]; energy intake (difference stated NS;  $p=0.69$ ); blood lipids at 24 months (difference stated NS; no  $p$ -value reported); and BP at 24 months (difference stated NS; no  $p$ -value reported). The mean change in reported exercise minutes per week (time period not reported – assumed over 0–24 months) was  $31.5 \pm 12$  additional minutes per week in TM-CD across all measurements compared with augmented usual care (AUC) (variance measure not stated; difference  $p=0.008$ )
- Facilitators/barriers not reported as outcomes: none reported
- Intercentre variability: not reported
- Conflict of interests: none reported

## Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Yes
2. Was the allocation adequately concealed?	Unclear
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Unclear
6. Was the participant blinded?	Unclear
7. (i) Were there any unexpected imbalances in dropouts between groups? (ii) If so, were they explained or adjusted for?	(No)
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	Yes
9. (i) Did the analysis include an intention to treat analysis? (ii) If so, was this defined?	Yes Yes
10. (i) Did the analysis account for missing data? (ii) If so, were the methods appropriate?	Yes Yes

**Simkin-Silverman et al.**

Study details	Participants	Outcome measures
<p>Author: Simkin-Silverman <i>et al.</i> 73,100,105,107</p> <p>Year: 1998</p> <p>Country: USA</p> <p>Study design: RCT</p> <p>Number of centres: one</p> <p>Funding: National Heart, Lung and Blood Institute</p> <p>Recruitment dates: August 1992 to March 1994</p> <p>Setting: clinic (unclear whether university clinic)</p> <p>Length of follow-up: 54 months</p>	<p>Number of participants: 535 randomised. Lifestyle intervention (LI) <math>n=260</math>, control (C) <math>n=275</math>. Only results for the subgroups classified as overweight or obese at baseline are reported here (LI <math>n=117</math>; C <math>n=131</math>)</p> <p>Sample attrition/dropout: 509 attended 54-month visit and were analysed. Fourteen participants missing from the LI, and 12 from the C (reasons given)</p> <p>Attendance at sessions measured: yes</p> <p>Other measures of adherence: yes</p> <p>Sample crossovers: not reported</p> <p>Inclusion/exclusion criteria for study entry: aged 44–50 years, &lt;3 months amenorrhoea in 6 months prior to initial interview; not taking hormone replacement therapy; no surgically induced menopause (hysterectomy or bilateral oophorectomy); diastolic BP &lt; 95 mmHg; BMI between 20 and 34 kg/m<sup>2</sup>; fasting glucose &lt; 140 mg/dl; not taking any lipid-lowering agents, insulin, thyroid, antihypertensive, psychotropic medications; not treated for cancer in the past 5 years; not having participated in a weight reduction programme within the past 4 months</p> <p>Characteristics of participants:</p> <p>Any risk factors noted: none, other than baseline values for high- and low-density lipoprotein cholesterol, triglycerides, BP, menopausal status during follow-up</p> <p>Gender (M:F), <math>n</math> (%): 100% female</p> <p>Age (years), mean (SD): LI = 47 (SD = 2); C = 47 (SD = 2)</p> <p>Mean BMI, kg/m<sup>2</sup>: LI = 25 (SD = 3); C = 25 (SD = 3)</p> <p>53.6% (287/535) were normal weight (BMI <math>\leq 24.9</math> kg/m<sup>2</sup>) (LI = 143; C = 144)</p> <p>35.5% (190/535) were overweight (BMI = 25–29.9 kg/m<sup>2</sup>) (LI = 95; C = 95)</p> <p>10.8% (58/535) were obese (BMI <math>\geq 30</math> kg/m<sup>2</sup>). (LI = 22; C = 36)</p> <p>Weight lb, mean (SD): LI 148.0 (21.3); C 147.6 (21.9)</p> <p>Weight kg, mean (calculated by reviewer): LI 67.1; C 67.0</p> <p>% weight lost before starting: not reported</p> <p>Duration of overweight/obesity: not reported</p> <p>Previous weight loss attempts: not reported</p> <p>Physical activity level (kcal/wk): LI = 1248 (SD = 1064); C = 1412 (SD = 1386)</p> <p>Ethnicity: white LI = 92.1%; C = 91.8%</p> <p>Socioeconomic position: educated beyond high school (LI = 83.2%; C = 86.2%), employed for wages (LI = 86.2%; C = 86.1%)</p>	<p>Primary outcomes: weight, body fat distribution, and body composition. Measured in terms of BMI, waist-to-hip ratio and changes in fat-free mass (FFM) (Note: not consistently reported which outcomes were primary)</p> <p>Secondary outcomes:</p> <p>Physical activity, nutrient intake</p> <p>Lipids, BP, glucose levels, cigarette smoking, alcohol intake, menopausal status (not data extracted)</p> <p>Facilitators and barriers: not reported</p> <p>Methods of assessing outcomes:</p> <p>Weight measured with balanced beam scale</p> <p>Height measured by a stationary vertical height board</p>

**Intervention details****1. Intervention 1****(n=260): LI (Women's Healthy Lifestyle Project)**

**Aim or goal:** to prevent naturally occurring weight gain and sustain baseline lipid profiles during the perimenopausal to postmenopausal transition. Two phases – phase 1 (weeks 1–20) focus on modest weight loss, described as the intensive phase. Phase 2 (months 6–54) continued focus on weight loss, but also then weight stabilisation and maintenance

Phase 1 included 10 weekly group meetings followed by biweekly meetings for the remaining 10 weeks (in total there were 15 group meetings with approximately 20 women per group). Phase 2 – following the initial 5 months group meetings occurred at months 6, 7, 8, 10, 12 and 14. Participants attended refresher programmes on nutrition, weight control and physical activity between months 14 and 54 (no detail on frequency of these sessions)

**Diet:**

**Details, type of diet:** reduced fat and calorie diet (also lipid-lowering dietary strategies). Weight loss goals were tailored to baseline BMI. Women with BMI of 25 to 26 kg/m<sup>2</sup> were given 10 lb and women with a BMI or ≥ 27 kg/m<sup>2</sup> were given 15 lb weight loss goals. Women with normal weight (BMI ≤ 24 kg/m<sup>2</sup>) were asked to lose 5 lb

**Calories:** participants were given a 1300–1500 kcal meal plan (for first month). As participants met their weight goal their caloric intake was gradually increased until weight stabilised

**Proportions of diet:** lowering of dietary fat to 25% of daily calories, saturated fat to 7%, and dietary cholesterol to 100 mg/day (for first month)

**Monitoring:** self-monitoring daily using 7-day pocket diaries for 6 months

**Exercise:**

**Mode:** group meetings

**Type:** recommended activities: walking, aerobic dance, cycling, swimming, strength training

**Frequency and length of each session and total number sessions:** phase 1 (10 weekly group meetings followed by 10 biweekly meetings). At the third week participants instructed to increase physical activity in step-wise manner to expend 1000 kcal per week. Women already active but expending < 1500 kcal per week were encouraged to gradually increase activity to 1500 kcal. Women already expending 1500 kcal encouraged to maintain this level. During phase 2 there were refresher meetings which covered physical activity, among other things

**Delivered:** behavioural psychologists and nutritionists

**Level of supervision:** appears that participants supervised themselves largely, but there were regular group meetings in phase 1 and in phase 2 there was regular mail and telephone contact

**Monitoring:** self-monitoring on a daily basis for first 6 months

**Behaviour modification:**

**Mode:** group (approximately 20 women per group)

**Type:** mentions that it is an empirically-based cognitive behavioural approach to weight control, citing two references, one of which is the NIH Clinical Guidelines on obesity in adults, the other being a chapter in a handbook of obesity

**Content:** included the following: stimulus control, goal-setting, self-monitoring, modelling, problem solving, assertiveness training, relapse prevention, and cognitive and motivational techniques. For instance, participants were taught to identify cues in their environment to promote healthy eating and activity. They were instructed on how to set realistic goals and extensive time was spent on problem solving within the group. The coping strategies taught were based on the relapse prevention model

**Frequency and length of each session and total number sessions:** not explicit whether each of the weekly/biweekly sessions included behavioural approaches, but presume that most of the psychological techniques were taught during phase 1. Additional behavioural skills, support and motivation was provided in phase 2, where sessions focused on adherence, emotions and eating

**Delivered:** behavioural psychologists and nutritionists

**Ongoing support:**

After month 14 (in phase 2) participants were offered 6-week refresher programmes, specifically to help with maintenance of behaviour change

**Mode:** presume group

**Type:** individual or small group consultation was provided to those who experienced a rise in weight gain during phase 2. Mail and telephone contact (newsletter, self-monitoring diaries) also used

**Frequency and length of each session and total number sessions:** not stated

**Other details:**

Incentives and lotteries were used periodically for healthy lifestyle prizes to enhance attendance at group programmes and to encourage return of self-monitoring diaries

Other features of the intervention included: cooking demonstrations, and low-fat taste panels

Calcium supplementation (1200 mg/day) was given to offset any decreases in calcium during weight loss

**2. Intervention 2****(n=275):**

Assessment only control group (received a health education pamphlet on reducing cardiovascular risk factors and for those who were smokers, advice to quit)

## Results

<b>Outcomes</b>			
<b>Subset of participants overweight at baseline (BMI = 25–29.9 kg/m<sup>2</sup>)</b>	<b>LI (n = 95)</b>	<b>C (n = 95)</b>	<b>p-value between groups</b>
Weight change, mean kg (SD) % of initial weight lost 18 months	–3.5 (5.8) –4.6 <sup>a</sup>	0.1 (4.0) 0.07	<i>p</i> < 0.001
Weight change, mean kg (SD) % of initial weight lost 30 months	–2.7 (5.4) –3.5	0.3 (5.1) 0.41	<i>p</i> < 0.001
Weight change, mean kg (SD) % of initial weight lost 42 months	–1.4 (5.7) –1.7	1.3 (5.5) 1.9	<i>p</i> < 0.001
Weight change, mean kg (SD) % of initial weight lost 54 months	0.1 (6.1) 0.31	1.5 (5.2) 2.2	Not significant
<b>Subset of participants obese at baseline (BMI ≥ 30 kg/m<sup>2</sup>)</b>	<b>LI (n = 22)</b>	<b>C (n = 36)</b>	<b>p-value between groups</b>
Weight change, mean kg (SD) % of initial weight lost 18 months	–6.6 (8.4) –7.7	–0.5 (4.5) –0.36	<i>p</i> < 0.01
Weight change, mean kg (SD) % of initial weight lost 30 months	–4.3 (6.7) –5.0	2.9 (5.4) 3.5	<i>p</i> < 0.01
Weight change, mean kg (SD) % of initial weight lost 42 months	–2.0 (6.4) –2.3	1.9 (5.7) 2.5	<i>p</i> < 0.05
Weight change, mean kg (SD) % of initial weight lost 54 months	–0.2 (6.9) –0.17	3.1 (7.7) 3.7	Not significant
Percentage of participants at or below baseline weight at 54 months – (subset overweight at baseline)	57.3% (51/89)	Not reported	<i>p</i> = 0.352 <sup>b</sup>
Percentage of participants at or below baseline weight at 54 months – (subset obese at baseline)	40% (8/20)	Not reported	
Facilitators	Not reported	Not reported	Not reported
Barriers	Not reported	Not reported	Not reported

a Percentages are per cent of initial weight lost.

b For the comparison between baseline weight status (normal vs overweight vs obese for the LI group only).

Only results for participants classified as obese or overweight at baseline were extracted. Results for those classified as normal weight at baseline, and results for the whole sample irrespective of baseline weight classification have not been extracted.

Outcomes at 6 months reported, but not extracted.

## Methodological comments/notes

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- Allocation to treatment groups: states randomised. Actual method of randomisation not explicitly reported except that the sequence was prepared by the project's statistician prior to recruitment. Randomisation was done either in person at the Health Studies Clinic or by telephone to study personnel to ensure the participant was fully informed of the study design and to answer any questions prior to revealing the group assignment. Group assignments were concealed in envelopes labelled by study identification number, and the sequence remained confidential to study personnel until revealed to the participant during randomisation
- Blinding: outcome assessors were reported to be blinded to group assignment
- Comparability of treatment groups: the authors report that groups did not differ at baseline on primary dependent measures, nor were there any differences in dietary intake and physical activity (with the exception of alcohol use), or socio demographic data
- Method of data analysis: outcomes reported at 6, 18, 30, 42 and 54 months. Independent-sample *t*-tests using change scores from baseline were used to compare intervention and control groups on continuous methods. Chi-square analysis used to compare the percentage of LI and C participants who were at or below baseline weight at 54 months. Analysis of covariance (ANCOVA) used to examine physical activity, dietary adherence and weight change at 54 months. A probability value of 0.05 determined statistical significance for all tests
- ITT analysis: reports an ITT analysis and defines it as being an analysis that uses all available data from participants regardless of degree of intervention contact or adherence. Data from earlier assessments for the 26 non-attendees at the 54-month visit were included, but no data were carried forward to estimate the missing final assessment. It is not clear whether a true ITT analysis was conducted
- Sample size/power calculation: based on a series of power analyses (two-tailed comparisons with an alpha level of 0.05), taking into consideration the primary outcomes of the trial (low-density lipoprotein cholesterol and weight) and an estimated 10% loss to follow-up. A sample of 250 in each group allowed for sufficient power of 90% or greater to test both primary and subgroup comparisons between the study groups. Mentions that the sample size calculation took into account various planned subgroup analyses by menopausal status, but no discussion of the potential limitations of the subgroup outcomes based on baseline classification of normal, overweight or obese (e.g. that they may be underpowered)
- Attrition/dropout: reasons provided for both intervention and control group

### **General comments**

- Generalisability: results applicable mainly to perimenopausal women not being treated for hypertension, or not taking lipid-lowering medication, thyroid medication, psychotropic medication or insulin. Only just under half of those randomised were classified as overweight or obese at baseline (although weight loss goals were tailored to baseline BMI classification)
  - Outcome measures: a number of additional outcomes were reported, but were not data extracted. Attendance at follow-up assessments described as 'consistently excellent' (averaging 90%, with 95% at final assessment). Reports adherence to the physical activity and dietary goals
  - Facilitators/barriers not reported as outcomes: reports that intervention participants who were low adherers gained more weight (mean adjusted weight gain = 1.5 kg) than intervention participants who were high adherers (mean adjusted weight loss = 2.0 kg)
  - Intercentre variability: not applicable. Appears to be only one centre ('Health Studies Clinic')
  - Conflict of interests: none reported
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### Quality criteria for assessment

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1. Was the method used to generate random allocations adequate?	Yes
2. Was the allocation adequately concealed?	Yes
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Yes
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	No
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis?	Yes
(ii) If so, was this defined?	Yes
10. (i) Did the analysis account for missing data?	No
(ii) If so, were the methods appropriate?	

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## Skender et al.

Study details	Participants	Outcome measures
Author: Skender et al. <sup>79</sup> (Baseline population characteristics reported by Foreyt et al. <sup>108</sup> ) Year: 1996 Country: USA Study design: RCT Number of centres: not reported Funding: study supported in part by research grant DK30921 from the National Institutes of Health, Bethesda, MD Recruitment dates: not reported Setting: not reported. Participants were recruited from an urban area of Houston, TX Length of follow-up: 2 years after randomisation (1 year after end of treatment)	Number of participants: Diet and exercise (D + E): $n = 42$ Exercise only (E only): $n = 43$ Diet only (D only): $n = 42$ Waiting list control group (no data reported for these): $n = 38$ Total randomised: $n = 165$ Sample attrition/dropout: Numbers reported but not reasons <i>Completed 1-year treatment:</i> $n = 86/127$ (68%) <i>Completed 2-year follow-up:</i> Statistically significant differences between groups (overall $p = 0.03$ ; difference between diet and exercise groups $p = 0.014$ ) D + E: 21 (50%) D only: 15 (35.7%) E only: 25 (58%) Attendance at sessions measured: not reported Other measures of adherence: yes Sample crossovers: none reported Inclusion/exclusion criteria for study entry: men and women aged 25–45 years; volunteers recruited through (unspecified) media announcements; at least 14 kg overweight (Metropolitan Insurance height-weight tables); not engaged in regular exercise. No exclusion criteria specified Characteristics of participants: <i>Risk factors noted:</i> none Gender, M:F (%): 1. D + E: baseline: 21 : 21 (50 : 50) $n = 42$ ; 2-year follow-up: 10 : 11 (48 : 52) $n = 21$ 2. D only: baseline: 22 : 20 (52 : 48) $n = 42$ ; 2-year follow-up: 9 : 6 (60 : 40) $n = 15$ 3. E only: baseline: 23 : 20 (53 : 47) $n = 43$ ; 2-year follow-up: 13 : 12 (52 : 48) $n = 25$ <i>Baseline characteristics</i> <i>Reported by Foreyt et al.<sup>108</sup> for 86 participants who completed treatment</i> Weight (kg), mean $\pm$ SD: 1. (D + E): $97.60 \pm 25.48$ ( $n = 27$ ); 2. (D only): $97.65 \pm 21.96$ ( $n = 29$ ); 3. (E only): $93.92 \pm 20.83$ ( $n = 30$ ) (stated NS in text) <i>Reported by Skender et al.<sup>79</sup> for 61 participants who completed 2-year follow-up (not reported for all randomised participants):</i> Weight (kg), mean $\pm$ SD: 1. (D + E): $100.1 \pm 27.4$ ( $n = 21$ ); 2. (D only): $98.5 \pm 25.9$ ( $n = 15$ ); 3. (E only): $93.7 \pm 21.1$ ( $n = 25$ ) ( $p = 0.66$ ; NS) <i>Baseline characteristics for all participants not reported. Foreyt et al.<sup>108</sup> reported only for unspecified cohorts of the population (sample sizes variable but unexplained; data not extracted):</i> % body fat, mean $\pm$ SD: reported for unspecified cohort only (D + E: $n = 24$ ; D: $n = 22$ ; E: $n = 27$ ) Waist circumference (cm), mean $\pm$ SD: reported for unspecified cohort only (D + E: $n = 24$ ; D: $n = 23$ ; E: $n = 27$ ) Total number of minutes exercised: reported for unspecified cohort only (D + E: $n = 15$ ; D: $n = 18$ ; E: $n = 17$ ) Energy expenditure: reported for unspecified cohort only (D + E: $n = 15$ ; D: $n = 17$ ; E: $n = 16$ ) Age: not reported BMI, kg/m <sup>2</sup> : not reported % weight lost before starting: not reported Duration of overweight/obesity: not reported Previous weight loss attempts: not reported Physical activity level: not reported Ethnicity: not reported Socioeconomic position: not reported	Primary outcomes: (Reported, but not stated explicitly that this was a primary outcome): changes in body weight Secondary outcomes: (Reported, but not stated explicitly that these were secondary outcomes; not data extracted): attitudes to diet and exercise; adherence to diet and exercise; physical activity (1 year); % body fat (1 year); cardiorespiratory fitness (1 year) Facilitators and barriers: none explicitly assessed Methods of assessing outcomes: Weight measured using a balance beam scale <i>Subgroup analyses:</i> none. Note that attrition was reported separately by gender

**Intervention details****1. D+E****(n=42)**

Aim or goal: not explicitly reported

*Diet:*

*Type of diet:* participants were instructed to plan their daily meals and snacks from the foods recommended in the HYHEP, a nutritionally adequate, well-balanced low-cholesterol diet (reference cited). A table listing the calorie content of popular foods was provided. Instructors advised participants to adjust their caloric intake so that weight loss would not exceed 1 kg/week. Class instructors reviewed the food records weekly and returned them to participants at the next class

*Frequency and length of each session and total number sessions:* 12 weekly group instructional sessions followed by three biweekly sessions then eight monthly maintenance sessions (total 1 year). (Note discrepancy in text.) The group sessions were 60 minutes long, delivered as reported below for exercise  
*Calories:* not reported

*Proportions of diet:* to provide 30% of calories as fat, 50% as carbohydrate, and 20% as protein, based on HYHEP

*Monitoring:* daily food intake was monitored by participants recording the food eaten and calorie content of each portion in food diaries and (separately?) completing a self-monitoring questionnaire about diet (no details reported)

*Exercise:**Mode:* groups of approximately 15 participants

*Type:* lecture and discussion focused on the physical and psychological benefits of exercise. Proper methods of walking were taught on an indoor track during two supervised sessions. The walking regimen was adapted from a very gradual plan designed for the treatment of depression (reference cited) to maximize adherence. Participants were instructed to self-regulate the intensity of brisk walking based on heart rate, breathing difficulty, and perceived effort. They were instructed to exercise at a level that felt 'vigorous' but never 'strenuous'

*Frequency and length of each session and total number sessions:* as reported above for diet. The duration of beginning exercise sessions was as short as 5 minutes. The goal was three to five sessions per week of 45 minutes or more per session

*Delivered:* by registered dietitians who were trained and experienced in behaviour modification (exercise qualifications and competencies not reported)

*Level of supervision:* supervision only of intervention groups reported

*Monitoring:* self-monitoring questionnaire which included an hedonic five-point rating scale for exercise (no further details provided)

*Behaviour modification:**Mode:* groups of approximately 15 participants

*Type:* followed the principles outlined in the LEARN programme for weight control (reference cited)

*Content:* both diet behaviour modification and exercise behaviour modification involved the teaching or use of self-monitoring contracts to reward behaviour change (contingency contracting), stress management, stimulus control, goal-setting and maintenance techniques (references cited)

*Frequency and length of each session and total number sessions:* as reported above for diet

*Delivered:* as reported above for exercise

*Ongoing support:*

None reported other than 'maintenance' sessions noted above

Other details

*Financial deposits:* at the start of the study participants deposited US\$100 in an account which was refunded in increments according to the number of sessions attended

*Financial incentives:* participants were offered US\$35 for fulfilling the 2-year follow-up requirements

**2. E only****(n=43)**

Aim or goal: not explicitly reported

*Diet:*

*Type of diet:* participants were asked to maintain their current eating habits and nutrition was not discussed

*Frequency and length of each session and total number sessions:* not reported (participants continued their current eating habits)

*Calories:* not reported

*Proportions of diet:* not reported (participants continued their current eating habits)

*Monitoring:* none reported (participants continued their current eating habits)

*Exercise:**Mode:* as reported for D + E*Type:* as reported for D + E

*Frequency and length of each session and total number sessions:* as reported for D + E

*Delivered:* as reported for D + E

*Level of supervision:* as reported for D + E

*Monitoring:* as reported for D + E

*Behaviour modification:**Mode:* as reported for D + E*Type:* as reported for D + E*Content:* as reported for D + E

*Frequency and length of each session and total number sessions:* as reported for D + E

*Delivered:* as reported for D + E

*Ongoing support:*

None reported

Other details

*Financial deposits and incentives:* as reported for D + E

**3. D only****(n=42)**

Aim or goal: to produce 1kg/week loss of weight

*Diet:*

*Type of diet:* as reported for D + E

*Frequency and length of each session and total number sessions:* as reported for D + E

*Calories:* not reported

*Proportions of diet:* as reported for D + E

*Monitoring:* as reported for D + E

*Exercise:**Mode:* as reported for D + E

*Type:* normal physical activity only: participants were asked to maintain their relatively sedentary lifestyles and not to begin any new exercise programme

*Frequency and length of each session and total number sessions:* no exercise

*Delivered:* as reported for D + E

*Level of supervision:* as reported for D + E

*Monitoring:* none reported (participants continued their current physical activity)

*Behaviour modification:**Mode:* as reported for D + E*Type:* as reported for D + E*Content:* as reported for D + E

*Frequency and length of each session and total number sessions:* as reported for D + E

*Delivered:* as reported for D + E

*Ongoing support:*

None reported

Other details

*Financial deposits and incentives:* as reported for D + E



## Results

Outcomes	D + E (n=21)	D only (n=15)	E only (n=25)	p-value
Mean $\pm$ SD weight change (kg) from baseline (0–2 years) <sup>b,c</sup>	-2.2 $\pm$ 6.7	0.9 $\pm$ 7.7	-2.7 $\pm$ 9.2	$p=0.36$ (NS) <sup>a</sup>
Number (%) <sup>d</sup> of participants with weight gain (> 4.5 kg)	3 (14%) (Variance not reported)	4 (27%) (Variance not reported)	1 (4%) (Variance not reported)	Not reported
Number (%) <sup>d</sup> of participants with no weight change (within $\pm$ 4.5 kg)	10 (48%) (Variance not reported)	9 (60%) (Variance not reported)	18 (72%) (Variance not reported)	Not reported
Number (%) of participants with clinical success (weight loss > 4.5 kg)	8 (38%) (Variance not reported)	2 (13%) (Variance not reported)	6 (24%) (Variance not reported)	$p=0.36$ (NS) <sup>e</sup>
Facilitators	None reported	None reported	None reported	
Barriers	None reported	None reported	None reported	

D, diet only; D + E, diet and exercise; E, exercise only.

a ANOVA.

b Calculated from baseline weight for those attending follow-up at 24 months only.

c Gender had no significant influence on the relationship between treatment group and change in body weight over time.

d Calculated by reviewer; the percentage is of those participants who completed 2-year follow-up.

e Fisher's Exact test.

All results are presented for follow-up at 2 years after enrolment ( $n=61$ ).

Reported that mean weight change from end of treatment to follow-up (1–2 years) differed significantly between the intervention groups ( $p=0.005$ ; ANOVA), but no means or variances were provided. (Stated descriptively that marked weight gain occurred in D + E and D only groups, but not in the E only group.)

## Methodological comments/notes

- Allocation to treatment groups: stated only that participants were assigned randomly to treatment group by a table of random numbers. No other details of treatment allocation were reported
- Blinding: not reported
- Comparability of treatment groups: not reported for all randomised participants. Baseline comparability was only reported for initial weight of those participants who completed follow-up. Baseline comparability of some other variables was reported but for unknown cohorts of the population (the reported sample sizes do not correspond to any defined populations)
- Method of data analysis: Mantel–Haenszel  $\chi^2$  tests were used to compare gender and attrition across the intervention groups. ANOVA was used to examine differences between the interventions in weight changes over time
- ITT analysis: not reported
- Sample size/power calculation: not reported. Relatively small sample size
- Attrition/dropout: numbers reported but not reasons

### General comments

- Generalisability: participants had answered a newspaper advertisement, paid US\$100 initially to enrol, and were offered US\$35 for fulfilling the follow-up requirement. This may have had an impact on those taking part. The authors note (in the abstract) that the large outcome variability and 'unequal difficulty' of the regimens across groups limits the generalisability of the findings
- Outcome measures: unclear how missing data were accounted for (all outcome data excluded attrition). Participants' self-reported adherence to diet and exercise (no details provided) was recorded in diet and exercise questionnaires, but results were incompletely and inconsistently reported: 1. Diet and exercise (D + E): three participants (14.3%) reported adhering 'often' to dietary recommendations (adherence to exercise not reported); 2. Diet (D) only: one participant (6.7%) reported adhering 'often' to dietary recommendations; 3. Exercise (E) only: 11 participants (44%) reported 'exercising often during the year after treatment'
- Facilitators/barriers not reported as outcomes: none reported
- Intercentre variability: not reported, number of centres unclear
- Conflict of interests: none reported

### Quality criteria for assessment

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1. Was the method used to generate random allocations adequate?	Yes
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Unclear
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	Yes
(ii) If so, were they explained or adjusted for?	No
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis?	Not reported
(ii) If so, was this defined?	
10. (i) Did the analysis account for missing data?	No
(ii) If so, were the methods appropriate?	

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## Stevens et al. and Whelton et al.

Study details	Participants	Outcome measures
<p>Author: Stevens <i>et al.</i><sup>74</sup> and Whelton <i>et al.</i><sup>109</sup>            Linked to He <i>et al.</i><sup>110</sup> (one participating centre only.            Outcome data not extracted)            Year: 1993            Country: USA            Study design: RCT            Number of centres: six (although 10 for entire TOHP study)            Funding: National Heart, Lung and Blood institute            Recruitment dates: September 1987 to October 1988            Setting: not explicitly stated, appears to be hospital clinics            Length of follow-up: 18 months</p>	<p>Number of participants: total <math>n=564</math>, weight loss intervention <math>n=308</math>, usual-care control <math>n=256</math> [as part of a bigger study looking at non-pharmacological interventions to lower BP. See also Whelton <i>et al.</i><sup>111</sup> which compares three active treatments (combined) with controls so is therefore not relevant]            Sample attrition/dropout: only adherence/attendance reported. Unclear how many participants may have dropped out completely            Attendance at sessions measured: yes            Other measures of adherence: no            Sample crossovers: not applicable            Inclusion/exclusion criteria for study entry: aged between 30 and 54 years, between approximately 115% and 165% of desirable body weight, BMI of 26.1–36.1 kg/m<sup>2</sup> for men, 24.3–36.1 kg/m<sup>2</sup> for women, average BP (DBP) of 80–89 mmHg. Exclusion criteria: history of cardiovascular disease, diabetes mellitus, gastrointestinal tract disease, chronic renal failure, malignant neoplasm, current pregnancy or intent to become pregnant during the study, recent history of psychiatric disorders, or unwillingness to accept randomisation into any study group            Characteristics of participants: overall (data also reported separately for men and women in each group)            Any risk factors noted: yes, but for high BP (all high-normal BP)            Gender (M:F), <math>n</math> (%): weight loss 224:84 (72.7:27.3); control 161:95 (62.9:37.1) (<math>n</math>'s and % calculated by reviewer)            Age (years), mean (SD): weight loss: 43.1 ± 6.0; control 42.4 ± 6.2            BMI kg/m<sup>2</sup> mean (SD): weight loss: 29.5 ± 2.9; control 29.5 ± 2.8            Weight kg mean (SD): weight loss: 90.2 ± 13.3; control 89.3 ± 13.0            % weight lost before starting: not reported            Duration of overweight/obesity: not reported            Previous weight loss attempts: not reported            Physical activity level, vigorous exercise (resulting in perspiration) times/week mean (SD): weight loss: 2.0 ± 2.2; control 2.1 ± 2.3            Ethnicity %: weight loss: white 81.8, black 16.6; control: white 76.6, black 21.1            Socioeconomic position: not reported            If a mixed group of participants with pre-existing medical condition report <math>n</math> (%)'s with the condition: not applicable            Baseline information reported but not data extracted on % college graduates, % employed full-time, % married, health status [systolic BP (SBP), DBP, heart rate, height, cigarette smoking, alcohol intake, urinary sodium excretion), and energy intake (overall, and % energy from fat, % energy from saturated fat)</p>	<p>Primary outcomes: weight loss            Secondary outcomes: change in BP (SBP and DBP). Attendance (not data extracted)            Facilitators and barriers: not reported            Methods of assessing outcomes:            Weights were taken without shoes but including light, indoor clothing. Weights recorded for all participants during official clinic visits 3, 6, 12, and 18 months after study entry. Weights also recorded throughout the weight loss intervention            Methods of BP assessment not data extracted            Any self-reported outcomes? Yes – food diaries and exercise recorded (outcomes not reported)            Any subgroup analysis: weight loss by gender reported, and within gender by white ethnicity</p>
<p><b>Intervention details:</b> This study was part of phase 1 of the TOHP study. The comparison is one of three LIs that were tested in people with high to normal BP to study the efficacy and safety of non-pharmacologic therapy for the prevention of hypertension</p>		
<p><b>Weight loss intervention (<math>n=308</math>)</b></p> <p>Aim or goal: to achieve a weight loss of at least 4.5 kg during the first 6 months of intervention and to maintain this weight loss throughout the remaining 12 months of trial</p> <p>Study is not described as a weight maintenance study. However there were two phases. Firstly an intensive phase of an individual counselling session followed by 14 weekly group meetings (for the intensive phase it is generally unclear from study description what aspects of the intervention were provided during the individual sessions, and which in the weekly group meetings). After the intensive phase participants asked to attend monthly meetings for the duration of follow-up (18 months). This phase is described as 'Extended Intervention' and details are noted under 'Ongoing support' below</p>		<p><b>Usual-care control (<math>n=256</math>)</b></p> <p>No description provided</p>

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**Diet:**

*Details, type of diet:* focus on reducing total energy consumption by reducing fat, sugar and alcohol intake. Nutrition topics discussed included guidelines for healthy eating, reducing energy intake, identifying sources of dietary fat and methods for reducing fat intake, recipe modification, restaurant eating, social eating, menu planning, label reading, and shopping strategies. The importance of nutritional balance was discussed at group meetings and incorporated into comments on the food records. Goal of achieving gradual weight loss not to exceed 0.9 kg per week. After reaching goal weight, participants adjusted their energy intake gradually to maintain the new weight level

*Calories:* average energy intake not to fall below 1200 kcal, no upper limit stated

*Proportions of diet:* not explicitly stated. Counting energy intake from fat and the percentage of daily energy intake from fat suggested as an optional method for focussing on major sources of energy intake

*Monitoring:* participants encouraged to make series of small progressive steps to reduce energy intake. To help this, participants expected to keep food diaries for the first 14 weeks of the intervention, recording food intake for 3 of 7 days initially, increasing to 5 or more days per week by the fourth week of intervention. Entries included food description, estimate of amount eaten, and estimate of its energy value. Participants also asked to maintain graph of weight change from baseline

**Exercise:**

*Mode:* individual

*Type:* principally walking. Participants were given general exercise guidelines including warm-up and cool-down exercises, and appropriate application of such exercising as walking, cycling, circuit training, and selected recreational activities. Participants encouraged to become more aware of their normal daily routines and to incorporate more physical activities, such as using stairs rather than elevators, to enhance daily energy expenditure

*Frequency and length of each session and total number sessions:* initially to walk at least 3 days per week for a minimum of 20 minutes per session. As the intervention progressed exercise goal was 4–5 days per week with between 30 and 45 minutes of exercise per session, at an intensity of 40% to 55% of heart rate reserve (heart rate reserve had been determined empirically before intervention start)

*Delivered:* mainly self-directed

*Level of supervision:* mainly unsupervised, except for exercise demonstrations presented during meetings. Several meetings included supervised exercise periods in which the group leaders helped participants adjust their intensity of exercise to be consistent with protocol guidelines

*Monitoring:* participants asked to record daily exercise time as a bar graph, superimposed on the weight graph

**Behaviour modification:**

*Mode:* group 7–20 participants (plus occasional friends or family members there to provide support). At some point during each intervention session, the group was divided into smaller discussion groups for intensive review of each person's progress and plans for the next week

*Type:* behavioural self-management techniques (two references provided). Relapse prevention was also addressed (reference provided)

*Content:* strategies included setting reasonable short-term goals, formulating specific plans of action to achieve these goals, developing reinforcement and social support for each major element of the plan, keeping records to assess progress (monitoring of diet and exercise as noted above), and regularly evaluating and modifying action plans by using these records. During the smaller discussion groups, participants displayed graphs and discussed self-management efforts for the past week. Leaders facilitated discussion so that individuals worked on problem solving and developing specific and detailed goals and action plans for the next week. Relapse prevention included: introducing the concept of high-risk situations; identifying high-risk situations in which relapse was likely to occur; developing alternative coping strategies; teaching participants strategies for minimising the occurrence of high-risk situations. Walking opportunities were often made available

*Frequency and length of each session and total number sessions:* 14 weekly meetings, each of 90 minutes

*Delivered:* by a registered dietitian and a psychologist or exercise physiologist

**Ongoing support:**

After the intensive phase, intervention leaders attempted to make at least one intervention contact per month for the remainder of the trial. The type and exact number of contacts varied monthly according to individual needs

*Mode:* attendance options included any one or combination of the following: (1) monthly extended intervention group sessions, (2) group weigh-in sessions, (3) individual weigh-in sessions, and (4) individual counselling sessions

*Type:* extended follow-up groups were formed by combining several initial intervention groups. The format of the extended intervention meetings was similar to that of the initial intervention meetings. They featured formal presentations and group discussions on selected nutrition, exercise, and behavioural change topics as well as time for general discussion and problem solving, and for demonstrations/participation in exercise opportunities. A series of extended intervention session outlines were developed on the basis of the perceived needs of the participants. Each centre could adapt the sequence and content of session to meet the ethnic and situational needs of the participants

*Frequency and length of each session and total number sessions:* monthly meetings, length and number not explicitly stated

*Diet and Exercise:* during the extended intervention phase, subjects were encouraged to continue monitoring their weight and exercise. If a graph was not maintained an individual monitoring system of some type, such as recording the information on a calendar or in an appointment book, was encouraged

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## Other details:

If a meeting was missed an intervention leader scheduled a make-up visit as soon as possible. When participants were unable or unwilling to attend make-up visits, attempts were made to maintain contact through telephone calls and mailings

For the extended intervention frequent conference calls helped timely sharing and review of meeting experiences. All sessions were evaluated for effectiveness and archived for easy access

Attendance (at extended intervention meetings) was encouraged by the addition of occasional special events such as cooking demonstrations and guest speakers

A brief, informal meeting with a weigh-in was also offered between the monthly-extended sessions for those who missed the scheduled intervention meetings or who desired more frequent contact. Current weight and amount of exercise since last contact was obtained and individual strategies were discussed with participants during these weigh-ins. Walking opportunities were often made available in conjunction with the weigh-ins

Interventionists collaborated in the preparation of a detailed, session by session protocol and tested its feasibility at each centre with volunteer pilot subjects. This pilot was used to prepare the final version of the protocol. Ongoing quality control activities included biweekly conference calls, two all-centre staff training meetings, and a site visit to each centre

## Results

Outcomes	Weight loss (n= 308)	Control (n= 256)	p-value, 95% CI
Weight loss at 18 months, mean kg	Men 4.7, women 1.6	Men unchanged (no value provided), women + 0.2	$p < 0.001$ .
Difference in weight loss at 18 months between intervention and control groups, mean $\pm$ SEM <sup>a</sup>	Overall: $3.9 \pm 0.4$		
	Men: $4.7 \pm 0.5$ Women: $1.8 \pm 0.8$		$p < 0.01$ $p < 0.01$
Success at 18 months <sup>b</sup>	Men 45%, women 26%	Men 12%, women 18%	
Success at more than 24 or 30 months?	Phase II study included separately		
Facilitators	Not reported		
Barriers	Not reported		
Other intermediate outcomes	Not reported		

SEM, standard error of mean.

a Data from this analysis restricted to whites not extracted.

b Success defined as having met weight loss goal of 4.5 kg. Numbers not calculated as value of denominator not clear.

States that the average treatment effect remained highly significant when weight loss was expressed as a percentage change from baseline weight, or as the change in BMI but no data provided. The difference between women and men in percentage changes from baseline weight and change in BMI remained statistically significant although at a diminished level of significance ( $0.05 > p > 0.001$  for both measures at each follow-up).

Treatment effect on weight was more strongly modified by baseline weight than by sex. Paper provides data on estimated difference in weight loss for those less than, and more than the median weight (not data extracted). Differences in intervention effect were also examined by race (not data extracted).

Changes in measures of BP associated with changes in weight not data extracted.

## Methodological comments/notes

- Allocation to treatment groups: once eligibility for the trial was confirmed, participants in the high-weight stratum (who were those eligible for the weight loss intervention of interest here) were randomised to all TOHP treatment groups and controls. Each participating clinic notified the co-ordinating centre by telephone and obtained a randomisation assignment (no details of randomisation schedule). Clinics were also provided with sealed envelopes containing randomisation assignments for use when telephone contact with the co-ordinating centre was not possible (not stated if these were used). Once the assignment was communicated to the participant, he or she was considered officially randomised. Randomisation was to more than the two groups relevant to this review
- Blinding: the Whelton and colleagues<sup>109</sup> paper (p. 298) notes that a small sample of randomly selected high-weight participants from other LI arms had the same baseline assessments as those assigned to the weight loss intervention to maintain observer blinding. Baseline assessments obtained by blinded observers. He and colleagues<sup>110</sup> report that for one centre data collectors were also blinded at follow-ups, however, Sattersfield and colleagues<sup>112</sup> provide conflicting information stating that the lifestyle arm of the trial had an open design (while supplement interventions were double-blinded and placebo-controlled with data collectors for BP measurements blinded to treatment)
- Comparability of treatment groups: baseline similarity overall and by gender was examined. There were no significant differences between the two groups except that the intervention group had slightly larger proportion of men (72.7% vs 62.9%,  $p=0.02$ ). There was a higher proportion of black participants among women than among men in both groups
- Method of data analysis: statistical tests for differences in means or proportions included student's two-sample  $t$ -test (for means) and the chi-squared test of association (for proportions). Mean differences in weight change from baseline between intervention and control groups were assessed overall and for men and women separately with a  $t$ -test at each follow-up visit. Linear regression analysis was used to adjust for age, race, baseline BP and gender (when appropriate). However, because results did not change the unadjusted results are presented. A difference in treatment effect by gender was tested in a regression model with a gender-by-treatment interaction term. Data collectors were trained centrally, were required to pass certification examinations and periodic recertification evaluations
- ITT analysis: not reported (and therefore not defined). Appears unlikely that analysis is ITT
- Sample size/power calculation: power of 85% to detect a diastolic BP (DBP) effect of 2 mmHg in the complete study sample. For the weight reduction part of the trial there was a power of 96% to detect a DBP effect of 2 mmHg, and 93% power to detect a change of 3 mmHg in systolic BP (SBP). No further details are provided, and no comment made regarding power for detecting weight reduction, also unclear whether powered for subgroups
- Attrition/dropout: attendance reported but unclear how many participants dropped out completely and reasons for dropout not provided

### General comments

- Generalisability: not generalisable to older people due to inclusion criterion of age 30–54 years. Not generalisable to those with BMI > 36 kg/m<sup>2</sup>. Typical participants were well-educated, middle-aged, white males with a full time job. Participants were volunteers that may affect generalisability
- Outcome measures: the main focus of the trial is BP status. No further outcomes to weight loss, diet or exercise apparent
- Facilitators/barriers not reported as outcomes: not reported
- Intercentre variability: no comments found relating to this. Note that interventionists were all involved in the protocol preparation and piloting of this. Biweekly conference calls, two all-centre staff training meetings and a site visit ensured quality control
- Conflict of interests: no statement of conflicts of interest found

## Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Not reported
2. Was the allocation adequately concealed?	Yes
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Unclear
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups? (ii) If so, were they explained or adjusted for?	Not reported
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis? (ii) If so, was this defined?	Not reported
10. (i) Did the analysis account for missing data? (ii) If so, were the methods appropriate?	Not reported

### Stevens et al. and TOHP collaborative research group

Study details	Participants	Outcome measures
<p>Author: Stevens <i>et al.</i><sup>70</sup> and TOHP collaborative research group<sup>113</sup></p> <p>Data also reported in studies<sup>114–118</sup></p> <p>Year: 2001</p> <p>Country: USA</p> <p>Study design: RCT</p> <p>Number of centres: nine</p> <p>Funding: numerous grants from National Heart, Lung and Blood Institute</p> <p>Recruitment dates: December 1990 to March 1992</p> <p>Setting: clinics</p> <p>Length of follow-up: minimum of 36 months; additional data at 42 (<math>n=1458</math>, 61%) and 48 (<math>n=464</math>, 19%) months depending on randomisation date</p>	<p>Number of participants: <math>n=1191</math></p> <p>Weight loss (WL) group, <math>n=595</math></p> <p>Usual-care (UC) group, <math>n=596</math></p> <p>Part of an RCT of four groups: weight loss only, sodium reduction only, weight loss and sodium reduction, usual-care controls (<math>n=2382</math>)</p> <p>Sample attrition/dropout: at 18 months 50 were not included in the analysis in the WL group and 45 in the UC group; at 36 months these rates were 48 and 42, respectively</p> <p>Attendance at sessions measured: yes, although rates could differ depending on delay before first group session</p> <p>Other measures of adherence: yes</p> <p>Sample crossovers: none reported</p> <p>Inclusion/exclusion criteria for study entry: overweight adults with non-medicated DBP of 83–89 mmHg and SBP &lt; 140 mmHg, aged 30–54 years, BMI of 26.1–37.4 kg/m<sup>2</sup> for men and 24.4–37.4 kg/m<sup>2</sup> for women (approximately 110%–165% of ideal weight based on 1983 Metropolitan life tables)</p> <p>Exclusion criteria: current hypertension or treatment with medications that might affect BP, clinical or laboratory evidence of cardiovascular disease, diabetes mellitus, renal insufficiency [serum creatinine concentration <math>\geq 150 \mu\text{mol/l}</math> (<math>\geq 1.7 \text{ mg/dl}</math>) for men and <math>\geq 132 \mu\text{mol/l}</math> (<math>\geq 1.5 \text{ mg/dl}</math>) for women] or other serious illness, current or planned pregnancy, non-fasting serum glucose concentration of <math>\geq 200 \text{ mg/dl}</math>, alcohol intake of <math>\geq 21</math> drinks per week, residing more than 50 miles from the centre, evidence of unwillingness to adhere to the trial intervention or data collection procedures</p> <p>Characteristics of participants:</p> <p>Any risk factors noted: all participants had high–normal BP</p> <p>Gender (M:F), <math>n</math> (%): WL 375:220 (63.0:37.0); UC 407:189 (68.3:31.7)</p> <p>Age (years), mean (SD): WL 43.4 (6.1); UC 43.2 (6.1)</p> <p>BMI kg/m<sup>2</sup>, mean (SD), M:F: WL 31.0 (2.9):31.0 (3.6); UC 31.0 (2.9):30.8 (3.5)</p> <p>Weight, kg, mean (SD), M:F: WL 98.9 (12.3):84.1 (11.9); UC 98.54 (11.7):82.9 (10.9)</p> <p>Overall weight kg, mean (SE): WL 93.4 (14.1); UC 93.6 (13.5)</p> <p>Vigorous exercise, times per week: WL 2.0 (4.0); UC 1.8 (1.9)</p> <p>Ethnicity % white:black: WL 78:17.8; UC 79.5:17.3</p>	<p>Primary outcomes: BP (not extracted), weight loss</p> <p>Secondary outcomes: dietary intake, physical activity, medication use – not extracted</p> <p>Facilitators and barriers: none</p> <p>Methods of assessing outcomes:</p> <p>Weight measured to the nearest 0.2 kg (0.5 lb) by using a calibrated balance beam scale; participants wore indoor clothing without shoes</p> <p>Subgroup analyses by gender and ethnicity (not extracted)</p>

**Intervention details****WL****(n=595)**

Aim or goal: to lose at least 4.5 kg (10 lb) during the first 6 months of the intervention and to maintain the weight loss for the remainder of the trial. The intervention has a pre-intensive phase (while clinics accrued enough participants for the group intervention), an intensive phase, a transitional phase and then an extended phase. The transitional phase was designed to prevent relapse and to ease transition from weekly to less frequent contacts. The goal of the final extended phase was to maintain participants' behaviour changes

*Diet:*

*Details, type of diet:* focus on reducing caloric intake but weight loss of > 0.9 kg (2 lb) per week was discouraged

*Calories:* suggested that men not consume < 1500 kcal/day and women < 1200 kcal/day but with experience participants determined the caloric intake that produced moderate weight loss for them

*Proportions of diet:* states decreasing consumption of excess fat, sugar and alcohol

*Monitoring:* self-monitoring with daily food diaries, known as 'scorekeepers'. Asked to record intake for at least 6 days a week during the intensive phase, after this time the frequency was individualised. Progress also monitored at group meetings and by frequent measurement of weight

*Exercise:*

*Mode:* group discussion of goals but individual exercise

*Type:* primarily brisk walking, states moderate intensity exercise of approximately 40%–55% of heart rate reserve

*Frequency and length of each session and total number sessions:* to gradually increase activity from 10–15 minutes at least 3 days per week to 30–45 minutes per day, 4–5 days per week at an intensity of 40%–55% of heart rate reserve

*Delivered:* group discussion of exercise by dietitians and health educators, otherwise exercise was undertaken individually (four of the 14 sessions were specifically designated for engaging in physical activity)

*Level of supervision:* discussed at group interventions, otherwise assume self-supervised

*Monitoring:* graphs of physical activity per day used and recorded activity in the 'scorekeepers'. Progress reviewed at the group meetings

*Behaviour modification:*

*Mode:* individual counselling session until groups could be formed (at least one) and some group meetings or by telephone during the 'pre-intensive' phase, followed by group sessions thereafter. Groups of 11–34 participants

*Type:* states based on behaviour change principles, but no further details

*Content:* focus on self-directed behaviour change (behavioural self-management), nutrition education, information on physical activity, and social support for making and maintaining behaviour changes. Specifically included self-monitoring, short-term goal-setting, developing specific action plans to achieve objectives, developing alternative strategies for situations which trigger problem eating

*Frequency and length of each session and total number sessions:* monthly contact (pre-intensive phase) weekly for 14 weeks (intensive phase) then six biweekly meetings and then monthly meetings for additional 3–4 months (although one study publication suggests for 18 months) (transitional phase)

*Delivered:* led by dietitians and health educators (and some psychologists) who were centrally trained and had experience of conducting weight loss interventions

*Ongoing support:*

In the extended phase of the study participants were given options to keep them informed, including individual counselling sessions, special refresher group sessions (mini-modules) and biweekly meetings

*Mode:* could be group/individual/telephone/postcards/faxes

*Type:* refreshing or redelivering the intervention content, especially for those who had not lost weight initially or relapsed. Modules included a wide range of topics and activities that were determined by a combination of participant and interventionist interest, as well as by centre and local area resources, season of the year and current events

*Frequency and length of each session and total number sessions:* biweekly contacts for three to six sessions in each mini-module, offered six times a year (participants expected to attend at least three)

*Other details:*

Family members were invited to group meetings when the participant felt it helpful

**UC****(n=596)**

No details reported



## Results

Outcomes	WL group ( <i>n</i> =595)	UC group ( <i>n</i> =596)	Difference (SE), 95% CI, <i>p</i> -value
Weight change from baseline at 18 months, kg (SD), 95% CI, <i>n</i>	-2.0 (5.8), -2.5 to -1.5, <i>n</i> =545	0.7 (4.2), 0.4 to 1.6, <i>n</i> =551	-2.7 (0.3), -3.3 to -2.1, <i>p</i> <0.001
Weight change from baseline at 36 months, kg (SD), 95% CI, <i>n</i>	-0.2 (5.9), -0.7 to 0.3, <i>n</i> =547	1.8 (5.3), 1.3 to 2.2, <i>n</i> =554	-2.0 (0.2), -2.6 to -1.3, <i>p</i> <0.001
Facilitators	Not reported	Not reported	
Barriers	Not reported	Not reported	
Other intermediate outcomes	None	None	

## Methodological comments/notes

- Allocation to treatment groups: states participants were randomly assigned with equal probability to one of four groups. Those undertaking the assignment were blind to the intervention assignment, performed by telephone contact with the TOHP co-ordinating centre (in 77% of participants, as only open during normal working hours) or by opening a sealed, opaque envelope. Randomisation was stratified by clinic to provide an even distribution to the four groups at each site
- Blinding: clinic staff who were blinded to study group assignment assessed outcomes (questionnaires to data collectors at the end indicated 31.6% guessed correctly which intervention group a participant was in, which was more than expected by chance, 25%)
- Comparability of treatment groups: states baseline characteristics compared by *t*-tests and chi-square tests and groups were comparable (*p*-values reported for the comparison of the four treatment groups)
- Method of data analysis: two sample *t*-tests were used to compare changes in weight from baseline overall, by gender, ethnicity and by gender and ethnicity
- ITT analysis: not reported
- Sample size/power calculation: sample size (for primary outcome of BP) was expected to provide greater than 80% power to detect a treatment-related difference in DBP between the varying groups in the factorial design of the overall study. Not strictly powered for the weight outcome. Attrition/dropout: states weight data collected every 6 months, with special efforts to achieve high follow-up rates at 18 and 36 months. Numbers analysed reported but no reasons (except the few who died)

### General comments

- Generalisability: not generalisable to older people due to inclusion criterion of age 30–54 years. Study also undertaken in those described as 'moderately overweight' therefore excludes people with BMI > 37 kg/m<sup>2</sup>, also only applies to those with high-normal DBP. Candidates were canvassed from mass mailing, community screening, media advertising, and other sources and thus were volunteers to the study that may reduce the generalisability of the study. Some centres had higher proportions eligible after screening than others
- Outcome measures: 6-month outcome data reported for weight loss (not extracted here)
- Facilitators/barriers not reported as outcomes: none
- Intercentre variability: not reported, states quality control procedures including periodic retraining and monthly reviews were put in place
- Conflict of interests: none reported

### Quality criteria for assessment

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1. Was the method used to generate random allocations adequate?	Yes
2. Was the allocation adequately concealed?	Yes
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Yes
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	No
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis?	No
(ii) If so, was this defined?	
10. (i) Did the analysis account for missing data?	Not reported
(ii) If so, were the methods appropriate?	

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## Tate et al.

Study details	Participants	Outcome measures
Author: Tate <i>et al.</i> <sup>77</sup> (Linked to Jeffery <i>et al.</i> <sup>119</sup> and Raynor <i>et al.</i> <sup>120</sup> ) Year: 2007 Country: USA Study design: RCT (two arms) Number of centres: not reported (recruitment was from two centres) Funding: National Institutes of Health grants HL41330 and HL41332 Recruitment dates: not reported Setting: not reported but recruitment by public advertisement Length of follow-up: 30 months	Number of participants: Standard behavioural treatment (SBT) $n=93$ High physical activity (HPA) treatment group $n=109$ Total number randomised: $N=202$ Sample attrition/dropout: <i>HPA retention</i> : 94% at 6 months, 79% at 12 months, 80% at 18 months, 77% (84/109) at 30 months <i>SBT retention</i> : 90% at 6 months, 82% at 12 months, 87% at 18 months, 79% (74/93) at 30 months Total number of drop outs at 30 months: $n=44$ Attendance at sessions measured: not reported Other measures of adherence: none reported Sample crossovers: none Inclusion/exclusion criteria for study entry: age 25–50 years; overweight of 14–32 kg according to actuarial norms; free from serious concurrent medical or psychological problems thought to interfere with treatment Characteristics of participants: most demographic and baseline data not reported separately for each group. States there were no significant differences between treatment groups for age, gender, % of college graduates, white ethnicity, and mean BMI <i>Any risk factors noted</i> : no Gender (M:F), $n$ (%): 85:117 (42%:58%) ( $n$ : $n$ calculated by reviewer) Age (years), mean (SD): 42.2 (6.4) BMI $\text{kg/m}^2$ , $n$ (%): mean (SD): BMI 31.7 (2.6) $\text{kg/m}^2$ , range 26–44 Weight kg, mean: approximately 90.5 for both interventions (data extracted from graph by reviewer) % weight lost before starting: not reported Duration of overweight/obesity: not reported Previous weight loss attempts: not reported Physical activity level (assessed by self-report with Paffenbarger Physical Activity Questionnaire): baseline weekly energy expenditure (kcal/week), mean (SD): HPA 1278.0 (1369), $n=109$ . SBT 1286.0 (1258.0), $n=93$ Ethnicity: 80% white Socioeconomic position: not reported Pre-existing medical conditions: not reported	Primary outcomes: change in body weight Secondary outcomes: physical activity (energy expenditure); Dietary intake (energy intake kcal/day; protein g/day; fat g/day; carbohydrate g/day); Adverse effects of exercise programme – not extracted Facilitators and barriers: none reported Methods of assessing outcomes: Body weight: measured in clinic using a calibrated scale while the subject wore light street clothes and no shoes Height (used for BMI calculation): wall-mounted stadiometer <i>Subgroup analyses</i> : Tate <i>et al.</i> paper <sup>77</sup> reports weight changes for subgroups of consistently high exercisers versus all others

**Intervention details****SBT group****(n=93)**

**Aim or goal:** encourage increasing physical activity to reach standard 1000 kcal physical activity/week prescription during a behavioural weight loss programme

**Diet:**

*Type of diet:* calorie restriction, low fat

*Frequency and length of each session and number of sessions:* not reported explicitly for diet; probably as reported below for behaviour modification as this included nutritionists

*Calories:* goal to reduce daily energy intake to 1000–1500 kcal depending on initial body weight (no further details provided)

*Proportions of diet:* consume <20% of energy as fat

*Monitoring:* participants asked to keep complete diet records daily for the first 6 months and for 1 week/month thereafter during the 18-month intervention phase

**Exercise:**

*Mode:* not stated but appears to be individual

*Type:* not stated, but goal was to build up from energy expenditure of 250 kcal/week, increasing by 250 kcal/week, to energy expenditure of 1000 kcal/week (roughly equivalent to walking for 30 minutes/day)

*Frequency and length of each session and total number sessions:* not stated, but goal was to initiate a regular physical activity programme

*Delivered:* not stated, but appears to be no set class, instead self-directed by participant

*Level of supervision:* not stated, but appears to be unsupervised

*Monitoring:* participants were asked to keep complete physical activity records daily for the first 6 months and for 1 week/month thereafter during the 18-month intervention phase

**Behaviour modification:**

*Mode:* small groups, e.g. 10–20 participants

*Type:* no theoretical basis or definition of behaviour modification component reported

*Content:* didactic presentations of material needed to develop obesity management skills, group discussions, and problem solving. Session content adapted from prior research (referenced by Jeffery *et al.*<sup>119</sup>) included diet, physical activity, stimulus control, problem solving, goal-setting, social support, motivation, and relapse prevention topics

*Frequency and length of each session and total number sessions:* weekly meetings for first 6 months, biweekly from 6 to 12 months, then monthly from 12 to 18 months. No treatment contact after the 18-month programme until participants were re-contacted at 30 months for the final assessment

*Delivered:* led by trained interventionists (nutritionists, exercise physiologists, or psychologists) with expertise in both content area (i.e. physical activity and nutrition) and behavioural therapy

**Other details:**

Participants were not encouraged to recruit friends or family members

*Financial incentives:* none

**HPA group****(n=109)**

**Aim or goal:** encourage increasing physical activity to reach 2500 kcal physical activity/week during a behavioural weight loss programme

Study reports a weight management (weight loss) intervention (duration of intervention 18 months) with participants followed up for a further year after the end of the intervention (to determine how well weight loss maintained, but no intervention in this period)

**Diet:** identical goals as the SBT group

**Exercise:**

*Mode:* not explicitly stated but appears to be a mix of individual and group (with support partners,  $n=1-3$ ; see 'Other' details below)

*Type:* not stated, but goal was to build up to an energy expenditure of 2500 kcal/week by the end of the first 6 months of the intervention (roughly equivalent to walking <75 minutes/day)

*Frequency and length of each session and number of sessions:* not reported explicitly for diet; probably as reported below for behaviour modification as this included exercise physiologists

Appears also to be participant determined

*Delivered:* by exercise coaches (also referred to as exercise physiologists) skilled in exercise science and prescription

*Level of supervision:* the exercise coaches met with small groups of study participants before or after each group session. They reviewed exercise progress with each participant individually and provided encouragement, support, and problem-solving strategies for participants who were having difficulty reaching their physical activity goals

*Monitoring:* same as the SBT group

*Behaviour modification:* identical to that of the SBT group

**Ongoing support:**

Other than contact as described above during the intervention, there was no contact between the end of the intervention at 18 months and the final follow-up at 30 months

**Other details:**

Participants were strongly encouraged to recruit friends or family members to participate in the study with them due to prior research suggesting benefits of social support for exercise and maintenance of weight loss. Participants were encouraged to recruit one to three partners, overall 54% of this group recruited one or more support partners. Entry criteria for support partners were wider than for trial participants but they went through the same screening, received the same intervention and participated in same outcome assessments

*Financial incentives:* incentives of US\$3 for each week that participants achieved or exceed the energy expenditure goal of 2500 kcal/week during the last 6 months of active intervention (months 12–18). Participants were paid US\$50 for completing the 30-month assessment

## Results

Outcomes:	1. HPA	2. SBT	p-value
Weight loss kg, baseline to 18 months	6.7±8.1 ( <i>n</i> =87) (variance estimate not defined) <sup>a</sup>	4.1±8.3 ( <i>n</i> =80) (variance estimate not defined) <sup>a</sup>	<i>p</i> =0.04
Weight loss kg, baseline to 30 months (unclear whether this is an ITT analysis)	2.86 8.6 ( <i>n</i> =84) (variance estimate not defined)	0.9±8.9 ( <i>n</i> =74) (variance estimate not defined)	States no significant difference, <i>p</i> =0.16
Weight loss % of initial body weight, baseline to 30 months (unclear whether this is an ITT analysis)	3 (variance estimate not reported)	1 (variance estimate not reported)	States no significant difference, <i>p</i> -value not reported
Weight regain from 18 to 30 months, kg (unclear whether this is an ITT analysis)	5.9 5.9 ( <i>n</i> not reported) (variance estimate not defined)	5.3±7.0 ( <i>n</i> not reported) (variance estimate not defined)	States no significant difference, <i>p</i> -value not reported
Success at 30 months (ITT, assuming no weight loss for missing data)	Total weight loss ≥5% achieved by 26% Total weight loss ≥10% achieved by 12%		States no significant difference, <i>p</i> -value not reported
Facilitators	Not reported	Not reported	Not reported
Barriers	Not reported	Not reported	Not reported

a The standard error of the mean (SEM) shown in Figure 2 of Jeffery and colleagues<sup>119</sup> has bars which are much narrower than the variance estimates reported here, suggesting these are not SEM.

Taking all participants (both interventions together), mean (±SD) weight loss (kg) 0–30 months was significantly greater (*p*=0.04) in men (4.2±7.1) than in women (0.29±9.5).

Post hoc analyses were conducted by Tate and colleagues<sup>77</sup> in a selected 'high-adherence' exercise group but have not been data extracted.

These analyses were conducted to explore whether those reporting high levels of activity at all follow-ups were protected against weight regain.

Raynor and colleagues<sup>120</sup> reported on 122 of the 202 participants who had complete data, including complete dietary data but changes in foods eaten and weight were not reported by study group and have not been data extracted.

## Methodological comments/notes

- Allocation to treatment groups: randomisation and allocation procedures not described
- Blinding: not reported
- Comparability of treatment groups: stated there were no significant differences between treatment groups for age, gender, % of college graduates, white ethnicity, and mean BMI but data not reported separately for each group and no  $p$ -value(s) provided.<sup>119</sup> Examination of the baseline characteristics of study completers ( $n=168$ ) and study dropouts ( $n=34$ ) at 18 months found no significant difference in body weight, gender, exercise level, energy intake or percentage of energy from fat.<sup>119</sup> Examination of the baseline characteristics of study completers ( $n=158$ ) and study dropouts ( $n=44$ ) at 30 months found no significant difference in body weight, BMI, gender, energy intake or energy expenditure<sup>77</sup>
- Method of data analysis: continuous dependent variables (weight, total energy expenditure, and total energy intake) were analysed by using general linear modelling procedures for repeated measurements. Energy expenditure was not normally distributed, and the data were log transformed before analysis. Between-group comparisons of baseline characteristics, weight change or change in calories (exercise or diet) at specific end points were analysed by using ANOVA. Analyses of exercise subgroups controlled for baseline weight and gender
- ITT analysis: reported but not defined. For ITT analyses, participants for whom data were missing at any time point were assumed not to have lost any weight, and an approach of carrying the baseline forward was used
- Sample size/power calculation: not reported
- Attrition/dropout: reasons not provided. Stated that dropouts and completers did not differ in BMI, gender, energy expenditure and energy intake (other variables not examined). Jeffery and colleagues<sup>119</sup> reported an interaction for weight loss at 6 months between intervention and attrition. In HPA, subjects with complete data (for 18 months) had higher mean 6-month weight losses than those with incomplete data (i.e. those who did not complete 18 months) ( $p<0.02$ ). In SBT the pattern was reversed ( $p=0.10$ ). They stated that this strongly suggests that the assumption in their ANOVA analysis that the loss to follow-up is unbiased may not be correct. However they believed that the repeated measures ANOVA is likely to be biased toward the null hypothesis, i.e. in favour of no difference between the study groups. No test for an interaction beyond 6 months was reported

### General comments

- Generalisability: uncertain, but 80% white ethnicity and 43% college graduates so may not be representative of the overweight and obese population in the UK. Free from serious concurrent medical or psychological problems. Recruitment was by public advertisement and participants received monetary incentives. This may have had an impact on those taking part
- Outcome measures: reported as mean  $\pm$  unspecified variance estimate; effect size and statistical significance not reported for most outcomes. Additional measures reported but not data extracted: energy intake (kcal/day); protein (g/day); fat (g/day); carbohydrate (g/day); energy expenditure (kcal/week). Adverse effects of exercise programme (at 18 months only)<sup>119</sup>
- Facilitators/barriers not reported as outcomes: none, but note that discussion in Tate and colleagues<sup>77</sup> stated that failure to maintain higher levels of physical activity 1 year after treatment ended was the likely reason for the failure of the HPA group to achieve greater long-term weight loss than the SBT group. Discussion in Jeffery and colleagues<sup>119</sup> suggests that injuries may undermine the ability of participants to stick with an exercise programme over time (and the injury rate was consistently greater in the HPA treatment group than in the SBT group for the 18 months of this study)
- Intercentre variability: not mentioned. Number of centres not explicitly stated (seem to be only two)
- Conflict of interests: stated that none of the authors had a financial or personal conflict of interest

## Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Not reported
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups? (ii) If so, were they explained or adjusted for?	Unclear
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis? (ii) If so, was this defined?	Yes No
10. (i) Did the analysis account for missing data? (ii) If so, were the methods appropriate?	Yes Unclear

## Wadden et al.

Study details	Participants	Outcome measures
Author: Wadden <i>et al.</i> <sup>69,121</sup>	Number of participants:	Primary outcomes:
Years: 1986, 1988	Standard behaviour therapy (SBT) [referred in publication as Behavioural Therapy (BT)]: <i>n</i> = 18	(reported, but not stated explicitly that these were primary outcomes):
Country: USA	Combined treatment (VLCD + SBT): <i>n</i> = 23	weight loss; percentage of participants maintaining weight loss at 1 and 3 years' follow-up
Study design: RCT	Very-low-calorie diet (VLCD): <i>n</i> = 18	Secondary outcomes:
Number of centres: not reported	Total: <i>N</i> = 59	(reported, but not stated explicitly that these were secondary outcomes; not data extracted): depression;
Funding: researchers supported by three grants from: National Institute of Mental Health; National Institute of Child Health and Human Development; MacArthur Foundation's Network on Health Promoting and Disease Preventing Behaviors	Sample attrition/dropout:	psychological and physical consequences of regaining weight (not validated); BP
Recruitment dates: not reported	Not reported separately by intervention but stated that attrition was spread evenly across the interventions	Facilitators and barriers: none reported
Setting: not reported; VLCD intervention aimed to simulate physician's outpatient practice	<i>At end of treatment (4 or 6 months)</i> : overall 15.3% (nine participants)	Methods of assessing outcomes:
Length of follow-up: 3 years	<i>At 1-year follow-up</i> : overall 18.6% (11 participants)	Weight measured using a balance beam scale
	<i>At 3-year follow-up</i> : overall 23.7% (14 participants)	<i>Subgroup analyses</i> :
	Attendance at sessions measured: not reported	Interventions each stratified into three groups based on degree overweight
	Other measures of adherence: none reported	Post hoc comparison of participants who after 1-year follow-up did ( <i>n</i> = 19) or did not ( <i>n</i> = 26) receive additional therapy from external weight loss programmes
	Sample crossovers: none reported	
	Inclusion/exclusion criteria for study entry:	
	<i>Inclusion</i> : written approval from participant's physician; responders to newspaper advertisements; at least 25 kg overweight (based on height-weight tables of Metropolitan Insurance Company)	
	<i>Exclusion</i> : recent cardiac abnormality including myocardial infarction; history of cerebrovascular, kidney, or liver disease; cancer; type I diabetes; severe psychiatric illness	
	Characteristics of participants:	
	<i>Risk factors noted</i> : 14 participants (23.7%) were taking antihypertensive treatment	
	Reported only for 50 participants who completed treatment (VLCD = 15; SBT = 16; VLCD + SBT = 19):	
	Gender (M:F), <i>n</i> (%):	VLCD: 2:13 (13:87)
		SBT: 3:13 (19:81)
		VLCD + SBT: 2:17 (11:89)
	Age (years), mean ± SD:	VLCD: 44.3 ± 8.7
		SBT: 44.3 ± 8.6
		VLCD + SBT: 43.6 ± 7.8
	Height (cm), mean ± SD:	VLCD: 162.1 ± 7.0
		SBT: 166.5 ± 10.3
		VLCD + SBT: 165.6 ± 7.3
	Weight (kg), mean ± SD:	VLCD: 106.4 ± 18.4
		SBT: 112.2 ± 21.5
		VLCD + SBT: 108.0 ± 21.5
	Degree overweight (%), mean ± SD:	VLCD: 85.4 ± 27.4
		SBT: 91.8 ± 32.2
		VLCD + SBT: 90.7 ± 37.4
	BMI, kg/m <sup>2</sup> , <i>n</i> (%):	Not reported
	% weight lost before starting:	Not reported
	Duration of overweight/obesity:	Not reported
	Previous weight loss attempts:	Not reported
	Physical activity level:	Not reported
	Ethnicity:	Not reported
	Socioeconomic position:	Not reported
<b>Intervention details</b>		
Three <i>weight loss</i> interventions of duration 4 months (VLCD), 6 months (SBT) or 6 months (SBT + VLCD), each with follow-up at 1 year (reported in Wadden <i>et al.</i> <sup>121</sup> ). <i>Weight loss or maintenance</i> then assessed after 3 years (reported in Wadden <i>et al.</i> <sup>69</sup> ). During years 1–3, some participants (19%) received additional weight therapy from unspecified external sources while the remainder (81%) did not receive any additional weight therapy		

**Intervention details****SBT****(n = 18)**

Aim or goal: not reported

*Diet:**Type of diet:* 6-month duration, 1000–1200 kcal/day balanced diet of participants' choosing*Frequency and length of each session and total number sessions:* weekly 90-minute sessions of groups of 4–7 participants led by two doctoral-level clinical psychologists, following procedures described in detailed treatment manuals which differed for each intervention (no details reported)*Calories:**Months 1–6:* 1000–1200 kcal/day*Proportions of diet:* months 1–6: chosen by participants. No further details reported*Monitoring:* none reported*Exercise:**Mode:* three groups of 4–7 people*Type:* involved walking and using stairs. No other details reported*Frequency and length of each session and total number sessions:* as reported above for diet*Delivered:* by two doctoral-level clinical psychologists*Level of supervision:* not reported (assumed as for VLCD)*Monitoring:* none reported*Behaviour modification:**Mode:* three groups of 4–7 people*Type:* training in skills needed for weight loss maintenance*Content:* traditional behavioural methods of weight control taught (based on cited references). Included: recording eating behaviour; controlling stimuli associated with eating; slowing rate of consumption; modifying self-defeating thoughts and emotions associated with dieting; social support; and reinforcing changes in behaviour*Frequency and length of each session and total number sessions:* as reported for diet*Delivered:* by two doctoral-level clinical psychologists*Ongoing support:*

Scheduled follow-up meetings (no other details reported)

*Type:* group**VLCD + SBT****(n = 23)**

Aim or goal: not reported

*Diet:**Type of diet:* 6-month duration including a 2-month VLCD comprising a protein-sparing modified fast (months 1–4 same as VLCD; months 5–6 same as SBT);*Month 1:* 1000–1200 kcal/day balanced diet of participants' choosing*Months 2–3:* VLCD comprising a protein-sparing modified fast*Month 4:* return to conventional food*Months 5–6:* 1000–1200 kcal/day balanced diet of participants' choosing*Frequency and length of each session and total number sessions:* same as SBT*Calories:* months 1–4 same as VLCD; months 5–6 same as SBT;*Month 1:* 1000–1200 kcal/day*Months 2–3:* 400–500 kcal/day*Month 4:* return to 1000–1200 kcal/day (managed refeeding)*Months 5–6:* 1000–1200 kcal/day*Proportions of diet:**Month 1:* 'balanced calorie diet' (no details reported)*Months 2–3:* VLCD comprising meat, fish, fowl, plus daily supplements of 3 g each of potassium and sodium chloride and 800 mg of calcium*Month 4:* conventional food, with introduction of (in order) fruits and vegetables, breads and cereals, and fats*Months 5–6:* chosen by participants*Monitoring:* not reported (assumed the same as VLCD)*Exercise:**Mode:* three groups of 4–7 people*Type:* involved walking and using stairs. No other details reported*Frequency and length of each session and total number sessions:* as reported for diet*Delivered:* by the same people as SBT*Level of supervision:* not reported (assumed as for VLCD)*Monitoring:* none reported*Behaviour modification:**Mode:* as reported for SBT*Type:* as reported for SBT*Content:* as reported for SBT*Frequency and length of each session and total number sessions:* as reported for SBT*Delivered:* as reported for SBT**VLCD****(n = 18)**

Aim or goal: to simulate treatment as delivered in a physician's outpatient practice (no quantitative goal specified)

*Diet:**Type of diet:* 4-month duration including a 2-month VLCD comprising a protein-sparing modified fast*Months 1–4:* same as VLCD + SBT*Frequency and length of each session and total number sessions:* same as SBT*Calories:**Months 1–4:* same as VLCD + SBT*Proportions of diet:**Months 1–4:* same as VLCD + SBT*Monitoring:* participants were encouraged to record their food intake*Exercise:**Mode:* three groups of 4–7 people*Type:* no formal instruction in modifying exercise habits*Frequency and length of each session and total number sessions:* as reported for diet*Delivered:* by the same people as SBT*Level of supervision:* supervision only of discussion groups*Monitoring:* participants were encouraged to record their exercise*Behaviour modification:*

No behaviour modification. At weekly group meetings participants discussed their reactions to the diet but received no formal instruction in modifying their eating and exercise habits

*Ongoing support:*

Scheduled follow-up meetings (no other details reported)

*Mode:* group; size not reported*Type:* group*Frequency and length of each session and total number sessions:* six scheduled follow-up meetings at 1, 2, 3, 6, 9, and 12 months post-treatment (no other details reported)

Other details:

As reported for SBT



<p><i>Frequency and length of each session and total number sessions:</i> 11 scheduled follow-up meetings: fortnightly for 2 months post-treatment, then monthly for 4 months then at 2-month intervals for 6 months (no other details reported)</p> <p>Other details: Subjects paid US\$10 per visit plus US\$40 which was refunded at the 1-year follow-up</p>	<p><i>Ongoing support:</i> Scheduled follow-up meetings (no other details reported)</p> <p><i>Mode:</i> group; size not reported</p> <p><i>Type:</i> group</p> <p><i>Frequency and length of each session and total number sessions:</i> as reported for SBT</p> <p>Other details: As reported for SBT</p>
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## Results

Outcomes	VLCD + SBT (n = 16)	VLCD (n = 15)	SBT (n = 14)	p-value, 95% CI
Mean ± SD weight loss (kg)				
(a) uncorrected analysis <sup>a</sup>	(a) 6.53 ± 9.50	(a) 3.76 ± 8.85	(a) 4.76 ± 6.56	Stated NS; no p-values reported
(b) corrected analysis <sup>a</sup>	(b) 5.11 ± 8.28 (variance not reported)	(b) 2.20 ± 8.50 (variance not reported)	(b) 3.54 ± 6.26 (variance not reported)	
Mean proportion (%) of participants who equalled or exceeded their pre-treatment weight (stated that the % are approximate) (based on corrected analysis <sup>a</sup> )	38 (variance not reported)	47 (variance not reported)	43 (variance not reported)	Stated NS; no p-values reported
Mean proportion (%) of participants who maintained weight loss within 2 kg of their end-of-treatment weight (based on corrected analysis <sup>a</sup> )	19 (variance not reported)	13 (variance not reported)	7 (variance not reported)	Not reported
Mean proportion (%) of participants who maintained weight loss:				
(a) 5 kg or greater	(a) 44	(a) 33	(a) 29	Stated NS; no p-values reported
(b) 10 kg or greater	(b) 31 (variance not reported)	(b) 27 (variance not reported)	(c) 7 (variance not reported)	
(based on corrected analysis <sup>a</sup> ) Stated that the percentages are approximate				
Facilitators	None reported	None reported	None reported	
Barriers	None reported	None reported	None reported	

NS, not statistically significant.

a Some participants in each intervention group received additional external therapy 1–3 years after the end of treatment (VLCD: *n* = 8; SBT: *n* = 5; VLCD + SBT: *n* = 6).

All results are presented for follow-up at 3 years after end of treatment.

These participants lost on average 3.42 kg during additional therapy before participating in the 3-year follow-up. The *uncorrected analysis* includes these participants but does not take into account the effect of additional therapy on their weight. The *corrected analysis* includes these participants but accounts for the effect of additional therapy by subtracting their self-reported weight at the time they received additional therapy from their pre-treatment weight.

## Methodological comments/notes

- Allocation to treatment groups: participants were stratified into three blocks according to degree overweight. No other details of randomisation and treatment allocation were reported
- Blinding: not reported
- Comparability of treatment groups: few details were provided. Stated only that according to ANOVA there were no statistically significant pre-intervention differences ( $p > 0.10$ ) between groups in age, height, weight, percentage overweight or depression
- Method of data analysis: both ANOVA and ANCOVA were conducted to test for differences between interventions. In the ANCOVA, initial values for weight, BP, and depression were the covariates. The authors stated that as both methods yielded similar results only those of ANOVA were reported (unless otherwise noted in the paper)
- ITT analysis: not reported
- Sample size/power calculation: not reported. Small sample size
- Attrition/dropout: reasons for overall attrition reported (reasons not reported separately by intervention)

### General comments

- Generalisability: the study population was dominated by women but included some men. Participants had answered a newspaper advertisement and paid US\$10 per visit. This may have had an impact on those taking part
- Outcome measures: depression scores reported separately by intervention for 3-year follow-up (data not extracted)
- Facilitators/barriers not reported as outcomes: none reported
- Intercentre variability: not reported, number of centres unclear
- Conflict of interests: none reported

## Quality criteria for assessment

1. Was the method used to generate random allocations adequate?	Not reported
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Unclear <sup>a</sup>
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups? (ii) If so, were they explained or adjusted for?	No
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis? (ii) If so, was this defined?	Not reported
10. (i) Did the analysis account for missing data? (ii) If so, were the methods appropriate?	No

a Only reported for those completing treatment.

## Weinstock et al.

Study details	Participants	Outcome measures	
<p>Author: Weinstock et al.<sup>78,122</sup></p> <p>Year: 1998</p> <p>Country: USA</p> <p>Study design: RCT</p> <p>Number of centres: two</p> <p>Funding: National Institute of Mental Health/National Institutes of Health</p> <p>Recruitment dates: not stated</p> <p>Setting: university (Syracuse and Pennsylvania)</p> <p>Length of follow-up: 96 weeks</p>	<p>Number of participants: 128 women randomised to four groups<sup>a</sup>:</p> <p>Intervention 1: diet plus aerobic training (DA) (<i>n</i>=31)</p> <p>Intervention 2: diet alone (D) (<i>n</i>=29)</p> <p>Intervention 3: diet plus strength training (DS) (<i>n</i>=31)</p> <p>Intervention 4: diet plus combined strength and aerobic training (DSA) (<i>n</i>=29)</p> <p>Sample attrition/dropout:</p> <p>At week 48, 29 participants had discontinued treatment. Numbers discontinuing in each study group not given, though it is reported that there were no differences in attrition between interventions</p> <p>At week 96 it is stated that 22 participants returned for follow-up visit, though this is based on a subgroup analysis of a total of 45 women in intervention groups 2, 3 and 4</p> <p>Attendance at sessions measured: yes</p> <p>Other measures of adherence: adherence to diet was measured at weeks 5, 9, 13 and 17 based on weekly diet diaries</p> <p>Sample crossovers: none</p> <p>Inclusion/exclusion criteria for study entry: women only; overweight (BMI 39.5 ± 0.9 kg/m<sup>2</sup>). Excluded if bulimia nervosa; significant depression; major psychiatric disturbance (but not binge eating disorder); recent myocardial infarction; cerebrovascular, kidney, or liver disease; cancer; type I diabetes; pregnancy; use of medications known to affect weight and energy expenditure</p> <p>Characteristics of participants:</p> <p>Any risk factors noted: none</p> <p>Gender (M:F) – all female</p> <p>Age (years): mean (SD): DSA: 42.8 (8.3); DS: 40.0 (9.1); DA: 40.8 (7.9); D: 41.0 (8.8)</p> <p>BMI kg/m<sup>2</sup>: mean (SD): DSA: 35.3 (4.4); DS: 36.5 (6.0); DA: 37.3 (5.1); D: 36.4 (5.5)</p> <p>Weight kg, mean (SD): DSA: 92.4 (14.8); DS: 96.8 (14.2); DA: 98.7 (12.5); D: 96.3 (8.8)</p> <p>Age of onset of overweight/obesity, years (SD): DSA: 20.9 (11.3); DS: 20.0 (10.6); DA: 20.1 (9.5); D: 19.5 (8.8)</p> <p>Ethnicity: <i>n</i>=99: Caucasian, 28 African American, one Hispanic</p> <p>Baseline data on weight (kg), height, fat, % fat, fat free mass (FFM) and REE not data extracted</p>	<p>Primary outcomes: body composition, in terms of fat-free mass (FFM) and REE (as mentioned in study hypothesis)</p> <p>Secondary outcomes: weight, appetite, mood, insulin resistance, glucose tolerance, BP</p> <p>Facilitators and barriers: none</p> <p>Methods of assessing outcomes: weight measured using a balance-beam scale. Only weight outcomes are extracted here</p>	
<b>Intervention details</b>			
<p>Aim or goal: preservation of FFM and REE at weeks 24 and 48, resulting in superior maintenance of weight loss at week 48 (for participants taking part in the three exercise conditions compared with those who received diet alone). Women who received strength training, whether alone or in combination with aerobic activity, were expected to achieve best maintenance of FFM</p>			
<p><b>1. DA</b></p> <p><i>Diet:</i></p> <p><i>Details, type of diet:</i> meal replacement plus dinner entrée (weeks 2–17), refeeding (weeks 17–26), self-selected diet (weeks 22–48)</p> <p><i>Calories:</i> 900–925 kcal/day (weeks 2–17). Increasing to 1250 kcal/day (weeks 18–20); 1500 kcal/day (weeks 22–48)</p> <p><i>Proportions of diet:</i></p> <p>150 kcal, 15 g protein, 11.2 g carbohydrate, 5 g fat (per serving of the liquid meal replacement four times per day, weeks 2–17)</p> <p>280–300 kcal, 20 g protein, 35–40 g carbohydrate, 7 g fat (per dinner entrée, weeks 2–17)</p> <p>12–15% calories from protein, 55–60% from carbohydrate, and 15–30% from fat (weeks 22–48)</p>	<p><b>2. D</b></p> <p><i>Diet:</i></p> <p>As intervention DA</p> <p><i>Exercise:</i></p> <p>None. Participants agreed not to engage during the study in any programme of regular activity that resembled the aerobic or strength training conditions (but they were allowed to maintain lifestyle activities such as occasionally playing tennis, bowling or lunchtime walks). This was recorded in their activity logs</p> <p><i>Behaviour modification:</i></p> <p>As DA except there was no discussion of adherence</p>	<p><b>3. DS</b></p> <p><i>Diet:</i></p> <p>As intervention DA</p> <p><i>Exercise:</i></p> <p><i>Mode:</i> participants exercised with members of their behavioural treatment groups (up to week 28)</p> <p><i>Type:</i> strength training, using gym equipment such as the bench press, latissimus pull down, shoulder press (targeting large muscle groups). Exercises were performed with a resistance that allowed them to do ≥ 10 repetitions but not &gt; 14</p>	<p><b>4. DSA</b></p> <p><i>Diet:</i></p> <p>As intervention DA</p> <p><i>Exercise:</i></p> <p><i>Mode:</i> participants exercised with members of their behavioural treatment groups (up to week 28)</p> <p><i>Type:</i> 60% strength training, 40% aerobic activity. Women in the Syracuse cohort did step aerobics, women in the Pennsylvania cohort did treadmill walking and stationary bicycling (due to space constraints)</p>

<p><i>Monitoring:</i> participants kept weekly diet diaries. As part of the behavioural treatment component it is stated that participants were instructed in traditional behavioural methods that included recording food intake (amounts, calories, etc.). The refeeding protocol was supervised by a registered dietitian who coled group sessions from weeks 17–26</p> <p><i>Exercise:</i></p> <p><i>Mode:</i> participants exercised with members of their behavioural treatment groups (up to week 28)</p> <p><i>Type:</i> step aerobics</p> <p><i>Frequency and length of each session and total number sessions:</i></p> <p>Three sessions per week (non-consecutive days) for first 28 weeks, two per week during weeks 29–48. 12 minutes at week 1, additional 2 minutes to routine each week, by week 14 performed 40 minutes of stepping</p> <p>During weeks 29–48 they were assisted in developing at home exercise to replace the third exercise session deleted from their supervised training</p> <p><i>Delivered:</i> graduate students in exercise physiology who followed structured protocols</p> <p><i>Level of supervision:</i> all sessions were supervised (no further detail given)</p> <p><i>Monitoring:</i> Borg Rating of perceived Exertion Scale (to assess intensity of exercise). The aim was to exercise at moderate intensity</p> <p><i>Behaviour modification:</i></p> <p><i>Mode:</i> group sessions (7–10 members each)</p> <p><i>Type:</i> described as cognitive behavioural weight loss programme, based on the OPTIFAST programme</p> <p><i>Content:</i> practicing skills to maintain weight loss (first 28 weeks only). Participants were given manuals summarising materials for the first 28 weeks, and weeks 29–48</p> <p><i>Frequency and length of each session and total number sessions:</i> 28 weekly 90 minute sessions, followed by biweekly maintenance programme sessions (weeks 29–48)</p> <p><i>Delivered:</i> by clinical psychologists and groups coled by a dietitian (weeks 17–26)</p> <p>In addition the exercisers took approximately 5–10 minutes each week to discuss adherence to their exercise programme</p> <p><i>Ongoing support:</i></p> <p>Participants attended group sessions once every 3 months in the year following treatment. Between weeks 48–96 the women were encouraged to continue exercising unsupervised</p>	<p><i>Ongoing support:</i></p> <p>Mentions only that participants attended group sessions once every 3 months in the year following treatment</p>	<p><i>Frequency and length of each session and total number sessions:</i></p> <p>Three sessions per week (non-consecutive days) for first 28 weeks, two per week during weeks 29–48. Initial workouts lasted approx. 20 minutes, weeks 3–14 an extra set of exercises were added, participants eventually did two sets of each exercise at each session. By end of week 14 (until week 48) weight training lasted approx. 40 minutes per session. Resistance increased whenever participants were able to perform &gt; 14 repetitions for two consecutive sets</p> <p>During weeks 29–48 they were assisted in developing a personal programme of strength training to replace the third session deleted from the supervised practice (e.g. joining a health club)</p> <p><i>Delivered:</i> graduate students in exercise physiology who followed structured protocols</p> <p><i>Level of supervision:</i> all sessions were supervised (no further detail given)</p> <p><i>Monitoring:</i> not reported</p> <p><i>Behaviour modification:</i></p> <p>As DA</p> <p><i>Ongoing support:</i></p> <p>Participants attended group sessions once every 3 months in the year following treatment. Between weeks 48–96 the women were encouraged to continue exercising unsupervised</p>	<p><i>Frequency and length of each session and total number sessions:</i></p> <p>three sessions per week (non-consecutive days) for first 28 weeks, two per week during weeks 29–48. Women in this intervention progressed through the sequence of training on approximately the same schedule as those in interventions 2 and 3</p> <p><i>Delivered:</i> graduate students in exercise physiology who followed structured protocols</p> <p><i>Level of supervision:</i> all sessions were supervised (no further detail given)</p> <p><i>Monitoring:</i> Borg Rating of perceived Exertion Scale (to assess intensity of exercise)</p> <p><i>Behaviour modification:</i></p> <p>AS DA except there was no discussion of adherence</p> <p><i>Ongoing support:</i></p> <p>Mentions only that participants attended group sessions once every 3 months in the year following treatment</p>
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a Number randomised to each intervention not reported. Figures in parentheses are the number of women per group for whom baseline data are given, which sums to 120. The eight women who dropped out because of medical conditions or who became pregnant were not included in the presentation of baseline data (but other dropouts were, see 'Sample attrition/dropout').

## Results

Outcomes	D/DS/SA (groups 2, 3 and 4) combined	p-value, 95% CI
Maintenance of weight loss at week 96 <sup>a</sup> , mean (SE) kg	87.6 (2.8) kg. A 9.9kg net weight loss from baseline	Reports no significant differences between the diet and exercise groups at week 96
Weight regain (weeks 44 to 96) <sup>a</sup>	76% of participants gained weight, and 14 (64%) of 22 gained more than 5 kg	
BMI kg/m <sup>2</sup> , mean (SE)	Dropped to 32.7 (1.2) from 36.4 (1.4) at baseline (loss of 3.7)	

D, diet alone (D); DS, diet plus strength training; DSA, diet plus combined strength and aerobic training.

a Results pertain to 22 women attending week 96 follow-up from a subgroup of 45 women assigned to interventions 2, 3 and 4 (i.e. diet alone, diet plus strength training, and diet plus aerobic training, respectively) but not intervention 1 (diet plus combined strength and aerobic training). The subgroup comprises women enrolled in the first of two cohorts recruited to the study. This first cohort was treated at Syracuse University and originally included 68 women. It is presumed that exclusion of intervention 1 resulted in 45 women remaining in the analysis (Note: no reason is given for the exclusion of intervention 1 from the analysis of results at 96 weeks). Results are not given by intervention group, only for the cohort as a whole. Caution is advised in the interpretation of these results (see below under 'Sample size/power calculation').

## Methodological comments/notes

- Allocation to treatment groups: random, no further information given
- Blinding: no information given
- Comparability of treatment groups: authors state that the intervention groups did not differ significantly on measures of age, weight, fat, BMI, fat-free mass (FFM), REE, appetite or mood at baseline based on ANOVA
- Method of data analysis: changes in the principal measures assessed using ANCOVA, with initial values as covariates. Series of one-way univariate tests were used at each time period to maximize the available sample size. The Duncan test was used to determine specific differences among groups
- ITT analysis: ITT analysis not presented. Mentions that dropouts were retained in the analyses until the time of their attrition
- Sample size/power calculation: not reported. Note that week 96 results, as presented above, should be treated with caution as they are based on a subgroup of randomised participants (only women from the first of two cohorts treated and omitting one of the randomised intervention groups altogether). At week 96 only 22 of the 45 women in this subgroup were available for outcome measurement and the results are likely to be underpowered. Therefore, it is not possible to draw meaningful conclusions drawn from the data for changes in weight
- Attrition/dropout: reasons given for dropouts up to week 48. No reasons given for those dropping out between week 48 and 96

### General comments

- Generalisability: based on limited detail given the results are applicable mainly to Caucasian middle-aged obese women
- Outcome measures: no detail given on intermediate outcomes such as diet or exercise
- Facilitators/barriers not reported as outcomes: none
- Intercentre variability: preliminary ANOVA showed no significant difference between the two treatment cohorts in baseline measures of age, weight, fat, BMI, FFM, REE, appetite or mood. There were no treatment × cohort interactions hence the decision to collapse the two cohorts in the analysis
- Conflict of interests: none reported

### Quality criteria for assessment

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1. Was the method used to generate random allocations adequate?	Not reported
2. Was the allocation adequately concealed?	Not reported
3. Were the groups similar at the outset of the study in terms of prognostic factors, e.g. severity of disease?	Yes
4. Were outcome assessors blinded to the treatment allocation?	Not reported
5. Was the care provider blinded?	Not reported
6. Was the participant blinded?	Not reported
7. (i) Were there any unexpected imbalances in dropouts between groups?	No
(ii) If so, were they explained or adjusted for?	
8. Is there any evidence to suggest that the authors measured more outcomes than they reported?	No
9. (i) Did the analysis include an intention to treat analysis?	No
(ii) If so, was this defined?	
10. (i) Did the analysis account for missing data?	No
(ii) If so, were the methods appropriate?	

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# Appendix 6

## Excluded studies

### Participants

1. Leermakers EA, Anglin K, Wing RR. Reducing postpartum weight retention through a correspondence intervention. *Int J Obes* 1998;**22**:1103–9.
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6. Anderson LM, Quinn TA, Glanz K, Ramirez G, Kahwati LC, Johnson DB, *et al.* The effectiveness of worksite nutrition and physical activity interventions for controlling employee overweight and obesity: a systematic review. *Am J Prev Med* 2009;**37**:340–57.
7. Lombard CB, Deeks AA, Teede HJ. A systematic review of interventions aimed at the prevention of weight gain in adults. *Public Health Nutr* 2009;**12**:2236–46.

### Design

1. Abrams DB, Follick MJ. Behavioral weight loss intervention at the worksite: feasibility and maintenance. *J Consult Clin Psychol* 1983;**51**:226–33.
2. Andersson K, Karlstrom B, Freden S, Petersson H, Ohrvall M, Zethelius B. A two-year clinical lifestyle intervention program for weight loss in obesity. *Food Nutr Res* 2008;**52**.
3. 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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5. Dornelas EA, Wylie-Rosett J, Swencionis C. The DIET study: long-term outcomes of a cognitive-behavioral weight-control intervention in independent-living elders. Dietary intervention: evaluation of technology. *J Am Diet Assoc* 1998;**98**:1276–81.
6. Eichler K, Zoller M, Steurer J, Bachmann LM. Cognitive-behavioural treatment for weight loss in primary care: a prospective study. *Swiss Med Wkly* 2007;**137**:489–95.
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8. Graham LE, Taylor CB, Hovell MF, Siegel W. Five-year follow-up to a behavioral weight-loss program. *J Consult Clin Psychol* 1983;**51**:322–3.
9. Jakicic JM, Otto AD. Motivating change: modifying eating and exercise behaviors for weight management. *ACSMs Health & Fitness Journal* 2005;**9**:6–12.
10. Jerome GJ, Young DR, Brantley PJ, Coughlin JW, Erlinger TP, Cooper LS, *et al.* Effects of lifestyle modification interventions on social support: results from the PREMIER trial. *Circulation* 2006;**113**:e370.
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12. Miller PM, Sims KL. Evaluation and component analysis of a comprehensive weight control program. *Int J Obes* 1981;**5**:57–65.
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### Intervention

1. Dale KS, McAuley KA, Taylor RW, Williams SM, Farmer VL, Hansen P, *et al.* Determining optimal approaches for weight maintenance: a randomized controlled trial. *CMAJ* 2009;**180**:E39–E46.
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11. Li G, Zhang P, Wang J, Gregg EW, Yang W, Gong Q, *et al.* The long-term effect of lifestyle interventions to prevent diabetes in the China Da Qing Diabetes Prevention Study: a 20-year follow-up study. *Lancet* 2008;**371**:89.<sup>a</sup>
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### Comparator

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### Outcomes

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### Details intervention

1. Black DR, Lantz CE. Spouse involvement and a possible long-term follow-up trap in weight loss. *Behav Res Ther* 1984;**22**:557–62.
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### Length of follow-up

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#### <sup>a</sup>Diabetes prevention studies

A number of studies listed above were diabetes prevention studies. The diabetes prevention studies are aimed at a group with an existing risk factor to try to prevent the onset of disease. The interventions are therefore focused on the disease and not general weight loss. This differs from the hypertension prevention studies that are aimed at a group of overweight people

without known disease to prevent them getting a risk factor for a disease, not the disease itself. The interventions are therefore focused on general weight loss. As a general rule the diabetes prevention studies would have been excluded from the present review on this basis. However, in the listing above it can be seen that individual diabetes prevention studies were excluded on other grounds, such as the intervention not being a multicomponent approach.

### Cost-effectiveness review

#### Abstracts (insufficient information)

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#### Participants

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#### Intervention

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#### Study design

1. Fineberg HV. An economic analysis of eating and physical activity behaviors: exploring effective strategies to combat obesity. *Am J Prev Med* 2004;**27**:172–4.
2. Meenan RT, Stevens VJ, Funk K, Bauck A, Jerome GJ, Lien LF, *et al.* Development and implementation cost analysis of telephone- and Internet-based interventions for the maintenance of weight loss. *Int J Technol Assess Health Care* 2009;**25**:400–10.





## Appendix 7

### Unclear studies

It was not clear from the description of the interventions in the following studies whether the multicomponent intervention met the criteria of the current review and therefore trial authors were contacted for further advice. At the point of writing no further details had been received.

Study author	Length of follow-up	Details diet	Details exercise	Details behaviour
<sup>a</sup> Borg <i>et al.</i> 2002 <sup>123</sup>	29 months	Yes	Yes	Unclear
Hakala <i>et al.</i> 1994 <sup>124</sup>	5 years	Unclear	Unclear	Unclear
Hakala <i>et al.</i> 1993 <sup>125</sup>	5 years	Unclear	Unclear	No
Linde <i>et al.</i> 2006 <sup>126</sup>	24 months	Unclear	Unclear	Unclear
Ashley <i>et al.</i> 2001 <sup>127</sup>	24 months	Yes	Yes	Unclear
Svetkey <i>et al.</i> 2008 <sup>128</sup>	30 months	Unclear	Unclear	Unclear

a Author responded, however, details sent were insufficient to judge inclusion further.



## Appendix 8

### Informal assessment of key attributes of included studies

Study	Length of follow-up $\geq 2$ years	Sample size per arm $\geq 100$	Risk of bias low	Statistically significant effect $\geq 2$ years	Generalisability	Intervention reproducible <sup>a</sup>
Logue <i>et al.</i> 2005 <sup>72</sup>	Yes	Yes	Yes	No	Unclear	No
Stevens <i>et al.</i> 2001 <sup>70</sup>	Yes	Yes	Yes	Yes	Unclear	Yes
Simkin-Silverman <i>et al.</i> 1998 <sup>73</sup>	Yes	Yes	Yes	Yes	No	Yes
Jeffery and Wing 1995 <sup>75</sup>	Yes	No	No	Unclear	Unclear	Yes
Stevens <i>et al.</i> 1993 <sup>74</sup>	No	Yes	No	N/A	Unclear	Approximately

N/A, not applicable.

a None of the behavioural interventions can be precisely replicated.



## Appendix 9

# Data extractions for full papers for included studies in cost-effectiveness review

### Reference

The Counterweight Programme, 2010<sup>87</sup>

### Research question

What are the stated objectives of the evaluation?

To estimate the economic effectiveness of the Counterweight Programme

### Funding source

Roche Products Ltd

### Study population

What definition was used for (condition)?

Obese and overweight adults

What are the characteristics of the baseline cohort for the evaluation?

1906 adult patients (aged 18–75) in 65 UK general practitioner (GP) practices with BMI  $\geq 30$  kg/m<sup>2</sup> or  $\geq 28$  kg/m<sup>2</sup> with obesity-related comorbidities. Mean age 49.4 years, 77% female. Mean BMI 37.1 kg/m<sup>2</sup>. Diabetes present 13.5%. Cardiovascular disease 8%

### Interventions and comparators

What interventions/strategies were included?

Diet, exercise and behaviour intervention

Was a no treatment/supportive care strategy included?

Compared with no active intervention. Note: economic evaluation was based on a cohort study, rather than a randomised controlled trial (RCT)

Describe interventions/strategies

First line interventions were a prescribed-eating plan, a goal-setting approach, or a group intervention. These were all aimed at achieving an energy deficit of  $\geq 500$  kcal/day. Patients were asked to commit to nine appointments in 12 months, including six individual appointments (10–30 minutes) and six group sessions (1 hour each) over a 3-month period and then follow-up at 6, 9, 12 and 24 months. In addition to dietary component, physical activity and behaviour management components were also included. The physical activity component consisted of encouraging patients to take more than 30 minutes moderate physical activities on most days by incorporating activity into daily living, for example through walking more, and referral to existing exercise schemes. Patients who did not achieve more than 5% weight loss at 3 months were eligible for pharmacotherapy. Antiobesity medication was prescribed to approximately 8% of patients during the first 12 months

### **Analytical perspective**

What is the perspective adopted for the evaluation (health service, health and personal social services, third party payer, societal (i.e. including costs borne by individuals and lost productivity)?

UK NHS

### **Study type**

Cost-effectiveness/cost-utility/cost-benefit analysis?

Cost-utility

### **Institutional setting**

Where is/are the intervention(s) being evaluated usually provided?

Primary care

### **Country/currency**

Has a country setting been provided for the evaluation? What currency are costs expressed in and does the publication give the base year to which those costs relate?

UK £. 2001–3 for intervention and 2005 for model

### **Effectiveness**

Were the effectiveness data derived from: a single study, a review/synthesis of previous studies or expert opinion?

A single study (the Counterweight Programme)

Give the definition of treatment effect used in the evaluation

Mean weight change

Give the size of the treatment effect used in the evaluation

Mean weight change (kg) at 12 months ( $n = 642$ ) was  $-3.0$  (95% CI  $-3.5$  to  $-2.4$ ) and at 24 months ( $n = 357$ ) was  $-2.3$  kg (95% CI  $-3.2$  to  $-1.4$ ). Untreated patients are assumed to gain 1 kg weight per year

### Intervention costs

Were the cost data derived from: a single (observational) study, a review/synthesis of previous studies expert opinion?

A single study (the Counterweight Programme)

Were the methods for deriving these data adequately described (give sources if using data from other published studies)?

Costs of the intervention are described in another article (*J Health Serv Res Policy* 2008)<sup>36</sup>

List the direct intervention costs used in the evaluation – include resource estimates (and sources for these estimates, if appropriate) as well as sources for unit costs used

The cost was estimated for all practices in the UK having access to it over a 5-year period. Costs included remuneration for all clinicians time required for the intervention – training, GPs time for clinical and motivational assessment, practice nurse time for assessment, motivation, delivery of advice and review. Costs for the Counterweight Programme team, training resources and patient information materials were also included in the analysis. Costs for the intervention were based on the optimal attendance rate of at least six visits in 12 months. In addition the costs of weight management medications prescribed according to protocol were incorporated. Around 20% of patients followed up at 12 months or around 9% of the total intervention group were prescribed weight management drugs

Costs shown in Appendices 3 and 4 of prescribing article. However there are some discrepancies between the appendices

Summary of costs:

In year 0 there is a one-off cost of £1.9M to recruit and train the Weight Management Advisors (WMAs). In year 1 the costs are as follows:

National co-ordination costs £120,000

WMA teams cost £7.8M

Meetings with local staff cost £368,000

Costs to practices of the first wave of audit and training are £1.4M

Costs of the intervention in the first-wave practices are £23M



The total cost in year 1 is £33M, two-thirds of which is the practice nurse time and resources for the intervention

Costs in year 2 are similar but it is assumed that first wave practices recruit a further cohort of patients, so the total cost is higher at £45M. Similarly in year 3 first- and second-wave practices recruit further cohorts of patients so total costs are £56M, with costs in years 4 and 5 being £68M and £80M, respectively

The total cost over this period (including set-up) is £196M. In this time 2400 practices will have recruited five cohorts of 92 patients, 2400 practices will have recruited four cohorts, 2400 will have recruited three cohorts, and so on. In total 3.3 million people will have been recruited. The average cost per person recruited is thus £56.60 per patient

*Indicate the source for individual cost values (if appropriate)*

### **Other direct costs (costs incurred directly in treating patients)**

Were the cost data derived from: a single (observational) study, a review/synthesis of previous studies expert opinion?

Were the methods for deriving these data adequately described (give sources if using data from other published studies)?

Taken from published studies

List the costs used in the evaluation – if quantities of resource use are reported separately from cost values, show sources for the resource estimates as well as sources for unit costs used

Yearly costs per year included for medical conditions such as CHD (£1637), diabetes (£653) and colon cancer (£7320), based on (Ara and Brennan, 2005) and (O’leary, 2004)

*Indicate the source for individual cost values (if appropriate)*

### **Indirect costs (costs due to lost productivity, unpaid inputs to patient care)**

Were indirect costs included?

Not included

Describe how indirect costs were estimated (e.g. how days of lost productivity were estimated and how those days were valued)

N/A

*Indicate the source for individual cost values (if appropriate)*

### Health state valuations/utilities (if study uses quality of life adjustments to outcomes)

Were the utility data derived from: a single (observational) study, a review/synthesis of previous studies expert opinion. Were the methods for deriving these data adequately described (give sources if using data from other published studies)?

Several studies

List the utility values used in the evaluation

Utility values from the general population (Macran and colleagues<sup>88</sup>) were adjusted to obtain QALYs for individuals with any of the comorbidities, such as diabetes and CHD. The multipliers for diabetes and CHD were provided by Ara and Brennan (0.8661 and 0.8670, respectively). Individuals with colon cancer had a 5% lower QALY based on Lewis and colleagues<sup>129</sup>

**TABLE 24** Quality of life by BMI and gender

BMI (kg/m <sup>2</sup> )	Male	Female
<21	0.86	0.85
21–25	0.87	0.87
26–30	0.86	0.82
31–39	0.82	0.78
>39	0.88	0.75

As such, a man with a BMI of 31–39 who also has CHD, diabetes and colon cancer would have a utility value of 0.58 compared with the 0.82 reported in *Table 24* for an individual with no comorbidities

*Indicate the source for individual cost values (if appropriate)*

### Modelling

If a model was used, describe the type of model used (e.g. Markov state transition model, discrete event simulation). Was this a newly developed model or was it adapted from a previously reported model? If an adaptation, give the source of the original

A patient-level simulation model was used which was originally developed to provide input to the UK national guidance on obesity. (NICE, 2006)

What was the purpose of the model (i.e. why was a model required in this evaluation)?

To estimate lifetime outcome of a model cohort reflective of UK adult population

What are the main components of the model (e.g. health states within a Markov model)? Are sources for assumptions over model structure (e.g. allowable transitions) reported? (List them if reported)

The model works by randomly selecting an individual whose characteristics are based on those of the population (for example, BMI, age and gender) and following their healthcare costs and outcomes until death. The model assesses people over 6-month cycles. Each cycle each individual will experience a change in BMI (increase, decrease or no change). The individual can develop diabetes, CHD, or colon cancer depending on the prevalence of each disease at the BMI they are currently experiencing. There is a QALY associated with each health state. Patients are at increased risk of death if they experience one of these conditions

Patients are assumed to regain all 4 kg weight difference effect in two years following removal of the programme

Extract transition probabilities for (natural history/disease progression) model and show sources (or refer to table in text)

Prevalence of diabetes based on BMI level from Gregg and colleagues.<sup>130</sup> Prevalence of CHD based on Framingham equation as set out by Brindle and colleagues depending on age, smoking, blood pressure (BP), cholesterol, diabetes. Prevalence of colon cancer was derived from a study by Giovannucci and colleagues<sup>131</sup>

What is the model time horizon?

Lifetime

What, if any, discount rates have been applied in the model? Same rate for costs and outcomes?

3.5%

### **Results/analysis**

What measure(s) of benefit were reported in the evaluation?

QALY gain

Provide a summary of the clinical outcome/benefits estimated for each intervention/strategy assessed in the evaluation

For no active intervention, lifetime QALYs are 28.32, for baseline intervention lifetime QALYs are 28.38. QALY gain is 0.056

Provide a summary of the costs estimated for each intervention/strategy assessed in the evaluation

The lifetime cost to the NHS of no active intervention is £1884 and for the baseline intervention is £1857

Synthesis of costs and benefits – are the costs and outcomes reported together (e.g. as cost-effectiveness ratios)? If so, provide a summary of the results

The ICER is –£473 per QALY gained, i.e. cost saving

Give results of any statistical analysis of the results of the evaluation

N/A

Was any sensitivity analysis performed – if yes, what type(s) [i.e. deterministic (one-way, two-way etc.) or probabilistic]

One-way sensitivity analysis performed

What scenarios were tested in the sensitivity analysis? How do these relate to structural uncertainty (testing assumptions over model structure such as relationships between health states), methodological uncertainty (such as choices of discount rate or inclusion of indirect costs) or parameter uncertainty (assumptions over values of parameters in the model, such as costs, quality of life or disease progression rates)?

No sensitivity analyses for structural, methodological or assumptions

Give a summary of the results of the sensitivity analysis – did they differ substantially from the base case analysis? If so, what were the suggested causes?

Sensitivity analyses were conducted for background weight change for the untreated population. For background weight change of 0.5 kg/year and 0.3 kg/year the ICER was £2017 and £2651 respectively

### **Conclusions/implications**

Give a brief summary of the author's conclusions from their analysis

Even based on very limited estimates of the costs of obesity, the Counterweight Programme is highly cost-effective and will provide cost savings in the medium to long term

What are the implications of the evaluation for practice?

Counterweight represents a highly efficient use of health-care resources

### **Reference**

Roux and colleagues 2006<sup>86</sup>

### **Research question**

What are the stated objectives of the evaluation?

To conduct a clinical and economic evaluation of outpatient weight loss strategies in overweight and obese adult US women

### **Funding source**

Not stated

**Study population**

What definition was used for (condition)?

Overweight and obesity defined as BMI > 24.9 kg/m<sup>2</sup>

What are the characteristics of the baseline cohort for the evaluation?

Hypothetical cohort of 10,000 healthy, non-pregnant 35-year-old overweight and obese women with original BMI > 24.9 kg/m<sup>2</sup> and free from known CHD

**Interventions and comparators**

What interventions/strategies were included?

Each strategy consisted of a 6-month weight loss intervention followed by a 6-month maintenance programme

Diet only

Diet and pharmacotherapy

Diet and exercise

Diet, exercise and behavioural modification

Women unable to lose weight or maintain successful weight loss were assumed to remain at their age-adjusted original BMI

Was a no treatment/supportive care strategy included?

Routine care (not defined)

Describe interventions/strategies

Diet: reduction in caloric intake necessary to achieve a 10% weight loss under the supervision of a dietitian, in accordance with the American Heart Association guidelines

Pharmacotherapy: 120 mg orlistat three times per day for 6 months, then half this dose per day for 6 months maintenance phase

Exercise: three 45-minute structured exercise sessions per week of moderate intensity, led by a certified instructor, and two sessions per month to review clinical progress with an exercise therapist

Behavioural modification: 1 hour cognitive therapy counselling session led by a psychologist every other week

**Analytical perspective**

What is the perspective adopted for the evaluation (health service, health and personal social services, third party payer, societal (i.e. including costs borne by individuals and lost productivity)?

Societal

**Study type**

Cost-effectiveness/cost-utility/cost-benefit analysis?

Cost-effectiveness and cost-utility

**Institutional setting**

Where is/are the intervention(s) being evaluated usually provided?

Outpatient setting? Single urban setting (p. 1103)

**Country/currency**

Has a country setting been provided for the evaluation? What currency are costs expressed in and does the publication give the base year to which those costs relate?

Canada. Currency US\$. Base year 2001

**Effectiveness**

Were the effectiveness data derived from: a single study, a review/synthesis of previous studies or expert opinion?

Review (methods not clear) of published literature to identify RCTs from which four studies were selected for estimating efficacy (only referenced in online appendix, not accessible)

Give the definition of treatment effect used in the evaluation

10% BMI reduction after 6-month weight loss programme

Short-term success defined as maintenance of reduced BMI postintervention for at least 6 months

Long-term success defined as maintenance of reduced BMI for at least 5 years after intervention

Give the size of the treatment effect used in the evaluation

Change in BMI postintervention:

Routine care 0.26

Diet only -1.98

Diet and exercise -2.55

Diet and pharmacotherapy -4.55

Diet, exercise and behavioural modification -3.11

### Intervention costs

Were the cost data derived from: a single (observational) study, a review/synthesis of previous studies expert opinion?

Not clear

Were the methods for deriving these data adequately described (give sources if using data from other published studies)?

Not enough information

List the direct intervention costs used in the evaluation – include resource estimates (and sources for these estimates, if appropriate) as well as sources for unit costs used

	Routine care	Diet only	Diet and exercise	Diet and pharmacotherapy	Diet, exercise, behavioural modification
Direct non-medical costs and time-related per participant programme costs (6-month, US\$)	0	120	630	120	630
Direct medical per participant programme costs (6 month) US\$ (referenced overall but not individually, <i>Table 1</i> )	700	2150	2750	2820	3040

*Indicate the source for individual cost values (if appropriate)*

### Other direct costs (costs incurred directly in treating patients)

Were the cost data derived from: a single (observational) study, a review/synthesis of previous studies expert opinion?

Were the methods for deriving these data adequately described (give sources if using data from other published studies)?

Micro-costing techniques used to estimate resource use

Direct costs based on published data and valued using Medicare reimbursement rates

(Includes consultations, laboratory tests, chest X-rays, electrocardiogram and exercise stress test, and educational materials)

Unit costs and quantities not reported separately

Obesity-related morbidity and mortality, such as diabetes and CHD, used annual age and sex-specific treatment related costs (referenced)

Age-specific costs associated with CHD for women represented a published weighted average of the expected management costs of a non-fatal myocardial infarction, cardiac arrest and angina pectoris (referenced)

Annual age-specific direct health-care costs not specific to obesity-related morbidity were included (referenced)

List the costs used in the evaluation – if quantities of resource use are reported separately from cost values, show sources for the resource estimates as well as sources for unit costs used

	Costs
Cost of drug per pill (US\$) (published data)	1.32
6-month maintenance per-participant programme costs (US\$)	Programme incorporating any combination of diet, exercise and behaviour modification: 150 Programme incorporating pharmacotherapy: 360 Routine care: 0
Annual comorbidity treatment cost (US\$)	Hypertension: 616.62 Hypercholesterolemia: 176.34 Type 2 diabetes age-specific CHD first year: 10,850 CHD subsequent years: 1710 CHD fatal: 3665

*Indicate the source for individual cost values (if appropriate)*

### **Indirect costs (costs due to lost productivity, unpaid inputs to patient care)**

Were indirect costs included?

Yes (dietary changes, exercise equipment, fitness monitoring devices, fitness apparel, and transportation and time costs)

Describe how indirect costs were estimated (e.g. how days of lost productivity were estimated and how those days were valued)

Primary data collected from a survey of a community sample ( $n = 100$ ) of female weight management programme participants. The survey elicited demographic information and cost information using modified version of a previously described generic UK cost and use survey (referenced). Direct non-medical resources were valued using self-reported items prices. Self-reported mileage travelled to and from classes and associated physician visits to estimate travel costs. Total annual distance travelled in miles was valued per participant, based on published estimates. These per-person annual travel costs were totalled and averaged across all participants. Time costs estimated using survey data; time was valued by applying wage rates specific to their occupation. Time lost from work was valued using US national average wage rate. Wage rates for domestic child care and light cleaning services were used to value time lost from performing household duties

*Indicate the source for individual cost values (if appropriate)*



### **Health state valuations/utilities (if study uses quality of life adjustments to outcomes)**

Were the utility data derived from: a single (observational) study, a review/synthesis of previous studies expert opinion. Were the methods for deriving these data adequately described (give sources if using data from other published studies)?

General age-specific quality weights were derived from the Beaver Dam Health Outcomes study<sup>91</sup> and applied for women > 45 years of age. This was a longitudinal cohort study of health status and health-related quality of life for a random sample of adults (mean 64.1, range 45–89 years) in a community population. Four measures were used: Short-Form questionnaire-36 items, Quality of Well-being index, self-reported health status on a five point scale from 'excellent' to 'poor' and evaluation of current health using time trade-offs. These results were adjusted to reflect weight loss using quality weights derived from the study sample and comorbid diseases using a multiplicative function (and an additive function in sensitivity analyses). No further details given

Quality of life for the reduction in weight loss estimated from community sample with average per cent reductions in life expectancy that subjects were willing to give up through treatment with a single pill, free of charge and side effects but which would not prevent or cure health problems or incur survival benefit, to achieve sustained BMI reduction to the average weight for their height (0.87) and for 10% reduction in BMI (0.93). Quality weights rescaled to economic uses between death (0) and perfect health (1) using previously described methods (referenced)

Temporary decrements in QoL attributable to the interventions were assumed to be related to the intensity of effort required to participate in a particular programme from primary data analysis and were assigned for a 6-month period: QoL = 1 for routine care; QoL = 0.91 for diet, exercise, behavioural modification programme. Other programs of intermediate intensity were assigned values between 0.91 and 1

List the utility values used in the evaluation

Disease-specific quality weights:

Obesity = 0.87

10% reduction weight loss = 0.93

CHD = 0.75 (age-adjusted)

Type 2 diabetes = 0.75 (age-adjusted)

*Indicate the source for individual cost values (if appropriate)*

## Modelling

If a model was used, describe the type of model used (e.g. Markov state transition model, discrete event simulation). Was this a newly developed model or was it adapted from a previously reported model? If an adaptation, give the source of the original

First-order Monte Carlo simulation

What was the purpose of the model (i.e. why was a model required in this evaluation)?

Decision analytic techniques can be used to estimate effectiveness and cost-effectiveness of a number of alternative strategies to reduce BMI in overweight and obese women, taking into account best available data and future uncertainties in costs and benefits

What are the main components of the model (e.g. health states within a Markov model)? Are sources for assumptions over model structure (e.g. allowable transitions) reported? (List them if reported)

The model uses a state-transition framework with the natural history of obesity in a cohort of hypothetical women characterised as a sequence of annual transitions from one health state to another

Women enter the model aged 35 years free from known CHD. Each year a woman's BMI predicts the risk of developing hypertension, Type 2 diabetes or hypercholesterolemia, which predicts her risk of CHD and CHD death (diagram given)

Extract transition probabilities for (natural history/disease progression) model and show sources (or refer to table in text)

From <i>Table 1</i> <sup>66</sup>	Routine care	Diet only	Diet and exercise	Diet and pharmacotherapy	Diet, exercise, behavioural modification
Probability of programme compliance	1	0.84	0.86	0.69	0.90
Probability 10% weight loss at 6 months	0.05	0.26	0.68	0.96	0.95
Probability of weight loss maintenance at 1 year	0.5	0.15	0.55	0.37	0.67
Probability of weight loss maintenance at 5 years	Programmes without lifestyle modification: 0.1				0.2

What is the model time horizon?

Lifetime horizon

What, if any, discount rates have been applied in the model? Same rate for costs and outcomes?

3% discount rate for costs and benefits

## Results/analysis

What measure(s) of benefit were reported in the evaluation?

Life years and QALYs

Provide a summary of the clinical outcome/benefits estimated for each intervention/strategy assessed in the evaluation

From <i>Table 2</i> <sup>6</sup>	Routine care	Diet only	Diet and exercise	Diet and pharmacotherapy	Diet, exercise, behavioural modification
Discounted life expectancy (weeks)	24.119	24.120	24.129	24.128	24.170
Discounted QALY? (months)	18.183	18.169	18.255	18.248	18.426

Provide a summary of the costs estimated for each intervention/strategy assessed in the evaluation

From <i>Table 2</i>	Routine care	Diet only	Diet and exercise	Diet and pharmacotherapy	Diet, exercise, behavioural modification
Discounted lifetime costs US\$	121,120	122,440	123,240	122,660	124,200

Synthesis of costs and benefits – are the costs and outcomes reported together (e.g. as cost-effectiveness ratios)? If so, provide a summary of the results

Diet, exercise and behavioural modification was the dominant strategy. The ICER was US\$60,390 per life-year gained and US\$12,640 per QALY when compared with routine care

Give results of any statistical analysis of the results of the evaluation

N/A

Was any sensitivity analysis performed – if yes, what type(s) [i.e. deterministic (one-way, two-way etc.) or probabilistic]

Deterministic (one-way) sensitivity analysis performed

What scenarios were tested in the sensitivity analysis? How do these relate to structural uncertainty (testing assumptions over model structure such as relationships between health states), methodological uncertainty (such as choices of discount rate or inclusion of indirect costs) or parameter uncertainty (assumptions over values of parameters in the model, such as costs, quality of life or disease progression rates)?

Discount rate (methodological)

6-month programme costs (parameter)

Probability of compliance with 6-month intervention (parameter)

Mortality rates for CHD (parameter)

Comorbidity QoL (parameter)

Drug costs (parameter)

Give a summary of the results of the sensitivity analysis – did they differ substantially from the base case analysis? If so, what were the suggested causes?

Results were most sensitive to variation in the obesity-related effects on QoL and the likelihood of long-term weight loss maintenance. (Hard to tell which parameters had most effect on results as axis on the graph not labelled properly)

### **Conclusions/implications**

Give a brief summary of the author's conclusions from their analysis

Authors concluded that a multidisciplinary weight management programme of diet, exercise and behavioural modification for overweight and obese women may represent good value for money

What are the implications of the evaluation for practice?

Authors concluded also that although a three-component strategy appears to provide reasonable return on resources invested, the 'worthwhileness' of such a programme would depend on the resources displaced to fund it

Authors recommend that future research should aim to confirm the impacts of such combined programmes on QoL and the likelihood of long-term weight loss maintenance. Investments that improve long-term maintenance, even if costly, may provide good return in terms of population health gain for resources invested



# Health Technology Assessment programme

**Director,**  
**Professor Tom Walley, CBE,**  
 Director, NIHR HTA programme, Professor of Clinical Pharmacology,  
 University of Liverpool

**Deputy Director,**  
**Professor Hywel Williams,**  
 Professor of Dermato-Epidemiology,  
 Centre of Evidence-Based Dermatology,  
 University of Nottingham

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### Members

<p><b>Chair,</b>  <b>Professor Tom Walley, CBE,</b>          Director, NIHR HTA programme, Professor of Clinical Pharmacology, University of Liverpool</p>	<p>Dr Nick Hicks,          Consultant Adviser – Diagnostic Technologies and Screening Panel,          Consultant Advisor–Psychological and Community Therapies Panel</p>	<p>Professor Ruairidh Milne,          Director – External Relations</p>	<p>Professor Lindsay Turnbull,          Professor of Radiology, Centre for the MR Investigations, University of Hull          Chair – Diagnostic Technologies and Screening Panel</p>
<p>Professor Imti Choonara,          Professor in Child Health, Academic Division of Child Health, University of Nottingham          Chair – Pharmaceuticals Panel</p>	<p>Ms Susan Hird,          Consultant Adviser, External Devices and Physical Therapies Panel</p>	<p>Dr John Pounsford,          Consultant Physician, Directorate of Medical Services, North Bristol NHS Trust          Chair – External Devices and Physical Therapies Panel</p>	<p>Professor Scott Weich,          Professor of Psychiatry, Health Sciences Research Institute, University of Warwick          Chair – Psychological and Community Therapies Panel</p>
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<p>Dr Peter Davidson,          Director of NETSCC, Health Technology Assessment</p>			

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Department of Clinical Science,  
University of Bristol

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Professor in Stroke Rehabilitation,  
Associate Director UK Stroke  
Research Network, University of  
Nottingham

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Senior Clinical Lecturer and  
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of Anaesthetics, University of  
Oxford

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Warwick Medical School,  
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Clinical Trials Manager, Health  
Services and Public Health  
Services Board, Medical Research  
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**Professor Sallie Lamb,**  
Director,  
Warwick Clinical Trials Unit,  
Warwick Medical School,  
University of Warwick and Professor of  
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Rheumatology and Musculoskeletal Sciences,  
University of Oxford

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Professor of the Psychology of Health Care,  
Leeds Institute of Health Sciences,  
University of Leeds

**Programme Director,**  
**Professor Tom Walley, CBE,**  
Director, NIHR HTA programme, Professor of  
Clinical Pharmacology, University of Liverpool

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Department of Health Sciences,  
University of Leicester

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Professor of Health Statistics,  
Department of Health Sciences,  
University of York

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Consultant Upper GI Surgeon,  
Department of Social Medicine,  
University of Bristol

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Director, Clinical Trials Research  
Unit, University of Leeds

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Professor of Old Age Psychiatry,  
Psychiatry Research Group, School  
of Community-Based Medicine,  
The University of Manchester &  
National Clinical Director for  
Dementia, Department of Health

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Director, Centre for Healthcare  
Randomised trials (CHART),  
University of Aberdeen

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Health Sciences Research Group,  
University of Manchester

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Health Sciences, University of York

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Emergency Medicine, School of  
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Professor of Pharmacoeconomics,  
Centre for Economics and Policy  
in Health, Institute of Medical  
and Social Care Research, Bangor  
University

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Department of Cardiac and  
Vascular Science, St George's  
Hospital Medical School,  
University of London

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Professor of Women's Health and  
Clinical Epidemiology, Barts and  
the London School of Medicine,  
Queen Mary, University of London

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Professor of Primary Care  
Cardiovascular Research, Primary  
Care Clinical Sciences Building,  
University of Birmingham

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for Ageing and Health, Newcastle  
University

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Professor of Public Health,  
Peninsula Technology Assessment  
Group, Peninsula College  
of Medicine and Dentistry,  
Universities of Exeter and  
Plymouth

Professor Jonathan Sterne,  
Professor of Medical Statistics  
and Epidemiology, Department  
of Social Medicine, University of  
Bristol

Mr Andy Vail,  
Senior Lecturer, Health Sciences  
Research Group, University of  
Manchester

Professor Clare Wilkinson,  
Professor of General Practice and  
Director of Research North Wales  
Clinical School, Department of  
Primary Care and Public Health,  
Cardiff University

Dr Ian B Wilkinson,  
Senior Lecturer and Honorary  
Consultant, Clinical Pharmacology  
Unit, Department of Medicine,  
University of Cambridge

### Observers

Ms Kate Law,  
Director of Clinical Trials,  
Cancer Research UK

Dr Morven Roberts,  
Clinical Trials Manager, Health  
Services and Public Health  
Services Board, Medical Research  
Council

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### Observers

<p>Dr Tim Elliott, Team Leader, Cancer Screening, Department of Health</p> <p>Dr Catherine Moody, Programme Manager, Medical Research Council</p>	<p>Professor Julietta Patrick, Director, NHS Cancer Screening Programme, Sheffield</p> <p>Dr Kay Pattison, Senior NIHR Programme Manager, Department of Health</p>	<p>Professor Tom Walley, CBE, Director, NIHR HTA programme, Professor of Clinical Pharmacology, University of Liverpool</p>	<p>Dr Ursula Wells, Principal Research Officer, Policy Research Programme, Department of Health</p>
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### Members

<p><b>Chair,</b> <b>Professor Margaret Thorogood,</b> Professor of Epidemiology, University of Warwick Medical School, Coventry</p> <p>Dr Robert Cook, Clinical Programmes Director, Bazian Ltd, London</p> <p>Dr Colin Greaves, Senior Research Fellow, Peninsula Medical School (Primary Care)</p> <p>Mr Michael Head, Service User Representative</p>	<p>Professor Cathy Jackson, Professor of Primary Care Medicine, Bute Medical School, University of St Andrews</p> <p>Dr Russell Jago, Senior Lecturer in Exercise, Nutrition and Health, Centre for Sport, Exercise and Health, University of Bristol</p> <p>Dr Julie Mytton, Consultant in Child Public Health, NHS Bristol</p>	<p>Professor Irwin Nazareth, Professor of Primary Care and Director, Department of Primary Care and Population Sciences, University College London</p> <p>Dr Richard Richards, Assistant Director of Public Health, Derbyshire Country Primary Care Trust</p> <p>Professor Ian Roberts, Professor of Epidemiology and Public Health, London School of Hygiene &amp; Tropical Medicine</p>	<p>Dr Kenneth Robertson, Consultant Paediatrician, Royal Hospital for Sick Children, Glasgow</p> <p>Dr Catherine Swann, Associate Director, Centre for Public Health Excellence, NICE</p> <p>Professor Carol Tannahill, Glasgow Centre for Population Health</p> <p>Mrs Jean Thurston, Service User Representative</p> <p>Professor David Weller, Head, School of Clinical Science and Community Health, University of Edinburgh</p>
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### Observers

<p>Ms Christine McGuire, Research &amp; Development, Department of Health</p>	<p>Dr Kay Pattison, Senior NIHR Programme Manager, Department of Health</p>	<p>Professor Tom Walley, CBE, Director, NIHR HTA programme, Professor of Clinical Pharmacology, University of Liverpool</p>
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### Members

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<b>Deputy Chair,</b> <b>Professor E Andrea Nelson,</b> Reader in Wound Healing and Director of Research, University of Leeds	Dr Emma Clark, Clinician Scientist Fellow & Cons. Rheumatologist, University of Bristol	Dr Lorraine Pinnigton, Associate Professor in Rehabilitation, University of Nottingham	Dr Sarah Tyson, Senior Research Fellow & Associate Head of School, University of Salford
Professor Bipin Bhakta, Charterhouse Professor in Rehabilitation Medicine, University of Leeds	Mrs Anthea De Barton-Watson, Service User Representative	Dr Kate Radford, Senior Lecturer (Research), University of Central Lancashire	Dr Nefyn Williams, Clinical Senior Lecturer, Cardiff University
Mrs Penny Calder, Service User Representative	Professor Nadine Foster, Professor of Musculoskeletal Health in Primary Care Arthritis Research, Keele University	Mr Jim Reece, Service User Representative	
	Dr Shaheen Hamdy, Clinical Senior Lecturer and Consultant Physician, University of Manchester	Professor Maria Stokes, Professor of Neuromusculoskeletal Rehabilitation, University of Southampton	

### Observers

Dr Kay Pattison, Senior NIHR Programme Manager, Department of Health	Professor Tom Walley, CBE, Director, NIHR HTA programme, Professor of Clinical Pharmacology, University of Liverpool	Dr Ursula Wells, Principal Research Officer, Policy Research Programme, Department of Health
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## Interventional Procedures Panel

### Members

<b>Chair,</b> <b>Professor Jonathan Michaels,</b> Professor of Vascular Surgery, University of Sheffield	Ms Leonie Cooke, Service User Representative	Dr John Holden, General Practitioner, Garswood Surgery, Wigan	Dr Jane Montgomery, Consultant in Anaesthetics and Critical Care, South Devon Healthcare NHS Foundation Trust
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Professor Nicholas Clarke, Consultant Orthopaedic Surgeon, Southampton University Hospitals NHS Trust			Professor Yit Chiun Yang, Consultant Ophthalmologist, Royal Wolverhampton Hospitals NHS Trust

### Observers

Dr Kay Pattison, Senior NIHR Programme Manager, Department of Health	Dr Morven Roberts, Clinical Trials Manager, Health Services and Public Health Services Board, Medical Research Council	Professor Tom Walley, CBE, Director, NIHR HTA programme, Professor of Clinical Pharmacology, University of Liverpool	Dr Ursula Wells, Principal Research Officer, Policy Research Programme, Department of Health
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## Pharmaceuticals Panel

### Members

<b>Chair,</b> <b>Professor Imti Choonara,</b> Professor in Child Health, University of Nottingham	Dr James Gray, Consultant Microbiologist, Department of Microbiology, Birmingham Children's Hospital NHS Foundation Trust	Dr Dyfrig Hughes, Reader in Pharmacoeconomics and Deputy Director, Centre for Economics and Policy in Health, IMSCar, Bangor University	Dr Gillian Shepherd, Director, Health and Clinical Excellence, Merck Serono Ltd
<b>Deputy Chair,</b> <b>Dr Yoon K Loke,</b> Senior Lecturer in Clinical Pharmacology, University of East Anglia	Ms Kylie Gyertson, Oncology and Haematology Clinical Trials Manager, Guy's and St Thomas' NHS Foundation Trust London	Dr Maria Kouimtzi, Pharmacy and Informatics Director, Global Clinical Solutions, Wiley-Blackwell	Mrs Katrina Simister, Assistant Director New Medicines, National Prescribing Centre, Liverpool
Dr Martin Ashton-Key, Medical Advisor, National Commissioning Group, NHS London	Dr Jurjees Hasan, Consultant in Medical Oncology, The Christie, Manchester	Professor Femi Oyebo, Consultant Psychiatrist and Head of Department, University of Birmingham	Professor Donald Singer, Professor of Clinical Pharmacology and Therapeutics, Clinical Sciences Research Institute, CSB, University of Warwick Medical School
Mr John Chapman, Service User Representative	Dr Carl Heneghan, Deputy Director Centre for Evidence-Based Medicine and Clinical Lecturer, Department of Primary Health Care, University of Oxford	Dr Andrew Prentice, Senior Lecturer and Consultant Obstetrician and Gynaecologist, The Rosie Hospital, University of Cambridge	Mr David Symes, Service User Representative
Dr Peter Elton, Director of Public Health, Bury Primary Care Trust		Ms Amanda Roberts, Service User Representative	Dr Arnold Zermansky, General Practitioner, Senior Research Fellow, Pharmacy Practice and Medicines Management Group, Leeds University
Dr Ben Goldacre, Research Fellow, Division of Psychological Medicine and Psychiatry, King's College London		Dr Martin Shelly, General Practitioner, Silver Lane Surgery, Leeds	

### Observers

Dr Kay Pattison, Senior NIHR Programme Manager, Department of Health	Dr Heike Weber, Programme Manager, Medical Research Council	Dr Ursula Wells, Principal Research Officer, Policy Research Programme, Department of Health
Mr Simon Reeve, Head of Clinical and Cost- Effectiveness, Medicines, Pharmacy and Industry Group, Department of Health	Professor Tom Walley, CBE, Director, NIHR HTA programme, Professor of Clinical Pharmacology, University of Liverpool	

## Psychological and Community Therapies Panel

### Members

<b>Chair,</b> <b>Professor Scott Weich,</b> Professor of Psychiatry, University of Warwick, Coventry	Mrs Val Carlill, Service User Representative	Dr Jeremy J Murphy, Consultant Physician and Cardiologist, County Durham and Darlington Foundation Trust	Dr Paul Ramchandani, Senior Research Fellow/Cons. Child Psychiatrist, University of Oxford
<b>Deputy Chair,</b> <b>Dr Howard Ring,</b> Consultant & University Lecturer in Psychiatry, University of Cambridge	Dr Steve Cunningham, Consultant Respiratory Paediatrician, Lothian Health Board	Dr Richard Neal, Clinical Senior Lecturer in General Practice, Cardiff University	Dr Karen Roberts, Nurse/Consultant, Dunston Hill Hospital, Tyne and Wear
Professor Jane Barlow, Professor of Public Health in the Early Years, Health Sciences Research Institute, Warwick Medical School	Dr Anne Hesketh, Senior Clinical Lecturer in Speech and Language Therapy, University of Manchester	Mr John Needham, Service User Representative	Dr Karim Saad, Consultant in Old Age Psychiatry, Coventry and Warwickshire Partnership Trust
Dr Sabyasachi Bhaumik, Consultant Psychiatrist, Leicestershire Partnership NHS Trust	Dr Peter Langdon, Senior Clinical Lecturer, School of Medicine, Health Policy and Practice, University of East Anglia	Ms Mary Nettle, Mental Health User Consultant	Dr Lesley Stockton, Lecturer, School of Health Sciences, University of Liverpool
	Dr Yann Lefevre, GP Partner, Burrage Road Surgery, London	Professor John Potter, Professor of Ageing and Stroke Medicine, University of East Anglia	Dr Simon Wright, GP Partner, Walkden Medical Centre, Manchester
		Dr Greta Rait, Senior Clinical Lecturer and General Practitioner, University College London	

### Observers

Dr Kay Pattison, Senior NIHR Programme Manager, Department of Health	Dr Morven Roberts, Clinical Trials Manager, Health Services and Public Health Services Board, Medical Research Council	Professor Tom Walley, CBE, Director, NIHR HTA programme, Professor of Clinical Pharmacology, University of Liverpool	Dr Ursula Wells, Principal Research Officer, Policy Research Programme, Department of Health
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## Expert Advisory Network

### Members

Professor Douglas Altman,  
Professor of Statistics in Medicine,  
Centre for Statistics in Medicine,  
University of Oxford

Professor John Bond,  
Professor of Social Gerontology  
& Health Services Research,  
University of Newcastle upon Tyne

Professor Andrew Bradbury,  
Professor of Vascular Surgery,  
Solihull Hospital, Birmingham

Mr Shaun Brogan,  
Chief Executive, Ridgeway  
Primary Care Group, Aylesbury

Mrs Stella Burnside OBE,  
Chief Executive, Regulation and  
Improvement Authority, Belfast

Ms Tracy Bury,  
Project Manager, World  
Confederation of Physical Therapy,  
London

Professor Iain T Cameron,  
Professor of Obstetrics and  
Gynaecology and Head of the  
School of Medicine, University of  
Southampton

Professor Bruce Campbell,  
Consultant Vascular & General  
Surgeon, Royal Devon & Exeter  
Hospital, Wonford

Dr Christine Clark,  
Medical Writer and Consultant  
Pharmacist, Rossendale

Professor Collette Clifford,  
Professor of Nursing and Head  
of Research, The Medical School,  
University of Birmingham

Professor Barry Cookson,  
Director, Laboratory of Hospital  
Infection, Public Health  
Laboratory Service, London

Dr Carl Counsell,  
Clinical Senior Lecturer in  
Neurology, University of Aberdeen

Professor Howard Cuckle,  
Professor of Reproductive  
Epidemiology, Department  
of Paediatrics, Obstetrics &  
Gynaecology, University of Leeds

Professor Carol Dezateaux,  
Professor of Paediatric  
Epidemiology, Institute of Child  
Health, London

Mr John Dunning,  
Consultant Cardiothoracic  
Surgeon, Papworth Hospital NHS  
Trust, Cambridge

Mr Jonathan Earnshaw,  
Consultant Vascular Surgeon,  
Gloucestershire Royal Hospital,  
Gloucester

Professor Martin Eccles,  
Professor of Clinical Effectiveness,  
Centre for Health Services  
Research, University of Newcastle  
upon Tyne

Professor Pam Enderby,  
Dean of Faculty of Medicine,  
Institute of General Practice  
and Primary Care, University of  
Sheffield

Professor Gene Feder,  
Professor of Primary Care  
Research & Development, Centre  
for Health Sciences, Barts and The  
London School of Medicine and  
Dentistry

Mr Leonard R Fenwick,  
Chief Executive, Freeman  
Hospital, Newcastle upon Tyne

Mrs Gillian Fletcher,  
Antenatal Teacher and Tutor and  
President, National Childbirth  
Trust, Henfield

Professor Jayne Franklyn,  
Professor of Medicine, University  
of Birmingham

Mr Tam Fry,  
Honorary Chairman, Child  
Growth Foundation, London

Professor Fiona Gilbert,  
Consultant Radiologist and NCRN  
Member, University of Aberdeen

Professor Paul Gregg,  
Professor of Orthopaedic Surgical  
Science, South Tees Hospital NHS  
Trust

Bec Hanley,  
Co-director, TwoCan Associates,  
West Sussex

Dr Maryann L Hardy,  
Senior Lecturer, University of  
Bradford

Mrs Sharon Hart,  
Healthcare Management  
Consultant, Reading

Professor Robert E Hawkins,  
CRC Professor and Director of  
Medical Oncology, Christie CRC  
Research Centre, Christie Hospital  
NHS Trust, Manchester

Professor Richard Hobbs,  
Head of Department of Primary  
Care & General Practice,  
University of Birmingham

Professor Alan Horwich,  
Dean and Section Chairman,  
The Institute of Cancer Research,  
London

Professor Allen Hutchinson,  
Director of Public Health and  
Deputy Dean of ScHARR,  
University of Sheffield

Professor Peter Jones,  
Professor of Psychiatry, University  
of Cambridge, Cambridge

Professor Stan Kaye,  
Cancer Research UK Professor of  
Medical Oncology, Royal Marsden  
Hospital and Institute of Cancer  
Research, Surrey

Dr Duncan Keeley,  
General Practitioner (Dr Burch &  
Ptnrs), The Health Centre, Thame

Dr Donna Lamping,  
Research Degrees Programme  
Director and Reader in  
Psychology, Health Services  
Research Unit, London School of  
Hygiene and Tropical Medicine,  
London

Professor James Lindesay,  
Professor of Psychiatry for the  
Elderly, University of Leicester

Professor Julian Little,  
Professor of Human Genome  
Epidemiology, University of  
Ottawa

Professor Alistaire McGuire,  
Professor of Health Economics,  
London School of Economics

Professor Neill McIntosh,  
Edward Clark Professor of Child  
Life and Health, University of  
Edinburgh

Professor Rajan Madhok,  
Consultant in Public Health, South  
Manchester Primary Care Trust

Professor Sir Alexander Markham,  
Director, Molecular Medicine  
Unit, St James's University  
Hospital, Leeds

Dr Peter Moore,  
Freelance Science Writer, Ashted

Dr Andrew Mortimore,  
Public Health Director,  
Southampton City Primary Care  
Trust

Dr Sue Moss,  
Associate Director, Cancer  
Screening Evaluation Unit,  
Institute of Cancer Research,  
Sutton

Professor Miranda Mugford,  
Professor of Health Economics  
and Group Co-ordinator,  
University of East Anglia

Professor Jim Neilson,  
Head of School of Reproductive  
& Developmental Medicine  
and Professor of Obstetrics  
and Gynaecology, University of  
Liverpool

Mrs Julietta Patnick,  
Director, NHS Cancer Screening  
Programmes, Sheffield

Professor Robert Peveler,  
Professor of Liaison Psychiatry,  
Royal South Hants Hospital,  
Southampton

Professor Chris Price,  
Director of Clinical Research,  
Bayer Diagnostics Europe, Stoke  
Poges

Professor William Rosenberg,  
Professor of Hepatology and  
Consultant Physician, University  
of Southampton

Professor Peter Sandercock,  
Professor of Medical Neurology,  
Department of Clinical  
Neurosciences, University of  
Edinburgh

Dr Philip Shackley,  
Senior Lecturer in Health  
Economics, Sheffield Vascular  
Institute, University of Sheffield

Dr Eamonn Sheridan,  
Consultant in Clinical Genetics, St  
James's University Hospital, Leeds

Dr Margaret Somerville,  
Director of Public Health  
Learning, Peninsula Medical  
School, University of Plymouth

Professor Sarah Stewart-Brown,  
Professor of Public Health,  
Division of Health in the  
Community, University of  
Warwick, Coventry

Dr Nick Summerton,  
GP Appraiser and Codirector,  
Research Network, Yorkshire  
Clinical Consultant, Primary Care  
and Public Health, University of  
Oxford

Professor Ala Szczepura,  
Professor of Health Service  
Research, Centre for Health  
Services Studies, University of  
Warwick, Coventry

Dr Ross Taylor,  
Senior Lecturer, University of  
Aberdeen

Dr Richard Tiner,  
Medical Director, Medical  
Department, Association of the  
British Pharmaceutical Industry

Mrs Joan Webster,  
Consumer Member, Southern  
Derbyshire Community Health  
Council

Professor Martin Whittle,  
Clinical Co-director, National  
Co-ordinating Centre for Women's  
and Children's Health, Lymington



### **Feedback**

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***We look forward to hearing from you.***