Section 5: Management of obesity 2 (continued)

Sibutramine (Reductil): marketing authorisation suspended
On 21 January 2010, the MHRA announced the suspension of the marketing authorisation for the obesity drug sibutramine (Reductil). This follows a review by the European Medicines Agency which found that the cardiovascular risks of sibutramine outweigh its benefits. Emerging evidence suggests that there is an increased risk of non-fatal heart attacks and strokes with this medicine.

The MHRA advises that:

- Prescribers should not issue any new prescriptions for sibutramine (Reductil) and should review the treatment of patients taking the drug.
- Pharmacists should stop dispensing Reductil and should advise patients to make an appointment to see their doctor at the next convenient time.
- People who are currently taking Reductil should make a routine appointment with their doctor to discuss alternative measures to lose weight, including use of diet and exercise regimens. Patients may stop treatment before their appointment if they wish.

NICE clinical guideline 43 recommended sibutramine for the treatment of obesity in certain circumstances. These recommendations have now been withdrawn and healthcare professionals should follow the MHRA advice.

15 Clinical management of obesity (contd).

15.3 Adults

15.3.1 Factors to be considered in the clinical assessment of adults who are overweight or obese

[The aim of an initial assessment is to identify individuals who are at increased risk and who would benefit from intervention. This initial assessment should follow the classification of the degree of overweight or obesity as recommended by the GDG based on the earlier evidence reviews.

Therefore, the factors to be assessed at the initial presentation should be based on two evidence bases: one on the common comorbidities, and one on the effectiveness of weight loss in people with comorbidities and their expected health gain.

Further assessment(s) should aim to determine any determinants of energy imbalance.]

15.3.1.1 Evidence statements (Table 15.11)

Table 15.11 Evidence statements and grading

No.	Evidence statement	Grade
1	Initial assessment should aim to identify individuals at highest risk who have the potential to gain health benefits with weight loss, and maintenance of that weight loss	4
2	In adults who are overweight and obese, individuals at highest risk and with the potential to gain health benefits include those with current significant comorbidities, or those at high risk of developing significant comorbidities in the future	2++
3	In adults, reasons for energy imbalance are environment, genes, stress and psychological factors, current medication, life stage (early childhood and adolescence, pregnancy and childbirth, menopause) and life events (quitting smoking, marriage, giving up sport, holidays)	1++, 2++

15.3.1.2 Evidence review on factors to be assessed in adults and mature adolescents

In February 2005, the National Guideline Clearinghouse synthesised the recommendations on the assessment and treatment of obesity and overweight in adults from six published guidelines.[1] The different scopes, target populations, intended users, and practices covered can be seen in Appendix 15 (evidence tables of included studies). The authors of the synthesis identified areas of agreement between the included guidelines surrounding assessment. They concluded that:

> 'AGA, BWH, and Singapore MOH recommend screening for comorbid conditions, particularly obesity-related health risks, as part of the medical evaluation. The presence or absence of such conditions is helpful in determining the intensity of therapy. ACP refers to the assessment of comorbid conditions as part of an algorithm that is provided for the suggested management of obesity. AGA and Singapore MOH also recommend screening for psychiatric disorders, such as depression and binge eating, which may affect the success of therapy. BWH points to the presence of depression, disinhibition, and

binge eating at baseline as factors that increase the likelihood of weight regain after an initial weight loss.'[1]

No area of disagreement was noted for assessment.

The individual guideline recommendations on assessment are given in Table 15.12.

Table 15.12 Existing recommendations on assessment for obesity

AGA (2002)	A medical evaluation is needed to identify patients who either have, or are at risk for, obesity-related medical complications. This assessment should include a careful history, physical examination (including determination of BMI) and laboratory tests to identify eating and activity behaviours, weight history and previous weight loss attempts, obesity-related health risks, and current obesity-related medical illnesses.
ACP (2005)	No specific recommendations offered However, the assessment of comorbid conditions is indicated in an algorithm contained in the original guideline for the suggested management of obesity. Obesity-related comorbid conditions such as hypertension, impaired glucose tolerance, diabetes mellitus, hyperlipidaemia, and obstructive sleep apnoea are noted in the original guideline
ACPM (2001)	No recommendations offered
AGA (2002)	The medical evaluation should include an assessment of obesity-related health risks and current obesity-related medical illnesses. Obesity-related health risks, the presence of other disease risk factors, and coexisting obesity complications should be used to help determine the need for obesity therapy and the aggressiveness of the treatment approach. The presence of psychiatric illnesses (for example, severe depression, substance abuse, or binge-eating disorders) should also be assessed, as all of these disorders can derail weight loss efforts.
BWH (2003)	Clinicians should consider risk factors when deciding upon treatment Health risks associated with obesity include high blood pressure, type 2 diabetes, coronary heart disease,

	dyslipidaemia, stroke, osteoarthritis, sleep apnoea, cancer and mortality. These risks increase with increasing degrees of overweight and obesity. Specific factors, such as race, ethnicity, age, general and social conditions, may also increase or decrease an individual's health risks at different stages of overweight or obesity.
SINGAPORE MOH (2004)	In clinical evaluation of patients, practitioners should consider and exclude predisposing factors for, and secondary causes of, obesity (GPP) Overweight and obese adults should be screened for comorbid conditions and should be stratified according to their health risks, in particular for cardiovascular disease, prior to the commencement of treatment (grade C, level IV) The presence of depression and binge eating disorders in obese patients must be evaluated for, with appropriate referral for psychiatric treatment (grade B, level IIa)
USPSTF (2003)	No recommendations offered

ACP, American College of Physicians; ACPM, American College of Prevention Medicine; AGA, American Gastroenterological Association; BMI, body mass index; BWH, Brigham and Women's Hospital; MOH, Ministry of Health; USPSTF, United States Preventive Services Task Force.

The National Health and Medical Research Council (Australia) (NHMRC) guidelines[2] on the management of overweight and obesity in adults recommended that after discussing weight with the individual and whether measurements should be taken, the next steps were to assess and treat associated comorbidities (specifically to measure blood pressure, plasma cholesterol, lipids and glucose) and to determine the individual's need to lose weight. The decisions on which factors to assess were made on the identified common comorbidities (see Section 1 Chapter 3 section 3.1) and also on the evidence for the benefit of weight loss in individuals with these conditions. Diseases and conditions associated with obesity (see Table 15.13) were listed and further categorised into two groups: those with indirect links (as a result of metabolic consequences) and those with direct links (as a result of the excess weight).

Table 15.13 Diseases and conditions associated with obesity[2]

Relative risk (RR)	Associated with metabolic consequences	Associated with excess weight
Greatly increased RR > 3	Type 2 diabetes	Sleep apnoea
	Gall bladder disease	Breathlessness
	Hypertension	Asthma
	Dyslipidaemia	Social isolation and depression
	Insulin resistance	Daytime sleepiness and fatigue
	Non-alcoholic fatty liver	
Moderately increased RR 2 –3	Coronary heart disease	Osteoarthritis
	Stroke	Respiratory disease
	Gout/hyperuricaemia	Hernia
		Psychological problems
Slightly increased RR 1– 2	Cancer[a]	Varicose veins
	Reproductive abnormalities/impaired fertility	Musculoskeletal problems
	Polycystic ovaries	Bad back
	Skin complications	Stress incontinence
	Cataract	Oedema/cellulitis

[a] Breast, endometrial, colon and others.

The Agency for Healthcare Research and Quality (AHRQ) report on obesity in the elderly[3] concluded that:

> 'Those at risk for obesity-associated health problems stand to benefit most from intervention, if such intervention alters their weight-related risk. The strongest evidence for obesity intervention is for those with cardiovascular risk. Cardiovascular risk factors – including family history, diabetes, tobacco use, or dyslipidemia – can help identify this group.'[3]

Although no recommendations were made on this evidence, it seems logical that an initial assessment should focus on identifying those who have most to gain.

15.3.2 Energy imbalance in adults and mature adolescents

The NHMRC guidelines[2] considered that the reasons (how and why) for energy imbalance should be assessed. The mechanism for energy imbalance is the imbalance between food intake (total energy and the energy per unit weight of food) and the energy expenditure, but the evidence suggested that food intake and levels of physical activity could only be estimated approximately in a clinical (or non-specialist) setting.

Reasons for why this imbalance should occur were categorised into six key areas: environment, genes, stress and psychological factors, current medication, life stage (early childhood and adolescence, pregnancy and childbirth, menopause) and life events (quitting smoking, marriage, giving up sport, holidays). The authors made evidence statements as follows:

- The modern environment is a potent stimulus for obesity.
- Some rare cases of single-gene mutations cause severe obesity disorders, which usually manifest early in life.
- In general, cases of severe obesity are more likely to have a specific genetic basis than cases of overweight, which may result from environmental influences alone.
- Psychological stress can have variable effects on a person's body weight.
- Several prescription medications can cause weight gain.
- Obesity in childhood and adolescence is a risk factor for obesity later in life.
- The tracking of childhood obesity into adult obesity is stronger for older children than for younger ones.

- Pregnancy and menopause are critical periods for weight gain in women.
- It appears that a change in weight at menopause can be prevented by lifestyle change.
- Hormone replacement therapy after menopause can result in reduced body-fat gain (particularly on the upper body) when compared with a placebo.
- Certain life events – for example, marriage, holidays, and giving up sport – can have an influence on body fatness.
- Quitting smoking can cause significant weight gain – on average 5–6 kg in the first year.
- Lack of motivation and a history of failed attempts to lose weight may make it more difficult to maintain a low body weight.
- Psychological factors – including early life experiences – can play an important part in the development of overweight or obesity.[2]

15.3.3 Lifestyle interventions (diet, behaviour therapy and physical activity) for weight loss and other outcomes in adults

All summary statistics, other than those presented in the figures, can be found in Appendix 17. Please note that all summary statistics have been checked by a consultant statistician.

15.3.3.1 Evidence statements – diet (Table 15.14)

Table 15.14 Evidence statements and grading

No.	Evidence statement	Grade
1	Energy balance is critical to weight loss. Caloric expenditure must exceed caloric intake	2++ (see review on energy imbalance)
Weight loss		
2	Overall, a 600 kcal deficit diet or low-fat diet is effective for weight loss: a change of approximately –5 kg (95% CI -5.86kg to -4.75kg, range –0.40 kg to –7.80 kg) compared with usual care at 12 months Median weight change across all studies was approximately –4.6 kg (range –0.60 kg to –7.20 kg) for a 600 kcal deficit diet or low-fat diet and +0.60 kg (range +2.40 kg to –1.30kg) for usual care (n = 12 comparisons)	1++
3	Overall, a low-calorie diet (1000–1600 kcal/day) is effective for weight loss: a change of approximately –6 kg (95% CI -9.05kg to -3.24kg, range –5.30 kg to –7.00 kg) compared with usual care at 12 months Two studies showed an absolute weight change of –5.50 kg and –5.90 kg for the low-calorie diet compared with weight change of +1.50 kg and –0.60 kg for usual care (n = 2 comparisons)	1+
4	One study showed that a VLCD (420kcal per day) for a limited period of 8 weeks, resulted in a significant weight change of -13.40 kg (95% CI -18.43kg to -8.37kg) compared with usual care at 12 months. Absolute weight changes were –11.10 kg for the VLCD compared with +2.30 kg for usual care (n = 1 comparison)	1+

No.	Evidence statement	Grade
5	Overall, a low-calorie diet is as effective for weight loss as a 600 kcal deficit diet or low-fat diet: a change of approximately +1 kg (95% CI -1.06kg to 2.63kg, range +1.63 kg to +0.20 kg) compared with usual care at 12 months Two studies showed an absolute weight change of –0.82 kg and –3.00 kg for the low-calorie diet compared with weight change of –2.45 kg and –3.20 kg for the 600 kcal deficit diet or low-fat diet (n = 2 comparisons)	1+
6	One study showed that a VLCD (420kcal per day), for a limited period of 12 weeks, resulted in a (non-significant) weight change of –4.70 kg (95% CI -11.79kg to 2.39kg) compared with a 600 kcal deficit diet or low-fat diet at 24 months. Absolute weight changes were –6.70 kg for the VLCD compared with 2.00 kg for a 600 kcal deficit diet or low-fat diet (n = 1 comparison)	1+
7	Overall, a 800kcal/day VLCD (used for 4 days a week, in conjunction with a 1200kcal/day low-calorie diet) is as effective for weight loss as a continuous low-calorie diet: a change of approximately 0 kg (range +3.52 kg to –3.56 kg) compared with a low-calorie diet at 12 months (n = 1 comparisons) Overall, a 750kcal/day maximum VLCD (used for 2 days a week, in conjunction with a individualised low-calorie diet of weight in lbsx12-1000kcal) is as effective for weight loss as a continuous low-calorie diet: a change of approximately 0 kg (range +2.11 kg to –2.33 kg) compared with a low-calorie diet at 12 months (n = 2 comparisons from 1 study) Overall, a VLCD (800kcal/day for 8 weeks) is as effective for weight loss as a continuous low-calorie diet for 8 weeks: a change of approximately 1.13 kg (range +3.06 kg to –5.32 kg) compared with a low-calorie diet at 18 months (n = 2 comparisons from 1 study)	1++

No.	Evidence statement	Grade
8	Overall, a low-fat diet is as effective for weight loss as other diets (with the same calorie content): a change of approximately 0.5 kg (95% CI -1.14kg to 2.11kg, range +5.70 kg to –4.24 kg) compared with other diets at 12 months Median weight change across all studies was approximately –3.00 kg (range –1.60 kg to –5.20 kg) for a low-fat diet and –3.50 kg (range –0.96 kg to –8.70 kg) for other diets with the same calorie content (n = 5 comparisons)	1++
9	Overall, a PSMF (food-based, with a calorie content in the range of 1400–1900 kcal/day) is as effective for weight loss as a 600 kcal deficit diet or low-fat diet: a change of approximately –0.5 kg (95% CI -2.17kg to 1.04kg, range +1.10 kg to –1.88 kg) compared with a 600 kcal deficit diet or low-fat diet at 12 months Median weight change across all studies was approximately –4.34 kg (range –2.10 kg to –5.10 kg) for a PSMF and –3.10 kg (range –2.46 kg to –3.20 kg) for a 600 kcal deficit diet or low-fat diet (n = 3 comparisons)	1++
10	Overall, a PSMF (based on food or VLCD) is as effective for weight loss as low-calorie diet: a change of approximately –0.6 kg (95% CI -2.35kg to 1.11kg, range +0.90 kg to –4.00 kg) compared with low-calorie diet at 12 months. Median weight change across studies with a calorie content of approximately 400 kcal/day (food VLCD, alternating with a low-calorie diet) was approximately –14.20 kg (range –10.60 kg to –17.33 kg) for a PSMF and –10.50 kg (range –6.60 kg to -14.43 kg) for a low-calorie diet. One study showed that a PSMF (low carb, no details of calories), resulted in a (non-significant) weight change of +0.90 kg (95% CI -1.23kg to 3.03kg) compared with a low-calorie diet at 12 months. Absolute weight changes were –2.10 kg for the PSMF compared with –3.00 kg for a low-calorie diet (n = 4 comparisons)	1++

No.	Evidence statement	Grade
11	Overall, an 8-week PSMF (based on food with a calorie content of 1000 kcal/day) is as effective for weight loss as an 8-week VLCD (420kcal/day) PSMF: a change of approximately +1.5 kg (95% CI -1.57kg to 4.69kg, range +3.76 kg to –0.20 kg) compared with low-calorie diet at 18 months Median weight change across studies with a calorie content of approximately 1000 kcal/day (food based) was approximately -4.9kg (range -1.13kg to -8.64kg) for a protein sparing modified fast and –6.6kg (range -0.93kg to -12.40kg) for a very low calorie PSMF diet (meal replacements) (n = 4 comparisons from 1 study)	1++
12	One study showed that a low-calorie diet, resulted in a (non-significant) weight change of +0.30 kg (95% CI -2.42 to 3.02) compared with a very-low-fat diet at 12 months. Absolute weight changes were –3.00 kg for the low-calorie diet compared to –3.30 kg for a very-low-fat diet.	1+
13	One study showed that a protein sparing modified fast (based on food, calorie content 1700–1800 kcal/day), resulted in a weight change of +1.20 kg compared with a very-low-fat diet at 12 months. Absolute weight changes were –2.10 kg for the (food based) PSMF compared with –3.30 kg for a very-low-fat diet	1+
14	One study showed that a high-protein diet (25% of energy from protein, low glycaemic index), resulted in a (non-significant) weight change of –1.90 kg compared with a standard/medium-protein diet (12% of energy from protein, high glycaemic index) at 12 months. Absolute weight changes were –6.20 kg for the high-protein diet compared with –4.30 kg for a standard/medium-protein diet	1+
15	There is not enough evidence to compare the use of diets in populations with specific comorbidities	N/A
16	The effectiveness of all diets appears to change over time, with a trend for greater weight loss in the short term (up to 12 months), with a reduction in overall weight loss in the longer term (up to 60 months)	1++

No.	Evidence statement	Grade
Outcomes other than weight loss (from trials that reported weight loss)		
17	Overall, a 600 kcal deficit diet or low-fat diet is more effective in lowering total cholesterol levels than usual care: a change of approximately –0.21 mmol/l (95% CI -.34 to -0.08, range –0.34 mmol/l to –0.08 mmol/l) at 12 months Median change across studies was approximately –0.37 mmol/l (range –0.23 mmol/l to –0.42 mmol/l) for a 600 kcal deficit diet or low-fat diet and –0.15 mmol/l (range –0.03 mmol/l to –0.23mmo/l) for usual care A 600 kcal deficit diet or low-fat diet is also more effective in lowering levels of LDL-cholesterol (–0.13 mmol/l, 95% CI -0.26 to 0.00), HDL-cholesterol (+0.06 mmol/l, 95% CI 0.03 to 0.09), triglycerides (–0.19 mmol/l, 95% CI -0.31 to -0.06), systolic blood pressure (–3.78 mmHg, 95% CI -5.53 to -2.03), and diastolic blood pressure (–3.44mmHg, 95%CI -4.86 to -2.01) than usual care at 12 months (n = 4 comparisons)	1++
18	Overall, a 600 kcal deficit diet or low-fat diet is more effective in lowering total cholesterol levels than a PSMF (food-based, with a calorie content in the range of 1400–1900 kcal/day): a change of approximately –0.18 mmol/l (95% CI -0.35 to -0.02, range –0.15 mmol/l to –0.37 mmol/l) at 12 months Median change across studies was approximately –0.21 mmol/l (range –0.14 mmol/l to –0.26 mmol/l) for a 600 kcal deficit diet or low-fat diet and +0.01 mmol/l (range +0.16 mmol/l to –0.11mmo/l) for a PSMF (food-based, with a calorie content in the range of 1400–1900 kcal/day). But the PSMF appears to be more effective in improving HDL-cholesterol levels (+0.08 mmol/l, 95% CI 0.03 to 0.18), and triglyceride levels (–0.28 mmol/l, 95% CI -0.48 to -0.09) than a 600 kcal deficit diet or low-fat diet at 12 months (n = 3 comparisons)	1++
19	In people with insulin resistance, one study showed that a 600 kcal deficit diet or low-fat diet resulted in a lowering of fasting plasma glucose of –0.28 mmol/l (95% CI -0.47 to -0.09) compared to usual care at 12 months. Absolute changes were –0.21 mmol/l for the 600 kcal deficit diet or low-fat diet compared with +0.07 mmol/l for usual care (n = 1 comparison)	1+

No.	Evidence statement	Grade
20	In people with a family history of diabetes, one study showed that a low-fat diet resulted in lowering of total cholesterol levels of –0.42 mmol/l (95% CI -0.75 to -0.09) compared with a low-calorie diet at 12 months. Absolute changes were –0.18 mmol/l for the low-fat diet compared with +0.24 mmol/l for the low-calorie diet (n = 1 comparison)	1+
21	In people with type 2 diabetes, one study showed significant lowering of fasting plasma glucose (–4.50 mmol/l, 95% CI -7.07 to -1.93) and %HbA1c (–2.60%, 95% CI -4.36 to -0.84) at 18 months after use of a protein sparing modified VLCD (meal replacements or food based, 400 kcal/day) alternating with a low-calorie diet compared with continuous use of a low-calorie diet (n = 1 comparison)	1+
22	One study showed that a low-calorie diet, resulted in an increase in HDL-cholesterol levels of +0.10 mmol/l (95% CI 0.01 to 0.19) compared with a very-low-fat diet at 12 months. Absolute changes were +0.09 mmol/l for the low-calorie diet compared with –0.01 mmol/l for a very-low-fat diet (n = 1 comparison)	1+
23	One study showed that a PSMF (based on food, calorie content 1700–1800 kcal/day), resulted in an increase in HDL-cholesterol of +0.10 mmol/l (95% CI 0.02 to 0.18) compared with a very-low-fat diet at 12 months. Absolute changes were +0.09 mml/l for the PSMF compared to –0.01 mmol/l for a very-low-fat diet (n = 1 comparison)	1+
24	No significant differences were seen between diets for other outcomes at 12 months	1++
Harms		
25	No evidence statements can be made as reporting of harms and adverse events was rare and ad hoc	N/A

No.	Evidence statement	Grade
Generalisability		
26	Only two studies were conducted solely in the UK, with the majority of studies done in the USA (n = 29) Many of the studies (15 of the 34 unique studies) were based in secondary care or specialist outpatient or university clinics (although it was often difficult to assess exactly what setting), with only two based in primary care. Five workplace studies were included as the aim of the study was to evaluate the effectiveness of the diet and not the effect of the setting. However, the resulting effect may have been different if the intervention was delivered in a clinical setting Where reported, participants were recruited as volunteers (that is, through advertising) in 19 studies and through selection (that is, some element of referral or from waiting lists) in five studies It is difficult therefore to know how generalisable the results of the included studies are to the UK population, particularly in primary care	1++
27	From the included studies, the duration of intervention varied considerably (range 8 weeks to 48 months) and the rate of follow-up varied; for example, one study made contact every week for 18 months. However, most studies used either a one visit every month approach or an approach of decreased contact over time (for example, every 2 weeks, then every month, then every 2 months)	1++
28	Dietary advice and support were provided most often by a dietitian. Other personnel who delivered interventions were physicians, research nurses, health educators, graduate students, diet group leaders, experts in nutritional counselling and behavioural therapists	1++
29	One assumption could be that the effect size achieved in the included studies may be smaller in practice; in a less motivated, non-volunteer population and less intensive follow-up delivered by generalists	N/A

HDL, high-density lipoprotein; LDL, low-density lipoprotein; N/A, not applicable; PSMF, protein-sparing modified fast; VLCD, very-low-calorie diet.

15.3.3.2 Evidence review on dietary interventions

This review is primarily based on a health technology appraisal (HTA) published in 2004.[4] The aim of the HTA was to review systematically obesity treatments in adults to identify therapies that impact by achieving weight reduction, risk factor modification or improved clinical outcomes. All randomised controlled trials (RCTs) of dietary interventions in adults with a body mass index (BMI) of 28 or more were included. The duration of the trials had to be for 52 weeks or more. The main outcome was weight change in kilograms at 12 months' follow-up.

The diets were classified as follows:

- healthy eating advice
- 600 kcal/day deficit or low-fat diet
- low-calorie diet (1000–1600 kcal/day)
- very-low-calorie diet (VLCD) (< 1000 kcal/day)
- protein-sparing modified fast (PSMF) (carbohydrate content of 40 g or less)
- low-carbohydrate, high-monounsaturated-fat diet
- salt restriction.

Due to reporting issues, healthy eating advice and 600 kcal/day deficit or low-fat diets were classified together, along with diets where the fat or calorie restriction was not stated or could not be estimated.

We used the definitions as above when classifying diets. Because of some concerns about the definitions, we have tried to be explicit (that is, include as much detail as possible about the dietary content) in both the evidence tables and the evidence statements.

Other outcomes included longer-term weight loss and blood pressure, lipids and fasting blood glucose. However, these outcomes were reported in only some of the included trials so the results are based on more limited evidence (often only the results of one trial) than that of weight change at 12 months so caution should be exercised when interpreting these.

Another review is cited which addressed the diagnosis and treatment of obesity in older people (defined as aged 60 years or more), a technology assessment published in 2003 by the US Agency for Healthcare Research.[3]

The aim of the review was to reassess the evidence for the diagnosis and treatment of obesity in older people. The key clinical question relevant to this evidence review is 'Are there dietary or behavioural therapies that improve net health outcomes in obese older people?' The defined inclusion criteria for dietary interventions were:

- RCT of fair or good quality
- weight loss or reduction in BMI, waist circumference, waist-to-hip ratio as a reported outcome
- BMI of 25 kg/m^2 or more
- minimum 12-month follow-up
- population generalisable to a typical US primary care population
- sample mean age of 60 years or more.

Only one trial was reported as evaluating the effectiveness of a dietary intervention only (that is, not combined with any other intervention such as behavioural treatment) and satisfied the criteria above. However, when we examined this trial in detail, the intervention was not diet alone. See excluded studies (Appendix 16). No additional studies were identified from the Update searches.

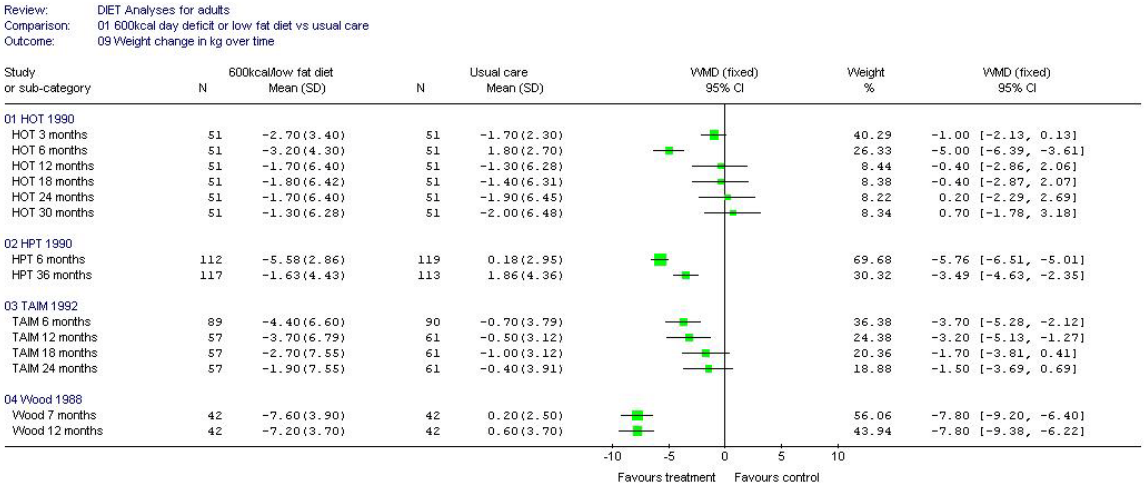
600 kcal/day deficit or low-fat diet* compared with usual care

A total of 13 RCTs were included in the Avenell HTA.[4] No additional studies were identified for this comparison. One study[5] was conducted in a workplace setting, but was included as the setting was not the focus of the study. One HTA included study was excluded[6-8] in this review because not all participants were overweight.

Weight loss

Overall, there was an significant weight change of –5.32 kg at 12 months in this group (weighted mean difference [WMD] 95% confidence interval (CI) –5.88 to -4.75)† when compared with a control group, and although there was statistical heterogeneity ($p \leq 0.00001$, $I^2 = 76.7\%$) between the 12 included studies the direction of effect was consistent.[4] (Figure 15.1). One cluster randomised controlled trial (C-RCT) reported a mean ± SD weight change at 12 months of -0.88 ± 4.0 kg for the diet group and 1.3 ± 3.0 kg for the control group (not statistically significant).

Figure 15.1 Maintenance of weight loss over time for all adults on a low-fat or 600 kcal/day deficit diet compared with usual care



* Due to lack of reporting, healthy eating advice and diets where the fat or calorie restriction was not estimable are included in this category.

† Recalculated with sample size halved for control group in Pritchard 1999[18]

Other outcomes

At 12 months, there were significant improvements in blood pressure (change in diastolic blood pressure [DBP] –3.44 mm Hg, WMD 95% CI –4.86 to –2.01 based on four trial results; change in systolic blood pressure [SPB] –3.78 mm Hg, WMD 95% CI –5.53 to –2.03 based on four trial results), lipids (change in total cholesterol –0.21, WMD 95% CI –0.34 to –0.08 based on four trial results), and fasting plasma glucose (change in fasting plasma glucose –0.28 mmol/l, WMD 95% CI –0.47 to –0.09 based on one trial) compared with usual care. But these were not maintained over time, even in obese populations with hypertension or type 2 diabetes. In an obese population with hypertension, changes in SBP and DBP in the diet group compared with the control group were not significant at 18 months (one study only). The data suggested that a low-fat diet or 600 kcal/day deficit diet prevented the development of diabetes and improved blood pressure control.[4]

Other factors

No additional analysis was carried out on the effect of age, ethnicity, socioeconomic status, previous treatment for obesity, motivation, frequency or length of the intervention in the HTA.[4]

Gender

Three studies recruited men only,[5;9;10] and a further four studies[11-14] had mainly male participants. No studies recruited women only.

The Dietary Intervention Study of Hypertension trial (DISH) showed no difference between men and women for weight loss (–11.0 kg vs –9.7 kg respectively, 45.8% and 46.8% lost 5% or more of initial body weight, respectively) at 56 weeks. Similarly, gender was not significantly associated with weight loss at 6 months in the Trial of Antihypertensive Interventions and Management (TAIM) study.[14]

Age

The age range of participants varied (overall, range 20 years minimum to 80 years maximum, where reported). Some studies recruited younger adults (for example, aged 25–49 years), whereas others recruited older people (for example, aged 50–80 years).

DISH showed no difference between people aged under 60 years and those aged 60 years or over for weight loss (–11.0 kg vs –8.5 kg, respectively, 46.7% and 45.4% lost 5% or more of initial body weight, respectively) at 56 weeks.

Other groups, including black and minority ethnic groups

Although the results of the DISH trial were analysed for groups of black and white participants, we have not reported the results here as the study was based in the USA. Therefore it may be less applicable to the UK population.

Current medical conditions

Of the included studies, four studies recruited only people with hypertension,[14-17] one trial included people with 'high normal' blood pressure,[12] one trial recruited people with glucose intolerance including some with diabetes, one trial recruited people with insulin resistance,[13] one trial recruited people with one or more risk factor,[5] and one trial recruited people who had had myocardial infarction (who also received exercise).[11] The remainder recruited otherwise healthy participants.

Setting and/or healthcare professional

One study reported that there was no difference between the effect of diet counselling delivered by the doctor and the dietitian compared with the dietitian alone. The cost of 1 kg weight loss was less for the dietitian-alone group (Aus$7.30 vs Aus$9.76).[18]

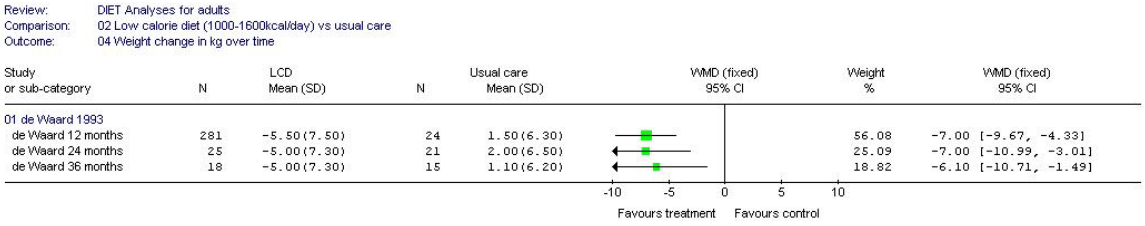
Low-calorie diet (1000–1600 kcal/day) compared with usual care

Only one study was included for this comparison in the HTA review.[19] No additional studies were identified.

Weight loss

One study (two trials based in Poland and the Netherlands) reported a weight change at 12 months of –6.25 kg (WMD 95% CI –9.05 to –3.45) compared with control. This weight loss was maintained over 36 months of follow-up.[19]

Figure 15.2 Maintenance of weight loss over time for women with breast cancer on a low-calorie diet (LCD) compared with usual care (results for Netherlands only)



Other outcomes

No other data on change in risk factors were reported.

Other factors

This trial was a single feasibility study of 107 women who were obese (BMI of 27 kg/m^2 or more), postmenopausal and who had undergone primary treatment for breast cancer with no signs of distant metastases.[19]

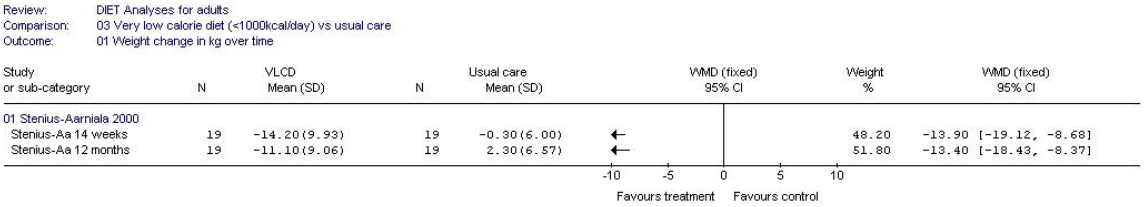
VLCD (< 1000 kcal/day) compared with usual care

Only one study was included for this comparison in the HTA review.[20] No additional studies were identified.

Weight loss

This trial reported results of a VLCD in obese participants with asthma. At 12 months, the weight change was –13.40 kg (WMD 95% CI –18.43 to –8.37) compared with control.[20]

Figure 15.3 Maintenance of weight loss over time for people with asthma on a very-low-calorie diet (VLCD) compared with usual care



Other outcomes

Two of the participants found the liquid diet intolerable and followed an alternative low-energy diet. No other outcomes (other than those associated with asthma – see below) were reported.

Other factors

Current medical conditions

The trial reported improvements in forced expiratory volume, forced vital capacity, exacerbations of asthma, the use of rescue medications and steroids.[20]

Low-calorie diet compared with 600 kcal/day deficit or low-fat diet

Only one study was included for this comparison in the HTA review.[21;22] One additional study was identified.[23]

Weight loss

At 12 months, the low-calorie diet was associated with a summary estimate of weight change of 0.78 kg (WMD 95% CI –1.06 to 2.63, based on two trials).

Other outcomes and factors

None were reported in Shah and coworkers' trial.[21] Mean metabolic cardiac risk factor levels and blood pressure measurements improved from baseline in the low-calorie diet group (significant changes were seen for triglycerides, low-density lipoprotein [LDL], high-density lipoprotein [HDL] levels, $p \leq 0.05$), but the changes were not statistically significant at 12 months compared with the low-fat group.[23]

Age and gender

Shah and coworkers[21] recruited only women aged 25–45 years, who were otherwise healthy. Dansinger and coworkers[23] recruited both men and women of any age, who had at least one identified risk factor.

VLCD compared with 600 kcal/day deficit or low-fat diet

Only one study was included for this comparison.[24] No additional studies were identified.

Weight loss

No data were reported for weight change at 12 months.

Simonen and coworkers[24] compared a VLCD (PSMF VLCD) to a low-fat diet in people with type 2 diabetes. At 24 months, the VLCD produced a weight change of –4.70 kg compared with the low-fat diet (WMD 95% CI –11.79 to 2.39).

Other outcomes and factors

Although this trial was undertaken in a population of people with type 2 diabetes and other clinical outcomes were reported, the authors of the review did not present these results due to concern over significant baseline differences between the groups in rates of treatment of diabetes and HbA1c levels.

VLCD compared with low-calorie diet

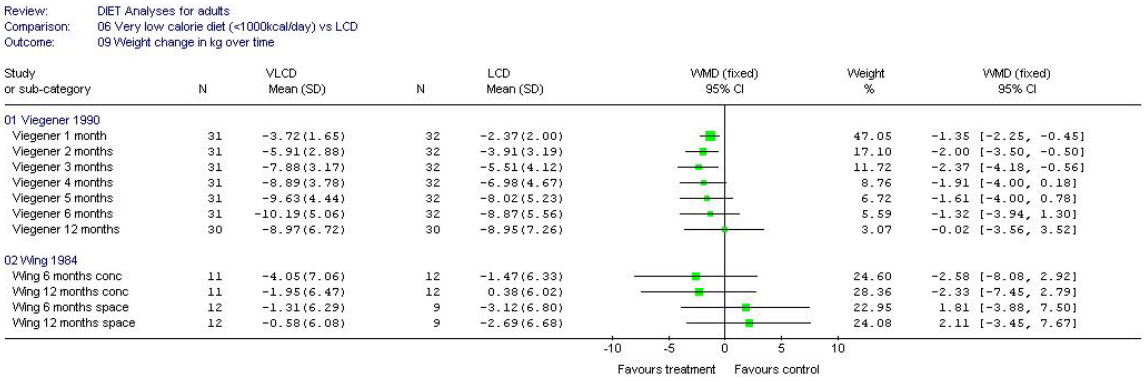
Three studies were included for this comparison in the HTA review.[25-27] No additional studies were identified. One study[27] was conducted in a workplace setting, but was included as the setting was not the focus of the study.

Also, two trials[25;26] compared the use of a VLCD for a short period of time, in conjunction with a low-calorie diet, to continuous use of a low-calorie diet.

Weight loss

At 12 months, based on three trials, VLCD was associated with a weight change of –0.15 kg compared with the low-calorie diet (WMD 95%CI –2.73 to 2.43). No significant effect was seen at 18 months (change of –1.13 kg, 95% CI –5.32 to 3.06, based on results from one trial only).[27]

Figure 15.4 Maintenance of weight loss over time for people on a very low-calorie diet (VCLD) compared with a low-calorie diet (LCD)



Other outcomes

No other outcomes were reported.

Other factors

No additional analysis was carried out on the effect of age, ethnicity, socioeconomic status, degree of obesity, current medical conditions, previous treatment for obesity, motivation or the setting or delivery of care.

Gender

One study recruited men (aged 26–52 years) only[27] and one recruited women (aged 21–59 years) only.[25]

Low-fat diet compared with another weight reducing diet

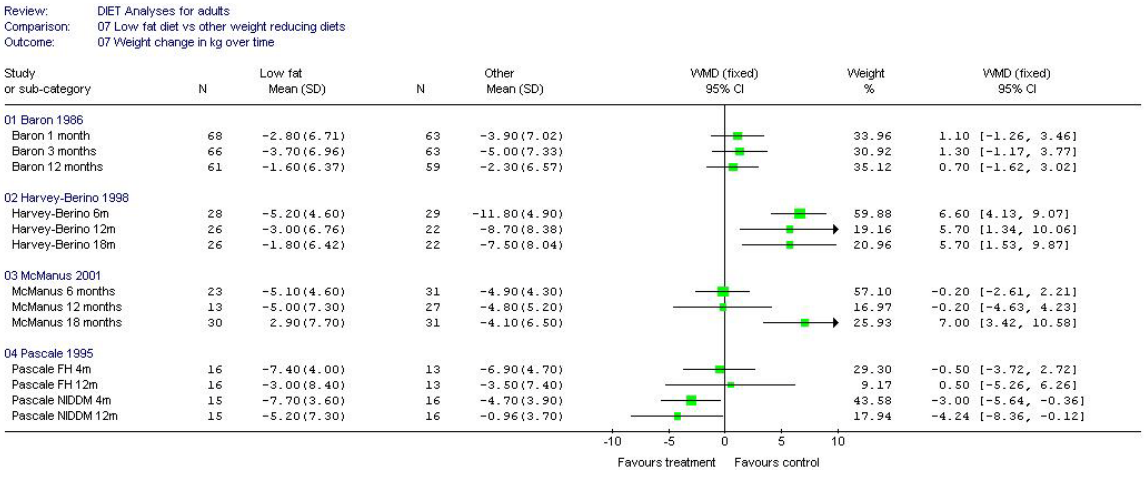
The HTA did not examine the comparisons of low-fat and low-calorie diets, where the aim of the trials was to evaluate the different types of diet using the same calorie value. The authors cited a Cochrane review[28] published in 2002. The results of trials which met our defined inclusion criteria are presented below). No additional studies were identified.

One study[29] was conducted in diet clubs and workplaces, but was included as the setting was not the focus of the study.

Weight loss

At 12 months, the overall weight change was 0.49 kg (WMD 95% CI –1.14 to 2.11 based on five trial results), again with significant heterogeneity (p = 0.03, I^2 = 62.6%).

Figure 15.5 Maintenance of weight loss over time for people on a low-fat diet compared with another weight reducing diet



Other outcomes

Only one trial[30] showed any significant effect on total cholesterol for women with a family history of diabetes. The other trials showing no significant differences on serum lipids, blood pressure or fasting blood glucose.[29;31;32]

Other factors

Gender and current medical conditions

One trial recruited women with a family history of diabetes or a diagnosis of non-insulin-dependent diabetes mellitus (NIDDM);[30] the remaining trials recruited mainly women, but who were otherwise healthy.[29;31;32]

A subgroup analysis found that a low-carbohydrate/low-fibre diet tended to be more successful for weight loss among women than a higher-carbohydrate/higher-fibre diet.[29]

Age

A subgroup analysis found that a low-carbohydrate/low-fibre diet tended to be more successful for weight loss among younger people (aged 40 years or less) than a higher-carbohydrate/higher-fibre diet.[29]

Social class

A subgroup analysis found that a low-carbohydrate/low-fibre diet tended to be more successful for weight loss among people in a lower social class (classes III–IV) than a higher-carbohydrate/higher-fibre diet.[29]

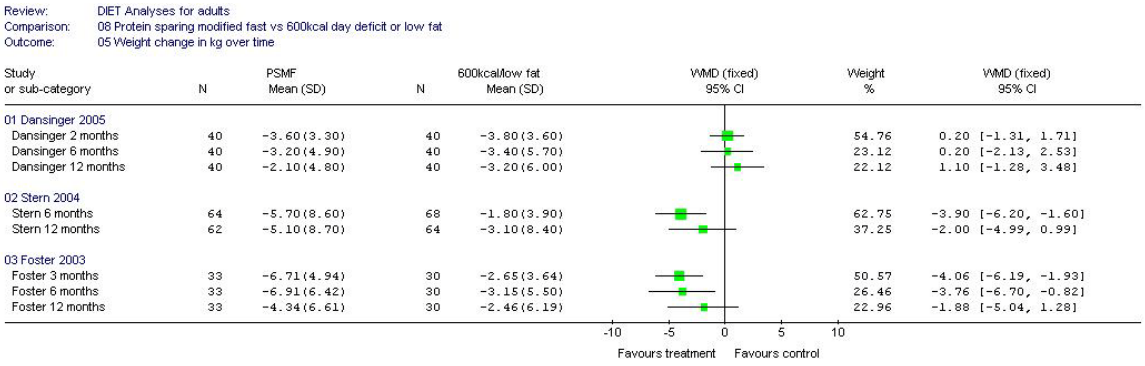
PSFM[‡] compared with 600 kcal/deficit or low-fat diet

Three trials have been published since the HTA[4] that evaluated the use of PSMF (caloried content approx 1400-1900kcal/day, food based)compared with a 600 kcal/deficit or low-fat diet in people who were overweight.[23;33-35]

Weight loss

At 12 months, the overall summary estimate of weight change was –0.56 kg (WMD 95% CI –2.17 to 1.04 based on three trial results) for the PSMF (**not** a VLCD) diet compared with a low-fat diet.

Figure 15.6 Maintenance of weight loss over time for people on a protein-sparing modified fast (PSMF) compared with a 600 kcal/deficit or low-fat diet



Other outcomes

Summary estimates at 12 months showed no significant difference between a PSMF diet and low-fat diet, apart from a significant increase in HDL levels (0.08 mmol/l, p = 0.001) on the PSMF. However, lower levels of adherence to the low-carbohydrate diet suggested that a low-fat diet may be more sustainable in the long term.[23]

Fasting plasma glucose was reported in both the Dansinger[23] and Stern studies.[33] The Stern paper did not report results overall but split into people who

[‡] Defined as a diet with 40 g or less of carbohydrate, irrespective of calorie content.

had diabetes and those who did not. Therefore, we were not able to estimate a summary effect, but results from the Dansinger trial[23] and subgroups of people with or without diabetes in the Stern trial[33] suggested that there was no significant difference between the diets.

Other factors

No additional analysis was done.

PSMF[§] compared with low-calorie diet

Seven RCTs were included in the Avenell HTA.[4] One additional study was identified for this comparison.[23]

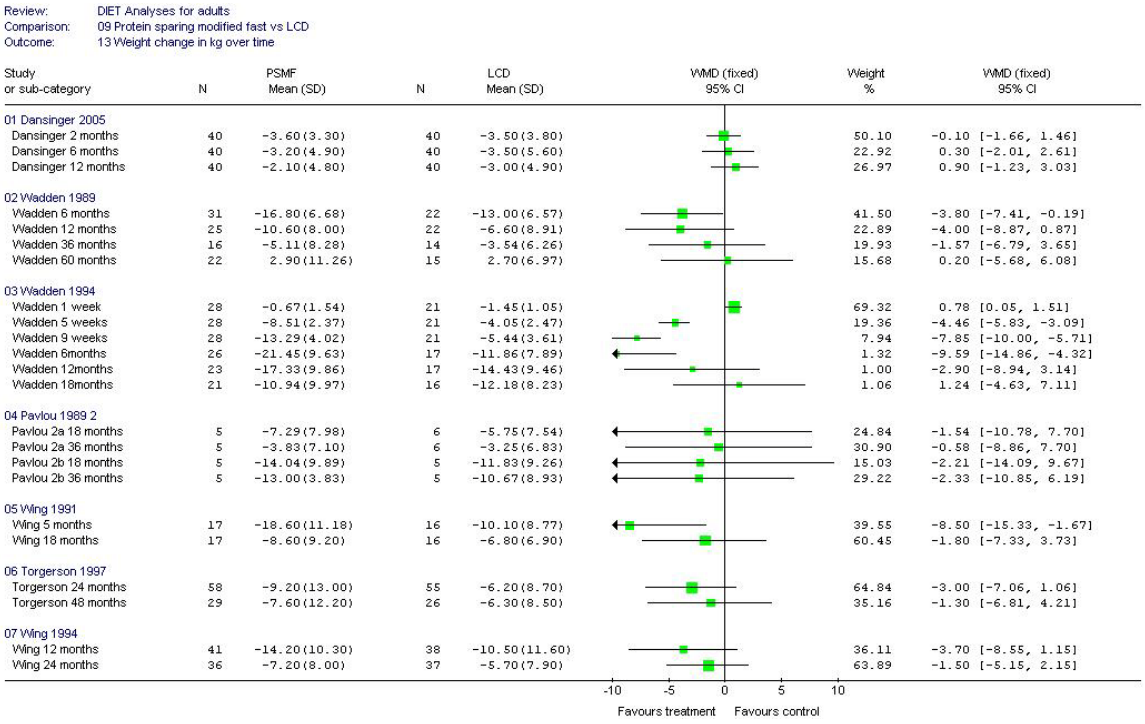
Weight loss

The overall weight change associated with a PSMF compared with a low-calorie diet at 12 months was –0.62 kg (WMD 95% CI –2.35 to 1.11 based on four trial results). No further significant effect was seen at 18[**], 24, 36 and 60 months. However, there was considerable range in the calorie content of each of the diets; three studies used approx 400-500kcal/day,[36-38] compared with one assumed to be much higher.[23]

[§] Defined as a diet with 40g or less of carbohydrate, irrespective of calorie content

[**] Problems with HTA analysis, but recalculated figures were still non-significant.

Figure 15.7 Maintenance of weight loss over time for people on a protein-sparing modified fast (PSMF) compared with a low-calorie diet (LCD)



Other outcomes

Dansinger and coworkers[23] showed no significant differences between PSMF and a low-calorie diet for changes in cholesterol, LDL or HDL levels, triglycerides, or blood pressure measurements at 12 months.

Other factors

Gender

Of the included trials, two recruited men only[27;39] and one recruited women only.[36] One trial recruited men, but then excluded them from the analysis due to small numbers.[37]

Torgerson and coworkers[40;41] did an intention to treat (ITT) analysis of results by men and women. At 24 months, the mean weight change in men was –13.0 ± 15.6 kg) in the PSMF group and –5.8 ± 9.7 kg in the low-calorie diet group (p = 0.1, non-significant). At 24 months, the mean weight change in

women was –6.8 ± 10.6 kg) in the PSMF group and –6.4 ± 8.4 kg) in the low-calorie diet group (non-significant). Similarly at 48 months, there was no statistically significant difference between the weight change in men and women who completed the study.

Wing and coworkers[38] found that women in the PSMF group lost significantly more weight at 12 months than did the low-calorie diet participants (14.1 kg vs 8.6 kg, $p < 0.023$). Men had comparable losses between the groups (15.4 kg and 15.5 kg). The percentage of women losing 15 kg or more or at least 5 BMI units was significantly greater in the PSMF group ($p < 0.01$ for both comparisons). The proportion of men achieving these two goals was similar in each group.

Current medical conditions

Most studies recruited otherwise healthy participants, but Dansinger and coworkers recruited people with at least one risk factor,[23] Wing and coworkerspeople with NIDDM,[38] and Wing and coworkers[39] people with type 2 diabetes.

PSMF[††] compared with VLCD

Both of the diets being compared in this study[27] could be classed as PSMF, but with different daily caloric values (420kcal/day vs 1000kcal/day).

Weight loss

No data for weight loss at 12 months were reported.

The summary estimate weight change at 18 months was 1.56 kg for the PSMF compared with a very-low-calorie diet (WMD 95% CI –1.57 to 4.69, based on results from one trial with multiple treatments).[27]

[††] Defined as a diet with 40 g or less of carbohydrate, irrespective of calorie content.

Other outcomes and factors

None were reported.

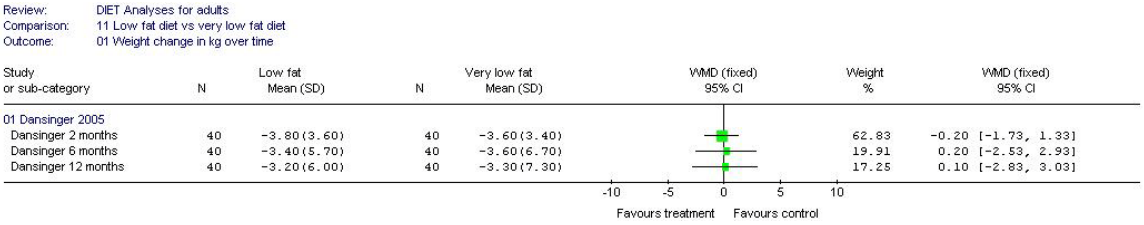
Low-fat diet compared with very-low-fat diet

One study was identified that compared a low-fat diet (Zone) and a very-low-fat diet (Ornish).[23]

Weight loss

There was an overall weight change at 12 months of 0.10 kg in the low-fat group compared with the very-low-fat group (95% CI –2.83 to 3.03).[23]

Figure 15.8 Maintenance of weight loss over time for people on a low-fat diet compared with a very-low-fat diet



Other outcomes and factors

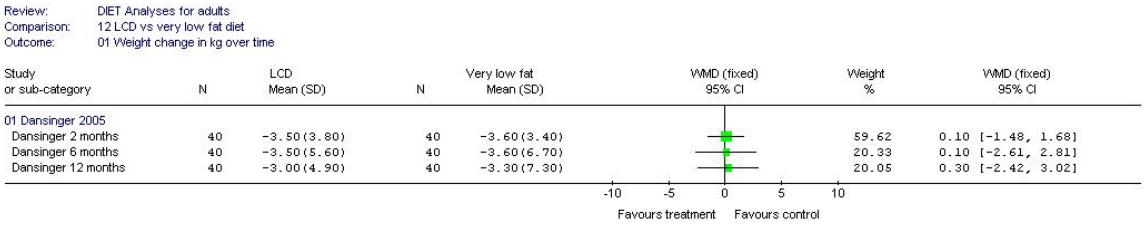
There were no significant changes in lipids and blood pressure between the groups. Although HDL levels increased in the low-fat group and decreased in the very-low-fat group (0.08 mmol/l vs –0.01 mmol/l), and DBP decreased in the lowfat group compared with an increase in the very-low-fat group (–1.20 mm Hg vs 0.20 mm Hg), these changes were not significantly different between the groups (p = 0.07 and p = 0.40, respectively).

Low-calorie diet compared with very-low-fat diet

Weight loss

One study published since the HTA found an overall weight change at 12 months of 0.30 kg in the low-calorie diet group compared with very-low-fat group (95% CI –2.42 to 3.02).[23]

Figure 15.9 Maintenance of weight loss over time for people on a low-calorie diet compared with a very-low-fat diet



Other outcomes and factors

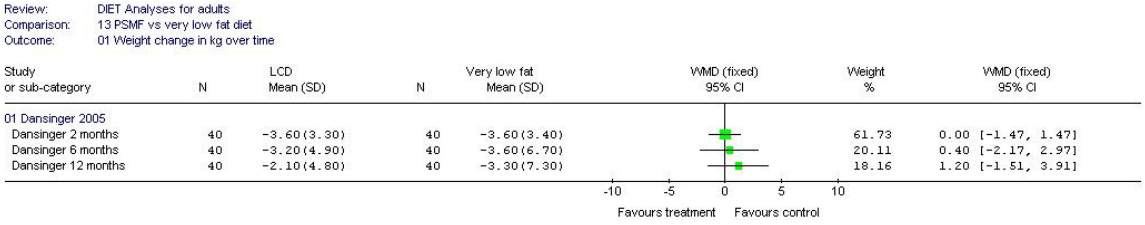
Changes in lipids and blood pressure were not significantly different between the groups, other than HDL levels which increased in the low-calorie diet group and decreased in the very-low-fat group (0.09 mmol/l vs –0.01 mmol/l, p = 0.04).

PSMF‡‡ compared with very-low-fat diet

Weight loss

One study published since the HTA found an overall weight change at 12 months of –1.20 kg in the PSMF (food based, low carb) group compared with the very-low-fat group (95% CI –1.51 to 3.91).[23]

Figure 15.10 Maintenance of weight loss over time for people on a protein-sparing modified fast (PSMF) compared with a very-low-fat diet



Other outcomes and factors

Changes in lipids and blood pressure were not significantly different between the groups, other than HDL levels which increased in the PSMF group and decreased in the very-low-fat group (0.09 mmol/l vs –0.01 mmol/l, p = 0.01).

‡‡ Defined as a diet with 40 g or less of carbohydrate, irrespective of calorie content.

Low glycaemic index (high-protein) diet compared with high glycaemic index (standard-protein) diet

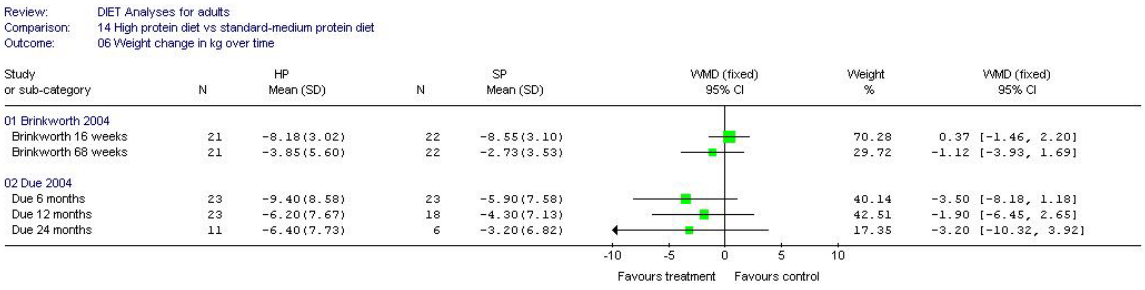
One Cochrane review was identified that evaluated the effect of low glycaemic diets on coronary heart disease and other risk factors (including weight). It was not clear whether participants in the included trials were overweight, so the review was excluded.[42]

Two trials were found that compared the effectiveness of a diet high in protein compared with a diet high in carbohydrate and lower in protein.[43;44]

Weight loss

The summary estimate weight change at 12 months was –1.90 kg for the high-protein (low glycaemic [GI]) diet compared with a standard/medium-protein (high GI) diet (WMD 95% CI –6.45 to 2.65, based on results from one trial).[44]

Figure 15.11 Maintenance of weight loss over time for people on a high-protein (HP) diet compared with a standard/medium-protein (S-MP) diet



Other outcomes and factors

None were reported.

Brinkworth and coworkers[43;45] recruited mainly women aged 20–65 years with hyperinsulinaemia. Due and coworkers[44] again recruited mainly women, but those who were otherwise healthy and aged 18–56 years of age.

15.3.3.3 Evidence statements – behaviour therapy (with or with diet) (Table 15.15)

Table 15.15 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss		
1	Overall, a combination of active support for diet (VLCD or low-calorie diet) and behaviour therapy (problem solving, relapse prevention, stimulus control, dealing with problem situations, assertion, behaviour chain analysis) is effective for weight loss: a change of approximately –4 kg (95% CI -5.77 to -1.70, range -1.40 kg to –5.20 kg) compared with a passive approach (advice or self-help) at 12 months Median weight change across all studies was approximately -3.86 kg (range –2.10 kg to –5.50 kg) for active support and -0.50 kg (range –0.30 kg to –0.70 kg) for passive intervention (n = 3 comparisons)	1++
2	One study showed a combination of active support for a VLCD diet and behaviour therapy resulted in weight change of –5.20 kg (95% CI -8.07 to -2.33) compared with a passive approach (advice or self-help) at 12 months Absolute weight changes were –5.50 kg for the VLCD compared with –0.30 kg for usual care (n = 1 comparison)	1+
3	One study showed a combination of diet and behaviour therapy (self-monitoring, goal setting, cognitive restructuring, problem solving, and environmental management) resulted in weight change of –3.51 kg (95% CI -5.60 to -1.42) compared to a healthy lifestyle information at 18 months Absolute weight changes were –4.61 kg for the diet and behaviour therapy compared with –1.10 kg for information (n = 1 comparison)	1+

No.	Evidence statement	Grade
4	Overall, a combination of diet (low-calorie diet and PSMF 400-500kcal/day food based) and behaviour therapy (cue avoidance, self-monitoring, stimulus control, slowing rate of eating, social support, planning, problem solving, assertiveness, cognitive restructuring, modifying thoughts, reinforcement of changes, relapse prevention, strategies for dealing with weight gain) is effective for weight loss: a change of approximately –7.6 kg (95% CI -11.96 to -3.36, range –6.80 kg to –8.19 kg) compared with diet alone at 12 months. Median weight change across all studies was –7.70 kg low-calorie diet and behaviour therapy and –12.89 for PSMF and behaviour therapy compared with –0.90 kg for low-calorie diet alone and –4.70 kg for PSMF alone (n = 2 comparisons)	1+
5	One study showed a combination of a PSMF diet (400–500 kcal/day based on food) and behaviour therapy resulted in weight change of –8.19 kg (95% CI -13.64 to -2.74) compared with diet alone at 12 months Absolute weight changes were –12.89 kg for the VLCD compared with –4.70 kg for usual care (n = 1 comparison)	1+
6	One study showed a combination of intensive behaviour therapy and VLCD (combination of 200 or 800kcal.day and 600kcal/day deficit) resulted in weight change of –1.18 kg (95% CI -4.16 to 1.80) compared with a less intensive approach at 12 months. Absolute weight changes were –7.58 kg for the intensive programme compared with –6.40 kg for the less intensive programme Contacts were every 2 weeks for 12 months, then six meetings in the next 12 months for the intensive group compared with meetings every 3 months in the less intensive group. Both groups met twice a week during the VLCD period (n = 1 comparison)	1+

No.	Evidence statement	Grade
7	One study showed a combination of 20 weeks' behaviour therapy (self-monitoring, goal setting, stimulus control) with a low-calorie diet and physical activity followed by 12 months of relapse prevention training was less effective for (+ 4.97 kg, 95% CI 0.46 to 9.48) compared with a combination of the 20 weeks' programme followed by 12 months of group problem solving. Absolute weight changes were –5.85 kg for the relapse prevention compared with –10.82 kg for problem solving (n = 1 comparison)	1+
8	Involving family members (usually spouses) in behavioural treatment programmes can be more effective for weight loss than targeting the overweight individual only. Overall, involving family members (in the same sessions as the individual) is effective for weight loss: a change of approximately –2.96 kg (95% CI -3.04 to 0.87) range –6.09 kg to 0.38 kg) compared with the individual alone at 12 months Median weight change across all studies was –7.04 kg family (range –3.80 kg to –8.75 kg) and –3.18 kg (range –2.10 kg to –7.42 kg) for the individual (n = 7 comparisons)	1++
9	Group behavioural programmes do not result in a greater weight loss than behavioural programmes aimed at individuals at 12 months At 24 months, one study showed that group intervention resulted in a significant weight difference of +8.10 kg (95% CI 2.19 to 14.01) compared to the individual alone Absolute weight changes were –4.20 kg for the group compared with –12.30 kg for individual intervention. This difference was not maintained at 60 months (n = 4 comparisons overall)	1++
10	The effectiveness of all interventions appears to change over time, with a trend for greater weight loss in the short term (up to 12 months), with a reduction in overall weight loss in the longer term (up to 60 months)	1++
Outcomes other than weight loss (from trials that reported weight loss)		
11	Few studies reported outcomes other than weight loss. Where these were reported, no significant effects of any intervention were seen at 12 months	1+

No.	Evidence statement	Grade
Harms (from trials that reported weight loss)		
12	No evidence statements can be made as reporting of harms and adverse events was rare and ad hoc	N/A
Generalisability (from trials that reported weight loss)		
13	Only two studies were conducted solely in the UK, with the majority of studies done in the US (n = 11) Many of the studies (11 of the 17 unique studies) were not explicit about their setting, with only one based in primary care. Where reported, participants were recruited as volunteers (that is, through advertising) in 10 studies and through selection (that is, some element of referral or from waiting lists) in five studies Therefore, it is difficult to know how generalisable the results of the included studies are to the UK population, particularly in primary care	1++
14	From the included studies, the duration of intervention varied considerably (range 10 weeks to 248 months) and the rate of follow-up varied; for example, one study made contact every week, then every 2 weeks for 17 months. However, most studies used an approach of decreased contact over time (for example, weekly, then every month, then every 2 months)	1++
15	Behaviour therapy and additional support was provided most often by dietitian and/or people with behavioural treatment or psychological expertise. Other personnel who delivered interventions were physicians, physiotherapists, health educators, graduate students, occupational therapist, and specially trained GPs	1++
16	One assumption could be that the effect size achieved in the included studies may be smaller in practice; in a less motivated, non-volunteer population and less intensive follow-up, delivered by generalists	N/A

GP, general practitioner; N/A, not applicable; PSMF, protein-sparing modified fast; VLCD, very-low-calorie diet.

15.3.3.4 Evidence review on behaviour therapy (with or without diet)

This review was primarily based on four key reviews.[4;46-48] A comparison of the reviews can be seen in Table 15.16. Additional searching was also done to identify any other RCTs published since these key reviews were published. Reference lists of other reviews were also cross-referenced.[49-51]

For this evidence review, only RCTs with a duration (including follow-up) of 12 months or more were included. Also, mean BMI of participants had to be 28 or over.

On the advice of our co-opted expert, we only included specific techniques as being behavioural treatment. Such techniques were defined as:

- drawing on the principles of learning theory: stimulus–behaviour contingencies or behaviour–reward contingencies
- assessment consisting of identifying and specifying problem behaviours and the circumstances in which they are elicited (both antecedents and consequences)
- treatment starting with setting specific, measurable and modest goals that are continually revised as progress is achieved
- target behaviours being monitored – usually by self-monitoring – to obtain a record of behaviour change
- behaviour change processes including stimulus control, graded exposure, extinction and reward
- having a perspective of educational: teaching behaviour change skills to the client. The term problem solving skills may be used, but this does not necessarily mean that the treatment contains the other elements of conventional behavioural treatment
- the use of the term cognitive (as in 'cognitive behaviour' therapy or CBT) may imply the inclusion of strategies designed to modify cognitions (thoughts) which can be identified as important stimuli for behaviour.

We identified a treatment as being behavioural if the study paper:

- used the terms behavioural treatment, cognitive behavioural treatment or behaviour therapy, CBT
- mentioned learning theory
- referred to the use of the common components of behavioural treatment (self-monitoring, goal-setting, stimulus control).

Study reports that used the following terms alone were excluded as not meeting our criteria for behavioural treatment

- motivational interviewing
- counselling
- learning
- psychological
- psychotherapy
- problem solving
- cognitive.

Table 15.16 Comparison of systematic reviews on behaviour therapy for weight loss in adults

ID	Avenell HTA[4]	Shaw CR[46]	Smith ICSI[47]	McTigue AHRQ[48]

ID	Avenell HTA[4]	Shaw CR[46]	Smith ICSI[47]	McTigue AHRQ[48]
Title	Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement	Psychological interventions for overweight or obesity	Behaviour therapy programmes for weight loss in adults	Diagnosis and treatment of obesity in the elderly
Published	2004	2005	2005	2003
Aim	To review systematically treatments for the prevention and management of obesity in adults	To assess the effects of psychological interventions for overweight or obesity as a means of achieving sustained weight loss	To evaluate the safety and efficacy of behaviour therapy programmes for weight loss in adults	To examine the data for the effectiveness of obesity diagnosis and treatment in older people
Included study designs	RCTs only	RCTs and quasi-RCTs only	RCTs, CCTs (not explicitly defined)	RCTs
Excluded study designs	–	–	–	–
Included participants	Adults aged 18 years and older	Adults aged 18 years or older defined as overweight or obese by any criteria (BMI, weight, WHR, WC)	Adults who are overweight or obese (not explicitly defined)	Adults aged 60 years or older (mean baseline). Population generalisable to USA. BMI ≥ 25

ID	Avenell HTA[4]	Shaw CR[46]	Smith ICSI[47]	McTigue AHRQ[48]
Excluded participants	People with bulimia nervosa, pregnant women. Studies where average BMI < 28 kg/m^2 for all groups combined	None reported	–	–
Interventions	Behavioural interventions (cognitive behaviour therapy, others including motivational interviewing)	Psychological interventions that could be identified as such	Behaviour therapy programmes (no further details)	Behaviour therapy (no further details)
Key outcomes	Weight change in kilograms	Weight or other indicator of body mass	Weight change (not defined explicitly)	Weight or other indicator of body mass
Duration	52 weeks or more	3 months (12 weeks) or more	Not reported	52 weeks
Databases searched	13 databases; handsearching; reference lists; abstracts and NRR; trialists and biomedical companies; experts	Five databases; ongoing trials; reference lists; experts (not done)	One database (Medline and PREMedline); reference lists; group members	Two databases; reference lists
Period searched	Inception to April 2001 (e-databases)	Inception to June 2003	Not reported, but 2003 studies included	1980 to February 2003
Language restrictions	None (reports only?)	None	Not reported	English language only

BMI, body mass index; CCT, controlled clinical trial; NRR, National Research Register; RCT randomised controlled trial; WHR, waist-to-hip ratio; WC waist circumference.

Diet and behaviour therapy versus usual care

One trial included in the HTA was excluded in this evidence review because there was no requirement that participants in the study were overweight or obese.[52] Hakalaand Karvetti[53] and Karvetti and Hakala[54] were also excluded as although the participants received counselling or lectures from a psychologist, no details of the behavioural techniques used were reported. Wing and coworkers[55] compared an active intervention on diet and behaviour therapy with passive information on diet and behaviour therapy, so was moved to the appropriate section.

One additional RCT was found comparing diet and defined (or named) behaviour therapy with usual care.[56]

Update searches identified one relevant study,[57] comparing diet and a cognitive behavioural programme with a waiting list control. The long term results (18 months after completion of the programme) support the evidence already reviewed in detail.

Weight loss

At 12 months, a combination of diet (no specific details other than 'balanced, fat-reduced nutrition') and behaviour therapy (self-monitoring, strategies to control eating behaviour, problem analysis and self-observation, alteration of cognitive patterns, social competence, relapse prevention) was associated with a summary estimate of weight change of –3.10 kg (WMD 95% CI –7.17 to 0.97, based on one comparison) compared with usual care.

Figure 15.12 Maintenance of weight loss over time for diet and behaviour therapy (BT) compared with usual care

Other outcomes

No outcomes (such as lipids or blood pressure) were reported. But improvements in psychological outcomes (such as control and attractiveness) were seen in the diet and behaviour therapy group compared with the control group.

Other factors

Gender and setting

Both men and women (mainly women) were recruited from referrals and from adverts. The trial was conducted in a primary care setting, by general practitioners (GPs) and tutors who had undergone specific training to deliver the programme of diet and behaviour therapy.

Diet and behaviour therapy versus information

One RCT was found comparing diet and defined (or named) behaviour therapy with a healthy lifestyle intervention.[58]

Weight loss

At 12 months, a combination of diet (classified as calorie deficit) and behaviour therapy (self-monitoring, goal setting, cognitive restructuring, problem solving, and environmental management) was associated with a summary estimate of weight change of –3.51 kg (WMD 95% CI –5.60 to-1.42, based on one comparison) compared with information.

Other outcomes

No outcomes (such as lipids or blood pressure) were reported. No physiological outcomes (related to arthritis) were found to be significantly different between the groups.

Other factors

Participants and current medical conditions

Both older men and women (mainly women) with ostearthritis were recruited from adverts and publicity.

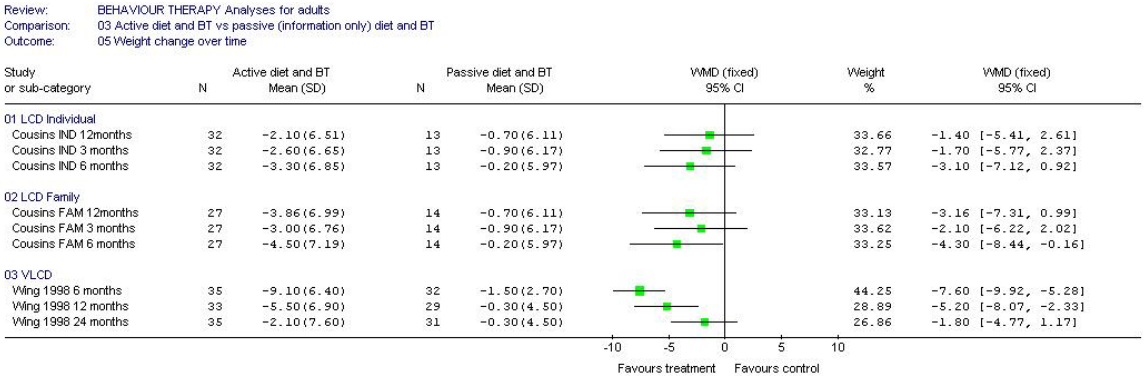
Active diet, and behaviour therapy versus passive (information based) diet and behaviour therapy

Two trials were included in this comparison.[55;59] Cousins and coworkers[58] compared the use of behaviour therapy and a low-calorie diet with information on diet and behaviour, and Wing and coworkers[55] used an VLCD in conjunction with behavioural techniques compared to self-help (diet and behaviour therapy).

Weight loss

At 12 months, the active diet and behaviour therapy (problem solving, relapse prevention, stimulus control, dealing with problem situations, assertion, behaviour chain analysis) was associated with a summary estimate of weight change of -3.73 kg (WMD 95% CI –5.77 to –1.70, based on three comparisons) compared with passive information. However, if the different diets were considered separately, only the VLCD (800-1000kcal/day) remained significantly more effective (weight change of –5.20 kg, 95% CI WMD 95% CI –8.07 to –2.33).

Figure 15.13 Maintenance of weight loss over time for active diet and behaviour therapy (BT) compared with passive diet and BT



Other outcomes

Only Wing and coworkers reported any outcomes other than weight. No significant changes were seen in any of the reported outcomes (lipids, blood pressure, triglycerides, fasting plasma glucose, %HbA1C) at 12 or 24 months, other than for total cholesterol (a change of –0.30 mmol/l WMD 95% CI –0.58 to –0.02) at 24 months (one trial).[55]

Other factors

Cousins and coworkers recruited women participants aged 18–45 years only,[59] and Wing and coworkers recruited mainly older women (inclusion criteria 40–55 years).[55]

Context and methodological notes

The Cousins study was included in the diet, activity, and behaviour therapy versus control section of the HTA. No details of the physical activity were reported (other than 'group exercise'), and the control group received a manual of diet and behaviour therapy strategies, so this study has been reclassified. Wing and coworkers[55] compared an active diet and behaviour therapy intervention with passive information on diet and behaviour therapy, so was moved to the appropriate section.

Family versus individual treatment

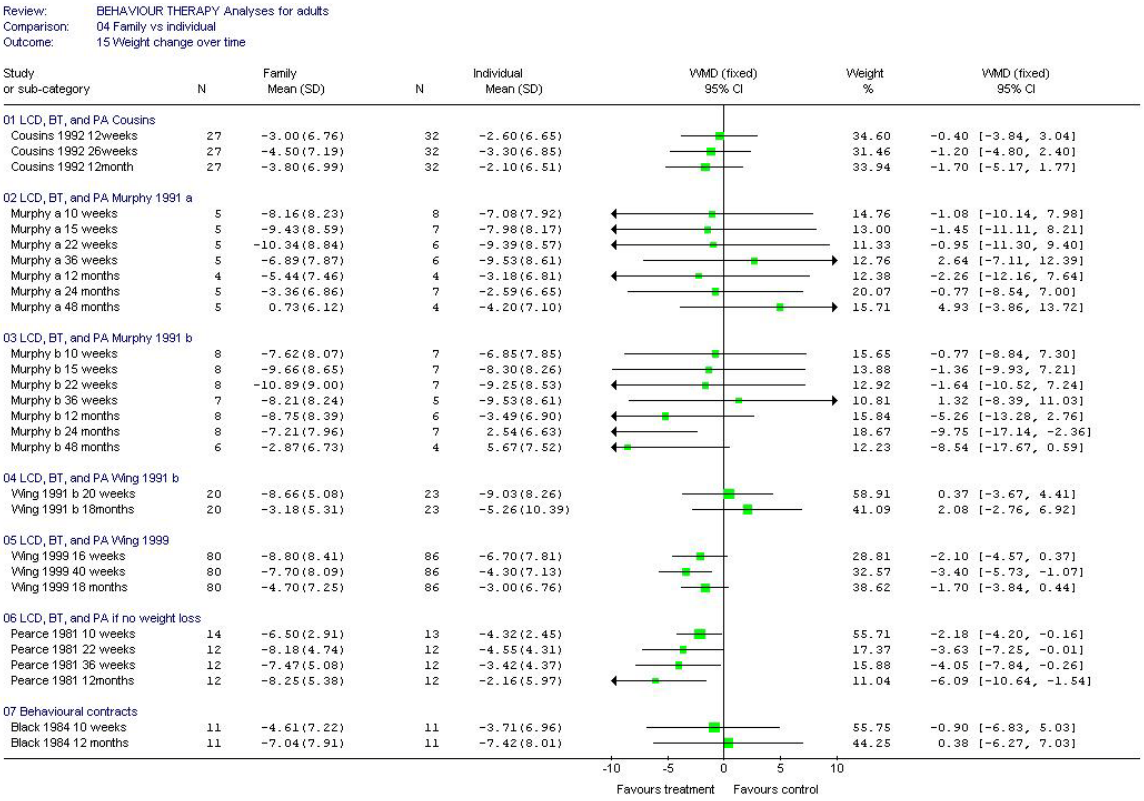
Seven trials were included in this comparison.[59-65]

Weight loss

At 12 months, the family-based intervention was associated with a summary estimate of weight change of –2.96 kg (WMD 95% CI –5.32 to –0.60, based on five comparisons) compared with individual intervention. However, if the different interventions were considered separately, only the intervention involving spouses (with low-calorie diet, behaviour therapy and physical activity if no weight loss)

remained significantly more effective (weight change of –6.09 kg, 95% CI WMD 95% CI –10.64 to –1.54).

Figure 15.14 Maintenance of weight loss over time for family compared with individual intervention



Other outcomes

Only Wing and coworkers[64] reported clinical outcomes other than weight. No changes were significant between interventions at any time points.

Other factors

Gender

Four of the trials recruited women only,[59;60;62;63] and overall the majority of participants were women.

Delivery

One of the trials recruited support from people other than family.[64] However, no details of the members and relationships of the support group were reported. All interventions were delivered to family and individual in the same sessions.[59-65]

One trial[64] noted a significant interaction of gender and treatment, such that women did better when treated with a spouse and men did better when treated individually.

Methodological and context notes

Slightly different figures from the HTA have been used for Black and Lantz[59] due to conversion/calculations rounding.

Also, there were some differences between 12 month follow-up. For example, Cousins and coworkers[58] assessed at 12 months from beginning of intervention, Black and Lantz[59] and Murphy and coworkers[60] assessed at 12 months after the end of the intervention which lasted 10 weeks. Also Wing and Jeffery[64] used 18 months' figures.

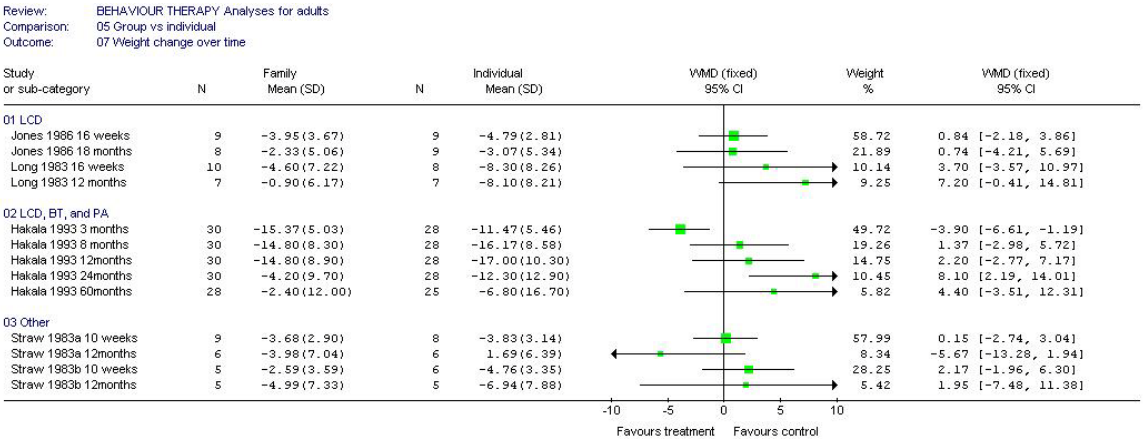
Group versus individual treatment

Four trials were included in this comparison.[66-69]

Weight loss

At 12 months, the group-based intervention was associated with a summary estimate of weight change of 1.59 kg (WMD 95% CI –1.81 to 5.00, based on four comparisons) compared to individual intervention. However, at 24 months, one trial[66] showed a significantly greater weight loss in the individual group compared with the group intervention.

Figure 15.15 Maintenance of weight loss over time for group compared with individual intervention



Other outcomes

No clinical outcomes were reported. One study[66] reported higher attendance rates in the individual groups than in the group sessions.

Other factors

Gender

Three of the four trials recruited women only.[67-69] Again, the majority of participants were women.

Degree of obesity

Hakala and coworkers recruited men and women who were severely overweight (at least 50% overweight).[66] The other trials recruited women who were overweight (different criteria used) but not severely obese specifically.

Setting

Two of the studies were set in the NHS.[66,67] None of the results were significant.

Diet and behaviour therapy versus diet

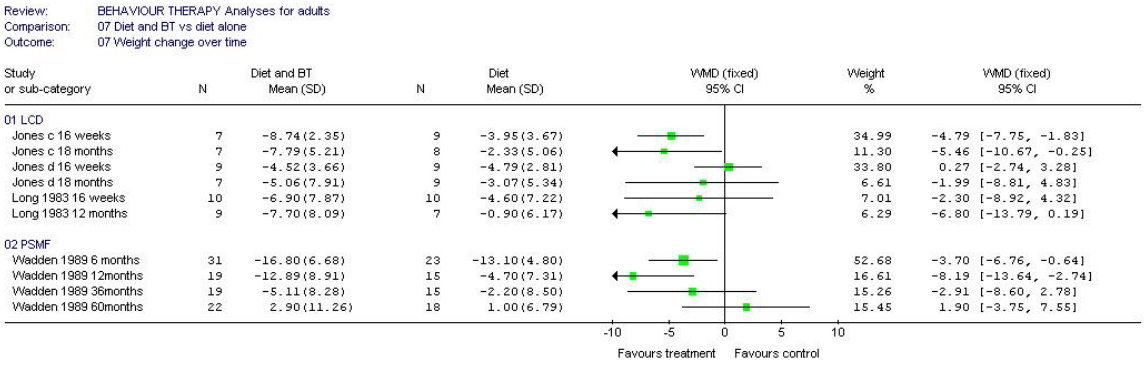
Phenix[70] was excluded from this review, as this was a PhD thesis and no subsequent published papers were identified.

Three trials were included in this comparison.[36;67;68] All compared the use of diets (low-calorie diet,[66,67] PSMF[37]) in conjunction with behaviour therapy compared to the use of the diet alone.

Weight loss

At 12 months, a combination of diet and behaviour therapy (cue avoidance, self-monitoring, stimulus control, slowing rate of eating, social support, planning, problem solving, assertiveness, cognitive restructuring, modifying thoughts, reinforcement of changes, relapse prevention, strategies for dealing with weight gain) was associated with a summary estimate of weight change of –7.66 kg (WMD 95% CI –11.96 to –3.36, based on two comparisons) compared with diet alone. However, if the different diets were considered separately, only the PSMF (food based 400–500 kcal/day) remained significantly more effective (weight change of –8.19 kg, 95% CI WMD 95% CI –13.64 to –2.74).

Figure 15.16 Maintenance of weight loss over time for diet and behaviour therapy (BT) compared with diet alone



Other outcomes

No other outcomes were reported.

Other factors

Gender

All trials in this section recruited women only.

Setting

Jones and coworkers[67] and Long and coworkers[68] were conducted in the NHS. Mixed results were seen, but a combination of group behaviour therapy and diet seemed to work better than individual behaviour therapy and diet at 6 months, although this was not statistically significant.

Different levels of intensity of behaviour therapy and diet

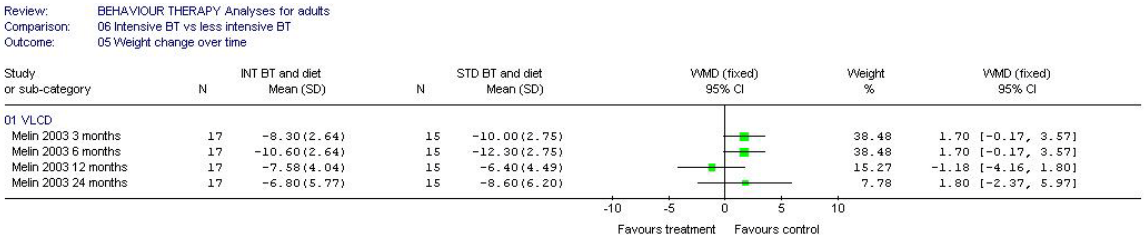
One study was identified that compared different levels of intensity of the same behavioural treatment programme in conjunction with periods of a VLCD.

Update searches identified a further study, showing that weight loss could be achieved even with relatively minimal follow-up contact (twice a year).[71]

Weight loss

At 12 months, a combination of VLCD and intensive behaviour therapy (self-monitoring, relapse situations, eating behaviour) was associated with a summary estimate of weight change of –1.18 kg (WMD 95% CI –4.16 to 1.80, based on one comparison) compared to a combination of VLCD and less intensive behaviour therapy.

Figure 15.17 Maintenance of weight loss over time for diet and intensive behaviour therapy (BT) compared with diet and less intensive BT



Other outcomes

Only significant differences were seen for blood pressure (both SBP and DBP) at 24 months, with the more intensive programme appearing to be more effective.

Other factors

Gender and setting

Both men and women (mainly women) were recruited from referrals to a secondary care obesity clinic.

Comparison of different behavioural treatments

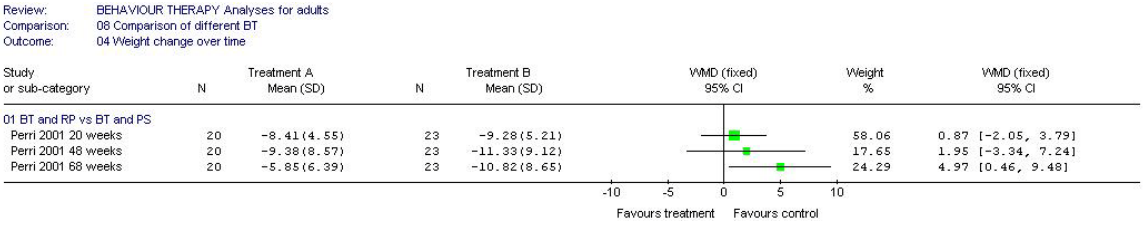
One study was identified that compared different types of behaviour therapy.[72]

Update searches identified one pilot study comparing different approaches to behavioural treatments.[73] Weight changes were similar, and therefore would not change either evidence statements or recommendations.

Weight loss

At 17 months, a combination of 20 weeks' behaviour therapy (self-monitoring, goal setting, stimulus control) with a low-calorie diet and physical activity followed by 12 months of relapse prevention training was associated with a summary estimate of weight change of +4.97 kg (WMD 95% CI 0.46 to 9.48, based on one comparison) compared with a combination of the 20 weeks' programme followed by 12 months of group problem solving. However, both groups did lose weight from baseline.

Figure 15.18 Maintenance of weight loss over time for behaviour therapy and relapse prevention maintenance compared with behaviour therapy and problem solving



Other outcomes

No other outcomes were significant.

Other factors

Gender and setting

In both trials, men and women (mainly women) were recruited from adverts. The setting was unclear.

15.3.3.5 Evidence statements – physical activity (alone or in combination with diet or behaviour therapy) (Table 15.17)

Table 15.17 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss		
1	Overall, physical activity (minimum of 30 minutes three times a week) is effective for weight loss: a change of approximately –3 kg (95% CI _4.00 to -2.18, range –2.00 kg to –4.60 kg) compared to no treatment at 12 months Median weight change across all studies was approximately -2.60 kg (range –0.90 kg to –4.00 kg) for physical activity and 0.60 kg (range 0.30 kg to 1.10 kg) for no treatment (n = 3 comparisons)	I++
2	One study showed physical activity (60 minutes of three times a week) resulted in a weight change of –2.36 kg (95% CI -4.41 to -0.31) compared with information at 18 months Absolute weight changes were –3.46 kg for activity compared with –1.10 kg for information (n = 1 comparison)	1+
3	Overall, physical activity alone (minimum of 30 minutes three times a week) was less effective for weight loss than diet alone at 12 months: a change of +3 kg (95% CI 2.28 to 4.35, range 3.10 kg to 3.80 kg). Median weight change across all studies was approximately –2.60 kg (range –0.90 kg to –4.00 kg) for physical activity and –6.40 kg (range-4.00 kg to –7.20 kg) for diet alone. (n = 3 comparisons)	1++

No.	Evidence statement	Grade
4	Overall, physical activity (minimum of 45 minutes three times a week) and diet (600 kcal/deficit or low fat) is effective for weight loss: a change of approximately –7 kg (95% CI -7.88 to -5.87, range –1.70 kg to –10.40 kg) compared with no treatment at 12 months Median weight change across all studies was approximately –5.10 kg (range 0.70 kg to –8.70 kg) for physical activity and diet and 1.30 kg (range 2.40 kg to –0.60 kg) for no treatment (n = 5 comparisons)	1++
5	One study showed a combination of physical activity (30 minutes of moderate exercise daily plus supervised resistance training twice a week) and diet (classified as calorie deficit) resulted in weight change of –3.50 kg (95% CI -4.27 to -2.73) compared with information at 12 months. Absolute weight changes were –4.50 kg for the activity and diet compared with –1.00 kg for information (n = 1 comparison)	1+
6	Overall, physical activity (minimum of 45 minutes three times a week) and diet (600 kcal/deficit or low fat) is effective for weight loss: a change of approximately –1.95 kg (95% CI -3.22 to -0.68) range –1.00 kg to –3.60 kg) compared o diet alone at 12 months Median weight change across all studies was approximately -5.60 kg (range –5.10 kg to –8.70 kg) for physical activity and diet and –4.10 kg (range –4.00 kg to –5.10 kg) for diet alone (n = 5 comparisons)	1++

No.	Evidence statement	Grade
7	Overall, a combination of physical activity (varying in level from three four sessions over 12 months to 30–45 minutes four to five times week), behaviour therapy (situational control, including cue avoidance, self-monitoring of calorie intake, eating behaviours and pulse rate, management of eating behaviours, relapse prevention, goal setting, cognitive reframing and coping imagery, stimulus control, social assertion, reinforcement techniques for enhancing motivation, cognitive strategies for replacing negative thinking with more positive statements and constructive self-statements), and diet (either calorie deficit or a low-calorie diet) is effective for weight loss: a change of –4.22 kg (95% CI -4.80 to -3.64, range –2.20 kg to –4.88 kg) compared with control (no treatment) at 12 months Median weight change across all studies was approximately –4.60 kg (range –3.33 kg to –5.87 kg) for the combined intervention and –0.48 kg (range 0.53 kg to –2.40 kg) for diet alone (n = 5 comparisons)	1++
8	Overall, a combination of physical activity (minimum 150 minutes per week), behaviour therapy (behaviour change goals and problem solving, goal setting, menu planning, self-efficacy, consideration of body image, social support, social eating, removing road blocks, positive thinking, dealing with high-risk situations and slips, cue elimination, stress management and relapse prevention, self-monitoring, problem solving, managing cues, stimulus control, positive assertion, positive thinking, holiday eating, social support, motivation, role playing, modelling food tasting and grocery store tours) and diet (either calorie deficit or a VLCD) is effective for weight loss: a change of –3.82 kg (95% CI -4.63 to -3.02, range 1.70 to –8.85) compared with information alone Median weight change across all studies was approximately –3.90 kg (range 2.50 kg to –8.00 kg) for the combined intervention and 0.15 kg (range 0.85 kg to –0.50 kg) for information (n = 6 comparisons)	1++

No.	Evidence statement	Grade
9	One study showed a combination of physical activity (individualised level), behaviour therapy (self-monitoring, stimulus control, reinforcement, cognitive change), and diet (calorie deficit) was associated with a summary estimate of weight change of –5.80 kg (WMD 95% CI –8.91 to –2.69, based on one comparison) compared with behaviour therapy (enhancing body acceptance, disentangling self-worth from weight, barriers transformation, increased support and assertion, self-monitoring) alone Absolute weight changes were –5.90 kg for the combined group compared with –0.10 kg for behaviour therapy. (n = 1 comparison)	1+
10	One study showed a combination of physical activity (approximately 45 minutes five times a week maximum), behaviour therapy (stimulus control, problem solving,; reducing barriers, exercising in different weather conditions), and diet (VLCD 800-1000kcal/day and 1200-1500kcal for maintenance) was associated with a summary estimate of weight change of –7.00 kg (WMD 95% CI –10.90 to –3.10, based on one comparison) compared with physical activity and behaviour therapy Absolute weight changes were –7.4 kg for the combined approach compared with –0.40 kg for activity and behaviour therapy (n = 1 comparison)	1+
11	Other benefits of physical activity (alone or in combination) include: ▪ delay of onset of diabetes in people with impaired glucose tolerance ▪ increased motility in older people with arthritis ▪ reduction in the risk of developing hypertension and other cardiovascular events ▪ reduction in medication use for comorbidities ▪ improved quality of life	1++
Comparison of different programmes		
12	No statement could be made on the effectiveness of different levels of intensity.	…
Outcomes other than weight loss (from trials that reported weight loss)		
13	Physical activity, either alone or in combination, improves other clinical outcomes, such as lipids and blood pressure. However, any improvements may not be maintained in the longer term (up to 36 months)	1+

No.	Evidence statement	Grade
14	No effect on cardiovascular fitness was observed based upon exercise intensity or duration	1+
Harms (from trials that reported weight loss)		
15	No evidence statements can be made as reporting of harms and adverse events was rare and ad hoc	N/A
Generalisability (from trials that reported weight loss)		
16	No studies were conducted in the UK, and 26 of the 33 unique studies were based in the USA Many of the studies did not report the setting, and only two studies were based in primary care. Three workplace studies were included as the aim of the study was to evaluate the effectiveness of the intervention and not the effect of the setting. However, the resulting effect may have been different if the intervention was delivered in a clinical setting Where reported, participants were recruited as volunteers (that is, through advertising) in 12 studies and through selection (that is, some element of referral or from screening programmes) in 10 studies Therefore, it is difficult to know how generalisable the results of the included studies are to the UK population, particularly in primary care	1++
18	From the included studies, the duration of intervention varied considerably (range 8 weeks to 36 months, including a 1 month inpatient programme) and the rate of follow-up varied; for example, one study made contact every week for 12 months. However, most studies used an approach of decreased contact over time (for example, weekly, then every 2 weeks, then monthly)	1++
19	A wide variety of personnel delivered the different components of the interventions; this included physicians, researchers, health educators, graduate students, exercise coaches, trained interventionists, dietitians, commercial services (physical activity), and psychologists	1++
20	One assumption could be that the effect size achieved in the included studies may be smaller in practice; in a less motivated, non-volunteer population and less intensive follow-up, delivered by generalists	N/A
21	The intensity and duration of exercise required to impact on long-term weight loss may be much higher than recommended in most behavioural treatment programmes	1++

N/A, not applicable; VLCD, very-low-calorie diet.

15.3.3.6 Evidence review on physical activity (alone or in combination with diet or behaviour therapy)

This review was primarily based on three key reviews.[4;48;74] A comparison of the reviews can be seen in Table 15.16. Although the AHRQ report did not specifically evaluate physical activity, some of the included RCTs included a physical activity component. Additional searching was also done to identify any other RCTs published since these key reviews were published. Reference lists of other reviews were also cross-referenced.

For this evidence review, only trials with a duration (including follow-up) of 12 months or more were included. Also, mean BMI of participants had to be 28 kg/m^2 or over.

Table 15.18 Comparison of systematic reviews on physical activity (alone or in combination with diet or behaviour therapy) for weight loss in adults

ID	Avenell HTA	Shaw CR	McTigue AHRQ
Title	Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement	Exercise for obesity	Diagnosis and treatment of obesity in the elderly
Published	2004	Unpublished	2003

ID	Avenell HTA	Shaw CR	McTigue AHRQ
Aim	To review systematically treatments for the prevention and management of obesity in adults	To assess regular exercise as a means of achieving sustained weight loss, using randomised controlled clinical trials. This review focused on participants who were overweight or obese and who were exercising for any purpose	To examine the data for the effectiveness of obesity diagnosis and treatment in older people
Included study designs	RCTs only	RCTs and quasi-RCTs only	RCTs
Excluded study designs	–	–	–
Included participants	Adults aged 18 years and older	Adults aged 18 years or older defined as overweight or obese by any criteria (BMI, weight, WHR, WC) Note: Also stated that BMI > 25 kg/m^2?	Adults aged 60 years or older (mean baseline); population generalisable to USA; BMI ≥ 25 kg/m^2
Excluded participants	People with bulimia nervosa, pregnant women; studies where average BMI < 28 for all groups combined	None reported	–

ID	Avenell HTA	Shaw CR	McTigue AHRQ
Interventions	Physical activity (including endurance exercise, and resistance training)	Exercise was defined as any form of physical activity performed on a repeated basis for a defined period of time (exercise training). Studies stating that they simply recommended increasing physical activity were not included in the analysis unless it was possible to quantify the exercise stimulus Studies that combined exercise and medication as an intervention were not included in the analysis, unless the study design allowed the effects of these two components to be separated	Did not specifically evaluate physical activity, but some of the included trials had a physical activity component
Key outcomes	Weight change in kilograms	Weight or other indicator of body mass	Weight or other indicator of body mass
Duration	52 weeks or more	3 months (12 weeks) or more	52 weeks
Databases searched	13 databases; handsearching; reference lists; abstracts and NRR; trialists and biomedical companies; experts	Four databases. ongoing trials; reference lists; experts (not done)	Two databases; reference lists

ID	Avenell HTA	Shaw CR	McTigue AHRQ
Period searched	Inception to April 2001 (e-databases)	Inception to 2003	1980 to February 2003
Language restrictions	None (reports only?)	None	English language only.

BMI, body mass index; CCT, controlled clinical trial; NRR, National Research Register; RCT randomised controlled trial; WHR, waist-to-hip ratio; WC waist circumference.

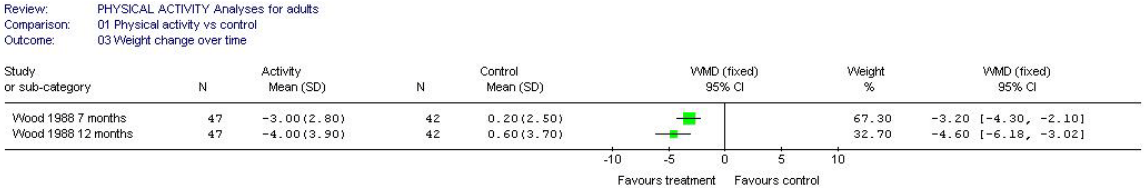
Physical activity versus control (no treatment)

Three trials were included in this comparison.[5;10;13]

Weight loss

At 12 months, physical activity (minimum of 30 minutes three times a week) was associated with a summary estimate of weight change of –3.09 kg (WMD 95% CI –4.00 to –2.18, based on three comparisons) compared with no treatment.

Figure 15.19 Maintenance of weight loss over time for physical activity compared with no treatment



Other outcomes

One trial[10] showed significant decreases in levels of triglycerides at 12 months (–0.30 mmol/l, WMD 95% CI –0.49 to –0.10) in the activity group, but other clinical outcomes were not significantly different between the groups.

Other factors

Gender

Two of the three included trials recruited men only.[5;10;75;76]

Current medical conditions

The Oslo Diet and Exercise Study (ODES) study recruited men and women who had athero-thrombogenic syndrome (or insulin resistance).

Age

All included studies recruited middle-aged people (age range 30–59 years).

Setting and delivery

Of the three trials, one was community based, one workplace based, and one based in a university clinic. None were based in the UK.

The physical activity was supervised in two studies[10;13] by 'highly qualified instructors' and 'training staff', respectively.

Context and methodological notes

The included studies in the Cochrane review were re-examined and either excluded (or were reassigned to alternative categories). The ODES study was also added.

Physical activity versus information

One trial was found that compared physical activity with information on a healthy lifestyle.[58;77]

Weight loss

At 18 months, mean ± SD weight change in kilograms was –3.46 ± 6.89 kg in the activity group, and –1.10 ± 6.23 kg in the information group. Mean weight change in the intervention group compared with behaviour therapy was –2.36 kg (95% CI –4.41 to –0.31).

Other outcomes

A significant improvement in the 6-minute walk distance ($p < 0.05$) was observed in the activity group.

Other factors

Current medical conditions

The included study recruited only participants with osteoarthritis of the knee.

Age

Messier[58] recruited older people only (aged 60 years or older).

Setting and delivery

The trial was based in an older people's independence centre in the USA. The physical activity could be done either in the centre or at home. Details of whether the facility-based training was supervised was not reported.

Physical activity versus diet

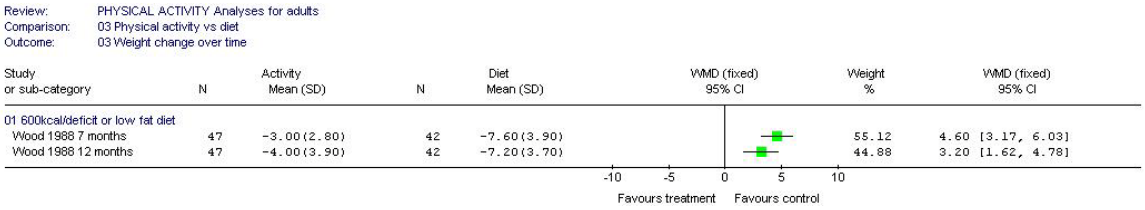
Three trials were included in this comparison.[5;10;13] All three diets were classified as 600 kcal/deficit or low-fat diets.

Weight loss

At 12 months, physical activity (minimum of 30 minutes three times a week) was associated with a summary estimate of weight change of +3.32 kg (WMD 95% CI

2.28 to 4.35, based on three comparisons) compared with a 600 kcal/deficit or low-fat diet.

Figure 15.20 Maintenance of weight loss over time for physical activity compared with diet



Other outcomes

No reported outcomes were significantly different overall at any time points.

Other factors

Gender

Two of the three included trials recruited men only.[5;10;75;76]

Current medical conditions

The ODES study recruited men and women who had athero-thrombogenic syndrome (or insulin resistance).

Age

All included studies recruited middle-aged people (age range 30–59 years).

Setting and delivery

Of the three trials, one was community based, one workplace based, and one based in a university clinic. None were based in the UK.

The physical activity was supervised in two studies[10;13] by 'highly qualified instructors' and 'training staff', respectively.

The dietary advice was delivered to individuals[5;10] or with the spouse initially.[13]

Context and methodological notes

The included studies in the Cochrane review were re-examined and either excluded (see Appendix 16) or were reassigned to alternative categories. The ODES study was also added.

Although the Wood[10] study did mention that behavioural strategies were used, no details were reported so the intervention was classed as diet only.

Physical activity versus diet and behaviour therapy

One trial was found that compared physical activity with diet and behaviour therapy.[58;77]

Weight loss

At 18 months, mean ± SD weight change in kilograms was –3.46 ± 6.89 kg in the activity group, and –4.61 ± 7.22 kg in the diet and behaviour therapy group. Mean weight change in the intervention group compared with behaviour therapy was 1.15 (95% CI –1.02 to 3.32).

Other outcomes

A significant improvement in the 6-minute walk distance ($p < 0.05$) was observed in the activity group.

Other factors

Current medical conditions

The included study recruited only participants with osteoarthritis of the knee.

Age

Messier[58] recruited older people only (aged 60 years or older).

Setting and delivery

The trial was based in an older people's independence centre in the USA. The physical activity could be done either in the centre or at home. Details of whether the facility-based training was supervised was not reported. No details of who delivered the behaviour therapy were reported, but the majority of sessions were group sessions.

Context and methodological notes

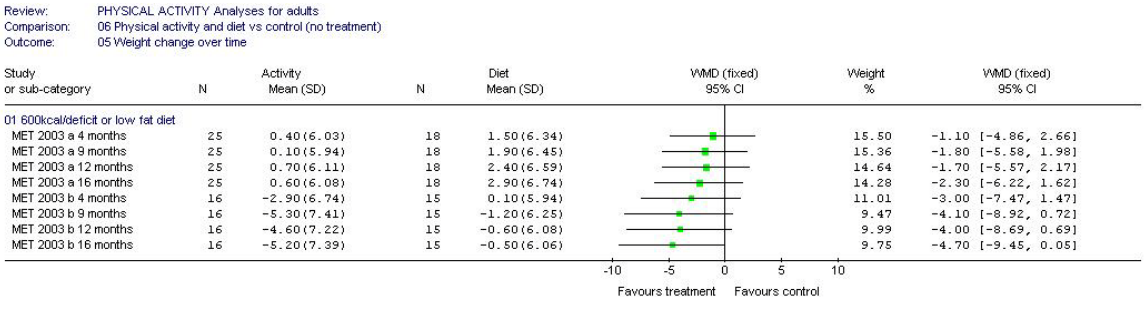
Two papers on the same study were identified which appeared to give different results. For this review, the Messier[58]paper was used, but Nicklas[77] was checked for apparent differences (possibly due to different populations used).

Physical activity and diet versus control (no treatment)
Three trials were included in this comparison.[13;78-87]

Weight loss

At 12 months, physical activity (minimum of 45 minutes three times a week) and diet (600 kcal/deficit or low fat) was associated with a summary estimate of weight change of –6.87 kg (WMD 95% CI –7.88 to –5.87, based on five comparisons) compared with a no treatment control.

Figure 15.21 Maintenance of weight loss over time for physical activity and diet compared with no treatment



Other outcomes

Overall, significant improvements in levels of total cholesterol (–0.27 mmol/l, WMD 95% CI –0.42 to –0.12, three comparisons), LDL-cholesterol (-0.20 mmol/l, WMD 95% CI –0.33 to –0.06, three comparisons), HDL-cholesterol (0.12 mmol/l, WMD 95% CI 0.09 to 0.16, three comparisons), triglycerides (–0.29 mmol/l, WMD 95% CI –0.41 to –0.17, three comparisons), fasting plasma glucose (-0.33 mmol/l, WMD 95% CI –0.54 to –0.12, three comparisons), DBP (-4.64 mm Hg, WMD 95% CI –6.04 to –3.25, three comparisons), and SBP (-4.60mm Hg, WMD 95% CI –6.61 to –2.58, three comparisons) at 12 months were seen in the activity and diet group, but other clinical outcomes were not significantly different between the groups.

Other factors

Gender

The authors of one trial[78] reported that 'exercise prevented weight gain in women and produced weight loss in men'.

Current medical conditions

The ODES study recruited men and women who had athero-thrombogenic syndrome (or insulin resistance).

Setting and delivery

Of the three trials, one was community based, and two were based in university clinics. None were based in the UK.

The physical activity was supervised in two studies (ODES and Midwest Exercise Trial) by 'highly qualified instructors'[13] and 'research assistants',[78] respectively.

The dietary advice was delivered to individuals (ODES[13]) or with the spouse initially (ODES[13]). In the Midwest Exercise trial, participants had to eat in the

university cafeteria, but no specific counselling was reported as being given (other than told to follow an ad-libitum diet of 30–35% fat, 45–55% carbohydrates, 10–25% protein).[78-80]

Context and methodological notes

The Finnish Diabetes Prevention Study (FDPS) (HTA) was moved to another section, as the control group did receive some specific dietary advice.

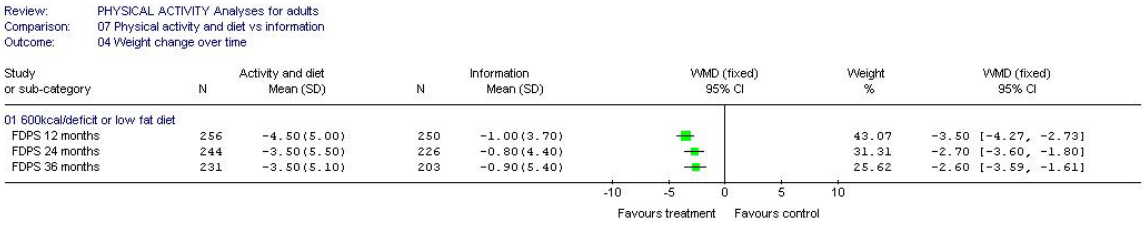
Physical activity and diet versus information

One RCT was found comparing physical activity and diet (600 kcal/deficit or low fat) with information.[88-90]

Weight loss

At 12 months, a combination of physical activity (30 minutes of moderate exercise daily plus supervised resistance training twice a week) and diet (classified as calorie deficit) was associated with a summary estimate of weight change of –3.50 kg (WMD 95% CI –4.27 to-2.73, based on one comparison) compared with information.

Figure 15.22 Maintenance of weight loss over time for physical activity and diet compared with information



Other outcomes

At 12 months, participants in the activity and diet group had greater improvements in HDL, triglyceride and fasting plasma glucose at 12 months than the information alone group. However, these were not maintained in the longer term (up to 36 months). In addition, participants in the activity and diet group were less likely to develop diabetes (p = 0.0001) during the study period.

Other factors

Participants and condition

People (majority women) were included if they had impaired glucose tolerance.

Delivery

A nutritionist gave individualised and group information on diet. The study physician and the nutritionist informed participants of general risk factors for diabetes. Physical activity was delivered either by an exercise instructor or physiotherapist if part of the study team, or if not, by commercial services (the delivery of the intervention varied across centres, depending on local availability of services and personnel).

Physical activity and diet versus diet alone

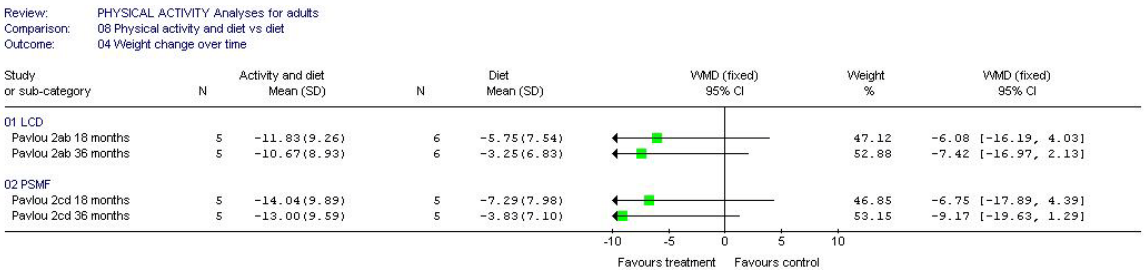
Three RCTs[13;27;81-87] and one pilot study[27] were included in this comparison.

Weight loss

At 12 months, a combination of physical activity (min 45 minutes three times a week) and diet (classified as 600 kcal/day deficit or low fat) was associated with a summary estimate of weight change of –1.95 kg (WMD 95% CI –3.22 to-0.68, based on three comparisons) compared to diet alone.

A significant difference was maintained at 18 months (–7.63 kg (WMD 95% CI -10.33 to-4.92, based on six comparisons), with dietary interventions including a low-calorie diet (1000 kcal/day) and PSMF (420 kcal/day).

Figure 15.23 Maintenance of weight loss over time for physical activity and diet compared with diet alone



Other outcomes

Overall, three comparisons from two trials[13;86] showed significant improvements in triglyceride levels at 12 months (–0.18 mmol/l, WMD 95%CI -0.31 to –0.06). Also blood pressure was improved (DBP –12.10 mm Hg, WMD 95%CI –15.20 to –9.00, and SBP –8.90 mm Hg, WMD 95%CI –13.65 to –4.15) at 18 months, but not at 12 months (one comparison).[27]

Other factors

Gender

Two studies (Pavlou 1989 1 and 1989 2) recruited men only.[27]

Current medical conditions

The ODES study recruited men and women who had athero-thrombogenic syndrome (or insulin resistance).

Setting and delivery

One study was community based,[13] two were workplace based,[27] and one was based in a university clinic.[86] None were based in the UK.

The physical activity was supervised in all studies. No details of who supervised the exercise were reported in three studies, but in one trial the exercise was supervised by 'highly qualified instructors'.[86]

Dietary interventions were delivered by nutritionists,[88] or by a registered dietitian.[86] There was a variety of methods of delivering the dietary advice: from counselling with the spouse[13] to weekly education sessions[27] (assumed to be group sessions).

Context and methodological notes

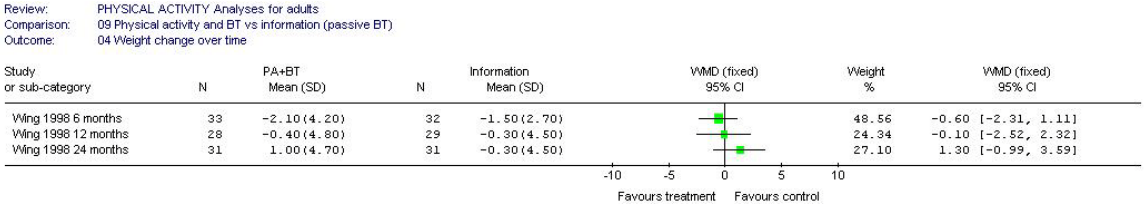
The included studies in the Cochrane review were re-examined and either excluded (see Appendix 16) or were reassigned to alternative categories. HTA studies were also included. However, the Phenix study[70] was excluded as was not a published paper, but a PhD thesis (no subsequent articles published, checked April 2005).

Physical activity and behaviour therapy versus passive (information or self-help) behaviour therapy

Weight loss

At 12 months, a combination of physical activity (approximately 45 minutes five times a week) and behaviour therapy (stimulus control, problem solving, reducing barriers, exercising in different weather conditions) was associated with a summary estimate of weight change of –0.10 kg (WMD 95% CI –2.52 to 2.32, based on one comparison) compared to passive (information, self-help) behaviour therapy (self-monitoring, goal setting, social support, relapse prevention, problem solving) alone.

Figure 15.24 Maintenance of weight loss over time for physical activity (PA) and behaviour therapy (BT) compared with information



Other outcomes

No other reported outcomes were significant.

Other factors

Age

Wing 1998 recruited people aged 40–55 years.[55]

Current medical conditions

Wing and coworkers recruited people who did **not** have diabetes, but who had one or both biological parents with diabetes.[55]

Setting and delivery

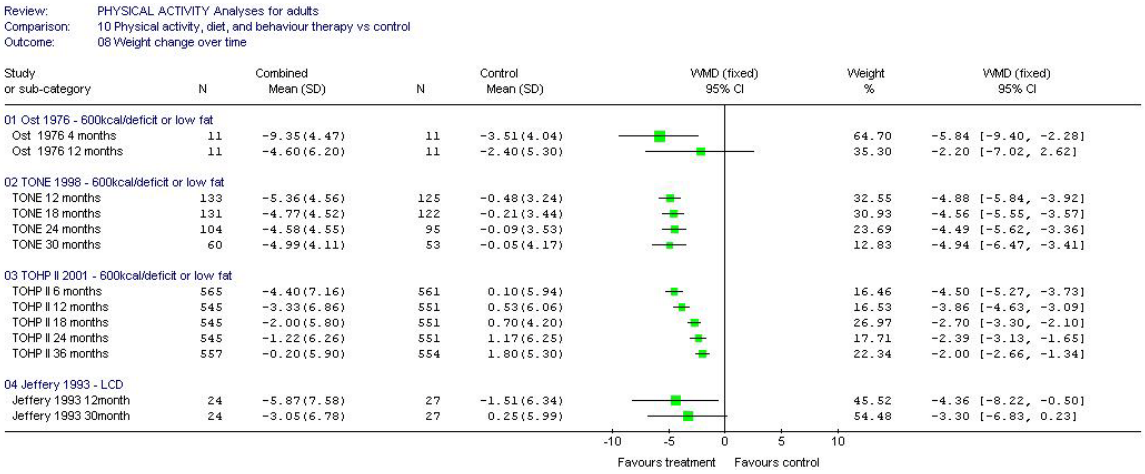
Wing and coworkers' study was assumed to be based in a university hospital in the USA.[55] Behavioural treatments and information on exercise were delivered in lectures given by a team led by a behaviour therapist and an exercise physiologist, who also supervised the exercise.

Physical activity, diet and behaviour therapy versus control (no treatment)
Six trials were included in this comparison.[91-102]

Weight loss

At 12 months, a combination of physical activity (varying in level from three sessions to 30–45 minutes 4 to 5 times week), behaviour therapy (situational control, including cue avoidance, self-monitoring of calorie intake, eating behaviours and pulse rate, management of eating behaviours, relapse prevention, goal setting, cognitive reframing and coping imagery, stimulus control, social assertion, reinforcement techniques for enhancing motivation, cognitive strategies for replacing negative thinking with more positive statements and constructive self-statements), and diet (either calorie deficit or a low-calorie diet) was associated with a summary estimate of weight change of –4.22 kg (WMD % CI –4.80 to –3.64, based on five comparisons) compared with control.

Figure 15.25 Maintenance of weight loss over time for physical activity, diet and behaviour therapy compared with control



Other outcomes

From the reported outcomes, no significant differences were seen other than for blood pressure. Both DBP and SBP were statistically significantly improved at all time points (other than DBP at 36 months) in populations with 'high normal' blood pressure or with diagnosed hypertension.

Other factors

Age

The included studies covered a wide range of ages (25–45 years,[102] 60–80 years TONE[92]).

Current medical conditions

Jalkanen's[99] and the TOHP studies[96-98] included participants with hypertension.

Gender

The TOHP I study[96] suggested although there were sex differences in the results for blood pressure, these were largely (but not exclusively) due to the differential weight loss for men and women.

Ethnicity

Subanalysis from the TONE study suggested that white participants lost more weight than black (African American) participants without, but not with, a concurrent focus on sodium reduction.[92-95]

Setting and delivery

One study was based in primary hypertension clinics,[99] three were based in university clinics or academic health centres,[92-98] and two gave no details of the setting. None of the studies were based in the UK.

Where reported, dietary components were delivered by professionals with expertise in nutrition.

Where reported, physical activity components were delivered by physiotherapists,[99] or exercise physiologists.[96] Activity was supervised in one study[99] (Jalkanen) and took place in the weekly sessions in the TOHP studies.[96-98]

Behaviour therapy was delivered by psychologists,[96;99] trained interventionists,[92;102] undergraduates with a thorough knowledge[91] or health educator.[97] The majority of studies used a group format. TONE[92] used a mixture of individual and group sessions, and the Ost study[91] was unclear but appeared to be individual sessions.

Context and methodological notes

Several studies[55;59;103;104]were moved to various other sections as the control group was considered to have received some intervention, even if the intervention was passive (for example, provision of a manual alone without additional support).

Physical activity, diet and behaviour therapy versus information

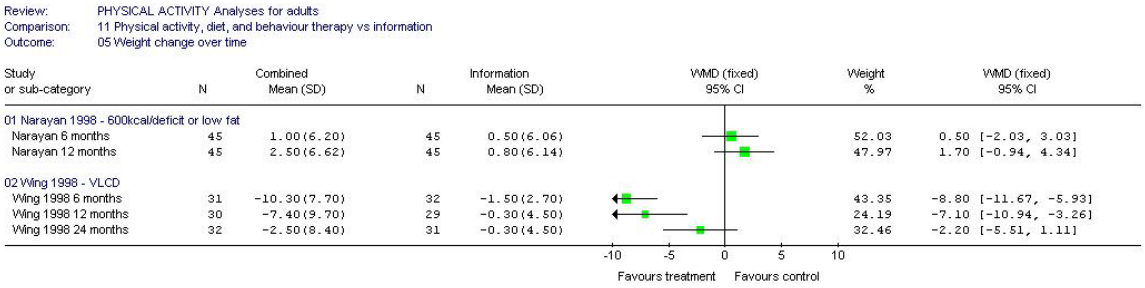
Seven trials were included in this comparison.[55;58;77;103-108]

Weight loss

At 12 months, a combination of physical activity (minimum 150 minutes per week), behaviour therapy (behaviour change goals and problem solving, goal setting, menu planning, self-efficacy, consideration of body image, social support, social eating, removing road blocks, positive thinking, dealing with high-risk situations and slips, cue elimination, stress management and relapse prevention, self-monitoring, problem solving, managing cues, stimulus control, positive assertion, positive thinking, holiday eating, social support, motivation, role playing, modelling food tasting and grocery store tours), and diet (either calorie deficit or a VLCD) was associated with a summary estimate of weight change of –3.82 kg (WMD 95% CI –4.63 to –3.02, based on six comparisons) compared with information alone.

Narayan and coworkers' study[104] which included only Pima Indians as the study population, appeared to be an outlier at 12 months.

Figure 15.26 Maintenance of weight loss over time for physical activity, diet and behaviour therapy compared with information



Other outcomes

The majority of clinical outcomes were not significantly different between groups and were not maintained over time (where reported). However, Wing and coworkers showed improved levels of triglycerides at 6 and 24 months (not at 12 months.[55]

Also both DBP and SBP were improved significantly at 12 months (DBP -1.74 mm Hg, WMD 95%CI –3.43 to –0.04, and SBP –3.59 mm Hg, WMD 95%CI

–6.31 to –0.86, based on three comparison) but this was not maintained at 24 months.

Wolf and coworkers[108] also reported that participants in the combined group lowered their use of medications, primarily diabetes medications, by 0.8 medications per day more than participants treated with usual care ($p = 0.03$). In seven of nine quality-of-life domains, the combined group improved compared with usual care ($p < 0.05$).

Other factors

Gender

Djuric and coworkers included women only, and the rest of the studies had a majority of women participating.[105]

Current medical conditions

Mayer-Davis and coworkers[107] included only people with diabetes, Lindhahl and coworkers[103] those with abnormal glucose tolerance, Messier[58] older people with arthritis, and Djuric and coworkers[105] survivors of breast cancer.

Setting and delivery

Studies were conducted in a variety of settings, including primary care. No studies were based in the UK.

Dietary components were delivered by dietitians[55;105] and nutritionists,[107] where reported. Physical activity components were delivered by exercise physiologists[55] and nutritionists.[107] Activity was supervised in two studies (during the inpatient stage[103] and walk with the therapist at weekly meetings[55]). Behaviour therapy was delivered by behaviour therapists and health educators.

Lindahl and coworkers delivered all interventions in a 1-month stay at a wellness centre, repeated in a 4-day stay at 12 months.[103]

Context and methodological notes

Some studies were excluded from this section for the following reasons: weight change in the control (education) group was not reported;[52] no requirement for participants to be overweight;[109] and because the intervention was not delivered in a clinical setting.[105,110]

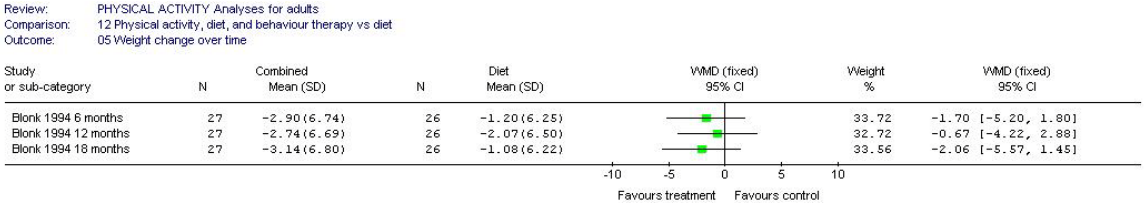
Physical activity, diet and behaviour therapy versus diet

Only one study compared physical activity, diet, and behaviour therapy with diet.[111]

Weight loss

At 12 months, a combination of physical activity (supervised training plus home-based activity), behaviour therapy (self-monitoring, stimulus control, self-reinforcement, cognitive restructuring and relapse prevention training), and diet (calorie deficit) was associated with a summary estimate of weight change of -0.67 kg (WMD 95% CI –4.22 to 2.88, based on one comparison) compared to diet alone.

Figure 15.27 Maintenance of weight loss over time for physical activity diet and behaviour therapy compared with diet



Other outcomes

No reported outcomes were significant.

Other factors

Current medical conditions

Blonk and coworkers recruited only people with type 2 diabetes.[111]

Setting and delivery

The study was conducted in the Netherlands, and no detail of setting was reported.

A dietitian provided dietary education. Group sessions on behaviour therapy were led by a psychologist experienced in eating disorders. Group exercise training was led by two physiotherapists, so assumed to be supervised.

Context and methodological notes

Phenix cluster RCT[70] (HTA study) excluded as no published papers could be identified (unpublished PhD thesis only).

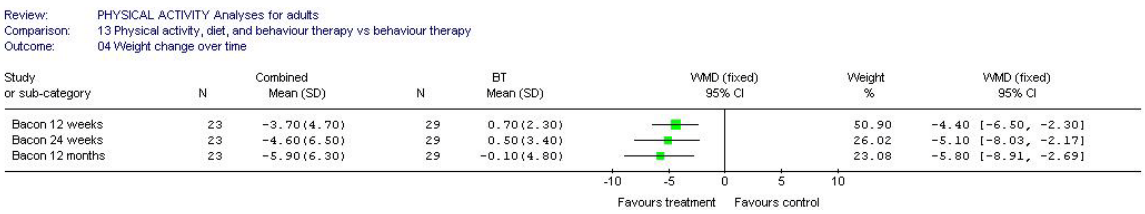
Physical activity, diet and behaviour therapy versus behaviour therapy

Only one study compared physical activity, diet and behaviour therapy with behaviour therapy.[112]

Weight loss

At 12 months, a combination of physical activity (individualised level), behaviour therapy (self-monitoring, stimulus control, reinforcement, cognitive change), and diet (calorie deficit) was associated with a summary estimate of weight change of –5.80 kg (WMD 95% CI –8.91 to –2.69, based on one comparison) compared with behaviour therapy (enhancing body acceptance, disentangling self-worth from weight, barriers transformation, increased support and assertion, self-monitoring) alone.

Figure 15.28 Maintenance of weight loss over time for physical activity, diet and behaviour therapy (BT) compared with BT



Other outcomes

No reported outcomes were significant.

Other factors

Age

Only women aged 30–45 years were recruited.

Gender

Bacon and coworkers[112] recruited women only. The participants also had to be 'chronic dieters' (defined as a Restraint score greater than 15).

Setting and delivery

Bacon's study was conducted in the USA and assumed to be based in university clinics.

The diet programme was taught by an experienced registered dietitian, based on the LEARN manual. The non-diet programme was facilitated by a counsellor with experience of using that approach previously. Both interventions were delivered in group formats. Activity was not supervised.

Physical activity, diet and behaviour therapy versus physical activity

One trial was found that compared physical activity, diet and behaviour therapy with physical activity.[58;77]

Weight loss

At 18 months, mean ± SD weight change in kilograms was –5.20 ± 6.89 kg in the combined group, and –3.46 ± 6.89 kg in the activity group. Mean weight change in the intervention group compared with activity was –1.74 (95% CI –3.98 to 0.50).

Other outcomes

At 18 months, no significant differences in improvement were seen for self-reported physical function, motility or pain between groups.

Other factors

Current medical conditions

The included study recruited only participants with osteoarthritis of the knee.[58]

Age

Messier and coworkers recruited older people only (aged 60 years or older).[58]

Setting and delivery

The trial was based in an older people's independence centre in the USA. The physical activity could be done either in the centre or at home. No details of whether the facility-based training was supervised were reported. No details of who delivered the behaviour therapy were reported, but the majority of sessions were group sessions.

Context and methodological notes

Two papers on the same study were identified and which appeared to give different results. For this review, the Messier paper was used[58], but Nicklas[77] was checked for apparent differences (possibly due to different populations used).

Physical activity, diet and behaviour therapy versus diet and behaviour therapy

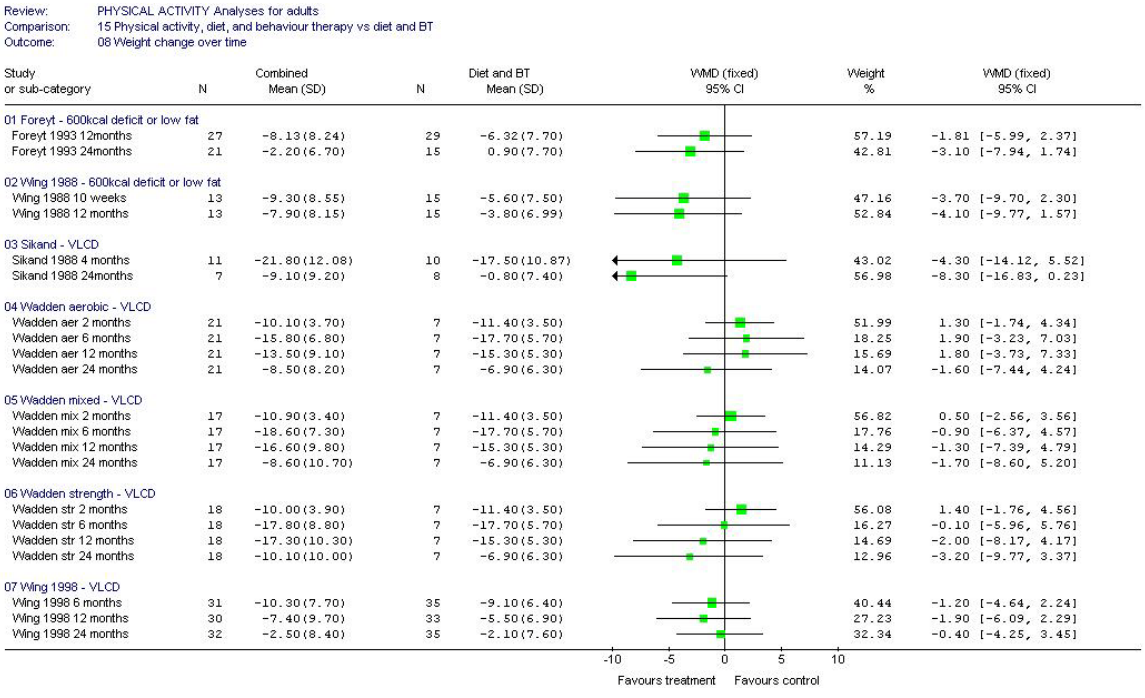
Six studies were included in this comparison.[55;58;77;113-117]

Weight loss

At 12 months, a combination of physical activity (min 45 minutes three times a week), behaviour therapy (contracts to reward behaviour change, stress management, stimulus control and goal setting, cognitive behaviour therapy, slowing down rate of eating, reducing eating signals in the home, social pressures, pre-planning and relapse prevention techniques, problem solving, reducing barriers, exercising in different weather conditions), and diet (calorie deficit or VLCD) was associated with a summary estimate of weight change of -1.59 kg (WMD 95% CI –3.67 to 0.49, based on six comparisons) compared with diet and behaviour therapy.

No significant difference was seen between the two approaches at any reported time point.

Figure 15.29 Maintenance of weight loss over time for physical activity, diet and behaviour therapy (BT) compared with diet and BT



Other outcomes

No reported outcomes were significant.

Other factors

Gender

Sikand and coworkers[115] and Wadden and coworkers[116] recruited women only.

Current medical conditions

Wing and coworkers[117] recruited people with type 2 diabetes. Wing and coworkers[55] recruited people who did **not** have diabetes, but who had one or both biological parents with diabetes. Messier and coworkers recruited older people with arthritis.[58]

Setting and delivery

All studies were based in the USA, and where reported, were conducted in university clinics.

Dietary components were delivered by dietitians where reported. Similarly, activity was delivered by exercise physiologists, where reported. The activity was supervised in two studies (initially),[113;117] but individuals were also encouraged to exercise on their own. Also supervised activity was undertaken in two studies (walk with the therapist at weekly meetings).[116;117] It was unclear in one study.111

Behaviour therapy was delivered by behaviour therapists,[58] dietitians with experience in behaviour modification,[113] and clinical psychologists.[116] All studies used a group format for delivery.

Context and methodological notes

The Phenix cluster RCT[70] (HTA study) was excluded as no published papers could be identified (unpublished PhD thesis only). Also the Kaplan[52] (HTA study) was excluded as all participants received the Exchange diet and an exercise prescription based on the results of the graded exercise test.

Wadden[116] was added to the meta-analysis as follows: 26 week results added to 6 months, 48 week results added to 12 months, and 100 weeks added to 24 months.

Wing[117] was moved to the section comparing physical activity, diet and behaviour therapy with physical activity and behaviour therapy.

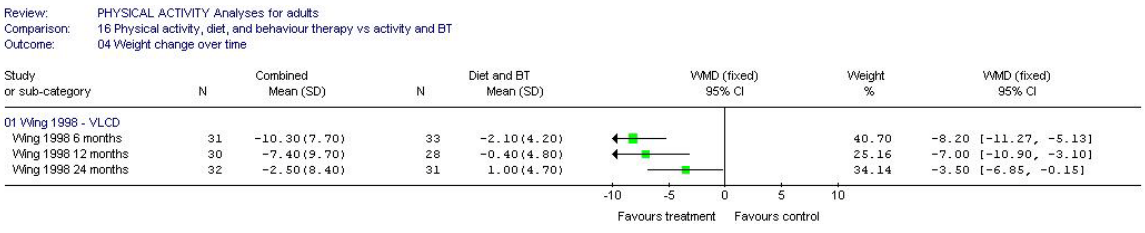
Physical activity, diet and behaviour therapy versus physical activity and behaviour therapy

One study compared a combined approach with physical activity and behaviour therapy.[55]

Weight loss

At 12 months, a combination of physical activity (approximately 45 minutes five times a week maximum), behaviour therapy (stimulus control, problem solving, reducing barriers, exercising in different weather conditions), and diet (VLCD) was associated with a summary estimate of weight change of –7.00 kg (WMD 95% CI –10.90 to –3.10, based on one comparison) compared with physical activity and behaviour therapy.

Figure 15.30 Maintenance of weight loss over time for physical activity, diet and behaviour therapy (BT) compared with activity and BT



Other outcomes

Some clinical outcomes (such as cholesterol, triglycerides, and SBP) improved in the short term (6 months), but the differences were not maintained beyond that time.

Other factors

Age

Wing and coworkers included only people aged 40–55 years.[117]

Current medical conditions

Wing recruited people who did **not** have diabetes, but who had one or both biological parents with diabetes.[117]

Setting and delivery

The study was based in the USA and assumed to be in a university hospital.

Group meetings were led by a multidisciplinary team, with primary therapists for activity being a behaviour therapist and an exercise physiologist, and for diet a behaviour therapist and a registered dietitian. The activity was supervised (walk with the therapist at weekly meetings).

Intensity of physical activity

This review was based upon six RCTs[118-123] which varied either exercise intensity (kilocalories expended per week) or duration (length of exercise time) or both. Weight loss was not the primary outcome measure in all of these studies but each trial did vary exercise prescriptions and report weight loss between groups. For this evidence review, only trials with a duration (including follow-up) of 12 months or more were included. Also, mean BMI of participants had to be 28 or over. Due to the nature of the studies (weight loss not being a primary outcome, heterogeneity of the interventions) no summary statistics were calculated.

Additional studies comparing exercise with stretching[124;125], walking vs resistance training[126], and intensive vs a control exercise programme[127] were identified in the Update searches. However, because the GDG considered that there was a lack convincing evidence overall, recommendations would be based on accepted national guidance,[128] so these have not been added to this review.

Weight loss

Between group weight losses were observed in only two of the seven studies reviewed. Jakicic and coworkers reported no significant difference between the long and short bout exercise groups but weight loss was significantly different between the short bout group which used exercise equipment (treadmill) and the short bout group which did not use a treadmill.[120] In Jeffery and coworkers' study the between-group weight loss in the high physical activity group (2500 kcal/week) and the standard behaviour group (1000 kcal/week) was significant at 18 months ($p = 0.04$).[123]

Other outcomes

There were no significant cardiovascular differences reported.

Other factors

Gender

Four of the included trials recruited women only.[118-121] Overall, the majority of participants were women.

Age

All included studies recruited middle-aged people (age range 25–58 years).

Setting and delivery

All studies were US based. Exercise settings varied between home and exercise centre and between supervised and unsupervised. Reporting of home-based, unsupervised exercise was by self-report.

15.3.4 Pharmacological interventions[♣]

15.3.4.1 Evidence statements – orlistat (Table 15.19)

Table 15.19 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss and maintenance		
1	Overall, people taking orlistat were 33% (95% CI 28% to 37%) more likely to achieve at least a 5% weight loss at 12 months (approximate mean of people who achieved 5% weight loss or more 54%, range 33–73%) than people taking placebo (approximate mean of people who achieved 5% weight loss or more 32%, range 13–50%) (n = 14 studies) For people with type 2 diabetes and for people with hypertension, a minimum 5% weight loss was also more likely (28%, 95% CI 20% to 35%, n = 3 studies, 39%, 95% CI 12% to 43%, n = 1 study respectively) However, the use of orlistat does not guarantee weight loss. In one trial, approximately 8% of the orlistat group and 18% of the control group did not lose any weight or actually put weight on	
2	Overall, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective for weight loss than placebo and diet: a change of approximately –3.3 kg (95% CI -3.55kg to -3.00kg, range –1.0 kg to –4.4 kg) at 12 months. Median weight change across studies was approximately –5.4 kg (range –3.3 kg to –10.6 kg) for orlistat and –2.7 kg (range –0.9 kg to –7.6 kg) for placebo (n = 15 studies)	1++

[♣] Detailed information on previous technology appraisals are described in section 15.3.11.

No.	Evidence statement	Grade
3	In people who are otherwise healthy, or have one or more identified risk factors, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective for weight loss than placebo and diet: a change of approximately –3.6 kg (95% CI -3.96kg to -3.27kg, range –1.0 kg to –4.4 kg) at 12 months. Median weight change across studies was approximately –6.0 kg (range –3.3 kg to –10.6 kg) for orlistat and –3.0 kg (range –0.9 kg to –7.6 kg) for placebo (n = 11 studies)	1++
4	In people with type 2 diabetes, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective for weight loss than placebo and diet: a change of approximately –2.7 kg (95% CI -.3.18kg to -2.18kg, range -2.4 kg to –2.9 kg) at 12 months. Median weight change across studies was approximately –3.9 kg (range –3.8 kg to –4.7 kg) for orlistat and –1.3 kg (range –1.4 kg to –1.8 kg) for placebo (n = 3 studies)	1++
5	In people with hypertension, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective for weight loss than placebo and diet: a change of approximately -2.7 kg (95% CI -3.79kg to -1.61kg) at 12 months. Absolute weight change was approximately –5.4 kg for orlistat and –2.7 kg for placebo (n = 1 study)	1+
6	Overall, In people who are otherwise healthy, orlistat (120 mg three times a day) in combination with diet is more effective for weight loss than placebo and diet: a change of approximately -3.3 kg (95% CI -4.15kg to -2.37kg, range –2.9 kg to –3.6 kg) at 24 months. Median weight change across studies was approximately -4.2 kg (range –2.5 kg to –6.0 kg) for orlistat and -0.1 kg (range +1.0 kg to –3.0 kg) for placebo (n = 2 studies)	1++

No.	Evidence statement	Grade
7	Overall, in people who are otherwise healthy, orlistat (120 mg three times a day) in combination with diet is more effective for weight loss than placebo and diet: a change of approximately -2.8 kg (95% CI -3.29kg to -2.31kg) at 48 months Absolute weight change across studies was approximately -5.8 kg for orlistat and –3.0 kg for placebo (n = 1 study)	1++
8	Overall, in people who are otherwise healthy, the use of orlistat in combination with either a 1000 kcal deficit diet or a 500 kcal deficit diet resulted in a similar weight loss at 12 months: -9.5 kg compared with –8.6 kg. (n = 1 study)	
Weight regain		
9	Two studies showed the effect on weight change over the subsequent 12 months when orlistat was withdrawn after the initial 12 months treatment. People who continued on orlistat regained, on average, approximately half as much weight as those on placebo (+3.2 kg vs +5.6 kg, $p < 0.001$). (n = 2 studies)	1++
Outcomes other than weight loss (from trials that reported weight loss)		
10	Overall, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering total cholesterol levels than placebo and diet: a change of approximately –0.36 mmol/l (95% CI -0.40mmol/l to -0.31mmol/l, range –0.46 mmol/l to –0.23 mmol/l) at 12 months. Median change across studies was approximately –0.21 mmol/l (range –0.51 mmol/l to +0.03 mmol/l) for orlistat and +0.16 mmol/l (range –0.08 mmol/l to +0.41mmo/l) for placebo (n = 12 studies)	1++

No.	Evidence statement	Grade
11	In people who are otherwise healthy, or have one or more identified risk factors, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering total cholesterol levels than placebo and diet: a change of approximately –0.35 mmol/l (95% CI -0.35mmol/l to -0.28mmol/l, range –0.43 mmol/l to –0.23 mmol/l) at 12 months Median change across studies was approximately –0.08 mmol/l (range –0.51 mmol/l to +0.03 mmol/l) for orlistat and +0.20 mmol/l (range –0.08 mmol/l to +0.30mmo/l) for placebo (n = 8 studies)	1++
12	In people who have type 2 diabetes, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering total cholesterol levels than placebo and diet: a change of approximately –0.40 mmol/l (95% CI -0.50mmol/l to -0.30mmol/l, range –0.46 mmol/l to -0.33 mmol/l) at 12 months. Median change across studies was approximately -0.27 mmol/l (range –0.30 mmol/l to –0.05 mmol/l) for orlistat and +0.08 mmol/l (range +0.06 mmol/l to +0.41mmo/l) for placebo (n = 3 studies)	1++
13	In people who have hypertension, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering total cholesterol levels than placebo and diet: a change of approximately –0.32 mmol/l (95% CI -0.47mmol/l to -0.17mmol/l) at 12 months Mean absolute change was approximately –0.36 mmol/l for orlistat and –0.04 mmol/l for placebo (n = 1 studies)	1++
14	In people with type 2 diabetes, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering triglyceride levels than placebo and diet: a change of approximately –0.22 mmol/l at 12 months (95% CI -0.45mmol/l to -0.28mmol/l, range –0.28 mmol/l to -0.13 mmol/l) Median change across studies was approximately 0.02 mmol/l (range –0.25 mmol/l to +0.18 mmol/l) for orlistat and +0.28 mmol/l (range +0.03 mmol/l to +0.31 mmo/l) for placebo (n = 3 studies)	

No.	Evidence statement	Grade
15	Overall, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering %HbA1c levels than placebo and diet: a change of approximately –0.23 at 12 months (95% CI -0.28 to -0.17, range –0.47 to –0.11) Median change across studies was approximately –0.20 (range –0.75 to +0.08) for orlistat and +0.08 (range –0.41 to +0.32) for placebo (n = 6 studies)	
16	In people with type 2 diabetes, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering %HbA1c levels than placebo and diet: a change of approximately –0.36 at 12 months (95% CI -0.45 to -0.28, range –0.47 to –0.34) Median change across studies was approximately –0.62 (range –0.75 to –0.15) for orlistat and –0.27 (range –0.41 to +0.32) for placebo (n = 3 studies)	
17	Overall, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering fasting plasma glucose levels than placebo and diet: a change of approximately –0.24 mmol/l (95% CI -0.31mmol/l to -0.18mmol/l, range –1.30 mmol/l to –0.08 mmol/l) at 12 months Median change across studies was approximately -0.19 mmol/l (range –2.00 mmol/l to +0.10 mmol/l) for orlistat and +0.09 mmol/l (range –1.08 mmol/l to +0.70mmo/l) for placebo n = 10 studies)	1++
18	In people with type 2 diabetes, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering fasting plasma glucose levels than placebo and diet: a change of approximately –0.84 mmol/l (95% CI -1.04mmol/l to -0.64mmol/l, range –1.30 mmol/l to –0.55 mmol/l) at 12 months Median change across studies was approximately –1.63 mmol/l (range –2.00 mmol/l to +0.04 mmol/l) for orlistat and –0.70 mmol/l (range –1.08 mmol/l to +0.70mmo/l) for placebo (n = 3 studies)	1++

No.	Evidence statement	Grade
19	Overall, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering blood pressure than placebo and diet: a change of approximately -1.42 mm Hg DBP (95% CI -1.80 to -1.05, range –3.00 mm Hg to +0.40 mm Hg) at 12 months and –1.98 mm Hg SBP (95% CI -2.54 to -1.42, range –3.94 mm Hg to +0.40 mm Hg) at 12 months Median change across studies for DBP was approximately –2.20 mm Hg (range –11.40 mm Hg to –0.90 mm Hg) for orlistat and –1.30 mm Hg (range –9.20 mm Hg to +2.00 mm Hg) for placebo Median change across studies for SBP was approximately –2.10 mm Hg (range –13.30 mm Hg to +2.00 mm Hg) for orlistat and –0.90 mm Hg (range –11.00 mm Hg to +4.15 mm Hg) for placebo (n = 12 DBP, 13 SBP studies)	1++
20	In people who were otherwise healthy, or had one or more identified risk factors, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering blood pressure than placebo and diet: a change of approximately –1.38 mm Hg DBP (95% CI -1.79 to -0.97, range –2.40 mm Hg to +0.40 mm Hg) at 12 months and –2.04 mm Hg SBP (95% CI -2.67 to -1.41, range –3.70 mm Hg to +0.40 mm Hg) at 12 months Median change across studies for DBP was approximately –2.10 mm Hg (range –5.50 mm Hg to –0.90 mm Hg) for orlistat and –1.30 mm Hg (range –3.10 mm Hg to +2.00 mm Hg) for placebo Median change across studies for SBP was approximately –2.70 mm Hg (range –7.30 mm Hg to +2.00 mm Hg) for orlistat and –0.90 mm Hg (range –5.20 mm Hg to +3.00 mm Hg) for placebo (n = 9 studies)	1++

No.	Evidence statement	Grade
21	In people with type 2 diabetes, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering blood pressure than placebo and diet: a change of approximately –1.28 mm Hg DBP (95% CI -2.40 to -0.15, range –1.30 mm Hg to –1.24 mm Hg) at 12 months and –1.62 mm Hg SBP (95% CI -2.99 to -0.25, range -3.94 mm Hg to –0.30 mm Hg) at 12 months. Median change across studies for DBP was approximately -1.70 mm Hg (range –2.30 mm Hg to –1.01 mm Hg) for orlistat and –0.39 mm Hg (range –1.00 mm Hg to +0.23 mm Hg) for placebo. Median change across studies for SBP was approximately -1.20 mm Hg (range –2.10 mm Hg to +0.21 mm Hg) for orlistat and –0.30 mm Hg (range –0.90 mm Hg to +4.15 mm Hg) for placebo. (n = 2 DBP, 3 SBP studies)	1++
22	In people with hypertension, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering blood pressure than placebo and diet: a change of approximately –2.20 mm Hg (95% CI -3.62 to -0.78) DBP at 12 months and –2.30 mm Hg (95% CI -4.87 to 0.27) SBP at 12 months. Mean absolute change for DBP was –11.40 mm Hg for orlistat and –9.20 mm Hg for placebo Mean absolute change for SBP was –13.30 mm Hg for orlistat and –11.00 mm Hg for placebo (n = 1 study)	1++
23	Orlistat (120 mg three times a day) plus lifestyle changes significantly decreased the progression to type 2 diabetes compared with placebo plus lifestyle changes: a 37.3% decrease in the risk of developing diabetes at 4 years In people with impaired glucose tolerance at baseline, the decrease in the risk of developing diabetes was 45% at 4 years (n = 1 study)	1+

No.	Evidence statement	Grade
24	Only two studies reported outcomes relating to satisfaction or quality of life. Both reported significant improvements for selected outcomes in the orlistat group (greater satisfaction with weight loss medication, weight loss, weight loss programme, less weight related distress, increased vitality) compared with placebo. However, the same outcomes were not reported in both papers and therefore it is difficult to make any definitive statement about quality of life (n = 2 studies)	1++
25	Not all studies reported an analysis of which outcomes were statistically independent of weight loss. Of those studies that did report some associations, the most often reported outcomes independent of weight loss were total cholesterol levels and LDL cholesterol levels The association between weight loss and %HbA1c levels was less conclusive, with mixed results reported	1++
Harms (from trials that reported weight loss)		
26	Orlistat treatment is associated with increased rates of gastrointestinal events. However, these are frequently mild and transient	1++
Generalisability (from trials that reported weight loss)		
27	Of the 19 included trials, the majority included people with a BMI or 28 kg/m^2 or more (n = 10), or of 30 or more (n = 8) 13 studies had a maximum cut-off for BMI for participants; this ranged from 38 kg/m^2 (n = 1) to 50 kg/m^2 (n = 1), with most studies (n = 8) having a maximum BMI of 43 kg/m^2. Of those studies where a maximum was not defined, only one study reported the range for the participants, with the highest BMI being 59.3 kg/m^2 The evidence on the effectiveness of orlistat for people with a BMI of 50 kg/m^2 or more is therefore extremely limited	1++

No.	Evidence statement	Grade
28	Only three studies were conducted solely in the UK, with the majority of studies done in the USA (n = 8 studies) The majority of studies were based in secondary care (although it was often difficult to assess exactly what setting), with only two based in primary care and one in both secondary and primary care. One study was community based Where reported, participants were recruited as volunteers (that is, through advertising) and through selection (that is, referral or from waiting lists) in two studies It is difficult therefore to know how generalisable the results of the included studies are to the UK population, particularly in primary care	1++
29	From the included studies, the follow-up rate varied from every 2–4 weeks (n = 2), to every 3 months (n = 1). Most studies used either a schedule of contact every month for the duration of the study (n = 5), or an approach of decreased contact over time (every 2 weeks, then every month, then every 2 months) (n = 5)	1++
30	Dietary advice and support was provided most often by a dietitian (n = 8). However, in three studies, the aim was pragmatic and the intervention was delivered by general physicians with no additional training, or (for 80% of the participants) by generalists who would 'not be as experienced' as staff in specialist centres or by the practice nurse. Only one study reported using a expert in cognitive behavioural modification, but the aim of this study was to assess the effect of complete lifestyle intervention, not the effect of drug treatment specifically	1++
31	One assumption could be that the effect size achieved in the included studies may be smaller in practice, in a less motivated, non-volunteer population and less intensive follow-up, delivered by generalists. However, conversely those attending hospital/specialist clinics, or participating in trials may be more resistant than most patients seen in primary care	N/A
Combining drugs		
32	There is no evidence on the combining of orlistat and sibutramine. The actions of the drugs are not synergistic and the prescribing of a combination of these drugs is not recommended in the Summary of product characteristics	4

BMI, body mass index; DBP, diastolic blood pressure; N/A, not applicable; SBP, systolic blood pressure.

15.3.4.2 Evidence review on orlistat

This review was primarily based on two key reviews.[4;129] A comparison of the reviews can be seen in Table 15.16. Additional searching was also done to identify any other RCTs published since these key reviews were published. Reference lists of other relevant reviews were also cross-referenced. Update searches did not identify any additional relevant studies.

For this evidence review, only trials with a duration (including follow-up) of 12 months or more were included. Also, mean BMI of participants had to be 28 or over.

Table 15.20 Comparison of systematic reviews on orlistat for weight loss in adults

ID	Avenell HTA[4]	O'Meara HTA[120]
Title	Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement	A rapid and systematic review of the clinical effectiveness and cost effectiveness of orlistat in the management of obesity
Published	2004	2001 (and published review in 2004)
Aim	To review systematically treatments for the prevention and management of obesity in adults	To assess systematically the clinical effectiveness and cost effectiveness of orlistat in the management of obesity
Included study designs	RCTs only	RCTs
Excluded study designs	–	–
Included participants	Adults aged 18 years and over	Participants defined as overweight or obese or participants who wished to maintain weight loss, having previously been overweight or obese

ID	Avenell HTA[4]	O'Meara HTA[120]
Excluded participants	People with bulimia nervosa, pregnant women. Studies where average BMI < 28 kg/m^2 for all groups combined	None reported
Interventions	Orlistat (either alone or in combination)	Orlistat (either alone or in combination)
Key outcomes	Weight change in kilograms	Weight or other indicator of body mass
Duration	52 weeks or more	None, other than 12 months duration for company submissions
Databases searched	13 databases; handsearching; reference lists; abstracts and NRR; trialists and biomedical companies; experts	Not reported?
Period searched	Inception to April 2001 (e-databases)	Not reported?
Language restrictions	None (reports only?)	English, French, Dutch or German only

BMI, body mass index; NRR, National Research Register; RCT, randomised controlled trial.

Orlistat and diet versus placebo and diet

16 studies were included in this comparison.[130-152]

Weight loss

See summary statistics (Tables 15.21–15.23) for results for the individual studies.

Table 15.21 Orlistat and diet vs placebo and diet: weight loss (12 months)

Population	Weight loss compared with placebo (95% CI) at 12 months	No. of studies
All studies	–3.27 kg (–3.55 to –3.00)	15

Healthy or mixed	–3.61 kg (–3.96 to –3.27)	11
Type 2 diabetes	–2.68 kg (–3.18 to –2.07)	3
Hypertension	–2.70 kg (–3.79 to –1.61)	1

Table 15.22 Orlistat and diet vs placebo and diet: weight loss (24 months)

Population	Weight loss compared with placebo (95% CI) at 24 months	No. of studies
All studies (all healthy or mixed)	–3.26 kg (–4.15 to –2.37)	2

Table 15.23 Orlistat and diet vs placebo and diet: weight loss (48 months)

Population	Weight loss compared with placebo (95% CI) at 48 months	No. of studies
All studies (all healthy or mixed)	–2.80 kg (–3.29 to –2.31)	1

Weight maintenance

See summary statistics (Table 15.24 and Appendix 17).

Table 15.24 Orlistat and diet vs placebo and diet: weight maintenance

Population	Weight loss compared with placebo (95% CI) at 12 months	No. of studies
All studies	-0.19 kg (–0.97 to 0.58)	3

Other outcomes

See summary statistics (Tables 15.25–15.32 and Appendix 17).

Table 15.25 Orlistat and diet vs placebo and diet: total cholesterol

Population	Change in total cholesterol compared with placebo (95% CI) at 12 months	No. of studies
All studies	–0.36 mmol/l (–0.40 to –0.31)	12
Healthy or mixed	–0.35 mmol/l (–0.40 to –0.30)	8
Type 2 diabetes	–0.40 mmol/l (–0.50 to –0.30)	3
Hypertension	–0.32 mmol/l (–0.47 to –0.17)	1

Table 15.26 Orlistat and diet vs placebo and diet: LDL-cholesterol

Population	Change in LDL compared with placebo (95% CI) at 12 months	No. of studies
All studies	–0.30 mmol/l (–0.33 to –0.27)	12
Healthy or mixed	–0.31 mmol/l (–0.35 to –0.28)	8
Type 2 diabetes	–0.28 mmol/l (–0.35 to –0.20)	3
Hypertension	–0.20 mmol/l (–0.32 to –0.08)	1

Table 15.27 Orlistat and diet vs placebo and diet: HDL-cholesterol

Population	Change in HDL compared with placebo (95% CI) at 12 months	No. of studies
All studies	–0.04 mmol/l (–0.05 to –0.03)	10
Healthy or mixed	–0.05 mmol/l (–0.06 to –0.03)	7
Type 2 diabetes	–0.01 mmol/l (–0.04 to 0.02)	3
Hypertension	Not reported	–

Table 15.28 Orlistat and diet vs placebo and diet: triglycerides

Population	Change in triglycerides compared with placebo (95% CI) at 12 months	No. of studies
All studies	–0.01 mmol/l (–0.06 to +0.03)	10
Healthy or mixed	+0.04 mmol/l (–0.01 to +0.09)	7
Type 2 diabetes	–0.22 mmol/l (–0.32 to –0.12)	3
Hypertension	Not reported	–

Table 15.29 Orlistat and diet vs placebo and diet: %Hb1Ac

Population	Change in %Hb1Ac compared with placebo (95% CI) at 12 months	No. of studies
All studies	–0.23% (–0.28 to –0.17)	6
Healthy or mixed	–0.15% (–0.21 to –0.09)	3
Type 2 diabetes	–0.36% (–0.45 to –0.28)	3
Hypertension	Not reported	–

Table 15.30 Orlistat and diet vs placebo and diet: fasting plasma glucose

Population	Change in fasting plasma glucose compared with placebo (95% CI) at 12 months	No. of studies
All studies	–0.24 mmol/l (–0.31 to –0.18)	10
Healthy or mixed	–0.18 mmol/l (–0.24 to –0.11)	7
Type 2 diabetes	–0.84 mmol/l (–1.04 to –0.64)	3
Hypertension	Not reported	–

Table 15.31 Orlistat and diet vs placebo and diet: diastolic blood pressure

Population	Change in DBP compared with placebo (95% CI) at 12 months	No. of studies
All studies	–1.42mmHg (–1.80 to –1.05)	12
Healthy or mixed	–1.38mmHg (–1.79 to –0.97	9
Type 2 diabetes	–1.28mmHg (–2.40 to –0.5151)	2
Hypertension	–2.20mmHg (–3.62 to –0.78)	1

Table 15.32 Orlistat and diet vs placebo and diet: systolic blood pressure

Population	Change in SBP compared with placebo (95% CI) at 12 months	No. of studies
All studies	–1.98mmHg (–2.54 to –1.42)	13
Healthy or mixed	–2.04mmHg (–2.67 to –1.41)	9
Type 2 diabetes	–1.62mmHg (–2.99 to –0.25)	3
Hypertension	–2.30mmHg (–4.87 to 0.27)	1

Other factors

Age

Derosa and coworkers[133] included people aged over 40 years only, Kelley and coworkers[138] and Miles and coworkers[143] people aged 40–65 years, Swinburn and coworkers[150] people aged 40–70 years, and Torgerson and coworkers[151] people aged between 30 and 60 years.

Current medical conditions

Most studies included people who were otherwise healthy, or had one or more risk factors.[131,140,150,151] Hollander and coworkers,[137] Kelley and coworkers,[138] and Miles and coworkers[143] included people with type 2 diabetes only. Only people

with raised cholesterol levels were included by Broom and coworkers[131] and Derosa and coworkers.[133] Bakris and coworkers[130] included people with hypertension and who were taking antihypertensive medication.

Setting

Of those studies that reported details of the setting, most were university research clinics or outpatient clinics.

Two were based in primary care alone[135,140] and one was based in both primary and secondary care.[131]

Country

Two studies only were conducted in the UK.[131,134]

Recruitment

Recruitment was by referral or from clinical databases in Finer and coworkers' study (partially),[134] and in two other studies.[133,145] However, most studiesdid not report details of recruitment.

Methodological and context notes

The summary statistics were only calculated by subgroup (that is, weight reduction and weight maintenance) as comparing different outcomes, so we considered it was not appropriate to combine for an overall effect size.

The comparison of failures to achieve 5% or 10% weight loss was only done at 12 months, where the data were available.

Note that many studies calculated weight loss from after a trial run-in period. Therefore, the absolute weight loss may be an under-estimate. Details can be seen in the Evidence tables.

Orlistat and diet versus placebo and then orlistat and diet
One study was identified for this comparison.[153]

Weight loss

See summary statistics (Appendix 17).

Other outcomes

See summary statistics (Appendix 17).

Other factors

Participants had raised cholesterol.

Orlistat and lifestyle modification versus control (waiting list)
Only one study compared orlistat and lifestyle modification with a waiting list control.[154]

Weight loss

See summary statistics (Appendix 17).

Other outcomes

Women in the intervention group had significant improvements in total cholesterol and LDL-cholesterol. No other (usual) outcomes were significant.

Other factors

Age

Included women were aged 21–65 years.

Current medical conditions

Women with borderline hypertension or diabetes treated with oral medications were permitted to participate if their physician also consented.

Setting

The study was based in a community setting in the USA, and included only women of Mexican American descent.[154]

Orlistat and 1000 kcal/day deficit diet versus orlistat and 500 kcal/day deficit diet

One study was identified and participants only continued if they achieved a 5% or more weight loss from baseline at 3 and 6 months.[155]

Weight loss

See summary statistics (Appendix 17).

Other outcomes

See summary statistics (Appendix 17).

Other factors

No details reported (see Table 15.19 [Generalisability]).

15.3.4.3 Evidence statements – sibutramine (Table 15.33)

Table 15.33 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss		
1	Sibutramine (in combination with diet) is more effective for weight loss than placebo and diet alone: a change of approximately –4.7 kg (95% CI -5.38kg to -4.03kg, range –2.80 kg to –7.80 kg) at 12 months Median weight change across studies was approximately –5.25 kg (range –4.40 kg to –8.00 kg) for sibutramine and –0.45 kg (range 0.50 kg to –2.60 kg) for placebo at 12 months (n = 8 comparisons)	1++
2	Sibutramine (in combination with diet, activity and behaviour modification) is more effective for weight loss than placebo and diet, activity and behaviour modification: a reduction of approximately 3.5 kg (95% CI -4.45kg to -2.51kg) at 12 months (n = 2 comparisons)	1++
3	In people with type 2 diabetes, sibutramine in combination with diet is more effective for weight loss than placebo and diet (–5.70 kg, 95% CI -6.84kg to -4.54kg) Median weight change was approximately –7.10 kg (range –5.50 kg to –8.00 kg) for sibutramine compared with –0.20 kg (range –0.20 kg to –2.60 kg) for placebo at 12 months (n = 3 comparisons)	1++
4	In people with hypertension, sibutramine in combination with diet is more effective for weight loss than placebo and diet (–4.00 kg, 95% CO -5.30kg to -2.70kg). Median weight change was approximately –4.45 kg (range –4.40 kg to –4.50 kg) for sibutramine compared with –0.45 kg (range –0.40 kg to –0.50 kg) for placebo at 12 months. (n = 2 comparisons)	1++

No.	Evidence statement	Grade
Weight maintenance		
5	Sibutramine can be more effective than placebo in weight maintenance after 18 months, having 43% of participants maintaining 80% or more of their original 6 month weight loss compared with 16% in the placebo group (n = 1 study)	1+
6	Evidence from one trial suggests that sibutramine helped maintain at least 5% of weight loss in 69% of participants, and 10% weight loss in 46% of the participants after 18 months. However, participants who did not achieve 5% weight loss over 6 months of treatment were excluded from the maintenance phase. (n = 1 study)	1+
Weight regain		
7	There is evidence that suggests that 3 months after stopping treatment, weight gain was 4.3 (±3.1) kg in the sibutramine group, compared to 2.3 (±2.9) kg in the placebo group (n = 1 study)	1+
Outcomes other than weight loss (from trials that reported weight loss)		
9	Overall, sibutramine and diet had an effect in changing HDL levels by +0.10 mmol/l (95% CI +0.06 to +0.14, range +0.08 mmol/l to +0.11 mmol/l) compared with placebo and diet Median change was approximately +0.12 mmol/l (range +0.10 mmol/l to +0.34 mmol/l) for sibutramine compared with +0.03 mmol/l (range (0.00 mmol/l to +0.23 mmol/l) for placebo at 12 months (n=5 studies)	1++
10	Overall, sibutramine and diet had an effect in lowering triglyceride levels by –0.18 mmol/l (95% CI -0.28 to -0.08, range –0.05 mmol/l to –0.30 mmol/l) compared with placebo and diet Median change was approximately –0.20 mmol/l (range –0.05 mmol/l to –0.44 mmol/l) for sibutramine compared with –0.01 mmol/l (range –0.11 mmol/l to –0.21 mmol/l) for placebo at 12 months (n=6 comparisons)	1++

No.	Evidence statement	Grade
11	For people with type 2 diabetes, significant lowering of levels was seen in the sibutramine groups for levels of fasting plasma glucose (–0.40 mmol/l, 95% CI -0.81 to 0.00) and triglycerides (–0.30 mmol/l, 95% CI -0.59 to -0.01)) compared with placebo at 12 months (n = 2 studies)	1++
12	For people with hypertension, SBP did not differ significantly between groups, but at 12 months DBP increased in the treatment group compared to placebo (+3.20, 95% CI 1.53 to 4.87) (n = 2 studies)	1++
Harms (from trials that reported weight loss)		
13	Common side effects associated with sibutramine treatment were headaches, constipation and dry mouth	1++
Generalisability (from trials that reported weight loss)		
14	Of the 13 included trials, the majority included people with a BMI or 27 kg/m^2 or more (n = 7) Eight studies had a maximum cut-off for BMI for participants; this ranged from 40 kg/m^2 (n = 5) to 50 kg/m^2 (n = 1) The evidence on the effectiveness of sibutramine for people with a BMI of 50 kg/m^2 or more is therefore extremely limited	1++

No.	Evidence statement	Grade
15	One study was entirely conducted in the UK, whilst two others which consisted of multicentre trials, included people from the UK. The majority of the studies were conducted in the US The majority of the studies were based in university research clinics or outpatient clinics, with only three trials being based in a primary care setting. Two studies were multicentre trials, one with 21 primary and secondary care centres, and one with with eight European secondary care centres Recruitment was by referral from general practitioners and family doctor internists in one study. All other studies did not provide details of recruitment Follow-up rate varied from every month (n = 5), to every 3 monthly visit (n = 1). Most of the studies applied an approach of decreased contact over time, although differing slightly from study to study	

BMI, body mass index; DBP, diastolic blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure.

15.3.4.4 Evidence review on sibutramine

Sibutramine and diet versus placebo and diet

Seven studies were included in this comparison.[156-164]

Weight loss

See summary statistics for results for the individual studies (Table 15.34 and Appendix 17).

The marketing authorisation for sibutramine has been suspended. See front cover for details.

Table 15.34 Sibutramine and diet versus placebo and diet: weight loss

Population	Weight loss compared with placebo (95% CI) at 12 months	No. of comparisons
All studies	–4.71 kg (–5.38 to –4.03)	8
Healthy or mixed	–4.32 kg (–5.41 to –3.22)	3
Type 2 diabetes	–5.69 kg (–6.84 to –4.54)	3
Hypertension	–4.00 kg (–5.30 to –2.70)	2

Weight loss was maintained at 15 months (–3.70 kg, 95% CI –5.71 to –1.69) on a weight reduction programme, and also when used with a weight maintenance programme (–3.40 kg, 95% CI –4.45 to –2.35).

Other outcomes

No significant differences were seen for levels of total cholesterol, LDL-cholesterol, %HbA1c, fasting plasma glucose or SBP overall at 12 months. Levels of HDL-cholesterol (+0.10 mmol/l), and triglycerides (–0.18 mmol/l) improved at 12 months. DBP increased significantly at 12 months (+2.16 mm Hg, 95% CI 1.20 to 3.11) in the sibutramine group compared with placebo.

For people with type 2 diabetes, significant improvements were seen in the sibutramine groups for levels of fasting plasma glucose (–0.40 mmol/l) and triglycerides (–0.30 mmol/l) compared with placebo at 12 months.

For people with hypertension, SBP did not differ significantly between groups, but at 12 months DBP increased in the treatment group compared with placebo (+3.20, 95% CI 1.53 to 4.87).

Other factors

Age and gender

The ages of participants ranged overall from 17 to (maximum defined) 70 years of age. The majority of the participants were women.

Current medical conditions

Three trials included people who were otherwise healthy,[156;158;159] two studies people with type 2 diabetes,[162;164] and two studies people with well-controlled hypertension.[157;163]

Setting

One study[158] was based in a primary care setting and another study[164] included 21 primary and secondary care centres in several countries. The remaining studies were based in either university research clinics or outpatient clinics. The Sibutramine Trial of Obesity Reduction and Maintenance (STORM)[159] study was conducted in eight European health centres (appeared to be primary care).

Country

Only Smith and Goulder's study[158] was conducted exclusively in the UK. One Study[156] was conducted in France. McNulty and coworkers' study[164] was conducted in England, Canada, France, Belgium. STORM[159] was conducted in eight European countries, including the UK.

Recruitment

In Smith and Goulder's study[158] the participants were recruited by by general practitioners and family doctor internists. Apfelbaum and coworkers[156] recruited participants from 12 medical centres, although no details were given. In STORM,[159] participants were recruited from local health centres. All other studies did not provide details of recruitment.

Sibutramine and diet with activity versus placebo and diet with activity

One trial compared the use of sibutramine or placebo with diet (50% carbohydrates, 30% fats, 20% proteins) and activity (30 minutes of walking per day) in people with type 2 diabetes.[165]

Weight loss

No significant difference in weight loss was seen at 12 months, although both groups had lost weight (–4.10 kg sibutramine vs –1.40kg placebo).

Other outcomes

Significant improvements were seen in the sibutramine group at 12 months for levels of LDL-cholesterol (–0.37 mmol/l) and %HbA1c (–-0.70).

Other factors

Participants had type 2 diabetes, were taking glibenclamide, and were mainly women. The study was based in secondary care in Mexico.

Sibutramine and diet with activity and behaviour therapy versus placebo and diet with activity and behaviour therapy

Two trials compared the use of sibutramine or placebo with a combination lifestyle intervention.[166;167]

Weight loss

A significant difference in weight loss was seen at 12 months (–3.48 kg, 95% CI –4.45 to –2.51) between the two groups.

Other outcomes

No significant changes were seen at 12 months.

Other factors

Participants in both studies were otherwise healthy, and the majority were women.

Sibutramine and lifestyle versus lifestyle intervention alone then sibutramine and lifestyle for all participants

One trial compared the use of sibutramine and lifestyle with lifestyle intervention alone in people with type 2 diabetes.[168;169] After 12 months, the standard lifestyle group was prescribed sibutramine.

Weight loss

A significant difference in weight loss was seen at 12 months (–6.50 kg sibutramine compared to lifestyle alone), but at 24 months, the standard lifestyle (followed with 12 months sibutramine) group lost more weight than the sibutramine (continuous for 24 months) group (–8.10 kg vs –4.60 kg, respectively).

Other outcomes

No significant changes were seen at any time points.

Other factors

Participants had type 2 diabetes and were mainly women. The study was based in a research centre in the USA.

Sibutramine with a combination lifestyle intervention versus sibutramine, low-calorie diet and activity

One trial was included in this comparison.[170;171]

Update searches identified one additional study by the same authors, using a similar, but extended protocol.[172] This study concluded that the use of sibutramine in combination with lifestyle was more effective than either

sibutramine or lifestyle alone. Therefore, as the study supported the detailed evidence review, no further details are reported here.

Weight loss

A significant difference in weight loss was seen at 12 months (–10.61 kg, 95% CI –14.64 to –6.58).

Other outcomes

Authors reported significant reductions at 12 months in triglyceride and low-density lipoprotein cholesterol levels but systolic and diastolic blood pressure both increased significantly ($p<0.05$ for all).

Other factors

Participants were women who were otherwise healthy. The study was based in a research clinic in the USA.

Sibutramine and diet versus placebo and diet (for 4 months) then open label sibutramine for all participants

One trial was included in this comparison.[173]

Weight loss

A significant difference in weight loss was seen at 4 months (–4.10 kg, 95% CI -7.58 to –0.62), but this was not maintained at 12 months, although both groups did lose weight (–12.90 kg sibutramine for 12 months, –11.90 kg placebo then diet).

Other outcomes

No other outcomes were reported.

Other factors

Participants were women who were otherwise healthy. The study was based in an obesity management centre in the Czech Republic.

Sibutramine in combination with orlistat

Wadden and coworkers[171] (continuation trial of Wadden and coworkers[170]) evaluated whether adding orlistat to sibutramine would induce further weight loss in participants who previously had lost weight while taking sibutramine alone. The initial period of the trial (that is, sibutramine alone) lasted 12 months, with the period using both drugs lasting only 16 weeks. Because the period of evaluation of the combination was only 16 weeks, this trial did not meet our criteria of a 12 month follow-up (for the combination), so it was excluded from the review.

15.3.4.5 Summary of previous NICE Technology Appraisals - drugs

Orlistat

The Technological Appraisal Guidance- No.22: Guidance on the use of Orlistat for the treatment of obesity in adults (2004) stated that orlistat should be prescribed for people who have lost at least 2.5kg by dietary control and increased physical activity alone in the month prior to first prescription. This guideline recommends that pharmacological treatment should be initiated only after dietary, exercise and, additionally, behavioural approaches have been started (NICE 1.2.5.1, full guideline 1.7.5.1).

The Technological Appraisal Guidance- No.22: Guidance on the use of Orlistat for the treatment of obesity in adults (2004) did not recommend the continuation of therapy beyond 12 months. This guideline recommends that the decision to use drug therapy for greater than 12 months (usually for weight maintenance) should be made after discussing potential benefits and limitations with the patient (NICE 1.2.5.20, full guideline 1.7.5.20).

See also Section 6 for the detailed health economic modelling.

Sibutramine

The Technological Appraisal Guidance- No.31: Guidance on the use of Sibutramine for the treatment of obesity in adults (2001) recommended a starting dose of 10mg/day. This guideline does not recommend a starting dose but suggests that prescription should be in accordance to the drug's summary of product characteristics (NICE 1.2.5.4, full guideline 1.7.5.4).

See also Section 6 for the detailed health economic modelling.

15.3.5 Surgery and referral to specialist services[♣]

15.3.5.1 Evidence statements (Table 15.35)

Table 15.35 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss (surgery vs non-surgery)		
1	Evidence supports the use of surgery for weight loss in people for whom surgery is an appropriate option One RCT showed that at 12 months, the use of an exceptional diet, with intensive follow-up (approximately 30 contacts per year initially) and support (outpatient clinic visits and group meetings) can achieve similar results to surgery (–18.0 kg vs –22.0 kg) in people with at least 60% excess weight, but these results are not maintained at 24 months Surgery remains more effective than a non-surgical approach for people who are obese (BMI ≥ 38 kg/m^2 for women, ≥ 34 for men) in the longer term (measured up to 10 years after surgery)	1+, 2+
2	Percentage EWL was not reported by any of the included studies comparing surgery and non-surgical interventions	N/A
3	In one study reporting the effects of surgery on weight maintenance, weight loss from surgery can be maintained up to 10 years after surgery (approx 17% excess weight loss).	2+
4	There is a lack of evidence comparing surgical and non-surgical options in groups with a mean BMI ≥ 50 kg/m^2	N/A
Weight loss (by different procedures)		
5	Laparoscopic RYGB resulted in a significantly higher % EWL at all measured time points when compared with LAGB (n = 1)	2+
6	DS-BPD and RYGB show similar rates of % EWL at 12 (53% vs 54%) and 24 months (63% vs 67%)	3
7	From observational studies, % EWL was as follows: Procedure — 24 months Median (range) — 60 months Median (range)	2++

[♣] Detailed information on previous technology appraisals are described in section 15.3.11

No.	Evidence statement			Grade
	LAGB	54.5% (38% to 87%) n = 16	54% (44% to 66%) n = 6	
	Laparoscopic GB	69% (67% to 83%) n = 5	82% n = 1	
	Open GB	65% (55% to 71%) n = 3	57% (56% to 58%) n = 2	
	DS-BPD	71.5% (67% to 78%) n = 4	69% (66% to 73%) n = 4	

From observational studies, mean change in BMI was as follows:

Procedure	24 months Median (range)	60 months Median (range)
LAGB	-11.9 (-19.2 to -8.9) n = 17	-11 (-12.8 to -8.9) n = 4
Laparoscopic GB	-16.8 (-20.86 to -16.8) n = 3	Not reported
Open GB	-18.5 (-19 to -18.4) n = 3	Not reported
DS-BPD	-23 n = 1	-20.3 (-21 to -17.1) n = 3

Outcomes other than weight loss (from trials that reported weight loss)

No.	Evidence statement	Grade
8	Surgery was associated with improvements in clinical outcomes (such as blood pressure, cholesterol levels, triglycerides and glucose) compared with non-surgical intervention (n = 1)	2+
9	People who underwent surgery were less likely to develop type 2 diabetes at both 2 and 8 years, or hypertension at 2 years, but not at 8 years, compared with those who had non-surgical intervention Recovery from other conditions (such as hyperinsulinaemia and hypertriglyceridaemia) was also more likely in people who had surgery (n = 1)	2+
10	Where reported, the majority of people experienced remission or improvement of associated comorbidities, including diabetes, hypertension, arthritis, sleep apnoea, after surgery	2+
11	Where reported, the majority of people experienced improvement in quality of life after surgery	2+
12	Both LAGB and LGBP resulted in lower rates of hypertension, diabetes up to 24 months after surgery, but LGBP was associated with a lower rate of dyslipidaemia compared with LAGB (n = 1)	2+
13	Laparoscopic GBP was associated with a shorter hospital stay than open GBP in two studies but a similar length of stay in two other studies	1+
14	Mean length of stay is higher for DS-BPD than for RYGB (8.7 vs 5.9 days)	3
Harms (from trials that reported weight loss)		
15	In trials comparing surgery with non-surgical interventions, mortality rates between groups were not compared	1+, 2+
16	In one comparative study, LAGB was associated with similar rates of early complications to LGBP (p = 0.36), but with higher levels of late complications (p = 0.001). Mortality was nil in both groups (n = 1)	2+
17	Reoperation rates were higher in the LAGB group compared with the LGBP group (26.2% vs 10.7% overall) (n = 1)	2+
18	Reoperation rates were similar in both laparoscopic and open GBP procedures, but late complications were more common in the open GBP group (24% vs 11%)	1+

<table>
<tr><th>No.</th><th>Evidence statement</th><th>Grade</th></tr>
<tr><td>19</td><td>In the four trials comparing laparoscopic and open GBP conversion rates from laparoscopic to open surgery ranged from 2.5% to 23%

Complication rates (minor 7.6% vs 11.8% and major 7.6% vs 9.2%) were similar in both lap and open GBP procedures (Nguyen), and early complications were similar for both techniques, but complication rates after 30 days were lower in the laparoscopic group.</td><td>1+</td></tr>
<tr><td>20</td><td>Sick leave tended to be lower in the LGBP group than in the open GBP group, but this was not seen across all studies</td><td>1+</td></tr>
<tr><td>21</td><td>Quality of life (several scores such as physical functioning) tended to be higher in the LGBP group at 1 month, but there was no significant difference between groups from 3 to 6 months onwards</td><td>1+</td></tr>
<tr><td>22</td><td>Where reported, some patients experienced significant nutritional adverse effects after surgery, which required intervention</td><td>2+</td></tr>
<tr><td>23</td><td>No evidence was identified to support routine psychological assessment. Many studies did not report any details of the preoperative work-up</td><td>N/A</td></tr>
<tr><td>24</td><td>From observational studies, reoperation rates were as follows
<table><tr><th>Procedure</th><th>Median
(range)</th></tr><tr><td>LAGB</td><td>6.5%
(0.5% to 24%)
n = 16</td></tr><tr><td>Laparoscopic GB</td><td>1.8%
(0.03% to 9.8%)
n = 4</td></tr><tr><td>Open GB</td><td>5%
(2.8% to 12%)
n = 3</td></tr><tr><td>DS-BPD</td><td>3.9%
(2.7% to 6.3%)
n = 5</td></tr></table></td><td>2++</td></tr>
</table>

<table>
<tr><th>No.</th><th>Evidence statement</th><th>Grade</th></tr>
<tr><td>25</td><td>Revision rates varied across operations, and studies. From the observational studies, 2.3% of laparoscopic adjustable bands were removed, 0.06% of the LGBPs were reversed, and approximately 4.75% (median, range 3.8% to 6.8%, n = 4) of DS-BPDs were revised; the majority for lengthening of the common limb for nutritional problems</td><td>2+</td></tr>
<tr><td>26</td><td>From observational studies, mortality rates were as follows
<table><tr><td>Procedure</td><td>Median
(range)</td></tr><tr><td>LAGB</td><td>0.0%
(0% to 0.6%)
n = 16</td></tr><tr><td>Laparoscopic GB</td><td>0.4%
(0% to 1.1%)
n = 5</td></tr><tr><td>Open GB</td><td>0.5%
(0% to 1.5%)
n = 4</td></tr><tr><td>DS-BPD</td><td>0.5%
(0% to 1.4%)
n = 5</td></tr></table></td><td>2++</td></tr>
<tr><td>27</td><td>DS-BPD and RYGB have similar rates of wound infection (22% vs 20%), postoperative anastomotic leaks (6% vs 3%) and mortality (0.9% vs 0.8%)</td><td>3</td></tr>
<tr><td>28</td><td>Staged surgery is an appropriate surgical option for people with BMI > 50 kg/m^2, but the evidence on weight loss and other outcomes remains limited</td><td>2+</td></tr>
<tr><td colspan="3">Generalisability (from trials that reported weight loss)</td></tr>
<tr><td>29</td><td>Most of the studies were based in large, specialist centres with high levels of support. Results may change if the centre is small or the setting is non-specialist.</td><td>1+, 2+, 3</td></tr>
<tr><td>30</td><td>Higher hospital and surgeon volume is associated with lower rates of mortality and complications</td><td>2+</td></tr>
<tr><td colspan="3">Competencies and training</td></tr>
</table>

No.	Evidence statement	Grade
31	There are learning curves associated with bariatric surgery and the individual procedures. Appropriate training is associated with complication rates and mortality similar to those when the rate plateau has been reached	2+
Referral to specialist services		
32	No evidence on the referral criteria to specialist services was identified	N/A

DS-BPD, duodenal switch and biliopancreatic diversion; EWL, excess weight loss; GB, gastric banding; GBP, gastric bypass; LAGB, laparoscopic adjustable gastric banding; LGBP, laparoscopic gastric bypass; RCT, randomised controlled trial; RYGB, Roux-en-Y gastric bypass.

15.3.5.2 Evidence review on different surgical procedures

This review was primarily based on two key reviews.[174;175] Additional searching was also done to identify any other trials published since these key reviews were published. Reference lists of other reviews were also cross-referenced. [176;177]

On expert advice, we widened our inclusion criteria for study design, and included study designs as follows:

- RCTs
- controlled clinical trials
- controlled before-and-after studies
- case series.

The focus of the study had to be the effectiveness of the surgical procedure, with a key (required) outcome of weight loss. Other criteria for inclusion were a minimum period of follow-up (mean or median) of at least 12 months for RCTs, and (for studies other than RCTs) a minimum follow-up of 24 months and minimum number of 150 participants.

The evidence review only considered procedures that were currently being performed. These are of three types: restrictive, restrictive/malabsorptive, malabsorptive/restrictive.

- Restrictive: the gold standard is laparoscopic adjustable gastric banding (LAGB). Vertical gastric banding (VBG) was a forerunner to laparoscopic gastric banding, but had high rates of complications/failure. Both operations have similar, expected clinical outcomes. Laparoscopic gastric banding restricts intake (volume) of solid food. Older operations are VBG, horizontal gastroplasty, open adjustable banding.

- Restrictive/malabsorptive: gold standard is gastric bypass (Roux-en-Y), which mainly restricts dietary intake but also reduces absorption.

- Malabsorptive/restrictive: these are more similar to the older operations. The gold standard is duodenal switch (DS) and biliopancreatic diversion (BPD). These reduce calorie absorption, with limited restriction.

Gastric balloons are a short-term option, so were not considered as an appropriate surgical intervention for this review. Therefore, we did not review the evidence for this procedure.

The areas reviewed were as follows:

- Surgery versus non-surgical interventions

- LAGB versus gastric bypass (comparative studies)

- LAGB versus DS-BPD (comparative studies)

- DS-BPD versus gastric bypass (comparative studies)

- Laparoscopic gastric bypass versus open gastric bypass (comparative studies)

- Gastric bypass (open or laparoscopic) (single-arm studies)

- LAGB (single-arm studies)
- DS-BPD (single-arm studies)

Although we have reported details of complication rates associated with each procedure, caution should be used when interpreting these. Many of the series were undertaken over a long period of time, and initial rates of complications were often higher than would be anticipated for an established procedure or service (see Learning curve review below for further details). Also, concern was raised about the effect of different procedures on food intake (and therefore nutrient intake) and appetite. Where studies reported such outcomes, these have been reported, but it should be noted that this is an area of active research.

Also, because of the heterogeneous nature of the populations included in the series and the different levels of reporting, the rates differed considerably across studies.

An evidence review was also undertaken, using the same criteria as above, to evaluate the effectiveness of staged surgery for people with a BMI of 55 kg/m^2 or more.

Surgery versus non-surgical interventions

Some of the studies originally included in the HTA have been excluded as they considered the use of procedures no longer performed.[178] Also, two cohort studies included in the Cochrane review[174] were excluded as they did not have a minimum of 150 participants.[179;180] No additional studies were identified.

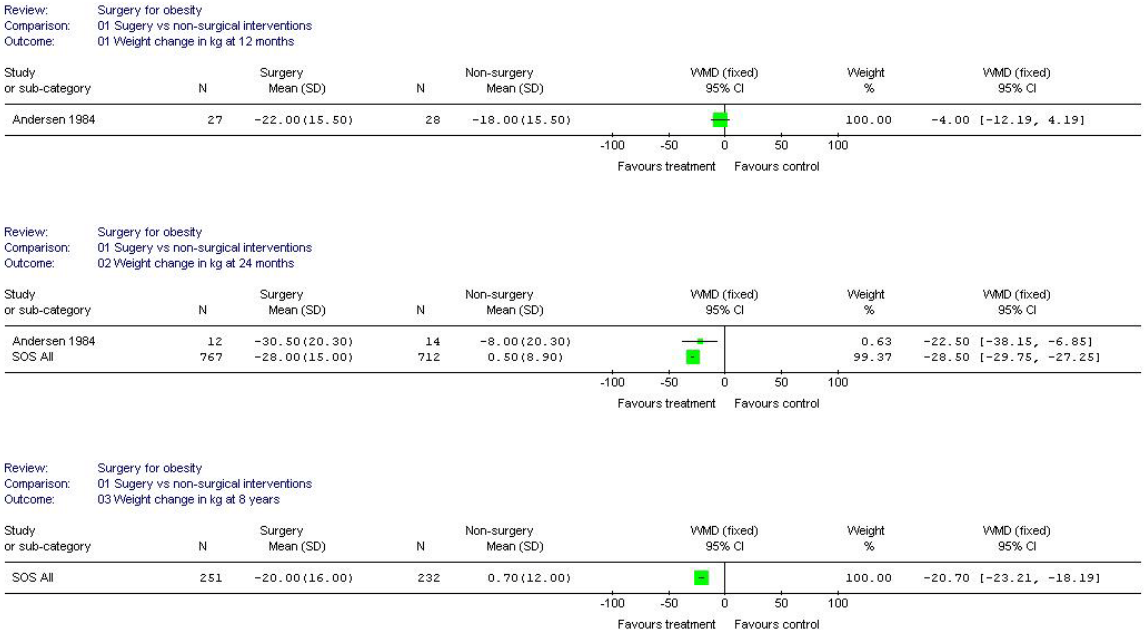
Three studies met our inclusion criteria,[181-183] and details can be seen in Appendix 15. Two of these were RCTs,[181;182] and one was a matched cohort study.[183-198]

No additional studies were identified in the Update searches (see Methods chapter for details).

Weight loss (Figure 15.31)

See evidence tables and statements (Table 15.35). No summary statistics were calculated due to differences in study design, and lack of data to include all relevant studies and time points.

Figure 15.31 Weight loss for surgery compared with non-surgical interventions



Other outcomes

See evidence tables (Appendix 15).

Restrictive surgery

This section was primarily based on the Technology Evaluation Centre (TEC) review of 2005[175] which evaluated laparoscopic gastric banding compared with various other procedures. Of the four included studies comparing the effectiveness of laparoscopic gastric banding with other procedures, two case–control studies met our inclusion criteria.[199;200] as Hell and coworkers study[201] had fewer than 150 participants, and Morino and coworkers[202] compared laparoscopic gastric banding with VBG, which is no longer performed.

Of the 46 single-arm studies (excluding 6 with fewer than 150 participants, a further 16 with a follow-up of less than 24 months, and 5 because no weight loss data were reported), 20 met our inclusion criteria (see Appendix 15 for details).[203-222] We also identified one additional paper[223] published since the TEC review.[175]

Update searches identified a further four relevant new or updated single-arm studies.[224-227] Three of these studies did not add any additional data to the evidence already reviewed in detail, with weight loss and revision rates being within the ranges reported in the evidence statements above. One study[224] however, examined the effectiveness of LAGB in people with a BMI less than, or equal to 35kg/m^2. This was a retrospective study using sub-group data from the Angrisani study[204] already included in the evidence review. Because of the retrospective nature of the study, and lack of other supporting evidence on this (the authors themselves noted in the Conclusions that surgical indications for BMI≤35 were questionable), we have not reported the data in this review.

Weight loss

See evidence tables Appendix 15

Other outcomes

See evidence tables Appendix 15 and evidence statements Table 15.35.

From those studies that reported revision rates, removal of the band occurred in approximately 2.3% (median) of participants (range 0.6%–15%). Approximately 6.5% (median) of patients were reoperated on (range 0.5–24%).

In addition:

- Dargent[213] reported that comorbidities improved in all people who lost 25% or more of excess weight (no further details).

- Favretti and colleagues[214] noted that 20% of patients who had excess weight loss greater than 30% lost compliance to dietetic, psychological and surgical advice.

- In the Frigg study,[215] the rate of remission and improvement in comorbiditites were: hypertension 58% and 42%, diabetes 75% and 8%, dyspnea 85% and 12%, arthralgia 52% and 24%, reflux 79% and 11%, self-esteem 45% and 39%, and general physical performance 58% and 33%. An improvement in stress incontinence, sleep apnoea, peripheral oedema, and regulation of menstruation was also reported. Greater weight loss was associated with greater reduction in dyspnoea, arthralgia, self-esteem, and physical performance. Hypertension, diabetes, reflux, and oedema improved independent of the amount of weight loss.

- US Food and Drug Administration (FDA) data[210] showed improvements in quality of life measures, such as depression, appearance, physical and emotional function, pain, general, mental, and physical health (no statistical significance reported).

- O'Brian and coworkers[219] reported improvements for people with diabetes (54% asymptomatic, 43% better control), asthma (Asthma Severity Score from 44.5 to 14.3, $p < 0.001$, 100% reduction in medication), dyslipidaemia (reduction from 34% to 9% of people with triglyceride levels > 2.0 mmol/l), hypertension (complete resolution in 55%, improvement in 31%), sleep apnoea (33% to 2%), gastro-oesophageal reflux disease (GORD) (76% complete resolution, 14% significantly improved), and quality of life (Beck Depression Index 18.0 to 7.8, $p < 0.001$, Medical Outcome Survey Short Form 36 subscales all returned to normal scores).

- Spivak and coworkers[220] reported improvements in hypertension (recovered 40%, improved 23%), diabetes (recovered 29%, improved 36%), hypercholesterolaemia (recovered 67%, improved 0%), sleep apnoea (recovered 38%, improved 13%), and GORD (recovered 82%, improved 5%).

- Weiner and coworkers[222] reported that 92% of people were satisfied with the general success, and this was associated with an improvement in quality of life. Improvements were also seen for people with hypertension (recovered 38%, improved 57%, diabetes (recovered 38%, improved 63%), and asthma (recovered 6%, improved 9%).

Restrictive/malabsorptive surgery

This section was primarily based on the TEC review of 2005[175] which evaluated gastric bypass compared with various other procedures. Eight of the nine included studies either compared the effectiveness of gastric bypass with procedures that are no longer performed (see other sections for comparisons with LAGB and DS-BPD) or did not meet the inclusion criteria for non-RCTs. In addition, Westling and Gustavsson[228] compared open versus laparoscopic GB, so was reviewed elsewhere.

Open gastric bypass

An additional search for single-arm studies of open GB found seven studies which met our inclusion criteria.[229-235] We focused the review on Roux-en-Y gastric bypass, as that is the commonest method performed in the UK. Details of the studies can be seen in Appendix 15. Any comparative studies comparing open gastric bypass with other included procedures were reviewed in the appropriate section.

Update searches identified one additional study.[236] Whilst the mean weight loss was within the range as reported above in the evidence statements, reoperation rates were considerably higher overall (27%). However, two techniques were used (silastic ring and, in the later cases, Fobi pouch) and the reoperation rates were 70% and 7% respectively. The reoperation rate for the newer technique is therefore within the range expected.

Weight loss

See evidence tables Appendix 15 and evidence statements Table 15.35.

Other outcomes

See evidence tables Appendix 15 and evidence statements Table 15.35.

Three studies reported details of reoperation rates:

- Reoperations were required because of suspicion of anastomotic leak in two patients (only one proved to have a leak), inadvertent removal of a gastrostomy tube (one patient) and small bowel obstruction (five patients).[230]
- Pories and coworkers[233] reported a reoperation rate of 2.8% (no details).
- Reoperation due to early and late complications was done in 12% of patients.[235]

In addition, Avinoah and coworkers[229] reported meat intolerance in over half of people and significant, but gradual, decreases in mean iron saturation, haemoglobin, and mean corpuscular volume. Mean vitamin B-12 levels declined significantly during the first four years but showed signs of improvement in the longer term. No significant change was seen in serum folic acid, and levels of serum albumin were normal throughout. People who took vitamin and mineral supplements had significantly higher mean values of vitamin B-12, folic acid and iron saturation than those who did not.

Balsiger and coworkers[230] reported a decrease in use of antihypertensive medication (36% to 16%), insulin (12% to < 1%), and anti-inflammatory medication (33% to 9%). Also, 93% of people were satisfied at 3 years after the gastric bypass, with early postprandial satiety in 84% of people and decreased appetite in 82%. Gastrointestinal events (such as constipation, heartburn, vomiting) were rare, but 22% of people reported diarrhoea at least once a week.

Csendes and coworkers[231] reported improvements in diabetes (resolved 100%), hyperlipidaemia (resolved 92.5%, improved 7.4%), hypertension (resolved 63.6%, improved 36.3%) and osteoarticular problems (resolved 73.3%, improved 26.6%). Quality of life was also much better with respect to self-esteem (81.6%),

work capacity (63.2%), sociability (52.9%), and physical capacity (83.9%), but for the majority, sexual activity remained as before the operation (42.5%). The final Bariatric Analysis and Reporting Outcome System (BAROS) index in 96.6% of people was very good or excellent.

Pories and coworkers[233] reported improvements in non-insulin-dependent diabetes mellitus or impaired glucose tolerance (IGT) (91% maintained normal fasting plasma glucose and HbA1c levels) and hypertension (58.1% to 14%). Also, improvements were almost always seen in cardiopulmonary function, sleep apnoea, snoring, asthma, peptic reflux, arthritis, fertility and mental health (including mood).

Schoepel and coworkers[234] reported improvements in diabetes (75%), hypertension (81%), GORD (86%), back pain (66%), arthritis (52%), sleeping problems (59%), skin rashes (67%), urinary incontinence (74%) and shortness of breath (92%). Over 90% of people showed an improvement in self-esteem, over 85% in physical activity and over 80% in social activity. Two-thirds of people increased their workload. Almost two-thirds reported an increase in sexual activity.

We were not able to get a complete full-text copy of the Torres paper,[235] so have reported only those outcomes as published in the TEC review[175].

Laparoscopic gastric bypass

An additional search for single-arm studies of laparoscopic gastric bypass found five studies which met our inclusion criteria.[237-241] We focused the review on Roux-en-Y gastric bypass, as that is the commonest method performed in the UK. Details of the studies can be seen in Appendix 15. Any comparative studies comparing laparoscopic gastric bypass with other included procedures are reviewed in the appropriate section.

No additional studies were identified in the Update searches.

Weight loss

See evidence tables (Appendix 15) and evidence statements (Table 15.35).

Other outcomes

See evidence tables (Appendix 15) and evidence statements (Table 15.35).

Reversal of the laparoscopic gastric bypass was reported in only one paper, and was done in only one patient (out of 1497 operations).[238] Revision for a leak at the jejunojejunostomy was also reported in one patient (out of 275).[239] Reoperation rates for indications including cholecystectomy and leaks also varied (median 1.8%, range 0.03–9.8%).

In addition, Schauer and coworkers[239] reported that 97% of people available to follow-up would choose laparoscopic gastric bypass again, if given the opportunity, and 95% of people reported an improvement in their quality of life. Also, improvements were seen in comorbidities such as diabetes (resolved 82%, improved 18%), hypercholesterolaemia (resolved 63%, improved 33%), osteoarthritis or degenerative joint disease (resolved 41%, improved 47%), GORD (resolved 72%, improved 24%), hypertension (resolved 70%, improved 18%), sleep apnoea (resolved 74%, improved 19%), hypertriglyceridaemia (resolved 57%, improved 29%), depression (resolved 8%, improved 47%), urinary incontinence (resolved 44%, improved 39%) and asthma (resolved 13%, improved 69%). Other conditions that either improved or resolved for the majority of people (although the numbers were small for some conditions) were peripheral oedema, migraine headaches, gout, coronary heart disease, chronic obstructive pulmonary disease, congestive heart failure and obesity hyperventilation syndrome. Venous insufficiency remained unchanged in 71% of people but improved in 29% of the seven people with this condition.

Schauer and coworkers[240] evaluated the effect of laparoscopic gastric bypass in people with impaired fasting glucose or type 2 diabetes. Improvements were seen in fasting plasma glucose and Hb1Ac (returned to normal levels 83%,

markedly improved 17%). Also, a significant reduction in use of oral antidiabetic agents (80%) and insulin (79%) was reported. People with the shortest duration of IGT or diabetes (< 5 years), the mildest form of type 2 diabetes (diet controlled), and the greatest weight loss after surgery were most likely to achieve complete resolution of their type 2 diabetes. Other improvements were seen in hypertension (resolved 36%, improved 53%), hypercholesterolaemia (resolved 37%, improved 41%), sleep apnoea (resolved 33%, improved 47%), symptoms of diabetic neuropathy (improved 50%) and erectile dysfunction (18%, although 82% were unchanged).

Wittgrove and Clark[241] reported improvements in GORD (resolved 98%), diabetes (resolved 98%, improved 2%) and hypertension (resolved 92%).

Laparoscopic versus open gastric bypass

This was primarily based on Colquitt and coworkers' Cochrane review.[174] Four RCTs were included.[228;242-244] Because there was a body of RCT evidence comparing these two procedures, we did not review lower level evidence, such as case series.

No additional studies were identified in the Update searches.

Weight loss

See evidence tables (Appendix 15) and evidence statements (Table 15.35)..

Other outcomes

See evidence tables (Appendix 15) and evidence statements (Table 15.35).

Malabsorptive/restrictive surgery

This review considered the evidence for the effectiveness of DS (with BPD) and was based primarily on the 2005 TEC review.[175]

One study comparing DS-BPD and Roux-en-Y gastric bypass was included[245] and seven single-arm studies (all included in the TEC review)[246-252]. One further

observational study has been published,[223] but did not meet the criterion of 150 participants: only 40 people underwent DS-BPD and 90 people Roux-en-Y gastric bypass.

No additional studies were identified in the Update searches.

Weight loss

See evidence tables (Appendix 15) and evidence statements (Table 15.35).

Other outcomes

See evidence tables (Appendix 15) and evidence statements (Table 15.35).

Revisions were reported in:

- 5.7% of patients to increase the length of the common channel.[246]
- 2.7% of patients to increase the length of the common limb due to malnutrition.[248]
- 3.8% of patients due to low protein and excess weight loss, excess diarrhoea, or poor weight loss. Also one reversal was reported due to patient demand.[249]
- 6.8% of patients for recurrent protein malnutrition.[250]

Overall reoperation rates also varied (median 3.9%, range 2.7–6.3%).

In addition, Anthone and coworkers[246] reported that no clinical sequelae occurred from hypocalcaemia or anaemia in patients who did not require revision of the length of the common channel. No evidence of hepatic dysfunction or liver failure was seen. No specific food intolerances were seen, and reported mean energy intake was 1600 calories (approximately 63% of preoperative intake).

Biron and coworkers[247] showed that, for people with an initial BMI less than 50 kg/m^2, a residual BMI of 35 kg/m^2 caused a significant drop in the degree of satisfaction from 90% to 40%. For super-obese people (BMI ≥ 50 kg/m^2), the

same critical point was found at a BMI of 40 kg/m^2 where satisfaction dropped from 91% to 57%.

Guedea and coworkers[248] reported that glycaemia, cholesterolaemia and triglyceridaemia resolved in 100% of people, and 82.4% stopped antihypertensive medication at 12 months. Sleep apnoea also resolved in 100% and osteoarthritis and difficulty in walking improved in 84%. Menstruation became regular in 100% of women. The results of the operation (using the BAROS classification) were assessed as either excellent or very good at 5 years by 66% of people.

Hess and Hess[249] reported normal blood sugar levels for 100% of people with diabetes prior to surgery. In a sample of 100, 9% required iron supplementation or surgery (for excessive uterine bleeding). Although alkaline phosphatase was elevated in a sample of 100 people, vitamin D levels were within the normal range although low. The authors stressed the need for adequate vitamin D and calcium supplementation.

Marinari and coworkers[250] reported that 3.5% of operations were classified as a failure, 11% were fair results, 22.8% good, 39.5% very good and 23.2% as excellent results using the BAROS classification.

Slater and coworkers[251] focused specifically on vitamin and calcium deficiencies following BPD. Generally, the incidence of deficiencies increased over time. By year 4, 48% of the participants were found to have low calcium levels (from 15% at year 1) and 63% had low levels of vitamin D (57% at year 1). Low vitamin A was found in 69% of participants at 4 years (52% at 1 year) and low vitamin K in 68% (51% at 1 year). However, the incidence of low levels of vitamin E or zinc did not increase over time (vitamin E 0% at 1 year, 4% at 4 years; zinc 51% at 1 year, 50% at 4 years). The authors recommended high levels of supplementation after such surgery, and highlighted the need for ‘long-term nutritional monitoring’.

Totte and coworkers[252] reported improvements in hypercholesterolaemia (resolved 100%), type 2 diabetes (resolved 100%), type 1 diabetes (improved 100%), hypertension (resolved 83.6%, improved 17.4%), hypertension and cardiomyopathy (improved 100%), Pickwickian syndrome (resolved 100%), respiratory insufficiency (resolved 82%, improved 18%), sleep apnoea (resolved 66.6%, improved 33.3%), severe arthritic pain (improved 100%) and depression (improved 85.6%).

Staged surgery

This review considered the evidence for the effectiveness of staged surgery in people with a BMI of 50 kg/m^2 or greater. Due to the limited evidence on this technique, no limitations on study duration or number of participants were imposed. Four relevant studies were identified.[253-256]

Arteaga and coworkers[253] examined the morbidity and mortality of a two-step approach to surgery (jejunoileal bypass, converted to a Roux-en-Y gastric bypass at 6–24 months). Regan and coworkers[256] described their experience of a two-stage gastric bypass (laparoscopic sleeve gastrectomy, followed by laparoscopic Roux-en-Y gastric bypass). Milone and coworkers[254] compared laparoscopic sleeve gastrectomy and intragastric gastric balloon as a first stage procedure, before conversion to DS-BPD. However, these authors only reported results for the initial stage, so this study is not considered further in this review. Similarly, although Nguyen and coworkers[255] described the use of a staged procedure (modified Roux-en-Y gastric bypass, followed by completion of the sleeve gastrectomy), no results were reported so the study was excluded.

No additional studies were identified in the Update searches.

Weight loss

Arteaga and coworkers[253] reported weight loss of approximately 53.4 kg (n = 20/24) after the first stage of surgery (mean follow-up of 14.1 months). Mean BMI decreased from 63.0 to 46.9, and excess weight loss was 44.3%. Of the

eight people who went on to have the second stage surgery, mean total weight loss was 80.0 kg and excess weight loss 62%.

Of the seven patients who underwent surgery in Regan and coworkers' study,[256] mean weight loss was 36 kg after stage one (mean follow-up 11 months), and 55 kg in total after stage two (mean follow-up 2.5 months, n = 6/7). Mean BMI decreased from 63 kg/m^2 to 50 kg/m^2, and then to 44 kg/m^2 at each stage. Excess weight loss was 33% and 46%, respectively.

Other outcomes

Complication rates were:

- for stage one – 8.3% for major complications and no deaths. At stage two, one major complication (12.5%) and no deaths. Overall, the complication rate was 9.4%[253]
- 35.7% for overall complications, and no deaths.[256]

No quality of life or other outcomes were reported in either study.

15.3.5.3 Evidence review on competencies and training for bariatric surgery

A recently published evidence-based guideline was identified that made recommendations on the competencies and skills required of surgeons undertaking bariatric surgery.[257] Graded recommendations were that:

- 'All surgeons performing obesity surgery should have an adequate technical expertise (based on high quality evidence).
- S/he should be a qualified and certified general or gastrointestinal surgeon with additional training in obesity surgery (based on medium quality evidence).

- Technical expertise in laparoscopic surgery alone is insufficient to start a bariatric surgery programme (based on medium quality evidence).'

Learning curve and the effect on operative outcomes

We identified several papers on the effect of the learning curve for our procedures of interest. Inclusion criteria for this review were as for the other surgical reviews (see above), except that no study duration was defined. Also the effect of the learning curve had to be the focus of the study, or a comparison of initial and the later operations had to be reported.

Seven studies were identified: five on laparoscopic gastric bypass,[237;258-261] one on laparoscopic and open gastric bypass,[262] and one on laparoscopic adjustable gastric banding.[263] No additional studies were identified in the Update searches. Results from the five studies on laparoscopic gastric bypass were as follows.

Ballesta-Lopez and coworkers[237] analysed a consecutive series of 600 patients to determine problems that arise during the learning curve. The rate plateau of morbidity and mortality (no details reported) was reached after the first 18 patients when the surgical technique was revised and fully standardised. The authors concluded that although the complication rate plateau is often cited as 75–100 operations, this could be lower if adequate training was provided.

Kligman and coworkers[258] reported results of the initial 160 consecutive patients undergoing laparoscopic gastric bypass by a single surgeon over a 24-month period. Patients were divided into quartiles for data analysis. Duration of surgery decreased significantly between quartiles ($p < 0.01$). However, the conversion rate (3.1%) and mean hospital length of stay (2.1 ± 2.4 days) were unaffected by surgeon experience. In addition, the complication rates did not change statistically between quartiles. The authors suggested that throughout the learning curve laparoscopic gastric bypass could be accomplished with acceptable complication rates, conversion rates and hospital length of stay, and that the duration of surgery decreases with experience.

Oliak and coworkers[259] aimed to determine the length of the learning curve for a skilled laparoscopic surgeon. The study population consisted of the first 225 consecutive laparoscopic gastric banding procedures attempted by one laparoscopic surgeon. The average operative time decreased (from 189 minutes in the first 75 patients to 125 minutes in the last 75 patients). Most of the improvement in operative time occurred over the first 75 patients. The perioperative complication rate decreased (from 32% in the first 75 patients to 15% in the second and third groups of 75 patients). Complication rates did not significantly decrease after the first 75 patients. Low mortality and conversion rates were achieved early in the series. The authors concluded that low mortality rates and low conversion rates could be achieved early in the learning curve. Complication rates plateaued after approximately 75 operations, and operative times decreased substantially over the initial 75 cases. Operative times continued to decrease at a slower rate beyond the initial 75 cases.

Schauer and coworkers[260] determined the effect of operative experience on outcomes in the first 150 consecutive patients. The patients were divided into three groups (1, 2 and 3) of 50 consecutive patients, and outcomes for each group were compared. The patients in group 3 had a larger BMI ($p < 0.05$), were more likely to have had prior abdominal surgery, and were more likely to have secondary operations at the time of gastric bypass. The operating time decreased (from a mean of 311 minutes in group 1 to 237minutes in group 3), and technical complications were reduced by 50% after 100 cases. The authors concluded that operative time and technically related complications decreased with operative experience even though heavier patients and higher-risk patients were more predominant in the third group.

Shikora and coworkers[261] evaluated technical experience and patient volume on complication rates in the first 750 consecutive patients. For the first 100 cases, the overall complication rate was 26% with a mortality of 1%. This complication rate decreased to approximately 13% and was stable for the next 650 patients (11% to 13.4%). Complications possibly related to technique decreased (trocar

site wound infection 8% to 2%, splenic injury 1% to 0%, bowel obstruction 5% to 0%, GI track leak 3% to 0%), while others (such as intraluminal bleeding, thromboembolism, anastomotic stricture) remained approximately the same. The overall mean operating time was 138 minutes (range, 65–310 minutes). It decreased from 212 minutes for the first 100 cases to 132 minutes for the next 650 and 105 minutes (range, 65–200 minutes) for the last 100 cases. The authors concluded that morbidity and mortality could be reduced by up to 50% with experience.

Ballantyne 2005[262] compared learning curves for three surgeons in terms of surgical time for laparoscopic gastric bypass and open gastric bypass. Median time for the first surgeon reduced for each subsequent 100 operations: (175 minutes, 125 minutes, 110 minutes, and 100 minutes resp). Median time for second surgeon was 120 minutes overall, and for the third surgeon 173 minutes. The length of surgery significantly correlated with surgical experience in terms of numbers of operations and the BMI of patient. The authors concluded that the length of surgery continued to shorten beyond 400 operations for the first surgeon. Previous fellowship training in laparoscopic gastric bypass shortened surgical times during the initial clinical experience as an attending for the second surgeon.

Weiner and coworkers[263] evaluated the outcomes of the first 100 patients and the total number of 984 patients undergoing LAGB. All complications were seen during the first 100 procedures. During the learning curve, more band removals were performed (6/100 compared with 7/884), migration was higher (1/100 compared with 2/884), slippages were higher (12/100 compared with 32/884) and port revisions were higher (3/100 compared with 11/884).

Training and the effect on operative outcomes

We identified only one paper on the effect of the training on our procedures of interest. Inclusion criteria for this review were as for the other surgical reviews (see above), except that no study duration was defined. No additional studies were identified in the Update searches.

Kothari and coworkers[264] reported on the outcomes of laparoscopic gastric bypass following completion of an advance laparoscopic fellowship. Outcomes were measured prospectively and analysed by different time quartiles to assess the effect of the training. Upon quartile analysis, there was no difference in complication rates, and the complication rates were comparable to published outcomes in the literature. The authors concluded that fellowships in advanced laparoscopy with emphasis on laparoscopic gastric bypass provided the optimal training environment for the acquisition of necessary skills. With fellowship training, complication rates were comparable to published outcomes in the literature without a period of higher complications (the learning curve).

15.3.5.4 Evidence review on hospital and surgeon volume and surgical outcomes

Inclusion criteria for this review were as for the other surgical reviews (see above), except that no study duration was defined. Also the effect of the volume of operations had to be the focus of the study. Three relevant studies were identified.[265-267] No additional studies were identified in the Update searches.

Courcoulas and coworkers[265] explored the volume–outcome relation for gastric bypass surgery. They analysed 4685 cases of gastric bypass surgery for obesity, undertaken between 1999 and 2001. Statistical modelling techniques were used to determine whether mortality or the adverse outcome rate was significantly related to hospital and surgeon volume. Outcomes were adjusted for risk factors such as age, gender, comorbidities and others. There was a significant risk-adjusted relation between surgeon volume and adverse outcome (postoperative complications, non-routine hospital transfers), and the same trend was observed for deaths. Surgeons who performed fewer than 10 procedures per year had a 28% risk of adverse outcome and a 5% risk of death, compared with 14% ($p < 0.05$) and 0.3% ($p = 0.06$), respectively, for high-volume surgeons. The effect of hospital volume did not reach statistical significance, but there was an interaction between surgeon and hospital volume. Surgeons who performed 10–50 cases per year operating in low-volume hospitals had a 55% risk of adverse

outcome ($p < 0.01$). The authors concluded that risk-adjusted in-hospital adverse outcome was significantly lower when gastric bypass is performed by higher-volume surgeons.

Flum and coworkers[266] evaluated the risk of early mortality of patients undergoing bariatric surgery. A retrospective cohort study of16,155 Medicare patients undergoing bariatric procedures (mean age 47.7 years, 75.8% women) was conducted. The rate of 30-day, 90-day and 1-year mortality was 2.0%, 2.8% and 4.6%, respectively. The odds of death at 90 days were 1.6 times higher (95% CI 1.3 to 2.0) for patients of surgeons with less than the median surgical volume of bariatric procedures (among Medicare beneficiaries during the study period) after adjusting for age, gender and comorbidity index. The authors concluded that the risk of early death after bariatric surgery was considerably higher overall than previously suggested and associated with lower surgeon volume of bariatric procedures. Other associations with early death were advancing age and male sex.

Nguyen and coworkers[267] examined the effect of hospital volume on morbidity, mortality and costs in academic centres. All patients who underwent Roux-en-Y gastric bypass were included (n = 24,166). There were 22 high-volume (n = 13,810), 27 medium-volume (n = 7634), and 44 low-volume (n = 722) hospitals included in the study. Compared with low-volume hospitals, patients who underwent gastric bypass at high-volume hospitals had a shorter length of hospital stay (3.8 vs 5.1 days, $p < 0.01$), lower overall complications (10.2% vs 14.5%, $p < 0.01$), lower complications of medical care (7.8% vs 10.8%, $p < 0.01$), and lower costs ($10,292 vs $13,908, $p < 0.01$). The expected mortality rate (adjusted for severity) was similar between high- and low-volume hospitals (0.6% vs 0.6%,), demonstrating similarities in characteristics and severity of illness between groups. The observed mortality, however, was significantly lower at high-volume hospitals (0.3% vs 1.2%, $p < 0.01$). In a subset of patients older than 55 years, the observed mortality was 0.9% at high-volume centres compared with 3.1% at low-volume centres ($p < 0.01$). The authors concluded that bariatric

surgery performed at hospitals with more than 100 cases annually was associated with a shorter length of stay, lower morbidity and mortality and decreased costs. This volume–outcome relation was even more pronounced for a subset of patients older than 55 years, for whom in-hospital mortality was three-fold higher at low-volume compared with high-volume hospitals. High-volume hospitals also had a lower rate of overall postoperative and medical care complications, which may have been related in part, to the formalisation of the structures and processes of care.

15.3.5.5 Summary of previous NICE Technology Appraisal – surgery

Surgical Interventions

The Technological Appraisal Guidance- No.46: Guidance on the use of surgery to aid weight reduction for people with morbid obesity (2002) defined people as being morbidly obese if they have a BMI either equal or greater than 40kg/m², or between 35kg/m² and 40kg/m² in the presence of significant co-morbid conditions that could be improved by weight loss. This guideline also recommends surgical intervention as a first line option for people with BMI equal to or greater than 50kg/m² (NICE 1.2.6.7).

The Technological Appraisal Guidance- No.46: Guidance on the use of surgery to aid weight reduction for people with morbid obesity (2002) recommends that choice of intervention should be based upon best available evidence, facilities and equipment available, and experience of the surgeon who would perform the operation. This guideline concurs with this but additionally would include the degree of obesity and the presence of any comorbidities. (NICE 1.2.6.3, full guideline 1.7.6.3).

The Technological Appraisal Guidance- No.46: Guidance on the use of surgery to aid weight reduction for people with morbid obesity (2002) recommended that databases should be established by hospitals wanting to develop their service, to enable outcomes to be monitored in both the short term and the long term. This guideline recommends making arrangements for prospective audits to monitor

outcomes both in the short term and the long term (NICE 1.2.6.5, full guideline 1.7.6.5).

See also Section 6 for the detailed health economic modelling.

15.3.6 Evidence review on referral to specialist care for adults and mature adolescents

In February 2005, the National Guideline Clearinghouse synthesised the recommendations on the assessment and treatment of obesity and overweight in adults from six published guidelines.[1]

There was only one specific set of recommendations on referral (Table 15.36).

Table 15.36 Recommendation on referral

Singapore Ministry of Health (2004)	The presence of depression and binge-eating disorders in obese patients must be evaluated for, with appropriate referral for psychiatric treatment (grade B, level IIa)

The NHMRC[2] recommended that when single-gene mutation obesity is confirmed, the patient should be referred to a specialist who deals with these problems (level B). Reasons for referral from primary to secondary care may include:

- the view that morbid obesity is a condition that cannot be managed effectively in primary care
- failure of conventional treatment or
- for assessment for the suitability for pharmacological treatment.

Most of these referrals would be to registered dietitians, private sector slimming organisations, physicians, community-based programmes/self-help groups, trained exercise specialists or bariatric surgeons. People would normally be

referred from secondary to tertiary care if long-term conventional and pharmacological treatment had failed and if they met the eligibility criteria for surgery.[268]

Due to the lack of evidence in this area, the GDG discussed the role of secondary and tertiary care for people with obesity. Key roles for specialist services were considered to be:

- the assessment of possible causes of severe obesity, including genetic causes, medication for other conditions, rare neurologic/metabolic conditions
- the assessment of people with complex disease states and/or complex needs.

Specialist clinics or services were also considered to be the most appropriate setting for:

- trialling new drugs or using older drugs in novel ways (such as off licence or new combinations)
- pushing the boundaries of management, such as specialised diets
- deciding on treatment (drug or surgery) for people with a BMI greater than 40 kg/m^2
- providing a higher level of care than available in primary or general secondary care
- providing leadership, education and being a source of reference and information for primary or general secondary care.

In the experience of the GDG, people were most often referred to specialist services if:

- BMI was greater than 40 kg/m^2
- treatment in primary care or general secondary care had failed

- the obesity or causes were considered ‘unusual’, and therefore may be of research interest.

No additional studies were identified in the Update searches.

15.3.7 Interventions in a UK clinical setting

The following review was presented to the GDG to inform any recommendations about the delivery of care. The GDG considered that no recommendations could be made based on the available evidence. Therefore, the review is presented here for completeness only.

15.3.7.1 Evidence statements (Table 15.37)

Table 15.37 Evidence statements and grading

No.	Evidence statement	Grade
1	Weight loss of approximately 2.9 kg can be achieved (in people who attend) through dietary advice given every month for four sessions by a dietitian in an outpatient clinic (n = 1)	1–
2	Structured, multifaceted approaches to obesity management in primary care can improve process outcomes, such as recording of data, and increase the number of times weight is discussed in the consultation (n = 2)	1+
3	The Counterweight programme (structured, multifaceted approach) in primary care may be effective in producing clinically significant weight loss in around a third of participants. However, another study evaluating a similar approach found no significant effect on weight. (n = 2)	As above
4	Training of healthcare professionals is an important component of any structured, multifaceted intervention. However, intensive training (6–8 hours), with continued support from dedicated nutritionists, appears to be more effective that training (4.5 hours) alone	As above

15.3.7.2 Evidence review on interventions delivered in a UK clinical setting

This review aims to provide corroborative evidence from the UK on the effectiveness of any intervention designed to address the management of

overweight or obesity in adults and children. The inclusion criteria were as follows:

- **Interventions:** Any intervention which targeted providers' management of obesity and aimed to improve provider practice or patient outcomes or target the individual (such as diet, physical activity). Only studies conducted in the UK were included.
- **Setting**: Only those interventions conducted in a clinical setting are included. Other settings are covered in other evidence reviews.
- **Participants**: All qualified healthcare professionals involved in the management of obesity and/or all individuals classified as overweight or obese (mean initial BMI ≥ 28 kg/m^2 for adults).
- **Outcomes**: Studies reporting weight, diet or physical activity outcomes were included provided that baseline and follow-up data were provided.
- **Length of follow-up**: At least 12 weeks duration. Length of follow-up was measured from commencement of the intervention.
- **Study design**: Only studies with a control or comparison group were included.

Excluded studies are listed in Appendix 16.

The Centre for Reviews and Dissemination (CRD) review on non-clinical settings was cross-referenced, as were other relevant reviews. Excluded references from the intervention reviews were also reassessed for inclusion.

Interventions for the management of obesity and overweight in children

We identified nine studies that could be potentially relevant for this review, although only one of these presented a control/comparison group. However, this study was excluded on the basis of the date of its publication (1971) and therefore being of little relevance to services as they exist currently.[269] We also

identified two informative papers that evaluated the WATCH IT programme[270] in Leeds, and the role of physiotherapists in combating childhood obesity in England.[271] However, none of the identified papers met our inclusion criteria (see Appendix 16).

Interventions targeted at individuals (adults)

Two studies were identified that assessed the effect of an intervention targeted at the individual patient in a clinical setting.[272;273] One study compared the effect of a low-fat (reduced fat intake by 10%) high complex carbohydrate diet, low-fat high simple carbohydrate diet and control (maintenance of fat intake at habitual amounts of approximately 35–40% of energy) in people with at least three identified risk factors for metabolic syndrome (note: however, overweight or obesity was not a requirement). At least 60% of total energy intake was provided free from the study grocery shop. Participants collected their food once or twice a week from the shop, where they could also discuss their energy and macronutrient intakes with the dietitian.[272] This intervention did not appear to be a pragmatic and implementable approach to weight loss, so the results were not reported in this review.

One small (under-powered), quasi-randomised controlled trial[273] compared a 500 kcal deficit diet and a health eating diet (based on the 'Balance of good health') in adults referred to a dietetic department for weight loss. Participants were invited to four sessions with a dietitian. held at 4-weekly intervals. Both groups lost, on average, clinically significant amounts of body weight by 12 weeks. However, the dropout rate for both groups was high (69% overall at 12 weeks).

Complex interventions targeted at healthcare professionals

Two trials were identified the evaluated the effectiveness of implementing programmes for the management of obesity and overweight. Both trials were conducted in primary care and involved elements of training, process and organisational change, and combined lifestyle interventions.

Moore and colleagues evaluated a training programme designed to improve the management of obesity delivered by primary care teams.[274] The programme included several components:

- **A nutrition training programme**: This was delivered in three 90-minute sessions, at intervals of no less that 1 week, and no more than 2 weeks apart. All GPs and practice nurses were invited. The training was delivered by four dietitians trained in the standardised delivery of the programme. A model approach was promoted, which included best practice, and was brief enough to be delivered in primary care. Primary care teams then devised individualised weight management protocols to implement in their practice. Practitioners were given a 'ready reckoner' to calculate the appropriate caloric intake for individuals.

- **Model of management**: Practitioners were expected to see patients approximately every 2 weeks until they lost 10% of initial body weight and then approximately every 1–2 months to support weight maintenance. Current and target weight and dietary and activity targets were to be recorded in the patient records. This was to facilitate the continuity of support from the practice team.

- **Lifestyle information for patients**: This included information on the clinical benefit of weight loss, and effective interventions, including reducing energy intake, increasing physical activity, and the use of obesity drugs. A 500 kcal/day deficit diet was recommended, and diet sheets and other written resources were provided.

Control practices were asked to provide usual care. Consecutively attending adults, aged 16–64 with a BMI of 30 kg/m^2 or over, were asked to participate.

At 12 months, there was no difference between the intervention and control group patients with regard to weight (mean weight change +0.3 kg intervention vs –0.7 kg control, p = 0.5), but some improvements were seen in practitioner

knowledge, the likelihood of weight being discussed in the consultation, and the recording of weight, target weight and dietary targets.

The authors noted limitations of the study: mainly female participants, skewed towards extreme obesity (mean BMI approximately 37 kg/m^2 overall), high dropout rate (although the study remained 80% powered).

Another study aimed to evaluate the effectiveness of the Counterweight Programme in improving the management of obesity in primary care using a structured approach.[275;276] The programme is based on the evidence-based quality assessment cycle and is in four phases.

- **Phase 1 Audit and project development** – **setting priorities**: The aim of the audit was to determine current approaches. Data were collected on weight screening rates, availability of equipment and patient education materials, and the current organisation of care. Also, baseline attitudes, knowledge, confidence and willingness to treat of the GPs and practice nurses were assessed. The health burden of obesity for each practice was also measured.

- **Phase 2 Practice training and support** – **setting guidelines**: Audit results were fed back in a 1-hour workshop with the GPs and practice nurses, and the treatment pathway and priorities for implementation were also discussed. The role of the GP was identify suitable patients for management during routine clinical practice, and to refer on to the practice nurses. GPs were expected to raise weight as an issue as appropriate and to possibly discuss the benefit of a 5–10% weight loss. A desk-top flip chart was provided to facilitate patient screening and the assessment of motivation. The GP intervention was designed to be opportunistic and of 1–5 minutes duration. A 6–8-hour training programme was designed to teach core competencies to practice nurses. A structured approach was used to cover topics such as screening and assessment, principles of healthy eating and energy balance, dietary approaches to weight management, physical activity guidelines, behaviour change strategies, pharmacotherapy, patient monitoring and ethical

considerations. Training manuals were provided to support formal workshops. Guidance was also provided on the use of Counterweight Programme patient education materials. A variety of teaching methods were used, including problem-based learning through case studies, group discussion and practical exercises in line with adult learning theory. A weight management adviser (a state registered dietitian with specialist experience) worked with the practice nurse once or twice a month to facilitate clinics and patient groups. After 6 months, the weight management adviser was mainly involved in data collection and training new practice nurses.

- **Phase 3 Patient intervention** – **measuring performance**: Weight loss targets were set at 5–10% of initial body weight. Patient screening and treatment pathways were developed. Theoretical approaches were used for both changing clinical and patient behaviour. For example, the screening pathway encouraged clinicians to consider stages of change of the individual patient. The screening pathway was designed to target those at highest risk (BMI ≥ 30 kg/m^2 or BMI ≥ 28 kg/m^2 with comorbidities). The treatment pathway suggested a 3-month minimum lifestyle intervention (either in group or individual formats) as the first line approach. Practice nurses were encouraged to see individual patients for six appointments (10–30 minutes each) over the 3-month period, or for six group sessions of 1 hour. Quarterly follow-up appointments were recommended, where treatment and weight loss were reviewed. At 3 months, people who had lost ≥ 5% were recommended to continue with the lifestyle approach, whereas those had not were considered for alternative lifestyle interventions, pharmacotherapy or referral to a dietitian. Additional options were dependent on local obesity policies and services. If 10% of initial body weight was lost, weight maintenance was advised. Relapse prevention was discussed and weight check appointments offered at least quarterly.

- **Phase 4 Evaluation** – **improving performance (back to Phase 1)**: Evaluation (in the form of an RCT) is currently ongoing.

Theoretical approaches to changing practice have been employed to design multifaceted interventions targeting barriers to change (see Table 15.38). Control practices were audited but received no further intervention other than feedback of the audit results.

The trial is currently ongoing and is due to report full results soon. Interim results show however that for those participants who have data at 12 months, that the mean weight change was –3.2 kg (n = 445), and that 32.6% reached greater than 5% weight loss from baseline. One in six people entering the programme achieved a 5% weight loss or more (ITT analysis) at 12 months.[247]

The different interventions used can be seen in Figure 15.32.

Table 15.38 Theoretical approaches to changing clinical practice and Counterweight strategies[247] - see paper for full details

Approach	Counterweight strategy
Internal	
Educational	• Local Counterweight Steering groups established • Use of practice-based training in small interactive groups • Use of case studies, cofacilitating clinics and patient groups
Epidemiological	• Development of treatment pathway consistent with evidence-based obesity guidelines • Counterweight newsletter, practice meetings
Marketing	• Audit and needs assessment, setting practice priorities • Regular feedback
External	
Behavioural	• Baseline audit, regular feedback • Patient recall letters and flagging of notes
Social interaction	• Practice meetings • Cofacilitation of clinics and groups • Local consultant lead • Involvement of key PCT leads
Organisational	• Monitoring and feedback of outcomes • Use of screening and treatment guidelines, group programme
Coercive	• NSFs for CHD and diabetes • NICE guidelines for orlistat and sibutramine • Local HIMPs

Figure 15.32 Proportion of individuals reaching 12 months allocated treatment types over the 12 months[247] (adapted)

Intervention	Percentage of patients allocated over 12 months (n=446)

One-to-one intervention	61%
Group intervention	30%
One-to-one and group intervention	5%
Pharmacotherapy	22%
Dietitian	7%
Exercise referral	8%
Commercial	5%
Weight maintenance	16%
Secondary care	0%

15.3.8 Patients' and healthcare professionals' views and attitudes to the management of overweight or obesity

To inform the development of recommendations relating to patient-centred care, we reviewed evidence on barriers to change and attitudes in the clinical setting (specifically the consultation) reported by healthcare professionals and/or individuals who were overweight or obese.

- **Types of study**: Those that assessed barriers and attitudes (individual/HCP/family/carer/other) to the management of weight **in the clinical setting**. In addition, qualitative studies identifying barriers/motivation to management of overweight/obesity (focus groups, interviews, surveys). Barriers and attitudes had to be identified by participants themselves, not presupposed by researchers, and were restricted to studies from the UK.

- **Types of participant**: (i) Healthcare professionals such as GPs, practice nurses, dietitians and health visitors; (ii) family/carers of obese and/or overweight adults, adolescents, and children; and (iii) obese and/or overweight adults, adolescents, children, and their parents.

We identified two published studies that explored this topic in children and adolescents.

- Types of outcome: participants' views on the management of weight **in the clinical setting**.

General practices are important in the management of overweight and obese people as they are frequently the first access point to care. Approximately 75% of the population see their GP during a year, and about 90% in 5 years.[277] Patients are then seen by a GP directly because of overweight or obesity, associated comorbidities or some condition that is not connected to weight. Thus, GPs, practice nurses, dietitians and health visitors can play a major role in helping people with weight problems.

This review aims to outline and clarify barriers and attitudes to the management of weight in a clinical setting that are felt to exist by healthcare professionals, patient and family/carers.

15.3.8.1 Healthcare professionals' views in primary care

(See also Section 1, Chapter 3 section 3.5.)

Owen[278] conducted a study via focus groups interviews (based on semi-structured questions) among five groups of healthcare professionals (GPs, dietitians, practice nurses, health visitors and school nurses). The findings echoed those of the National Audit Office,[268] calling for a multidisciplinary training and activity programme to be implemented across Wales to ensure healthcare professionals know what advice should be given for weight management.

Despite this call for training, it is frequently unfeasible, as practitioners have expressed their uncertainty of being able to devote so much time for indepth training.[274]

Hankey and coworkers[279] conducted a study on the attitudes, beliefs and eating habits of health professionals with respect to obesity, nutrition and weight management. This study consisted of a postal questionnaire survey of 1400 GPs, 613 practice nurses and 360 practice dietitians who were members of the British Dietetic Association in Scotland. The overall response rate was 65%.

This survey showed that there were discrepancies between professional groups with regard to knowledge of obesity, nutrition and weight management. One

example was the disagreement around the role of fat and sugar in increasing obesity. Nearly half of the GPs and 38% of the practice nurses answered incorrectly, whereas 75% of the dietitians correctly answered that fat was the most enhancing factor. Also, almost 65% of all GPs, practice nurses and dietitians believed that people can adhere to an 800–1200 kcal/day diet without weight loss. Knowledge on the measurement of waist circumference appeared to be weakly understood.[279]

Overall this study demonstrated that health professionals had gaps in their knowledge of nutrition and obesity management, which could create misleading advice. Also, the majority of the respondents felt that weight management advice should be given by professionals with specific training. Practice nurses reported feeling unskilled in regard to giving weight management advice, but many mentioned not having available time to undertake specific training.[279]

In a similar study, Mercer and Tessier[280] carried out interviews with GPs and practice nurses within the Greater Glasgow Healthboard area. Of 30 GPs and 30 practice nurses who were contacted, 10 GPs and 10 practice nurses agreed to be interviewed. The majority of interviews showed that weight management was an unpopular task, with the GPs preferring to delegate it to the practice nurse. This thus created the feeling in practice nurses of patients being 'off-loaded' on them. Another issue raised by GPs and practice nurses was a sense of frustration derived from patients' lack of motivation or lack of success of attempted interventions. Guidelines were also revealed not to be frequently used among GPs, and GPs felt that the Scottish Intercollegiate Guidelines Network (SIGN) was over-promoting the use of slimming pills.[280]

This issue of GPs asserting that treating obesity was not within their professional domain, and that management obesity should chiefly be the responsibility of the patient, arose clearly in a study conducted by Epstein and Ogden[281] and also in a study by Ogden and coworkers[282] Epstein and Ogden[281] conducted semi-structured interviews with 21 GPs (130 GPs were invited to participate) working

in an inner London primary care trust. The GPs claimed that patients tended to see obesity as medical problem, which should be managed by the doctor. According to the authors, this contradiction was then hard to balance with the GPs' lack of faith in the effectiveness of existing treatments, and the urge to ensure good patient–doctor relationships. The second study[282] consisted of a cross-sectional survey with comparisons of models of obesity made between GPs and patients. Questionnaires were completed by 89 GPs and 599 patients. Findings showed that patients pointed out internal uncontrollable causes for the onset of obesity, although would rely on external factors to treat it. On the other hand, GPs blended in cause and solution to internal factors that resided in the patient.

The studies therefore show consistently that GPs and patients have different views. GPs would prefer patient-based interventions in primary care with regard to obesity management, and patients would opt for a professionally led approach.

To briefly summarise the debate on what can hinder or influence the practice of healthcare professionals in primary care, Maryon-Davis[277] enumerated the most commonly reported barriers to effective treatment in this particular clinical setting:

- psychological complexities of cases
- high rate of relapse
- perceived lack of effective interventions
- lack of time
- lack of resources
- lack of onward referral options.

15.3.8.2 Practice nurses' and health visitors' views of managing overweight and/or obesity

Green and coworkers[283] aimed to examine health visitors and practice nurses knowledge regarding the assessment and management of obesity through a postal questionnaire sent to 35 health visitors and 49 practice nurses based at 24 practices within one regional health authority. The questionnaire assessed knowledge concerning diet, behavioural techniques and physical activity regarding obesity management, and was completed and returned by 17 health visitors and 28 practice nurses.

Several respondents were unclear on how to calculate or interpret BMI, and were unaware that a high central fat distribution was linked with greater risk of health problems associated with obesity. In most cases, dietary advice did follow current recommendations, as recommending a low-fat diet, although in some cases this did not occur, as advice would be to follow a reduced carbohydrate diet. Advice on physical activity also varied in quality and quantity. Few respondents mentioned tailoring either dietary or physical activity to cultural or socioeconomic needs.[283]

Similarly in another study,[284] many respondents felt that the advice they gave was useful but was only followed sometimes by patients, and that the responsibility lay with the patients.

Ogden and Hoppe[284] studied ways of improving practice nurses' management of obesity. This was attempted by having practice nurses complete a questionnaire regarding their obesity-related beliefs and behaviours, before and 1 month after being randomly assigned to a 'learner-centred' group (which received a leaflet and was asked to attend an interactive seminar), or 'expert' group (which received a leaflet), or a control group.

The intervention itself did not have any effect on practice nurses' beliefs about obesity, and no effects on the patients' weight. Nevertheless, practice nurses in the 'learner' group reported spending more time on their consultations and being

more patient centred, with the result of having patients more satisfied with the consultation. On the other hand, practice nurses in the 'expert' group reported that they gave advice more frequently and were less patient centred, resulting in an increase in patients' confidence in achieving weight loss.[284]

15.3.8.3 Dietitians' views of managing overweight and/or obesity

Harvey and coworkers[285] explored the role of the level of severity (obese vs overweight) on the perceptions of dietitians towards overweight and obese people, and how their views interacted with their practice. For this, they randomly selected 210 dietitian members of the British Dietetic Association, with a further 68 questionnaires given to dietitians who worked in a clinical capacity. One hundred and fifty-eight were returned from the postal survey and 29 returned by the extra group. The questionnaire explored topics such as causes for overweight and obesity, attitudes, responsibility of those who are obese or overweight, the reported practices of dietitians, and the association between views and practice.

The results showed that attitudes towards overweight and obese people were neutral to positive, although overweight people were rated more positively than those who were obese. Dietitians also perceived obese people as being more responsible for their excess weight than those who were overweight. Interestingly, greater merit was perceived in treating obese rather than overweight people.[285]

15.3.8.4 Patients'/clients' views on the management of obesity

Tod and Lacey[286] conducted a qualitative research project that outlined factors that encouraged or hindered overweight people from low-income groups accessing weight loss services. They recruited 16 people from the South Yorkshire Coalfields Health Action Zone, who attended Slimming World (a slimming club). Semi-structured interviews were conducted with all participants. Despite the sample size and lack of generalisability of this study, some themes emerged.

The main triggers that encouraged people to take action were embarrassment and humiliation, health-related problems or warnings, fear, and critical events such as holidays, weddings or birthdays. Main barriers reported related to issues of denial of their weight and a previous bad experience (such as being the biggest in the group, previous failure, public weighing). The authors contended that, as the experience of being overweight and obese adds frailty and vulnerability, and the triggers to take action are somehow distressing, services should be encouraged to have the adequate level of motivational support.[286]

Barker and Cooke[287] also looked at the perspectives of those who were overweight, obese or in the process of losing weight, by conducting one-to-one interviews and qualitative discussion groups. Those who were defined as overweight had a BMI ranging from 25 kg/m^2 to 29 kg/m^2; and those defined as obese had a BMI of 30 kg/m^2 or more. Slimmers were defined as someone who had been overweight in the last 2 years and had lost at least 6 kg and maintained that loss for at least 6 months. The study addressed issues ranging from perceptions of being overweight to reasons to be overweight, and the strategies that could be undertaken to lose weight.

Most relevant barriers were related to people being unclear about the benefits of weight reduction, and the extreme sacrifices that represented being on a diet which meant having to give up certain pleasures. This then had an effect of inducing long delays in initiating diets.[287]

15.3.8.5 Family/parents' views on the management of obesity

Edmunds[288] explored, through indepth interviews, parental perceptions of help-seeking experiences with healthcare professionals in central and south-west England. The children were aged from 4 to 15 years, and volunteers were recruited through healthcare professionals, posters in primary care settings and advertising in local papers. Children who attended weight loss groups were also recruited. Included in the weight history components of the interview were standardised shapes of children.

Parents were generally quite positive in their responses regarding healthcare professionals, although a diverse range of responses were reported when they sought child weight management help. The authors suggested that such a finding could be due to the healthcare professional's concern in not adding further distress to either parent or child, or simply not knowing in which way to help. Again, there appeared to be a tendency for healthcare professionals to leave weight as an individual responsibility and for blaming the parent for the child being overweight.[288]

15.3.9 Role of professionally organised therapies in the management of overweight and obesity

The following review was presented to the GDG to inform any recommendations about the use of 'alternative' or 'complementary' therapies. The GDG considered that no recommendations could be made based on the available evidence. Therefore, the review is presented here for completeness only.

15.3.9.1 Evidence statements (Table 15.39)

Table 15.39 Evidence statement and grading

No.	Evidence statement	Grade
1	There is little convincing evidence to support the use of complementary therapies in weight loss and/or maintenance in adults.	1++

15.3.9.2 Evidence review on professionally organised therapies

Professionally organised therapies as defined by the House of Commons are: acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy. We found one high-quality systematic review that was both comprehensive and recent.[289] This paper, published by Pittler and Ernst in 2005, aimed to review complementary therapies for reducing body weight, and included six systematic reviews and meta-analyses based on RCTs and 25 additional RCTs. Only one of the included RCTs was eligible for inclusion against our established criteria for

treatment and follow-up duration of a minimum of 12 months for adults, reporting an 18-month trial. No studies on the effectiveness of these therapies on children or adolescents were retrieved. Furthermore, no studies on the effectiveness of chiropractic or osteopathy in the treatment of obesity were found.

Acupuncture/acupressure

Pittler and Ernst referred to one systematic review that included four sham controlled RCTs.[290] Two of the trials reported a decrease in hunger, and the other two did not report any difference in body weight compared with the sham acupuncture. The review concluded that the effect of acupuncture or acupressure for weight loss was not based in the results of rigorous clinical studies. Similar conclusions were drawn in another non-systematic review.[291]

Dietary supplements

Although Pittler and Ernst reviewed the use of over-the-counter dietary, supplements, this was outside the scope of the guidance.

Homeopathy

The authors reported that two RCTs were identified. In one study, *Helianthus tuberosus* D1 was given to patients with a mean BMI of 29 kg/m^2, and after 3 months the treatment groups had lost a mean 7.1 kg which was significantly different from the placebo group. The other trial, which aimed to study Thyroidinum 30 cH, did not reach any difference between treatment group and placebo.

Hypnotherapy

The authors reported one meta-analysis (that included six RCTs) that aimed to compare hypnotherapy plus cognitive behaviour therapy with cognitive behaviour therapy alone. The results showed that adding hypnotherapy to cognitive behaviour therapy only slightly decreased body weight. The authors also referred to a further RCT with hypnotherapy directed at either stress reduction or energy intake, compared to dietary advice. Results showed a significantly greater weight reduction compared with control groups.

15.3.10 Effectiveness of brief interventions in primary care and other general clinical settings in improving outcomes for people who are overweight and obese

15.3.10.1 Evidence statements (Table 15.40)

Table 15.40 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss		
1	Evidence from one study suggests that a brief intervention without nutritional counselling delivered to overweight patients aged between 25 and 65 years does not help achieve weight loss at 12 months	1+
Generalisability (from trials that reported weight loss)		
2	Generalisability of the findings remains unclear, as no study was conducted in the UK	N/A
3	Generalisability of the findings is hindered by the lack of evidence	N/A

N/A, not applicable.

15.3.10.2 Evidence review on brief interventions

This section reviews evidence on the effectiveness of brief interventions in primary care and other general clinical settings in improving outcomes for adults who are overweight and obese.

Types of study

- RCTs
- clinical controlled trials based in the UK (corroborative evidence).

Types of participant

- Children and adults who were overweight or obese.

Types of outcome

- primary outcomes to be measured (not self-reported) estimates of overweight in per cent and BMI

- secondary outcomes to be behaviour change, participants' views, measures of self-esteem, health status, well-being and quality of life.

Only RCTs with a minimum duration of 12 months (including follow-up, 6 months for children) that aimed to assess the effectiveness of brief interventions in primary care and other general clinical settings in improving outcomes for adults who are overweight and obese, were included. Moreover, studies were required to specifically include overweight and/or obese participants.

The majority of studies on such interventions were chiefly in alcohol use disorders and smoking cessation. Beyond the lack of studies that met the above parameters, another challenge was how to define a 'brief intervention'. Across the literature, different studies have given diverse definitions of 'brief interventions'.[292–293] As an example, Babor[294] defines one contact as 'minimal', one to three sessions as 'brief', five to seven sessions as 'moderate' and eight or more sessions as 'intensive' treatment (Moyer et al. 2002[293]). What can also happen is that what is mean by 'brief' can be reported as 'extended' in another study (Jonson et al.[292] quoted by Moyer et al.[293]). Despite these contradictions in the available literature, we chose to use Babor's definition,[294] by including studies with no more than four sessions.

From our searches we retrieved three studies that matched our inclusion criteria. However, two of these were excluded after discussion, as one was based in a blood pressure clinic and was published in 1978, and the other study included non-overweight participants and did not perform subgroup analysis.

Pritchard and coworkers[18] studied the clinical and cost outcomes of providing nutritional counselling to patients aged between 25 and 65 years with either hypertension, type 2 diabetes or were overweight (BMI > 25 kg/m^2). Results of the study were stratified per group, thus its inclusion in the review. Two groups (dietitian and doctor/dietitian) were given counselling focused on principles of good nutrition and exercise and addressed problem areas in lifestyle and dietary patterns. In the latter group, the participants were also seen by the GP at

baseline and by the same GP on two other occasions during the 12 months for 5 minutes each time to encourage and monitor the participant. The control group (which matches Babor's definition of brief intervention) received results of initial screening and were advised to discuss their queries with the GP at appointment. They received usual care (including monitoring, advice and prescriptions) from GP but no dietitian counselling. At 12 months, mean ± SD weight change in kilograms was –5.10 ± 7.36 kg in the dietitian group, 0.60 ± 6.08 kg in the control and –6.20 ± 7.67 kg in the dietitian and doctor group. Weight change in both intervention groups was significant (–5.70 kg [95% CI –8.05 to –3.35]; –6.80 kg [95% CI –9.17 to –4.43], respectively) compared to the control group. Moreover, significant decreases in mean blood pressure in participants with hypertension were reported in both intervention groups compared with the control group.[18]

No studies including children were identified.

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