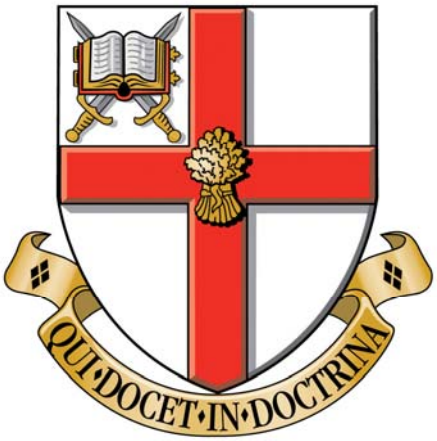

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Do UK based Weight Management Programmes Cause Weight Loss Maintenance in Adults? A Systematic Review

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8th October 2012

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Abstract

The aim of this dissertation was to examine whether UK based weight management programmes promote weight loss maintenance (follow up of 12 months to assess effectiveness of intervention on weight loss) in adults through the process of a systematic review. The World Health Organisation (WHO) has described obesity as a “global epidemic”. Weight management comprises two phases; weight loss and weight loss maintenance. The latter phase is the true goal for obesity and the most difficult element of weight management to achieve. However much less is known about this as compared with the weight loss phase. There is little purpose in committing time and money to reducing obesity if the weight is regained. This is counter-productive and weight loss maintenance is essential to combat the obesity epidemic. Searches were made for relevant information from a variety of scientific online databases and journals. Seven articles met the inclusion criteria and were analysed in the review. All studies incorporated a multi-component (diet, exercise, behavior modification) intervention approach. All control and intervention groups reported weight loss at 12 months when compared with baseline. All groups received an intervention. One study reported a significant difference ($P<0.05$) between groups. Four studies reported on at least one component (diet, physical activity, behavior modification) however there was not enough information to conclude whether they complied with national guidelines (NICE CG43 and SIGN 115). High attrition rates and loss to follow up are problematic for each study except one. Analysis on an intention to treat basis was common however this is problematic and there are alternative methods which may be more suitable for dealing with missing data.

Declaration

This work is original and has not been previously submitted in support of a degree, qualification or other course.

Signed **----------**

Alison Moore

Dated **----------**

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1 Introduction

1.1 Obesity – General Overview

The World Health Organisation (WHO) has described obesity as a "global epidemic" (http//www.who.int/). It defines it as "a condition of abnormal or excessive fat accumulation in adipose tissue, to the extent that health may be impaired". WHO utilises body mass index (BMI) to classify overweight, underweight and obesity in adults. It calculates BMI by dividing an individual's weight (kg) by height (m^2).

Table 1: The International Classification of Adult Underweight, Overweight and Obesity According to BMI

Classification	BMI(kg/m^2)	
	Principal cut-off points	**Additional cut-off points**
Underweight	<18.50	<18.50
Severe thinness	<16.00	<16.00
Moderate thinness	16.00 - 16.99	16.00 - 16.99
Mild thinness	17.00 - 18.49	17.00 - 18.49
Normal range	**18.50 - 24.99**	**18.50 - 22.99**
		23.00 - 24.99
Overweight	**≥25.00**	**≥25.00**
Pre-obese	25.00 - 29.99	25.00 - 27.49
		27.50 - 29.99
Obese	**≥30.00**	**≥30.00**
Obese class I	30.00 - 34.99	30.00 - 32.49
		32.50 - 34.99
Obese class II	35.00 - 39.99	35.00 - 37.49
		37.50 - 39.99
Obese class III	≥40.00	≥40.00

Source: Adapted from (WHO, 1995, WHO, 2000).

Research has demonstrated several limitations of BMI measurement, for example, it cannot distinguish fat from muscle, bone and other lean body mass (WHO, 1995 and WHO, 2000). It can lead to misclassification among ethnic groups, in particular overestimation of African Americans therefore overstating the true difference in obesity between whites and African Americans (Burkhauser and Cawley 2008). (Ko et al (2001) recommended that BMI cut off values of 23 kg/m^2 and 26 kg/m^2 be used to define overweight and obesity respectively in Hong Kong Chinese. This study assessed body fat of 5153 Hong Kong Chinese by bioelectrical impedance. The receiver operating characteristic curve showed that the BMI corresponding to the conventional upper limit of normal body fat was 22.5-23.1 kg/m^2 and the BMI corresponding to the 90 percentiles of body fat was 25.4-26.1 kg/$m^{2.}$

Despite these limitations the BMI formula has been shown to give valid estimates of body fat in males and females of all ages when compared to skin fold thickness measurement or bioelectrical impedance analysis data (Deurenberg, Westrate, Seidell, 1991).

Many UK commercial weight loss programs use BMI to assess weight classification of members. Weight watchers (http://www.weightwatchers.co.uk), Slimming World (http://www.slimmingworld.com), and Unislim (http://www.unislim.com) provide BMI calculators on their websites and access to this is free of charge i.e. no membership required. It is non-invasive, inexpensive and easy to use by individuals and clinicians therefore promoting ease of comparability across populations (National Obesity Observatory). The National Institute for Clinical Excellence (CG43, 2006) and Scottish Intercollegiate Guidelines Network (Guideline 115, 2010) recommend that BMI should be measured in conjunction with waist circumstance when measuring overweight and obesity for those with BMI of less than 35 kg/m^2 to refine assessment of risk of obesity-related co morbidities. For adults with a BMI of 35 kg/m^2 or more, risks are assumed to be very high with any waist circumference.

Obesity is directly associated with cardiovascular diseases, type II diabetes and some forms of cancer (Bray, 2004, Xavier Pi-Sunyer, 2002). Certification of obesity as a cause of death in England is increasing (Duncan, Griffity, Rutter & Goldacre, 2010). The latter research paper found that when obesity was coded as an underlying cause of death, the most common other conditions mentioned were heart failure, pulmonary embolism, diabetes mellitus and pneumonia. When obesity was coded as a condition contributing to death, but not as the underlying cause, the most common underlying certified causes were chronic ischemic heart disease, acute myocardial infarction, chronic obstructive pulmonary disease and diabetes mellitus.

The Organisation for Economic Co-operation and Development (OECD) which produced health data in 2011 (OECD Health Data, 2011) detail that the obesity rate among adults in the UK (based on actual measures of weight and height) have risen from 14% in 1991 was 23% in 2009. The Foresight report, Tackling Obesities: Future Choices project was commissioned by the UK government and published in 2007 (Future Choices Project, 2007) (www.foresight.gov.uk). This report examined current obesity trends in the UK and assessed where councils can use their local leadership role to positively change obesity levels and create healthier environments. It predicted that if no action was taken, 60% of men, 50% of women and 25% of children would be obese by 2050. This report estimates the direct cost to the UK government to be £4.2 billion and Foresight have forecast that if the current trend continues this will more than double by 2050. The government responded in 2008 with a cross-government strategy called Healthy Weight Healthy Lives (Department of Health, 2008). The aim of this report is to reverse obesity by ensuring that everybody is able to achieve and maintain a healthy weight. The initial focus is on children with an aim to reduce obesity to 2000 levels. The latest progress report was published in March 2010, 'Healthy Weight, Healthy Lives. Two Years On' (Department of Health, 2010). This report states that 'good progress is being made'. For example, child obesity in under 11's is levelling off but prevalence remains high. Child obesity prevelance reduced from 17.3% in 2005 to 13.9% in

2008. 'Change4Life' was launched in January 2009. It cost £75 million and is a three year programme. This is a social marketing movement aimed at getting people to eat well, move more and live longer. More than 400,000 families have joined. In February 2010 the government launched Change4Life for adults. There is no progress report on this yet.

One in four adults in the UK is obese, so successful weight management programs are urgently required (Truby, 2011). Weight Watchers currently claim 2 million UK members and Rosemary Connelly claim in excess of 700,000 UK members. There is a paucity of systematic reviews of commercial weight loss programs in the UK and these are required to summarise the research evidence in order to assess effectiveness (Wing, 2010). Weight management comprises two phases; weight loss and weight loss maintenance (Finer, 2001). The latter phase has been cited as the true goal for obesity management and the most difficult element of weight management to achieve but much less is known about this as compared with the weight loss phase. (Anderson, Vichitbandra & Kryscio, 1999).

1.2 Obesity and Primary Care Intervention

The cross-government strategy ' Healthy Weight, Healthy Lives' ' (Department of Health, 2008) identifies primary care as the first port of call for advice about weight control, creating a need for simple, effective interventions to be delivered by primary care teams. The National Institute for Health and Clinical Excellence (National Institue for Health and Clinical Excellence, Clinical Guideline CG43, 2006) recommend that clinical management be offered to obese patients by primary care physicians.

A relevant study (Browne, Stride, Psarou, Thompson & Brewins, 2007)noted that nurses in primary care play a key role in managing obesity. Practice Nurses (82%) felt that lack of obesity management training was apparent and did not believe that organisational support was in place. Only nine respondents (2.3%) provided input into a group intervention for obesity management. This study reported that within an area of 60,000 obese adults there

were about 2700 (4.5%) individuals being supported and assessed within any four weeks by primary care. This indicates the level of activity and scale of the problem. Epstein (2005) conducted a qualitative study of 21 GP's working in an inner London primary care trust regarding their views on treatment of obese patients. This study reported that these physicians felt that obesity was not within their professional domain and would resist any government pressure to accept obesity as part of their workload. No statistics or data was reported.

The previous two studies focus on obesity management and treatment. The Foresight Report declares that "the distinction between prevention and treatment is important". Aucott, Riddell and Smith (2011) conducted the first UK based study to assess attitudes of general practitioners, registrars and their trainers toward obesity prevention in adults. A postal questionnaire was sent to all GP registrars (GPR) and GP trainers (GPT) in Scotland of which there were 103 and 91 respectively. The questions included individual details, opinions about current obesity prevention strategies and facts about current obesity prevention practices. 51% responded representing 5% of Scottish GP's. There were large differences in opinion between GPR's and GPT's as to whether primary care could and/or should prevent obesity. 36% GPR's and 8% GPT's felt that primary care can help prevent obesity. 37% GPR's and 5% of GPT's felt that primary care should prevent obesity. Despite the belief that obesity prevention is best supported from within primary care particularly from GPR's, these GP's did not feel that the responsibility of obesity prevention should be solely theirs. The fear of obesity swamping primary care is reflected by recent UK studies suggesting that GP's consider obesity not to be a medical problem (Mercer & Tessier, 2001, Alexander et al, 2007). In addition common barriers to obesity management include limited training and knowledge (Terre, Hunter, Poston, Haddock & Steward, 2007, Treyzon, 2005).

The Counterweight Project (Ross, Laws, Reckless & Lean, 2008) provided evidence of an effective model of weight management in primary care. This model consisted of four stages:

1) Audit and project development - specialist obesity dieticians were the weight management advisors and they facilitated programme implementations
2) Practice training and support - the practice care nurse (PCN) was identified as the most suitable person to deliver the weight management intervention. They attended an 8 hour training programme and incorporated the appointments into appointments which were usually spent managing comorbid conditions. The role of the GP was to identify suitable patients for the intervention.
3) Nurse led patient intervention – the PCN delivered patient education through weight management discussion, communication of information and the transfer of behaviour skills and strategies during each session.
4) Evaluation – A patient data set was devised and included baseline weight, weight circumference, blood pressure, fasting lipids, glucose. This study used evidence based pathways which included strategies to empower clinicians and patients.

Primary outcome measures were weight change and percentage of patients achieving $\geq$5% loss at 12 and 24 months. Primary care practice nurses from 65 UK general practices delivered interventions to 1906 patients with BMI $\geq$ 30kg/m^2 or $\geq$ 28kg/$m^{2.}$ Mean weight change in those who attended and had data at 12 months (n=642) was -3.0kg and at 24 months was (n=357) was -2.3kg. Among attendees at specific time-points 30.7% had maintained weight loss of 5% at 12 months and 31.9% at 24 months. A total of 761 (54%) of all 1419 patients who had been enrolled in the programme for > 12 months provided data at or beyond 12 months. By applying the mean change in BMI observed, to the costs of prescribing medications at varying BMI levels expected savings of 6.3% of prescribing costs for all patients and 8% of the programme cost offset in year one, increasing to 22% when attendance and follow up is optimal. There was no control group in this study and this prevents exact quantification of the Counterweight Programme achievements.

This is the first known study to use an evidence based approach which aims to empower patients. The impact on secondary outcomes such as obesity related diseases was not possible outside a formal heavily funded research setting. This study demonstrates that practice nurses can achieve and maintain clinically beneficial patient weight loss when weight management training is provided to them. It is important to note that one in five practices withdrew from the programme due to lack of resources and time and changes in clinical staff. It is relevant that practices were asked to incorporate this programme into routine clinical practices without additional funding and this may have been a significant barrier.

Weight management programmes may not always be available through local general practice. Time for implementing the scheme and staff training together with lack of funding can constrain general practice participation as demonstrated by the Ross, Laws, Reckless and Lean (2008). Lavin et al (2006) recognise this and assessed the feasibility and benefits of implementing a 'Slimming on Referral' service using a local commercial weight management group by primary care. 107 patients participated and inclusion criteria included BMI $\geq$ 30kg/m^2 and age $\geq$18 years. Patients were offered free attendance at a local Slimming World (SW) group for 12 consecutive weeks. 91 patients (85%) patients attended a group with 62 completing 12 weeks. Average weight loss in participants was 5.4% (6.4% baseline weight). 47 patients chose to self fund for a further 12 weeks. Based on SW fees in 2004 the cost per patient to cover membership and 12 weeks attendance at a group was £44.50 with primary care trust discount. Practices estimated that each referral used 20 minutes of nurse and administrator time which added a notional £7 per patient when salaries were considered. Referral without the constraints of a research study would take less time with minimal data collection. This study estimated that 12 weeks of Sibutramine would cost £112 per patient and £124 for Orlistat. This does not include a weight management programme as recommended by NICE (CG43, 2006). One to one treatment by a dietician would cost £55 - £115 per patient. Slimming World offers a practical solution where there is no in-house

weight management programme. This study reported that lower income people are less likely to access healthcare and yet experience a greater risk of obesity. This emphasises the importance of providing accessible free treatment for this group. More recently (Jebb et al, 2011) conducted a randomised controlled trial comparing primary care referral to a commercial provider for weight loss treatment with standard care.

772 overweight or obese patients from Australia, Germany and UK were randomly assigned to either 12 months standard care as defined by the national treatment guidelines of each country or 12 months free membership to a commercial programme (Weight Watchers) and followed up for 12 months. 377 participants were assigned to the commercial group and 230 (61%) completed the 12 month assessment. 395 participants were assigned to standard care and 214 (54%) completed the 12 month assessment. Mean weight change at 12 months was -5.06kg for the commercial programme versus -2.25kg for those received with standard care. This study demonstrates that referral by a primary health care professional to a commercial weight loss programme which provides regular weighing, nutrition and exercise advise, motivation and group support can offer a clinically useful early intervention for weight management in overweight and obese people that can be delivered at large scale.

The largest audit of NHS referral to a commercial weight loss programme in the UK was detailed in an observational study carried out by Ahern, Olston, Asten & Jebb (2011). This offered Weight Watchers (WW) on Prescription by the NHS. Data was obtained from the WW NHS Referral Scheme database for 29,326 referral courses started after 2nd April 2007 and ending before 6th October 2009 [90% female; median age 49 years (IQR 38 - 61 years); median BMI 35.1 kg/m^2 (IQR 31.8 - 39.5 kg/m^2).

Participants received vouchers (funded by the PCT following referral by a healthcare professional) to attend 12 WW meetings. Body weight was measured at WW meetings and relayed to the central database. Median weight change for all referrals was -2.8 kg [IQR -5.9 - -0.7 kg] representing -3.1% initial weight. 33% of all courses resulted in loss of ≥5% initial

weight. 54% of courses were completed. Median weight change for those completing a first course was -5.4 kg [IQR -7.8 - -3.1 kg] or -5.6% of initial weight. 57% lost ≥5% initial weight. These results are comparable with those of the Ross, Laws, Reckless and Lean (2008) (25.3% of participants lost ≥5% at 3 months, 40.2% at 6 months and 33.7% at twelve months) and Slimming on Referral programme (completing a 12 week course lost 5.4 kg, with 57% losing ≥5% baseline weight).

Twelve weeks is a relatively brief duration and data on longer term outcomes is necessary to assess whether this treatment has a significant impact on long term health. Repeat referrals comprised a quarter of the study group and although their weight diminished they did achieve additional weight loss therefore longer participation may improve weight loss. This will have increased intervention costs for the NHS and the long term impact of this scheme needs to be established.

1.3 Role of Weight Management Programs in Weight Management

There is evidence to support the use of weight loss programs as an effective method for weight management once the client remains active in the program.

Heshka et al (2003)compared weight loss with self-help compared with a structured commercial program in a randomised trial in America. Waist circumference (P = .003) and body mass index (P<.001) decreased more in the commercial group. The results show that people offered two years free use of commercial weight management program achieved a mean weight loss of 2.0kg. Those two twenty minute consultations with a nutritionist and self-help resources achieved a mean weight loss of 0.2kg at the end of two years. It is relevant that participants who attended 78% or more of the commercial group sessions maintained a mean weight loss of 5kg at the end of the two year study. It is also important to

note that results were obtained in a regular commercial weight loss program and not in an academic or research environment.

Rock et al (2010)found that mean weight loss 7.4kg for the centre based group (pre packaged food, planned menu and physical activity), 6.2kg for the telephone based group (one to one weight loss counselling) and 2.0kg for the usual care control group (two weight loss counselling sessions with a dietetics professional and monthly contacts) after two years. It must be noted that the cost of participation was free and individuals may be reluctant to pay under normal circumstances for the cost of meals, counselling sessions and telephone. In addition the study was unblinded and this may have influenced participant's behaviour and effectiveness. This research demonstrates the dependent relationship between success (weight loss and maintenance) with telephone one to one counselling and regular face to face contact. This is difficult to incorporate into medical practice given the limitation on NHS resources (McTigue et al, 2003).

The figures used in the previous two studies were calculated according to intention to treat, using baseline observation carried forward for missing data. Although the studies were conducted in America both are two years in duration. There is a paucity of similar type studies of this time scale in the UK.

The only non-commercially funded UK study's to examine the efficacy of commercial weight loss programs are Lighten Up (Jolly et al, 2010) and BBC Trials (Truby et al, 2006).

Lighten Up is a randomised controlled trial comparing a range of 12-week commercial and NHS weight reduction programmes with a comparator group who are provided with 12 vouchers enabling free entrance to a local leisure centre. The weight reduction programmes are:

(i) Weight Watchers,

(ii) Slimming World,

(iii) Rosemary Conley,

(iv) A group-based dietetics-led programme (Size Down),

(v) General practice one-to-one counselling,

(vi) Pharmacy-led one-to-one counselling,

(vii) Choice of any of the 6 programmes.

People with obesity or overweight with a co-morbid disorder are invited to take part by a letter from their general practitioner. The sample size is 740 participants.

The primary outcome was weight loss at three months and secondary outcomes were weight loss at one year, self-reported physical activity at 3 and 12 months follow-up and percentage weight-loss at 3 months and one year. All programmes achieved significant weight loss from baseline to programme end (range 1.37 kg (general practice) to 4.43kg (Weight Watchers), and all except general practice and pharmacy provision resulted in significant weight loss at one year. Commercial services achieved significantly greater weight loss. (mean difference 2.3 (1.3 to 3.4) kg).

The BBC trial was a six month randomised unblinded control trial. It compared the effects of four commercial weight loss diets available to adults in the UK. These comprised

- Dr Atkins' new diet revolution,
- Slim-Fast plan,
- Weight Watchers pure points programme, and
- Rosemary Conley's eat yourself slim diet and fitness plan.

Behaviour modification, a feature of all these group programs, teaches participants to control their environment in relation to food. Body fat and weight were reduced in all participants by six months. Average weight loss was 5.9 kg and average fat loss was 4.4 kg over six

months. This trial demonstrates that adults who are motivated to follow commercial diets for six months can achieve weight loss and fat loss. This study recommends that given the limited resources for weight management in the NHS, healthcare practitioners should discuss with their patients programmes known to be effective.

1.4 Clinically Significant Weight Loss - Reduction in Obesity Related Diseases

The principles of weight management are primarily to achieve clinically significant weight loss and secondarily to maintain weight loss (Finer, 2001). For pharmacological interventions effectiveness for intentional weight loss is defined as >5% of initial weight in those with obesity related diseases and 10% for those without co morbidity (Committee for Proprietary Medicinal Products, 1997) and (Food and Drug Administration, 1997).

While studies describing an intentional weight loss of 5% or 10% will be examined and shown to produce clinically significant benefits it may not redefine a person from an obese state to a non-obese state. It is important to distinguish between intentional and unintentional weight loss because the causes and consequences can differ significantly (Wing & Hill, 2001). A relevant study (French, Jeffery, Folsom, Williamson & Byers, 1995) revealed that women who had intentionally lost $\geq$ 20 lbs were more likely to report weight losses due to lower calorie diets, exercise and weight loss groups, while women who had unintentionally lost $\geq$ 20 lbs were more likely to report losses due to depression or stress. The findings of this study promote further research into understanding why women lose weight and it is necessary to examine further the relationship between body weight changes and health outcomes.

(Dansinger, Gleason, Griffith, Selker, Schaefer, 2005) demonstrate that weight loss through commercial diets can improve cardiac related risk factors at one year. 160 patients were randomly assigned to one of four popular diets:

- Atkins,
- Ornish,
- Weight Watchers and
- Zone diets.

Mean (SD) weight loss at 1 year was 2.1 (4.8) kg for Atkins (21 [53%] of 40 participants completed, P = .009), 3.2 (6.0) kg for Zone (26 [65%] of 40 completed, P = .002), 3.0 (4.9) kg for Weight Watchers (26 [65%] of 40 completed, P < .001), and 3.3 (7.3) kg for Ornish (20 [50%] of 40 completed, **P** = .007). Each diet significantly reduced the low-density lipoprotein/high-density lipoprotein (HDL) cholesterol ratio by approximately 10% (all P<.05), with no significant effects on blood pressure or glucose at 1 year. For each diet, decreasing levels of total/HDL cholesterol, C-reactive protein, and insulin were significantly associated with weight loss (mean r = 0.36, 0.37, and 0.39, respectively) with no significant difference between diets (P = .48, P = .57, P = .31, respectively).

The number of participants who did not complete the study at months 2, 6, and 12 were 34 (21%), 61 (38%), and 67 (42%), respectively. At 1 year, there was a non-significant trend (P = .08) toward a difference in discontinuation rates between the more extreme diets (48% for Atkins and 50% for Ornish) and moderate diets (35% for Zone and 35% for Weight Watchers). Had the participants been able to select their diet choice the adherence rates may have been greater as selection choice may have better facilitated such aspects as their personality or lifestyle. Therefore it is important to note that this study only evaluated dietary components. It is reported that the high discontinuation rates for Atkins and Ornish suggest that these diets are possibly too extreme. Practical techniques are required to reduce low adherence rates and perhaps offer a wider range of options to facilitate all participants. Only 25% of the initial participants sustained a 1-year weight loss of more than 5% of initial body weight and approximately 10% of participants lost more than 10% of body weight. It is apparent that these diets assessed under clinical conditions benefit the minority of

individuals who can sustain a high dietary adherence level. This study concludes that poor sustainability and adherence rates resulted in modest weight loss and cardiac risk factor reductions for each diet group. However cardiac risk factor reductions were associated with weight loss regardless of diet type implying that adherence level rather than diet type was the key determinant of clinical benefits. Further investigations of the potential health benefits of these diets would be appropriate by studying cardiovascular outcomes.

Sacks et al (2009) demonstrated the clinically significant benefits of weight loss through diets and subsequent reduction in cholesterol levels and high blood pressure. They assigned 800 participants to one of four diets;

- 20% fat, 15% protein, and 65% carbohydrates (low-fat, average-protein);
- 20% fat, 25% protein, and 55% carbohydrates (low-fat, high-protein);
- 40% fat, 15% protein, and 45% carbohydrates (high-fat, average-protein); and
- 40% fat, 25% protein, and 35% carbohydrates (high-fat, high-protein).

All the diets reduced risk factors for cardiovascular disease and diabetes at 6 months and 2 years. At 2 years, the two low-fat diets and the highest-carbohydrate diet decreased low-density lipoprotein cholesterol levels more than did the high-fat diets or the lowest-carbohydrate diet (low-fat vs. high-fat, 5% vs. 1% [P=0.001]; highest-carbohydrate vs. lowest-carbohydrate, 6% vs. 1% [P=0.01]). The lowest-carbohydrate diet increased HDL cholesterol levels more than the highest-carbohydrate diet (9% vs. 6%, P=0.02).

All the diets decreased triglyceride levels similarly, by 12 to 17%. All the diets except the one with the highest carbohydrate content decreased fasting serum insulin levels by 6 to 12%; the decrease was larger with the high-protein diet than with the average-protein diet (10% vs. 4%, P=0.07). Blood pressure decreased from baseline by 1 to 2 mm Hg, with no significant differences among the groups (P>0.59 for all comparisons).

Most of the weight loss occurred in the first 6 months. Changes from baseline differed among the diet groups by less than 0.5 kg of body weight and 0.5 cm of waist circumference. A total of 185 of the participants (23%) continued to lose weight from 6 months to 2 years; the mean (±SD) additional weight loss was 3.6±3.5 kg, for a mean total loss from baseline of 9.3±8.2 kg, with no significant differences among the diet groups. At 2 years, 31% to 37% of the participants had lost at least 5% of their initial body weight, 14% to 15% of the participants in each diet group had lost at least 10% of their initial weight, and 2% to 4% had lost 20 kg or more (P>0.20 for the comparisons between diets). After 12 months, all groups, on average, slowly regained body weight. 80% of participants completed the trial and attendance was strongly associated with weight loss (0.2kg per session attended).

These two studies provide evidence of the clinically significant benefits of intentional weight loss on obesity related risk factors. Whilst these studies have demonstrated the clinically significant benefits of at least 5% weight loss it must be noted that it cannot automatically be assumed that weight gain <5% is not clinically significant.

1.5 Weight Loss Maintenance

Long term weight loss maintenance has been cited as an elusive goal (Wing & Phelan, 2005). A study by (Ulen, Hulzinga, Beech & Elasy, 2008) demonstrated that a weight loss of 8% - 10% by six months is regained. Whilst weight loss maintenance studies detail the prevalence of success or failure there is a lack of consistent criteria to define this (Stevens, Truesdale & McClain, 2006). Expert committees have addressed the definition of weight loss maintenance following weight loss.

The Institute of Medicine (IOM) define weight loss maintenance as losing at least 5% of body weight or reducing BMI by at least one unit and keeping below this minimum for at least a year (Institute of Medicine, National Academy of Sciences, 1995).

By this definition there is no limit on the amount of weight that can be regained once net weight loss remains below the criterion. This definition assumes that the bounds around which weight maintenance is placed are known. However several different methods could be used to choose this body weight. For example in a clinical setting weight maintenance may refer to maintenance of a current weight or weight after weight loss. An observational study may define weight maintenance as staying within set bounds of the weight at the first examination or around the mean weight over all examinations.

The National Heart Lung and Blood Institute (NHLBI) clinical guidelines define successful weight maintenance after weight loss as a weight regain of <3kg (6.6 pounds) in two years and a sustained reduction of in waist circumference of at least 4cm (National Heart Lung and Blood Institute, 1998). This definition does not consider intentional weight loss. Although any weight maintenance definition will be somewhat arbitrary it should be compatible with national and international expert committees current recommendations and permit study comparison. In addition an appropriate definition of weight maintenance should include designated body weight under standardised conditions and avoid the use body weight percentages.

Although it has been demonstrated that participants of a structured weight loss program will regain all of their weight loss within 3- 5 years (Stunkard, McClaren-Hume, 1959), there is room for optimism. Two long term research studies, National Weight Control Registry (Graham, Bond, Hill & Wing, 2011) and Look AHEAD study (Wadden, 2006) and have demonstrated evidence to the contrary.

The National Weight Control Registry (NWCR) is the largest prospective investigation of long-term successful weight loss maintenance. It tracks over 10,000 weight maintainers who are over 18 years old, have lost at least 30lb and have kept it off for a minimum of a year (Bond, Phelan, Hill, Wing 2009 & Thomas, Wing, 2009). In order to maintain weight loss, members report engaging in high levels of physical activity, eating a low-fat, low-calorie diet,

eating breakfast and self-monitoring weight. A key feature here is a consistent eating pattern across weekdays and weekends. Although participants self-report their current weight and height it is required that a physician verifies this to the registry.

Similar results were demonstrated by (Wadden et al, 2009)in a four year analysis of The Look AHEAD (Action for Health in Diabetes) study. This is the first randomised controlled trial to assess whether intentional weight loss combined with increased physical activity reduces cardiovascular morbidity and mortality in overweight individuals with type 2 diabetes (Ryan, Espeland, Foster, 2003).

The study began in 2001 and is scheduled to conclude in 2012. A total of 5145 participants have been randomly assigned to a usual care condition (Diabetes Support and Education) or to an intensive lifestyle intervention with a goal of inducing a loss of ≥7% of initial weight and increasing physical activity to ≥175 min/week. Participants regained approximately 25% of weight losses over year 1 and year 2 and 20% between year 2 and year 3 they regained only 8% of weight loss between year 3 and year 4.

These studies demonstrate that weight regain may slow down over time (2-5 years).

The NWCR have identified factors that could possibly predict successful weight loss maintainers. Findings demonstrate that individuals who kept their weight off for 2 years or more had a greater chance of similar outcome the following year.

Look AHEAD (Wadden et al, 2011) found that the larger the participants' weight loss the first year, the larger their loss at year 4. The odds of achieving a loss ≥ 10% of initial weight at year 4 were 9.8 (95% CI: 6.99–13.74) times greater for participants who lost ≥ 10% at year 1 compared to participants who lost < 5% at year 1 and 2.0 (95% CI: 1.41–2.96) times greater for participants who had lost 5.0 to 9.9% at year 1 compared with those who lost < 5% at year 1. Similar analyses revealed that the odds of achieving a loss ≥ 5% at year 4 were 9.3

(95% CI: 7.27–11.83) times greater for participants who lost ≥ 10% at 1 year and 2.4 (95% CI: 1.88–3.04) times higher for individuals who lost 5.0–9.9%, compared to participants who lost < 5% the first year.

This research demonstrates that with long-term participant support, weight loss achieved with a behavioural intervention is not invariably followed by a return to baseline weight. Patient support was provided in month 1-6 with three group meetings and one individual session. During months 7-12 group sessions were provided every other week with a monthly individual session.

Sessions were led by intervention teams that included registered dieticians, behavioural psychologists and exercise specialists. Successful weight loss maintenance is achievable however this depends on the definition criteria utilised within the study. This is important because it has been revealed that the true goal for obesity is weight loss maintenance and this is more difficult to achieve than weight loss (Fletcher, 1992). Furthermore these studies demonstrate that long term success increases once a specific weight loss has been maintained for 2-5 years. (McGuire, Wing, Klem, Lang, Hill Jo, 1999) detail that weight loss for ≥2 years is protective again subsequent regain and that by two years the likelihood of regaining 2.6kg in the coming year is only 50% and by five years the likelihood drops to 2.7%.

As demonstrated there is research to support the use of weight management programmes as an effective solution for weight management in terms of health benefits and cost to both UK population and UK government. NICE clinical guideline CG43 and SIGN clinical guideline 115 both recommend the use of multi component weight management programmes comprising diet, physical activity and behaviour modification. Both guidelines detail that if this is adhered then weight loss maintenance will follow. There is little point investing in change if weight is regained and obesity resumes therefore weight loss maintenance is a vital to combat obesity. At present there is limited information on this

therefore the effectiveness of weight management programmes on weight maintenance cannot be assessed. This systematic review will aim to assist with bridging this current gap in the research within the UK. Can weight loss programs promote weight loss maintenance (follow up of 12 months to assess effectiveness of intervention on sustained weight loss)?

2 Methodology

2.1 Research Questions

What is the effect of UK based weight management programmes on weight loss maintenance (follow up of 12 months to assess effectiveness of intervention on weight loss) for adults?

How do weight management programmes impact on adult weight loss maintenance of weight when focusing on diet, physical activity and behaviour modification?

What are the effects of withdrawal/loss to follow up on a weight management programme? How does this impact on statistical analysis and subsequent outcome of weight loss maintenance?

The research questions will be addressed by a systematic review of all literature pertaining to weight loss maintenance which is achieved through a weight management programme once the following inclusion criteria is met.

Weight loss maintenance is defined as follow up at 12 months to assess the impact of intervention on weight loss.

2.2 Inclusion Criteria

This criteria was developed to assist with identification of relevant studies to help with answering the research questions.

2.2.1 Population

Study participants UK adults (≥18 years) classified as overweight or obese with BMI of ≥25 kg/m^2

2.2.2 Intervention

Weight management programme comprising of a combination of diet, physical activity and behaviour change strategy to influence lifestyle.

Programmes must include a follow up of at least 12 months in order to assess the impact of interventions on sustained weight loss.

The programme is delivered by the health sector, in the community or commercially.

2.2.3 Comparators

Normal practice (as defined by the study)

Single-component weight management strategies

Other structured multi component weight management studies

2.2.4 Outcomes

Studies are required to include a measure of weight loss and weight loss maintenance.

Other inclusion criteria:

English language only

UK primary research study or review based on UK population- no meta-analysis

All of the initial relevance criteria have to be met to be included in the study. If any of these criteria failed then the study was excluded.

As stated above all studies must clearly specify the three components to ensure they were multicomponent and also to ensure that they were reproducible. The following criteria were reviewed in each study in respect of the three components to assess eligibility:

2.3 Research Plan

The research plan comprised of

- Key word search
- Searching key databases and journals
- Study Types
- Quality assessment
- Data Management

2.3.1 Key Word Search

Phase 1 of the search strategy involved keyword searches were conducted in order to produce a manageable number of search results.

The retrieval of causation studies cited in MEDLINE can be substantially enhanced by selected combinations of indexing terms and text words (Wilczynski Haynes, 2003). This study found that combinations of terms reached peak sensitivity of 93%. Compared with the best single term, multiple terms increased sensitivity for sound studies by 15.5% (absolute increase), but with some loss of specificity when sensitivity was maximised. Combining terms to optimise sensitivity and specificity achieved sensitivities and specificities both above 80%. They recommended using alternative word and terms to broaden the search.

The medical subject heading (MeSH) subject headings include “obesity”, “weight gain”, “weight loss”, and “weight loss programs” (United States National Library of Medicine, 2012).

The keywords that were used alone or in combination are detailed in table 2.0. The search protocol is aimed at increasing the specificity as the process continues.

Table 2.0. Search Terms and Synonyms

	Key Word	Synonyms
Population Under Study	Adults	Age over 18 years
Outcome of Interest	Weight Loss Maintenance	Weight gain/regain, obesity, reducing weight, overweight, weight loss, weight management, body fat, BMI
Potential Source of Influence	Weight Management Program	Weight reduction program, diet, exercise, plan

These keywords were then combined using Boolean search operators in order to obtain maximal search capacity. It allows the combination of words and phrases into a search statement to retrieve documents from databases. It consists of three logical operators, 'OR', 'AND', 'NOT'. For example within the context of this review is "weight loss maintenance AND diet", "weight loss program AND weight regain".

The first search comprised the population under study (and/or synonyms) 'Adults' and the outcome of interest 'weight loss maintenance'.

This search yielded in excess of 300 articles therefore the search was refined further.

The second search comprised the key words 'adults' AND 'weight loss programme' This search still yielded more than 300 articles and so the search was again refined The third search used a search phrase directly related to the question i.e. 'weight loss programme related to weight loss maintenance in adults'

2.4 Searching Key Databases and Journals

The key databases which were reviewed included:

- PUBMED
- PsycInfo
- CINAHL
- The Cochrane Database of Systematic Reviews
- The Cochrane Central Register of Controlled Trials (CENTRAL)

The journals which were reviewed included:

- Obesity management
- Obesity research
- The International Journal of Obesity
- Medicine and Science in sport and exercise
- Preventative medicine
- Research quarterly for exercise and sport
- British Medical Journal
- The Lancet
- Nutrition Journal
- British Journal of Nutrition
- European Journal of Clinical Nutrition

Phase two of the search strategy involved a more detailed search on the reference lists from the original research papers. The bibliographies of the retrieved articles were reviewed.

Grey literature was sought by to obtain unpublished studies and ongoing trials by searching UK Clinical Research Network Portfolio controlled trials multiple register. None were found. The search includes:

- International Standard Randomised Controlled Trial Number Register,
- National Institutes of Health,
- ClinicalTrials.gov,
- Action Medical Research,
- Medical Research Council,
- NHS Health Technology Assessment,
- Wellcome Trust,
- UK Clinical Trials Gateway);
- World Health Organisation,
- International Clinical Trials Registry Platform,
- GSK Clinical Trial Register.

2.5 Quality Assessment

All studies which met the inclusion criteria were subjected to a process of quality assessment. (Downs & Black, 1998) checklist is used to assess the methodological quality of randomised and non-randomised trials of health care intervention. The “Checklist for Measuring Quality” (Downs & Black, 1998) addresses the increasing demand for the use of evidence from systematic reviews and meta-analyses to support program and policy decisions in public health decision-making.

This tool can be used to assess the quality of original or primary source research articles and to synthesise evidence from quantitative studies for public health practitioners, policy makers and decision-makers. The tool provides both an overall score for study quality and a numeric score out of a possible 28 points. The five sections include questions about:

- Study quality (10 items) – the overall quality of the study;
- External validity (3 items) – the ability to generalize findings of the study;
- Study bias (7 items) – to assess bias in the intervention and outcome measure(s);
- Confounding and selection bias (6 items) – to determine bias from sampling or group assignment; and
- Power of the study (1 items) – to determine if findings are due to chance. Administration of the tool can happen either within a systematic review process, or as a quality assessment tool for individual articles.

2.6 Data Management

Data from each article was accurately recorded in a tabulated summary in Appendix 1. The information recorded is relevant to answering the research questions and enables consistency of comparability across the selected studies.

3 Results

Seven studies met the inclusion criteria and these comprised three RCT's, two cluster RCT'S, one pilot and one cohort (audit) study. Quality assessment was conducted using Downs & Black check list as described in the methodology section. A maximum score of 28 can be obtained on this checklist. One point is attributed to 27 questions with two points for question five. The list was adapted for the audit and pilot study and questions 21-24 were omitted. This table is detailed in Appendix 2.

The highest score of 93% was achieved by three studies. Jolly et al (2011) and Nanchahal et al (2012) achieved zero score for questions 14 and 24. Neither study made an attempt to blind study subjects to the intervention which they received (question 14). Concealment of the randomised intervention assignment from participants and health care staff until recruitment was complete and irrevocable was not done. Moore et al (2003) scored zero for questions 9 and 25. Loss to follow up was not described (question 9) and there was not adequate adjustment for confounding in the analyses from which the main findings were drawn (question 25). Davies et al (2007) scored 89%. Zero points were attributed to question 14, 15 and 24. No attempt was made to blind those measuring the main outcomes of the intervention (question 15). Relton, Strong and Li (2011) scored 86% and achieved zero score for questions 10, 25, 27. Actual probability values were not reported (question 10) and the study did not detail the statistical power used (question 27). Ross, Laws, Reckless and Lean (2008) was scored 77%. Zero score was attributed to questions 9, 10, 25 and 27. A score of 75% was achieved by McConnon et al. Zero score was attributed to questions 8, 10, 14, 15, 17, 24 and 25. All important adverse events that may be a consequence of the intervention were not reported (question 8) and it is unclear whether analysis adjusted for different lengths of follow up (question 17).

What is the effect of UK based weight management programmes on weight loss maintenance (follow up of 12 months to assess effectiveness of intervention on weight loss) for adults?

Seven studies assess the impact of weight management programmes for a twelve month period. The key parameters of these studies are displayed in table 3 and table 4.

Table 3: Summary of results relating to research question 1(Mean Weight Change & Weight Loss)

Study	Quality Score	Study Type	Population	Inclusion & Exclusion Criteria	Mean Baseline Weight (kg) & BMI(kg/m²)	Mean Weight (kg) & BMI(kg/m²) change from Baseline to 12 months	Difference Between Baseline & 12 Months(P<0.05) Between Groups (Intervention & Control)
Moore et al (2003)	26(93%)	Cluster RCT	44 general practices/8 43 patients	Inclusion Patient body mass index ≥ 30 kg/m^2 Patient aged 16 to 64 years to Exclusion Staff were excluded in they worked in primary care but between practices. No patient exclusion criteria detailed	Weight Intervention=100.8 Control=100.2 BMI Intervention = 37.0 Control = 36.9	Weight Intervention= -0.5 Control=-0.9 BMI Intervention=-0.1 Control = -0.1	Weight P=0.7 BMI = 0.96
McConnon et al (2006)	21(75%)	RCT	221 participants	Inclusion BMI >30 kg/m2 18–65 years of age (due to body composition changes over the age of 65 years) Able to access the Internet at least once per week Able to read and write in English (for the purposesof accessing the site and completing questionnaires) Exclusion Pregnant or lactating women Women planning on becoming pregnant within the next year.Any illness or reason where the GP feels that the patient should not be taking part in a clinical trial.	Weight Intervention=98.9 Control=97.9 BMI Intervention =34.5 Control = 34.4	Weight Intervention=-1.3 Control=-1.9	Weight P=0.56 BMI P=0.3

Study	Quality Score	Study Type	Population	Inclusion & Exclusion Criteria	Mean Baseline Weight (kg) & BMI(kg/m²)	Mean Weight (kg) & BMI(kg/m²) change from Baseline to 12 months	Difference Between Baseline & 12 Months(P<0.05) Between Groups (Intervention & Control)
Nanchahal et al (2012)	26(93%)	RCT	381 participants	Inclusion ≥ 18 years of age BMI ≥ 25kg/m² Attending a participating practice Willing to attend visits with a CAMWEL advisor for 12 months Exclusion Pregnancy or lactation Diagnosis of renal failure Use of a pacemaker Recent cancer diagnosis Participation in another weight management study	Weight Intervention=93.7 Control=90.95 BMI Intervention =33.92 Control = 33.02	Weight Intervention = -2.39 Control= -1.3 BMI Not provided	Weight P=0.35
Jolly et al (2011)	26(93%)	RCT	740 participants	Inclusion White Europeans and all ethnic groups apart from South Asians with no comorbidities: BMI ≥30 White Europeans and all ethnic groups apart from South Asians with comorbidities: BMI ≥28 South Asians with no comorbidities: BMI ≥25 South Asians with comorbidities GP had to confirm that the patient had no medical contraindications for any of the intervention programmes before a letter of invitation was sent. Exclusion Unable to understand English or were pregnant	Weight Intervention=93.41 Control=93.14 BMI Intervention =33.55 Control = 33.88	Weight Intervention= -2.08 Control= - 1.08 BMI Intervention = -0.69 Control = -0.45	Weight P = 0.69

Study	Quality Score	Study Type	Population	Inclusion & Exclusion Criteria	Mean Baseline Weight (kg) & BMI(kg/m²)	Mean Weight (kg) & BMI(kg/m²) change from Baseline to 12 months	Difference Between Baseline & 12 Months(P<0.05) Between Groups (Intervention & Control)
Davies et al (2007)	25 (89%)	Cluster RCT	207 general practices/824 adults	Inclusion Referral to study within 4 weeks of type 2 diagnosis & programme participation within 12 weeks. Exclusion None listed	Weight Intervention=91.8 Control=91.6 BMI Intervention = 32.3 Control = 32.4	Weight Intervention= -2.98 Control= -1.86 BMI Not provided	Weight P = 0.027 BMI Not provided
Ross, Laws, Reckless & Lean (2008)	17 (77%)	Cohort Study	65 general practices, 1906 patients	Inclusion body mass index (BMI) ≥30 kg/m2 or ≥28 kg/m2 with obesity-related comorbidities Exclusion None detailed	Weight Not provided BMI All participants 37.1.	Weight Change = -2.96 BMI Change = -1.08	No control group 39.9% of 'completers' achieved >5% weight loss at 12 months
Relton, Strong & Li (2011)	19 (86%)	Pilot	402 participants	Inclusion ≥BMI .22.5 kg/m^2 Lived in NHS Eastern and Coastal Kent area.Obtained consent from GP if <21 or > 65 years, breast feeding a baby > 6 weeks old,chronic medical condition thatrequired regular medical checks, were taking prescription medication, or had been advised to eat a special diet to treat a medical condition. Exclusion Breast feeding a baby ≥6weeks old	Weight 101.8 BMI 34.6	Weight Change = -4.0 BMI Not provided	No control group

Table 4 Summary of Results Relating to Research Question 1 (Intervention Type)

Study	Quality Score	Study Type	Intervention	Usual Care	Intervention Duration	Follow Up
Moore et al (2003)	26(93%)	Cluster RCT	4.5 hour training programme (3 training sessions) for general practitioners and practice nurses promoting an obesity management model (clinical benefit of weight loss & effective treatment options i.e. diet, exercise, behaviour change). Practitioners saw patients every two weeks until 10% weight loss and then every 1-2 months thereafter for weight maintenance.	Routine clinical practice	18 months	3, 12,18 months
McConnon et al (2006)	21(75%)	RCT	Intervention website set up providing advice, tools & information (weight loss, exercise, behaviour change). Participants were given demonstration & username & password. Participants managed own care & asked to log on once a week during the trial. Participants were provided with personalised advice & motivational statements were generated based on self-reported progress. Generic emails were sent if participants did not visit site regularly.	Advised to continue with usual approach to weight Given written information at baseline outlining information available within primary care.	12 months	6, 12 months

Study	Quality Score	Study Type	Intervention	Usual Care	Intervention Duration	Follow Up
Nanchahal et al (2012)	26(93%)	RCT	Structured one to one programme session (30mins) delivered over 14 visits by trained advisors. Participants attended sessions every fortnight for first 12 weeks, every 3 weeks for 12 weeks & monthly for next 12 weeks. Participants were given pedometers & hand outs associated with each session. General practitioners received NICE clinical guidelines on obesity	Participants were asked to contact their GP to receive usual weight management care which could include referral to dietician, exercise on referral, 'shape up' programme, prescription of weight loss medication, weight loss surgery or no further treatment. General practitioners received NICE clinical guidelines on obesity	9 months	6, 12 months
Jolly et al (2011)	26(93%)	RCT	Commercial Operators (weight watchers, slimming world, rosemary conley)-vouchers for 12 consecutive weeks. Size Down Programme (NHS based programme led by food advisors & trained by dietetics department)-six sessions. Weigh in sessions at 9 & 12 weeks. General Practice/Pharmacy-12 one to one sessions	Sent vouchers for 12 free sessions at local leisure centre. No appointments were made or advice or support given.	3 months	3 months 12 months
Davies et al (2007)	25(89%	Cluster RCT	Structured group education programme for 6 hours delivered by 2 healthcare professional educators	"Enhanced standard care" Control practices were provided with same contact time with healthcare professionals as intervention practices. Allowed to use these resources as they saw fit within their usual care routine.	12 months	4,8,12 months

Study	Quality Score	Study Type	Intervention	Usual Care	Intervention Duration	Follow Up
Ross, Laws, Reckless & Lean (2008)	16(73%)	Cohort Study	Counterweight Programme - 4 phases: 1)Practice audit & needs assessment, 2)practice support & training, 3)practice nurse led intervention, 4)evaluation <u>Practice Intervention</u> 1 hour training for GP's and 8 hour training for PN's including review of Counterweight screening & treatment pathways, importance of raising the issue of weight with patients & review of benefits of 5-10% weight loss. Peer support to GP's & PN's until competency was achieved – usually took 6 months. <u>Patient Intervention</u> Individuals contemplating change or taking action were offered the Counterweight Programme.9 appointments in 12 months after initial screening i.e. 6 individual appointments(10-30 mins each) or 6 group sessions(1 hour each) over 3 months.	Not Applicable	24 months	6,9,12,24 months
Relton, Strong & Li 2011	18(82%)	Pilot	Plans ranged from 15lb(6.8kg) weight loss over 3 months to 50lb(22.7kg) weight loss over 7 months. Max plan length was 13 months. Rewards ranged £70 to £425 per annum. P4P (pound for pound) credited participants monthly for cumulative weight loss up at a max target weight loss rate of 7.1lb (3.2kg) per month & for weight loss maintenance. Accumulated financial rewards plus 50% bonus of total max reward were given if final target weight loss at plan completion was achieved	Not applicable	Dependent on individual plan duration.	Monthly until plan completion

All studies reported weight loss from baseline to 12 months for intervention group however only Davies et al reported a significant difference between groups. Whilst all studies incorporated weight management intervention with a combination of diet, physical activity and behavior change strategy to influence lifestyle as recommended by NICE and SIGN obesity guidelines the application varied greatly and the intervention type varied considerably.

McConnon et al (2006) reported a mean weight loss of 1.9kg in the usual care group and a weight loss of 1.3kg in the intervention group. There was no significant difference between the intervention and control group weight loss from baseline to 12 Months (P=0.56). This study also reported that 22% of internet responders lost 5% or more of the baseline weight at 12 months with 18% of the usual care group losing “at least this amount”. It was not possible to calculate the latter figure as not enough information was provided in the study. Similarly Moore et al (2003) reported no significant difference in weight change (P=0.7) or BMI (0.96) at 12 months between groups after the intervention. Although the patients in the intervention group were 1kg heavier than control group at 12 months there was no significant difference (P=0.5)

Nanchalal et al (2012) reported that a higher proportion of the intervention group (32.7%) than the control group (20.4%) lost 5% or more of their baseline weight (P=0.04). In contrast Davies et al (2007) reported that although both groups lost weight at 12 months the intervention group showed a greater weight loss : -2.98kg compared with 1.86kg which resulted in a significant difference P=0.027 after adjusting for baseline and cluster effect. The modest (1.1kg) but statistically significant difference in weight loss was sustained to 12 months.

Although there was no significant difference between the comparator group and the intervention groups (P = 0.69) at 12 months by Jolly et al it should be noted that all programmes except general practice and pharmacy provision resulted in significant weight loss at 12 months when comparing each group individually. For example there

was a significant difference (P=0.024) for Weight Watcher participants between baseline and 12 months. This study also reported that 22.4% of the intervention group and 17% of the comparator group achieved 5% loss in body weight at one year.

The anticipated outcome focus by Ross, Laws, Reckless and Lean (2008) was a clinically meaningful weight loss of 5% or more up to 12 months. The results indicate that 'completers' achieved successful weight loss with 39.9% achieving a weight loss of 5% or more at 12 months. The mean weight change for completers at 12 months was -4.5kg. Relton, Strong and Li (2011) also reported that those who remained active in the programme had lost significantly more weight than those who were inactive and who had failed to complete their plan. The overall mean weight loss for all participants was 6.4kg at 12 months. The estimated 12 month mean weight loss for all participants in the programme is 4.0kg under an assumption of return to baseline weight for those who do not report 12 month weights. They also reported that 69.2% of those who were active in the programme (25%) achieved weight loss $\geq$5%.

How do weight management programmes impact on weight loss maintenance ((follow up of 12 months to assess effectiveness of intervention on weight loss)) focusing on effect on diet, physical activity and behaviour modification?

Four studies out of seven reported on the impact of a weight loss programme in terms of at least one of the following; diet, physical activity or behaviour modification at 12 months. The key parameters of these studies are displayed in table 5

Table 5: Summary of results relating to research question 2

Study	Quality Score	Study Type	Population	Diet at 12 Months Between Groups (P≤0.05)	Physical Activity at 12 Months Between Groups (P≤0.05)	Behaviour Modification at 12 Months Between Groups (P≤0.05)
McConnon et al (2006)	21(75%)	RCT	221 participants	P≥0.05	P=0.6	No Data
Nanchahal et al (2012)	26(93%)	RCT	381 participants	P=0.036	P=0.206	P=0.093
Jolly et al (2011)	26(93%)	RCT	740 participants	No Data	P=0.097	No data
Davies et al (2007)	25(89%	Cluster RCT	207 general practices/ 824 adults	No Data	P=0.81	No Data

The studies detailed in table 5 assessed one of the following elements of the weight management programme; diet, physical activity, behaviour modification. All results are self reported and assessment was by questionnaire.

Two studies reported on dietary change between baseline and 12 months between groups. Nanchahal (2012) reported on changes in eating and activity habits by participants who lost 5% or more of baseline weight compared with those who did not. Participants who lost 5% or more of baseline weight were more likely to state that they had reduced portion sizes and fat and sugar intake than those who did not (P=0.036). McConnon et al (2007) reported in text that there was no significant difference between groups at 12 months but did provide a 'P' value for this.

All four studies reported on changes in physical activity from baseline to 12 months and no significant differences were reported between the groups. McConnon et al reported 'a significant reduction in self-rated physical activity score over the intervention period (P=0.6) with a mean reduction of 0.34 in the sample'. Nanchahal reported no evidence of increasing physical activity levels between the groups (P=0.206). Jolly et al (2011) detail that self reported physical activity increased between baseline (mean=560 kcals/week) and follow up (mean=1552kcals/week) at 12 months in all groups. At one year follow up the mean physical activity reported by the intervention groups was 1502kcals/week compared with 1899kcals/week for the comparator group however there was no significant difference (P=0.97). There was a significant difference ($P \leq 0.001$) in physical activity (kcals/week) from baseline to one year for each group when compared individually. Similarly Davies et al (2007) used a continuous scale to measure physical activity. at baseline, four, eight and 12 months. The participants in the intervention group showed a greater increase in physical activity at 12 months (P=0.81).

One study reported on behavior modification. Nanchahal et al (2012) stated that there was no significant difference between groups at 12 months (P=0.093).

What is the effect of withdrawal/loss to follow up within a weight management programme on weight loss maintenance (follow up of 12 months in order to assess the impact of interventions on weight loss)? How is this dealt with in the statistical analysis and subsequent outcome?

Six studies have statistically assessed the effect of participant withdrawal from the weight management programme and subsequent loss to follow up. The key parameters of these studies are detailed in table 6 and table 7.

Table 6: Summary of results relating to research question 3 (Basis of Statistical Analysis)

Study	Checklist Score	Study Type	Population	Baseline Sample Size	Intention to Treat (ITT)	Baseline Observation Carried Forward(BOCF) Weight Loss at 12 months(kg)	Last Observation Carried Forward(LOCF) Weight Loss at 12 months(kg)	Adjustment
Moore et al (2003)	26(93%)	Cluster RCT	44 general practices/843 adults	660 adults (22 practices recruiting 30 patients each)	Where Possible	No	No	Withdrawl & loss to follow up Cluster & within cluster variation
McConnon et al (2006)	21(75%)	RCT	221 adults	180 adults	Unclear	Yes – reported but no group data provided	Yes - reported but no group data provided	Loss to Follow Up Loss to follup up & missing data
Nanchahal et al (2012)	26(93%	RCT	381 adults	228 adults	Yes	No	No	Loss to Follow Up Missing data (Multiple Imputation)
Jolly et al (2011)	26(93%)	RCT	740 adults	70 adults per group(8 groups).	Yes	Intervention 1.94kg Control 1.08kg	Intervention 2.83kg Control 1.33	Cluster & Within Cluster Variation Loss to Follow Up & Missing Data
Davies et al (2007)	25(89%	Cluster RCT	207 general practices/824 adults	630 adult (315 per study arm)	Yes	No	No	Failure to Consent & Drop Out Rate Cluster Effect
Relton, Strong & Li 2011	18(82%)	Pilot	402 adults	Not Provided	Yes	No	No	Adjust baseline co-variates Loss to follow up/Missing Data

Table 7 Summary of Results Relating to Research Question 3 (Loss to Follow Up):

Study	Assumed Loss to Follow Up at 12 Months	Actual Loss To Follow Up at 12 Months	Power Calculation	Basis of Calculation	Mean Difference Detection Required at 12 Months
Moore et al (2003)	15%	Intervention 33% Control 33%	80%	Clinical significance of ≥5% or 3-5kg weight loss	3-5kg
McConnon et al (2006)	22%	Intervention 51% Control 30%	80%	Detection of 5 kg weight loss (approximately 5% of body weight) or less than 2.5 kg/m2 in BMI	Not provided
Nanchahal et al (2012)	40%	Intervention 56% Control 40%	90%	Clinical significance of ≥5%-10% weight loss, an average of ≥7%-	6.9kg weight loss
Jolly et al (2011)	20%	Intervention 39% Control 28%	90%	Clinical significance of ≥5%-10% weight loss	2kg
Davies et al (2007)	20%	Intervention=8% Control = 11%	Not Provided	Clinical significance of ≥5% weight loss	Not Provided
Relton, Strong & Li 2011	Not provided	38%	N/A	Proportion of weight loss ≥5% or ≥10%.	Not Provided

The clinical significance of ≥5% weight loss has been reported in five studies (table 6(b)) which have been incorporated into statistical analysis. In addition three studies also specified a mean weight difference detection required at 12 months. Moore et al (2003) required ≥5% weight loss or 3-5kg weight loss. The study design incorporated 80% power to detect a mean difference in weight between treatment arms of approximately 3-5kg, assuming 5% significance and a within practice correlation coefficient of 0.05. Nanchahal et al (2012) required a detection of 6.9kg mean weight difference at 12 months between the two groups with two sided statistical significance of 1%, power at 90% and the correlation coefficient between baseline and follow up values set at 0.7. Jolly et al (2011) reported that in order to detect a 2kg difference at 90% power and 5% significance and assumed 20% loss to follow up therefore 100 adults per group were recruited with an estimated 70 adults required to participate

Assumed and actual loss to follow up (LTFU) varied considerably. Moore et al (2003) made an allowance of 15% which required approximately 660 patients (22 practices, 30 patients each). Actual LTFU up was 33% for each group. Nanchahal assumed LTFU up at 12 months of 40% and it was estimated that 380 participants were required. Actual LTFU was 56% for the intervention group and 40% for the control group. Jolly et al (2011) assumed LTFU of 20% and actual LTFU was 39% for intervention group and 28% for control group. In contrast Davies et al assumed drop out rate of 20% was greater than actual loss to follow up i.e. did not attend the practice (intervention=8% and control = 11%). The total number of adults recruited was 1000 in order to secure a necessary 630 participants (315 per arm)

Two studies calculated last observation carried forward (LOCF) and baseline observation carried forward (BOCF). McConnon et al (2006) investigated differences between the groups using covariance analysis (ANCOVA) on weight at 12 months. This adjusted for any imbalance in age, sex, baseline weight introduced by losses to follow up. Primary analysis was conducted on all available data. Both groups lost a significant amount of weight over time, but the

difference in change between the groups at 12 months was non-significant (P=0.56). ANCOVA using weight at 12 months as the dependent variable, adjusting for age, sex, baseline weight, baseline physical activity score and baseline confidence score revealed that the Internet group were 0.6 kg heavier (95% CI: -1.4 to 2.5, p = 0.56) than the usual care group after 12 months (Figure 2). Similar results were produced from BOCF data (Internet group 0.8 kg heavier (95% CI: -0.4 to 1.9, p = 0.2)) and LOCF data (Internet group 0.5 kg heavier (95% CI: -0.8 to 1.8, p = 0.4)).

Jolly et al (2011) analysed BOCF in the primary analysis and LOCF data was analysed in a sensitivity analysis. The intervention group lost 1kg more than the general practice participants at 12 months however there was no significant difference (P=0.69). When BOCF, the general practice participants still had the lowest weight loss from baseline (1.08kg (95% confidence interval 0.1 to 2.1) kg) compared with the intervention at 1.94kg. LOCF demonstrated 1.18kg greater weight loss at 12 months for the intervention group when compared with the control group..

Five studies conducted statistical analysis on an intention to treat basis with Moore et al (2003) applying this 'where possible'. Five studies adjusted for loss to follow up and subsequent missing data. Davies et al adjusted for failure to consent and drop out rate. Relton, Strong and Li (2011) adjusted for baseline co-variates. This study based statistical analysis on two assumptions. Twelve month weight data were not available for 262 of the 301 participants who were inactive at 12 months (33 plan completers and 229 who had failed to complete their plan). Firstly, it was assumed that the self-reported 12 month weights for the 39 randomly selected inactive participants were representative of all participants who were inactive at 12 months, therefore the estimate of the mean weight loss at 12 months for all participants in the P4P programme is 5.0 kg (95% CI: 3.4–6.6 kg). Secondly, it was assumed that those who failed to complete their plan returned to their baseline weight at 12 months, then the estimated overall

mean weight loss for all participants in the programme is 4.0 kg (95% CI: 2.4–5.6 kg). Mean weight loss of participants active at 12 months were calculated and compared with those who were inactive. Logistic regression was used to adjust for baseline covariates (age, sex, baseline BMI, target weight loss).

Two cluster RCT's made an adjustment to account for cluster and within cluster variation. Davies et al (2007) used 'robust generalised estimating equations with exchangeable correlation structure'.Moore et al (2003) analysed change in both continuous and categorical outcome variables by using STATA.

4 Discussion

What is the effect of UK based weight management programmes on weight loss maintenance (follow up of 12 months in order to assess the impact of interventions on weight loss) for adults?

Seven studies in this systematic review examined weight loss in adults as a result of a weight management programme with a follow up of 12 months based in the UK.

One of the studies (Davies et al, 2007) reported a significant difference (P=0.027) in weight loss between intervention (2.98kg) and control (1.86kg) group at 12 month follow up. Four studies (two RCT's and two cluster RCT's) reported weight loss at 12 months with no significant difference between control and intervention group. One pilot study (Ross, Laws, Reckless & Lean (2008) and one audit (Relton, Strong & Li 2011) both reported weight loss at 12 months as result of an intervention. Although no significant difference was reported in the RCT's this does not mean that the intervention was completely ineffective. For example, the significant difference reported by Davies et al translates to intervention group weight loss of 1.1kg greater than control group at 12 month follow up. Jolly et al reported 1kg weight loss at 12 months but no significance difference. It raises several questions. For example, did the control group receive any intervention? What did the intervention group receive? What was the duration between intervention end and follow up measurements? What were the attrition rates? How was the outcome measured?

The Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2011) detail that a control group may receive placebo, no treatment, standard treatment or an active

intervention such as standard drug. If studies are testing for similar outcome but used different control interventions then this should be considered when reviewing and comparing studies.

Of the two cluster RCT's Moore et al (2003) reported the least amount of weight loss of 0.9kg at 12 months in the control group which compares less favorably with Davies et al (2007) who reported weight loss of 1.86kg. The control group in Moore et al (2003) study participated in 'routine clinical practice' and no further information was detailed within the study. It is relevant to note that Davies et al (2007) control group received 'enhanced standard care'. This group was provided with the same contact time with healthcare professionals as the intervention group. They were allowed to use these resources as they saw fit within usual care. In addition one inclusion criteria that all participants had to meet was referral to the study within four weeks of being diagnosed with type 2 diabetes. This may have provided motivation for all participants therefore contributing towards weight loss in both groups at 12 months when compared with baseline.

Of the three randomised controlled trials McConnon et al (2006) reported the greatest control group mean weight loss at 12 months of 1.9kg. Participants in this group were advised to continue with usual approach to weight loss and provided with information at baseline outlining information available in primary care. The quality score was 75% for this study which was lower than the other two RCT's at 93%. This report stated that analysis was based on 'all available data'. However it is not clear whether participants who did not start the analysis were excluded from the intervention. Full application of intention to treat (ITT) is only possible when complete outcome data are available for all randomised subjects. ITT is inadequately described and applied in this study. Clinical effectiveness may be overestimated if ITT is not done (Bollini, Pampallona, Tibaldi, Kupelnick & Munizza, 1990). Nanchahal (2012) reported weight loss of 1.3kg at 12 months. These participants were asked to contact their GP to receive usual weight

management care. This could include referral to a dietitian, exercise on referral, 'shape up' programme, prescription of weight loss medication, weight loss surgery or no other treatment. This treatment offered more than that provided to the control group by Jolly et al (2011) who lost less weight at 1.08kg at 12 months. They were sent vouchers for 12 free sessions at a local sports centre. Participants were not given an appointment to attend and were given no individual advice or support on diet or exercise. All control groups lost weight at 12 months when compared with baseline. These results suggest that the intervention received may have contributed towards this. Also it is worth considering that having agreed to participate in a weight management trial could perhaps suggest motivation towards achieving weight loss.

Each study employed a different intervention and reported a range of mean weight losses at 12 months. For example, Jolly et al (2011) reported the most weight loss of the three RCT's of 2.98kg for intervention group and 12 months weights were recorded for 68% of participants. Nanchahal (2012) reported 2.39kg and McConnon et al (2006) 1.3kg. Nanchalal et al (2012) intervention involved a structured one to one programme delivered over 14 visits with a trained provider and 12 month weights were recorded for 57% of participants. Jolly et al (2012) involved group visits by participants to a commercial training provider. In contrast McConnon et al (2006) provided participants with no group contact and minimal face to face contact with study co-coordinators. Participants were responsible for daily internet contact themselves with motivational statements provided based on individual progress. It is not detailed how many participant weights were recorded at 12 months however it is reported that 29% were using the website at 12 months. It is not clear whether lower weight loss at 12 months follow up is linked with self help intervention or less participant engagement or possibly a combination of both. These factors warrant further consideration in future studies.

The studies demonstrate that intervention is contributing towards weight loss for both groups at 12 months. However we do not know that participants would not have lost weight anyway and having agreed to take part in the trial perhaps motivation is a factor. However the lack of a significant difference between intervention and control group may be attributable to the intervention provided to the control group. For example, what results would absolutely no intervention for the control group produce? Could there be a link between intervention duration or intensity and weight loss from baseline to 12 month follow up?

Nanchahal et al intervention duration was 9 months and Jolly et al intervention was 12 weeks, both with follow up at 12 months. The mean weight loss from baseline to 12 months for intervention group was 2.39kg and 2.08kg respectively. McConnon et al intervention duration was 12 months and intervention group weight loss was 1.3kg. The less effective self-help approach together with poor engagement with the intervention tool of 29% may have contributed to this lower weight loss when compared with the other two RCT's. Also it is not possible to conclude how intense each intervention was. Davies et al (2007) reported intervention group mean weight loss from baseline to 12 months of 2.98kg. A six hour structured group education programme was delivered by two healthcare educators to participants. It is not detailed what care, if any, participants received after this. It must be noted that participants were referred to this study within four weeks of diagnosis for type 2 diabetes therefore motivation may have been a factor for successful weight loss and maintenance. Moore et al (2003) reported a lower mean weight loss at 12 months of 0.5kg for the intervention group. General practitioners or practice nurses saw patients every two weeks until 10% of weight was lost and then every 1-2 months until study end. These studies do not provide enough information to assess whether intensity or duration of the intervention can promote weight loss at 12 month follow up when compared with baseline. Further research is required in this respect. For example, would

intense interventions of a shorter duration promote sustained weight loss at 12 month follow up? What are the cost implications and how do they compare to longer less intense interventions?

The cohort study (Ross, Laws, Reckless & Lean 2008) reported mean weight change at 12 months of -2.96kg and 'Pounds for Pounds' (P4P) weight loss scheme (Relton, Strong & Li 2011) reported mean weight change of -4.0kg. However the plan completion rate of 38% was lower than that reported by Ross, Laws, Reckless & Lean (2008) at 75%. It is not clear what factors contributed towards this. Perhaps P4P was more rigid in structure than Counterweight having focused on achieving target weight loss at plan completion, monthly weigh in, and cumulative credit on this basis up to maximum weight loss of 3.2kg per month. Ross, Laws, Reckless & Lean (2008) focus was on 5-10% weight loss and they provided participants with nine appointments in 12 months after initial screening i.e. 6 individual appointments(10-30 mins each) or 6 group sessions(1 hour each) over 3 months The financial incentive provided by Relton, Strong and Li (2011) study may have promoted motivation required for participants to achieve weight loss goals. However the absence of a control group means that it is unknown whether this weight loss would have been observed in a control group who were equally motivated to lose weight but were not offered the programme.

The motivational aspect of each study merits discussion because this could be a potential contributory factor towards weight loss. The fact that all control groups lost weight at 12 months when compared with baseline and having volunteered to participate in a weight management trial would suggest a certain element of motivation. The financial motivation provided by Relton, Strong & Li (2011) may have been a factor for recruitment and participation however it is relevant to note that at 12 months 34% of participants were inactive and failed to complete their plan, 7% completed and left and 14% were active. Mean weight loss of 4kg at 12 month follow up suggest that money could be a contributory motivational factor in this study. A randomised

controlled trial is required to compare the intervention with a control group. It should also be recognised that the incompleteness of data at 12 months means that the overall estimation of weight loss is sensitive to assumptions made about the weight change trajectory of participants with no 12 month weight. Participants in the trial by Davies et al (2007) could possibly have been motivated having been referred to this study within four weeks of type 2 diabetes diagnosis. This may also be reflected in the low attrition rates when compared with the other studies. Attrition will be discussed in question 3. However it is also important to consider that participants from study by McConnon et al (2006) and Moore et al (2003) were extremely obese (BMI ≥ 30 kg/m^2) and therefore it is likely that many also had co-morbidities. Jolly et al (2011) specify co-morbidities in the inclusion criteria and subsequent eligibility. Therefore perhaps the time scale between diagnosis and referral is relevant in promoting and sustaining weight loss at 12 month follow up..

How do weight management programmes impact on adult participants of UK based weight management programmes on weight loss maintenance (follow up of 12 months to assess effectiveness of intervention on weight loss) focusing on effect on diet, physical activity and behaviour modification? Is there a significant difference (P≤0.05) between groups at 12 months?

As previously noted NICE CG43 recommends the use of multi component intervention with tailored advice on physical activity, eating behavior, healthy eating and lifestyle changes. It specifies that people should be expected to lose no more than 0.5-1kg per week and that programmes that do not meet these criteria are unlikely to maintain long term weight loss. SIGN 115 recommends that weight management programmes include diet, physical activity and behavior change in order to achieve weight loss and maintenance of same. It specifies that diets should produce 600kcal daily deficiency and physical activity should equate to loss of 1800-

2500 kcal weekly. This translates to 225-300 minutes of moderate intensity per week or five 45-60 minute sessions. Behavior modification guidelines include less television watching and regular self weighing. This raises several questions in respect of this systematic review. Have results for all three components been reported? Have 'P' values been reported for each component and is there a significant difference between firstly the groups and secondly each component ($P \leq 0.05$)? Are national guidelines being met or exceeded?

Four studies (table 5) have reported using a multi-component weight loss approach and have assessed and provided results on at least one of these components. All information was self reported and obtained using questionnaires. No significant difference was found between groups at 12 months for any component in the four studies.

McConnon et al (2006) reported no dietary significant difference between groups in text only and no further information was provided. Nanchalal et al reported on all three components. Diet ($p=0.036$) is closest to the significant difference value of 0.05 when compared with physical activity ($p=0.206$) and behavior modification ($p=0.093$). Why is this? Is this the easiest or most convenient element to change or control? Diet data was based on participants who completed the 12 months follow up. Those that lost 5% or more of baseline weight stated a reduction in portion sizes and fat and sugar intake. A higher proportion (one in three compared with one in five) of the intervention group lost at least 5% initial weight (difference 14.7%(3.0 to 26.4, $P=0.01$). Participants who lost 5% or more of baseline weight were more likely to state that they had reduced portion sizes and fat and sugar intake than those who did not ($P=0.036$). It should be noted that loss of 5% or more of baseline weight may not reduce a person from an obese to a non obese state. It is difficult to put these results into context because there is not enough information provided. What are the characteristics of these participants i.e. how many were

overweight ($\geq$25 kg/m^2) or obese ($\geq$30 kg/m^2)? What were the portion sizes and what was energy intake?.

All four studies reported on changes in physical activity from baseline to 12 months and no significant differences were reported between the groups. Participants in the study by Nanchahal et al (2012) were more likely to use the stairs instead of a lift, join a gym and walk instead of take a car. Did the intervention group exercise more the control group? Davies et al (2007) reported that physical activity levels for intervention group were greater than that of the control group at 12 months with no significant difference (P=0.81). However the latter two studies did not specify how much exercise the participants were doing at baseline i.e. were they meeting or exceeding the guidelines? How does this compare to results at 12 months?. Jolly et al reported increased physical activity changes at 12 months between baseline (mean 560kcals/week) and 12 months (mean=1552 kcals/week) in both groups. It should be noted that at programme end the intervention group reported greater mean physical activity levels of 1958kcals/week than the control group at 1608 kcals/week. However the mean increase from programme end (12 weeks) to 12 months was greater in the control group at 158 kcals/week than in the intervention group which reported a decrease of 495 kcals/week (mean activity levels 1463kcals/week). Therefore whilst the intervention resulted in weight loss an increase in physical activity was not sustained at 12 months. The control group received 12 vouchers for local leisure centre and it is likely that the emphasis in such a venue would promote physical activity once you enter the facility which is perhaps reflected in the results of this study. The intervention group meetings did not include actual exercise participation. It was about guidance, motivation and associated benefits and subsequent weigh in. Participants taking time out to go to these sessions would also have to make time for exercise sessions. Also the individual cost of continuing with the intervention after programme end must be considered and compared with that of attending the leisure centre. The cost of the intervention was provided in this study but

not the cost of the control intervention. This could have prompted cessation of attendance after programme end by intervention participants. Although provision of vouchers to an exercise facility can promote weight loss at 12 months it should be noted that having agreed to participate in this trial the control group may be more motivated than those referred by say a GP or PN. Similarly McConnon et al (2007) reported a reduction in self-rated physical activity score over the intervention period (P=0.6) with a mean reduction of 0.34 in the sample with no further information provided.

Nanchahal et al (2012) was the only study to report on behavior modification. Participants who lost 5% or more of baseline weight reported that attending regular meetings, discussion on portion sizes and using a pedometer were useful and they would continue to do this to maintain their weight. Further information is required in order to identify other influential elements. For example, did participants report spending less time watching television? How did they reward themselves for weight loss?

Questions are still outstanding which need to be addressed. Whilst these studies incorporate a multi-component approach to weight loss it is not clear whether NICE and SIGN guidelines are realistic. Do they need to be revised? Do they contribute to a sustainable weight loss at 12 month follow up? Jolly et al is the only study which has provided enough data to answer some of these questions and the intervention group met SIGN physical activity guidelines at 12 months follow up. Physical activity in the intervention group had decreased at 12 months when compared with baseline. Therefore are these guidelines sustainable? It cannot be concluded whether physical activity was the strongest component because no ‘P’ values have been reported for diet and behavior modification in this study. Reporting of further detail such as frequency, intensity, timing and type of physical activity would be beneficial. Assessment and data reporting of all three components is required in future studies in order to identify which is

the weakest and strongest component and also to investigate a significant difference. It is relevant to compare not only intervention and control group but also assess whether there is a significant difference between the three components. Detail should be reported for daily energy intake and expenditure in order to compare it with the guidelines.

How is withdrawal/loss to follow up within a weight management programme (continuation of programme or follow up of at least 12 months in order to assess the impact of interventions on weight loss) dealt with in the statistical analysis?

The basis of calculation for each study has reported using the definition of clinical significance associated with ≥5% weight loss. It is relevant to note that the health benefits associated with this is unknown within each study because it has not been measured. This definition should be interpreted with caution because it implies that there is no limit on the amount of weight that can be regained once net weight loss remains below the criterion. It assumes that the bounds around which weight loss maintenance is placed are known. Moore et al and McConnon et al have included a designated body weight. Going forward all studies should consider incorporating similar in addition to specification of standardised conditions. This prompts the question that if all these studies are using this same definition then why is there such variation in the sample size and assumed loss to follow up (LTFU) between the six studies (table 6 and table 7)? This is an important question because it impacts on the estimated sample size and subsequent (LTFU) and missing data. An accurate estimation of LTFU may be achieved by reviewing and comparing assumed and actual LTFU figures thereby reducing the need for adjustment and subsequent bias as will now be discussed.

Due to the different assumptions made by various methods regarding accounting for missing data the analytical methods chosen may influence interpretation of study results. Six studies have statistically assessed the effect of participant withdrawal from the weight management

programme and subsequent loss to follow up. The key parameters of these studies are detailed in table 6 and table 7. Intention to treat (ITT) means that the participants were analysed in the groups to which they were randomised regardless of whether they adhered to the intervention. Therefore participants who strayed from the protocol were kept in the analysis. This estimates the effects of allocating an intervention in practice not the subgroup of participants who adhere to it (Bollini, Pampallona, Tibaldi, Kupelnick & Munizza, 1990). Five of these studies have used the intention to treat (ITT) analysis. Moore et al (2003) used it 'where possible', however if ITT is not used then overestimation of clinical effectiveness may be caused. The randomisation feature may be lost if analysis is not performed on the groups produced by the randomisation process (Hollis, 1999). Although McConnon et al (2003) report in the text that analysis was ITT they provide data results for responders and non-responders. This is acceptable to do however full application of ITT is possible only when complete outcome data are available for all randomised subjects. A problem with ITT is loss to follow up as demonstrated by all six studies. This means that the outcome may not be measured on those that drop out but the ITT principle suggests that they should still be included in the analysis. Data may not be available for these participants and so in order to include them it is necessary to find out whether data is available for them or impute the outcomes. Therefore assumptions on the lost participants must be made. There are many approaches to this. For example, Jolly et al assumed that participants for whom weight at follow-up was not available had their baseline weight for the primary analysis. Davies et al did not replace missing outcomes and derived an average over time of continuous outcomes. This effect measured the cumulative effect of the treatment and has the maximum number of participants. It should be noted that the latter study had participant loss of 8% in the intervention group and 11% in the control group which is lower when compared with the other five studies suggesting that these levels are unusually low. One cause of this could be motivation because all participants were referred within four weeks of being diagnosed with type 2 diabetes. The outcome for this study was a continuous measure and imputation for missing

data is more difficult as there are more than two possibilities for each participant (Newell, 1992). Although Nanchahal et al reported in the text that missing values were imputed the strategy for this was not reported. Did they assume the best strategy i.e. did participants achieve an average clinically significant weight loss of 7%? Did they assume the worst strategy i.e. did participants return to baseline weight or gain weight?

The baseline observation carried forward (BOCF) is one approach used to handle missing data from early treatment discontinutation. This requires that the patient remain active in the in the trial for response evaluation. If the patient drops out the baseline information is used as the final response regardless of the reason for drop out. In contrast the last observation carried forward (LOCF) uses the last observed non missing value in place of the missing endpoint. McConnon et al used both of these methods. They report that BOCF and LOCF results were similar to those found using ANCOVA statistical analysis. They report in text that the intervention group was 0.8kg heavier and 0.5kg heavier than the control group at 12 months. Complete cases reported control group weight loss of 0.6kg more than the intervention group. However no further data was provided. Jolly et al reported BOCF greater weight loss between intervention group of 0.86kg and LOCF of 1.5kg when compared with the control group. Complete cases reported 1.18kg greater weight loss in the intervention group. LOCF results should be treated with caution because it provides biased estimates of treatment effects. In addition LOCF is liable to underestimate the treatment effect if there is approximately equal drop out in both groups. Jolly et al report a difference in drop out rate for intervention group of 39% and control group of 28%. The assumed LTFU was 20%. McConnon et al reported a drop out rate for intervention of 51% and control group of 30%. The assumed LTFU was 22%. It should also be noted that these cases of unequal drop outs the bias can be much larger in either direction. Multiple imputation can also be used to handle missing data. Nanchalal et al utilised this method. They detailed that ‘for each outcome the full set of imputation variables comprised the outcomes at each of the

three occasions together with a set of baseline variables selected for their non-negligible association with missingness and weight loss". Alternatively analysis of available data but consideration of drop out rate as a marker of trial quality should be considered. Single imputation cannot reflect the uncertainty about the actual value. Therefore analysis that treat imputed values like observed values can underestimate this uncertainty leading to standard errors that are too small and p-values which are systematically too significant.

Imputation of missing data necessary for a full ITT analysis is controversial. It may be best to report results for available participants only. The effects on missing participants should also be considered by sensitivity analysis. In addition it would be beneficial to consider treatment related and non-treatment related reasons for dropout and actual treatment outcomes from patients.

5 CONCLUSION

The consequences of an obese population have been described in the 'Introduction' section. The health and financial implications of increasing obesity in the UK are detailed by Foresight (Future Choices Project, 2007). In order to take control of this situation with an aim to reduce obesity levels the government responded with 'Healthy Weight, Healthy Lives' in 2008. This commitment, support and action by the UK government are essential in order to reverse the rising tide of obesity.

'Healthy Weight, Healthy Lives' (2008) identify primary care as the first port of call for advice about weight control and NICE (2006) recommend that clinical management be offered to obese patients by primary care physicians. However research (section 1.2) has reported that general practitioners and practice nurses' lack the necessary training and education in this area promoting a reluctance to deal with the obesity epidemic single handedly. The limited resources within the NHS have prompted outsourcing to commercial weight management programmes. This relieves pressure on general practices in terms of time and finance. It also offers participants a wide selection of venues and times.

The principles of weight management are primarily to achieve clinically significant weight loss and secondly to maintain lost weight. Whilst the clinically significant benefits of $\geq$5% weight loss have been demonstrated it is important to note that it cannot automatically be assumed that <5% weight loss is not clinically significant. Weight maintenance is often cited as an elusive goal and the more difficult component of weight management to achieve. However studies detailed in section 1.5 (weight loss maintenance) demonstrate that this is possible. The problem is weight regain. There is little purpose in committing time and money to reducing obesity if the weight is regained. This is counter-productive and weight loss maintenance is essential. Research has

revealed that defining this is problematic and as such does not promote ease of comparability across studies. Going forward although any weight maintenance definition will be somewhat arbitrary it should be compatible with national and international expert committees. It should also include a designated body weight under standardised conditions and avoid the use of body weight percentage loss.

NICE CG43 and SIGN 115 national guidelines recommend the use of multi-component weight management programmes which comprise diet, physical activity and exercise in order to lose weight and maintain a healthy body weight. The inclusion criteria reflect this requirement and a systematic review was conducted of all literature pertaining to weight loss maintenance through a multi-component weight management programme. Weight loss maintenance was defined as follow up at 12 months to assess effectiveness of intervention on weight loss. Seven studies met the eligibility criteria and quality was assessed with three studies scoring 93% and one scoring 89%, 82%, 75% 73%.

What is the effect of UK based weight management programmes on weight loss maintenance (follow up of 12 months to assess effectiveness of intervention on weight loss) for adults?

Both groups in all studies reported weight loss at 12 months. All control groups received an intervention and the research suggests that this could have contributed towards weight loss at 12 months and possibly lack of a significant difference between groups. In addition it is worth considering that having agreed to participate in a weight management trial could perhaps prompt motivation towards achieving weight loss. One study (Davies et al, 2007) reported a significant difference between groups. Attrition rates were low when compared with the other studies. Motivation was possibly greater given that all participants were referred within four weeks of being diagnosed with type two diabetes which may have prompted motivation.

However it is important to consider that participants in the study by McConnon et al (2006), Moore et al (2003) and Jolly et al (2011) were all obese and it is likely that they too had co-morbidity. In fact this was part of the eligibility criteria in the latter study. Therefore perhaps the time scale between diagnosis and referral to weight management RCT is relevant and certainly warrants further investigation in future research studies. One study (Relton, Strong & Li, 2011) paid participants to lose weight and reported greater weight loss at 12 months when compared with the other six studies. However attrition rates were high. The absence of a control group means that it is unknown whether this weight loss would have been observed in a control group who were equally motivated to lose weight but not offered the programme. Different interventions were used in each study and there are so many variables that it was not possible to draw conclusions as to the most effective. There is not enough information to confirm the extent to which intensity and duration of intervention has affected the outcome. Also all control groups received an intervention which impacted on results and subsequent outcome.

How do weight management programmes impact on weight loss maintenance ((follow up of 12 months to assess effectiveness of intervention on weight loss)) focusing on effect on diet, physical activity and behaviour modification?

Whilst all seven studies reported using this approach only four studies reported results on at least one of these components. All information was self reported and obtained using questionnaires and there were no significant difference between groups for any component. National clinical guidelines (SIGN 115 & NICE CG43) detail the exercise, diet and behavior modification are necessary to lose and maintain weight. One study (Nanchahal et al, 2012) reported on all three components and ‘p’ value for diet was closest to the significant difference level of 0.05 when compared with the other two components. It is not clear whether this is the strongest component because a significant difference between components was not

investigated. A significant difference should be assessed not only between groups but also between components. This will identify the weakest and strongest component and identify in which direction focus is required. One study (Jolly et al, 2011) provided enough information on physical activity levels to compare it to the national guidelines. The intervention group is in line with national guidelines when compared with baseline and intervention end (12 weeks) but this was not sustained to 12 months. It is relevant to consider whether a longer intervention period would have sustained these levels. It cannot be concluded whether the national guidelines are sustainable and/or require revision. In future studies it is important that results from all components be reported. Information on energy intake and expenditure must be assessed. This will enable comparability with the national guidelines and assessment of whether these are realistic or sustainable.

How is withdrawal/loss to follow up within a weight management programme (continuation of programme or follow up of at least 12 months in order to assess the impact of interventions on weight loss) dealt with in the statistical analysis?

Withdrawal and loss to follow up is a problem for all but one study (Davies et al, 2007). Due to the different assumptions made by different methods regarding accounting for missing data the analytical methods chosen may influence interpretation of results. It is relevant to note that all study's refer to the clinically significant health benefits associated with $\geq$5% weight loss however the health benefits of this in each study is unknown because it has not been measured. High attrition rates were apparent in all but one study. Four studies were conducted on an intention to treat (ITT) basis. One study was unclear and another did it where possible. Imputation of missing data for a full ITT analysis is controversial. Adjustments must be made to take account of this. The studies describe three methods used to account for missing data; baseline observation carried forward (BOCF), Last observation carried forward (LOCF) and multiple imputation (MI). There are advantages and disadvantages with each method. It may be best to

report results for available participants only. The effects on missing participants should be considered by a sensitivity analysis. In addition it would be relevant to consider treatment related and non-treatment related reasons for dropout and actual treatment outcomes for patients. Alternatively analysis of available data but consideration of drop out rate as a marker of trial quality would be acceptable. It should also be noted that the assumed loss to follow up is lower than actual loss to follow up in all but one study. If this element of each study were to be reviewed then perhaps there would be a smaller gap between assumed and actual therefore less adjustments would be required.

All seven studies are pragmatic and assess whether the intervention works under real life conditions in terms that matter to the patient. It is concerned with whether the intervention works and not how or why. This study type is beneficial for deciding what services should be provided but give limited insight into the mechanics of the intervention. Perhaps the issues discussed in this dissertation could be further answered through explanatory research. This would assess whether an intervention works under ideal or selected conditions and is concerned with how and why an intervention works. Although these studies are valuable for understanding questions of efficacy they are of limited value when assessing whether we should provide a service to a wide variety of patients in a wide variety of circumstances. The distinction between pragmatic and explanatory research is important because it will determine key methodological issues relating to patient selection, definition of the intervention and controls, use of blinding and placebos, choice of outcome measure and type of analysis.

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7 Appendix 1

Data collection form

Intervention review – RCTs and non-RCTs

This form can be used as a guide for developing your own data extraction form. Sections can be expanded and added, and irrelevant sections can be removed. It is difficult to design a single form that meets the needs of all reviews, so it is important to consider carefully the information you need to collect, and design your form accordingly. Information included on this form should be comprehensive, and may be used in the text of your review, 'Characteristics of included studies' table, risk of bias assessment, and statistical analysis.

Notes on using a data extraction form:

- Be consistent in the order and style you use to describe the information for each report.
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.

Review title or ID
Weight management in primary care: the Counterweight Project – Study 3

Study ID *(surname of first author and year first full report of study was published e.g. Smith 2001)*
Ross, Laws, Reckless & Lean (2005)

Report ID *(if different to Study ID)*	**Report IDs of other reports of this study** *(e.g. duplicate publications, follow-up studies)*
The Counterweight Team, 2008 The Counterweight Team, 2008	Evaluation of the Counterweight Programme for obesity management in primary care: a starting point for continuous improvement Engaging patients, clinicians and health funders in weight management: the Counterweight Programme

Notes:

Weight management in primary care: the Counterweight Project:

Overview: *Weight Change at 12 months*

Evaluation of the Counterweight Programme for obesity management in primary care: a starting point for continuous improvement

Overview: Primary outcome measures were weight change and percentage of patients achieving >5% loss at 12 and 24 months

Engaging patients, clinicians and health funders in weight management: the Counterweight Programme

Overview: To explore key barriers and facilitators of practice and patient engagement in the Counterweight Programme and to describe key strategies used to address barriers in the wider implementation of this weight management programme in UK primary care

Relevance of the Project ("Methods – Design")

When Counterweight was established there was no evaluated model for weight management in primary care. A cluster randomisation model including a deferred intervention would have had limitations, because data collection could have an intervention effect. A within-practice experimental design with a control group was not possible, as

Counterweight works with the whole practice team.

'Practice Intervention'

The unique feature of this programme was the mentoring provided by the weight management advisers in routine clinical settings.

'Patient Intervention'

No additional incentive (other than reporting outcomes back to practices) was offered to practices for data measurement and recording.

General Information

Date form completed *(dd/mm/yyyy)*	17/07/2012
Name/ID of person extracting data	Alison Moore
Reference citation	
Study author contact details	The Counterweight Team Telephone: 07968 820081/07803 726604 Email: enquiries@counterweight.org
Publication type *(e.g. full report, abstract, letter)*	Full Report
Notes:	

Study eligibility

Study Characteristics	**Eligibility criteria** *(Insert inclusion criteria for each characteristic as defined in the Protocol)*	**Eligibility criteria met?** Yes	**Location in text or source** *(pg & ¶/fig/table/other)*
Type of study	Randomised Controlled Trial	☐ No ☐	
	Quasi-randomised Controlled Trial	☐ No ☐	
	Controlled Before and After Study • Contemporaneous data collection • Comparable control site • At least 2 x intervention and 2 x control clusters	☐ No ☐	
	Interrupted Time Series • At least 3 time points before and 3 after the intervention • Clearly defined intervention point	☐ No ☐	
	Other design (specify): Prospective evaluation of a new continuous improvement model for weight management in primary care.	☐ ☐ ☐	
Participants	Mean age for 1906 patients at baseline was 49.4 years (SD 13.5 years, range 18.1–76.0 years); 77% were female; and, of those enrolled in the programme, obesity was severe (mean weight 101.1 kg, BMI 37.1 kg/m2). Nearly three-quarters of patients had ≥1, nearly half ≥2, and over a quarter ≥3 obesity-related comorbidities (Table 1).	☐ ☐ ☐	
Types of intervention	Primary care practice nurses from 65 UK general practices delivered interventions to 1906 patients with body mass index (BMI) ≥30 kg/m2 or ≥28 kg/m2 with obesity-related comorbidities. 1. Practice Intervention 2. Participant Intervention	☐ ☐ ☐	
Types of	Primary Outcome	☐ ☐ ☐	

outcome measures	Primary outcome measures were weight change at 12 and 24 months and percentage of patients achieving and maintaining ≥5% loss at these time points. <u>Secondary Outcome</u> total-cholesterol low-density lipoprotein cholesterol HDL-cholesterol systolic blood pressure diastolic blood pressure fasting glucose (in patients with diabetes only) H		
INCLUDE Yes **EXCLUDE** ☐			
Reason for exclusion			
Notes:			

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

Characteristics of included studies

Methods

	Descriptions as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
Aim of study *(e.g. efficacy, equivalence, pragmatic)*	To determine to what extent measures of success seen in intensive clinical trials can be achieved in routine primary care. Primary outcome measures were weight change and percentage of patients achieving ≥5% loss at 12 and 24 months.	
Design*(e.g. parallel, crossover, non-RCT)*	Prospective evaluation of a new continuous improvement model for weight management in primary care.	
Unit of allocation *(by individuals, cluster/ groups or body parts)*	Groups	
Start date	1st January 2001	'Patient Intervention'

End date	31st December 2004		Patient Intervention'
Duration of participation *(from recruitment to last follow-up)*	Recruitment was continuous and data capture for the evaluation presented in this paper was from 1 January 2001 to 31 December 2004.		Patient Intervention'
Ethical approval needed/ obtained for study	☐ ☐ ☐ Yes	The Counterweight Programme was approved by the UK West Midlands Multi-Centre Research Ethics Committee (UK 99/07/74) and subsequently by Local Research Ethics Committees in each area	
Notes: The aim of collecting secondary outcome data was to assess whether data followed expected well-documented trends in line with associated weight management,10,11 rather than to assess the impact of weight change. A data set of investigations related to secondary consequences of obesity was recommended and collected in line with local guidelines and policies. Counterweight aimed to improve identification and management of secondary diseases, such as diabetes and hypertension, including the use of appropriate medications.(Patient Intervention)			

Participants

	Description *Include comparative information for each intervention or comparison group if available*		**Location in text or source** *(pg & ¶/fig/table/other)*
Population description *(from which study participants are drawn)*	65 general practices from seven UK regions		'Method, Design'
Setting *(including location and social context)*	Primary Care Practices that reflected UK profiles, varying in size, location, and category of social deprivation, were invited to participate.		
Inclusion criteria	body mass index (BMI) ≥30 kg/m2 or ≥28 kg/m2 with obesity-related comorbidities		
Exclusion criteria	Not mentioned		
Method of recruitment of participants *(e.g. phone, mail, clinic patients)*	Patients were identified for the Counterweight Programme by GPs and practice nurses during normal appointments.		
Informed consent obtained	☐ ☐ ☐ Unclear		
Total no. randomised *(or total pop. at start of study for NRCTs)*	N/A		

Clusters *(if applicable, no., type, no. people per cluster)*	N/A	
Baseline imbalances	N/A	
Withdrawals and exclusions *(if not provided below by outcome)*	The 56 practices identified 2095 patients, of which 1906 satisfied eligibility criteria. At data-set closure, 1419 patients had reached ≥12 months, and 825 had reached 24 months.	'Results'
Age	Mean age for 1906 patients at baseline was 49.4 years (SD 13.5 years, range 18.1–76.0 years);	'Patient Characteristics' Table 1
Sex	77% were female; and,	
Race/Ethnicity	Not provided	
Severity of illness	Of those enrolled in the programme, obesity was severe (mean weight 101.1 kg, BMI 37.1 kg/m2).	'Patient Characteristics' Table 1
Co-morbidities	Nearly three-quarters of patients had ≥1, nearly half ≥2, and over a quarter ≥3 obesity-related comorbidities (Table 1).	
Other relevant sociodemographics	According to practice location by using the Carstairs Index (Scotland),22 and the Jarman Index (England).23 It was recognised that this would not necessarily reflect individual patient status but was expected to reflect the practice profile very broadly. In England (E) affluence is split into 10 categories, with category one being the most deprived; while in Scotland (S) there are seven categories, with seven being the most deprived. As scales and bandings differ the following aggregates were used: affluent = E8–10, S1–2, intermediate = E4–7,S3–5, and deprived = E1–3, S6–7. <u>Results</u> Twenty-two practices from deprived areas, 22 from intermediately-deprived areas, and 12 practices from affluent areas contributed 36.4%, 29.5%, and 34.2% of patients respectively	'Patient Intervention'
Subgroups measured	N/A	
Subgroups reported	N/A	
Notes:		

Outcomes

Copy and paste table for each outcome.

Outcome 1

	Description as stated in report/paper **Weight Change at 12 months** **Weight change at 24 months**	**Location in text or source** *(pg & ¶/fig/table/other)*
Outcome name	Weight change who had lost ≥5% of their initial weight	Table 3
Time points measured *(specify whether from start or end of intervention)*	Baseline, 3, 6, 9, 12 months	
Time points reported	Baseline, 3, 6, 9, 12 months	
Outcome definition *(with diagnostic criteria if relevant)*	Weight change who had lost ≥5% of their initial weight	
Person measuring/ reporting	The practice nurse role was to deliver patient education through discussion about weight management, communication of information, and the transfer of behaviour change skills and strategies during weight-management sessions. In several practices healthcare assistants took on this role. Weight management advisers conducted patient consultations	
Unit of measurement *(if relevant)*	N/A	
Scales: upper and lower limits *(indicate whether high or low score is good)*	N/A	
Is outcome/tool validated?	☐ ☐ ☐ Yes N/A	
Imputation of missing data *(e.g. assumptions made for ITT analysis)*	Baseline data are presented for all 1906 enrolled patients, together with results at 3, 6, 12, and 24 months. As some patients missed one or more appointments or dropped out, mean weight changes reflect a patient sub-group of those who attended, comprising different individuals at different time-points.	'Results'
Assumed risk estimate *(e.g. baseline or population risk noted in Background)*		
Power		

Notes:

Discussion

This study presents, for the first time, prospective evidence of an effective model of weight management for primary care. Of the practices that initially agreed to implement Counterweight, 86% became active, and weight change data compare favourably with those achieved in specialist research settings.9

Despite ***no extra practice funding,*** more than two-thirds of practices enrolled new patients beyond 12 months, allocating time previously spent managing obesity somewhat haphazardly. Almost half of all patients attended 12-month follow-up. The most favourable results were seen in high attenders, suggesting that processes to optimise attendance and retention are worthy of further investigation.

Other

Study funding sources *(including role of funders)*	Roche Products Ltd provided an initial 6-year unencumbered educational grant-in-aid to the Counterweight Project Board and to Robert Gordon's University, Aberdeen. Roche Products Ltd had no input to the design and conduct of the study; nor to collection, management, analysis, and interpretation of the data; and nor to preparation, review, or approval of the manuscript. The programme was designed and run by the Counterweight Project Team independent of Roche Products Ltd. Since completion of the evaluation phase in 2005, the Scottish Government has funded the Counterweight Programme. In England individual Primary Care Trusts commission the programme. No commercialorganisation has any ongoing interest in the Counterweight Programme. The Weight Management Adviser team is employed by the Robert Gordon University, and central data collection and analyses are managed by Glasgow University. There is a Counterweight website: www.counterweight.org	
Possible conflicts of interest *(for study authors)*	GFL,3 GSF,5 MFQ,3 JHB,1–4 SMH,3 NF,1–5 DWH,1–4 HMR,3,6 DJH,5 SR,5 DSM,5 BS5 declare potential competing interests: Have acted as consultants. 2Have received lecture honoraria. 3Have attended national/international meetings as guests of Roche Products Ltd. 4Involvement as above with other pharmaceutical companies with an interest in obesity. 5Research grant. 6HMR was employed by Roche Products Ltd 2000–2007 but reported and was responsible to the Chair of the Counterweight Project Team. HMR was employed by the Robert Gordon University from 2007. The programme national coordinator was employed by the sponsor, but reported, and was responsible, to the Chair of the Counterweight Project Team. All intellectual property rights reside with the Counterweight Project Team	
Notes:		
Notes:		

Definitions

Assumed risk estimate	An estimate of the risk of an event or average score without the intervention, used in Cochrane 'Summary of findings tables'. If a study provides useful estimates of the risk of average score of different subgroups of the population, or an estimate based on a representative observational study, you may wish to collect this information.
Change from baseline	A measure for a continuous outcome calculated as the difference between the baseline score and the post-intervention score.
Clusters	A group of participants who have been allocated to the same intervention arm together, as in a cluster-randomised trial, e.g. a whole family, town, school or patients in a clinic may be allocated to the same intervention rather than separately allocating each individual to different arms.
Co-morbidities	The presence of one or more diseases or conditions other than those of primary interest. In a study looking at treatment for one disease or condition, some of the individuals may have other diseases or conditions that could affect their outcomes.
Compliance	Participant behaviour that abides by the recommendations of a doctor, other health care provider or study investigator (also called adherence or concordance).
Contemporaneous data collection	When data is collected at the same point(s) in time or covering the same time period for each intervention arm in a study (that is, historical data are not used as a comparison).
Controlled Before and After Study	A non-randomised study design where a control population of similar characteristics and performance as the intervention group is identified. Data are collected before and after the intervention in both the control and intervention groups
Exclusions	Participants who were excluded from the study or the analysis by the investigators.
Imputation	Assuming a reasonable value for a measure where the true value is not available (e.g. assuming last observation carried forward for missing participants).
Integrity of delivery	The degree to which the specified procedures or components of an intervention are delivered as originally planned.
Interrupted Time Series	A research design that collects observations at multiple time points before and after an intervention (interruption). The design attempts to detect whether the intervention has had an effect significantly greater than the underlying trend.
Post-intervention	The value of a continuous outcome measured at some time point following the beginning of the intervention (may be during or after the intervention period).
Power	The probability that a trial will detect, as statistically significant, an intervention effect of a specified size.
Providers	The person or people responsible for delivering an intervention and related care, who may or may not require specific qualifications (e.g. doctors, physiotherapists) or training.
Quasi-randomised controlled trial	A study in which the method of allocating people to intervention arms was not random, but was intended to produce similar groups when used to allocate participants. Quasi-random methods include: allocation by the person's date of birth, by the day of the week or month of the year, by a person's medical record number, or just allocating every alternate person.
Reanalysis	Additional analysis of a study's results by a review author (e.g. to introduce adjustment for correlation that was not done by the study authors).

Report ID	A unique ID code given to a publication or other report of a study by the review author (e.g. first author's name and year of publication). If a study has more than one report (e.g. multiple publications or additional unpublished data) a separate Report ID can be allocated to each to help review authors keep track of the source of extracted data.
Sociodemographics	Social and demographic information about a study or its participants, including economic and cultural information, location, age, gender, ethnicity, etc.
Study ID	A unique ID code given to an included or excluded study by the review author (e.g. first author's name and year of publication from the main report of the study). Although a study may have multiple reports or references, it should have one single Study ID to help review authors keep track of all the different sources of information for a study.
Theoretical basis	The use of a particular theory (such as theories of human behaviour change) to design the components and implementation of an intervention
Unit of allocation	The unit allocated to an intervention arm. In most studies individual participants will be allocated, but in others it may be individual body parts (e.g. different teeth or joints may be allocated separately) or clusters of multiple people.
Unit of analysis	The unit used to calculate N in an analysis, and for which the result is reported. This may be the number of individual people, or the number of body parts or clusters of people in the study.
Unit of measurement	The unit in which an outcome is measured, e.g. height may be measured in cm or inches; depression may be measured using points on a particular scale.
Validated	A process to test and establish that a particular measurement tool or scale is a good measure of that outcome.
Withdrawals	Participants who voluntarily withdrew from participation in a study before the completion of outcome measurement.

Sources:

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Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

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Data collection form

Intervention review – RCTs and non-RCTs

This form can be used as a guide for developing your own data extraction form. Sections can be expanded and added, and irrelevant sections can be removed. It is difficult to design a single form that meets the needs of all reviews, so it is important to consider carefully the information you need to collect, and design your form accordingly. Information included on this form should be comprehensive, and may be used in the text of your review, 'Characteristics of included studies' table, risk of bias assessment, and statistical analysis.

Notes on using a data extraction form:

- Be consistent in the order and style you use to describe the information for each report.
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.

Review title or ID
A pragmatic randomised controlled trial in primary care of the Camden Weight Loss (CAMWEL) programme

Study ID *(surname of first author and year first full report of study was published e.g. Smith 2001)*
Nanchahal et al (2012)

Report ID *(if different to Study ID)*	**Report IDs of other reports of this study** *(e.g. duplicate publications, follow-up studies)*

Notes:

General Information

Date form completed *(dd/mm/yyyy)*	17th July 2012
Name/ID of person extracting data	Alison Moore
Reference citation	
Study author contact details	
Publication type *(e.g. full report, abstract, letter)*	Randomised Controlled Trial

Notes:
To evaluate effectiveness of a structured one-to-one behaviour change programme on weight loss in obese and overweight individuals.

Study eligibility

Study Characteristics	**Eligibility criteria** *(Insert inclusion criteria for each characteristic as defined in the Protocol)*	**Eligibility criteria met?** Yes	No	Unclear	**Location in text or source** *(pg & ¶/fig/table/other)*
Type of study	Randomised Controlled Trial	Yes ☐		☐	
	Quasi-randomised Controlled Trial	☐	No	☐	
	Observational Study	☐	No	☐	
	Controlled Before and After Study • Contemporaneous data collection • Comparable control site • At least 2 x intervention and 2 x control clusters	☐	Yes	☐	
	Interrupted Time Series • At least 3 time points before and 3 after the intervention • Clearly defined intervention point	☐	☐	Yes	Baseline, 6 months, 12 months
	Other design (specify):	☐	No	☐	
Participants	381 adults with body mass index 25 kg/m2 randomly assigned to intervention (n¼191) or control (n¼190) group.	☐	☐	☐	
Types of intervention	A structured one-to-one programme, delivered over 14 visits during 12 months by trained advisors in three primary care centres compared with usual care in general practice. It follows NICE guidelines and offers multi component intervention with tailored advice on physical activity, eating behaviour, healthier eating and lifestyle changes. **Background to Intervention:** The intervention combined evidence-based components recognised as essential for behaviour change and successful weight loss[23]—healthier eating, increased physical activity incorporated into patients' everyday lifestyles, tailored goal setting, keeping food and activity diaries, self-monitoring, positive reinforcement, coping with lapses and	Yes ☐		☐	

high-risk situations and long-term support—derived from theoretical frameworks underpinning health promotion that have an emphasis on long-term changes in habits. This includes, for example, social cognitive theory,[24] which addresses diet and activity-related social support, outcome expectations, self-efficacy and self-regulation as well as diet and physical activity monitoring to assess changes over time and goal setting.[25] It also emphasised SMART (Specific, Measurable, Attainable, Relevant, Timely) goal setting, the relationship between goals and satisfaction and the achievement of goals and rewards, and systems thinking,[26] which focuses on environmental changes and stresses long-term changes in routines. The programme also incorporated NICE guidance on management of overweight and obesity[27] as well as evidence-based principles of behaviour modification,[23] adherence to treatment[28] and results from our pilot study (figure 1).

Staff Training

Six CAMWEL advisors were recruited from various occupational backgrounds including healthcare, in line with the NHS health trainers initiative.[35] The advisors received initial training over 2 days and further meetings with the research team every 3–4 months. Training of advisors included briefing on the obesity epidemic; food and physical activity behaviours associated with excess weight; principles of best practice and behaviour change strategies; evidence for what has been shown to work in weight loss management programmes; the use of motivational interviewing methods, counselling techniques and cognitive–behavioural therapy methods to provide tailored support for behaviour change; together with details of the study design and role play. All advisors were given a copy of the National Obesity Forum CD-Rom 'Managing Obesity in Primary Care'.

A script and schedule of topics for discussion were provided to the advisors for each session. The topics included personally agreed weight loss goals, eating and physical activity goals, exploration of motivations for losing weight, personal cues to reduce unhealthy eating and sedentary behaviour, support from family and

	friends, triggers associated with habits and routines, long-term benefits of small changes and the importance of scheduling and time management. A commercially available weight management software package (http://www.perfect-diet-tracker.com) was used to record and monitor participant progress and keep notes of each session by the advisors. The advisors were provided with access to a book giving the calorie content of foods available in the UK,[33] a kit including 100-calorie portions of various food items and Adams Food and Alcohol Portion Pots (http://www.adamsportionpot.com). **Participants Background** The intervention participants were given pedometers and handouts associated with each session, including a tailored motivational booklet to encourage increased levels of physical activity and a book of walks in the local area specially prepared for the study (appendix 1). Further details are available from the corresponding author (KN).		
Types of outcome measures	Primary: The aim of this study was to develop and evaluate the efficacy of an intervention programme with 12 month follow up for an ethnically diverse overweight/obese population recruited from general practices . Secondary: Changes in weight, per cent body fat, waist circumference, blood pressure and heart rate between baseline and 12 months. Behaviour change (after Table 5) Participant satisfaction with care received by allocation group at 12 months (Table 4) Participant assessment with care received by allocation group at 12 months (Table 4)	Yes ☐ ☐	
INCLUDE Yes EXCLUDE ☐			

Reason for exclusion	

Notes:

Usual Care Group:

provided a copy of the Quick reference NICE clinical guideline on Obesity to all participating general practitioners (GPs)[27] and asked control participants to contact their general practice to receive usual weight management care provided by the practice, which could include referral to a dietitian (http://www.camden.nhs.uk/adult-weight-management-service.htm), exercise on referral, the 'Shape-Up' programme (http://camden.gov.uk/ccm/navigation/leisure/sport-and-physical-activity/get-active-and-healthy/lose-weight/), prescription of weight loss medication, weight loss surgery or no further treatment.

All participants were given the British Heart Foundation booklet: "So you want to lose weight … for good."[36]

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

Characteristics of included studies

Methods

	Descriptions as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
Aim of study *(e.g. efficacy, equivalence, pragmatic)*	Pragmatic parallel group RCT trial reflecting the likely performance of the programme as delivered in practice.	'S&W' end section para 5 & 'Aims' 1st para
Design*(e.g. parallel, crossover, non-RCT)*	RCT	
Unit of allocation *(by individuals, cluster/ groups or body parts)*	Two groups – intervention and usual care	
Start date	January 2010	'Results' pg 4 para 1
End date	January 2011	
Duration of participation *(from recruitment to last follow-up)*	18 Months Recruitment July 2009 – January 2010 Study Jan 2010-Jan 2011	'Recruitment' section

Ethical approval needed/ obtained for study	☐ ☐ ☐ Yes	'Footnote'-Ethics approval was provided by the London School of Hygiene & Tropical Medicine Ethics Committee etc	
Notes: All GP practices in Camden were visited and invited to attend. Confounding Variables – Partially Considered: No amending BMI to account for ethnic background such as Asian. Were participants taking any medication, including slimming medication that might affect results? Effect of £30 on outcome?			

Participants

	Description *Include comparative information for each intervention or comparison group if available*	**Location in text or source** *(pg & ¶/fig/table/other)*
Population description *(from which study participants are drawn)*	All GP practices were visited & invited to participate Participating practices were wrote to a sample of patients with BMI≥25kg/m2	'Recruitment' section para 2
Setting *(including location and social context)*	Camden – local GP practice. 23/39 practices opted to participate in the study. The intervention takes place in one of three primary care centres compared with usual care in general practice (asbstract – 'interventions')	'Recruitment' section
Inclusion criteria	≥ 18 years of age BMI ≥ 25kg/m² Attending a participating practice Willing to attend visits with a CAMWEL advisor for 12 months	'Baseline Measurements' paragraph
Exclusion criteria	Pregnancy or lactation Diagnosis of renal failure Use of a pacemaker Recent cancer diagnosis Participation in another weight management study	

Method of recruitment of participants *(e.g. phone, mail, clinic patients)*	-Participating practices wrote to a sample of patients with BMI $\geq$ 25kg/m² -GP's & PN's had a referral 'prescription' pad with a tear-off slip given to patient with contact details of the trial office -Posters & fliers were put in waiting areas and local pharmacies. -Final 6 wks of recruitment period 3 practices supplemented recruitment by sending text messages to potentially eligible patients using electronic record (EMIS) and messaging (Iplato) systems. *All practices were reimbursed for time spent on recruitment*		
Informed consent obtained	Yes	Written consent required and letter from GP	"Baseline Measurements', para 1 (5th line)
Total no. randomised *(or total pop. at start of study for NRCTs)*	191 participants randomised to intervention 190 participants randomised to control group		
Clusters *(if applicable, no., type, no. people per cluster)*	N/A		
Baseline imbalances	At Baseline: Height measurements (no shoes) Weight measurements (light clothes & using Tanita scales). Scales also reported % body fat, BMR, & metabolic age (age expected for a given value of BMR) Waist measurements Blood Pressure & Heart Rate *All this information was printed out & given to participants*		'Baseline Measurements'
Withdrawals and exclusions *(if not provided below by outcome)*	8 excluded – did not meet inclusion criteria 3 excluded - declined to participate		See 'Figure 2' chart
Age	Median Age – 48.5 years		'Baseline Characteristics'
Sex	72.63% women – control group & 71.73% women – intervention group		
Race/Ethnicity	Control Group: 70.63% - Caucasian Intervention Group: 74.25% - Caucasian		
Severity of illness	Low *Intervention(57 in total lost to follow up)* 6 months: 4 participants were lost to follow up due to personal illness 12 months: 6 participants were lost to follow up due to personal illness *Control (61 in total lost to follow up)* Unknown reasons for loss to follow up		

Co-morbidities	None	
Other relevant sociodemographics	The London Borough of Camden has areas of affluence alongside areas of deprivation. 47% in employment are educated to degree level or above. 17% in employment have no qualifications. 27% of Camden belong to minority ethnic groups	'Recruitment' section
Subgroups measured	N/A	
Subgroups reported	N/A	

Notes:

GP consent had to be granted for participant to be included (baseline measurements para)

£30 voucher was given to participants who completed each follow up appointment ("Outcomes" para 1)

Self completed questionnaires included the following validated measures ("Outcomes" para 2):

-EuroQol Visual Analogue Scale

-Obesity & Weight Loss Quality of Life

-Hospital anxiety & depression scale

-Rosenburg measure of self-esteem

-Duke-UNC Functional Social Support Questionairre

-Three factor eating questionnaire

-Physical activity (PAR Q)

-Socio demographic information

Deprivation was ascertained by using the Index of Multiple Deprivation based on the participants postal code

Baseline Characterics

The majority (72%) were women,

12% (47/381) had diagnosed diabetes,

1.3% (5/381) were on antipsychotic medication,

60% were in employment,

47% were university graduates and 73% described their ethnicity as Caucasian (table 1).

Participants wanted to lose an average of 18 kg (SD =12.4), representing 16.7% of their baseline weight.

There were no significant differences between groups for any of these variables.

Response Rates

There were no significant differences in follow-up rate at 12 months by randomisation group (60.0% control, 53.9% intervention, p=0.23), but those followed up tended to be older, have lower BMI, fat mass and per cent body fat, and were less likely to be from a deprived area than those not followed up (table 2).

Intervention groups

Copy and paste table for each intervention and comparison group

Intervention Group 1

	Description as stated in report/paper	Location in text or source *(pg & ¶/fig/table/other)*
Group name	Intervention	
No. randomised to group *(specify whether no. people or clusters)*	191 randomly assigned to intervention group	
Theoretical basis *(include key references)*	N/A	
Description *(include sufficient detail for replication, e.g. content, dose, components)*	-Structured one to one programme -Delivered over 14 visits during 12 months by trained advisors in three primary care centres *Advisors* -6 CAMWEL advisors were recruited and trained -Participants were invited to attend 30 minute sessions with an advisor every fortnight for the first 12 weeks, every 3 weeks for 12 weeks & monthly for the next 12 weeks (14 sessions) -A script & schedule of topics for discussion were provided to the advisors for each session *Participants* -Given pedometers -Given hand outs associated with each session including tailored motivational booklet to encourage increased levels of physical activity	
Duration of treatment period	12 months	
Timing *(e.g. frequency, duration of each episode)*	Participants were invited to attend 30 minute sessions with an advisor every fortnight for the first 12 weeks, every 3 weeks for 12 weeks & monthly for the next 12 weeks (14 sessions)	
Delivery *(e.g. mechanism, medium, intensity, fidelity)*	30 minute sessions with an advisor	
Providers *(e.g. no., profession, training, ethnicity etc. if relevant)*	Advisors were recruited from various occupational backgrounds including healthcare, in line with the NHS health trainers initiative.	
Co-interventions	N/A	
Economic variables *(i.e. intervention cost, changes in other costs as result of intervention)*	Cost analysis is noted to have been provided in a separate paper July 2012-AM contacted authors and they responded that this paper was in progress and not available yet.	

Resource requirements *(e.g. staff numbers, cold chain, equipment)*	Participation of local (Camden) GP practice - 23/39 practices opted to participate in the study. All practices were reimbursed for time spent on recruitment – details to be provided in separate paper. £30 voucher was given to participants who completed each follow up appointment ("Outcomes" para 1) Three centres were provided for participants of interevention group to attend sessions.	
Integrity of delivery	High	
Compliance	Compliance of advisors - high	
Notes:		

Outcomes

Copy and paste table for each outcome.

Outcome 1

	Description as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
Outcome name	Primary Oucome: Mean Difference in Weight Loss Based on the intention-to-treat analysis using imputed missing values (table 3), at 12-month follow-up, structured support resulted in a mean difference in weight loss between the two groups of _0.70 (_2.71 to 0.76) kg. A higher proportion of participants lost 5% or more of their baseline weight in the intervention (32.7%, 95% CI 24.9% to 40.5%) when compared with the usual care (20.4%, 95% CI 13.3% to 27.5%) group (OR 1.80 (1.02 to 3.18, p¼0.04).	Print Table 3
Time points measured *(specify whether from start or end of intervention)*	Baseline 6 months (noted in figure 2) 12 months	
Time points reported	Baseline 6 months 12 months	Table 3
Outcome definition *(with diagnostic criteria if relevant)*	Weight loss of 7% at 12 months from baseline (see section 'sample size')	
Person measuring/ reporting	CAMWEL advisors	

Unit of measurement *(if relevant)*	**Height**: measured to the nearest 0.1 cm using a stadiometer. **Weight** (in light clothing) was measured using the Tanita (BC 420 MA) scales. The scales also reported per cent body fat, basal metabolic rate and metabolic age (age expected for a given value of basal metabolic rate). **Waist** was measured midway between the iliac crest and the costal margin to the nearest 0.1 cm. **Blood pressure and heart** rate were measured using a digital automatic monitor (Omron Model M10-IT), with the average of three readings recorded 0.2 where possible.	
Scales: upper and lower limits *(indicate whether high or low score is good)*	Inclusion criteria - BMI ≥25 kg/m2	
Is outcome/tool validated?	☐ ☐ ☐ Yes No **Unclear**	
Imputation of missing data *(e.g. assumptions made for ITT analysis)*	Primary analyses were conducted on an intention-to-treat basis, using multiple imputation (MI) to account for missing data at follow up. Exclusion of subjects with missing data is inefficient and can lead to biased results if those dropped are atypical in some respect50 and MI can both increase efficiency and reduce bias in such settings. Missingness in this study is dominated by attrition, but there are also some intermediate missing outcome values and missing baseline values (although not for weight) so the 'Fully Conditional Specification' form of MI has been used.53 For each outcome, the full set of imputation variables comprised the outcomes at each of the three occasions, together with a set of baseline variables selected for their non-negligible association with missingness or weight loss. The imputation procedure was carried out separately for the two groups (intervention and control), and the resulting multiply imputed data sets were combined for the final MI analysis. A total of 200 imputations were used to stabilise the results and to ensure negligible loss of power.50 Analyses using only data on participants who completed 12-month follow-up were also conducted. Exploratory analyses (not using MI) were conducted excluding subjects who had bariatric surgery or were prescribed weight loss medication during the course of the trial. We also examined whether the degree of weight loss was associated with baseline characteristics or with changes in health or quality-of-life measures. Analyses were performed using STATA V.11.	

Assumed risk estimate *(e.g. baseline or population risk noted in Background)*	High loss to follow up but used multiple imputation used to counter any biases.	
Power		

Notes:

Secondary Outcomes were differences in waist circumference, per cent body fat, blood pressure and heart rate from baseline to 12 months.

The printout from the Tanita scales, including weight, BMI and metabolic age, was given to all participants.

For all outcomes, the following baseline variables were included: age, weight, per cent body fat, BMI, fat mass, metabolic age, deprivation status and employment status as well as totals from the Obesity and Weight Loss Quality-of Life, EuroQol Visual Analogue Scale, Hospital Anxiety and Depression Scaleanxiety, Three-Factor Eating Questionnaire emotional eating and RPAQ scales.

Multiple Imputation, the practice of 'filling in' missing data with plausible values, is an attractive approach to analyzing incomplete data

AM – discuss the use of multiple imputation (MI)

Other

Study funding sources *(including role of funders)*	This work was supported by Camden Primary Care Trust (NHS Camden). The funding source had no role in the design or conduct of the study; collection, management, analysis or interpretation of the data and preparation, review or approval of the manuscript.	
Possible conflicts of interest *(for study authors)*	All authors have completed the Unified Competing Interest form at http://www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that KN, TP, EH, MH, AS, UG and JLT had salary support from NHS Camden for the submitted work. AK was Director of Public Health at Camden Primary Care Trust between 2004 and 2009. The views expressed here are personal, and no financial support was received for the other authors' involvement in the CAMWEL Trial. No authors have had a relationship with companies that might have an interest in the submitted work in the previous 3 years nor do their spouses, partners or children have financial relationships that may be relevant to the submitted work. DH is on the scientific advisory board for LighterLife and no other authors have non-financial interests that may be relevant to the submitted work.	
Notes:		

Risk of Bias assessment

See Chapter 8 of the Cochrane Handbook. Additional domains may be added for non-randomised studies.

Domain	**Risk of bias** Low risk **High risk** Unclear	**Support for judgement** **Result – high loss to follow up but similar to other weight management studies.**	**Location in text or source** **Strenghts & limitations**
Random sequence generation *(selection bias)*	**Yes** ☐ ☐	Participants were randomly allocated (allocation ratio1:1) to the control or intervention group (TP, EH, AS), using a computer-generated randomisation application written in VBA for MS Access (TP). The Taves method of minimisation48 was used to ensure the groups were balanced for general practice, gender, age group (#50/ >50 years), BMI category (#30/>30 kg/m2), diagnosis of diabetes (yes/no) and taking antipsychotic medication or not	'Randomisation' section

Allocation concealment *(selection bias)*	☐ ☐ **Unclear**		
Blinding of participants and personnel *(performance bias)*	☐ **No** ☐	**Outcome group: All/** No	
(if separate judgement by outcome(s) required)	☐ ☐ **Unclear**	**Outcome group:** N/A -	
Blinding of outcome assessment *(detection bias)*	**Yes** ☐ ☐	**Outcome group: All/** The study was single blinded with members of the study team assessing baseline and follow-up measurements blinded to group assignment.	
(if separate judgement by outcome(s) required)	☐ ☐ **N/A**	**Outcome group:** N/A	
Incomplete outcome data *(attrition bias)*	**Yes** ☐ ☐	**Outcome group: All/** All	
(if separate judgement by outcome(s) required)	☐ ☐ ☐	**Outcome group:** N/A	
Selective outcome reporting? *(reporting bias)*	☐ **No** ☐		
Other bias	☐ ☐ ☐		

Notes:
"Selective reporting of outcomes within published studies based on the nature or direction of their results has been widely suspected, but direct evidence of such bias is currently limited to case reports"..*Empirical evidence for selective reporting of outcomes in randomized trials: comparison of protocols to published articles*; ***JAMA.*** ***2004 May 26;291(20):2457-65)***

Data and analysis

Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.

For RCT/CCT
Continuous outcome

	Description as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*

Comparison		Control group – usual care with GP					
Outcome		Primary Outcome: Mean Difference in Weight Loss					
Subgroup		N/A					
Time point *(specify from start or end of intervention)*		18 Months Recruitment July 2009 – January 2010 Study Jan 2010-Jan 2011					
Post-intervention or change from baseline?		Measured and reported 6 & 12 months					
Results	**Intervention**			**Comparison**			
	Mean 6 months	SD - 1.73	**No. Participants** 134	**Mean 6 months**	SD - 0.95	No. Participants 129	
	Mean 12 Months	-2.39	103	**Mean 12 Months**	-1.31	114	
Any other results reported *(e.g. mean difference, CI, P value)*							
No. missing participants		*Loss to Follow Up (Intervention)* 6 months (n=57) 12 months (n=88)		*Loss to Follow Up (Control)* *6 months (n=61)* *12 months (n=76)*			
Reasons missing		6 months -could not be contacted(n=41) -personal illness (n=4) -family illness(n=4) -moved house (n=4) -no time to attend(n=4) 12 months -Could not be contacted(n=31) -Declined to attend/Unspecified reason(n=21) -DNA appointment(n=15) -personal illness(n=6) -no time to attend(n=4) -Felt waste of time to attend(n=2) -Pregnancy(n=1) -Unknown(n=8)		6 months -Unknown(n=61) 12 months -Could not be contacted(n=30) -Declined to attend(unspecified reason)(n=9) -DNA appointment(n=15) -Personal illness(n=1) -no time to attend(n=4) -felt to be waste of time attending(n=3) -unknown(n=14)			Figure 2
No. participants moved from other group		None		None			

Reasons moved	N/A	N/A	
Unit of analysis *(individuals, cluster/ groups or body parts)*	Groups		
Statistical methods used and appropriateness of these *(e.g. adjustment for correlation)*	Comparisons between groups for continuous variables were performed using two-sample t tests and regression methods, adjusting for the baseline value of the variable. c2 tests and logistic regression were used for categorical variables. Changes were calculated as value at follow-up minus baseline value. Primary analyses were conducted on an intention-to-treat basis, using multiple. imputation (MI) to account for missing data at follow up.		
Reanalysis required? *(specify)*	☐ ☐ ☐ No		
Reanalysis possible?	☐ ☐ ☐ No		
Reanalysed results			

Notes:

Exploratory Analysis

Thirty-eight participants were known to have been prescribed drugs for weight loss or to have undergone

weight loss surgery during the trial period. Of these, 27were followed up at 12 months (12 control: mean weight change _2.44 kg (_7.15 to 2.27); 15 intervention: mean weight change _3.51 kg (_6.95 to _0.08)). The difference

between groups was 1.07 kg (_4.32 to 6.46, p¼0.69). In analysis excluding these participants, those in the intervention

group showed significantly greater reductions in weight (1.72 kg (0.29 to 3.14, p¼0.02)), waist circumference (2.52 cm (0.32 to 4.72, p¼0.03)), BMI (0.63 kg/m2 (0.11 to 1.14, p¼0.02)) and per cent baseline weight loss (1.94% (0.32 to 3.56, p¼0.02)) when compared with the control group at 12 months. In addition, a higher

For RCT/CCT
Other outcome

	Description as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
Comparison	Intervention –v- control group	
Outcome	Waist Circumference Percentage body fat Percentage weight change Heart rate The intervention programme was also associated with weak evidence of beneficial trends in waist circumference, per cent body fat and per cent weight change. Heart rate was reduced by 3.7 (0.3 to 7.0, p¼0.03) beats per minute in the intervention group compared with the control group.	"secondary outcomes" page 7

Subgroup	N/A				
Time point *(specify from start or end of intervention)*	18 Months Recruitment July 2009 – January 2010 Study Jan 2010-Jan 2011				
No. participant	Intervention		Control		
Results	Intervention result	SD (or other variance)	Control result	SD (or other variance)	**See Table 3 for results on:** Waist Circumference (cm) Percent body fat Percent weight loss Percent lost >5% baseline weight BMI kg/m_2 Systolic BP Diastolic BP Heart Rate(BPM)
	Overall results		SE (or other variance)		
Any other results reported	N/A				
No. missing participants	?????		?????		
Reasons missing	?????		?????		
No. participants moved from other group	N/A		N/A		
Reasons moved	N/A		N/A		
Unit of analysis *(by individuals, cluster/groups or body parts)*	Individuals and groups				
Statistical methods used and appropriateness of these	Comparisons between groups for continuous variables were performed using two-sample t tests and regression methods, adjusting for the baseline value of the variable. c2 tests and logistic regression were used for categorical variables. Changes were calculated as value at follow-up minus baseline value. Primary analyses were conducted on an intention-to-treat basis, using multiple. imputation (MI) to account for missing data at follow up.				
Reanalysis required? *(specify)*	☐ Yes ☐ No ☐ Unclear				

Reanalysis possible?	☐ Yes ☐ No ☐ Unclear		
Reanalysed results			
Notes:			

Definitions

Assumed risk estimate	An estimate of the risk of an event or average score without the intervention, used in Cochrane 'Summary of findings tables'. If a study provides useful estimates of the risk of average score of different subgroups of the population, or an estimate based on a representative observational study, you may wish to collect this information.
Change from baseline	A measure for a continuous outcome calculated as the difference between the baseline score and the post-intervention score.
Clusters	A group of participants who have been allocated to the same intervention arm together, as in a cluster-randomised trial, e.g. a whole family, town, school or patients in a clinic may be allocated to the same intervention rather than separately allocating each individual to different arms.
Co-morbidities	The presence of one or more diseases or conditions other than those of primary interest. In a study looking at treatment for one disease or condition, some of the individuals may have other diseases or conditions that could affect their outcomes.
Compliance	Participant behaviour that abides by the recommendations of a doctor, other health care provider or study investigator (also called adherence or concordance).
Contemporaneous data collection	When data is collected at the same point(s) in time or covering the same time period for each intervention arm in a study (that is, historical data are not used as a comparison).
Controlled Before and After Study	A non-randomised study design where a control population of similar characteristics and performance as the intervention group is identified. Data are collected before and after the intervention in both the control and intervention groups
Exclusions	Participants who were excluded from the study or the analysis by the investigators.
Imputation	Assuming a reasonable value for a measure where the true value is not available (e.g. assuming last observation carried forward for missing participants).
Integrity of delivery	The degree to which the specified procedures or components of an intervention are delivered as originally planned.
Interrupted Time Series	A research design that collects observations at multiple time points before and after an intervention (interruption). The design attempts to detect whether the intervention has had an effect significantly greater than the underlying trend.
Post-intervention	The value of a continuous outcome measured at some time point following the beginning of the intervention (may be during or after the intervention period).
Power	The probability that a trial will detect, as statistically significant, an

	intervention effect of a specified size.
Providers	The person or people responsible for delivering an intervention and related care, who may or may not require specific qualifications (e.g. doctors, physiotherapists) or training.
Quasi-randomised controlled trial	A study in which the method of allocating people to intervention arms was not random, but was intended to produce similar groups when used to allocate participants. Quasi-random methods include: allocation by the person's date of birth, by the day of the week or month of the year, by a person's medical record number, or just allocating every alternate person.
Reanalysis	Additional analysis of a study's results by a review author (e.g. to introduce adjustment for correlation that was not done by the study authors).
Report ID	A unique ID code given to a publication or other report of a study by the review author (e.g. first author's name and year of publication). If a study has more than one report (e.g. multiple publications or additional unpublished data) a separate Report ID can be allocated to each to help review authors keep track of the source of extracted data.
Sociodemographics	Social and demographic information about a study or its participants, including economic and cultural information, location, age, gender, ethnicity, etc.
Study ID	A unique ID code given to an included or excluded study by the review author (e.g. first author's name and year of publication from the main report of the study). Although a study may have multiple reports or references, it should have one single Study ID to help review authors keep track of all the different sources of information for a study.
Theoretical basis	The use of a particular theory (such as theories of human behaviour change) to design the components and implementation of an intervention
Unit of allocation	The unit allocated to an intervention arm. In most studies individual participants will be allocated, but in others it may be individual body parts (e.g. different teeth or joints may be allocated separately) or clusters of multiple people.
Unit of analysis	The unit used to calculate N in an analysis, and for which the result is reported. This may be the number of individual people, or the number of body parts or clusters of people in the study.
Unit of measurement	The unit in which an outcome is measured, e.g. height may be measured in cm or inches; depression may be measured using points on a particular scale.
Validated	A process to test and establish that a particular measurement tool or scale is a good measure of that outcome.
Withdrawals	Participants who voluntarily withdrew from participation in a study before the completion of outcome measurement.

Sources:

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Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

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Data collection form

Intervention review – RCTs and non-RCTs

This form can be used as a guide for developing your own data extraction form. Sections can be expanded and added, and irrelevant sections can be removed. It is difficult to design a single form that meets the needs of all reviews, so it is important to consider carefully the information you need to collect, and design your form accordingly. Information included on this form should be comprehensive, and may be used in the text of your review, 'Characteristics of included studies' table, risk of bias assessment, and statistical analysis.

Notes on using a data extraction form:

- Be consistent in the order and style you use to describe the information for each report.
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.

Review title or ID
Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised

Study ID *(surname of first author and year first full report of study was published e.g. Smith 2001)*
Davies et al, 2008

Report ID *(if different to Study ID)*	**Report IDs of other reports of this study** *(e.g. duplicate publications, follow-up studies)*

Notes:
Adults with type 2 diabetes were referred within four weeks of diagnosis, with those in the intervention arm attending a structured group education programme within 12 weeks of diagnosis

General Information

Date form completed *(dd/mm/yyyy)*	20th July 2012
Name/ID of person extracting data	Alison Moore
Reference citation	
Study author contact details	
Publication type *(e.g. full report, abstract, letter)*	Full Study

Notes:
There are 6 studies on DESMOND which assess various elements. The focus for this dissertation is on Study 2 (my list) in particular.

Study eligibility

Study Characteristics	**Eligibility criteria** *(Insert inclusion criteria for each characteristic as defined in the Protocol)*	**Eligibility criteria met?** Yes	**Location in text or source** *(pg & ¶/fig/table/other)*
Type of study	Cluster Randomised Controlled Trial	Yes ☐ ☐	
	Quasi-randomised Controlled Trial	☐ No ☐	
	Controlled Before and After Study • Contemporaneous data collection • Comparable control site • At least 2 x intervention and 2 x control clusters	☐ No ☐	
	Interrupted Time Series • At least 3 time points before and 3 after the intervention • Clearly defined intervention point	☐ No ☐	
	Other design (specify):	☐ No ☐	
Participants	824 adults (55% men, mean age 59.5 years).	Yes ☐ ☐	
Types of intervention	A structured group education programme for six hours delivered in the community by two trained healthcare professional educators compared with usual are.	☐ ☐ ☐	
Types of outcome measures		☐ ☐ ☐	
INCLUDE Yes **EXCLUDE** ☐			
Reason for exclusion			

Notes:
DESMOND sessions are interactive and the educators are trained to promote a non-didactic approach.
As well as providing practical information about diet, activity, goal-setting and self-management of diabetes,
the sessions are intended to encourage individuals to share with the group their own experiences of being diagnosed as diabetic
In the control arm, consenting patients received their practice's usual care for diabetes. 'Usual care' is not standardized across practices. In many cases, this might include a group-based educational intervention, but it might also involve one-to-one counselling with a specialist diabetes nurse or some other form of education. (Study Mgt Section)
Control practices were resourced to enable them to provide contact time with healthcare professionals equivalent to that provided by the structured group education programme. The practices were allowed to use the resources as they saw fit within their usual care routine. Participating practices in the control arm were therefore resourced to provide a robust comparator to the intervention and so received "enhanced" standard care. (Study 3 – Table 1)

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

Characteristics of included studies

Methods

	Descriptions as stated in report/paper		**Location in text or source** *(pg & ¶/fig/table/other)*
Aim of study *(e.g. efficacy, equivalence, pragmatic)*	To evaluate the effectiveness of a structured group education programme on biomedical, psychosocial, and lifestyle measures in people with newly diagnosed type 2 diabetes.		Abstract
Design*(e.g. parallel, crossover, non-RCT)*	Cluster RCT Setting 207 general practices in 13 primary care sites in the United Kingdom.		
Unit of allocation *(by individuals, cluster/ groups or body parts)*	Cluster		
Start date			
End date			
Duration of participation *(from recruitment to last follow-up)*	1st October 2004 -		
Ethical approval needed/ obtained for study	☐ ☐ ☐ Yes	This study was approved by the Huntingdon local research ethics committee.	

Notes:
Referral of patients with newly diagnosed type 2 diabetes began on 1 October 2004 and ended on 31 January 2006."Results"
Study management
At each site a local coordinator oversaw the trial, recruited and trained practices, and maintained contact with practice staff. Performance of the sites and local coordinators was monitored regularly, with each site
receiving a visit before the trial and a minimum of one monitoring visit per year. Practice staff sent biomedical
data to the local coordinator for forwarding to the central coordinating centre.

Participants

	Description *Include comparative information for each intervention or comparison group if available*		**Location in text or source** *(pg & ¶/fig/table/other)*
Population description *(from which study participants are drawn)*	The trial was carried out in 13 sites in primary care, involving 17 primary care organisations across England and Scotland. Randomisation was at practice level, with stratification by training status and type of contract with the primary care organisation (General Medical Services or Personal Medical Services). Randomisation was undertaken independently at the University of Sheffield using Random Log (D Machin, University of Southampton).		"Methods"
Setting *(including location and social context)*	13 sites in primary care		
Inclusion criteria	Participants with type 2 diabetes were referred within four weeks of diagnosis, with those in the intervention arm attending a structured group education programme within 12 weeks of diagnosis.		"Methods"
Exclusion criteria	We excluded participants if they were aged less than 18 years, had severe and enduring mental health problems, were not primarily responsible for their own care, were unable to participate in a group programme (for example, housebound or unable to communicate in English), or were participating in another research study.		"Methods"
Method of recruitment of participants *(e.g. phone, mail, clinic patients)*	Clinic Patients		"Methods"
Informed consent obtained	☐ ☐ ☐ Yes	Participantsgave informed consent in accordance with the guidelines from the International Conference on Harmonisation and WHO good clinical practice standards.	"Methods"

Total no. randomised *(or total pop. at start of study for NRCTs)*	207 **practices** randomised (105 control, 102 intervention) 824 **Adults** Patient Control Randomistation Patients referred from 77 practices (n=488) Patient Intervention Randomisation Patients referred from 85 practices (n=621)	Flowchart pg 4
Clusters *(if applicable, no., type, no. people per cluster)*	13 Clusters	
Baseline imbalances		
Withdrawals *(if not provided below by outcome)*	**INDIVIDUAL NOT PROVIDED – PRACTICE INFORMATION ONLY** Control Intervention 4 months N=6 N=4 8months N=9 N=10 12months N=8 N=7	
Age	Characteristics Control group (n=387) Intervention group (n=437) Mean (range) age (years) 60.0 (29-87) 59.0 (28-87)	
Sex	Control Intervention % (No) women* 43 (168) 47 (204)	
Race/Ethnicity	Control Intervention % (No) white European 94 (327) 94 (398)	
Severity of illness	Low – referred to trial if diagnosed with Type 2 diabetes within 4 weeks.	
Co-morbidities	Unknown but see Table 4	
Other relevant sociodemographics	Not provided	
Subgroups measured	Not provided	
Subgroups reported	Not provided	
Notes:		

Intervention groups

Copy and paste table for each intervention and comparison group

Intervention Group 1

	Description as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
Group name	Intervention	
No. randomised to group *(specify whether no. people or clusters)*	102 invited practices Patients referred from 85 practices (n=621) Consented (n=437, 70%) Completed questionnaire (n=420)	
Theoretical basis *(include key references)*		

Description *(include sufficient detail for replication, e.g. content, dose, components)*	The structured group education programme is based on a series of psychological theories of learning: Leventhal's common sense theory,24 the dual process theory,25 and the social learning theory.26 The philosophy of the programme was founded on patient empowerment, as evidenced in published work.27 28 **The intervention** was devised as a group education programme, with a written curriculum suitable for the broadest range of participants, to be deliverable in a community setting and to be integrated into routine care. **Registered healthcare professionals** received formal training to deliver the programme and were supported by a quality assurance component of internal and external assessment to ensure consistency of delivery. **The programme** was six hours long, deliverable in either one day or two half day equivalents and facilitated by two educators. Learning was elicited rather than taught, with the behaviour of the educators promoting a non-didactic approach. The contents of the curriculum were aimed specifically at participants attending within 12 weeks of diagnosis. Most of the curriculum was focused on lifestyle factors, such as food choices, physical activity, and cardiovascular risk factors. Attendees were encouraged to consider medication as an option in their self managementstrategy. The programme activates participants to consider their own personal risk factors and, in keeping with theories of self efficacy,26 to choose a specific, achievable goal of behaviour change to work on. The broad content of the curriculum and an overview of the quality assurance have been reported elsewhere.22 The programme module was intended as the first step in an ongoing cycle of diabetes care, integrating education with clinical management. The randomised controlled trial therefore had three important functions: an evaluation of the intervention itself and its generalisability, an assessment of the effectiveness of providing structured group education at diagnosis, and showing at what point any benefits of education begin to diminish.	"The Intervention"
Duration of treatment period	**The programme** was six hours long, deliverable in either one day or two half day equivalents and facilitated by two educators	
Timing *(e.g. frequency, duration of each episode)*	**The programme** was six hours long, deliverable in either one day or two half day equivalents and facilitated by two educators	
Delivery *(e.g. mechanism, medium, intensity, fidelity)*	Group educations programme	

Providers *(e.g. no., profession, training, ethnicity etc. if relevant)*	**Registered healthcare professionals** received formal training to deliver the programme and were supported by a quality assurance component of internal and external assessment to ensure consistency of delivery.	
Co-interventions	N/A	
Economic variables *(i.e. intervention cost, changes in other costs as result of intervention)*	See study 5 or 6	
Resource requirements *(e.g. staff numbers, cold chain, equipment)*	Primary care practice	
Integrity of delivery	High	
Compliance	High	
Notes:		

Outcomes

Copy and paste table for each outcome.

Outcome 1

	Description as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
	Haemoglobin A1c levels, Blood pressure, weight, blood lipid levels, smoking status, physical activity, quality of life, beliefs about illness, depression, and emotional impact of diabetes at baseline and up to 12 months	
Outcome name	Biomedical Questionnaire	
Time points measured *(specify whether from start or end of intervention)*	Baseline, 4, 8, 12 months	
Time points reported	Baseline 4, 8, 12 months	

Outcome definition *(with diagnostic criteria if relevant)*	We collected outcome measures at baseline and at 4, 8, and 12 months. Biomedical data were collected at practice visits. Questionnaire data were collected from participants at the beginning of the study and by postal questionnaire at 4, 8, and 12 months. We sent out a reminder and a further copy of the questionnaire if the original was unreturned after two weeks.		
Person measuring/ reporting	Registered healthcare professionals received formal training to deliver the programme and were supported by a quality assurance component of internal and external assessment to ensure consistency of delivery.		
Unit of measurement *(if relevant)*	BMI, KG, % body fat etc		
Scales: upper and lower limits *(indicate whether high or low score is good)*	Low BMI and weight is good		
Is outcome/tool validated?	☐ ☐ ☐ Yes	Reputable questionaires used and valid BMI, weight, supervision	
Imputation of missing data *(e.g. assumptions made for ITT analysis)*	No Missing outcomes were not replaced and we derived an average over time of continuous outcomes.		"statistical analysis"
Assumed risk estimate *(e.g. baseline or population risk noted in Background)*			
Power	90%		"Sample Size"
Notes: Assuming a failure to consent rate of 20% (not eligible as well as declining to participate) and a dropout rate of 20%, 1000 participants (500 in each arm) needed to be referred. "statistical analysis"			

Other

Study funding sources *(including role of funders)*	Funding: This study was funded by Diabetes UK. The project office administration was funded by an unrestricted educational grant from Novo Nordisk. The researchers were independent of any of the study funders. The study sponsor was the University Hospitals of Leicester N HS Trust. The research team and the principle investigator were employees of the sponsor during the period of the study.	
Possible conflicts of interest *(for study authors)*	Competing interests: None declared.	
Notes:		

Data and analysis

Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.

For RCT/CCT
Continuous outcome

	Description as stated in report/paper						**Location in text or source** *(pg & ¶/fig/table/other)*
Comparison	Control Group – Usual Care						
Outcome	Biomedical Lifestyle						
Subgroup	N/A						
Time point *(specify from start or end of intervention)*	Unknown						
Post-intervention or change from baseline?							
Results	**Intervention**			**Comparison**			
	Mean	SD *(or other variance, specify)*	No. participants	Mean	SD *(or other variance, specify)*	No. participants	
Any other results reported *(e.g. mean difference, CI, P value)*	Lifestyle Outcomes (smoking and physical activity) Scores for belief in illness Depression and emotional impact of diabetes						
No. missing participa	**NOT PROVIDED – PRACTICE INFORMATION ONLY** Control Practice Intervention 4 months N=6 N=4 8months N=9 N=10 12months N=8 N=7						
Reasons missing	Not provided unless the person died						
No. participants moved from other group	N/A					N/A	

Reasons moved	N/A		
Unit of analysis *(individuals, cluster/ groups or body parts)*	Cluster / Group/ Individual		
Statistical methods used and appropriateness of these *(e.g. adjustment for correlation)*	**Statistical analysis** Statistical analysis was carried out on an **intention to treat** basis. Results are reported according to consolidated standards of reporting trials guidelines for cluster randomised trials.40 We summarised continuous variables using means, standard deviations, medians, and ranges, and categorical variables using counts and percentages. **Missing outcomes were not replaced** and we derived an average over time of **continuous outcomes.** This procedure measures the cumulative effect of the treatment and has the maximum number of participants. To **adjust for a potential clustering effect** we used robust generalised estimating equations41 with exchangeable correlation structure. For binary outcomes we used a logit link with a binomial distribution for the outcome, and for continuous outcomes we used an identity link with a normal distribution. For ordinal outcomes we used an ordinal regression model with proportional odds assumption, **adjusted for clusters**.42 To investigate whether changes in illness beliefs are predictive of changes in outcome variable, we carried out multiple regressions with adjustment for age, sex, and baseline value of the outcome variable. Variables were entered in specified sequence, and we report standardised regression weights (β). **Adjustments were not made for multiple testing.** All the results from planned analyses are reported and small P values are interpreted taking into account the overall pattern of the results. Statistical significance was set at 5%. Data were analysed independently at the University of Sheffield using Stata version 9.		
Reanalysis required? *(specify)*	☐ ☐ ☐ No		
Reanalysis possible?	☐ ☐ ☐ N/A		
Reanalysed results			

Notes:

This study concerned multiple sites and educators. –consistency – how to maintain it?

The programme involved 34 educators, trained for two days. Quality assurance was provided during the trial to ensure consistency in the quality and integrity of the intervention delivered. As a result, this intervention is replicable.

The significance of our results to clinical practice lies in their generalisability.

In summary, our structured group education programme encapsulates a patient centred approach to diabetes care.

WHAT IS ALREADY KNOWN ON THIS TOPIC

The diabetes national service framework promotes structured education for all from diagnosis of diabetes

However, until now, there has been no scientific evaluation and no programmes demonstrably meeting all the quality criteria

WHAT THIS STUDY ADDS

A structured group education programme for patients with newly diagnosed type 2 diabetes was associated with benefits in illness beliefs, weight loss, physical activity, smoking status, and depression but not in haemoglobin A1c levels

Most of the changes were sustained over 12months without further reinforcement

The intervention is generalisable and replicable

Definitions

Assumed risk estimate	An estimate of the risk of an event or average score without the intervention, used in Cochrane 'Summary of findings tables'. If a study provides useful estimates of the risk of average score of different subgroups of the population, or an estimate based on a representative observational study, you may wish to collect this information.
Change from baseline	A measure for a continuous outcome calculated as the difference between the baseline score and the post-intervention score.
Clusters	A group of participants who have been allocated to the same intervention arm together, as in a cluster-randomised trial, e.g. a whole family, town, school or patients in a clinic may be allocated to the same intervention rather than separately allocating each individual to different arms.
Co-morbidities	The presence of one or more diseases or conditions other than those of primary interest. In a study looking at treatment for one disease or condition, some of the individuals may have other diseases or conditions that could affect their outcomes.
Compliance	Participant behaviour that abides by the recommendations of a doctor, other health care provider or study investigator (also called adherence or concordance).
Contemporaneous data collection	When data is collected at the same point(s) in time or covering the same time period for each intervention arm in a study (that is, historical data are not used as a comparison).
Controlled Before and After Study	A non-randomised study design where a control population of similar characteristics and performance as the intervention group is identified. Data are collected before and after the intervention in both the control and intervention groups
Exclusions	Participants who were excluded from the study or the analysis by the investigators.
Imputation	Assuming a reasonable value for a measure where the true value is not available (e.g. assuming last observation carried forward for missing participants).
Integrity of delivery	The degree to which the specified procedures or components of an intervention are delivered as originally planned.
Interrupted Time Series	A research design that collects observations at multiple time points before and after an intervention (interruption). The design attempts to detect whether the intervention has had an effect significantly greater than the underlying trend.
Post-intervention	The value of a continuous outcome measured at some time point following the beginning of the intervention (may be during or after the intervention period).
Power	The probability that a trial will detect, as statistically significant, an intervention effect of a specified size.
Providers	The person or people responsible for delivering an intervention and related care, who may or may not require specific qualifications (e.g. doctors, physiotherapists) or training.
Quasi-randomised controlled trial	A study in which the method of allocating people to intervention arms was not random, but was intended to produce similar groups when used to allocate participants. Quasi-random methods include: allocation by the person's date of birth, by the day of the week or month of the year, by a person's medical record number, or just allocating every alternate person.

Reanalysis	Additional analysis of a study's results by a review author (e.g. to introduce adjustment for correlation that was not done by the study authors).
Report ID	A unique ID code given to a publication or other report of a study by the review author (e.g. first author's name and year of publication). If a study has more than one report (e.g. multiple publications or additional unpublished data) a separate Report ID can be allocated to each to help review authors keep track of the source of extracted data.
Sociodemographics	Social and demographic information about a study or its participants, including economic and cultural information, location, age, gender, ethnicity, etc.
Study ID	A unique ID code given to an included or excluded study by the review author (e.g. first author's name and year of publication from the main report of the study). Although a study may have multiple reports or references, it should have one single Study ID to help review authors keep track of all the different sources of information for a study.
Theoretical basis	The use of a particular theory (such as theories of human behaviour change) to design the components and implementation of an intervention
Unit of allocation	The unit allocated to an intervention arm. In most studies individual participants will be allocated, but in others it may be individual body parts (e.g. different teeth or joints may be allocated separately) or clusters of multiple people.
Unit of analysis	The unit used to calculate N in an analysis, and for which the result is reported. This may be the number of individual people, or the number of body parts or clusters of people in the study.
Unit of measurement	The unit in which an outcome is measured, e.g. height may be measured in cm or inches; depression may be measured using points on a particular scale.
Validated	A process to test and establish that a particular measurement tool or scale is a good measure of that outcome.
Withdrawals	Participants who voluntarily withdrew from participation in a study before the completion of outcome measurement.

Sources:

Cochrane Collaboration Glossary, 2010. Available from http://www.cochrane.org/training/cochrane-handbook.

Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Last JM (editor), A Dictionary of Epidemiology, 4th Ed. New York: Oxford University Press, 2001.

Schünemann H, Brożek J, Oxman A, editors. GRADE handbook for grading quality of evidence and strength of recommendation. Version 3.2 [updated March 2009]. The GRADE Working Group, 2009. Available from http://www.cc-ims.net/gradepro.

Cluster randomisation

Cluster randomised trial designs can be used to overcome some of the problems associated with ‘lifestyle intervention’ trials in general practice. A cluster randomisation trial is one in which intact social units, or clusters of individuals rather than individuals themselves, are randomised to different intervention groups.9 When randomisation occurs at the group level, all participants

recruited from the practice, school or workplace are allocated to either the intervention or the control group. The outcomes to measure the effect of the intervention are still assessed at the individual level, but the level at which the comparison is made is the practice, school or workplace. Cluster RCT design is recommended when delivery of an intervention is likely to affect others within the group or cluster.6,9–11 Cluster RCTs are being used increasingly where delivery of an intervention is at a group (or practice) level,12,13 and outcomes are measured at the patient level.14

Data collection form

Intervention review – RCTs and non-RCTs

This form can be used as a guide for developing your own data extraction form. Sections can be expanded and added, and irrelevant sections can be removed. It is difficult to design a single form that meets the needs of all reviews, so it is important to consider carefully the information you need to collect, and design your form accordingly. Information included on this form should be comprehensive, and may be used in the text of your review, 'Characteristics of included studies' table, risk of bias assessment, and statistical analysis.

Notes on using a data extraction form:

- Be consistent in the order and style you use to describe the information for each report.
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.

Review title or ID
Improving management of obesity in primary care: cluster randomised trial

Study ID *(surname of first author and year first full report of study was published e.g. Smith 2001)*
Moore, 2003

Report ID *(if different to Study ID)*	**Report IDs of other reports of this study** *(e.g. duplicate publications, follow-up studies)*

Notes:

General Information

Date form completed *(dd/mm/yyyy)*	19th July 2012
Name/ID of person extracting data	Alison Moore
Reference citation	
Study author contact details	
Publication type *(e.g. full report, abstract, letter)*	Full Study

Notes:
The objective of this study is to evaluate a training programme intended to improve the management of obesity, delivered to general practice teams.

Study eligibility

Study Characteristics	**Eligibility criteria** *(Insert inclusion criteria for each characteristic as defined in the Protocol)*	**Eligibility criteria met?** Yes	No	Unclear	**Location in text or source** *(pg & ¶/fig/table/other)*
Type of study	Cluster Randomised Controlled Trial	Yes ☐		☐	
	Quasi-randomised Controlled Trial	☐	No	☐	
	Controlled Before and After Study • Contemporaneous data collection • Comparable control site • At least 2 x intervention and 2 x control clusters	☐	No	☐	
	Interrupted Time Series • At least 3 time points before and 3 after the intervention • Clearly defined intervention point	☐	No	☐	Baseline, 3, 12, 18 months
	Other design (specify):	☐	No	☐	
Participants	44 general practices invited consecutively attending obese adults to participate; 843 patients attended for collection of baseline data and were subsequently randomised.	Yes ☐		☐	
Types of intervention	4.5 hour training programme promoting an obesity management model to GP's & PN's. The training covered information on the clinical benefit of weight loss and effective treatment options, including reduction of dietary energy intake, increased physical activity, and pharmaceutical intervention.	Yes ☐		☐	
Types of outcome measures	Difference in weight between patients in intervention and control groups at 12 months (main outcome measure) and at 3 months and 18 months; change in practitioners' knowledge and behaviour in obesity management consultations	☐	☐	☐	
INCLUDE ☐ **EXCLUDE** ☐					

Reason for exclusion	
Notes:	

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

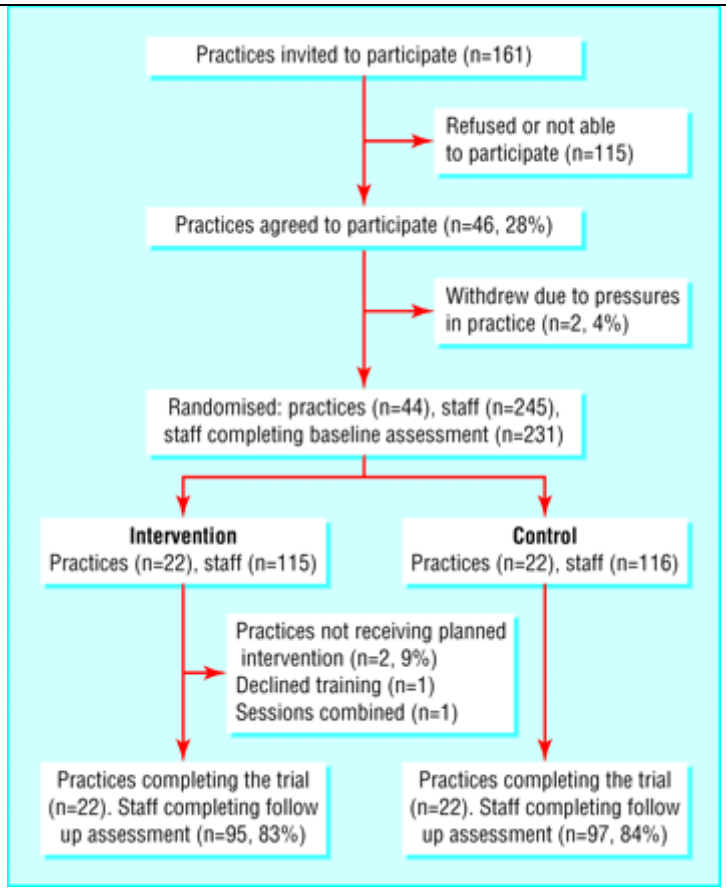
Characteristics of included studies

Methods

	Descriptions as stated in report/paper		**Location in text or source** *(pg & ¶/fig/table/other)*
Aim of study *(e.g. efficacy, equivalence, pragmatic)*	To evaluate a training programme intended to improve the management of obesity, delivered to general practice teams		
Design*(e.g. parallel, crossover, non-RCT)*	Cluster RCT		
Unit of allocation *(by individuals, cluster/ groups or body parts)*	Cluster		
Start date	The only reference is 'Training was delivered between June and November 2000'. There is no participant start date mentioned.		'Results'
End date	The only reference is 'Training was delivered between June and November 2000'. There is no participant start or end date mentioned.		
Duration of participation *(from recruitment to last follow-up)*	Not specified		
Ethical approval needed/ obtained for study	☐ ☐ ☐ Yes	Ethical approval The Northern and Yorkshire regional medical research ethics committee and five local research ethics committees approved the study	
Notes:			

Participants

	Description *Include comparative information for each intervention or comparison group if available*		**Location in text or source** *(pg & ¶/fig/table/other)*
Population description *(from which study participants are drawn)*	44 general practices invited consecutively attending obese adults to participate; 843 patients attended for collection of baseline data and were subsequently randomised.		
Setting *(including location and social context)*	Northern and Yorkshire region of England		
Inclusion criteria	The study protocol required practice staff to invite consecutively attending obese adults (body mass index ≥ 30 kg/m^2) aged 16 to 64 years to participate in the trial over a defined **six month recruitment period**		Recruitment
Exclusion criteria	All general practitioners and practice nurses in the 44 practices (a total of 245 staff) were eligible to participate. In a previous trial,8 staff working in primary care but between practices (for example, district nurses and health visitors) were a source of contamination, so we asked for these staff to be excluded from the study.		Recruitment
Method of recruitment of participants *(e.g. phone, mail, clinic patients)*	Patients were asked to return a consent form to the practice by stamped addressed envelope or on their next visit. The recruitment strategy was extended to include assistance from study personnel and mail shots. Towards the end of the recruitment period, a researcher accessed the list of patients who had been recruited in the early stages and invited them to attend for collection of baseline data, so that all patients had been weighed within two months of randomisation. All practices were randomised simultaneously in June 2000.		Recruitment
Informed consent obtained	☐ ☐ ☐ Yes	Patients were asked to return a consent form to the practice by stamped addressed envelope or on their next visit.	
Total no. randomised *(or total pop. at start of study for NRCTs)*	44 practices, 245 staff,		Figure 1
Clusters *(if applicable, no., type, no. people per cluster)*	Intervention – Practice (22), Staff (115) Control – Practice (22), Staff (116)		Figure 1
Baseline imbalances			

Withdrawals and exclusions *(if not provided below by outcome)*	 View larger version:	
Age	Mean age Intervention 48.4(10.9) years (SD) Control 48.8(12.2) years (SD)	
Sex	Male 104 (25%) – Intervention Male 116 (27%) - Control	
Race/Ethnicity	Not provided	
Severity of illness	Extremely obesity	
Co-morbidities	Not provided	
Other relevant sociodemographics	Median (interquartile range) socioeconomic status 3.4 (-0.9-5.8) 2.4 (0.1-7.1)	
Subgroups measured	N/A	
Subgroups reported	N/A	
Notes:		

Intervention groups

Copy and paste table for each intervention and comparison group

Intervention Group 1

	Description as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
Group name	Intervention	
No. randomised to group *(specify whether no. people or clusters)*	Intervention – 22 Practices, 115 staff, 415 patients Control – 22 Practices, 116 Staff, 428 patients	
Theoretical basis *(include key references)*	N/A	

Description *(include sufficient detail for replication, e.g. content, dose, components)*	At the start of the intervention period, we provided all practices with a list of their patients who had entered the trial. The educational strategy was based on a previous nutrition training programme.8 We delivered three 90 minute sessions, intended to be delivered at intervals of no less than one week and no more than two weeks apart, to the 22 intervention practices. We asked all general practitioners and practice nurses to attend all three sessions. Four dietitians were trained in the standardised delivery of the training and then delivered the programme to small group, multidisciplinary general practice teams. The programme promoted a model approach to obesity treatment, which incorporated best evidence and was perceived to be brief enough that primary care staff could deliver it to their patients. The training covered information on the clinical benefit of weight loss and effective treatment options, including reduction of dietary energy intake, increased physical activity, and pharmaceutical intervention. The model of obesity management entailed practitioners seeing patients regularly (about every two weeks) until they had lost 10% of their original body weight and then less regularly (about every one to two months) for maintenance of weight over a sustained period. Current and target weight and dietary and activity targets were to be recorded in the patients' records to facilitate continuity of support across practice teams. Prescription of a moderate energy deficit diet was advocated, as recommended by the Scottish Intercollegiate Guidelines Network.11 A "ready reckoner" was produced to allow practitioners to estimate a patient's daily energy requirement and then to calculate a daily 500 kcal (2.5 MJ) deficit. Diet sheets and supporting written resources facilitated the dietary prescription to patients. At the end of the three training sessions, practices devised individualised weight management protocols based on the model and were encouraged to implement this with patients recruited to the study. Control practices were asked to provide usual care to their patients.	
Duration of treatment period	No exact dates provided 6 month recruitment period and 18 month intervention/follow up	
Timing *(e.g. frequency, duration of each episode)*	Patients saw practitioners regularly (about every 2 weeks) until they lost 10% of body weight and then less regularly (1-2 months) for maintenance	
Delivery *(e.g. mechanism, medium, intensity, fidelity)*	patients attended a one to one meeting with practitioner	
Providers *(e.g. no., profession, training, ethnicity etc. if relevant)*	General practitioners and practice nurses	

Co-interventions	N/A	
Economic variables *(i.e. intervention cost, changes in other costs as result of intervention)*	No financial incentives were provided to the practice	
Resource requirements *(e.g. staff numbers, cold chain, equipment)*	Participation of practices and time for training and delivering the intervention	
Integrity of delivery	Unclear	
Compliance	Unclear	

Notes:

Impact of the Intervention

Practitioners' knowledge of the principles of obesity management improved, and trained practitioners were more likely to implement weight management strategies promoted in the training. Patients from trained practices were seen more often and were more likely to have ***weight, target weights, and dietary targets documented in their records***, but in absolute terms the level of implementation was low. Target weights were recorded for only 14% of participating patients in trained practices, compared with just 3% of participating patients in control practices, in the year after delivery of the training. Patients in trained practices attended two more consultations than did those in control practices, averaging eight consultations in the year after the intervention. Treatment as per protocol would entail fortnightly follow up until 10% of initial body weight was lost, potentially some 20 or more consultations in the year. ***The low level of implementation of the obesity management model means that we cannot draw conclusions about its effectiveness.***

Outcomes

Copy and paste table for each outcome.

Outcome 1

	Description as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
	Difference in weight between patients in intervention and control groups at 12 months (main outcome measure) and at 3 months and 18 months; change in practitioners' knowledge and behaviour in obesity management consultations.	
Outcome name	Weight 3 months after training 12 months after training 18 months after training	

Time points measured *(specify whether from start or end of intervention)*	Baseline, 3, 12, 18 months	
Time points reported	Baseline, 3, 12, 18 months	
Outcome definition *(with diagnostic criteria if relevant)*	Mean Weight Mean BMI	
Person measuring/ reporting	Researchers were collecting outcome measurements GP and PN were reporting	
Unit of measurement *(if relevant)*	Weight (kg) BMI kgm2	
Scales: upper and lower limits *(indicate whether high or low score is good)*		
Is outcome/tool validated?	☐ ☐ ☐ Unclear	
Imputation of missing data *(e.g. assumptions made for ITT analysis)*	No A clinically significant effect of intervention can be achieved with as little as 5% (or 3-5 kg) weight loss in obese people.1 2 We designed the study to have 80% power to detect a mean difference in weight between treatment arms of approximately 3-5 kg, assuming 5% significance and a within practice correlation coefficient of 0.05. Allowing for withdrawal and loss to follow up of 15%, this gave a required number of patients per treatment arm of approximately 660, equivalent to 22 practices recruiting 30 patients each. We collated all data on a purposefully designed database by using Microsoft Access software. We analysed change in both continuous and categorical outcome variables by using STATA to account for both within cluster and between cluster variation. We did analyses on an intention to treat basis, where possible	
Assumed risk estimate *(e.g. baseline or population risk noted in Background)*		
Power	80%	
Notes:		

Other

Study funding sources *(including role of funders)*	Funding NHS Executive, Northern and Yorkshire	
Possible conflicts of interest *(for study authors)*	None declared	
Notes:		

Data and analysis

Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.

For RCT/CCT
Continuous outcome

	Description as stated in report/paper Mean Weight 3,12,18 months Mean BMI Change in Practitioners knowledge of Obesity Management						**Location in text or source** *(pg & ¶/fig/table/other)*
Comparison	Control Group						
Outcome	Mean Weight 3,12,18 months Mean BMI Change in Practitioners knowledge of Obesity Management						
Subgroup	N/A						
Time point *(specify from start or end of intervention)*	Not clear						
Post-intervention or change from baseline?							
Results	**Intervention**			**Comparison**			
	Mean	SD *(or other variance, specify)*	No. participants	Mean	SD *(or other variance, specify)*	No. participants	
Any other results reported *(e.g. mean difference, CI, P value)*	Mean Weight 3,12,18 months Mean BMI Change in Practitioners knowledge of Obesity Management						
No. missing participants	Withdrew detailed above but no 'missing data' reported						

Reasons missing	Not provided		
No. participants moved from other group	None		
Reasons moved	N/A		
Unit of analysis *(individuals, cluster/ groups or body parts)*	Cluster and individual		
Statistical methods used and appropriateness of these *(e.g. adjustment for correlation)*	As above – no mention of accounting for missing data		
Reanalysis required? *(specify)*	☐ ☐ ☐ No		
Reanalysis possible?	☐ ☐ ☐ No		
Reanalysed results	N/A		
Notes:			

Other information

	Description as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*

Key conclusions of study authors	This training programme resulted in only limited implementation of an approach to obesity management and did not achieve improved patient weight loss. A more in-depth training programme might be more successful at changing practitioners' behaviour but is unlikely to be generalisable to most general practices in the United Kingdom. Other strategies to manage obesity in primary care urgently need to be considered and evaluated. These might include motivated and dedicated obesity specialists placed at the level of the primary care trust, use of leisure services, and use of the commercial weight loss sector. **Comment** Analysis was on 'intention to treat' where possible Samples were biased towards women Sample was skewed towards extreme obesity Retention was a problem Reduce/Eliminate Contamination: GP's & PN's only were offered training. In reality enforcing this is difficult & many additional practice staff (district nurses & health visitors) turned up for training. Previous study (8) demonstrated that this was a source of contamination so these were excluded to avoid this. Although they detected no evidence of contamination between the intervention groups this cannot be ruled out.	
References to other relevant studies		
Correspondence required for further study information *(from whom, what and when)*		
Notes:		

Definitions

Assumed risk estimate	An estimate of the risk of an event or average score without the intervention, used in Cochrane 'Summary of findings tables'. If a study provides useful estimates of the risk of average score of different subgroups of the population, or an estimate based on a representative observational study, you may wish to collect this information.
Change from baseline	A measure for a continuous outcome calculated as the difference between the baseline score and the post-intervention score.
Clusters	A group of participants who have been allocated to the same intervention arm together, as in a cluster-randomised trial, e.g. a whole family, town, school or patients in a clinic may be allocated to the same intervention rather than separately allocating each individual to different arms.
Co-morbidities	The presence of one or more diseases or conditions other than those of primary interest. In a study looking at treatment for one disease or condition, some of the individuals may have other diseases or conditions that could affect their outcomes.
Compliance	Participant behaviour that abides by the recommendations of a doctor, other health care provider or study investigator (also called adherence or concordance).
Contemporaneous data collection	When data is collected at the same point(s) in time or covering the same time period for each intervention arm in a study (that is, historical data are not used as a comparison).
Controlled Before and After Study	A non-randomised study design where a control population of similar characteristics and performance as the intervention group is identified. Data are collected before and after the intervention in both the control and intervention groups
Exclusions	Participants who were excluded from the study or the analysis by the investigators.
Imputation	Assuming a reasonable value for a measure where the true value is not available (e.g. assuming last observation carried forward for missing participants).
Integrity of delivery	The degree to which the specified procedures or components of an intervention are delivered as originally planned.
Interrupted Time Series	A research design that collects observations at multiple time points before and after an intervention (interruption). The design attempts to detect whether the intervention has had an effect significantly greater than the underlying trend.
Post-intervention	The value of a continuous outcome measured at some time point following the beginning of the intervention (may be during or after the intervention period).
Power	The probability that a trial will detect, as statistically significant, an intervention effect of a specified size.
Providers	The person or people responsible for delivering an intervention and related care, who may or may not require specific qualifications (e.g. doctors, physiotherapists) or training.
Quasi-randomised controlled trial	A study in which the method of allocating people to intervention arms was not random, but was intended to produce similar groups when used to allocate participants. Quasi-random methods include: allocation by the person's date of birth, by the day of the week or month of the year, by a person's medical record number, or just allocating every alternate person.

Reanalysis	Additional analysis of a study's results by a review author (e.g. to introduce adjustment for correlation that was not done by the study authors).
Report ID	A unique ID code given to a publication or other report of a study by the review author (e.g. first author's name and year of publication). If a study has more than one report (e.g. multiple publications or additional unpublished data) a separate Report ID can be allocated to each to help review authors keep track of the source of extracted data.
Sociodemographics	Social and demographic information about a study or its participants, including economic and cultural information, location, age, gender, ethnicity, etc.
Study ID	A unique ID code given to an included or excluded study by the review author (e.g. first author's name and year of publication from the main report of the study). Although a study may have multiple reports or references, it should have one single Study ID to help review authors keep track of all the different sources of information for a study.
Theoretical basis	The use of a particular theory (such as theories of human behaviour change) to design the components and implementation of an intervention
Unit of allocation	The unit allocated to an intervention arm. In most studies individual participants will be allocated, but in others it may be individual body parts (e.g. different teeth or joints may be allocated separately) or clusters of multiple people.
Unit of analysis	The unit used to calculate N in an analysis, and for which the result is reported. This may be the number of individual people, or the number of body parts or clusters of people in the study.
Unit of measurement	The unit in which an outcome is measured, e.g. height may be measured in cm or inches; depression may be measured using points on a particular scale.
Validated	A process to test and establish that a particular measurement tool or scale is a good measure of that outcome.
Withdrawals	Participants who voluntarily withdrew from participation in a study before the completion of outcome measurement.

Sources:

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Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Last JM (editor), A Dictionary of Epidemiology, 4th Ed. New York: Oxford University Press, 2001.

Schünemann H, Brożek J, Oxman A, editors. GRADE handbook for grading quality of evidence and strength of recommendation. Version 3.2 [updated March 2009]. The GRADE Working Group, 2009. Available from http://www.cc-ims.net/gradepro.

Data collection form

Intervention review – RCTs and non-RCTs

This form can be used as a guide for developing your own data extraction form. Sections can be expanded and added, and irrelevant sections can be removed. It is difficult to design a single form that meets the needs of all reviews, so it is important to consider carefully the information you need to collect, and design your form accordingly. Information included on this form should be comprehensive, and may be used in the text of your review, 'Characteristics of included studies' table, risk of bias assessment, and statistical analysis.

Notes on using a data extraction form:

- Be consistent in the order and style you use to describe the information for each report.
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.

Review title or ID
Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: Lighten Up randomised controlled trial

Study ID *(surname of first author and year first full report of study was published e.g. Smith 2001)*
Jolly et al (2011)

Report ID *(if different to Study ID)*	**Report IDs of other reports of this study** *(e.g. duplicate publications, follow-up studies)*

Notes:

This study investigates the effectiveness of several pragmatic interventions in primary care patients recruited in the NHS.

'Pragmatic Interventions'

Pragmatic research asks whether an intervention works under real-life conditions and whether it works in terms that matter to the patient. It is simply concerned with whether the intervention works, not how or why. Pragmatic studies are most useful for deciding what services should be provided but give only limited insight into why interventions do or do not work.

Explanatory research asks whether an intervention works under ideal or selected conditions. It is more concerned with how and why an intervention works. Explanatory studies are valuable for understanding questions of efficacy but are of limited value for telling us whether we should provide a service to a wide variety of patients in a wide variety of circumstances.

The distinction between pragmatic and explanatory research is important because it will determine key methodological issues relating to patient selection, definition of the intervention and controls, use of blinding and placebos, choice of outcome measure and type of analysis.

General Information

Date form completed *(dd/mm/yyyy)*	25th July 2012
Name/ID of person extracting data	Alison Moore
Reference citation	
Study author contact details	
Publication type *(e.g. full report, abstract, letter)*	Full Report
Notes:	

Study eligibility

Study Characteristics	**Eligibility criteria** *(Insert inclusion criteria for each characteristic as defined in the Protocol)*	**Eligibility criteria met?** Yes	**Location in text or source** *(pg & ¶/fig/table/other)*
Type of study	Randomised Controlled Trial	Yes ☐ ☐	
	Quasi-randomised Controlled Trial	☐ No ☐	
	Controlled Before and After Study • Contemporaneous data collection • Comparable control site • At least 2 x intervention and 2 x control clusters	☐ No ☐	
	Interrupted Time Series • At least 3 time points before and 3 after the intervention • Clearly defined intervention point	☐ No ☐	
	Other design (specify):	☐ No ☐	
Participants	740 obese or overweight men and women with a comorbid disorder identified from general practice records.	☐ ☐ ☐	
Types of intervention	• Weight loss programmes of 12 weeks' duration: Weight Watchers; • Slimming World; • Rosemary Conley; • group based dietetics led programme;	Yes ☐ ☐	

	• general practice one to one counselling; pharmacy led one to one counselling; • choice of any of the six programmes. • Thecomparator group was provided with 12 vouchers enabling free entrance • to a local leisure (fitness) centre.		
Types of outcome measures	The primary outcome was weight loss at programme end (12 weeks). Secondary outcomes were weight loss at one year, self reported physical activity, and percentage weight loss at programme end and one year.	☐ ☐ ☐	
INCLUDE Yes **EXCLUDE** ☐			
Reason for exclusion			
Notes:			

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

Characteristics of included studies

Methods

	Descriptions as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
Aim of study *(e.g. efficacy, equivalence, pragmatic)*	To assess the effectiveness of a range of weight management programmes in terms of weight loss.	
Design*(e.g. parallel, crossover, non-RCT)*	Eight arm randomised controlled trial	
Unit of allocation *(by individuals, cluster/ groups or body parts)*	Groups	
Start date	Recruitment took place from January to May Follow-up assessments took place between April 2009 and August 2010	"Participants" "Outcome Assessment"
End date	August 2010	"Outcome Assessment"

Duration of participation *(from recruitment to last follow-up)*	17 months		
Ethical approval needed/ obtained for study	☐ ☐ ☐ Yes	Ethical approval: South Birmingham Research Ethics Committee (08/H1207/331) granted ethical approval.	"Conclusion"
Notes:			

Participants

	Description *Include comparative information for each intervention or comparison group if available*	**Location in text or source** *(pg & ¶/fig/table/other)*
Population description *(from which study participants are drawn)*	Eligible participants were registered with general practices in South Birmingham Primary Care Trust, were aged at least 18 years, and had a raised body mass index recorded in their primary care notes within the previous 15 months. The body mass index threshold for invitation was that which makes them eligible for primary care obesity management services in the NHS and varied according to ethnic group and the presence or absence of comorbidities (box 1). The threshold for invitation for people with no obesity related comorbidity was a body mass index of 30 or above. For people of South Asian ethnicity, this threshold was lower. The general practitioner had to confirm that the patient had no medical contraindications for any of the intervention programmes before a letter of invitation was sent. We excluded patients if they were unable to understand English or were pregnant. Seventeen practices took part.	"Population"
Setting *(including location and social context)*	1. The participants allocated to commercial providers had a choice of times and venues. 2. The Size Down Programme is an NHS group based programme led by food advisers recruited from the local community and trained by the dietetics department; sessions took place in various community venues. 3. Participants randomised to the general practice or pharmacy arms attended 12 one to one sessions in the general practice or pharmacy 4. Participants allocated to the comparator group were sent vouchers for 12 free sessions at a local authority run leisure centre (a council run facility open to all members of the public and usually consisting of a swimming pool, fitness suite, and other sports halls or courts).	

Inclusion criteria	**Criteria for invitation to weight loss programmes** • White Europeans and all ethnic groups apart from South Asians with no comorbidities: BMI ≥30 • White Europeans and all ethnic groups apart from South Asians with comorbidities: BMI ≥28 • South Asians with no comorbidities: BMI ≥25 • South Asians with comorbidities The general practitioner had to confirmthat the patient had no medical contraindications for any of the intervention programmes before a letter of invitation was sent	Box 1
Exclusion criteria	We excluded patients if they were unable to understand English or were pregnant. Seventeen practices took part.	"Population"
Method of recruitment of participants *(e.g. phone, mail, clinic patients)*	Eligible participants were registered with general practices in South Birmingham Primary Care Trust. *Eligible patients were invited to participate in the trial by a standard letter from their general practitioner,* which included the patients' information leaflet and a free telephone number for a call centre managing the recruitment and randomisation. The nurses at the call centre provided more information to patients about the trial, collected baseline information, took verbal consent, and randomised patients to the trial arms. The nurses then booked participants into their first treatment session and sent confirmation, along with verification of consent and information on how to withdraw from the trial if they changed their minds. Participants allocated to the general practice, pharmacy, or minimal intervention (comparator) groups were sent details about how to arrange their first session.	"Population"
Informed consent obtained	☐ ☐ ☐ Yes — Verbal consent obtained	"Population"
Total no. randomised *(or total pop. at start of study for NRCTs)*	740 randomised Weight Watchers (n=100) Slimming World (n=100) Rosemary Conley (n=100) Size Down (n=100) General Practice (n=70) Pharmacy (n=70) Choice (n=100) Exercise Comparator (n=100)	Table 1
Clusters *(if applicable, no., type, no. people per cluster)*	N/A	

Baseline imbalances	N/A	
Withdrawals and exclusions *(if not provided below by outcome)*	At programme end, 658 (88.9%) participants were followed up; 522 (70.5%) were followed up at one year (fig 1⇓).	Figure 1
Age	Mean (SD) age (years) **WW** 50.71 (14.56) **SW** 48.84 (14.91) **RC** 49.76 (14.51) **Size Down** 48.75 (15.63) **General Practice** 50.48 (13.79) **Pharmacy** 48.94 (15.82) **Choice** 47.45 (14.35) **Exercise Comparator** 49.67 (13.83)	
Sex	Men are as below: Work out as % and then get female participants. **WW =** 28 **SW =** 35 **RC** = 31 **Size Down** =36 **General Practice** = 23(33) **Pharmacy =** 19(27) **Choice** = 30(30) **Exercise Comparator** =25(25)	
Race/Ethnicity	See table 1	
Severity of illness	Not provided	
Co-morbidities	Obesity	
Other relevant sociodemographics		
Subgroups measured	N/A	
Subgroups reported	N/A	
Notes:		

Intervention groups

Copy and paste table for each intervention and comparison group

Intervention Group 1 – Commercial Operator

	Description as stated in report/paper	Location in text or source *(pg & ¶/fig/table/other)*
	The participants allocated to the commercial operators Weight Watchers, Slimming World, and Rosemary Conley had a choice of locations and times for the programme.13-15 Participants were provided with vouchers that exempted them from paying for 12 consecutive weeks of the programmes. Each programme was provided in accordance with the respective organisation's guidance and ran continuously, with no set start date; the group leaders were trained by the respective organisations. The trial participants attended alongside people who paid to attend the programmes. **Weight Watchers** is group based, and the participant was able to join at any time. One to one support is available for new members and during weighing. This is followed by a group talk from the leader, with discussion. Meetings took place in community venues and lasted one hour. Core programme material delivered over five weeks included a food points system (based on age, sex, height, weight, and activity), beating hunger, taking more physical activity, eating out, and keeping motivated. Other sessions delivered to the whole group covered recipes, health and nutrition, and keeping active. The plan aims for 500 kcal (2.09 MJ) deficit/day, leading to 0.5-1.0 kg weight loss a week. Physical activity is encouraged; the objective is to gradually build up to 10 000 steps daily. Predominant strategies used to change behaviour included stages of change, food and activity diaries, goal setting, and evaluation of progress. Rewards are given for every 3.2 kg (7 lb) lost and for loss of 5% and 10% of body weight. **Slimming World** is group based, and the participant was able to join at any time. Meetings took place in community venues and lasted 90 minutes. Also included is access to a website, magazines, and one to one telephone support from a consultant or other members. Members are encouraged to eat mainly foods with low energy density to achieve satiety, plus some extras rich in calcium and fibre, with controlled amounts of high energy dense foods. Weight loss goals are set by the individual. Physical activity is encouraged, with gradual build up to 30 minutes of moderately intense activity five days a week. The theoretical background is based on transactional analysis and motivational interviewing. Predominant behaviour change strategies used included weekly weighing; group support; and group praise for weight loss, new decisions, and continued commitment even in the absence of weight loss. Awards are given for 3.2 kg (7 lbs) lost and loss of 10% of body weight. Individual support, if needed, uses self monitoring of food and emotions, for and against evaluations, visualisation	

Group name	Weight Watchers, Slimming World, Rosemary Conley	
No. randomised to group *(specify whether no. people or clusters)*	WW = (n=100) SW = (n=100) RC = (n=100)	
Theoretical basis *(include key references)*	N/A	
Description *(include sufficient detail for replication, e.g. content, dose, components)*	N/A	
Duration of treatment period	12 consecutive weeks of the programmes.	
Timing *(e.g. frequency, duration of each episode)*	Weekly	
Delivery *(e.g. mechanism, medium, intensity, fidelity)*	Meetings	
Providers *(e.g. no., profession, training, ethnicity etc. if relevant)*	Commercial weight programmes - the group leaders were trained by the respective organisations.	
Co-interventions	N/A	
Economic variables *(i.e. intervention cost, changes in other costs as result of intervention)*	See *Table 7*	
Resource requirements *(e.g. staff numbers, cold chain, equipment)*	To detect a 2 (SD 3.2) kg difference in weight loss at the three months' follow-up between any of the planned interventions and the comparator group, with 90% power and 5% significance level and assuming 20% loss to follow-up, we needed 70 participants randomised to each group. The sample size calculation did not take account of adjustments for multiple comparisons. To account for dropouts, we allocated 100 participants to each arm, except for the general practice and pharmacy arms. Because of limited availability, provision of these programmes was restricted to 70 participants per arm, resulting in a total sample size of 740 participants. We selected the 2 kg difference as being achievable from previous published studies,7 17 and an important contribution towards a 5% weight loss, which is associated with clinically meaningful health benefits.	

Integrity of delivery	High	
Compliance	Compliance of commercial provider = unknown	
Notes:		

Intervention Group 2 The Size Down Programme

	Description as stated in report/paper The Size Down Programme was an NHS group based programme run in community venues by support workers trained by the dietetics service. This provided six weekly two hour sessions, with follow-up sessions at nine and 12 weeks. All participants joined together in week one of the programme. Its particular focus was on long term changes in patterns of eating behaviour, achieving a balanced diet, and increasing physical activity in daily life, and it used an interactive style. Topics covered included managing behaviour around food and prevention of relapse, the eatwell plate, nutritional information, planning strategies to deal with lapses into previous dietary behaviours, interactive visual aids to show the fat and sugar content of foods, and adaptation of recipes. The theoretical background was based on the cycle of change (Prochaska and Di Clemente). The benefits of physical activity, setting goals, and finding activities to fit into life were discussed. Predominant behaviour change strategies used included goal setting, stages of change, and self monitoring with a food diary.	**Location in text or source** *(pg & ¶/fig/table/other)*
Group name	The Size Down Programme	
No. randomised to group *(specify whether no. people or clusters)*	100	
Theoretical basis *(include key references)*	N/A	

Description *(include sufficient detail for replication, e.g. content, dose, components)*	As above	
Duration of treatment period	This provided six weekly two hour sessions, with follow-up sessions at nine and 12 weeks	
Timing *(e.g. frequency, duration of each episode)*	Unknown	
Delivery *(e.g. mechanism, medium, intensity, fidelity)*	Group sessions (6 weeks / 2 hour sessions)	
Providers *(e.g. no., profession, training, ethnicity etc. if relevant)*	Provided support workers trained by the dietetics service	
Co-interventions	N/A	
Economic variables *(i.e. intervention cost, changes in other costs as result of intervention)*	See Table 2	
Resource requirements *(e.g. staff numbers, cold chain, equipment)*	community venues and support workers	
Integrity of delivery	Unknown	
Compliance	Unknown	
Notes:		

Intervention Group 3 General Practice or Pharmacy

	Description as stated in report/paper The general practice and pharmacy programmes comprised 12 one to one sessions in the general practice or pharmacy. The first session was planned to last 30 minutes, with follow-up sessions of 15-20 minutes. Sessions were client led and based around a problem solving approach. Sessions included weight and dieting history, exploration of goals and expectations of patients, the eatwell plate, setting goals to reduce calorie intake and increase physical activity, planning strategies to deal with challenging situations, use of food diaries, and maintaining weight loss. Weight loss goals were 5-10% of starting body weight, at a rate of 0.5-1 kg/week over three to six months, followed by maintenance. Physical activity goals were to aim to slowly increase activity levels to achieve 30 minutes of moderate activity on five days each week. The theoretical basis used stages of change and motivational interviewing. Predominant behaviour change strategies included goal setting, self monitoring with food diaries, hunger scale, waist measurements, and physical activity. Resources were provided as homework for discussion in the next session or for personal reflection. Participants were encouraged to reward themselves for success.	**Location in text or source** *(pg & ¶/fig/table/other)*
Group name	General Practice and Pharmacy Programmes	
No. randomised to group *(specify whether no. people or clusters)*	General Practice n=70 Pharmacy = 70	
Theoretical basis *(include key references)*	N/A	

Description *(include sufficient detail for replication, e.g. content, dose, components)*	Sessions were client led and based around a problem solving approach. Sessions included weight and dieting history, exploration of goals and expectations of patients, the eatwell plate, setting goals to reduce calorie intake and increase physical activity, planning strategies to deal with challenging situations, use of food diaries, and maintaining weight loss. Weight loss goals were 5-10% of starting body weight, at a rate of 0.5-1 kg/week over three to six months, followed by maintenance. Physical activity goals were to aim to slowly increase activity levels to achieve 30 minutes of moderate activity on five days each week. The theoretical basis used stages of change and motivational interviewing. Predominant behaviour change strategies included goal setting, self monitoring with food diaries, hunger scale, waist measurements, and physical activity. Resources were provided as homework for discussion in the next session or for personal reflection. Participants were encouraged to reward themselves for success.	
Duration of treatment period	The general practice and pharmacy programmes comprised 12 one to one sessions in the general practice or pharmacy. The first session was planned to last 30 minutes, with follow-up sessions of 15-20 minutes.	
Timing *(e.g. frequency, duration of each episode)*	Implied weekly but not stated	
Delivery *(e.g. mechanism, medium, intensity, fidelity)*	12 one to one sessions	
Providers *(e.g. no., profession, training, ethnicity etc. if relevant)*	general practice or pharmacy	
Co-interventions	N/A	
Economic variables *(i.e. intervention cost, changes in other costs as result of intervention)*	See Table 7	
Resource requirements *(e.g. staff numbers, cold chain, equipment)*	Participating GP surgeries and pharmacies	
Integrity of delivery	Unknown	
Compliance	Unknown	

Notes:

Intervention Group 4 Comparator Group

	Description as stated in report/paper Participants allocated to the comparator group were sent vouchers for 12 free sessions at a local authority run leisure centre (a council run facility open to all members of the public and usually consisting of a swimming pool, fitness suite, and other sports halls or courts). Participants were not given an appointment to attend and were given no individual advice or support on diet or physical activity. Box 2 gives further details of the interventions, and fuller details are online.	**Location in text or source** *(pg & ¶/fig/table/other)*
Group name	Exercise / Comparator Group	
No. randomised to group *(specify whether no. people or clusters)*	100	
Theoretical basis *(include key references)*	N/A	
Description *(include sufficient detail for replication, e.g. content, dose, components)*	As above	
Duration of treatment period	Not specified	
Timing *(e.g. frequency, duration of each episode)*	Not specified	
Delivery *(e.g. mechanism, medium, intensity, fidelity)*	Delivered by attendance and participation in leisure facilities	
Providers *(e.g. no., profession, training, ethnicity etc. if relevant)*	Leisure facility	
Co-interventions	N/A	
Economic variables *(i.e. intervention cost, changes in other costs as result of intervention)*	See Table 7	
Resource requirements *(e.g. staff numbers, cold chain, equipment)*	Leisure Centre	
Integrity of delivery	Unknown	

Compliance	Unknown	
Notes:		

Outcomes

Copy and paste table for each outcome.

Outcome 1 – Primary Outcome

	Description as stated in report/paper **Weight Loss at Programme End**	**Location in text or source** *(pg & ¶/fig/table/other)*
Outcome name	**Weight Loss at Programme End (12 weeks)**	
Time points measured *(specify whether from start or end of intervention)*	Baseline Three months Twelve months	
Time points reported	Programme End (Three Months) Twelve Months	
Outcome definition *(with diagnostic criteria if relevant)*	The primary outcome was weight loss at three months' follow-up (programme end).	
Person measuring/ reporting	**Programme End (Three Months)** If participants were still attending their allocated weight loss intervention at programme end, the service providers weighed them and provided this data to the research team.	
Unit of measurement *(if relevant)*	kg	
Scales: upper and lower limits *(indicate whether high or low score is good)*		
Is outcome/tool validated?	☐ ☐ ☐ Unclear	
Imputation of missing data *(e.g. assumptions made for ITT analysis)*	Unsure "We assumed participants for whom weight at follow-up was not available to have their baseline weight for the primary analyses"	
Assumed risk estimate *(e.g. baseline or population risk noted in Background)*	Unknown	
Power	90%	

Notes: Statistic Analysis: We preferred objectively measured weight, but we used self reported weights when they were the only measures available.

Outcome 2 - Secondary outcomes were weight loss at one year, self reported physical activity, and percentage weight loss at programme end and one year.

	Description as stated in report/paper Secondary outcomes were weight loss at one year, self reported physical activity, and percentage weight loss at programme end and one year.	**Location in text or source** *(pg & ¶/fig/table/other)*
Outcome name	Weight Loss at 1 Year Self Reported Physical Activity Percentage Weight Loss at Programme End and One Year	
Time points measured *(specify whether from start or end of intervention)*	Baseline Three months Twelve months	
Time points reported	Three months Twelve months	
Outcome definition *(with diagnostic criteria if relevant)*	Secondary outcomes were weight loss at one year, self reported physical activity, and percentage weight loss at programme end and one year.	
Person measuring/ reporting	**Weight Loss at 12 Months** A trained practice nurse, health trainer, or researcher blinded to the allocation group did the one year assessment at the participant's general practice or home. This included assessment of weight and height, the IPAQ-short, and a free text question about their opinion of the service and whether they had tried any other weight loss programmes or strategies over the course of the year. The scales used for weight measurement during the study period in the practices and by the weight management services were all checked with standardised weights, unless a record of recent calibration was available.	
Unit of measurement *(if relevant)*	Weight Loss at 1 Year – kg Self Reported Physical Activity – Percentage Weight Loss at Programme End and One Year - %	

Scales: upper and lower limits *(indicate whether high or low score is good)*	Unknown		
Is outcome/tool validated?	☐ ☐ ☐ Unclear		
Imputation of missing data *(e.g. assumptions made for ITT analysis)*	Unsure "We assumed participants for whom weight at follow-up was not available to have their baseline weight for the primary analyses"		
Assumed risk estimate *(e.g. baseline or population risk noted in Background)*	Unknown		
Power	90%		
Notes:			

Other

Study funding sources *(including role of funders)*	The study was funded by NHS South Birmingham. PAveyard is supported by a National Institute for Health Research (NIHR) career scientist award. AD is supported by a senior research fellowship award from the NIHR. KJ was part funded by the NIHR through the Collaborations for Leadership in Applied Health Research and Care for Birmingham and Black Country (CLAHRC-BBC) programme. The views expressed in this publication are those of the authors and not necessarily those of the NIHR, the Department of Health, NHS South Birmingham, the University of Birmingham, or the CLAHRC-BBC Steering Group. JD and JB were employed by the sponsoring organisation. Their roles are outlined above. The writing of the report and the decision to submit the article for publication rested with the authors from the University of Birmingham	
Possible conflicts of interest *(for study authors)*	All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: PAveyard and AL have received hospitality from Weight Watchers on one occasion; JD and JB were employed by the funding organisation and managed the service.	
Notes:		

Data and analysis

Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.

For RCT/CCT

Continuous outcome

	Description as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
	Weight Loss at Programme End (12 Weeks)	

Comparison		Commercial Provider The Size Down Programme GP or Pharmacy Comparator Group					
Outcome		Weight Loss at Programme End (12 weeks)					
Subgroup		N/A					
Time point *(specify from start or end of intervention)*		Follow-up assessments took place between April 2009 and August 2010					
Post-intervention or change from baseline?		Yes – See Table 2 and Table 3					
Results	**Intervention**			**Comparison**			
	Mean	SD *(or other variance, specify)*	No. participants	Mean	SD *(or other variance, specify)*	No. participants	
Any other results reported *(e.g. mean difference, CI, P value)*		**Secondary Outcomes:** Weight Loss at 1 Year – kg Self Reported Physical Activity – Percentage Weight Loss at Programme End and One Year - % **Exploratory Analysis:** In an exploratory subgroup analysis, we examined weight loss separately in men and women by using a regression model, with the arm to which they were allocated and age as covariates. Furthermore, we examined whether the effects of each intervention varied by sex by adding multiplicative interaction terms for intervention by sex to the model. This is because commercial weight loss interventions are almost invariably run by women and treat their clients in groups dominated by women, so the effectiveness might vary by sex					
No. missing participants							
Reasons missing		Not provided					
No. participants moved from other group		N/A		N/A			
Reasons moved		N/A		N/A			

Unit of analysis *(individuals, cluster/ groups or body parts)*	Groups		
Statistical methods used and appropriateness of these *(e.g. adjustment for correlation)*	We did all analyses according to intention to treat and using Stata v11.0 and SPSS v17.0. We preferred objectively measured weight, but we used self reported weights when they were the only measures available. We assumed participants for whom weight at follow-up was not available to have their baseline weight for the primary analyses. We also did a sensitivity analysis using the last recorded weight as the follow-up weight.		
Reanalysis required? *(specify)*	☐ ☐ ☐ **No**		
Reanalysis possible?	☐ ☐ ☐ Yes No Unclear	N/A	
Reanalysed results	N/A		
Notes:			

Other information

	Description as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
Key conclusions of study authors	Commercially provided weight management services are more effective and cheaper than primary care based services led by specially trained staff, which are ineffective.	
References to other relevant studies		
Correspondence required for further study information *(from whom, what and when)*	N/A	

Notes:

What is already known on this topic

Some commercial and primary care based weight management programmes have been shown to produce significantly greater weight loss than in a control group after one year

What this study adds

In a primary care population, group based programmes produced significant weight loss at one year after a 12 week programme

One to one primary care based programmes were ineffective and most costly to provide

Short commercial and NHS group based programmes have the potential to produce clinically useful weight loss at one year follow-up

Definitions

Assumed risk estimate	An estimate of the risk of an event or average score without the intervention, used in Cochrane 'Summary of findings tables'. If a study provides useful estimates of the risk of average score of different subgroups of the population, or an estimate based on a representative observational study, you may wish to collect this information.
Change from baseline	A measure for a continuous outcome calculated as the difference between the baseline score and the post-intervention score.
Clusters	A group of participants who have been allocated to the same intervention arm together, as in a cluster-randomised trial, e.g. a whole family, town, school or patients in a clinic may be allocated to the same intervention rather than separately allocating each individual to different arms.
Co-morbidities	The presence of one or more diseases or conditions other than those of primary interest. In a study looking at treatment for one disease or condition, some of the individuals may have other diseases or conditions that could affect their outcomes.
Compliance	Participant behaviour that abides by the recommendations of a doctor, other health care provider or study investigator (also called adherence or concordance).
Contemporaneous data collection	When data is collected at the same point(s) in time or covering the same time period for each intervention arm in a study (that is, historical data are not used as a comparison).
Controlled Before and After Study	A non-randomised study design where a control population of similar characteristics and performance as the intervention group is identified. Data are collected before and after the intervention in both the control and intervention groups
Exclusions	Participants who were excluded from the study or the analysis by the investigators.
Imputation	Assuming a reasonable value for a measure where the true value is not available (e.g. assuming last observation carried forward for missing participants).
Integrity of delivery	The degree to which the specified procedures or components of an intervention are delivered as originally planned.
Interrupted Time Series	A research design that collects observations at multiple time points before and after an intervention (interruption). The design attempts to detect whether the intervention has had an effect significantly greater than the underlying trend.
Post-intervention	The value of a continuous outcome measured at some time point following the beginning of the intervention (may be during or after the intervention period).
Power	The probability that a trial will detect, as statistically significant, an intervention effect of a specified size.
Providers	The person or people responsible for delivering an intervention and related care, who may or may not require specific qualifications (e.g. doctors, physiotherapists) or training.
Quasi-randomised controlled trial	A study in which the method of allocating people to intervention arms was not random, but was intended to produce similar groups when used to allocate participants. Quasi-random methods include: allocation by the person's date of birth, by the day of the week or month of the year, by a person's medical record number, or just allocating every alternate person.

Reanalysis	Additional analysis of a study's results by a review author (e.g. to introduce adjustment for correlation that was not done by the study authors).
Report ID	A unique ID code given to a publication or other report of a study by the review author (e.g. first author's name and year of publication). If a study has more than one report (e.g. multiple publications or additional unpublished data) a separate Report ID can be allocated to each to help review authors keep track of the source of extracted data.
Sociodemographics	Social and demographic information about a study or its participants, including economic and cultural information, location, age, gender, ethnicity, etc.
Study ID	A unique ID code given to an included or excluded study by the review author (e.g. first author's name and year of publication from the main report of the study). Although a study may have multiple reports or references, it should have one single Study ID to help review authors keep track of all the different sources of information for a study.
Theoretical basis	The use of a particular theory (such as theories of human behaviour change) to design the components and implementation of an intervention
Unit of allocation	The unit allocated to an intervention arm. In most studies individual participants will be allocated, but in others it may be individual body parts (e.g. different teeth or joints may be allocated separately) or clusters of multiple people.
Unit of analysis	The unit used to calculate N in an analysis, and for which the result is reported. This may be the number of individual people, or the number of body parts or clusters of people in the study.
Unit of measurement	The unit in which an outcome is measured, e.g. height may be measured in cm or inches; depression may be measured using points on a particular scale.
Validated	A process to test and establish that a particular measurement tool or scale is a good measure of that outcome.
Withdrawals	Participants who voluntarily withdrew from participation in a study before the completion of outcome measurement.

Sources:

Cochrane Collaboration Glossary, 2010. Available from http://www.cochrane.org/training/cochrane-handbook.

Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Last JM (editor), A Dictionary of Epidemiology, 4th Ed. New York: Oxford University Press, 2001.

Schünemann H, Brożek J, Oxman A, editors. GRADE handbook for grading quality of evidence and strength of recommendation. Version 3.2 [updated March 2009]. The GRADE Working Group, 2009. Available from http://www.cc-ims.net/gradepro.

Data collection form

Intervention review – RCTs and non-RCTs

This form can be used as a guide for developing your own data extraction form. Sections can be expanded and added, and irrelevant sections can be removed. It is difficult to design a single form that meets the needs of all reviews, so it is important to consider carefully the information you need to collect, and design your form accordingly. Information included on this form should be comprehensive, and may be used in the text of your review, 'Characteristics of included studies' table, risk of bias assessment, and statistical analysis.

Notes on using a data extraction form:

- Be consistent in the order and style you use to describe the information for each report.
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.

Review title or ID
The Internet for weight control in an obese sample: results of a randomised controlled trial

Study ID *(surname of first author and year first full report of study was published e.g. Smith 2001)*
McConnon et al (2007)

Report ID *(if different to Study ID)*	**Report IDs of other reports of this study** *(e.g. duplicate publications, follow-up studies)*

Notes:

General Information

Date form completed *(dd/mm/yyyy)*	17th July 2012
Name/ID of person extracting data	Alison Moore
Reference citation	
Study author contact details	
Publication type *(e.g. full report, abstract, letter)*	Full Study

Notes:

Study eligibility

Study Characteristics	**Eligibility criteria** *(Insert inclusion criteria for each characteristic as defined in the Protocol)*	**Eligibility criteria met?** Yes	**Location in text or source** *(pg & ¶/fig/table/other)*
Type of study	Randomised Controlled Trial	Yes ☐ ☐	
	Quasi-randomised Controlled Trial	☐ No ☐	
	Controlled Before and After Study • Contemporaneous data collection • Comparable control site • At least 2 x intervention and 2 x control clusters	☐ ☐ ☐	
	Interrupted Time Series • At least 3 time points before and 3 after the intervention • Clearly defined intervention point	☐ ☐ ☐	Baseline, 6 months, 12 months
	Other design (specify):	☐ ☐ ☐	
Participants	Obese volunteers (n = 221) were randomly assigned to Internet group (n = 111) or usual care group (n = 110).	Yes ☐ ☐	
Types of intervention	Supports a lifestyle approach to treating obesity, offering a combination of dietary advice, physical activity advice and behaviour therapy	Yes ☐ ☐	
Types of outcome measures	The primary outcome was the ability of the Internet package to promote change in weight and BMI over six and 12 months compared with usual care. Secondary outcomes were the ability of the Internet package to promote change in reported lifestyle behaviours compared with usual care, along with differences in quality of life.	Yes ☐ ☐	
☐ **INCLUDE** Yes			
Reason for exclusion			

Notes:

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

Characteristics of included studies

Methods

	Descriptions as stated in report/paper		**Location in text or source** *(pg & ¶/fig/table/other)*
Aim of study *(e.g. efficacy, equivalence, pragmatic)*	• To develop an Internet-based interactive and personalised package for weight control (http://www.ukweightcontrol.co.uk) • To explore acceptability of the Internet-based package to potential users • To conduct a randomised-controlled trial on the effectiveness of the Internet-based package in promoting weight loss compared with usual care • To promote the results through publication and dissemination via local and national health and community networks		
Design*(e.g. parallel, crossover, non-RCT)*	RCT		
Unit of allocation *(by individuals, cluster/ groups or body parts)*	Groups		
Start date	Recruitment May – November 2003		
End date	1st January 2004 1st January 2005		
Duration of participation *(from recruitment to last follow-up)*	12 months		
Ethical approval needed/ obtained for study	☐ ☐ ☐ Yes	Participants were recruited from GP practices in Leeds, UK, following ethical approval from Leeds (West) Research Ethics Committee in August 2002.	"Methods" *Participants*

Notes:
The start and end dates are not specifically mentioned in this paper however I checked this with the 'controlled trials register (http://www.controlled-trials.com/isrctn/pf/58621669) and they provided me with the anticipated start and end dates which I have applied above.

Participants

	Description *Include comparative information for each intervention or comparison group if available*	**Location in text or source** *(pg & ¶/fig/table/other)*
Population description *(from which study participants are drawn)*	Participants were recruited from GP practices in Leeds, UK, following ethical approval from Leeds (West) Research Ethics Committee in August 2002. The sample was predominantly white (95%), female (77%), with a mean (sd) age of 45.8 (10.6). The mean (sd) weight of the sample was 98.4 kg (17.4) with a median (IQR) BMI of 34.4 (31.9–38.7). Preliminary analysis showed no significant differences between the two groups at baseline (Table 1).	"Methods" *Participants* "Results" *Baseline characteristics*
Setting *(including location and social context)*	The setting was the internet at a chosen location by the participant. On confirmation of informed written participant and GP consent, a baseline appointment was scheduled for each eligible participant, where height and weight were measured by the researcher and a baseline questionnaire completed, before each participant was randomly allocated into either the Internet group (n = 111) or the usual care group (n = 110).	"Methods" *Participants*
Inclusion criteria	• BMI >30 kg/m2 • 18–65 years of age (due to body composition changes • over the age of 65 years) • Able to access the Internet at least once per week • Able to read and write in English (for the purposes of accessing the site and completing questionnaires)	Short paper *'Inclusion Criteria'*
Exclusion criteria	• Pregnant or lactating women • Women planning on becoming pregnant within the • next year • Any illness or reason where the GP feels that the patient • should not be taking part in a clinical trial.	Short paper *'Inclusion Criteria'*

Method of recruitment of participants *(e.g. phone, mail, clinic patients)*	Posters and flyers were placed in patient waiting areas, advertising the study and asking interested potential participants to call the study centre or to inform their GP or practice nurse of their interest. ***Study procedure*** Eligible participants will be sent a covering letter, participant information sheet, consent form and an initial approach questionnaire. Consenting participants will be contacted by telephone to arrange a first visit with the research team at their GP surgery. At the first visit height, weight, waist and hip circumference will be measured for each participant. The baseline questionnaire will then be administered. At this point the participant will be randomly allocated using minimisation (Minim) into either the treatment group or the usual care group. Because of the nature of the intervention, it is not possible to blind either the participants or the researchers to the group assignment. Participants will be followed-up 6 months and 12 months after randomisation. At these visits they will have their height, weight, waist and hip measurements repeated, and will be asked to complete a further questionnaire at each visit.	"Methods" *Participants* *Small Study*
Informed consent obtained	☐ ☐ ☐ Yes	And GP consent obtained also
Total no. randomised *(or total pop. at start of study for NRCTs)*	221 randomised participants	Figure 1
Clusters *(if applicable, no., type, no. people per cluster)*	N/A	
Baseline imbalances	????	
Withdrawals and exclusions *(if not provided below by outcome)*	14 exclusions	Figure 1
Age	Intervention Mean Age = 48.1 years Control Group Mean Age = 47.4 years	Table 2 Comparison of baseline characteristics of responders by treatment group

Sex	Gender Male/Female % Responders 21%/79% Non Responders 22%/78%	Table 3: Comparison of baseline characteristics of responders versus non-responders
Race/Ethnicity	Not mentioned	
Severity of illness	Not mentioned	
Co-morbidities	Obesity BMI >30 kg/m2	
Other relevant sociodemographics	Not mentioned	
Subgroups measured	N/A	
Subgroups reported	N/A	
Notes:		

Intervention groups

Copy and paste table for each intervention and comparison group

Intervention Group

	Description as stated in report/paper	Location in text or source
	The intervention Current research evidence supports a lifestyle approach to treating obesity, offering a combination of dietary advice, physical activity advice and behaviour therapy [14-17]. Based on these guidelines and clinical evidence, the intervention website was developed to reflect these factors. The website provided advice, tools and information to support behaviour change in terms of dietary and physical activity patterns. It was designed to enable patients to manage their own care and to vary the frequency of use according to their own needs. The website also offered personalised advice to participants, which, in the context of this trial, involved targeting the information provided to an individual, based on their responses to a series of online questions regarding eating and activity habits and current weight status. This enabled specific motivational statements to be generated to participants whenever they visited the website. Motivational statements were generated based on participants self report of progress in terms of reaching their personal behaviour change goals. In addition, details of progress in terms of self-reported weight loss were stored on the website, accessible only to the individual concerned. Automatic generic e-mails were generated if participants did not visit the website regularly to encourage them to visit more often. The website and questionnaires were piloted in a sample of overweight University staff. The results of this pilot were used to inform the final version of the website. The trial aimed to compare the additional effect of the website against usual care available within the UK. Participants randomised into the Internet group were given a demonstration of the website and its services, along with a username and password to access the website and were asked to log on to the website at least once a week over the trial period. Participants randomised to the usual care group were advised to continue with their usual approach to weight loss and were given a small amount of printed information at baseline, reflecting the type of information	"The intervention" Small Study *"Intervention Group"*

Group name	Intervention	
No. randomised to group *(specify whether no. people or clusters)*	111	Figure 1
Theoretical basis *(include key references)*		
Description *(include sufficient detail for replication, e.g. content, dose, components)*	<u>*What the UK Weight Control Site Will Do*</u> The UK weight control site will provide free weight management information based on the best possible advice from experts in the field. It will enable patients to manage their own care and to vary the frequency of use according to their own needs. The site will offer personalised advice to participants, which, in the context of the Internet, involves targeting the information provided to an individual individual based on their responses to a series of online questions. This will enable targeted motivational statements to be generated to participants whenever they visit the site. In addition, details of progress in terms of self-reported weight loss will be stored on the site, accessible only to the individual concerned. Participants will be given a demonstration of the website and its services, along with a username and password to access the site. They will be encouraged to log on frequently over the first few days in order to get accustomed to the site. After that participants will be encouraged to visit the site as often as they wish. Site usage will be monitored, along with the nature of participant queries and the time spent in dealing with them. Automatic emails will be generated if participants do not visit the site regularly to encourage them to visit more often	
Duration of treatment period	12 months	
Timing *(e.g. frequency, duration of each episode)*	Baseline 6 months after randomisation 12 months after randomisation	
Delivery *(e.g. mechanism, medium, intensity, fidelity)*	UK weight control site via the internet	

Providers *(e.g. no., profession, training, ethnicity etc. if relevant)*	***Unclear*** It is unclear whether or how training was provided to GP's & PN's however it is noted that interested potential participants to call the study centre or to inform their GP or practice nurse of their interest. It is unclear who responds to queries and who provides individual plans and motivational element of the interventions. **Authors Contributions** SK is the Principal Investigator, who conceived of the idea and obtained funding for the study. EH is a co-applicant on the grant and provides advice and guidance on the study design and conduct of the RCT. AM is co-ordinating the day-to-day running of the study. JP was the initial research manager on the project, who put together the content of the site and now advises on the web site content. DG is the statistician on the study. JT is the database manager and web designer/web master. All authors have contributed to the set up and design of the study. JR is an advisor on the study on aspects relating to project management.	"Methods *Participants"* *Small Study*
Co-interventions	N/A	
Economic variables *(i.e. intervention cost, changes in other costs as result of intervention)*	***Cost-effectiveness results*** The cost-effectiveness analysis showed that total costs were higher in the Internet group than the usual care group (£992.40 compared to £276.12). This difference was almost entirely due to the fixed cost of developing the website package. When this fixed cost was excluded total costs were actually lower in the Internet group. In terms of incremental cost effectiveness [26] the incremental ratio is £39,248 (£716.28/0.01825). Thus a decision maker would have to be willing to pay £39,248 per QALY to choose the Internet program over the usual care approach. AS shown in the cost-effectiveness acceptability curve (Figure 3) the decision about which is the most cost effective strategy is uncertain. At willingness to pay values of £20,000–£30,000 per QALY, it is unlikely that Internetbased support would be regarded as cost-effective (probability it is cost-effective is less than 0.5). As the service becomes more widely available, fixed costs will be spread over a greater number of individuals, thus total costs will reduce. This is likely to produce a much more favourable cost per QALY.	

Resource requirements *(e.g. staff numbers, cold chain, equipment)*	***Sample size*** With 180 participants in total we should be able to detect a difference of 5 kg weight loss (approximately 5% of body weight) or less than 2.5 kg/m2 in BMI between the two groups with 80% power. This assumes a two-sample t-test, 5% significance levels, a standard deviation for weight of 12 kg and for BMI of 5.5 kg/m2. An additional 22% of participants will be recruited to take account of any loss to follow-up, giving a target recruitment figure of 220 NOTE: Minimal resource requirements in terms of location and spatial capacity due to internet use. Possible training costs attributed to GP/PN but not detailed here so unknown quantum.	
Integrity of delivery	Medium	
Compliance	***Use of the website by Internet group participants*** Fifty-nine participants (53%) reported using the website at six months with 32 (29%) of these still using the website at 12 months and 52 participants (47%) indicating that they never used the website. The mean (sd) number of logons over the trial was 15.8 (15.2), this ranged from a minimum of one logon to a maximum of 77 logons. The data failed to reveal any correlation between the number of logons and weight loss (p = 0.16). Only 26% of the Internet group respondents at six months reported using the Internet daily for general use and no relationship between Internet use and number of logons to the website over the 12 months was established (CI = -10.1 to 12.9, p = 0.82). Despite high attrition and low utilisation, of those who had reported use of the website at six months 39 (63%) rated it easy or very easy to use at six months, and 49 (78%) rated it as clear or very clear. With 28 (85%) and 25 (76%) of those respondents reporting use of the QALY.	
Notes: ***'Usual Care' Group*** Participants randomised to this group will be advised to continue with their usual approach to weight loss, e.g. to contact their GP, obtain a dietetic referral, or visit commercial slimming clubs. Participants will be given a small amount of printed information to prevent 'resentful demoralisation'. This will be developed to reflect the type of information available both within the primary care setting and featured on the website.		

Outcomes

Copy and paste table for each outcome.

Outcome 1

	Description as stated in report/paper Primary outcome was the ability of the Internet package to promote change in weight and BMI over six and 12 months compared with usual care	**Location in text or source** *(pg & ¶/fig/table/other)*
Outcome name	Internet Group	
Time points measured *(specify whether from start or end of intervention)*	Baseline 6 Months 12 Months	
Time points reported	Baseline 12 Months	
Outcome definition *(with diagnostic criteria if relevant)*	Primary outcome was the ability of the Internet package to promote change in weight and BMI over six and 12 months compared with usual care	
Person measuring/ reporting	**<u>Authors Contributions</u>** SK is the Principal Investigator, who conceived of the idea and obtained funding for the study. EH is a co-applicant on the grant and provides advice and guidance on the study design and conduct of the RCT. AM is co-ordinating the day-to-day running of the study. JP was the initial research manager on the project, who put together the content of the site and now advises on the web site content. DG is the statistician on the study. JT is the database manager and web designer/web master. All authors have contributed to the set up and design of the study. JR is an advisor on the study on aspects relating to project management.	
Unit of measurement *(if relevant)*	N/A	
Scales: upper and lower limits *(indicate whether high or low score is good)*		
Is outcome/tool validated?	☐ ☐ ☐ Unclear	
Imputation of missing data *(e.g. assumptions made for ITT analysis)*	Primary analyses were based on all existing data Analyses using LOCF and BOCF were performed to assess the robustness of the primary analysis for the effect of losses to follow up and missing data. An additional 22% of participants were recruited to take account of any loss to follow up.	"Statistical Analysis" "Sample Size"

Assumed risk estimate *(e.g. baseline or population risk noted in Background)*	High attrition and low compliance	
Power	80%	
Notes:		

Outcome 2

	Description as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
	Secondary outcomes were the ability of the Internet package to promote change in reported lifestyle behaviours compared with usual care, along with differences in quality of life	
Outcome name	Usual Care	
Time points measured *(specify whether from start or end of intervention)*	Baseline 6 months 12 months	
Time points reported	Baseline 12 Months	
Outcome definition *(with diagnostic criteria if relevant)*	Secondary outcomes were the ability of the Internet package to promote change in reported lifestyle behaviours compared with usual care, along with differences in quality of life	
Person measuring/ reporting	**Authors Contributions** SK is the Principal Investigator, who conceived of the idea and obtained funding for the study. EH is a co-applicant on the grant and provides advice and guidance on the study design and conduct of the RCT. AM is co-ordinating the day-to-day running of the study. JP was the initial research manager on the project, who put together the content of the site and now advises on the web site content. DG is the statistician on the study. JT is the database manager and web designer/web master. All authors have contributed to the set up and design of the study. JR is an advisor on the study on aspects relating to project management.	

Unit of measurement *(if relevant)*	Lifestyle and dietary habits were assessed with a questionnaire previously used in the UK Women's Cohort Study [18]. This questionnaire obtained information on methods of cooking, portion size and frequency of consumption of various foods and participants' 'dieting' practices. Physical activity level was assessed using the Baecke physical activity questionnaire which measures work, leisure and sports activity providing a comprehensive evaluation of habitual physical activity [19]. Quality of life was assessed using the EuroQol questionnaire, a short, self administered questionnaire which was also used in the cost effectiveness analysis [20]. A brief series of questions were used to assess participants' confidence in their ability to make positive lifestyle changes on a scale of one to seven (where one indicates not at all confident and seven indicates very confident). These measures were combined in one questionnaire, which participants completed at baseline, six months and 12 months. Additional questions were added at six and 12 months for the purpose of the cost-effectiveness analysis of the programme. Participants in the Internet group also completed an additional section on their use and views of the website at six and 12 months.	
Scales: upper and lower limits *(indicate whether high or low score is good)*	N/A	
Is outcome/tool validated?	☐ ☐ ☐ Unclear	
Imputation of missing data *(e.g. assumptions made for ITT analysis)*	As before	
Assumed risk estimate *(e.g. baseline or population risk noted in Background)*	High attrition and low compliance	
Power	80%	

Notes:

Secondary measures

A significant reduction in self-rated physical activity score over the intervention period was identified ($p < 0.005$)
with a mean reduction of 0.34 in the sample, the difference in change between the two groups over the 12
months was non-significant ($p = 0.6$). Quality of life was shown to increase significantly over the trial ($p = 0.03$),
however no between group differences were established ($p = 0.8$). No significant changes in dietary habits or confidence
scores were detected over the 12 months.

Other

Study funding sources *(including role of funders)*	The Health Foundation	
Possible conflicts of interest *(for study authors)*	None declared	
Notes:		

Data and analysis

Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.

For RCT/CCT

Continuous outcome

	Description as stated in report/paper **Weight Loss**	**Location in text or source** *(pg & ¶/fig/table/other)*
Comparison	Internet –v- Usual Care	
Outcome	Primary – weight loss at 12 months Secondary outcomes were the ability of the Internet package to promote change in reported lifestyle behaviours compared with usual care, along with differences in quality of life	
Subgroup	N/A	
Time point *(specify from start or end of intervention)*	Recruitment May-November 2003. 1st January 2004 1st January 2005	

Post-intervention or change from baseline?	**Primary Outcome** *Change in weight and BMI* Change in BMI between the two groups at 12 months was non-significant, with a mean difference of 0.3 kg/m2 (CI = -0.5 to 1, p = 0.4), ranging from -5.9 kg/m2 to +3.8 kg/m2 for the Internet group and -8.1 kg/m2 to +3.5 kg/m2 for the usual care group at 12 months. Both groups lost a significant amount of weight over time, but the difference in change between the groups at 12 months was non-significant. ANCOVA using weight at 12 months as the dependent variable, adjusting for age, sex, baseline weight, baseline physical activity score and baseline confidence score revealed that the Internet group were 0.6 kg heavier (95% CI: -1.4 to 2.5, p = 0.56) than the usual care group after 12 months (Figure 2). Similar results were produced from BOCF data (Internet group 0.8 kg heavier (95% CI: -0.4 to 1.9, p = 0.2)) and LOCF data (Internet group 0.5 kg heavier (95% CI: -0.8 to 1.8, p = 0.4)), demonstrating the robustness of the results to alternative assumptions. We were also interested in the loss of 5% body weight, as this is associated with significant improvements in health [25]. Investigating weight loss as a percentage of the baseline weight, 22% of Internet responders lost 5% or more of their baseline weight by 12 months, with 18% of the usual care group losing at least this amount. **Secondary Outcome** A significant reduction in self-rated physical activity score over the intervention period was identified (p < 0.005) with a mean reduction of 0.34 in the sample, the difference in change between the two groups over the 12 months was non-significant (p = 0.6). Quality of life was shown to increase significantly over the trial (p = 0.03), however no between group differences were established (p = 0.8). No significant changes in dietary habits or confidence scores were detected over the 12 months.		
Any other results reported *(e.g. mean difference, CI, P value)*			
No. missing participants	**Intervention Group** *Lost to Follow Up* 6 months (n=42) 12 months (n=15) 12 month follow up (n=54)	**Usual Care Group** *Lost to Follow Up* 6 months (n=27) 12 months (n=6) 12 month follow up (n=77)	

Reasons missing	*Lost to Follow Up* 6 months (n=42) -Couldn't contact(23) -Withdrawn(15) -DNA Visit(3) -Moved house(1) 12 months (n=15) Couldn't contact(7) -Withdrawn(3) -DNA Visit(3) -Pregnant(2)	*Lost to Follow Up* 6 months (n=27) -Couldn't contact (11) -Withdrawn (10) -Did not attend visit (3) -Pregnant (2) -Moved house (1) 12 months (n=6) -Couldn't contact(5) -Withdrawn(1)	
No. participants moved from other group	None	None	
Reasons moved	N/A	N/A	
Unit of analysis *(individuals, cluster/ groups or body parts)*	Groups		
Statistical methods used and appropriateness of these *(e.g. adjustment for correlation)*	***Sample size*** A sample size of 180 participants was required to detect a difference of 5 kg weight loss (approximately 5% of body weight) or less than 2.5 kg/m2 in BMI between the two groups with 80% power, assuming a two-sample t-test, 5% significance levels, a standard deviation for weight of 12 kg and for BMI of 5.5 kg/m2. An additional 22% of participants were recruited to take account of any loss to follow-up, giving a recruitment target figure of 220. ***Statistical analysis*** Analyses were performed using Statistical Package for the Social Sciences (SPSS for Windows, version 11.5; SPSS, Chicago, IL). Independent sample t-tests (or non-parametric tests where appropriate) and chi-squared tests were used to investigate differences in baseline characteristics and response rates between the two groups. Analysis of covariance (ANCOVA) on weight at 12 months was used to investigate the difference between the two groups. This adjusted for any imbalance in age, sex, baseline weight, baseline physical activity score or baseline confidence score introduced by losses to follow-up. Changes in secondary measures were investigated using ANCOVA djusting for possible baseline imbalances as before. Primary analyses were conducted based on all available data. Analyses using LOCF and BOCF were performed to assess the robustness of the primary analysis for the effect oflosses to follow up and missing data.		
Reanalysis required? *(specify)*	☐ ☐ ☐ No		
Reanalysis possible?	☐ ☐ ☐ No		
Reanalysed results			

Notes:

Definitions

Assumed risk estimate	An estimate of the risk of an event or average score without the intervention, used in Cochrane 'Summary of findings tables'. If a study provides useful estimates of the risk of average score of different subgroups of the population, or an estimate based on a representative observational study, you may wish to collect this information.
Change from baseline	A measure for a continuous outcome calculated as the difference between the baseline score and the post-intervention score.
Clusters	A group of participants who have been allocated to the same intervention arm together, as in a cluster-randomised trial, e.g. a whole family, town, school or patients in a clinic may be allocated to the same intervention rather than separately allocating each individual to different arms.
Co-morbidities	The presence of one or more diseases or conditions other than those of primary interest. In a study looking at treatment for one disease or condition, some of the individuals may have other diseases or conditions that could affect their outcomes.
Compliance	Participant behaviour that abides by the recommendations of a doctor, other health care provider or study investigator (also called adherence or concordance).
Contemporaneous data collection	When data is collected at the same point(s) in time or covering the same time period for each intervention arm in a study (that is, historical data are not used as a comparison).
Controlled Before and After Study	A non-randomised study design where a control population of similar characteristics and performance as the intervention group is identified. Data are collected before and after the intervention in both the control and intervention groups
Exclusions	Participants who were excluded from the study or the analysis by the investigators.
Imputation	Assuming a reasonable value for a measure where the true value is not available (e.g. assuming last observation carried forward for missing participants).
Integrity of delivery	The degree to which the specified procedures or components of an intervention are delivered as originally planned.
Interrupted Time Series	A research design that collects observations at multiple time points before and after an intervention (interruption). The design attempts to detect whether the intervention has had an effect significantly greater than the underlying trend.
Post-intervention	The value of a continuous outcome measured at some time point following the beginning of the intervention (may be during or after the intervention period).
Power	The probability that a trial will detect, as statistically significant, an intervention effect of a specified size.
Providers	The person or people responsible for delivering an intervention and related care, who may or may not require specific qualifications (e.g. doctors, physiotherapists) or training.

Quasi-randomised controlled trial	A study in which the method of allocating people to intervention arms was not random, but was intended to produce similar groups when used to allocate participants. Quasi-random methods include: allocation by the person's date of birth, by the day of the week or month of the year, by a person's medical record number, or just allocating every alternate person.
Reanalysis	Additional analysis of a study's results by a review author (e.g. to introduce adjustment for correlation that was not done by the study authors).
Report ID	A unique ID code given to a publication or other report of a study by the review author (e.g. first author's name and year of publication). If a study has more than one report (e.g. multiple publications or additional unpublished data) a separate Report ID can be allocated to each to help review authors keep track of the source of extracted data.
Sociodemographics	Social and demographic information about a study or its participants, including economic and cultural information, location, age, gender, ethnicity, etc.
Study ID	A unique ID code given to an included or excluded study by the review author (e.g. first author's name and year of publication from the main report of the study). Although a study may have multiple reports or references, it should have one single Study ID to help review authors keep track of all the different sources of information for a study.
Theoretical basis	The use of a particular theory (such as theories of human behaviour change) to design the components and implementation of an intervention
Unit of allocation	The unit allocated to an intervention arm. In most studies individual participants will be allocated, but in others it may be individual body parts (e.g. different teeth or joints may be allocated separately) or clusters of multiple people.
Unit of analysis	The unit used to calculate N in an analysis, and for which the result is reported. This may be the number of individual people, or the number of body parts or clusters of people in the study.
Unit of measurement	The unit in which an outcome is measured, e.g. height may be measured in cm or inches; depression may be measured using points on a particular scale.
Validated	A process to test and establish that a particular measurement tool or scale is a good measure of that outcome.
Withdrawals	Participants who voluntarily withdrew from participation in a study before the completion of outcome measurement.

Sources:

Cochrane Collaboration Glossary, 2010. Available from http://www.cochrane.org/training/cochrane-handbook.

Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Last JM (editor), A Dictionary of Epidemiology, 4th Ed. New York: Oxford University Press, 2001.

Schünemann H, Brożek J, Oxman A, editors. GRADE handbook for grading quality of evidence and strength of recommendation. Version 3.2 [updated March 2009]. The GRADE Working Group, 2009. Available from http://www.cc-ims.net/gradepro.

Data collection form

Intervention review – RCTs and non-RCTs

This form can be used as a guide for developing your own data extraction form. Sections can be expanded and added, and irrelevant sections can be removed. It is difficult to design a single form that meets the needs of all reviews, so it is important to consider carefully the information you need to collect, and design your form accordingly. Information included on this form should be comprehensive, and may be used in the text of your review, 'Characteristics of included studies' table, risk of bias assessment, and statistical analysis.

Notes on using a data extraction form:

- Be consistent in the order and style you use to describe the information for each report.
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.

Review title or ID
The 'Pounds for Pounds' weight loss financial incentive scheme: an evaluation of a pilot in NHS Eastern and Coastal Kent

Study ID *(surname of first author and year first full report of study was published e.g. Smith 2001)*
Relton, Strong & Li (2011)

Report ID *(if different to Study ID)*	**Report IDs of other reports of this study** *(e.g. duplicate publications, follow-up studies)*

Notes:

General Information

Date form completed *(dd/mm/yyyy)*	19th July 2011
Name/ID of person extracting data	Alison Moore
Reference citation	
Study author contact details	Relton, 2011

Publication type *(e.g. full report, abstract, letter)*	Full Study - Pilot
Notes:	

Study eligibility

Study Characteristics	**Eligibility criteria** *(Insert inclusion criteria for each characteristic as defined in the Protocol)*	**Eligibility criteria met?** Yes	r	**Location in text or source** *(pg & ¶/fig/table/other)*
Type of study	Randomised Controlled Trial	☐ No	☐	
	Quasi-randomised Controlled Trial	☐ No	☐	
	Controlled Before and After Study • Contemporaneous data collection • Comparable control site • At least 2 x intervention and 2 x control clusters	☐ No	☐	
	Interrupted Time Series • At least 3 time points before and 3 after the intervention • Clearly defined intervention point	☐ No	☐	
	Other design (specify): Pilot Study	Yes ☐	☐	Measurements taken at baseline & monthly thereafter up to 12 month programme completion.
Participants	402 participants with a mean age of 45.1 years and a mean baseline weight of 101.8 kg. Approximately three quarters (77.4%) of participants were obese (as defined as BMI _30 kg/m2). Despite up-weighting in the random sample of invited participants, only 41.5% of those who activated their plan were male and only 31.3% were from deprived areas.	Yes ☐	☐	
Types of intervention	'Weight Wins' commercial programme The P4P programme tied rewards directly to weight loss results. Plans ranged from 15 lb (6.8 kg) weight loss over 3 months to 50 lb (22.7 kg) weight loss over 7 months, with optional additional weight 'maintenance' periods. The	Yes ☐	☐	

	maximum overall plan length was 13 months. Rewards ranged from £70 to £425 per year according to the P4P algorithm. P4P credited participants monthly for cumulative weight loss up to a maximum target weight loss rate of 7.1 lb (3.2 kg) per month, and for maintenance of weight loss. Participants received their accumulated financial rewards, plus a bonus equal to 50% of the total maximum reward if they had achieved their final target weight at plan completion. Participants were provided with a booklet of weight loss tips.		
Types of outcome measures	• Weight change from baseline to final recorded weight at 12 months • Weight change at 12 months • Estimated weight loss at 12 months and sensitivity analysis	Yes ☐ ☐	
INCLUDE ☐ **EXCLUDE** ☐			
Reason for exclusion			
Notes: Weight Wins is a personal financial incentive plan for weight loss. Incentive plans are available directly to the public and via organisations such as employers who are concerned about employees health. Members are motivated by email and telephone support and online interactive tools Weight Wins follows NICE obesity guidelines and rewards gradual long term weight loss and maintenance. Weight Wins is a broad base commercial weight loss programme. It is recognised by the National Obesity Forum and NHS. Participants chose a weight loss plan based on their target weight. Plans ranged from 15 lb (6.8 kg) weight loss over 3 months to50 lb (22.7 kg) weight loss over 7 months, with optional additional 'maintenance' periods. Rewards, which were received after successful plan completion, ranged from £70 to £425 per year.			

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

Characteristics of included studies

Methods

	Descriptions as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*

Aim of study *(e.g. efficacy, equivalence, pragmatic)*	Financial incentive programmes have the potential to modify health-related behaviours, including those associated with achieving weight loss. This study evaluated a pilot NHS commissioned financial incentive weight loss programme, based on the commercial Weight Wins 'Pounds for Pounds' programme.		
Design*(e.g. parallel, crossover, non-RCT)*	Pilot		
Unit of allocation *(by individuals, cluster/ groups or body parts)*	Groups		
Start date	January 2009		"Design & Setting"
End date	March 2010		
Duration of participation *(from recruitment to last follow-up)*	Recruitment January and February 2009		"Results", "Recruitment"
Ethical approval needed/ obtained for study	☐ ☐ ☐ Unclear	Ethical approval: This paper reports a service evaluation conducted on behalf of NHS Eastern and Coastal Kent, and therefore did not require ethical approval.	
Notes: *The P4P Programme itself was provided by a commercial company 'Weight Wins'*			

Participants

	Description *Include comparative information for each intervention or comparison group if available*	**Location in text or source** *(pg & ¶/fig/table/other)*

Population description *(from which study participants are drawn)*	19% were NHS employees, 27% were from males and 32% were from individuals with postcodes in deprived areas (national IMD2007 score quintiles 4 and 5). **Table 1** Baseline characteristics Participants (plan starters), n 402 Age in years, mean (SD) 45.1 (11.7) NHS employee, n (%) 171 (42.5) Baseline weight (kg), mean (SD) 101.8 (46.1) Male, n (%) 167 (41.5) Baseline BMI (kg/m2), mean (SD) 34.6 (5.4) Proportion BMI _30 kg/m2, n (%) 311 (77.4) Proportion BMI _40 kg/m2, n (%) 67 (16.7) Plan length (months), mean (SD) 11.6 (2.1), range 3–13 Target weight loss (kg), mean (SD) 16.7 (12.3) Affluent postcodea, n (%) 35 (8.7) Intermediate postcodea, n (%) 241 (60.0) Deprived postcodea, n (%) 126 (31.3) A Using IMD2007 quintiles 1–5: affluent, 1; in	Results, Recruitment
Setting *(including location and social context)*	Participants were weighed at baseline and monthly thereafter until plan completion. Weights were obtained at 'weigh-in' centres provided at various locations across the geographical area covered by NHS Eastern and Coastal Kent in GP surgeries, community pharmacies, gyms and weight loss clubs.	Outcome Measures & Method for Follow Up
Inclusion criteria	Adults were eligible for the programme if they lived within the NHS Eastern and Coastal Kent area and reported a target weight such that, having obtained this, they would still have a BMI .22.5 kg/m2. Applicants were required to report that they had obtained consent from their general practitioner if they were under 21, over 65, breast feeding a baby over 6 weeks old, had a chronic medical condition that required regular medical checks, were taking prescription medication, or had been advised to eat a special diet to treat a medical condition. .	
Exclusion criteria	Pregnant women and women breastfeeding a baby under 6 weeks old were ineligible	
Method of recruitment of participants *(e.g. phone, mail, clinic patients)*	The programme was advertised on the NHS Eastern and Coastal Kent website to NHS staff and to the general public. Individuals interested in the programme applied by completing a web form indicating how much weight they wished to lose, and for how long they wished to maintain their weight loss, along with their age, sex, height and postcode.	

Informed consent obtained	☐ Yes ☐ No ☐ **Unclear**	A random sample of 728 applicants was sent letters accepting them onto the P4P programme. The sample was stratified by sex, deprivation score and whether the participant was an NHS employee, with up-weighting of the proportion of males in the sample to 49%, residents from deprived areas to 42% and NHS employees to 23% to ensure adequate representation of these groups. A total of 402 of the 728 invited (55%) activated their individualized P4P plan by attending an initial independent weigh-in.	
Total no. randomised *(or total pop. at start of study for NRCTs)*	A random sample of 728 applicants was sent letters accepting them onto the P4P programme. The sample was stratified by sex, deprivation score and whether the participant was an NHS employee, with up-weighting of the proportion of males in the sample to 49%, residents from deprived areas to 42% and NHS employees to 23% to ensure adequate representation of these groups. A total of 402 of the 728 invited (55%) activated their individualized P4P plan by attending an initial independent weigh-in.		
Clusters *(if applicable, no., type, no. people per cluster)*	N/A		
Baseline imbalances	N/A		
Withdrawals and exclusions *(if not provided below by outcome)*	Plan lengths ranged from 3 to 13 months (mean: 11.6 months, median: 12 months). At 12 months 101 participants were active on the programme, 53 participants had completed a plan and left the programme ('inactive at 12 months, plan completed') and 248 participants had left the programme without completing a plan ('inactive at 12 months, failed to complete plan'). Those who were inactive at 12 months, but who had completed their plan, had been active for a mean of 9.2 months, whereas those who were inactive at 12 months, but who had failed to complete their plan, had been active for a mean of 3.3 months.		Plan lengths and drop outs

Age	Age in years, mean (SD) 45.1 (11.7)	
Sex	Male, n (%) 167 (41.5)	
Race/Ethnicity	Not provided	
Severity of illness	No detail given	
Co-morbidities	Obesity	
Other relevant sociodemographics	Affluent postcodea, n (%) 35 (8.7) Intermediate postcodea, n (%) 241 (60.0) Deprived postcodea, n (%) 126 (31.3)	Table 1
Subgroups measured	N/A	
Subgroups reported	N/A	
Notes:		

Intervention groups

Copy and paste table for each intervention and comparison group

Intervention Group 1

	Description as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
	The P4P programme tied rewards directly to weight loss results. Plans ranged from 15 lb (6.8 kg) weight loss over 3 months to 50 lb (22.7 kg) weight loss over 7 months, with optional additional weight 'maintenance' periods. The maximum overall plan length was 13 months. Rewards ranged from £70 to £425 per year according to the P4P algorithm. P4P credited participants monthly for cumulative weight loss up to a maximum target weight loss rate of 7.1 lb (3.2 kg) per month, and for maintenance of weight loss. Participants received their accumulated financial rewards, plus a bonus equal to 50% of the total maximum reward if they had achieved their final target weight at plan completion. Participants were provided with a booklet of weight loss tips.	
Group name	P4P programme	

No. randomised to group *(specify whether no. people or clusters)*	728 invited 402 activated their plan by attending initial weigh in.	
Theoretical basis *(include key references)*	N/A	
Description *(include sufficient detail for replication, e.g. content, dose, components)*	The P4P programme tied rewards directly to weight loss results. Plans ranged from 15 lb (6.8 kg) weight loss over 3 months to 50 lb (22.7 kg) weight loss over 7 months, with optional additional weight 'maintenance' periods. The maximum overall plan length was 13 months. Rewards ranged from £70 to £425 per year according to the P4P algorithm. P4P credited participants monthly for cumulative weight loss up to a maximum target weight loss rate of 7.1 lb (3.2 kg) per month, and for maintenance of weight loss. Participants received their accumulated financial rewards, plus a bonus equal to 50% of the total maximum reward if they had achieved their final target weight at plan completion. Participants were provided with a booklet of weight loss tips.	
Duration of treatment period	Plans ranged from 15 lb (6.8 kg) weight loss over 3 months to 50 lb (22.7 kg) weight loss over 7 months, with optional additional weight 'maintenance' periods. The maximum overall plan length was 13 months.	
Timing *(e.g. frequency, duration of each episode)*	Participants were weighed at baseline and monthly thereafter until plan completion.	
Delivery *(e.g. mechanism, medium, intensity, fidelity)*	Weights were obtained at 'weigh-in' centres provided at various locations across the geographical area covered by NHS Eastern and Coastal Kent in GP surgeries, community pharmacies, gyms and weight loss clubs.	
Providers *(e.g. no., profession, training, ethnicity etc. if relevant)*	Weight Wins trained staff – assuming this but not confirmed in paper	
Co-interventions	N/A	
Economic variables *(i.e. intervention cost, changes in other costs as result of intervention)*	Financial incentive	

Resource requirements *(e.g. staff numbers, cold chain, equipment)*	Commercial weight management company	
Integrity of delivery	Not specified	
Compliance	Not specified	
Notes:		

Outcomes

Copy and paste table for each outcome.

Outcome 1

	Description as stated in report/paper 1. Weight Change at 12 Months **2.** Estimated weight loss at 12 months in all participants and sensitivity analysis	**Location in text or source** *(pg & ¶/fig/table/other)*
Outcome name	**Weight Change at 12 Months**	
Time points measured *(specify whether from start or end of intervention)*	There were 101 participants actively attending a weighing-in centre at 12 months, either in an ongoing plan of length .12 months (n ¼ 63) or completing a 12 month plan (n ¼ 38). In addition to this, self-reported 12 month weights were obtained via email or telephone interview for 39 participants. Of these, 20 were randomly selected from the 53 participants who were inactive at 12 months, but who had completed a plan (median plan length: 9 months, range: 3–11). The remaining 19 were randomly selected from the 248 participants who were inactive at 12 months, but who had failed to complete their plan (median plan length: 9 months, range: 4–11). Table 3 shows mean 12 month weight loss for the active at 12 months group and for the two groups who were inactive at 12 months.	
Time points reported	Baseline and 12 months	
Outcome definition *(with diagnostic criteria if relevant)*	Table 3 Weight loss at 12 months	
Person measuring/ reporting	Weight Wins representative	
Unit of measurement *(if relevant)*	kilogram	

Scales: upper and lower limits *(indicate whether high or low score is good)*	N/A	
Is outcome/tool validated?	☐ ☐ ☐ **Unclear**	
Imputation of missing data *(e.g. assumptions made for ITT analysis)*	No but estimated weight loss at 12 months in all participants and sensitivity analysis. In the full cohort of participants we calculated mean weight loss between baseline and final recorded weight, proportion of participants with weight loss _5% of baseline and proportion with weight loss _10% of baseline. We explored in a logistic regression model the association between achievement of _5% weight loss and age, sex, level of social deprivation, baseline BMI and target weight loss. We calculated mean weight loss and proportion achieving _5% weight loss in those participants who were active (defined as attending monthly weigh-ins) at 12 months. We compared this active group with random samples from two inactive groups. The first group, 'inactive at 12 months(plan completed)', were those who had completed plans of shorter than 12 months duration. The second group, 'inactive at 12 months (failed to complete plan)', were those individuals no longer in the programme at 12 months because they had dropped out (ceased monthly weigh-ins before the end of their chosen plan). For both comparisons we used logistic regression to adjust for baseline covariates (age, sex, level of social deprivation, baseline BMI and target weight loss).	
Assumed risk estimate *(e.g. baseline or population risk noted in Background)*	N/A	
Power		

Notes:

Baseline characteristics in Table 1 but no detail for same characteristics at 12 months

Statistics:

We estimated overall 12 month weight loss in all participants under two assumptions. The first assumption was that the 12 month weight loss results from the two random samples of those who had left the programme were representative of the 12 month weight loss results from all those who had left the programme. The second assumption was that those who had left the programme without completing their plan had returned to their baseline weight at 12 months.

Results (abstract)

Mean baseline weight for the 402 participants was 101.8 kg (SD 46.1 kg), with 77.4% having a BMI _30 kg/m2. Clinically significant weight loss (_5%) occurred in 44.8% [95% confidence interval (CI): 40.0–49.7%] of participants. Estimated mean weight loss at 12 months was 4.0 kg (95% CI: 2.4–5.6 kg) under the assumption of return-to-baseline weight for those who had left the programme before reporting a 12 month weight.

Estimated weight loss at 12 months in all participants and sensitivity analysis

Twelve month weight data were not available for 262 of the 301 participants who were inactive at 12 months (33 plan
completers and 229 who had failed to complete their plan).

If we assume, firstly, that the self-reported 12 month weights for the 39 randomly selected inactive participants
were representative of all participants who were inactive at 12 months, then the estimate of the mean weight loss at 12 months for all participants in the P4P programme is 5.0 kg (95% CI: 3.4–6.6 kg). Secondly, if we assume that those
who failed to complete their plan returned to their baseline weight at 12 months, then the estimated overall mean weight loss for all participants in the programme is 4.0 kg (95% CI: 2.4–5.6 kg).

Other

Study funding sources *(including role of funders)*	C.R. receives financial support from the University of Sheffield. M.S. is supported by a UK Medical Research Council Health Services Research/Health of the Public research training fellowship [grant number G0601721].	
Possible conflicts of interest *(for study authors)*	Not specified	
Notes: 'Active' is defined as attending monthly weigh in's (statistical analysis)		

Definitions

Assumed risk estimate	An estimate of the risk of an event or average score without the intervention, used in Cochrane 'Summary of findings tables'. If a study provides useful estimates of the risk of average score of different subgroups of the population, or an estimate based on a representative observational study, you may wish to collect this information.
Change from baseline	A measure for a continuous outcome calculated as the difference between the baseline score and the post-intervention score.
Clusters	A group of participants who have been allocated to the same intervention arm together, as in a cluster-randomised trial, e.g. a whole family, town, school or patients in a clinic may be allocated to the same intervention rather than separately allocating each individual to different arms.
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Compliance	Participant behaviour that abides by the recommendations of a doctor, other health care provider or study investigator (also called adherence or concordance).
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than the underlying trend.

Post-intervention	The value of a continuous outcome measured at some time point following the beginning of the intervention (may be during or after the intervention period).
Power	The probability that a trial will detect, as statistically significant, an intervention effect of a specified size.
Providers	The person or people responsible for delivering an intervention and related care, who may or may not require specific qualifications (e.g. doctors, physiotherapists) or training.
Quasi-randomised controlled trial	A study in which the method of allocating people to intervention arms was not random, but was intended to produce similar groups when used to allocate participants. Quasi-random methods include: allocation by the person's date of birth, by the day of the week or month of the year, by a person's medical record number, or just allocating every alternate person.
Reanalysis	Additional analysis of a study's results by a review author (e.g. to introduce adjustment for correlation that was not done by the study authors).
Report ID	A unique ID code given to a publication or other report of a study by the review author (e.g. first author's name and year of publication). If a study has more than one report (e.g. multiple publications or additional unpublished data) a separate Report ID can be allocated to each to help review authors keep track of the source of extracted data.
Sociodemographics	Social and demographic information about a study or its participants, including economic and cultural information, location, age, gender, ethnicity, etc.
Study ID	A unique ID code given to an included or excluded study by the review author (e.g. first author's name and year of publication from the main report of the study). Although a study may have multiple reports or references, it should have one single Study ID to help review authors keep track of all the different sources of information for a study.
Theoretical basis	The use of a particular theory (such as theories of human behaviour change) to design the components and implementation of an intervention
Unit of allocation	The unit allocated to an intervention arm. In most studies individual participants will be allocated, but in others it may be individual body parts (e.g. different teeth or joints may be allocated separately) or clusters of multiple people.
Unit of analysis	The unit used to calculate N in an analysis, and for which the result is reported. This may be the number of individual people, or the number of body parts or clusters of people in the study.
Unit of measurement	The unit in which an outcome is measured, e.g. height may be measured in cm or inches; depression may be measured using points on a particular scale.
Validated	A process to test and establish that a particular measurement tool or scale is a good measure of that outcome.
Withdrawals	Participants who voluntarily withdrew from participation in a study before the completion of outcome measurement.

Sources:
Cochrane Collaboration Glossary, 2010. Available from http://www.cochrane.org/training/cochrane-handbook.

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8 Appendix 2 – Quality Assessment

Quality Assessment – Checklist (Downs & Black, 1998)

Randomised Controlled Trials

Questions	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	Summary Max 28	Percentage
Author																													
Moore et al (2003)	1	1	1	1	2	1	1	1	0	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	26	93%
McConnon et al (2006)	1	1	1	1	2	1	1	0	1	0	1	1	1	0	0	1	0	1	1	1	1	1	1	0	0	1	1	21	75%
Nanchahal et al (2012)	1	1	1	1	2	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	0	1	1	1	26	93%
Jolly et al (2011)	1	1	1	1	2	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	0	1	1	1	26	93%
Davies et al (2007)	1	1	1	1	2	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	0	1	1	1	25	89%

Non Randomised Controlled Trials

Author	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	Summary Max 22	Percentage
Ross, Laws, Reckless & Lean (2008)	1	1	1	1	2	1	1	1	0	0	1	1	1	0	0	0	1	1	1	1					0	0	0	16	73%
Relton, Strong & Li (2011)	1	1	1	1	2	1	1	1	1	0	0	1	1	0	0	1	1	1	1	1					0	1	0	18	82%

Question 1-10 = Reporting

Question 11-13 = External Validity

Question 14-20 = Internal Validity Bias

Question 21-26 = Internal Validity Confounding (selection bias)

Question 27 = Power

Questions – Quality Assessment Checklist (Downs & Black, 1998)

Q1. Clear hypothesis/aim/objective clearly described

Q2. Main outcomes to be measured clearly described in the Introduction or Methods section

Q3. Characteristics of the patients included in the study clearly described

Q4. Interventions of interest clearly described

Q5. Distributions of principal confounders in each group of subjects to be compared clearly described

Q6. Main findings of the study clearly described

Q7. Estimates of the random variability in the data for the main outcomes

Q8. All important adverse events that may be a consequence of the intervention reported

Q9. Characteristics of participants lost to follow-up described

Q10. Actual probability values reported for the main outcomes except where the probability value is less than .001

Q11. Asked a representative sample of the population to undertake the study

Q12. Subjects who were prepared to participate who were representative of the entire population from which they were recruited

Q13. The staff, places, and facilities where the patients were treated, representative of the treatment the majority of participants receive

Q14. Were identified as attempting to blind study subjects to the intervention they have received

Q15. Made an attempt to blind those measuring the main outcomes of the intervention

Q16. Made clear any results that were based on “data dredging”

Q17. Adjusted for different lengths of follow-up of participantsts, or in case-control studies the same time period between the intervention and outcome

Q18. Were identified as using appropriate statistical tests used to assess the main outcomes

Q19. Reliable compliance with the intervention/s

Q20. Accurate main outcome measures

Q21. Participants in different intervention groups (trials and cohort studies), or cases and controls (case-control studies), recruited from the same population

Q22. Study subjects in different intervention groups (trials and cohort studies,) or cases and controls (case-control studies), recruited over the same period of time

Q23. Study subjects randomised to intervention groups

Q24. Randomised intervention assignment concealed from both participants and health care staff until recruitment was complete and irrevocable

Q25. Adequate adjustment for confounding in the analyses from the main findings

Q26. Losses of patients to follow-up taken into account

Q27. Sufficient power was described to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%