A pragmatic randomised controlled trial of the Camden Weight Loss (CAMWEL) programme.

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A pragmatic randomised controlled trial of the Camden Weight Loss (CAMWEL) programme.

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Contributorship statement:

KN, JT, NT, DH, AK, SE & AH contributed to conception and design.
MH, JT, KN, EH, AS, UG contributed to acquisition of data
KN, TP, EH, MK, AH contributed to analysis and interpretation of data
KN drafted the article
KN, JT, AH revised it critically for important intellectual content
All authors contributed to final approval of the version to be published

Summary

Article focus

- Evaluate structured one-to-one weight management programme
- Delivery by trained non-specialists
- Primary care

Key messages

- Clinically important level of weight loss achieved by higher proportion of participants in intervention (34%) compared to control group (19%)
- Intervention group reported higher level of satisfaction with support received
- Primary care interventions are unlikely to be sufficient to tackle the obesity epidemic

Strengths and Limitations

- Relatively low threshold of BMI≥25 for inclusion, with few exclusions, so wide applicability of findings
- High loss to follow-up (43%), although similar to other studies in the area; used multiple imputation to counter any biases.

Abstract (max 300 words)

- **Objectives** - To evaluate effectiveness of a structured one-to-one behaviour change programme on weight loss in obese and overweight individuals.
- **Design** - Randomized controlled trial.
- **Setting** - 23 general practices in Camden, London.
- **Participants** - 381 adults with body mass index ≥ 25 kg/m^2 randomly assigned to intervention (n=191) or control (n=190) groups.
- **Interventions** - A structured one-to-one programme, delivered over 14 visits during 12 months by trained advisors in three primary care centres, compared to usual care in general practice.
- **Outcome measures** – Changes in weight, %body fat, waist circumference, blood pressure and heart rate between baseline and 12 months
- **Results** - 217/381 (57.0%) participants were assessed at 12 months: missing values were imputed. The intervention group achieved a greater mean weight loss of 0.70 kg (0.67 to 2.17, P=0.35) compared to the control group. A higher proportion of the intervention than control group lost 5% or more of their baseline weight (Odds ratio: 1.7 (1.4 to 2.7, P=0.04)). The intervention group achieved a lower mean heart rate (mean difference 3.68 beats per minute (0.31 to 7.04, P=0.03)) than the control group and consistent but non-statistically significant greater reductions in waist circumference, %body fat, systolic blood pressure and diastolic blood pressure. Participants in the intervention group reported more positive assessment of their care compared to the control group.
- **Conclusions** – Despite lack of a significant difference in mean weight loss between intervention and control groups, trained non-specialist advisors can deliver a structured programme and achieve clinically beneficial weight loss in some patients in primary care. The intervention group also reported a higher level of satisfaction with the support received. Primary care interventions are unlikely to be sufficient to tackle the obesity epidemic and effective population wide measures are also necessary.
- **Trial registration –** Clincaltrials.gov NCT00891943

WHAT IS ALREADY KNOWN ON THIS TOPIC

The NICE guidelines for the management of overweight and obese patients provide general recommendations for discussing weight and improving diet and physical activity levels.

However, there are no randomised controlled trials of one-to-one weight management programmes in non-diabetic patients with 12-months follow-up in general practice in the UK.

WHAT THIS STUDY ADDS

A structured weight management programme for overweight and obese patients delivered by trained non- specialists was associated with a clinically important level of weight loss, although there was no strong evidence that the average difference in weight between groups was improved by the intervention.

Intervention participants reported greater satisfaction with care than did the usual care participants.

Primary care interventions are unlikely to be sufficient to address the obesity epidemic and need to be complemented with robust public health policies.

Introduction

Overweight and obesity are major public health problems,[1] representing the fifth leading cause of death in the world[2] and an increasing global challenge.[3] Obesity has severe impacts on health, increasing the risk of type 2 diabetes, hypertension, some cancers, heart and liver disease.[1, 4 5] The Foresight Report[6] estimated the National Health Service costs attributable to obesity in 2007 as £4.2 billion. In 2010, 68% of men and 58% women in England were overweight or obese (Body Mass Index (BMI) ≥25 kg/m^2).[7]

Obesity is a chronic condition requiring lifelong management as weight loss is often regained.[8, 9] Achieving changes in behaviour is challenging,[10] largely due to an inability to maintain healthy eating and physical activity behaviours.[11] Modest weight loss (3-9%) can prevent type 2 diabetes, improve fasting plasma glucose, blood pressure and lipids, and reduce antihypertensive medication.[12, 13 14-16] Most overweight patients would like help with weight management from their general practices,[17] and this is feasible in the short-term (3-12 months)[18, 19] and estimated to be cost saving to the NHS,[20] although few recall receiving weight control advice from a health professional.[21]

The aim of this study was to develop and evaluate the efficacy of an intervention programme with twelve months follow up, for an ethnically diverse overweight/obese population recruited from general practices in a pragmatic randomised controlled trial following the Medical Research Council framework for complex interventions.[22] To our knowledge, there are currently no other published randomised controlled trials of one-to-one lifestyle intervention delivered in UK general practice to overweight/obese patients without co-morbidities.

Methods

Aims

The aim of the study was to assess, by means of a pragmatic parallel group randomized controlled trial (RCT), the effects on anthropometric measures, health-related parameters and the sense of well-being of offering individualized weight management advice in primary care to overweight/obese people who wished to lose weight; and to identify the key factors influencing the outcome of the intervention.

The primary outcomes were the differences between the control and intervention groups in changes in body weight, waist circumference, percent body fat, blood pressure and heart rate from baseline to 12 months and proportion who lost 5% of their baseline weight.

Interventions

The intervention combined evidence-based components recognized 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 high-risk situations and long-term support – and 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; goal setting.[25] It also has an emphasis on 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 emphasizes 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).[18] Six CAMWEL advisors were recruited from various occupational backgrounds including healthcare, in line with the NHS health trainers initiative.[29] The advisors received initial training over two days, and further meetings with the research team every three to four 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 behaviour 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'. Participants were invited to attend 30-minute sessions with the advisor every fortnight for the first 12 weeks, three-weekly for 12 weeks, and finally monthly for the next 12 weeks, making a total of 14 sessions. 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,[30] a kit including 100 calorie portions of various food items, Adams Food and Alcohol Portion Pots (www.adamsportionpot.com). 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).

There is no current comparator 'gold standard' treatment programme available for weight management in general practice. In this pragmatic trial of a complex intervention, we assess the benefit of the intervention compared to routine clinical practice. We provided a copy of the Quick reference NICE clinical guideline on Obesity to all participating 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 (BHF) booklet: 'So you want to lose weight … for good'.[31]

Recruitment

All general practices in Camden were visited and invited to participate in the trial. Participants were recruited between July 2009 and January 2010 from 23 of 39 NHS Camden general practices. The London Borough of Camden has areas of relative affluence alongside areas of relative deprivation, with approximately 35% of the population living in areas classified as some of the most deprived in England.[32] Education levels are also disparate, with 47% of people in employment being educated to degree level or above, whilst 17% of working age people have no qualifications.[33] Camden has an ethnically diverse population, with 27% belonging to minority ethnic groups.[33]

Several recruitment approaches were used. Primarily, participating practices wrote to a sample of patients with body mass index (BMI) ≥25 kg/m^2; GPs and Practice Nurses (PNs) were provided with referral 'prescription' pads with a tear-off slip to be given to the patient with contact details of the trial office; and posters and flyers were placed in practice waiting areas and local pharmacies. During the final six weeks of the recruitment period, three practices supplemented recruitment by sending text messages to potentially eligible patients using their electronic record (EMIS) and messaging (iPLATO) systems. All practices were reimbursed for time spent on recruitment.

Baseline measurements

Potential participants were screened by telephone for eligibility (MH, EH, TP). Inclusion criteria were age 18 years and above, BMI≥ 25 kg/m^2, attending a participating practice and willing to attend visits with a CAMWEL advisor over 12 months. Exclusion criteria were pregnancy or lactation, diagnosis of renal failure, use of a pacemaker, recent diagnosis of cancer, or participation in another weight management study. Following GP consent,

participants were scheduled for screening appointments with a researcher (MH) at one of three practices. The study was explained and the participant invited to give informed written consent and to complete the baseline questionnaire. Height (without shoes) was 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 percent body fat, basal metabolic rate and metabolic age (age expected for a given value of basal metabolic rate). Waist was measured mid-way 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 where possible. The printout from the Tanita scales, including weight, BMI and metabolic age, was given to all participants.

Outcomes

All participants were invited for follow up at 6 and 12 months. A letter was sent three weeks prior to the due date, followed by a telephone call to arrange the appointment. Three attempts were made to contact each participant. Measurements taken at baseline were repeated and participants were asked to complete a questionnaire. A £30 voucher was provided for their time to all participants who completed each follow-up appointment.

The self-completed questionnaires included the following validated measures: EuroQol Visual Analogue Scale (EQ-VAS), Obesity and Weight Loss Quality-of-Life (OWLQOL)[34]; Hospital Anxiety and Depression Scale (HADS)[35]; Rosenberg measure of self-esteem[36]; Duke-UNC Functional Social Support Questionnaire (FSSQ)[37]; Three-Factor Eating Questionnaire (TFEQ-18)[38]; and physical activity (RPAQ)[39]; as well as socio-demographic information. Deprivation was ascertained using the Index of Multiple Deprivation (IMD) based on the participant's home address post code.[40]

In addition, at follow-up we used the Patient Assessment of Care for Chronic Conditions (PACIC) [41, 42] to assess the participants' views on the care they received from the advisors and the GP practice on helping them lose weight. A brief series of statements was used to assess participants' confidence in their ability to manage their weight on a scale of one (disagree strongly) to four (agree strongly). Further questions asked about the type of help received from the GP practice regarding weight loss, changes made in behaviours related to weight management, and experience of study participation. Participants in the intervention group also completed an additional section to ascertain how helpful they found the sessions and materials provided as part of the CAMWEL programme.

Randomization

Participants were randomly allocated (allocation ratio 1:1) to the control or intervention group (TP, EH, AS), using a computer-generated randomization application written in VBA for MS Access (TP). The Taves method of minimization[43] was used to ensure the groups were balanced for general practice, gender, age group (≤50/ >50 years), BMI category (≤30/>30 kg/m^2), diagnosis of diabetes (yes/no), and taking anti-psychotic medication or not.

Blinding

The study was single-blinded with members of the study team assessing baseline and follow-up measurements blinded to group assignment.

Sample size

In our pilot study participants had a mean weight of 98.1 kg (SD 17.3 kg) at baseline.[18] Since a loss of 5-10% of body weight in obese adults is associated with significant reductions in the risk of obesity co-morbidities, we considered a difference in weight between groups of 7% at 12 months follow-up to be clinically important. For the sample size calculation, we wished to detect a mean weight difference of 6.9 kg 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 conservatively set at 0.7. We thus calculated a total sample size of 228 (114 per group). Assuming a loss to follow up at 12 months of 40%,[44] it was estimated that 380 participants would be required.

Statistical methods

Comparisons between groups for continuous variables were performed using two-sample t-tests and regression methods, adjusting for the baseline value of the variable. Chi-sq 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. Exclusion of subjects with missing data is inefficient and can lead to biased results if those dropped are atypical in some respect[45] and MI can both increase efficiency and reduce bias in such settings.[46,47] 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.[48] 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. For all outcomes the following baseline variables were included: age, weight, percent body fat, BMI, fat mass, metabolic age, deprivation status and employment status as well as totals from the OWLQOL, EQVAS, HADS anxiety, TFEQ emotional eating and RPAQ scales. The imputation procedure was carried out separately for the two groups (intervention and control) and the resulting multiply imputed datasets were combined for the final MI analysis. A total of 200 imputations were used to stabilize the results and to ensure negligible loss of power.[45] Analyses using only data on participants who completed 12-month follow-up were also conducted.

Exploratory analyses 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 version 11.

Ethical approval

The study was approved by the London School of Hygiene & Tropical Medicine Ethics Committee, the Camden and Islington Community Research Ethics Committee (reference number 09/H0722/22) and the North Central London Research Consortium.

Results

Participants were followed up at 6 months between January 2010 and July 2010; and at 12 months between July 2010 and January 2011. Participant flow through the trial is shown in Figure 2.

Baseline characteristics

We recruited 381 participants with a median age of 48.5 years (inter-quartile range 37.5 to 60.4), weighing 60.1 to 152.2 kg, with waist circumference of 76 to 147 cm. The majority (72%) were women, 12% (47/381) had diagnosed diabetes, 1.3% (5/381) were on anti-psychotic medication, 60% were in employment, 47% were university graduates and 73% described their ethnicity as white (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

Measurements were obtained for 69% (n=263) of the sample at 6 months and 57% (n=217) at 12 months. 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 percent body fat, and were less likely to be from a deprived area than those not followed up (Table 2).

Primary Outcomes

Based on the intention-to-treat analysis using imputed missing values (Table 3), at 12 months 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 when compared to usual care group (odds ratio 1.73 (1.38 to 2.66, P=0.04). The intervention programme was also associated with weak evidence of beneficial trends in waist circumference, percent body fat, and percent weight change. Heart rate was reduced by 3.7 (0.3 to 7.0, P=0.03) beats per minute in the intervention group compared to the control group.

Based on data for participants who completed the 12-month follow-up (Table 3) a higher proportion (one in three compared to one in five) in the intervention group had lost at least 5% of their initial weight (difference 14.7% (3.0 to 26.4, P=0.01)) and experienced a greater average reduction in waist circumference (difference 1.88 cm (0.01 to 3.76, P=0.05)) compared to those in the control group. Weak evidence of reductions in weight, %body fat, BMI, blood pressure and heart rate were observed in the intervention compared to the control group. The absolute risk reduction for losing 5% baseline weight was 14.7 % (3.0 to 26.4) and the number needed to treat was 6.8 (3.8 to 33.2). A higher proportion of those in the intervention group (84%, 21/25) who had lost ≥5% at 6 months had managed to keep this level of weight loss at 12 months compared to those in the control group (61.5%, 8/13). We were unable to identify characteristics of the sub-group of participants more likely to lose 5% of their baseline weight.

Secondary Outcomes

No evidence of differences was found between the two groups on any of the psychological or quality of life measures.

Trial participation

Participants in the intervention group were more satisfied than those in the control group with the level of weight loss achieved and they found participation in the trial and feedback of physical measurements helpful (Table 4). The intervention group also reported receiving more patient centred care than those in the control group as measured by the PACIC scales (Table 5). Detailed analysis of the interviews and focus groups with a sub-set of the participants will be reported elsewhere.

The intervention programme

Participants reported that regular meetings with the advisor was the most helpful aspect of the programme; the least helpful was the handouts provided (Table 6). The most helpful sessions were the first (getting started), eighth (positive thinking) and twelfth (staying active). The most helpful handouts were 'Rate Your Plate', 'CAMWEL Walks' and 'Staying Active', the least helpful were 'Building A Better Recipe' and 'Meal Plans'. The majority (84%) said they would choose to continue to meet an advisor beyond the 12 months of the current study, with most (73%) preferring to see the advisor at least every four weeks.

Behaviours associated with losing 5% or more of baseline weight

Participants who lost 5% or more of their baseline weight were more likely to state that they had reduced their fat and sugar intake in the previous six months than those who did not; there was no evidence of increasing levels of physical activity between the groups (Table 7). They also reported that attending regular meetings with a non-judgmental advisor, discussion on portion sizes and use of the pedometer were particularly useful and would continue to monitor food intake to maintain their weight.

Exploratory analysis

38 participants were known to have been prescribed drugs for weight loss or to have undergone weight loss surgery during the trial period. Of these, 27 were 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, p = 0.69). In analysis excluding these participants, those in the intervention group showed significantly greater reductions in weight (1.72 kg (0.29 to 3.14, P= 0.02)), waist circumference (2.52 cm (0.32 to 4.72, P=0.03)), BMI (0.63 kg/m2 (0.11 to 1.14, P=0.02)) and percent baseline weight loss (1.94% (0.32 to 3.56, P=0.02)) when compared with the control group at 12 months. In addition, a higher proportion of participants in the advisor group lost ≥5% of their baseline weight when compared to the control group (odds ratio 2.68 (1.13 to 5.70, P=0.03)).

The number of sessions attended was available for 87 participants of whom 40 > (46%) attended more than 70% (10/14) of the available sessions. Half (50%) of the participants attending more than 70% of the programme lost 5% or more of their baseline weight compared to a quarter (23%) who attended fewer sessions (difference 26.5%; 95%CI: 6.9 to 46.3; p=0.01).

Discussion

Principal findings

The structured one-to-one weight loss programme delivered by non-specialists in general practice did not achieve the pre-specified difference in average weight loss of 7%. However it did result in a higher proportion of the participants losing 5% or more of their baseline weight compared to those randomized to usual care (odds ratio 1.73 (1.38 to 2.66)) which is considered a clinically important outcome in similar trials. This suggests that people likely to benefit from such a programme are a subset of the total study population but we were unable to identify particularcharacteristics that would permit identification of a receptive group in advance. There was some evidence that the intervention group experienced greater reductions in mean weight, waist circumference and % body weight than the control group. While the overall effects on weight loss are modest they are not unimportant.

Strengths and weaknesses of the study

The key strengths of the CAMWEL programme are its wide applicability to overweight and obese people from diverse backgrounds as there were few exclusions, feasibility of its delivery in primary care by non-specialist trained advisors and a patient-centred approach to making sustainable changes to diet and physical activity easily incorporated into peoples' daily lives.

Limitations include the slow initial recruitment although this improved over time, particularly with mobile phone text message use.[49] Loss to follow up was high (43%) although similar to that of other weight loss studies in the UK.[50, 51 52 53]The response rate in the DESMOND diabetes management trial[19] was substantially higher (91%), perhaps because participants were recently diagnosed diabetics and therefore highly motivated. High attrition in RCTs of weight loss is well recognized,[54] with a recent review reporting losses to follow-up of 30-60%.[44]

We used multiple imputation for missing values in primary outcomes to counter any biases due to loss to follow-up as high level of attrition involves considerable uncertainty about outcomes for participants lost to follow-up. We included patients with BMI≥25 as NICE recommends treatment at this level although this relatively low threshold and broad inclusion criteria may have diluted the results in terms of average weight loss thus needing a larger sample to detect significant differences.

Participants in the control group were advised to contact their general practice to receive the usual care provided for weight loss. We provided all GPs with NICE guidelines on obesity and participants with the BHF booklet on weight loss as well as feedback on the measurements taken at six months. This provision of support could be one reason why participants in the control group also lost weight over the period of the trial which resulting in greater similarity of changes in the two groups and would represent bias if the GPs altered their usual care by virtue of trial participation. Another study[55] suggested participants may be disappointed by allocation to usual care when they had entered the trial with preferences for allocation to the intervention group. The response to disappointment may trigger behaviour change and contribute to the weight loss seen in the control group and thus entail performance bias (McCambridge, personal communication).

Behaviour change interventions tend to be complex with multiple components and it is difficult to assess the effectiveness of different components. This was a pragmatic trial reflecting the likely performance of the programme as delivered in practice. While the fidelity of the delivery of the intervention could be examined in more detail, we have shown that patient assessment of the structured support by trained advisors is significantly better than usual care.

Cost-effectiveness analyses are required to inform decision-making about the value of attaining these outcomes and will be reported in a separate paper.

Putting the study in context

Seven published RCTs of similar interventions conducted in UK general practice have been conducted (see Table 8). With the exception of a trial in newly diagnosed diabetics, these provided no strong evidence of differences in weight loss between intervention and control groups, except for those using a commercial provider (Weight Watchers). Our trial achieved results at least comparable with the more targeted interventions based in general practice.

Implications

We have demonstrated that one-to-one structured support by a trained advisor in general practice can help people wishing to lose weight to change their behaviour sufficiently to lead to a clinically important loss in weight. Understanding how the intervention worked and why it worked just for some participants as well as its cost-effectiveness are important and we will explore these in our subsequent research. The importance of our results lies in their generalisability. Our results, together with those from other researchers, suggest that individual approaches in general practice can achieve modest benefits for the National Health Service. However, primary care interventions are unlikely to be sufficient to address the obesity epidemic and effective population wide policy measures are needed as well, including increasing energy expenditure through active travel[56] and reducing dietary intake.

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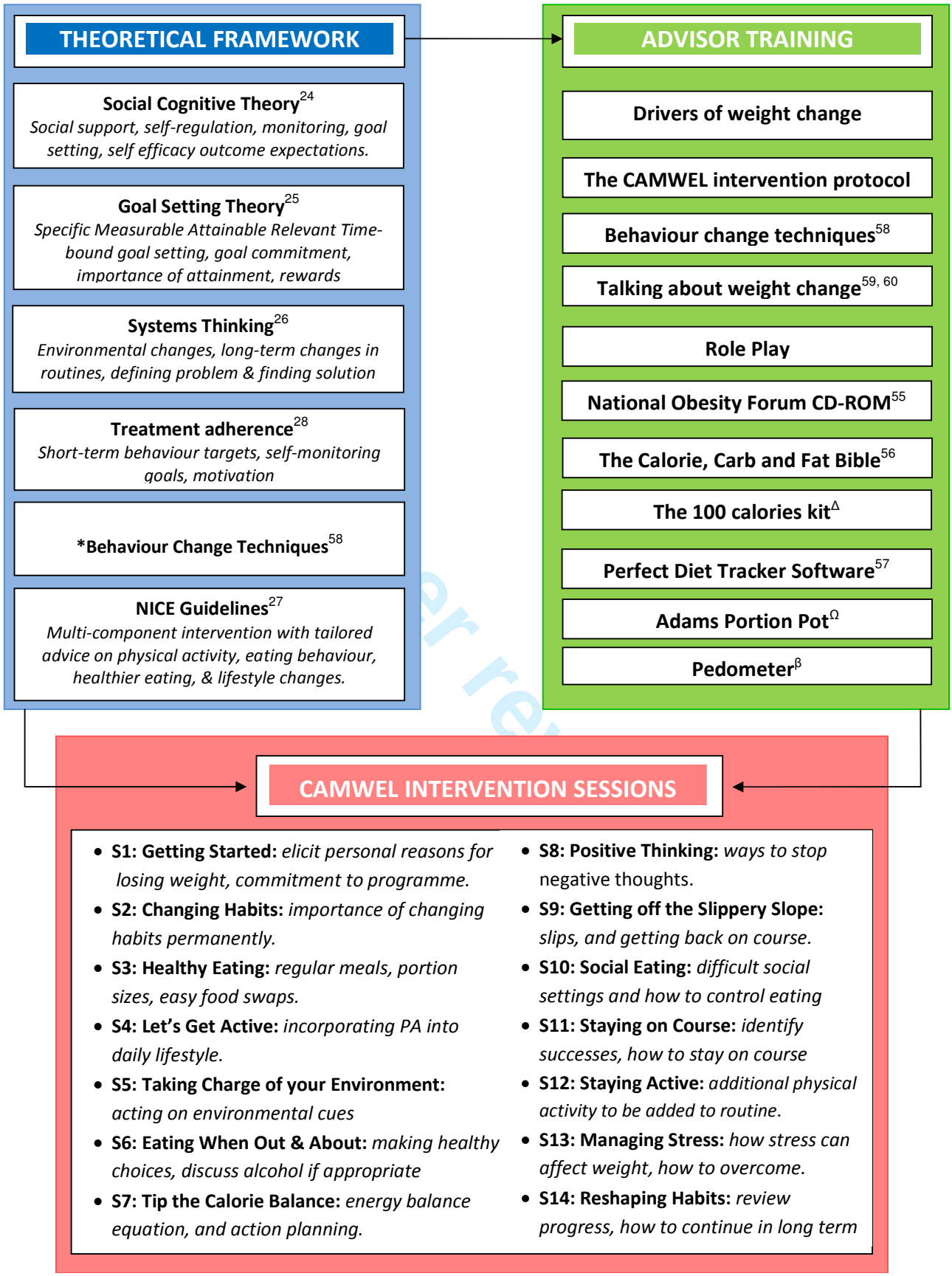
Competing interest

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that KN, TP, EH, MH, AS, UG and JT 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.

All authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis

Data sharing: no additional data available.

Figure 1: CAMWEL Intervention Framework



* Provide information on consequences, Prompt intention formation, Prompt barrier identification, Provide general encouragement, Model or demonstrate behaviour, Prompt specific goal setting, Prompt review of behavioural goals, Prompt self-monitoring of behaviour, Provide feedback on performance, Agree on behavioural contract, Plan social support, Prompt self-talk, Relapse prevention, Stress management, Motivational interviewing.

[Δ] *The 100 Calories Kit was designed by the CAMWEL Team, and was made up of 100 calorie portions of a variety of foods such as crisps, rice, pasta, biscuit, peanuts, and raisons.*

[β] *The pedometers used were DW701 Yamax Digiwalker for BMI<35, and NEW-LIFESTYLES NL-800 for BMI>35.*

[Ω] *Adams Portion Pot – www.adamsportionpot.com*

Figure 2 Flow of participants through the trial

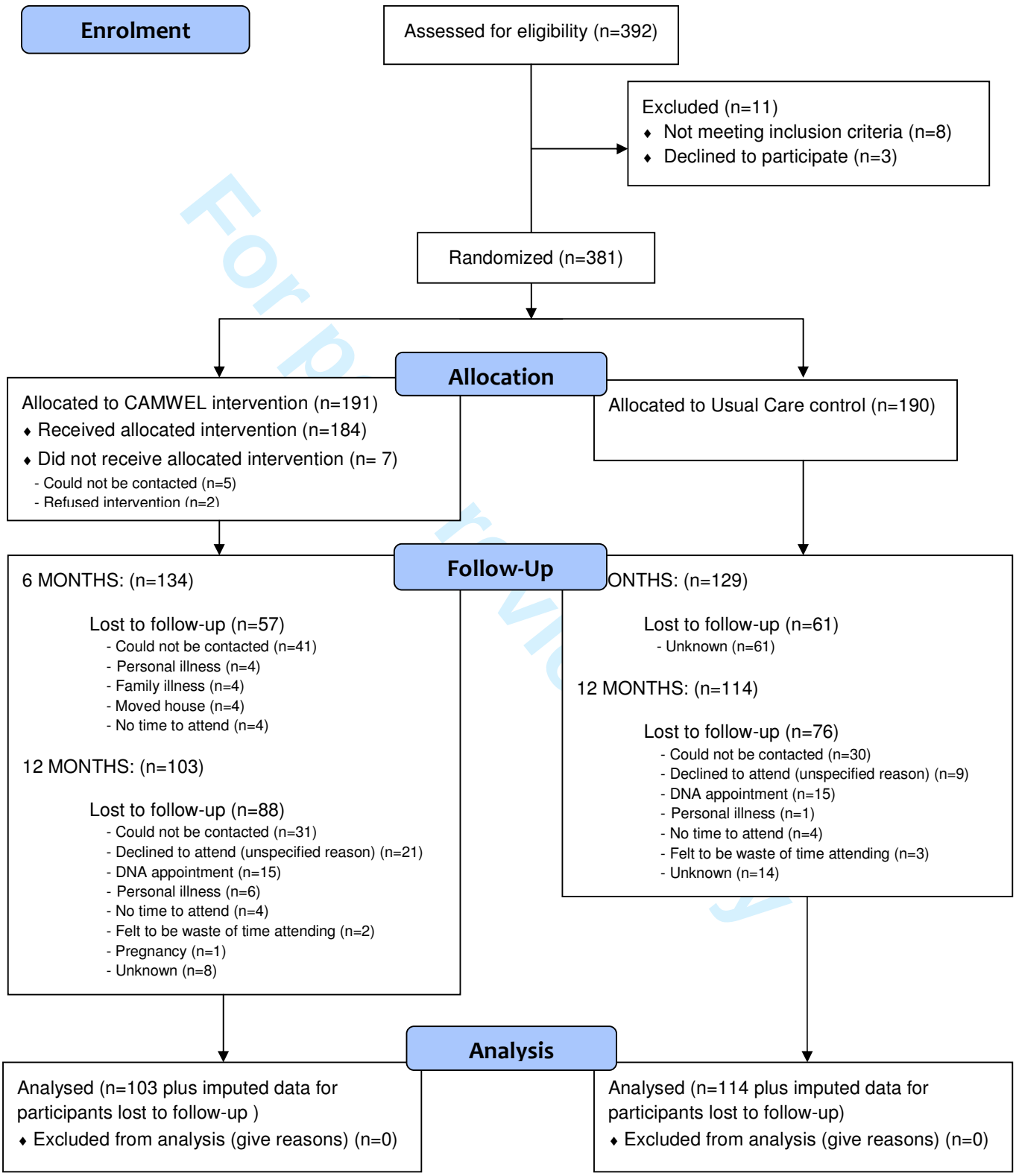


Table 1 Baseline characteristics of participants wishing to lose weight allocated to usual care (control) or to the CAMWEL programme (intervention). Values are means (standard deviations) unless stated otherwise. [Number of subjects may differ for each variable]

Characteristics	Control group (n=190)		Intervention group (n=191)		All (n=381)	
Age (years)	49.35	(15.45)	48.17	(14.09)	48.76	(14.77)
Age group (years)						
18- <35	20.53	(39)	20.94	(40)	20.73	(79)
35- <50	32.63	(62)	31.41	(60)	32.02	(122)
50- <60	19.47	(37)	24.08	(46)	21.78	(83)
≥60	27.37	(52)	23.56	(45)	25.46	(97)
Body weight (kg)	90.95	(18.12)	93.70	(18.40)	92.33	(18.29)
Waist circumference (cm)	105.83	(13.01)	107.56	(12.78)	106.70	(12.91)
Percent body fat	38.90	(7.83)	39.45	(8.06)	39.18	(7.93)
Fat mass (kg)	35.83	(12.82)	37.28	(12.70)	36.52	(12.76)
Muscle mass (kg)	52.18	(10.05)	53.39	(10.55)	52.76	(10.30)
Body mass index (kg/m^2)	33.02	(5.40)	33.92	(5.64)	33.47	(5.53)
% (n) BMI 25-<30	31.05	(59)	25.65	(49)	28.35	(108)
% (n) BMI ≥30	68.95	(131)	74.35	(142)	71.65	(273)
Systolic blood pressure (mm Hg)	126.42	(20.44)	127.43	(20.17)	126.92	(20.28)
Diastolic blood pressure (mm Hg)	82.15	(12.36)	83.40	(12.83)	82.77	(12.59)
Heart Rate (beats per minute)	76.68	(12.05)	75.94	(12.03)	76.32	(12.03)
Demographic details, % (n)						
Gender: Female	72.63	(138)	71.73	(137)	72.18	(275)
Ethnicity: White	70.63	(101)	74.25	(124)	72.58	(225)
Education						
No qualifications	14.19	(21)	8.82	(15)	11.32	(36)
O/A-level or equivalent	27.71	(41)	38.23	(65)	33.33	(106)
University degree	48.65	(72)	44.71	(76)	46.54	(148)
Employment						
Employed full-time	37.50	(57)	49.12	(84)	43.65	(141)
Employed half-time	19.08	(29)	14.04	(24)	16.41	(53)
unemployed	43.42	(66)	36.84	(63)	39.94	(129)
Area Deprivation (IMD)						
Lowest quartile (deprived)	26.06	(49)	23.94	(45)	25.00	(94)
2nd	25.00	(48)	23.40	(44)	24.20	(91)
3rd quartile	25.53	(47)	25.00	(47)	25.27	(95)
Highest quartile (affluent)	23.40	(44)	27.66	(52)	25.53	(96)
Family member overweight	78.67	(118)	77.33	(133)	77.95	(251)
Quality of Life (range of values for each scale)						
EQ-VAS (0, 100)	48.22	(30.18)	47.42	(30.68)	47.80	(30.40)
Self-esteem (1, 30)	18.51	(6.01)	18.95	(5.89)	18.74	(5.94)
Social support (1, 5)	3.84	(1.03)	3.91	(1.02)	3.87	(1.03)
Depression (0, 19)	6.07	(4.20)	6.34	(4.31)	6.21	(4.25)
Anxiety (0, 19)	7.81	(4.32)	8.66	(4.83)	8.25	(4.60)
Obesity-related QoL (0, 102)	51.29	(26.71)	48.55	(25.47)	49.85	(26.06)

EQ-VAS=EuroQol Visual Analogue Scale; Qol= Quality of Life

Table 2 Comparison of baseline characteristics of participants followed up at 12 months and those lost to follow-up (Mean (St Error) unless otherwise stated)

	Followed-up		Lost to follow-up		Difference (Lost to follow-up – Followed-up)		
					Mean	(95% CI)	P value
Number (%)	217	(57.0)	164	(43.0)			
Age (years)	51.22	(1.01)	45.50	(1.10)	-5.72	(-2.77 to -8.68)	<0.001
Weight (kg)	90.86	(1.19)	94.26	(1.48)	3.39	(-0.31 to 7.10)	0.072
Waist (cm)	106.50	(0.89)	106.96	(0.99)	-0.46	(-2.18 to 3.10)	0.732
%body fat	38.47	(0.55)	40.10	(0.60)	1.63	(0.02 to 3.24)	0.048
BMI (Kg/m^2)	32.92	(0.37)	34.18	(0.44)	1.26	(0.14 to 2.37)	0.028
Metabolic age (years)	60.70	(0.98)	56.50	(1.08)	-4.20	(-1.28 to -7.06)	0.005
Fat mass (kg)	35.26	(0.93)	38.14	(1.07)	2.88	(0.10 to 5.67)	0.043
Muscle mass (kg)	52.49	(0.76)	53.10	(0.86)	0.61	(-1.65 to 2.87)	0.60
Basal Metabolic Rate (kcal)	1682	(23.17)	1721	(27.23)	39.0	(-31.0 to 109.0)	0.27
% (n) Female	70.97	(154)	73.78	(121)	2.81	(-6.23 to 11.86)	0.54
% (n) Married/cohabiting	45.36	(83)	48.00	(60)	2.64	(-8.70 to 13.99)	0.65
% (n) White ethnicity	73.02	(138)	71.90	(87)	-0. 11	(-11.32 to 9.10)	0.83
% (n) No qualifications	13.16	(25)	8.59	(11)	-4.56	(-11.40 to 2.27)	0.21
% (n) Employed	81.68	(107)	71.90	(87)	-9.78	(-20.17 to 0.61)	0.06
% (n) Deprived area	19.16	(41)	32.72	(53)	13.55	(4.61 to 22.50)	0.003
Self-esteem	19.14	(0.44)	18.15	(0.55)	-0.99	(-2.38 to 0.40)	0.16
Social support	3.86	(0.08)	3.91	(0.09)	0.05	(-0.18 to 0.29)	0.64
Anxiety	4.73	(0.14)	5.13	(0.16)	0.40	(-0.01 to 0.82)	0.06
Depression	3.51	(0.13)	3.68	(0.17)	0.17	(-0.23 to 0.59)	0.40
EQ-VAS	62.44	(1.53)	54.92	(2.31)	-7.52	(-2.05 to-12.98)	0.007
Obesity and Weight- related Quality of Life	47.31	(1.89)	53.56	(2.37)	6.25	(0.33 to 12.18)	0.039

EQ-VAS=EuroQol Visual Analogue Scale

Table 3 Changes in outcomes at 6 and 12 months and treatment differences between participants wishing to lose weight allocated to a structured one-to-one weight loss programme (intervention) or to usual care (control).

Variables	Unadjusted change from baseline (95% confidence interval)				Average difference between groups (intervention-control)	T-test/ Chisq	Difference between groups based on multiple imputation* (§odds ratio)	P value
	Control group		Intervention group					
	Number	Mean (95% CI)	Number	Mean (95% CI)	Mean (95% CI)	p value		
Weight (kg)								
6 months	129	-0.95 (-1.74 to -0.16)	134	-1.73 (-2.47 to -0.99)	-0.78 (-1.85 to 0.30)	0.16	-0.69 (-1.80 to 0.41)	0.22
12 months	114	-1.31 (-2.23 to -0.37)	103	-2.39 (-3.46 to -1.31)	-1.08 (-2.49 to 0.32)	0.13	-0.70 (-2.17 to 0.76)	0.35
Waist circumference (cm)								
6 months	125	-2.19 (-3.12 to -1.26)	129	-3.36 (-4.42 to -2.29)	-1.17 (-2.58 to 0.24)	0.10	-0.90 (-2.35 to 0.55)	0.22
12 months	112	-1.49 (-2.59 to -0.40)	100	-3.37 (-4.91 to -1.82)	-1.88 (-3.76 to -0.01)	0.05	-1.22 (-3.10 to 0.66)	0.20
% body fat								
6 months	125	-0.12 (-0.66 to 0.42)	131	-0.89 (-1.36 to -0.43)	-0.77 (-1.48 to -0.06)	0.03	-0.77 (-1.51 to -0.04)	0.04
12 months	111	-0.23 (-1.02 to 0.57)	101	-0.72 (-1.27 to -0.15)	-0.49 (-1.47 to 0.49)	0.32	-0.71 (-1.71 to 0.28)	0.16
Percent weight loss								
6 months	129	-1.04 (-1.88 to -0.20)	134	-1.78 (-2.51 to -1.05)	-0.74 (-1.85 to 0.36)	0.19	-0.73 (-1.91 to 0.44)	0.22
12 months	114	-1.38 (-2.39 to -0.37)	103	-2.59 (-3.65 to -1.54)	-1.21 (-2.66 to 0.23)	0.10	-0.79 (-2.37 to 0.79)	0.33
% lost ≥5% baseline weight								
6 months	129	13.18 (7.34 to 19.02)	134	23.88 (16.66 to 31.10)	10.70 (1.41 to 19.98)	0.03	1.77 (1.36 to 2.83) §	0.06
12 months	114	19.30 (12.05 to 26.54)	103	33.98 (24.83 to 43.13)	14.68 (3.01 to 26.35)	0.01	1.73 (1.38 to 2.66) §	0.04
Body mass index (kg/m^2)								
6 months	129	-0.36 (-0.65 to -0.07)	134	-0.60 (-0.86 to -0.34)	-0.24 (-0.63 to 0.14)	0.22	0.20 (-0.18 to 0.59)	0.30
12 months	114	-0.48 (-0.82 to -0.13)	103	-0.83 (-1.22 to -0.44)	-0.35 (-0.87 to 0.16)	0.18	0.34 (-0.18 to 0.85)	0.20
Systolic blood pressure (mm Hg)								
6 months	121	-2.92 (-6.56 to 0.73)	128	0.29 (-3.54 to 4.12)	3.20 (-2.07 to 8.45)	0.23	3.33 (-1.34 to 8.00)	0.16
12 months	103	-0.97 (-5.02 to 3.07)	90	-0.71 (-3.97 to 2.54)	0.25 (-5.01 to 5.50)	0.92	-0.01 (-4.65 to 4.64)	0.99
Diastolic blood pressure (mm Hg)								
6 months	121	-2.29 (-4.70 to 0.12)	128	-1.52 (-3.98 to 0.95)	0.77 (-2.66 to 4.21)	0.66	1.87 (-1.12 to 4.87)	0.22
12 months	103	0.83 (-1.89 to 3.56)	90	-0.68 (-2.83 to 1.46)	-1.51 (-4.96 to 1.93)	0.39	-1.59 (-4.77 to 1.60)	0.33
Heart Rate (beats per minute)								
6 months	120	2.38 (0.21 to 4.55)	127	-0.47 (-2.79 to 1.85)	-2.86 (-6.02 to 0.31)	0.08	-2.42 (-5.47 to 0.62)	0.12
12 months	104	-0.23 (-2.82 to 2.36)	90	-2.68 (-5.33 to 0.02)	-2.44 (-6.14 to 1.25)	0.19	-3.68 (-7.04 to -0.31)	0.03

*For all outcomes the following baseline variables were included: age, weight, percent body fat, BMI, fat mass, metabolic age, deprivation status and employment status as well as totals from the OWLQOL, EQVAS, HADS anxiety, TFEQ emotional eating and RPAQ scales.

Table 4: Participant satisfaction with care received by allocation group at 12 months

	Intervention		Control		Difference between groups (Intervention – Control)	
	n/N	% (se)	n/N	% (SE)	% (95% CI)	P value
Satisfied with level of weight loss achieved	37/60	61.7 (6.3)	14/61	23.0 (5.4)	38.7 (22.5 to 54.9)	<0.0001
Found participating in CAMWEL helpful in meeting goals	51/59	86.4 (4.4)	27/60	45.0 (6.4)	41.4 (26.1 to 56.8)	<0.0001
Found getting feedback on physical measurements at baseline & 6 months helpful	39/58	67.2 (6.3)	20/57	35.1 (6.3)	32.2 (14.9 to 49.5)	<0.0001
Found BHF booklet[31] helpful	50/58	86.2 (4.5)	38/53	71.7 (6.2)	14.5 (0.0 to 29.5)	0.06

Table 5: Participant assessment of care received by allocation group at 12 months

	Intervention		Control		Difference between groups (intervention-control)	
	n	Mean (SE)	n	Mean (SE)	Mean (95% CI)	P Value
Patient Assessment of Care for Chronic Conditions (PACIC)*						
Patient Activation	58	3.29 (0.17)	56	1.46 (0.13)	1.83 (1.40 to 2.26)	<0.0001
Asked for my ideas						
Given choices						
Asked about any problems						
Delivery System Design/ Decision Support	58	3.79 (0.14)	55	1.70 (0.16)	2.09 (1.68 to 2.50)	<0.0001
Written list of things to do						
Care well organised						
How what I do influences weight						
Goal Setting	58	3.35 (0.13)	54	1.64 (0.14)	1.71 (1.32 to 2.09)	<0.0001
Asked to talk about my goals						
Helped to set specific goals						
Given copy of my weight loss plan						
Encouraged to attend sessions						
Asked questions about health habits						
Problem Solving/ Contextual Counselling	58	3.34 (0.16)	56	1.66 (0.15)	1.69 (1.26 to 2.12)	<0.0001
Thought about my beliefs & traditions when making recommendations						
Helped to make plan for my daily life						
Plan ahead even for difficult circumstances						
Asked how weight affected me						

*Patient Assessment of Care for Chronic Conditions (PACIC) score [41, 42]

Table 6: Views of participants in the intervention group at 12 months follow-up regarding the helpfulness of different aspects of the intervention programme. The handouts are listed below the session when they were first introduced.

Intervention programme element	Percent	Helpful (SD)	n/N
Regular meetings with advisor	67.9	(47.1)	38/56
Agreeing small changes	60.0	(49.4)	33/55
Tracking changes	58.1	(49.8)	33/55
Discussing personalized goals	57.1	(50.0)	32/56
Use of pedometer	55.6	(50.2)	30/54
Receiving printout of weight change	50.0	(50.5)	27/54
Use of computer during meetings	46.3	(50.3)	25/54
Sequence of topics	32.7	(47.3)	18/56
Handouts in general	32.1	(47.1)	19/56
Use of handouts in improving eating habits	30.3	(46.4)	17/56
Session 1: Getting Started	50.9	(50.5)	28/55
Benefits of healthy habits	35.7	(48.3)	20/56
Recording your routines	36.4	(48.4)	20/55
Deciding to change	33.3	(47.5)	18/54
Behaviour change diary	17.0	(37.9)	9/53
Food diary	31.5	(47.1)	17/54
Activity diary	30.9	(46.6)	17/55
Session 2: Changing Habits	40.7	(49.6)	22/54
Just one more step	31.5	(46.9)	17/54
Problem solving	16.7	(37.6)	9/54
Build a better recipe	16.7	(37.6)	9/54
Session 3: Healthy Eating	40.7	(49.6)	22/54
Rate your plate	34.5	(50.0)	19/55
Easy food swaps	29.6	(46.1)	16/54
Healthy drinks	23.6	(42.9)	13/55
EatWell	37.0	(48.7)	20/54
Session 4: Being Active	42.6	(49.9)	23/54
Being active handout	34.5	(48.0)	19/55
Cut the fat and sugar	36.3	(48.5)	20/55
Steps chart	28.8	(45.7)	15/52
CAMWEL walks	42.6	(49.9)	23/54
	35.9	(48.4)	19/53
Session 5: Taking charge of your environment			
Eat well on the cheap	27.8	(45.2)	15/54
Your environment	20.4	(40.7)	11/54
Goals and rewards	31.5	(46.9)	17/54
Session 6: Eating Out	30.2	(46.3)	16/53
Eating when out and about	31.5	(46.9)	17/54
Alcohol and your diet	25.9	(44.2)	14/54
Session 7: Tipping the balance	32.7	(47.4)	17/52
Tipping the balance	18.5	(39.2)	10/54
Session 8: Positive thinking	45.3	(50.3)	24/53
Positive thinking	29.6	(46.1)	16/54
Session 9: Getting off the slippery slope	34.6	(48.0)	18/52
Slippery slope	22.2	(42.0)	12/54
Change 4 life local walking map[62]	20.4	(40.7)	11/54
Session 10: Social Eating	32.1	(47.1)	17/53
Social eating	24.5	(43.4)	13/53
Session 11: Staying on course	37.7	(48.9)	20/53
Staying on course	20.8	(40.9)	11/53
Healthy snacking	25.9	(44.2)	14/54
Meal plans	22.2	(43.0)	12/53
Indian meal plans	15.1	(36.1)	8/53
Meal plans, minimum cooking	16.7	(37.6)	9/54
Session 12 Staying active	41.5	(49.7)	22/53
Staying Active	20.8	(40.9)	11/53
Party season	17.3	(38.2)	9/52
Session 13: Managing stress	34.0	(47.8)	18/53
Day-to-day stress	18.9	(39.5)	10/53
Session 14: reshaping habits	32.1	(47.1)	17/53
Reshaping habits	19.2	(39.8)	10/52
Travel Camden walking map[63]	27.8	(45.2)	15/54
Camden architecture walking guide[64]	26.9	(44.8)	14/52
Camden Belsize walk map[65]	29.6	(46.1)	16/54
Jubilee walkway map[66]	21.2	(41.2)	11/52
Get walking keep walking[67]	19.2	(39.7)	10/52

Table 7: Reported changes* in eating and activity habits by participants who lost 5% or more of baseline weight compared to those who did not.

	Lost 5% or more of baseline weight				Difference between groups (Yes – No)	
	Yes (N=41)		No (N=111)			
	n	%	n	%	% (CI)	P value
What changes have you made to your diet during the last 12 months? (Tick all that apply)						
Reduced my fat intake	35	85.4	66	59.5	25.9 (11.7 to 40.1)	0.003
Reduced my sugar intake	24	58.5	43	38.7	19.8 (22.0 to 37.4)	0.029
Reduced my portion sizes	28	68.3	58	52.3	16.0 (-0.97 to 33.0)	0.077
What changes have you made to your activity levels in the last 12 months? (Tick all that apply)						
Used the stairs instead of taking the lift	17	41.5	31	27.9	13.6 (-3.7 to 30.8)	0.111
Joined a gym specifically to lose weight	13	31.7	20	18.0	13.7 (-2.2 to 29.6)	0.069
Get off one stop earlier when travelling by bus or tube	8	19.5	16	14.4	5.1 (-8.7 to 8.9)	0.444
Walk rather than take car for journeys that are less than one mile	21	51.2	44	39.6	11.6 (-6.2 to 29.4)	0.200
How will you continue to manage your weight' will you						
Monitor your food intake?	32	78.1	59	52.7	25.4 (9.69 to 41.1)	0.005
Control your portions?	26	63.4	59	52.7	10.7 (-6.67 to 28.1)	0.237
Use a pedometer?	13	31.7	20	17.9	13.8 (-2.1 to 29.8)	0.065
Monitor your activity patterns?	23	56.1	44	39.3	16.8 (-0.86 to 34.4)	0.063

*Data missing for 75 participants who did not complete this section of the questionnaire.

Table 8: Studies on weight loss conducted in general practice in the UK with 12 months follow-up.

Study	Design	Intervention	Eligibility criteria	Weight (Kg) at baseline Mean (sd)	Percent (n/N) followed-up at 12 months	Mean weight change (Kg) at 12 months				Lost ≥5% baseline weight in intervention group % (95% CI)
						Intervention	Control	Difference (95% CI)	P value	
Moore et al BMJ (2003)[68]	Cluster RCT	Trained GPs, nurses	BMI≥30	-	67.7 (565/834)	-0.6	-0.9	1.0[1]	0.5	-
McConnon et al BMC (2007)[50]	RCT	Access to website	BMI≥30; Access to Internet	98.4 (17.4)	59.3 (131/221)	-1.3	-1.9	0.6 (1.4 to 2.5)	0.56	22
Davies et al, DESMOND BMJ (2007)[19]	RCT	Group sessions	Newly diagnosed Type 2 diabetes	-	90.9 (729/824)	-3.0	-1.9	-1.0 (-1.9 to -0.12)	0.03	-
Ross et al, Counterweight BJGP (2008)[51]	Audit	Trained practice nurses	BMI≥30; BMI≥28 with co-morbidities	-	45.2 (642/1419)	-3.0	-	-	-	31 (27 to 34)
Ahern et al, Weight Watchers BMC (2011)[69]	Audit	Weight Watchers meetings	BMI≥30; NHS Referral scheme	94.3 (IQR 83.7-107.7)	53	Median= -2.8	-	-	-	33
Jebb et al, Weight Watchers Lancet (2011)[52]	RCT	Weight Watchers meetings	BMI 27-35 + 1risk factor	86.7	57.5 (444/772)	-5.1	-2.2	-3.2 (-4.2 to -2.1)	<0.0001	47*
Jolly et al BMJ (2011)[53]	RCT	Various**	White BMI≥30/≥28 + co-morbidity S Asian BMI≥25/≥23 + co-morbidity	91.7 (17.9)	70.5 (522/740)	-3.5	-1.1	-2.5 (-4.2 to -0.8)	0.02	31 (22 to 41)
CAMWEL	RCT	One-to-one sessions	BMI≥25	92.3 (18.3)	57 (217/381)	-2.4	-1.3	-1.1 (-2.5 to 0.3)	0.13	34 (25 to 43)

[1]Difference between groups at 12 months; * based on graph in Table 3; ** range of commercial or primary care led programmes, intervention results given for Weight Watchers.

Appendix: The structure of the CAMWEL intervention programme

Session Number	Week	Topic Materials	Handouts	
1	0	Getting started: establish working relationship and good rapport with participant; elicit personal reasons for losing weight, build commitment to program, and introduce lifestyle changes approach. BHF 'So you want to lose weight' booklet	Sequence of topics Appointment card Benefits of Healthy Habits Recording your routines Deciding to Change	Behaviour Change Diary Food Diary Activity Diary
2	2	Changing habits: Review progress, explain importance of changing habits permanently and introduce the five steps to solving problems.	Problem Solving Build a Better Recipe Just One More Step	(Behaviour Change Diary) (Food Diary) (Activity Diary)
3	4	Healthy eating: Review progress, explain importance of regular meals, portion sizes, keeping a record and discuss making easy food swaps. (Adam Portion pots; 100 kcal portion size food box)	FSA EatWell booklet Rate Your Plate Easy Food Swaps Healthy Drinks Food labels card	(Activity Diary)
4	6	Let's get active: Review progress, explain importance of activity guidelines and discuss ways of incorporating physical activity into participant's lifestyle.	Being Active Your Guide to Walking in Camden Cut the fat and sugar Camden outdoor gyms	Steps chart Printed weight graph (Rate your plate)
5	8	Taking charge of your environment: Review progress, explain importance of cues and discuss ways of changing the environment to make losing weight the 'easy' option.	Your Environment Goals & Rewards Eat Well on the Cheap	(Rate your plate) (Steps Chart) Printed weight graph
6	10	Eating when out and about: Review progress, explain keys to making healthy choices when out and about and discuss alcohol if appropriate.	Healthy choices Alcohol and your diet Eating when out and about	(Rate your plate) (Steps chart)
7	12	Tip the calorie balance: Review progress at 3-month stage of programme; explain energy balance equation, importance of healthy eating, being active, social support and action planning.	Tipping the calorie balance Individual printed weight graph	(Steps Chart) (Rate your plate)
8	15	Positive thinking: Review progress and introduce ways to stop negative thoughts and 'talk back' with positive ones.	Positive Thinking Camden Walk4Life maps	(Food diary) (Activity diary) (Steps chart)

				(Rate your plate) (Behaviour Change Diary)
9	18	Getting off the slippery slope: Review progress, identify reasons for slips and ways of getting back on course.	Slippery Slope Camden Walk4Life maps BHF 'Healthy meals, Healthy Heart' or 'Food should be fun & healthy' menus Individual printed weight graph	
10	21	Social eating: Review progress, discuss social settings where it may be difficult to stay in control of eating healthily and ways to overcome this and enjoy healthy social eating.	Social eating Individual printed weight graph	
11	27	Staying on course: Review progress, identify successful changes made and identify situations where participant not in control and discuss ways of overcoming barriers.	Staying on course Healthy snacking 100 Calorie portions Meal plans- Indian/ Minimum cooking Individual printed weight graph	(Rate your plate) (Food diary) (Steps chart) (Activity Diary)
12	31	Staying active: Review progress; discuss additional changes made and how further activity can be added into lifestyle.	Staying active Individual printed weight graph	(Activity Diary) (Steps chart)
13	35	Managing stress: Review progress; discuss how stress affects weight and ways to manage stress.	Day to day stress Individual printed weight graph	(Activity Diary) (Steps chart) (Rate your plate) (Food Diary)
14	47	Reshaping habits: Review progress since start of programme; discuss ways of continuing to lose/ maintain changes in the long term.	Reshaping habits Cancer Research UK's Ten top tips Camden architecture & walking guide Travel Camden: Camden walking map; Belsize walk; Jubilee Walk Individual printed weight graph Certificate of Achievement	(Rate your plate) (Food Diary) (Steps chart) (Activity Diary)

References

1. Whitlock, G., et al., *Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies.* Lancet, 2009. **373**(9669): p. 1083-96.
2. WHO, *Global Health Risks: Mortality and burden of dieases attributable to selected major risks*. 2009, World Health Orgainisation: Geneva, Switzerland.
3. Finucane, M.M., et al., *National, regional, and global trends in body-mass index since 1980: systematic analysis of health examination surveys and epidemiological studies with 960 country-years and 9·1 million participants.* The Lancet, 2011. **377**(9765): p. 557-567.
4. Whitlock, G., S. Lewington, and C.N. Mhurchu, *Coronary heart disease and body mass index: a systematic review of the evidence from larger prospective cohort studies.* Semin Vasc Med, 2002. **2**(4): p. 369-81.
5. Haslam D, J.W., *Obesity.* Lancet, 2005. **366**: p. 1197-1209.
6. Foresight, *Tackling Obesities: Future Choices – Project Report.* 2007.
7. Craig R, M.J.e., *2010 Health Survey for England*. 2011, The NHS Information Centre: Leeds.
8. Perri, M.G., et al., *Extended-care programs for weight management in rural communities: the treatment of obesity in underserved rural settings (TOURS) randomized trial.* Arch Intern Med, 2008. **168**(21): p. 2347-54.
9. Perri, M.G., S.F. Sears, Jr., and J.E. Clark, *Strategies for improving maintenance of weight loss. Toward a continuous care model of obesity management.* Diabetes Care, 1993. **16**(1): p. 200-9.
10. Kinmonth, A.-L., et al., *Efficacy of a theory-based behavioural intervention to increase physical activity in an at-risk group in primary care (ProActive UK): a randomised trial.* The Lancet, 2008. **371**(9606): p. 41-48.
11. Wing, R.R. and S. Phelan, *Long-term weight loss maintenance.* Am J Clin Nutr, 2005. **82**(1 Suppl): p. 222S-225S.
12. Aucott, L., et al., *Weight loss in obese diabetic and non-diabetic individuals and long-term diabetes outcomes--a systematic review.* Diabetes Obes Metab, 2004. **6**(2): p. 85-94.
13. Poobalan, A., et al., *Effects of weight loss in overweight/obese individuals and long-term lipid outcomes--a systematic review.* Obes Rev, 2004. **5**(1): p. 43-50.
14. Avenell, A., et al., *Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement.* Health Technol Assess, 2004. **8**(21): p. iii-iv, 1-182.
15. Norris, S.L., et al., *Long-term effectiveness of weight-loss interventions in adults with pre-diabetes: a review.* Am J Prev Med, 2005. **28**(1): p. 126-39.
16. Norris, S.L., et al., *Long-term effectiveness of lifestyle and behavioral weight loss interventions in adults with type 2 diabetes: a meta-analysis.* Am J Med, 2004. **117**(10): p. 762-74.
17. Potter, M.B., J.D. Vu, and M. Croughan-Minihane, *Weight management: what patients want from their primary care physicians.* J Fam Pract, 2001. **50**(6): p. 513-8.
18. Nanchahal, K., et al., *Weight-management interventions in primary care: a pilot randomised controlled trial.* Br J Gen Pract, 2009. **59**(562): p. e157-66.
19. Davies, M.J., et al., *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 controlled trial.* BMJ, 2008. **336**(7642): p. 491-5.
20. Trueman, P., et al., *Long-term cost-effectiveness of weight management in primary care.* Int J Clin Pract, 2010. **64**(6): p. 775-83.
21. Wardle, J., Johnson, F., *Weight and dieting: examining levels of weight concern in British adults.* Int J Obes Relat Metab Disord, 2002. **26**(8): p. 1144-9.
22. Campbell, M., et al., *Framework for design and evaluation of complex interventions to improve health.* BMJ, 2000. **321**(7262): p. 694-6.

23. Jones, L.R. and T.A. Wadden, *State of the science: behavioural treatment of obesity.* Asia Pac J Clin Nutr, 2006. **15 Suppl**: p. 30-9.
24. Bandura, A., *Health Promotion by Social Cognitive Means.* Health Educ Behav, 2004. **31**(2): p. 143-164.
25. Locke, E.A. and G.P. Latham, *Building a practically useful theory of goal setting and task motivation : A 35-year odyssey.* American Psychologist, 2002. **57**(9): p. 705-717.
26. Alemi, F., et al., *Continuous self-improvement: systems thinking in a personal context.* Jt Comm J Qual Improv, 2000. **26**(2): p. 74-86.
27. NICE, *Obesity: Quick reference guide 2*. 2006, National Institute for Health & Clinical Excellence: London, UK.
28. Koenigsberg, M.R., D. Bartlett, and J.S. Cramer, *Facilitating treatment adherence with lifestyle changes in diabetes.* Am Fam Physician, 2004. **69**(2): p. 309-16.
29. Department of Health, *Health Trainers - Review to date*. 2009, Department of Health: London, UK.
30. Costain, L., Kellow, J, Walton, R, , *The Calorie, Carb and Fat Bible 2009*. 2009: Weight Loss Resources.
31. British Heart Foundation, *So You Want to Lose Weight... For Good*, in *British Heart Foundation*. 2005: London, UK.
32. *NHS Camden Annual Report & Accounts*. 2009/10, Camden Primary Care Trust
33. LHA, *Health Profile 2010: Camden*. 2010, Local Health Authority.
34. Patrick, D.L., D.M. Bushnell, and M. Rothman, *Performance of Two Self-Report Measures for Evaluating Obesity and Weight Loss.* Obes Res, 2004. **12**(1): p. 48-57.
35. Olsson, I., A. Mykletun, and A.A. Dahl, *The Hospital Anxiety and Depression Rating Scale: a cross-sectional study of psychometrics and case finding abilities in general practice.* BMC Psychiatry, 2005. **5**: p. 46.
36. Rosenberg, M., *Society and the Adolescent Self Image.* 1965, Princeton, NJ: Princeton University Press.
37. Broadhead WE, G.S., de Gruy FV, et al. , *The Duke-UNC Functional Social Support Questionnaire: measurement of social support in family medicine patients. .* Med Care, 1988. **26**(7): p. 709-723.
38. Karlsson, J., et al., *Psychometric properties and factor structure of the Three-Factor Eating Questionnaire (TFEQ) in obese men and women. Results from the Swedish Obese Subjects (SOS) study.* Int J Obes Relat Metab Disord, 2000. **24**(12): p. 1715-25.
39. Besson, H., et al., *Estimating physical activity energy expenditure, sedentary time, and physical activity intensity by self-report in adults.* Am J Clin Nutr. **91**(1): p. 106-114.
40. Department for Communities and Local Government, *The English Indices of Deprivation 2010*. 2010: London, UK.
41. Glasgow, R.E., et al., *Development and validation of the Patient Assessment of Chronic Illness Care (PACIC).* Med Care, 2005. **43**: p. 436 - 444.
42. Schmittdiel, J., et al., *Patient Assessment of Chronic Illness Care (PACIC) and improved patient-centered outcomes for chronic conditions.* J Gen Intern Med, 2008. **23**(1): p. 77-80.
43. Scott, N.W., et al., *The method of minimization for allocation to clinical trials. a review.* Control Clin Trials, 2002. **23**(6): p. 662-74.
44. Douketis, J.D., et al., *Systematic review of long-term weight loss studies in obese adults: clinical significance and applicability to clinical practice.* Int J Obes (Lond), 2005. **29**(10): p. 1153-67.
45. Carpenter JR, Kenward M *Missing Data in Clinical Trials - A Practical Guide.* UK National Health Service, National Co-ordinating Centre for Research on Methodology., 2008.
46. Rubin, D.B., *Multiple Imputation for Nonresponse in Surveys*. 1987: Wiley-Blackwell.
47. Kenward, M.G. and J. Carpenter, *Multiple imputation: current perspectives.* Stat Methods Med Res, 2007. **16**(3): p. 199-218.

48. Royston P, *Multiple imputation of missing values.* STATA Journal, 2004. **4**(3): p. 227-241.
49. Nanchahal, K., et al., *Challenges in recruitment to clinical trials and lessons learned from a randomized controlled trial of a weight management intervention in general practice*, in *XI International Conference on Obesity*. 2010, IASO: Stockholm, Sweden.
50. McConnon, A., et al., *The Internet for weight control in an obese sample: results of a randomised controlled trial.* BMC Health Serv Res, 2007. **7**: p. 206.
51. Ross, H., et al., *Evaluation of the Counterweight Programme for obesity management in primary care: a starting point for continuous improvement.* Br J Gen Pract, 2008. **58**(553): p. 548-54.
52. Jebb, S.A., et al., *Primary care referral to a commercial provider for weight loss treatment versus standard care: a randomised controlled trial.* Lancet, 2011. **378**(9801): p. 1485-92.
53. Jolly, K., et al., *Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: Lighten Up randomised controlled trial.* BMJ, 2011. **343**.
54. Inelmen, E.M., et al., *Predictors of drop-out in overweight and obese outpatients.* Int J Obes Relat Metab Disord, 2005. **29**(1): p. 122-8.
55. Thomas, E.C., P.R.; Paterson, S.M.; Dziedzic, K.; Hay, E.M., *What influences participants' treatment preference and can it influence outcome? Results from a primary care based randomised trial for shoulder pain.* British Journal of General Practice, 2004. **54**(499): p. 93-96.
56. Woodcock, J., et al., *Public health benefits of strategies to reduce greenhouse-gas emissions: urban land transport.* Lancet, 2009. **374**(9705): p. 1930-43.
57. NOF, *National Obesity Forum - Managing Obesity in Primary Care*. 2004.
58. Byoni, *Perfect Diet Tracker Software*. 2010.
59. Abraham, C. and S. Michie, *A taxonomy of behavior change techniques used in interventions.* Health Psychol, 2008. **27**(3): p. 379-87.
60. Miller, W.R. and G.S. Rose, *Toward a theory of motivational interviewing.* Am Psychol, 2009. **64**(6): p. 527-37.
61. Foreyt, J.P. and W.S. Poston, 2nd, *What is the role of cognitive-behavior therapy in patient management?* Obes Res, 1998. **6 Suppl 1**: p. 18S-22S.
62. National Health Service, *Change 4 Life - Get active with Camden's Walking Maps*, in *NHS Camden*. 2009: London, UK.
63. *Travel Camden: Camden Walking Map*. 2009, Z-Cards Ltd: London, UK.
64. *Camden Architecture & Walking Guide*. 2009, Z Cards Ltd: London, UK.
65. *Belsize Walk: Primrose Hill to Parliament Hill*. 2005: London, UK.
66. *Jubilee Walkway Route Map and Guide*. 2009: London, UK.
67. *Get Walking Keep Walking*, in *The Ramblers*. 2009: London, UK.
68. Moore, H., et al., *Improving management of obesity in primary care: cluster randomised trial.* BMJ, 2003. **327**(7423): p. 1085.
69. Ahern, A., et al., *Weight Watchers on prescription: An observational study of weight change among adults referred to Weight Watchers by the NHS.* BMC Public Health. **11**(1): p. 434.

Response to reviewers' comments received from the BMJ

Reviewer: 1, Maira Bes-Rastrollo

MAJOR CONCERNS:
1)It is not clear for the reader how the authors did proceed with those participants who already took any kind of medication for weight loss or were on a special diet. Maybe, they should conduct exploratory analyses excluding those participants and explain how this fact could affect the results.

We included results on this p10 under Exploratory analysis.

2) Similarly, it is not clear to me, if the authors did take into account the incidence of chronic disease during follow-up such as cardiovascular disease, cancer or diabetes.

We did not take account of this as the incidence of these disease takes a long time and our follow-up was just over a period of 12 months.

3) Taking into account that participants were overweight or obese people, it should be interesting to know their weight cycling and to evaluate how this point may affect the results.

We do not have results for weight cycling; the only intermediate value we have for participants is at 6 months.

4) The authors explained that they used multiple imputation (MI) to account for missing data at follow-up. However, they only show the results for those participants who completed the 12-month follow-up (Table 3 and Abstract). Please, it should be interesting to know the obtained results from MI data.

Table 3 includes results for completers as well as imputed results. Only the results from imputed analyses are given in the Abstract.

5) I have my doubts about the randomly allocation procedure, since in Table 1 the control group and the intervention group seems that they are not well balanced. For example, in the intervention group they were more likely to be employed full-time than in the control group or in the intervention group they were more likely to be obese than in the control group. I assume that for this reason the authors adjusted the results through ANCOVA and logistic regressions. However, in Table 3 I can not see the variables for what did adjust for, since it is missing the footnote of Table 3. Please, include it and clarify this point.

The procedure was automated so any differences in groups occurred by chance. We have added this point to the text.

Details of values included in the imputation analysis are given on p8 and added as footnote to Table 3

6) In the same line, authors should present the adjusted results in the results section of the manuscript, instead of the crude results.

We only highlighted the results from the imputed analysis in the text.

7) Tables in general should be self-explanatory. Please, in Table 5, explain how you got the score for Patient Assessment of Care for Chronic Conditions (PACIC). You should also include it in the methods sections, at least a reference.

We have added the reference as footnote to the table.

8) Results in tables 4, 5 and 6 were based on participants in the intervention group (n between 52-60). These numbers of participants included only about 60% of those participants in the total intervention group followed-up for 12 months (n: 103). Please, include this point as a limitation in the discussion section.

We have already included loss to follow-up as a limitation in the discussion

9) Similarly, it is not clear to me from which participants were based the results of Table 7 (behaviours associated with losing 5% or more of baseline weight) since the total number of participants included in the table were 151 and not 217, the total number of participants assessed at 12 months. Please, clarify.

We have added a footnote regarding missing questionnaire data.

10) In Table 3 there are two mistakes on the average differences. For systolic blood pressure difference at 12 months should be +0.25 instead of -0.25. For heart rate difference should be -2.91 instead of -2.44. Please, check all the results.

We have checked all the data in this table and made the appropriate corrections.

MINOR POINTS:
The article has some typos:
1)Page. 3, “already” instead of “aleady”.
2)Page 16, Table 1, please clarify the age groups and correct the group for BMI >=30.
3)Page 18, Table 3, please delete the space in the lower limit of 95% CI for BMI average difference at 6 months.
4)Page 24, Table 8, please delete the symbol of percentage in the Weight Watchers BMC 2011 study.

We have made the above corrections

Reviewer: 2, Elizabeth Denney-Wilson

Comments:
Prevention and management of overweight and obesity are major challenges for primary health care practitioners, and this study presents evidence from a unique intervention conducted in the primary care setting using trained health advisors. The paper is well written and would be of interest to clinicians, policy-makers and researchers.

The study design is appropriate and the methods well explained. The intervention uses a sound theoretical frameowrk and combines all of the aspects known to be effective in weight management interventions. I am concerned about the short training programme offerred to health advisors (many of whom do not appear to have health-related backgrounds). The training programme covered a great deal of required knowledge in addition to practical skills that the advisors needed to implement the training. can the investigators comment on the evaluation of the skills developed and the fidelity of the programme delivery? Can you also comment on why trained health advisors were chosen rather then practice nurses or dieticians?

We did not formally assess the skills or the fidelity of the delivery - we have audio and video recordings of sessions but have not been successful in obtaining funding to analyse them.

As we say on p5, we were following the guidance of the NHS health trainers initiative

The study design and methods seem appropriate as were the statistical analyses. the impression given to the reader is of a very well thought-through intervention and analysis plan. The participants are well decsribed and exclusion criteria modest, which is a strength of the study. The results clearly present the primary outcomes, but could the authors also comment on changes in secondary outcomes? And were there any differences in the other data collected (like the extensive self report data collected with validated questionnaires; I'm not sure why the questionnaires are mentioned if they are not reported upon?). And were there any changes in sednetary behaviours-in particular TV viewing? On page 11, I suggest the authors refrain from terms such as "strong" evidence. What does that mean exactly? Also, could the authors quantify the stated "reduced fat and sugar" and "walked more" as this could mean a number of things?

We will be exploring the findings from other outcomes in a separate paper. We have only included reference to questionnaires used in the imputation.We have deleted the word 'strong' and included the exact wording of the questions in the table.

In the discussion, could the authors explain the second paragraph, as it is not clear what is meant by "....our study did not identify significantly different changes in quality of life between the groups because it was not powered to do so but confirms similar results from other RCTs of weight loss"

We have removed this paragraph and will present findings on secondary outcomes elsewhere.

Did the authors find any differences bewteen participants who completed all the sessions, 50% of sessions, 75% of sessions etc-it would be useful to know what "dose" is required to initiate weight loss?

We have done these analyses and reported the results under the Exploratory Analyses paragraph.

There are two typos-an extra full-stop on line 5, page 9, and an extra semi colon on page 11, line 21.

We have made these corrections.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5, 7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5, 6, Fig 1, Appx 1, (supplementary files)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5, 7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	8

	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6, 7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig 2 (p15)
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 2, p15
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6, 9
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1, p16
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	8-10; tables 1 –

		by original assigned groups	7
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9, 10, table 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	9, table 3
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	10
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	supplementary file
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	13

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

A pragmatic randomised controlled trial of the Camden Weight Loss (CAMWEL) programme.

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Contributorship statement:

KN, JT, NT, DH, AK, SE & AH contributed to conception and design.
MH, JT, KN, EH, AS, UG contributed to acquisition of data
KN, TP, EH, MK, AH contributed to analysis and interpretation of data
KN drafted the article
KN, JT, AH revised it critically for important intellectual content
All authors contributed to final approval of the version to be published

Summary

Article focus

- Evaluate structured one-to-one weight management programme
- Delivery by trained non-specialists
- Primary care

Key messages

- Clinically important level of weight loss achieved by higher proportion of participants in intervention (34%) compared to control group (19%)
- Intervention group reported higher level of satisfaction with support received
- Primary care interventions are unlikely to be sufficient to tackle the obesity epidemic

Strengths and Limitations

- Relatively low threshold of BMI>=25 for inclusion, with few exclusions, so wide applicability of findings
- High loss to follow-up (43%), although similar to other studies in the area, used multiple imputation to counter any biases.

Abstract (max 300 words)

- **Objectives** - To evaluate effectiveness of a structured one-to-one behaviour change programme on weight loss in obese and overweight individuals.
- **Design** - Randomized controlled trial.
- **Setting** - 23 general practices in Camden, London.
- **Participants** - 381 adults with body mass index ≥ 25 kg/m^2 randomly assigned to intervention (n=191) or control (n=190) groups.
- **Interventions** - A structured one-to-one programme, delivered over 14 visits during 12 months by trained advisors in three primary care centres, compared to usual care in general practice.
- **Outcome measures** – Changes in weight, %body fat, waist circumference, blood pressure and heart rate between baseline and 12 months
- **Results** - 217/381 (57.0%) participants were assessed at 12 months: missing values were imputed. The intervention group achieved a greater mean weight loss of 0.70 kg (0.67 to 2.17, P=0.35) compared to the control group. A higher proportion of the intervention than control group lost 5% or more of their baseline weight (Odds ratio: 1.7 (1.4 to 2.7, P=0.04)). The intervention group achieved a lower mean heart rate (mean difference 3.68 beats per minute (0.31 to 7.04, P=0.03)) than the control group and consistent but non-statistically significant greater reductions in waist circumference, %body fat, systolic blood pressure and diastolic blood pressure. Participants in the intervention group reported more positive assessment of their care compared to the control group.
- **Conclusions** – Despite lack of a significant difference in mean weight loss between intervention and control groups, trained non-specialist advisors can deliver a structured programme and achieve clinically beneficial weight loss in some~~motivated~~ patients in primary care ~~with a greater proportion of participants losing 5% or more of their baseline weight compared to usual care~~. The intervention group also reported a higher level of satisfaction with the support received. Primary care interventions are unlikely to be sufficient to tackle the obesity epidemic and effective population wide measures are also necessary.
- **Trial registration –** Clincaltrials.gov NCT00891943

WHAT IS ALREADY KNOWN ON THIS TOPIC

The NICE guidelines for the management of overweight and obese patients provide general recommendations for discussing weight and improving diet and physical activity levels.

However, there are no randomised controlled trials of one-to-one weight management programmes in non-diabetic patients with 12-months follow-up in general practice in the UK.

WHAT THIS STUDY ADDS

A structured weight management programme for overweight and obese patients delivered by trained non- specialists was associated with a clinically important level of weight loss, although there was no strong evidence that the average difference in weight between groups was improved by the intervention.

Intervention participants reported greater satisfaction with care than did the usual care participants.

Primary care interventions are unlikely to be sufficient to address the obesity epidemic and need to be complemented with robust public health policies.

Introduction

Overweight and obesity are major public health problems,[1] representing the fifth leading cause of death in the world[2] and an increasing global challenge.[3] Obesity has severe impacts on health, increasing the risk of type 2 diabetes, hypertension, some cancers, heart and liver disease.[1, 4 5] The Foresight Report[6] estimated the National Health Service costs attributable to obesity in 2007 as £4.2 billion. In 2010, 68% of men and 58% women in England were overweight or obese (Body Mass Index (BMI) ≥25 kg/m^2).[7]

Obesity is a chronic condition requiring lifelong management as weight loss is often regained.[8, 9] Achieving changes in behaviour is challenging,[10] largely due to an inability to maintain healthy eating and physical activity behaviours.[11] Modest weight loss (3-9%) can prevent type 2 diabetes, improve fasting plasma glucose, blood pressure and lipids, and reduce antihypertensive medication.[12, 13 14-16] Most overweight patients would like help with weight management from their general practices,[17] and this is feasible in the short-term (3-12 months)[18, 19] and estimated to be cost saving to the NHS,[20] although few recall receiving weight control advice from a health professional.[21]

The aim of this study was to develop and evaluate the efficacy of an intervention programme with twelve months follow up, for an ethnically diverse overweight/obese population recruited from general practices in a pragmatic randomised controlled trial following the Medical Research Council framework for complex interventions.[22] To our knowledge, there are currently no other published randomised controlled trials of one-to-one lifestyle intervention delivered in UK general practice to overweight/obese patients without co-morbidities.

Methods

Aims

The aim of the study was to assess, by means of a pragmatic parallel group randomized controlled trial (RCT), the effects on anthropometric measures, health-related parameters and the sense of well-being of offering individualized weight management advice in primary care to overweight/obese people who wished to lose weight; and to identify the key factors influencing the outcome of the intervention.

The primary outcomes were the differences between the control and intervention groups in changes in body weight, waist circumference, percent body fat, blood pressure and heart rate from baseline to 12 months and proportion who lost 5% of their baseline weight.

Interventions

The intervention combined evidence-based components recognized 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 high-risk situations and long-term support – and 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; goal setting.[25] It also has an emphasis on 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 emphasizes 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).[18] Six CAMWEL advisors were recruited from various occupational backgrounds including healthcare, in line with the NHS health trainers initiative.[29] The advisors received initial training over two days, and further meetings with the research team every three to four 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 behaviour 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'. Participants were invited to attend 30-minute sessions with the advisor every fortnight for the first 12 weeks, three-weekly for 12 weeks, and finally monthly for the next 12 weeks, making a total of 14 sessions. 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,[30] a kit including 100 calorie portions of various food items, Adams Food and Alcohol Portion Pots (www.adamsportionpot.com). 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).

There is no current comparator 'gold standard' treatment programme available for weight management in general practice. In this pragmatic trial of a complex intervention, we assess the benefit of the intervention compared to routine clinical practice. We provided a copy of the Quick reference NICE clinical guideline on Obesity to all participating 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 (BHF) booklet: 'So you want to lose weight … for good'.[31]

Recruitment

All general practices in Camden were visited and invited to participate in the trial. Participants were recruited between July 2009 and January 2010 from 23 of 39 NHS Camden general practices. The London Borough of Camden has areas of relative affluence alongside areas of relative deprivation, with approximately 35% of the population living in areas classified as some of the most deprived in England.[32] Education levels are also disparate, with 47% of people in employment being educated to degree level or above, whilst 17% of working age people have no qualifications.[33] Camden has an ethnically diverse population, with 27% belonging to minority ethnic groups.[33]

Several recruitment approaches were used. Primarily, participating practices wrote to a sample of patients with body mass index (BMI) ≥25 kg/m^2; GPs and Practice Nurses (PNs) were provided with referral 'prescription' pads with a tear-off slip to be given to the patient with contact details of the trial office; and posters and flyers were placed in practice waiting areas and local pharmacies. During the final six weeks of the recruitment period, three practices supplemented recruitment by sending text messages to potentially eligible patients using their electronic record (EMIS) and messaging (iPLATO) systems. All practices were reimbursed for time spent on recruitment.

Baseline measurements

Potential participants were screened by telephone for eligibility (MH, EH, TP). Inclusion criteria were age 18 years and above, BMI≥ 25 kg/m^2, attending a participating practice and willing to attend visits with a CAMWEL advisor over 12 months. Exclusion criteria were pregnancy or lactation, diagnosis of renal failure, use of a pacemaker, recent diagnosis of cancer, or participation in another weight management study. Following GP consent,

participants were scheduled for screening appointments with a researcher (MH) at one of three practices. The study was explained and the participant invited to give informed written consent and to complete the baseline questionnaire. Height (without shoes) was 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 percent body fat, basal metabolic rate and metabolic age (age expected for a given value of basal metabolic rate). Waist was measured mid-way 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 where possible. The printout from the Tanita scales, including weight, BMI and metabolic age, was given to all participants.

Outcomes

All participants were invited for follow up at 6 and 12 months. A letter was sent three weeks prior to the due date, followed by a telephone call to arrange the appointment. Three attempts were made to contact each participant. Measurements taken at baseline were repeated and participants were asked to complete a questionnaire. A £30 voucher was provided for their time to all participants who completed each follow-up appointment.

The self-completed questionnaires included the following validated measures: EuroQol Visual Analogue Scale (EQ-VAS), Obesity and Weight Loss Quality-of-Life (OWLQOL)[34]; Hospital Anxiety and Depression Scale (HADS)[35]; Rosenberg measure of self-esteem[36]; Duke-UNC Functional Social Support Questionnaire (FSSQ)[37]; Three-Factor Eating Questionnaire (TFEQ-18)[38]; and physical activity (RPAQ)[39]; as well as socio-demographic information. Deprivation was ascertained using the Index of Multiple Deprivation (IMD) based on the participant's home address post code.[40]

In addition, at follow-up we used the Patient Assessment of Care for Chronic Conditions (PACIC) [41, 42] to assess the participants' views on the care they received from the advisors and the GP practice on helping them lose weight. A brief series of statements was used to assess participants' confidence in their ability to manage their weight on a scale of one (disagree strongly) to four (agree strongly). Further questions asked about the type of help received from the GP practice regarding weight loss, changes made in behaviours related to weight management, and experience of study participation. Participants in the intervention group also completed an additional section to ascertain how helpful they found the sessions and materials provided as part of the CAMWEL programme.

Randomization

Participants were randomly allocated (allocation ratio 1:1) to the control or intervention group (TP, EH, AS), using a computer-generated randomization application written in VBA for MS Access (TP). The Taves method of minimization[43] was used to ensure the groups were balanced for general practice, gender, age group (≤50/ >50 years), BMI category (≤30/>30 kg/m^2), diagnosis of diabetes (yes/no), and taking anti-psychotic medication or not.

Blinding

The study was single-blinded with members of the study team assessing baseline and follow-up measurements blinded to group assignment.

Sample size

In our pilot study participants had a mean weight of 98.1 kg (SD 17.3 kg) at baseline.[18] Since a loss of 5-10% of body weight in obese adults is associated with significant reductions in the risk of obesity co-morbidities, we considered a difference in weight between groups of 7% at 12 months follow-up to be clinically important. For the sample size calculation, we wished to detect a mean weight difference of 6.9 kg 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 conservatively set at 0.7. We thus calculated a total sample size of 228 (114 per group). Assuming a loss to follow up at 12 months of 40%,[44] it was estimated that 380 participants would be required.

Statistical methods

Comparisons between groups for continuous variables were performed using two-sample t-tests and regression methods, adjusting for the baseline value of the variable. ~~analysis of covariance (ANCOVA) for continuous variables.~~ Chi-sq 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. Exclusion of subjects with missing data is inefficient and can lead to biased results if those dropped are atypical in some respect[45] and MI can both increase efficiency and reduce bias in such settings.[46,47] 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.[48] 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. For all outcomes the following baseline variables were included: age, weight, percent body fat, BMI, fat mass, metabolic age, deprivation status and employment status as well as totals from the OWLQOL, EQVAS, HADS anxiety, TFEQ emotional eating and RPAQ scales. The imputation procedure was carried out separately for the two groups (intervention and control) and the resulting multiply imputed datasets were combined for the final MI analysis. A total of 200 imputations were used to stabilize the results and to ensure negligible loss of power.[45] Analyses using only data on participants who completed 12-month follow-up were also conducted.

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Exploratory analyses 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 version 11.

Ethical approval

The study was approved by the London School of Hygiene & Tropical Medicine Ethics Committee, the Camden and Islington Community Research Ethics Committee (reference number 09/H0722/22) and the North Central London Research Consortium.

Results

Participants were followed up at 6 months between January 2010 and July 2010; and at 12 months between July 2010 and January 2011. Participant flow through the trial is shown in Figure 2.

Baseline characteristics

We recruited 381 participants with a median age of 48.5 years (inter-quartile range 37.5 to 60.4), weighing 60.1 to 152.2 kg, with waist circumference of 76 to 147 cm. The majority (72%) were women, 12% (47/381) had diagnosed diabetes, 1.3% (5/381) were on anti-psychotic medication, 60% were in employment, 47% were university graduates and 73% described their ethnicity as white (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

Measurements were obtained for 69% (n=263) of the sample at 6 months and 57% (n=217) at 12 months. 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 percent body fat, and were less likely to be from a deprived area than those not followed up (Table 2).

Primary Outcomes

Based on the intention-to-treat analysis using imputed missing values (Table 3), at 12 months 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 when compared to usual care group (odds ratio 1.73 (1.38 to 2.66, P=0.04). The intervention programme was also associated with weak evidence of beneficial trends in waist circumference, percent body fat, and percent weight change. Heart rate was reduced by 3.7 (0.3 to 7.0, P=0.03) beats per minute in the intervention group compared to the control group.

Based on data for participants who completed the 12-month follow-up (Table 3) a higher proportion (one in three compared to one in five) in the intervention group had lost at least 5% of their initial weight (difference 14.7% (3.0 to 26.4, P=0.01)) and experienced a greater average reduction in waist circumference (difference 1.88 cm (0.01 to 3.76, P=0.05)) compared to those in the control group. Weak evidence of reductions in weight, %body fat, BMI, blood pressure and heart rate were observed in the intervention compared to the control group. The absolute risk reduction for losing 5% baseline weight was 14.7 % (3.0 to 26.4) and the number needed to treat was 6.8 (3.8 to 33.2). A higher proportion of those in the intervention group (84%, 21/25) who had lost ≥5% at 6 months had managed to keep this level of weight loss at 12 months compared to those in the control group (61.5%, 8/13). We were unable to identify characteristics of the sub-group of participants more likely to lose 5% of their baseline weight.

Secondary Outcomes

No ~~strong~~ evidence of differences was found between the two groups on any of the psychological or quality of life measures.

Trial participation

Participants in the intervention group were more satisfied than those in the control group with the level of weight loss achieved and they found participation in the trial and feedback of physical measurements helpful (Table 4). The intervention group also reported receiving more patient centred care than those in the control group as measured by the PACIC scales (Table 5). Detailed analysis of the interviews and focus groups with a sub-set of the participants will be reported elsewhere.

The intervention programme

Participants reported that regular meetings with the advisor was the most helpful aspect of the programme;~~,~~ the least helpful was the handouts provided (Table 6). The most helpful sessions were the first (getting started), eighth (positive thinking) and twelfth (staying active). The most helpful handouts were 'Rate Your Plate', 'CAMWEL Walks' and 'Staying Active', the least helpful were 'Building A Better Recipe' and 'Meal Plans'. The majority (84%) said they would choose to continue to meet an advisor beyond the 12 months of the current study, with most (73%) preferring to see the advisor at least every four weeks.

Behaviours associated with losing 5% or more of baseline weight

Participants who lost 5% or more of their baseline weight were more likely to state that they had reduced their fat and sugar intake in the previous six months than those who did not; there was no ~~strong~~ evidence of increasing levels of physical activity between the groups (Table 7). They also reported that attending regular meetings with a non-judgmental advisor, discussion on portion sizes and use of the pedometer were particularly useful and would continue to monitor food intake to maintain their weight.

Exploratory analysis

38 participants were known to have been prescribed drugs for weight loss or to have undergone weight loss surgery during the trial period. Of these, 27 were 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, p = 0.69). In analysis excluding these participants, those in the intervention group showed significantly greater reductions in weight (1.72 kg (0.29 to 3.14, P= 0.02)), waist circumference (2.52 cm (0.32 to 4.72, P=0.03)), BMI (0.63 kg/m^2 (0.11 to 1.14, P=0.02)) and percent baseline weight loss (1.94% (0.32 to 3.56, P=0.02)) when compared with the control group at 12 months. In addition, a higher proportion of participants in the advisor group lost ≥5% of their baseline weight when compared to the control group (odds ratio 2.68 (1.13 to 5.70, P=0.03)).

The number of sessions attended was available for 87 participants of whom 40 (46%) attended more than 70% (10/14) of the available sessions. Half (50%) of the participants attending more than 70% of the programme lost 5% or more of their baseline weight compared to a quarter (23%) who attended fewer sessions (difference 26.5%; 95%CI: 6.9 to 46.3; p=0.01).

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Discussion

Principal findings

The structured one-to-one weight loss programme delivered by non-specialists in general practice did not achieve the pre-specified difference in average weight loss of 7%. However it did result in a higher proportion of the participants losing 5% or more of their baseline weight compared to those randomized to usual care (odds ratio 1.73 (1.38 to 2.66)) which is considered a clinically important outcome in similar trials. This suggests that people likely to benefit from such a programme are a subset of the total study population but we were unable to identify particular characteristics that would permit identification of a receptive group in advance. There was some evidence that the intervention group experienced greater reductions in mean weight, waist circumference and % body weight than the control group. While the overall effects on weight loss are modest they are not unimportant.

Although quality of life has been reported to be related to weight loss,[18] our study did not identify significantly different changes in quality of life between the groups possibly because it was not powered to detect this, but confirms similar results from other RCTs of weight loss.[49]

Strengths and weaknesses of the study

The key strengths of the CAMWEL programme are its wide applicability to overweight and obese people from diverse backgrounds as there were few exclusions, feasibility of its delivery in primary care by non-specialist trained advisors and a patient-centred approach to making sustainable changes to diet and physical activity easily incorporated into peoples' daily lives.

Limitations include the slow initial recruitment although this improved over time, particularly with mobile phone text message use.[50] Loss to follow up was high (43%) although similar to that of other weight loss studies in the UK. The Counterweight study,[51] which was not a RCT, reported a follow-up rate of 45% and McConnon et al[52] reported 59% in a trial of an internet intervention compared to usual care.[53] [54]The response rate in the DESMOND diabetes management trial[19] was substantially higher (91%), perhaps because participants were recently diagnosed diabetics and therefore highly motivated. High attrition in RCTs of weight loss is well recognized,[55] with a recent review reporting losses to follow-up of 30-60%.[44]

We used multiple imputation for missing values in primary outcomes to counter any biases due to loss to follow-up as high level of attrition involves considerable uncertainty about outcomes for participants lost to follow-up. We included patients with BMI≥25 as NICE recommends treatment at this level although this relatively low threshold and broad inclusion criteria may have diluted the results in terms of average weight loss thus needing a larger sample to detect significant differences.

Participants in the control group were advised to contact their general practice to receive the usual care provided for weight loss. We provided all GPs with NICE guidelines on obesity and participants with the BHF booklet on weight loss as well as feedback on the measurements taken at six months. This provision of support could be one reason whymeant that participants in the control group also lost weight over the period of the trial

which ~~may have~~ resulting~~ed~~ in greater similarity of changes in the two groups and would represent bias if the GPs altered their usual care by virtue of trial participation. Another study[56] suggested participants may be disappointed by allocation to usual care when they had entered the trial with preferences for allocation to the intervention group. The response to disappointment may trigger behaviour change and contribute to the weight loss seen in the control group and thus entail performance bias (McCambridge, personal communication).

Behaviour change interventions tend to be complex with multiple components and it is difficult to assess the effectiveness of different components. This was a pragmatic trial reflecting the likely performance of the programme as delivered in practice. While the fidelity of the delivery of the intervention could be examined in more detail, we have shown that patient assessment of the structured support by trained advisors is significantly better than usual care.

Cost-effectiveness analyses are required to inform decision-making about the value of attaining these outcomes and will be reported in a separate paper.

Putting the study in context

~~Five~~ Seven published RCTs of similar interventions conducted in UK general practice have been conducted (see Table 8). With the exception of a ~~the~~ trial in newly diagnosed diabetics, these provided no strong evidence of differences in weight loss between intervention and control groups, except for those using a commercial provider (Weight Watchers). ~~—~~Our trial achieved results at least comparable with the more targeted interventions based in general practice.

Implications

We have demonstrated that one-to-one structured support by a trained advisor in general practice can help people wishing to lose weight to change their behaviour sufficiently to lead to a clinically important loss in weight. Understanding how the intervention worked and why it worked just for some participants as well as its cost-effectiveness are important and we will explore these in our subsequent research. The importance of our results lies in their generalisability. Our results, together with those from other researchers, suggest that individual approaches in general practice can achieve modest benefits for the National Health Service. However, primary care interventions are unlikely to be sufficient to address the obesity epidemic and effective population wide policy measures are needed as well, including increasing energy expenditure through active travel[57] and reducing dietary intake.

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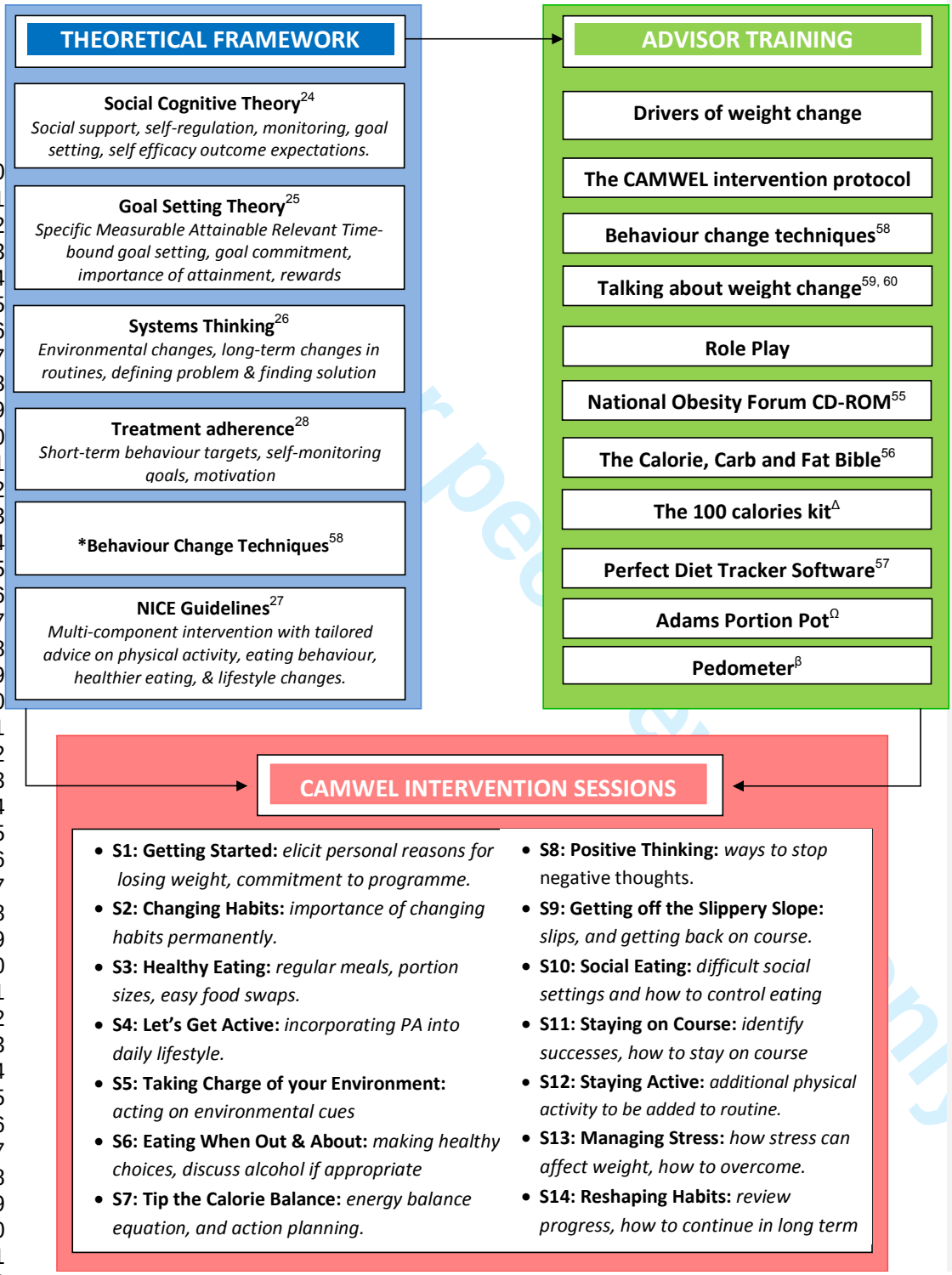
Competing interest

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that KN, TP, EH, MH, AS, UG and JT 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.

All authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis

Data sharing: no additional data available.

Figure 1: CAMWEL Intervention Framework



* Provide information on consequences, Prompt intention formation, Prompt barrier identification, Provide general encouragement, Model or demonstrate behaviour, Prompt specific goal setting, Prompt review of behavioural goals, Prompt self-monitoring of behaviour, Provide feedback on performance, Agree on behavioural contract, Plan social support, Prompt self-talk, Relapse prevention, Stress management, Motivational interviewing.

[Δ] *The 100 Calories Kit was designed by the CAMWEL Team, and was made up of 100 calorie portions of a variety of foods such as crisps, rice, pasta, biscuit, peanuts, and raisons.*

[β] *The pedometers used were DW701 Yamax Digiwalker for BMI<35, and NEW-LIFESTYLES NL-800 for BMI≥35.*

[Ω] *Adams Portion Pot – www.adamsportionpot.com*

Figure 2 Flow of participants through the trial

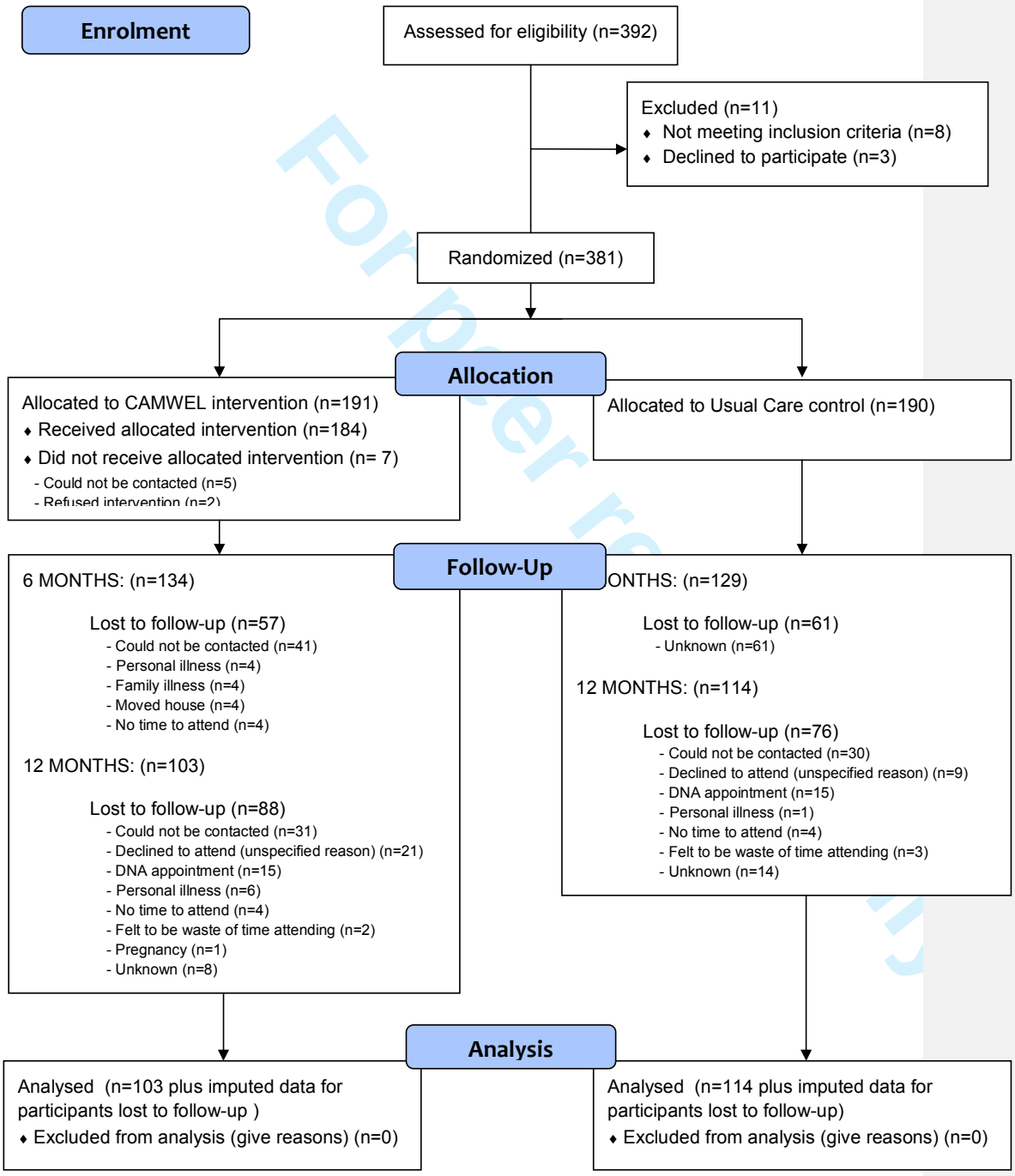


Table 1 Baseline characteristics of participants wishing to lose weight allocated to usual care (control) or to the CAMWEL programme (intervention). Values are means (standard deviations) unless stated otherwise. [Number of subjects may differ for each variable]

Characteristics	Control group (n=190)		Intervention group (n=191)		All (n=381)	
Age (years)	49.35	(15.45)	48.17	(14.09)	48.76	(14.77)
Age group (years)						
18- <35	20.53	(39)	20.94	(40)	20.73	(79)
35- <50	32.63	(62)	31.41	(60)	32.02	(122)
50- <60	19.47	(37)	24.08	(46)	21.78	(83)
≥60-	27.37	(52)	23.56	(45)	25.46	(97)
Body weight (kg)	90.95	(18.12)	93.70	(18.40)	92.33	(18.29)
Waist circumference (cm)	105.83	(13.01)	107.56	(12.78)	106.70	(12.91)
Percent body fat	38.90	(7.83)	39.45	(8.06)	39.18	(7.93)
Fat mass (kg)	35.83	(12.82)	37.28	(12.70)	36.52	(12.76)
Muscle mass (kg)	52.18	(10.05)	53.39	(10.55)	52.76	(10.30)
Body mass index (kg/m^2)	33.02	(5.40)	33.92	(5.64)	33.47	(5.53)
% (n) BMI 25-<30	31.05	(59)	25.65	(49)	28.35	(108)
% (n) BMI ≥30-	68.95	(131)	74.35	(142)	71.65	(273)
Systolic blood pressure (mm Hg)	126.42	(20.44)	127.43	(20.17)	126.92	(20.28)
Diastolic blood pressure (mm Hg)	82.15	(12.36)	83.40	(12.83)	82.77	(12.59)
Heart Rate (beats per minute)	76.68	(12.05)	75.94	(12.03)	76.32	(12.03)
Demographic details, % (n)						
Gender: Female	72.63	(138)	71.73	(137)	72.18	(275)
Ethnicity: White	70.63	(101)	74.25	(124)	72.58	(225)
Education						
No qualifications	14.19	(21)	8.82	(15)	11.32	(36)
O/A-level or equivalent	27.71	(41)	38.23	(65)	33.33	(106)
University degree	48.65	(72)	44.71	(76)	46.54	(148)
Employment						
Employed full-time	37.50	(57)	49.12	(84)	43.65	(141)
Employed half-time	19.08	(29)	14.04	(24)	16.41	(53)
unemployed	43.42	(66)	36.84	(63)	39.94	(129)
Area Deprivation (IMD)						
Lowest quartile (deprived)	26.06	(49)	23.94	(45)	25.00	(94)
2nd	25.00	(48)	23.40	(44)	24.20	(91)
3rd quartile	25.53	(47)	25.00	(47)	25.27	(95)
Highest quartile (affluent)	23.40	(44)	27.66	(52)	25.53	(96)
Family member overweight	78.67	(118)	77.33	(133)	77.95	(251)
Quality of Life (range of values for each scale)						
EQ-VAS (0, 100)	48.22	(30.18)	47.42	(30.68)	47.80	(30.40)
Self-esteem (1, 30)	18.51	(6.01)	18.95	(5.89)	18.74	(5.94)
Social support (1, 5)	3.84	(1.03)	3.91	(1.02)	3.87	(1.03)
Depression (0, 19)	6.07	(4.20)	6.34	(4.31)	6.21	(4.25)
Anxiety (0, 19)	7.81	(4.32)	8.66	(4.83)	8.25	(4.60)
Obesity-related QoL (0, 102)	51.29	(26.71)	48.55	(25.47)	49.85	(26.06)

EQ-VAS=EuroQol Visual Analogue Scale; Qol= Quality of Life

Table 2 Comparison of baseline characteristics of participants followed up at 12 months and those lost to follow-up (Mean (St Error) unless otherwise stated)

	Followed-up		Lost to follow-up		Difference (Lost to follow-up – Followed-up)		
					Mean	(95% CI)	P value
Number (%)	217	(57.0)	164	(43.0)			
Age (years)	51.22	(1.01)	45.50	(1.10)	-5.72	(-2.77 to -8.68)	<0.001
Weight (kg)	90.86	(1.19)	94.26	(1.48)	3.39	(-0.31 to 7.10)	0.072
Waist (cm)	106.50	(0.89)	106.96	(0.99)	-0.46	(-2.18 to 3.10)	0.732
%body fat	38.47	(0.55)	40.10	(0.60)	1.63	(0.02 to 3.24)	0.048
BMI (Kg/m^2)	32.92	(0.37)	34.18	(0.44)	1.26	(0.14 to 2.37)	0.028
Metabolic age (years)	60.70	(0.98)	56.50	(1.08)	-4.20	(-1.28 to -7.06)	0.005
Fat mass (kg)	35.26	(0.93)	38.14	(1.07)	2.88	(0.10 to 5.67)	0.043
Muscle mass (kg)	52.49	(0.76)	53.10	(0.86)	0.61	(-1.65 to 2.87)	0.60
Basal Metabolic Rate (kcal)	1682	(23.17)	1721	(27.23)	39.0	(-31.0 to 109.0)	0.27
% (n) Female	70.97	(154)	73.78	(121)	2.81	(-6.23 to 11.86)	0.54
% (n) Married/cohabiting	45.36	(83)	48.00	(60)	2.64	(-8.70 to 13.99)	0.65
% (n) White ethnicity	73.02	(138)	71.90	(87)	-0. 11	(-11.32 to 9.10)	0.83
% (n) No qualifications	13.16	(25)	8.59	(11)	-4.56	(-11.40 to 2.27)	0.21
% (n) Employed	81.68	(107)	71.90	(87)	-9.78	(-20.17 to 0.61)	0.06
% (n) Deprived area	19.16	(41)	32.72	(53)	13.55	(4.61 to 22.50)	0.003
Self-esteem	19.14	(0.44)	18.15	(0.55)	-0.99	(-2.38 to 0.40)	0.16
Social support	3.86	(0.08)	3.91	(0.09)	0.05	(-0.18 to 0.29)	0.64
Anxiety	4.73	(0.14)	5.13	(0.16)	0.40	(-0.01 to 0.82)	0.06
Depression	3.51	(0.13)	3.68	(0.17)	0.17	(-0.23 to 0.59)	0.40
EQ-VAS	62.44	(1.53)	54.92	(2.31)	-7.52	(-2.05 to-12.98)	0.007
Obesity and Weight- related Quality of Life	47.31	(1.89)	53.56	(2.37)	6.25	(0.33 to 12.18)	0.039

EQ-VAS=EuroQol Visual Analogue Scale

Table 3 Changes in outcomes at 6 and 12 months and treatment differences between participants wishing to lose weight allocated to a structured one-to-one weight loss programme (intervention) or to usual care (control).

Variables	Unadjusted change from baseline (95% confidence interval)				Average difference between groups (intervention-control)	T-test/ Chisq	Difference between groups based on multiple imputation* (~~analysis of covariance~~/§odds ratio§)	P value
	Control group		Intervention group					
	Number	Mean (95% CI)	Number	Mean (95% CI)	Mean (95% CI)	p value		
Weight (kg)								
6 months	129	-0.95 (-1.74 to -0.16)	134	-1.73 (-2.47 to -0.99)	-0.78 (-1.85 to 0.30)	0.16	-0.69 (-1.80 to 0.41)	0.22
12 months	114	-1.31 (-2.23 to -0.37)	103	-2.39 (-3.46 to -1.31)	-1.08 (-2.49 to 0.32)	0.13	-0.70 (-2.17 to 0.76)	0.35
Waist circumference (cm)								
6 months	125	-2.19 (-3.12 to -1.26)	129	-3.36 (-4.42 to -2.29)	-1.17 (-2.58 to 0.24)	0.10	-0.90 (-2.35 to 0.55)	0.22
12 months	112	-1.49 (-2.59 to -0.40)	100	-3.37 (-4.91 to -1.82)	-1.88 (-3.76 to -0.01)	0.05	-1.22 (-3.10 to 0.66)	0.20
% body fat								
6 months	125	-0.12 (-0.66 to 0.42)	131	-0.89 (-1.36 to -0.43)	-0.77 (-1.48 to -0.06)	0.03	-0.77 (-1.51 to -0.04)	0.04
12 months	111	-0.23 (-1.02 to 0.57)	101	-0.72 (-1.27 to -0.15)	-0.49 (-1.47 to 0.49)	0.32	-0.71 (-1.71 to 0.28)	0.16
Percent weight loss								
6 months	129	-1.04 (-1.88 to -0.20)	134	-1.78 (-2.51 to -1.05)	-0.74 (-1.85 to 0.36)	0.19	-0.73 (-1.91 to 0.44)	0.22
12 months	114	-1.38 (-2.39 to -0.37)	103	-2.59 (-3.65 to -1.54)	-1.21 (-2.66 to 0.23)	0.10	-0.79 (-2.37 to -0.79)	0.33
% lost ≥5% baseline weight								
6 months	129	13.18 (7.34 to 19.02)	134	23.88 (16.66 to 31.10)	10.70 (1.41 to 19.98)	0.03	1.77 (1.36 to 2.83) §	0.06
12 months	114	19.30 (12.05 to 26.54)	103	33.98 (24.83 to 43.13)	14.68 (3.01 to 26.35)	0.01	1.73 (1.38 to 2.66) §	0.04
Body mass index (kg/m^2)								
6 months	129	-0.36 (-0.65 to -0.07)	134	-0.60 (-0.86 to -0.34)	-0.24 (-0.63 to 0.14)	0.22	0.20 (-0.18 to 0.59)	0.30
12 months	114	-0.48 (-0.82 to -0.13)	103	-0.83 (-1.22 to -0.44)	-0.35 (-0.87 to 0.16)	0.18	0.34 (-0.18 to 0.85)	0.20
Systolic blood pressure (mm Hg)								
6 months	121	-2.92 (-6.56 to 0.73)	128	0.29 (-3.54 to 4.12)	3.20 (-2.07 to 8.45)	0.23	3.33 (-1.34 to 8.00)	0.16
12 months	103	-0.97 (-5.02 to 3.07)	90	-0.71 (-3.97 to 2.54)	**-0.25 (-5.01 to 5.5)**	0.92	-0.01 (-4.65 to 4.64)	0.99
Diastolic blood pressure (mm Hg)								
6 months	121	-2.29 (-4.70 to 0.12)	128	-1.52 (-3.98 to 0.95)	-0.77 (-2.66 to 4.21)	0.66	1.87 (-1.12 to 4.87)	0.22
12 months	103	0.83 (-1.89 to 3.56)	90	-0.68 (-2.83 to 1.46)	-1.51 (-4.96 to 1.93)	0.39	-1.59 (-4.77 to 1.60)	0.33
Heart Rate (beats per minute)								
6 months	120	2.38 (0.21 to 4.55)	127	-0.47 (-2.79 to 1.85)	-2.86 (-6.02 to 0.31)	0.08	-2.42 (-5.47 to 0.62)	0.12
12 months	104	-0.23 (-2.82 to 2.36)	90	-2.68 (-5.33 to 0.02)	**-2.44 (-6.14 to 1.25)**	0.19	-3.68 (-7.04 to -0.31)	0.03

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*For all outcomes the following baseline variables were included: age, weight, percent body fat, BMI, fat mass, metabolic age, deprivation status and employment status as well as totals from the OWLQOL, EQVAS, HADS anxiety, TFEQ emotional eating and RPAQ scales.

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Table 4: Participant satisfaction with care received by allocation group at 12 months

	Intervention		Control		Difference between groups (Intervention – Control)	
	n/N	% (se)	n/N	% (SE)	% (95% CI)	P value
Satisfied with level of weight loss achieved	37/60	61.7 (6.3)	14/61	23.0 (5.4)	38.7 (22.5 to 54.9)	<0.0001
Found participating in CAMWEL helpful in meeting goals	51/59	86.4 (4.4)	27/60	45.0 (6.4)	41.4 (26.1 to 56.8)	<0.0001
Found getting feedback on physical measurements at baseline & 6 months helpful	39/58	67.2 (6.3)	20/57	35.1 (6.3)	32.2 (14.9 to 49.5)	<0.0001
Found BHF booklet[31] helpful	50/58	86.2 (4.5)	38/53	71.7 (6.2)	14.5 (0.0 to 29.5)	0.06

Table 5: Participant assessment of care received by allocation group at 12 months

	Intervention		Control		Difference between groups (intervention-control)	
	n	Mean (SE)	n	Mean (SE)	Mean (95% CI)	P Value
Patient Assessment of Care for Chronic Conditions (PACIC)*						
Patient Activation	58	3.29 (0.17)	56	1.46 (0.13)	1.83 (1.40 to 2.26)	<0.0001
Asked for my ideas						
Given choices						
Asked about any problems						
Delivery System Design/ Decision Support	58	3.79 (0.14)	55	1.70 (0.16)	2.09 (1.68 to 2.50)	<0.0001
Written list of things to do						
Care well organised						
How what I do influences weight						
Goal Setting	58	3.35 (0.13)	54	1.64 (0.14)	1.71 (1.32 to 2.09)	<0.0001
Asked to talk about my goals						
Helped to set specific goals						
Given copy of my weight loss plan						
Encouraged to attend sessions						
Asked questions about health habits						
Problem Solving/ Contextual Counselling	58	3.34 (0.16)	56	1.66 (0.15)	1.69 (1.26 to 2.12)	<0.0001
Thought about my beliefs & traditions when making recommendations						
Helped to make plan for my daily life						
Plan ahead even for difficult circumstances						
Asked how weight affected me						

*Patient Assessment of Care for Chronic Conditions (PACIC) score [41, 42]

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Table 6: Views of participants in the intervention group at 12 months follow-up regarding the helpfulness of different aspects of the intervention programme. The handouts are listed below the session when they were first introduced.

Intervention programme element	Percent	Helpful (SD)	n/N
Regular meetings with advisor	67.9	(47.1)	38/56
Agreeing small changes	60.0	(49.4)	33/55
Tracking changes	58.1	(49.8)	33/55
Discussing personalized goals	57.1	(50.0)	32/56
Use of pedometer	55.6	(50.2)	30/54
Receiving printout of weight change	50.0	(50.5)	27/54
Use of computer during meetings	46.3	(50.3)	25/54
Sequence of topics	32.7	(47.3)	18/56
Handouts in general	32.1	(47.1)	19/56
Use of handouts in improving eating habits	30.3	(46.4)	17/56
Session 1: Getting Started	50.9	(50.5)	28/55
Benefits of healthy habits	35.7	(48.3)	20/56
Recording your routines	36.4	(48.4)	20/55
Deciding to change	33.3	(47.5)	18/54
Behaviour change diary	17.0	(37.9)	9/53
Food diary	31.5	(47.1)	17/54
Activity diary	30.9	(46.6)	17/55
Session 2: Changing Habits	40.7	(49.6)	22/54
Just one more step	31.5	(46.9)	17/54
Problem solving	16.7	(37.6)	9/54
Build a better recipe	16.7	(37.6)	9/54
Session 3: Healthy Eating	40.7	(49.6)	22/54
Rate your plate	34.5	(50.0)	19/55
Easy food swaps	29.6	(46.1)	16/54
Healthy drinks	23.6	(42.9)	13/55
EatWell	37.0	(48.7)	20/54
Session 4: Being Active	42.6	(49.9)	23/54
Being active handout	34.5	(48.0)	19/55
Cut the fat and sugar	36.3	(48.5)	20/55
Steps chart	28.8	(45.7)	15/52
CAMWEL walks	42.6	(49.9)	23/54
Session 5: Taking charge of your environment	35.9	(48.4)	19/53

Eat well on the cheap	27.8	(45.2)	15/54
Your environment	20.4	(40.7)	11/54
Goals and rewards	31.5	(46.9)	17/54
Session 6: Eating Out	30.2	(46.3)	16/53
Eating when out and about	31.5	(46.9)	17/54
Alcohol and your diet	25.9	(44.2)	14/54
Session 7: Tipping the balance	32.7	(47.4)	17/52
Tipping the balance	18.5	(39.2)	10/54
Session 8: Positive thinking	45.3	(50.3)	24/53
Positive thinking	29.6	(46.1)	16/54
Session 9: Getting off the slippery slope	34.6	(48.0)	18/52
Slippery slope	22.2	(42.0)	12/54
Change 4 life local walking map[63]	20.4	(40.7)	11/54
Session 10: Social Eating	32.1	(47.1)	17/53
Social eating	24.5	(43.4)	13/53
Session 11: Staying on course	37.7	(48.9)	20/53
Staying on course	20.8	(40.9)	11/53
Healthy snacking	25.9	(44.2)	14/54
Meal plans	22.2	(43.0)	12/53
Indian meal plans	15.1	(36.1)	8/53
Meal plans, minimum cooking	16.7	(37.6)	9/54
Session 12 Staying active	41.5	(49.7)	22/53
Staying Active	20.8	(40.9)	11/53
Party season	17.3	(38.2)	9/52
Session 13: Managing stress	34.0	(47.8)	18/53
Day-to-day stress	18.9	(39.5)	10/53
Session 14: reshaping habits	32.1	(47.1)	17/53
Reshaping habits	19.2	(39.8)	10/52
Travel Camden walking map[64]	27.8	(45.2)	15/54
Camden architecture walking guide[65]	26.9	(44.8)	14/52
Camden Belsize walk map[66]	29.6	(46.1)	16/54
Jubilee walkway map[67]	21.2	(41.2)	11/52
Get walking keep walking[68]	19.2	(39.7)	10/52

Table 7: Reported changes* in eating and activity habits by participants who lost 5% or more of baseline weight compared to those who did not.

	Lost 5% or more of baseline weight				Difference between groups (Yes – No)	
	Yes (N=41)		No (N=111)			
	n	%	n	%	% (CI)	P value
~~Changes made in previous 6 months~~What changes have you made to your diet during the last 12 months? (Tick all that apply)						
Reduced my fat intake	35	85.4	66	59.5	25.9 (11.7 to 40.1)	0.003
Reduced my sugar intake	24	58.5	43	38.7	19.8 (22.0 to 37.4)	0.029
Reduced my portion sizes	28	68.3	58	52.3	16.0 (-0.97 to 33.0)	0.077
What changes have you made to your activity levels in the last 12 months? (Tick all that apply)						
Used the stairs ~~more~~instead of taking the lift	17	41.5	31	27.9	13.6 (-3.7 to 30.8)	0.111
Joined a gym specifically to lose weight	13	31.7	20	18.0	13.7 (-2.2 to 29.6)	0.069
Get off one stop earlier when travelling by bus ~~earlier~~or tube	8	19.5	16	14.4	5.1 (-8.7 to 8.9)	0.444
Walk ~~more~~rather than take car for journeys that are less than one mile	21	51.2	44	39.6	11.6 (-6.2 to 29.4)	0.200
~~Changes likely to~~How will you continue to manage~~intain~~ your weight will you						
Monitor your food intake	32	78.1	59	52.7	25.4 (9.69 to 41.1)	0.005
Control your portion~~s size~~	26	63.4	59	52.7	10.7 (-6.67 to 28.1)	0.237
Use a pedometer	13	31.7	20	17.9	13.8 (-2.1 to 29.8)	0.065
Monitor your ~~physical~~ activity patterns	23	56.1	44	39.3	16.8 (-0.86 to 34.4)	0.063

*Data missing for 75 participants who did not complete this section of the questionnaire.

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Table 8: Studies on weight loss conducted in general practice in the UK with 12 months follow-up.

Study	Design	Intervention	Eligibility criteria	Weight (Kg) at baseline Mean (sd)	Percent (n/N) followed-up at 12 months	Mean weight change (Kg) at 12 months				Lost ≥5% baseline weight in intervention group % (95% CI)
						Intervention	Control	Difference (95% CI)	P value	
Moore et al BMJ (2003)[69]	Cluster RCT	Trained GPs, nurses	BMI≥30	-	67.7 (565/834)	-0.6	-0.9	1.0[1]	0.5	-
McConnon et al BMC (2007)[52]	RCT	Access to website	BMI≥30; Access to Internet	98.4 (17.4)	59.3 (131/221)	-1.3	-1.9	0.6 (1.4 to 2.5)	0.56	22
Davies et al , DESMOND BMJ (2007)[19]	RCT	Group sessions	Newly diagnosed Type 2 diabetes	-	90.9 (729/824)	-3.0	-1.9	-1.0 (-1.9 to -0.12)	0.03	-
Ross et al, Counterweight BJGP (2008)[51]	Audit	Trained practice nurses	BMI≥30; BMI≥28 with co-morbidities	-	45.2 (642/1419)	-3.0	-	-	-	31 (27-34)
Ahern et al, Weight Watchers BMC (2011)[70]	Audit	Weight Watchers meetings	BMI≥30; NHS Referral scheme	94.3 (IQR 83.7-107.7)	53%	Median= -2.8	-	-	-	33
Jebb et al, Weight Watchers Lancet (2011)[53]	RCT	Weight Watchers meetings	BMI 27-35 + 1risk factor	86.7	57.5 (444/772)	-5.1	-2.2	-3.2 (-4.2 to -2.1)	<0.0001	47*
Jolly et al BMJ (2011)[54]	RCT	various	White BMI≥30/≥28+co-morbidity S Asian BMI≥25/≥23+co-morbidity	91.7 (17.9)	70.5 (522/740)	-3.5	-1.1	-2.5 (-4.2 to -0.8)	0.02	31 (22 to 41)

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CAMWEL	RCT	One-to-one sessions	BMI≥25	92.3 (18.3)	57 (217/381)	-2.4	-1.3	1.1 (-0.32 to 2.5)	0.13	34 (25-43)

[1]Difference between groups at 12 months

Appendix: The structure of the CAMWEL intervention programme

Session Number	Week	Topic Materials	Handouts	
1	0	Getting started: establish working relationship and good rapport with participant; elicit personal reasons for losing weight, build commitment to program, and introduce lifestyle changes approach. BHF 'So you want to lose weight' booklet	Sequence of topics Appointment card Benefits of Healthy Habits Recording your routines Deciding to Change	Behaviour Change Diary Food Diary Activity Diary
2	2	Changing habits: Review progress, explain importance of changing habits permanently and introduce the five steps to solving problems.	Problem Solving Build a Better Recipe Just One More Step	(Behaviour Change Diary) (Food Diary) (Activity Diary)
3	4	Healthy eating: Review progress, explain importance of regular meals, portion sizes, keeping a record and discuss making easy food swaps. (Adam Portion pots; 100 kcal portion size food box)	FSA EatWell booklet Rate Your Plate Easy Food Swaps Healthy Drinks Food labels card	(Activity Diary)
4	6	Let's get active: Review progress, explain importance of activity guidelines and discuss ways of incorporating physical activity into participant's lifestyle.	Being Active Your Guide to Walking in Camden Cut the fat and sugar Camden outdoor gyms	Steps chart Individual printed weight graph (Rate your plate)
5	8	Taking charge of your environment: Review progress, explain importance of cues and discuss ways of changing the environment to make losing weight the 'easy' option.	Your Environment Goals & Rewards Eat Well on the Cheap	(Rate your plate) (Steps Chart) Individual printed weight graph
6	10	Eating when out and about: Review progress, explain keys to making healthy choices when out and about and discuss alcohol if appropriate.	Healthy choices Alcohol and your diet Eating when out and about	(Rate your plate) (Steps chart)
7	12	Tip the calorie balance: Review progress at 3-month stage of programme; explain energy balance equation, importance of healthy eating, being active, social support and action planning.	Tipping the calorie balance Individual printed weight graph	(Steps Chart) (Rate your plate)
8	15	Positive thinking: Review progress and introduce ways to stop negative thoughts and 'talk back' with positive ones.	Positive Thinking Camden Walk4Life maps	(Food diary) (Activity diary) (Steps chart) (Rate your plate) (Behaviour Change Diary)

9	18	Getting off the slippery slope: Review progress, identify reasons for slips and ways of getting back on course.	Slippery Slope Camden Walk4Life maps BHF 'Healthy meals, Healthy Heart' or 'Food should be fun & healthy' menus book Individual printed weight graph	
10	21	Social eating: Review progress, discuss social settings where it may be difficult to stay in control of eating healthily and ways to overcome this and enjoy healthy social eating.	Social eating Individual printed weight graph	
11	27	Staying on course: Review progress, identify successful changes made and identify situations where participant not in control and discuss ways of overcoming barriers.	Staying on course Healthy snacking 100 Calorie portions Meal plans- Indian/ Minimum cooking Individual printed weight graph	(Rate your plate) (Food diary) (Steps chart) (Activity Diary)
12	31	Staying active: Review progress; discuss additional changes made and how further activity can be added into lifestyle.	Staying active Individual printed weight graph	(Activity Diary) (Steps chart)
13	35	Managing stress: Review progress; discuss how stress affects weight and ways to manage stress.	Day to day stress Individual printed weight graph	(Activity Diary) (Steps chart) (Rate your plate) (Food Diary)
14	47	Reshaping habits: Review progress since start of programme; discuss ways of continuing to lose/ maintain changes in the long term.	Reshaping habits Cancer Research UK's Ten top tips Camden architecture & walking guide Travel Camden: Camden walking map; Belsize walk; Jubilee Walk Individual printed weight graph Certificate of Achievement	(Rate your plate) (Food Diary) (Steps chart) (Activity Diary)

References

1. Whitlock, G., et al., *Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies.* Lancet, 2009. **373**(9669): p. 1083-96.
2. WHO, *Global Health Risks: Mortality and burden of dieases attributable to selected major risks*. 2009, World Health Orgainisation: Geneva, Switzerland.
3. Finucane, M.M., et al., *National, regional, and global trends in body-mass index since 1980: systematic analysis of health examination surveys and epidemiological studies with 960 country-years and 9·1 million participants.* The Lancet, 2011. **377**(9765): p. 557-567.
4. Whitlock, G., S. Lewington, and C.N. Mhurchu, *Coronary heart disease and body mass index: a systematic review of the evidence from larger prospective cohort studies.* Semin Vasc Med, 2002. **2**(4): p. 369-81.
5. Haslam D, J.W., *Obesity.* Lancet, 2005. **366**: p. 1197-1209.
6. Foresight, *Tackling Obesities: Future Choices – Project Report.* 2007.
7. Craig R, Mindell .J. (eds), *2010 Health Survey for England*. 2011, The NHS Information Centre: Leeds.
8. Perri, M.G., et al., *Extended-care programs for weight management in rural communities: the treatment of obesity in underserved rural settings (TOURS) randomized trial.* Arch Intern Med, 2008. **168**(21): p. 2347-54.
9. Perri, M.G., S.F. Sears, Jr., and J.E. Clark, *Strategies for improving maintenance of weight loss. Toward a continuous care model of obesity management.* Diabetes Care, 1993. **16**(1): p. 200-9.
10. Kinmonth, A.-L., et al., *Efficacy of a theory-based behavioural intervention to increase physical activity in an at-risk group in primary care (ProActive UK): a randomised trial.* The Lancet, 2008. **371**(9606): p. 41-48.
11. Wing, R.R. and S. Phelan, *Long-term weight loss maintenance.* Am J Clin Nutr, 2005. **82**(1 Suppl): p. 222S-225S.
12. Aucott, L., et al., *Weight loss in obese diabetic and non-diabetic individuals and long-term diabetes outcomes--a systematic review.* Diabetes Obes Metab, 2004. **6**(2): p. 85-94.
13. Poobalan, A., et al., *Effects of weight loss in overweight/obese individuals and long-term lipid outcomes--a systematic review.* Obes Rev, 2004. **5**(1): p. 43-50.
14. Avenell, A., et al., *Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement.* Health Technol Assess, 2004. **8**(21): p. iii-iv, 1-182.
15. Norris, S.L., et al., *Long-term effectiveness of weight-loss interventions in adults with pre-diabetes: a review.* Am J Prev Med, 2005. **28**(1): p. 126-39.
16. Norris, S.L., et al., *Long-term effectiveness of lifestyle and behavioral weight loss interventions in adults with type 2 diabetes: a meta-analysis.* Am J Med, 2004. **117**(10): p. 762-74.
17. Potter, M.B., J.D. Vu, and M. Croughan-Minihane, *Weight management: what patients want from their primary care physicians.* J Fam Pract, 2001. **50**(6): p. 513-8.
18. Nanchahal, K., et al., *Weight-management interventions in primary care: a pilot randomised controlled trial.* Br J Gen Pract, 2009. **59**(562): p. e157-66.
19. Davies, M.J., et al., *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 controlled trial.* BMJ, 2008. **336**(7642): p. 491-5.
20. Trueman, P., et al., *Long-term cost-effectiveness of weight management in primary care.* Int J Clin Pract, 2010. **64**(6): p. 775-83.
21. Wardle, J., Johnson, F., *Weight and dieting: examining levels of weight concern in British adults.* Int J Obes Relat Metab Disord, 2002. **26**(8): p. 1144-9.
22. Campbell, M., et al., *Framework for design and evaluation of complex interventions to improve health*. BMJ, 2000. **321**(7262): p. 694-6.

23. Jones, L.R. and T.A. Wadden, *State of the science: behavioural treatment of obesity.* Asia Pac J Clin Nutr, 2006. **15 Suppl**: p. 30-9.
24. Bandura, A., *Health Promotion by Social Cognitive Means.* Health Educ Behav, 2004. **31**(2): p. 143-164.
25. Locke, E.A. and G.P. Latham, *Building a practically useful theory of goal setting and task motivation : A 35-year odyssey.* American Psychologist, 2002. **57**(9): p. 705-717.
26. Alemi, F., et al., *Continuous self-improvement: systems thinking in a personal context.* Jt Comm J Qual Improv, 2000. **26**(2): p. 74-86.
27. NICE, *Obesity: Quick reference guide 2*. 2006, National Institute for Health & Clinical Excellence: London, UK.
28. Koenigsberg, M.R., D. Bartlett, and J.S. Cramer, *Facilitating treatment adherence with lifestyle changes in diabetes.* Am Fam Physician, 2004. **69**(2): p. 309-16.
29. Department of Health, *Health Trainers - Review to date*. 2009, Department of Health: London, UK.
30. Costain, L., Kellow, J, Walton, R, , *The Calorie, Carb and Fat Bible 2009*. 2009: Weight Loss Resources.
31. British Heart Foundation, *So You Want to Lose Weight... For Good*, in *British Heart Foundation*. 2005: London, UK.
32. *NHS Camden Annual Report & Accounts*. 2009/10, Camden Primary Care Trust
33. LHA, *Health Profile 2010: Camden*. 2010, Local Health Authority.
34. Patrick, D.L., D.M. Bushnell, and M. Rothman, *Performance of Two Self-Report Measures for Evaluating Obesity and Weight Loss.* Obes Res, 2004. **12**(1): p. 48-57.
35. Olsson, I., A. Mykletun, and A.A. Dahl, *The Hospital Anxiety and Depression Rating Scale: a cross-sectional study of psychometrics and case finding abilities in general practice.* BMC Psychiatry, 2005. **5**: p. 46.
36. Rosenberg, M., *Society and the Adolescent Self Image.* 1965, Princeton, NJ: Princeton University Press.
37. Broadhead WE, G.S., de Gruy FV, et al. , *The Duke-UNC Functional Social Support Questionnaire: measurement of social support in family medicine patients. .* Med Care, 1988. **26**(7): p. 709-723.
38. Karlsson, J., et al., *Psychometric properties and factor structure of the Three-Factor Eating Questionnaire (TFEQ) in obese men and women. Results from the Swedish Obese Subjects (SOS) study.* Int J Obes Relat Metab Disord, 2000. **24**(12): p. 1715-25.
39. Besson, H., et al., *Estimating physical activity energy expenditure, sedentary time, and physical activity intensity by self-report in adults.* Am J Clin Nutr. **91**(1): p. 106-114.
40. Department for Communities and Local Government, *The English Indices of Deprivation 2010*. 2010: London, UK.
41. Glasgow, R.E., et al., *Development and validation of the Patient Assessment of Chronic Illness Care (PACIC).* Med Care, 2005. **43**: p. 436 - 444.
42. Schmittdiel, J., et al., *Patient Assessment of Chronic Illness Care (PACIC) and improved patient-centered outcomes for chronic conditions.* J Gen Intern Med, 2008. **23**(1): p. 77-80.
43. Scott, N.W., et al., *The method of minimization for allocation to clinical trials. a review.* Control Clin Trials, 2002. **23**(6): p. 662-74.
44. Douketis, J.D., et al., *Systematic review of long-term weight loss studies in obese adults: clinical significance and applicability to clinical practice.* Int J Obes (Lond), 2005. **29**(10): p. 1153-67.
45. Carpenter JR, Kenward M *Missing Data in Clinical Trials - A Practical Guide.* UK National Health Service, National Co-ordinating Centre for Research on Methodology., 2008.
46. Rubin, D.B., *Multiple Imputation for Nonresponse in Surveys*. 1987: Wiley-Blackwell.
47. Kenward, M.G. and J. Carpenter, *Multiple imputation: current perspectives.* Stat Methods Med Res, 2007. **16**(3): p. 199-218.

48. Royston P, *Multiple imputation of missing values.* STATA Journal, 2004. **4**(3): p. 227-241.
49. Maciejewski, M.L., D.L. Patrick, and D.F. Williamson, *A structured review of randomized controlled trials of weight loss showed little improvement in health-related quality of life.* Journal of Clinical Epidemiology, 2005. **58**(6): p. 568-578.
50. Nanchahal, K., et al., *Challenges in recruitment to clinical trials and lessons learned from a randomized controlled trial of a weight management intervention in general practice*, in *XI International Conference on Obesity*. 2010, IASO: Stockholm, Sweden.
51. Ross, H., et al., *Evaluation of the Counterweight Programme for obesity management in primary care: a starting point for continuous improvement.* Br J Gen Pract, 2008. **58**(553): p. 548-54.
52. McConnon, A., et al., *The Internet for weight control in an obese sample: results of a randomised controlled trial.* BMC Health Serv Res, 2007. **7**: p. 206.
53. Jebb, S.A., et al., *Primary care referral to a commercial provider for weight loss treatment versus standard care: a randomised controlled trial.* Lancet, 2011. **378**(9801): p. 1485-92.
54. Jolly, K., et al., *Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: Lighten Up randomised controlled trial.* BMJ, 2011. **343**.
55. Inelmen, E.M., et al., *Predictors of drop-out in overweight and obese outpatients.* Int J Obes Relat Metab Disord, 2005. **29**(1): p. 122-8.
56. Thomas, E.C., P.R.; Paterson, S.M.; Dziedzic, K.; Hay, E.M., *What influences participants' treatment preference and can it influence outcome? Results from a primary care based randomised trial for shoulder pain.* British Journal of General Practice, 2004. **54**(499): p. 93-96.
57. Woodcock, J., et al., *Public health benefits of strategies to reduce greenhouse-gas emissions: urban land transport.* Lancet, 2009. **374**(9705): p. 1930-43.
58. NOF, *National Obesity Forum - Managing Obesity in Primary Care*. 2004.
59. Byoni, *Perfect Diet Tracker Software*. 2010.
60. Abraham, C. and S. Michie, *A taxonomy of behavior change techniques used in interventions.* Health Psychol, 2008. **27**(3): p. 379-87.
61. Miller, W.R. and G.S. Rose, *Toward a theory of motivational interviewing.* Am Psychol, 2009. **64**(6): p. 527-37.
62. Foreyt, J.P. and W.S. Poston, 2nd, *What is the role of cognitive-behavior therapy in patient management?* Obes Res, 1998. **6 Suppl 1**: p. 18S-22S.
63. National Health Service, *Change 4 Life - Get active with Camden's Walking Maps*, in *NHS Camden*. 2009: London, UK.
64. *Travel Camden: Camden Walking Map*. 2009, Z-Cards Ltd: London, UK.
65. *Camden Architecture & Walking Guide*. 2009, Z Cards Ltd: London, UK.
66. *Belsize Walk: Primrose Hill to Parliament Hill*. 2005: London, UK.
67. *Jubilee Walkway Route Map and Guide*. 2009: London, UK.
68. *Get Walking Keep Walking*, in *The Ramblers*. 2009: London, UK.
69. Moore, H., et al., *Improving management of obesity in primary care: cluster randomised trial.* BMJ, 2003. **327**(7423): p. 1085.
70. Ahern, A., et al., *Weight Watchers on prescription: An observational study of weight change among adults referred to Weight Watchers by the NHS.* BMC Public Health. **11**(1): p. 434.

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A pragmatic randomised controlled trial in primary care of the Camden Weight Loss (CAMWEL) programme.

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KN, JT, NT, DH, AK, SE & AH contributed to conception and design.
MH, JT, KN, EH, AS, UG contributed to acquisition of data
KN, TP, EH, MK, AH contributed to analysis and interpretation of data
KN drafted the article
KN, JT, AH revised it critically for important intellectual content
All authors contributed to final approval of the version to be published

Summary

Article focus

- Evaluated structured one-to-one weight management programme
- Delivery by trained non-specialists
- Primary care setting

Key messages

- Clinically important level of weight loss achieved by higher proportion of participants in intervention (33%) compared to control group (20%)
- Intervention group reported higher level of satisfaction with support received
- Primary care interventions are unlikely to be sufficient to tackle the obesity epidemic

Strengths and Limitations

- Relatively low threshold of BMI≥25 for inclusion, with few exclusions, so wide applicability of findings
- High loss to follow-up (43%), although similar to other studies in the area; used multiple imputation to counter any biases.

Abstract (max 300 words)

- **Objectives** - To evaluate effectiveness of a structured one-to-one behaviour change programme on weight loss in obese and overweight individuals.
- **Design** - Randomized controlled trial.
- **Setting** - 23 general practices in Camden, London.
- **Participants** - 381 adults with body mass index ≥ 25 kg/m^2 randomly assigned to intervention (n=191) or control (n=190) groups.
- **Interventions** - A structured one-to-one programme, delivered over 14 visits during 12 months by trained advisors in three primary care centres, compared to usual care in general practice.
- **Outcome measures** – Changes in weight, %body fat, waist circumference, blood pressure and heart rate between baseline and 12 months
- **Results** - 217/381 (57.0%) participants were assessed at 12 months: missing values were imputed. The difference in mean weight change between the intervention and control groups was not statistically significant [0.70 kg (0.67 to 2.17, P=0.35)], although a higher proportion of the intervention (32.7%) than control group (20.4%) lost 5% or more of their baseline weight (Odds ratio: 1.80 (1.02 to 3.18, P=0.04)). The intervention group achieved a lower mean heart rate (mean difference 3.68 beats per minute (0.31 to 7.04, P=0.03)) than the control group. Participants in the intervention group reported higher satisfaction and more positive experiences of their care compared to the control group.
- **Conclusions** – Although there is no significant difference in mean weight loss between intervention and control groups, trained non-specialist advisors can deliver a structured programme and achieve clinically beneficial weight loss in some patients in primary care. The intervention group also reported a higher level of satisfaction with the support received. Primary care interventions are unlikely to be sufficient to tackle the obesity epidemic and effective population wide measures are also necessary.
- **Trial registration –** Clincaltrials.gov NCT00891943

WHAT IS ALREADY KNOWN ON THIS TOPIC

The NICE guidelines for the management of overweight and obese patients provide general recommendations for discussing weight and improving diet and physical activity levels.

However, there are no randomised controlled trials of one-to-one weight management programmes in non-diabetic patients with 12-months follow-up in general practice in the UK.

WHAT THIS STUDY ADDS

A structured weight management programme for overweight and obese patients delivered by trained non- specialists was associated with a clinically important level of weight loss, although there was no strong evidence that the average difference in weight between groups was improved by the intervention.

Intervention participants reported greater satisfaction with care than did the usual care participants.

Primary care interventions are unlikely to be sufficient to address the obesity epidemic and need to be complemented with robust public health policies.

Introduction

Overweight and obesity are major public health problems,[1] representing the fifth leading cause of death in the world[2] and an increasing global challenge.[3] Obesity has severe impacts on health, increasing the risk of type 2 diabetes, hypertension, some cancers, heart and liver disease.[1, 4 5] The Foresight Report[6] estimated the National Health Service costs attributable to obesity in 2007 as £4.2 billion. In 2010, 68% of men and 58% women in England were overweight or obese (Body Mass Index (BMI) ≥25 kg/m^2).[7]

Obesity is a chronic condition requiring lifelong management as weight loss is often regained.[8, 9] Achieving changes in behaviour is challenging,[10] largely due to an inability to maintain healthy eating and physical activity behaviours.[11] Modest weight loss (3-9%) can prevent type 2 diabetes, improve fasting plasma glucose, blood pressure and lipids, and reduce antihypertensive medication.[12, 13 14-16] Most overweight patients would like help with weight management from their general practices,[17] is feasible in the short-term (3-12 months)[18, 19] and estimated to be cost saving to the NHS,[20] although few recall receiving weight control advice from a health professional.[21]

The aim of this study was to develop and evaluate the efficacy of an intervention programme with twelve months follow up, for an ethnically diverse overweight/obese population recruited from general practices in a pragmatic randomised controlled trial following the Medical Research Council framework for complex interventions.[22] To our knowledge, there are currently no other published randomised controlled trials of one-to-one lifestyle interventions delivered in UK general practice to overweight/obese patients without co-morbidities.

Methods

Aims

The aim of the study was to assess, by means of a pragmatic parallel group randomized controlled trial (RCT), the effects on anthropometric measures, health-related parameters and the sense of well-being of offering individualized weight management advice in primary care to overweight/obese people who wished to lose weight; and to identify the key factors influencing the outcome of the intervention.

The primary outcome was the difference between the control and intervention groups in changes in body weight, and the secondary outcomes were differences in waist circumference, percent body fat, blood pressure and heart rate from baseline to 12 months.

Interventions

The intervention combined evidence-based components recognized 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 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).[18] Six CAMWEL advisors were recruited from various occupational backgrounds including healthcare, in line with the NHS health trainers initiative.[29] The advisors received initial training over two days, and further meetings with the research team every three to four 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 behaviour 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'. Participants were invited to attend 30-minute sessions with the advisor every fortnight for the first 12 weeks, every three weeks for 12 weeks, and finally monthly for the next 12 weeks, making a total of 14 sessions. 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,[30] a kit including 100 calorie portions of various food items, and Adams Food and Alcohol Portion Pots (www.adamsportionpot.com). 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).

There is no current comparator 'gold standard' treatment programme available for weight management in general practice. In this pragmatic trial of a complex intervention, we assess the benefit of the intervention compared to routine clinical practice. We provided a copy of the Quick reference NICE clinical guideline on Obesity to all participating 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 (BHF) booklet: 'So you want to lose weight … for good'.[31]

Recruitment

All general practices in Camden were visited and invited to participate in the trial. Participants were recruited between July 2009 and January 2010 from 23 of 39 NHS Camden general practices. The London Borough of Camden has areas of relative affluence alongside areas of relative deprivation, with approximately 35% of the population living in areas classified as some of the most deprived in England.[32] Education levels are also disparate, with 47% of people in employment being educated to degree level or above, whilst 17% of working age people have no qualifications.[33] Camden has an ethnically diverse population, with 27% belonging to minority ethnic groups.[33]

Several recruitment approaches were used. Primarily, participating practices wrote to a sample of patients with body mass index (BMI) ≥25 kg/m^2; GPs and Practice Nurses (PNs) were provided with referral 'prescription' pads with a tear-off slip to be given to the patient with contact details of the trial office; and posters and flyers were placed in practice waiting areas and local pharmacies. During the final six weeks of the recruitment period, three practices supplemented recruitment by sending text messages to potentially eligible patients using their electronic record (EMIS) and messaging (iPLATO) systems. All practices were reimbursed for time spent on recruitment.

Baseline measurements

Potential participants were screened by telephone for eligibility (MH, EH, TP). Inclusion criteria were age 18 years and above, BMI≥ 25 kg/m^2, attending a participating practice and willing to attend visits with a CAMWEL advisor over 12 months. Exclusion criteria were pregnancy or lactation, diagnosis of renal failure, use of a pacemaker, recent diagnosis of cancer, or participation in another weight management study. Following GP consent, participants were scheduled for screening appointments with a researcher (MH) at one of

three practices. The study was explained and the participant invited to give informed written consent and to complete the baseline questionnaire. Height (without shoes) was 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 percent body fat, basal metabolic rate and metabolic age (age expected for a given value of basal metabolic rate). Waist was measured mid-way 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 where possible. The printout from the Tanita scales, including weight, BMI and metabolic age, was given to all participants.

Outcomes

All participants were invited for follow up at 6 and 12 months. A letter was sent three weeks prior to the due date, followed by a telephone call to arrange the appointment. Three attempts were made to contact each participant. Measurements taken at baseline were repeated and participants were asked to complete a questionnaire. A £30 voucher was provided for their time to all participants who completed each follow-up appointment.

The self-completed questionnaires included the following validated measures: EuroQol Visual Analogue Scale (EQ-VAS), Obesity and Weight Loss Quality-of-Life (OWLQOL)[34]; Hospital Anxiety and Depression Scale (HADS)[35]; Rosenberg measure of self-esteem[36]; Duke-UNC Functional Social Support Questionnaire (FSSQ)[37]; Three-Factor Eating Questionnaire (TFEQ-18)[38]; and physical activity (RPAQ)[39]; as well as socio-demographic information. Deprivation was ascertained using the Index of Multiple Deprivation (IMD) based on the participant's home address post code.[40]

In addition, at follow-up we used the Patient Assessment of Care for Chronic Conditions (PACIC) [41, 42] to assess the participants' views on the care they received from the advisors and the GP practice on helping them lose weight. A brief series of statements was used to assess participants' confidence in their ability to manage their weight on a scale of one (disagree strongly) to four (agree strongly). Further questions asked about the type of help received from the GP practice regarding weight loss, changes made in behaviours related to weight management, and experience of study participation. Participants in the intervention group also completed an additional section to ascertain how helpful they found the sessions and materials provided as part of the CAMWEL programme.

Randomization

Participants were randomly allocated (allocation ratio 1:1) to the control or intervention group (TP, EH, AS), using a computer-generated randomization application written in VBA for MS Access (TP). The Taves method of minimization[43] was used to ensure the groups were balanced for general practice, gender, age group (≤50/ >50 years), BMI category (≤30/>30 kg/m^2), diagnosis of diabetes (yes/no), and taking anti-psychotic medication or not.

Blinding

The study was single-blinded with members of the study team assessing baseline and follow-up measurements blinded to group assignment.

Sample size

In our pilot study participants had a mean weight of 98.1 kg (SD 17.3 kg) at baseline.[18] Since a loss of 5-10% of body weight in obese adults is associated with significant reductions in the risk of obesity co-morbidities, we considered a difference in weight between groups of 7% at 12 months follow-up to be clinically important. For the sample size calculation, we wished to detect a mean weight difference of 6.9 kg 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 conservatively set at 0.7. We thus calculated a total sample size of 228 (114 per group). Assuming a loss to follow up at 12 months of 40%,[44] it was estimated that 380 participants would be required.

Statistical methods

Comparisons between groups for continuous variables were performed using two-sample t-tests and regression methods, adjusting for the baseline value of the variable. Chi-sq 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. Exclusion of subjects with missing data is inefficient and can lead to biased results if those dropped are atypical in some respect[45] and MI can both increase efficiency and reduce bias in such settings.[46,47] 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.[48] 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. For all outcomes the following baseline variables were included: age, weight, percent body fat, BMI, fat mass, metabolic age, deprivation status and employment status as well as totals from the OWLQOL, EQVAS, HADS anxiety, TFEQ emotional eating and RPAQ scales. The imputation procedure was carried out separately for the two groups (intervention and control) and the resulting multiply imputed datasets were combined for the final MI analysis. A total of 200 imputations were used to stabilize the results and to ensure negligible loss of power.[45] 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 version 11.

Ethical approval

The study was approved by the London School of Hygiene & Tropical Medicine Ethics Committee, the Camden and Islington Community Research Ethics Committee (reference number 09/H0722/22) and the North Central London Research Consortium.

Results

Participants were followed up at 6 months between January 2010 and July 2010; and at 12 months between July 2010 and January 2011. Participant flow through the trial is shown in Figure 2.

Baseline characteristics

We recruited 381 participants with a median age of 48.5 years (inter-quartile range 37.5 to 60.4), weighing 60.1 to 152.2 kg, with waist circumference of 76 to 147 cm. The majority (72%) were women, 12% (47/381) had diagnosed diabetes, 1.3% (5/381) were on anti-psychotic medication, 60% were in employment, 47% were university graduates and 73% described their ethnicity as white (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

Measurements were obtained for 69% (n=263) of the sample at 6 months and 57% (n=217) at 12 months. 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 percent body fat, and were less likely to be from a deprived area than those not followed up (Table 2).

Primary Outcome

Based on the intention-to-treat analysis using imputed missing values (Table 3), at 12 months 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 to the usual care (20.4%, 95% CI: 13.3 to 27.5%) group (odds ratio 1.80 (1.02 to 3.18, P=0.04).

Secondary Outcomes

The intervention programme was also associated with weak evidence of beneficial trends in waist circumference, percent body fat, and percent weight change. Heart rate was reduced by 3.7 (0.3 to 7.0, P=0.03) beats per minute in the intervention group compared to the control group.

Based on data for participants who completed the 12-month follow-up (Table 3) a higher proportion (one in three compared to one in five) in the intervention group had lost at least 5% of their initial weight (difference 14.7% (3.0 to 26.4, P=0.01)) and experienced a greater average reduction in waist circumference (difference 1.88 cm (0.01 to 3.76, P=0.05)) compared to those in the control group. Weak evidence of reductions in weight, %body fat, BMI, blood pressure and heart rate were observed in the intervention compared to the control group. The absolute risk reduction for losing 5% baseline weight was 14.7 % (3.0 to 26.4) and the number needed to treat was 6.8 (3.8 to 33.2). A higher proportion of those in the intervention group (84%, 21/25) who had lost ≥5% at 6 months had managed to keep this level of weight loss at 12 months compared to those in the control group (61.5%, 8/13).

We were unable to identify characteristics of the sub-group of participants more likely to lose 5% of their baseline weight.

No evidence of differences was found between the two groups on any of the psychological or quality of life measures.

Trial participation

Participants in the intervention group were more satisfied than those in the control group with the level of weight loss achieved and they found participation in the trial and feedback of physical measurements helpful (Table 4). The intervention group also reported receiving more patient centred care than those in the control group as measured by the PACIC scales (Table 5). Detailed analysis of the interviews and focus groups with a sub-set of the participants will be reported elsewhere.

The intervention programme

The majority of participants (38/56, 67.9%) reported that a regular meeting with the advisor was the most helpful aspect of the programme; the least helpful being the use of handouts in improving eating habits (17/56, 30.3%). The majority (84%) said they would choose to continue to meet an advisor beyond the 12 months of the current study, with most (73%) preferring to see the advisor at least every four weeks.

Behaviours associated with losing 5% or more of baseline weight

Participants who lost 5% or more of their baseline weight were more likely to state that they had reduced their fat and sugar intake in the previous six months than those who did not; there was no evidence of increasing levels of physical activity between the groups (Table 6). They also reported that attending regular meetings with a non-judgmental advisor, discussion on portion sizes and use of the pedometer were particularly useful and would continue to monitor food intake to maintain their weight.

Exploratory analysis

38 participants were known to have been prescribed drugs for weight loss or to have undergone weight loss surgery during the trial period. Of these, 27 were 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, p = 0.69). In analysis excluding these participants, those in the intervention group showed significantly greater reductions in weight (1.72 kg (0.29 to 3.14, P= 0.02)), waist circumference (2.52 cm (0.32 to 4.72, P=0.03)), BMI (0.63 kg/m2 (0.11 to 1.14, P=0.02)) and percent baseline weight loss (1.94% (0.32 to 3.56, P=0.02)) when compared with the control group at 12 months. In addition, a higher proportion of participants in the advisor group lost ≥5% of their baseline weight when compared to the control group (odds ratio 2.68 (1.13 to 5.70, P=0.03)).

The number of sessions attended was available for 87 participants of whom 40 (46%) attended more than 70% (10/14) of the available sessions. Half (50%) of the participants attending more than 70% of the programme lost 5% or more of their baseline weight compared to a quarter (23%) who attended fewer sessions (difference 26.5%; 95%CI: 6.9 to 46.3; p=0.01).

Discussion

Principal findings

The structured one-to-one weight loss programme delivered by non-specialists in general practice did not achieve the pre-specified difference in average weight loss of 7%. However it did result in a higher proportion of the participants losing 5% or more of their baseline weight compared to those randomized to usual care, which is considered a clinically important outcome in similar trials. This suggests that people likely to benefit from such a programme are a subset of the total study population but we were unable to identify particular characteristics that would permit identification of a receptive group in advance. There was some evidence that the intervention group experienced greater reductions in mean weight, waist circumference and % body weight than the control group. While the overall effects on weight loss are modest they are not unimportant.

Strengths and weaknesses of the study

The key strengths of the CAMWEL programme are its wide applicability to overweight and obese people from diverse backgrounds as there were few exclusions, feasibility of its delivery in primary care by non-specialist trained advisors and a patient-centred approach to making sustainable changes to diet and physical activity easily incorporated into peoples' daily lives.

Limitations include the slow initial recruitment although this improved over time, particularly with mobile phone text message use.[49] Loss to follow up was high (43%) although similar to that of other weight loss studies in the UK.[50, 51 52 53]The response rate in the DESMOND diabetes management trial[19] was substantially higher (91%), perhaps because participants were recently diagnosed diabetics and therefore highly motivated. High attrition in RCTs of weight loss is well recognized,[54] with a recent review reporting losses to follow-up of 30-60%.[44]

We used multiple imputation for missing values to counter any biases due to loss to follow-up as high level of attrition involves considerable uncertainty about outcomes for participants lost to follow-up. We included patients with BMI≥25 as NICE recommends treatment at this level although this relatively low threshold and broad inclusion criteria may have diluted the results in terms of average weight loss thus needing a larger sample to detect significant differences.

Participants in the control group were advised to contact their general practice to receive the usual care provided for weight loss. We provided all GPs with NICE guidelines on obesity and participants with the BHF booklet on weight loss as well as feedback on the measurements taken at six months. This provision of support could be one reason why participants in the control group also lost weight over the period of the trial esulting in greater similarity of changes in the two groups which would represent bias if the GPs altered their usual care by virtue of trial participation. Outcomes of RCTs may be influenced by participants' treatment preference[55] and research assessment procedures[56] triggering behaviour change and contributing to the weight loss seen in the control group.

Behaviour change interventions tend to be complex with multiple components and it is difficult to assess the effectiveness of different components. This was a pragmatic trial reflecting the likely performance of the programme as delivered in practice. While the fidelity

of the delivery of the intervention could be examined in more detail, we have shown that patient assessment of the structured support by trained advisors is significantly better than usual care.

Cost-effectiveness analyses are required to inform decision-making about the value of attaining these outcomes and will be reported in a separate paper.

Putting the study in context

Seven published RCTs of weight change conducted in UK general practice have been conducted (see Table 7). With the exception of a trial in newly diagnosed diabetics, these provided no strong evidence of differences in weight loss between intervention and control groups, except for those using a commercial provider (Weight Watchers). Our trial achieved results at least comparable with the more targeted interventions based in general practice.

Implications

We have demonstrated that one-to-one structured support by a trained advisor in general practice can help people wishing to lose weight to change their behaviour sufficiently to lead to a clinically important loss in weight. While one year may be too short a time to see all the benefits of a weight management intervention, the majority of participants found the Camwel programme helpful suggesting that they will continue to accrue benefit as they implement the behaviour change techniques learned during the study. Understanding how the intervention worked and why it worked just for some participants as well as its cost-effectiveness are important and we will explore these in our subsequent research. The importance of our results lies in their generalisability. Our results, together with those from other researchers, suggest that individual approaches in general practice can achieve modest benefits for the National Health Service. However, primary care interventions are unlikely to be sufficient to address the obesity epidemic and effective population wide policy measures are needed as well, including increasing energy expenditure through active travel [57] and reducing dietary intake.

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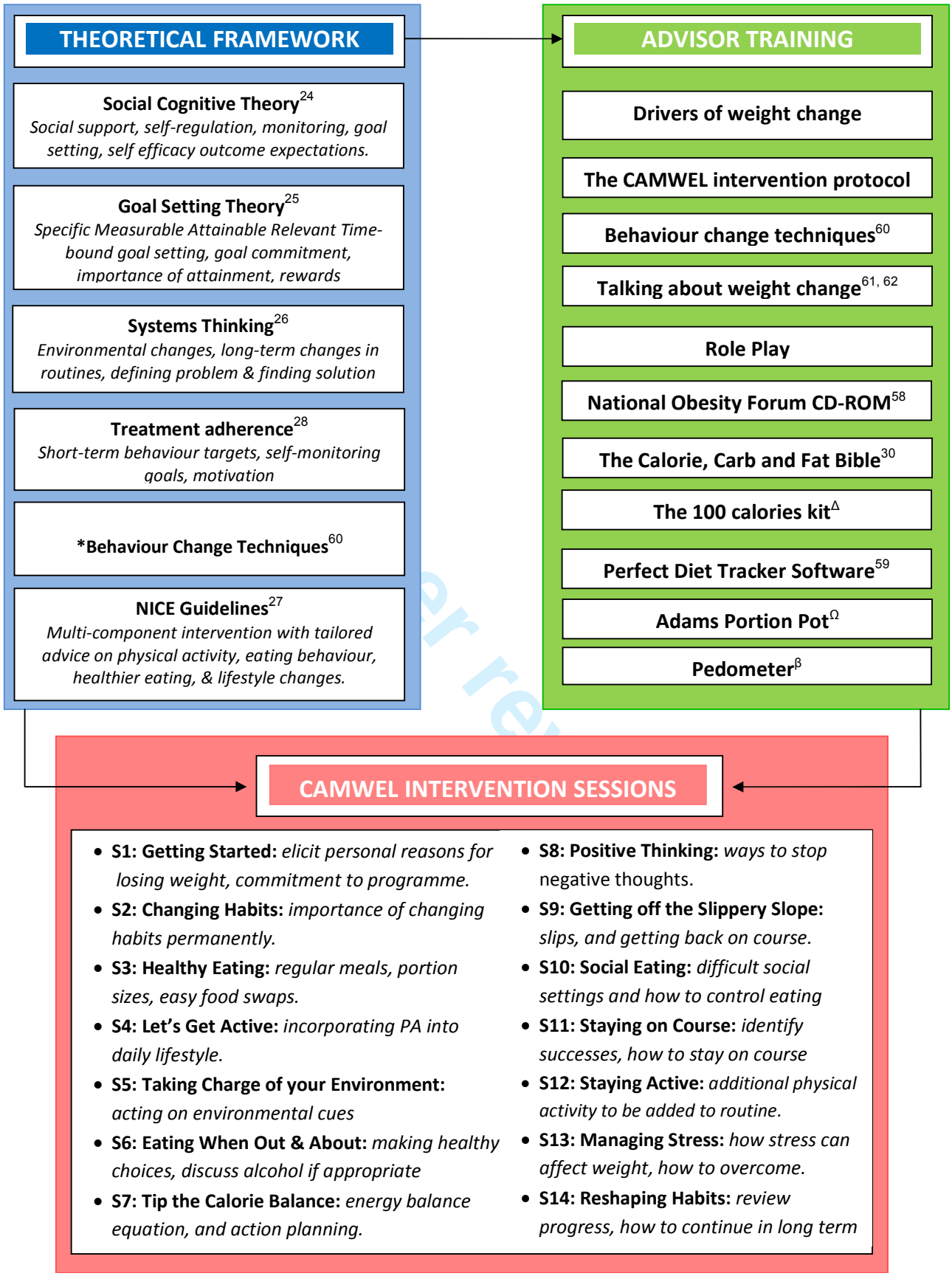
Competing interest

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that KN, TP, EH, MH, AS, UG and JT 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.

All authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis

Data sharing: no additional data available.

Figure 1: CAMWEL Intervention Framework



* Provide information on consequences, Prompt intention formation, Prompt barrier identification, Provide general encouragement, Model or demonstrate behaviour, Prompt specific goal setting, Prompt review of behavioural goals, Prompt self-monitoring of behaviour, Provide feedback on performance, Agree on behavioural contract, Plan social support, Prompt self-talk, Relapse prevention, Stress management, Motivational interviewing.

[Δ] *The 100 Calories Kit was designed by the CAMWEL Team, and was made up of 100 calorie portions of a variety of foods such as crisps, rice, pasta, biscuit, peanuts, and raisons.*

[β] *The pedometers used were DW701 Yamax Digiwalker for BMI<35, and NEW-LIFESTYLES NL-800 for BMI>35.*

[Ω] *Adams Portion Pot – www.adamsportionpot.com*

Figure 2 Flow of participants through the trial

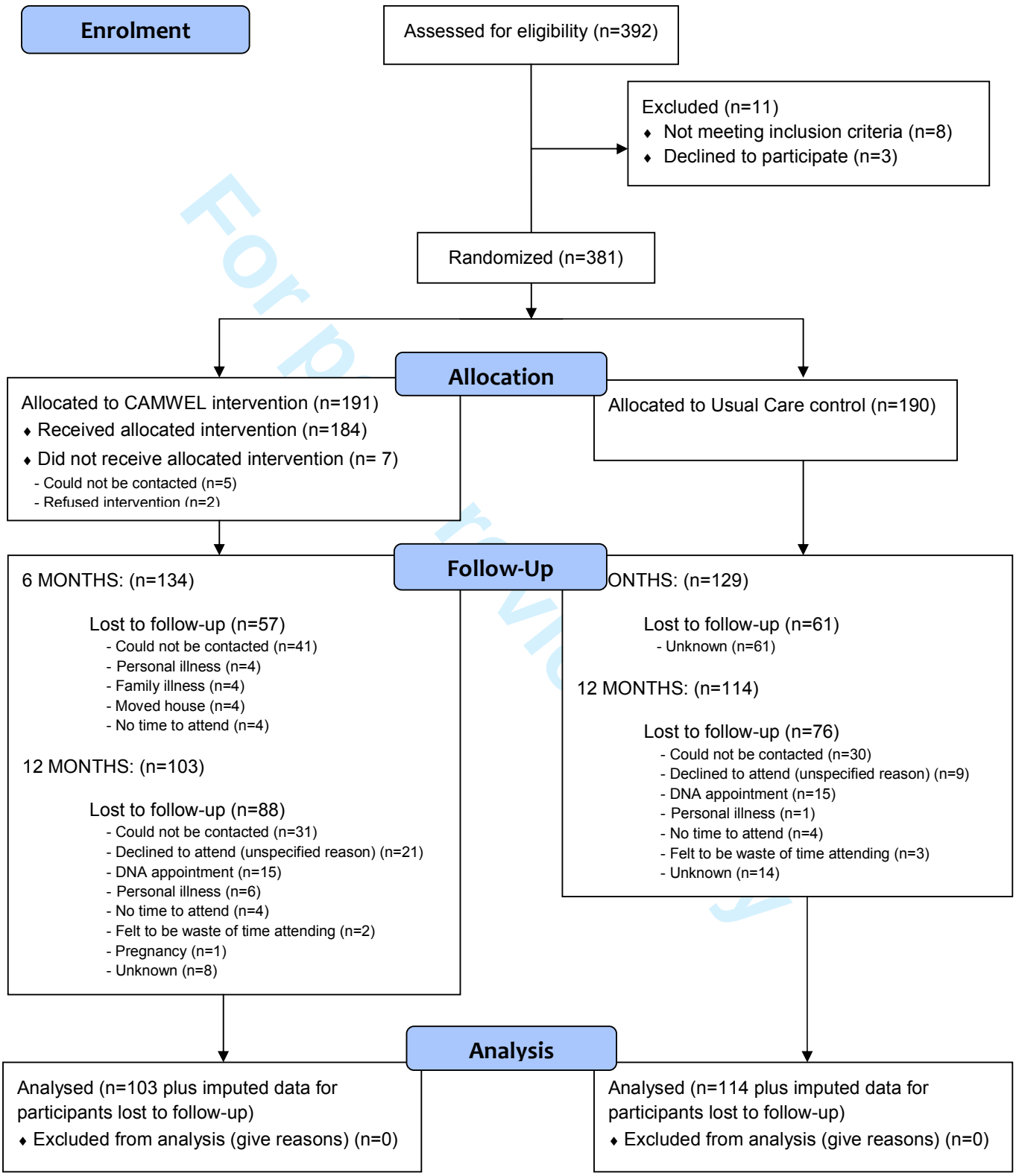


Table 1 Baseline characteristics of participants wishing to lose weight allocated to usual care (control) or to the CAMWEL programme (intervention). Values are means (standard deviations) unless stated otherwise. [Number of subjects may differ for each variable]

Characteristics	Control group (n=190)		Intervention group (n=191)		All (n=381)	
Age (years)	49.35	(15.45)	48.17	(14.09)	48.76	(14.77)
Age group (years)						
18- <35	20.53	(39)	20.94	(40)	20.73	(79)
35- <50	32.63	(62)	31.41	(60)	32.02	(122)
50- <60	19.47	(37)	24.08	(46)	21.78	(83)
≥60	27.37	(52)	23.56	(45)	25.46	(97)
Body weight (kg)	90.95	(18.12)	93.70	(18.40)	92.33	(18.29)
Waist circumference (cm)	105.83	(13.01)	107.56	(12.78)	106.70	(12.91)
Percent body fat	38.90	(7.83)	39.45	(8.06)	39.18	(7.93)
Fat mass (kg)	35.83	(12.82)	37.28	(12.70)	36.52	(12.76)
Muscle mass (kg)	52.18	(10.05)	53.39	(10.55)	52.76	(10.30)
Body mass index (kg/m^2)	33.02	(5.40)	33.92	(5.64)	33.47	(5.53)
% (n) BMI 25-<30	31.05	(59)	25.65	(49)	28.35	(108)
% (n) BMI ≥30	68.95	(131)	74.35	(142)	71.65	(273)
Systolic blood pressure (mm Hg)	126.42	(20.44)	127.43	(20.17)	126.92	(20.28)
Diastolic blood pressure (mm Hg)	82.15	(12.36)	83.40	(12.83)	82.77	(12.59)
Heart Rate (beats per minute)	76.68	(12.05)	75.94	(12.03)	76.32	(12.03)
Demographic details, % (n)						
Gender: Female	72.63	(138)	71.73	(137)	72.18	(275)
Ethnicity: White	70.63	(101)	74.25	(124)	72.58	(225)
Education						
No qualifications	14.19	(21)	8.82	(15)	11.32	(36)
O/A-level or equivalent	27.71	(41)	38.23	(65)	33.33	(106)
University degree	48.65	(72)	44.71	(76)	46.54	(148)
Employment						
Employed full-time	37.50	(57)	49.12	(84)	43.65	(141)
Employed half-time	19.08	(29)	14.04	(24)	16.41	(53)
unemployed	43.42	(66)	36.84	(63)	39.94	(129)
Area Deprivation (IMD)						
Lowest quartile (deprived)	26.06	(49)	23.94	(45)	25.00	(94)
2nd	25.00	(48)	23.40	(44)	24.20	(91)
3rd quartile	25.53	(47)	25.00	(47)	25.27	(95)
Highest quartile (affluent)	23.40	(44)	27.66	(52)	25.53	(96)
Family member overweight	78.67	(118)	77.33	(133)	77.95	(251)
Quality of Life (range of values for each scale)						
EQ-VAS (0, 100)	48.22	(30.18)	47.42	(30.68)	47.80	(30.40)
Self-esteem (1, 30)	18.51	(6.01)	18.95	(5.89)	18.74	(5.94)
Social support (1, 5)	3.84	(1.03)	3.91	(1.02)	3.87	(1.03)
Depression (0, 19)	6.07	(4.20)	6.34	(4.31)	6.21	(4.25)
Anxiety (0, 19)	7.81	(4.32)	8.66	(4.83)	8.25	(4.60)
Obesity-related QoL (0, 102)	51.29	(26.71)	48.55	(25.47)	49.85	(26.06)

EQ-VAS=EuroQol Visual Analogue Scale; Qol= Quality of Life

Table 2 Comparison of baseline characteristics of participants followed up at 12 months and those lost to follow-up (Mean (St Error) unless otherwise stated)

	Followed-up		Lost to follow-up		Difference (Lost to follow-up – Followed-up)	
					Mean	(95% CI)
Number (%)	217	(57.0)	164	(43.0)		
Age (years)	51.22	(1.01)	45.50	(1.10)	-5.72	(-8.68 to -2.77)
Weight (kg)	90.86	(1.19)	94.26	(1.48)	3.39	(-0.31 to 7.10)
Waist (cm)	106.50	(0.89)	106.96	(0.99)	-0.46	(-2.18 to 3.10)
%body fat	38.47	(0.55)	40.10	(0.60)	1.63	(0.02 to 3.24)
BMI (Kg/m^2)	32.92	(0.37)	34.18	(0.44)	1.26	(0.14 to 2.37)
Metabolic age (years)	60.70	(0.98)	56.50	(1.08)	-4.20	(-7.06 to -1.28)
Fat mass (kg)	35.26	(0.93)	38.14	(1.07)	2.88	(0.10 to 5.67)
Muscle mass (kg)	52.49	(0.76)	53.10	(0.86)	0.61	(-1.65 to 2.87)
Basal Metabolic Rate (kcal)	1682	(23.17)	1721	(27.23)	39.0	(-31.0 to 109.0)
% (n) Female	70.97	(154)	73.78	(121)	2.81	(-6.23 to 11.86)
% (n) Married/cohabiting	45.36	(83)	48.00	(60)	2.64	(-8.70 to 13.99)
% (n) White ethnicity	73.02	(138)	71.90	(87)	-0. 11	(-11.32 to 9.10)
% (n) No qualifications	13.16	(25)	8.59	(11)	-4.56	(-11.40 to 2.27)
% (n) Employed	81.68	(107)	71.90	(87)	-9.78	(-20.17 to 0.61)
% (n) Deprived area	19.16	(41)	32.72	(53)	13.55	(4.61 to 22.50)
Self-esteem	19.14	(0.44)	18.15	(0.55)	-0.99	(-2.38 to 0.40)
Social support	3.86	(0.08)	3.91	(0.09)	0.05	(-0.18 to 0.29)
Anxiety	4.73	(0.14)	5.13	(0.16)	0.40	(-0.01 to 0.82)
Depression	3.51	(0.13)	3.68	(0.17)	0.17	(-0.23 to 0.59)
EQ-VAS	62.44	(1.53)	54.92	(2.31)	-7.52	(-2.05 to-12.98)
Obesity and Weight- related Quality of Life	47.31	(1.89)	53.56	(2.37)	6.25	(0.33 to 12.18)

EQ-VAS=EuroQol Visual Analogue Scale

Table 3 Changes in outcomes at 6 and 12 months and treatment differences between participants wishing to lose weight allocated to a structured one-to-one weight loss programme (intervention) or to usual care (control).

Variables	Unadjusted change from baseline (95% confidence interval)				Average difference between groups (intervention-control)	T-test/ Chisq	Difference between groups based on multiple imputation* ([§]odds ratio)	P value
	Control group		Intervention group					
	Number	Mean (95% CI)	Number	Mean (95% CI)	Mean (95% CI)	p value		
Weight (kg)								
6 months	129	-0.95 (-1.74 to -0.16)	134	-1.73 (-2.47 to -0.99)	-0.78 (-1.85 to 0.30)	0.16	-0.69 (-1.80 to 0.41)	0.22
12 months	114	-1.31 (-2.23 to -0.37)	103	-2.39 (-3.46 to -1.31)	-1.08 (-2.49 to 0.32)	0.13	-0.70 (-2.17 to 0.76)	0.35
Waist circumference (cm)								
6 months	125	-2.19 (-3.12 to -1.26)	129	-3.36 (-4.42 to -2.29)	-1.17 (-2.58 to 0.24)	0.10	-0.90 (-2.35 to 0.55)	0.22
12 months	112	-1.49 (-2.59 to -0.40)	100	-3.37 (-4.91 to -1.82)	-1.88 (-3.76 to -0.01)	0.05	-1.22 (-3.10 to 0.66)	0.20
% body fat								
6 months	125	-0.12 (-0.66 to 0.42)	131	-0.89 (-1.36 to -0.43)	-0.77 (-1.48 to -0.06)	0.03	-0.77 (-1.51 to -0.04)	0.04
12 months	111	-0.23 (-1.02 to 0.57)	101	-0.72 (-1.27 to -0.15)	-0.49 (-1.47 to 0.49)	0.32	-0.71 (-1.71 to 0.28)	0.16
Percent weight loss								
6 months	129	-1.04 (-1.88 to -0.20)	134	-1.78 (-2.51 to -1.05)	-0.74 (-1.85 to 0.36)	0.19	-0.73 (-1.91 to 0.44)	0.22
12 months	114	-1.38 (-2.39 to -0.37)	103	-2.59 (-3.65 to -1.54)	-1.21 (-2.66 to 0.23)	0.10	-0.79 (-2.37 to 0.79)	0.33
% lost ≥5% baseline weight								
6 months	129	13.18 (7.34 to 19.02)	134	23.88 (16.66 to 31.10)	10.70 (1.41 to 19.98)	0.03	1.77 (0.96 to 3.23) [§1]	0.06
12 months	114	19.30 (12.05 to 26.54)	103	33.98 (24.83 to 43.13)	14.68 (3.01 to 26.35)	0.01	1.80 (1.02 to 3.18) [§2]	0.04
Body mass index (kg/m^2)								
6 months	129	-0.36 (-0.65 to -0.07)	134	-0.60 (-0.86 to -0.34)	-0.24 (-0.63 to 0.14)	0.22	0.20 (-0.18 to 0.59)	0.30
12 months	114	-0.48 (-0.82 to -0.13)	103	-0.83 (-1.22 to -0.44)	-0.35 (-0.87 to 0.16)	0.18	0.34 (-0.18 to 0.85)	0.20
Systolic blood pressure (mm Hg)								
6 months	121	-2.92 (-6.56 to 0.73)	128	0.29 (-3.54 to 4.12)	3.20 (-2.07 to 8.45)	0.23	3.33 (-1.34 to 8.00)	0.16
12 months	103	-0.97 (-5.02 to 3.07)	90	-0.71 (-3.97 to 2.54)	0.25 (-5.01 to 5.50)	0.92	-0.01 (-4.65 to 4.64)	0.99
Diastolic blood pressure (mm Hg)								
6 months	121	-2.29 (-4.70 to 0.12)	128	-1.52 (-3.98 to 0.95)	0.77 (-2.66 to 4.21)	0.66	1.87 (-1.12 to 4.87)	0.22
12 months	103	0.83 (-1.89 to 3.56)	90	-0.68 (-2.83 to 1.46)	-1.51 (-4.96 to 1.93)	0.39	-1.59 (-4.77 to 1.60)	0.33
Heart Rate (beats per minute)								
6 months	120	2.38 (0.21 to 4.55)	127	-0.47 (-2.79 to 1.85)	-2.86 (-6.02 to 0.31)	0.08	-2.42 (-5.47 to 0.62)	0.12
12 months	104	-0.23 (-2.82 to 2.36)	90	-2.68 (-5.33 to 0.02)	-2.44 (-6.14 to 1.25)	0.19	-3.68 (-7.04 to -0.31)	0.03

*For all outcomes the following baseline variables were included: age, weight, percent body fat, BMI, fat mass, metabolic age, deprivation status and employment status as well as totals from the OWLQOL, EQVAS, HADS anxiety, TFEQ emotional eating and RPAQ scales. [1]Percent lost ≥5% baseline weight control: 16.0 (9.7 to 22.3)%, intervention: 25.2 (18.0 to 32.3)%; [2]Percent lost ≥5% baseline weight control: 20.4 (13.3 to 27.5)%, intervention: 32.7 (24.9 to 40.5)%.

Table 4: Participant satisfaction with care received by allocation group at 12 months

	Intervention		Control		Difference between groups (Intervention – Control)	
	n/N	% (se)	n/N	% (SE)	% (95% CI)	P value
Satisfied with level of weight loss achieved	37/60	61.7 (6.3)	14/61	23.0 (5.4)	38.7 (22.5 to 54.9)	<0.0001
Found participating in CAMWEL helpful in meeting goals	51/59	86.4 (4.4)	27/60	45.0 (6.4)	41.4 (26.1 to 56.8)	<0.0001
Found getting feedback on physical measurements at baseline & 6 months helpful	39/58	67.2 (6.3)	20/57	35.1 (6.3)	32.2 (14.9 to 49.5)	<0.0001
Found BHF booklet[31] helpful	50/58	86.2 (4.5)	38/53	71.7 (6.2)	14.5 (0.0 to 29.5)	0.06

Table 5: Participant assessment of care received by allocation group at 12 months

	Intervention		Control		Difference between groups (intervention-control)	
	n	Mean (SE)	n	Mean (SE)	Mean (95% CI)	P Value
Patient Assessment of Care for Chronic Conditions (PACIC)*						
Patient Activation	58	3.29 (0.17)	56	1.46 (0.13)	1.83 (1.40 to 2.26)	<0.0001
Asked for my ideas						
Given choices						
Asked about any problems						
Delivery System Design/ Decision Support	58	3.79 (0.14)	55	1.70 (0.16)	2.09 (1.68 to 2.50)	<0.0001
Written list of things to do						
Care well organised						
How what I do influences weight						
Goal Setting	58	3.35 (0.13)	54	1.64 (0.14)	1.71 (1.32 to 2.09)	<0.0001
Asked to talk about my goals						
Helped to set specific goals						
Given copy of my weight loss plan						
Encouraged to attend sessions						
Asked questions about health habits						
Problem Solving/ Contextual Counselling	58	3.34 (0.16)	56	1.66 (0.15)	1.69 (1.26 to 2.12)	<0.0001
Thought about my beliefs & traditions when making recommendations						
Helped to make plan for my daily life						
Plan ahead even for difficult circumstances						
Asked how weight affected me						

*Patient Assessment of Care for Chronic Conditions (PACIC) score [41, 42]

Table 6: Reported changes* in eating and activity habits by participants who lost 5% or more of baseline weight compared to those who did not.

	Lost 5% or more of baseline weight				Difference between groups (Yes – No)	
	Yes (N=41)		No (N=111)			
	n	%	n	%	% (CI)	P value
What changes have you made to your diet during the last 12 months? (Tick all that apply)						
Reduced my fat intake	35	85.4	66	59.5	25.9 (11.7 to 40.1)	0.003
Reduced my sugar intake	24	58.5	43	38.7	19.8 (22.0 to 37.4)	0.029
Reduced my portion sizes	28	68.3	58	52.3	16.0 (-0.97 to 33.0)	0.077
What changes have you made to your activity levels in the last 12 months? (Tick all that apply)						
Used the stairs instead of taking the lift	17	41.5	31	27.9	13.6 (-3.7 to 30.8)	0.111
Joined a gym specifically to lose weight	13	31.7	20	18.0	13.7 (-2.2 to 29.6)	0.069
Get off one stop earlier when travelling by bus or tube	8	19.5	16	14.4	5.1 (-8.7 to 8.9)	0.444
Walk rather than take car for journeys that are less than one mile	21	51.2	44	39.6	11.6 (-6.2 to 29.4)	0.200
How will you continue to manage your weight will you						
Monitor your food intake?	32	78.1	59	52.7	25.4 (9.69 to 41.1)	0.005
Control your portions?	26	63.4	59	52.7	10.7 (-6.67 to 28.1)	0.237
Use a pedometer?	13	31.7	20	17.9	13.8 (-2.1 to 29.8)	0.065
Monitor your activity patterns?	23	56.1	44	39.3	16.8 (-0.86 to 34.4)	0.063

*Data missing for 75 participants who did not complete this section of the questionnaire.

Table 7: Studies on weight loss conducted in general practice in the UK with 12 months follow-up.

Study	Design	Intervention	Eligibility criteria	Weight (Kg) at baseline Mean (sd)	Percent (n/N) followed-up at 12 months	Mean weight change (Kg) at 12 months				Lost ≥5% baseline weight in intervention group % (95% CI)
						Intervention	Control	Difference (95% CI)	P value	
Moore et al BMJ (2003)[63]	Cluster RCT	Trained GPs, nurses	BMI≥30	-	67.7 (565/834)	-0.6	-0.9	1.0[1]	0.5	-
McConnon et al BMC (2007)[50]	RCT	Access to website	BMI≥30; Access to Internet	98.4 (17.4)	59.3 (131/221)	-1.3	-1.9	0.6 (1.4 to 2.5)	0.56	22
Davies et al, DESMOND BMJ (2007)[19]	RCT	Group sessions	Newly diagnosed Type 2 diabetes	-	90.9 (729/824)	-3.0	-1.9	-1.0 (-1.9 to -0.12)	0.03	-
Ross et al, Counterweight BJGP (2008)[51]	Audit	Trained practice nurses	BMI≥30; BMI≥28 with co-morbidities	-	45.2 (642/1419)	-3.0	-	-	-	31 (27 to 34)
Ahern et al, Weight Watchers BMC (2011)[64]	Audit	Weight Watchers meetings	BMI≥30; NHS Referral scheme	94.3 (IQR 83.7-107.7)	53	Median= -2.8	-	-	-	33
Jebb et al, Weight Watchers Lancet (2011)[52]	RCT	Weight Watchers meetings	BMI 27-35 + 1risk factor	86.7	57.5 (444/772)	-5.1	-2.2	-3.2 (-4.2 to -2.1)	<0.0001	47*
Jolly et al BMJ (2011)[53]	RCT	Various**	White BMI≥30/≥28 + co-morbidity S Asian BMI≥25/≥23 + co-morbidity	91.7 (17.9)	70.5 (522/740)	-3.5	-1.1	-2.5 (-4.2 to -0.8)	0.02	31 (22 to 41)
CAMWEL	RCT	One-to-one sessions	BMI≥25	92.3 (18.3)	57 (217/381)	-2.4	-1.3	-1.1 (-2.5 to 0.3)	0.13	34 (25 to 43)

[1]Difference between groups at 12 months; * based on graph in Table 3; ** range of commercial or primary care led programmes, intervention results given for Weight Watchers.

Appendix: The structure of the CAMWEL intervention programme

Session Number	Week	Topic Materials	Handouts	
1	0	Getting started: establish working relationship and good rapport with participant; elicit personal reasons for losing weight, build commitment to program, and introduce lifestyle changes approach. BHF 'So you want to lose weight' booklet	Sequence of topics Appointment card Benefits of Healthy Habits Recording your routines Deciding to Change	Behaviour Change Diary Food Diary Activity Diary
2	2	Changing habits: Review progress, explain importance of changing habits permanently and introduce the five steps to solving problems.	Problem Solving Build a Better Recipe Just One More Step	(Behaviour Change Diary) (Food Diary) (Activity Diary)
3	4	Healthy eating: Review progress, explain importance of regular meals, portion sizes, keeping a record and discuss making easy food swaps. (Adam Portion pots; 100 kcal portion size food box)	FSA EatWell booklet Rate Your Plate Easy Food Swaps Healthy Drinks Food labels card	(Activity Diary)
4	6	Let's get active: Review progress, explain importance of activity guidelines and discuss ways of incorporating physical activity into participant's lifestyle.	Being Active Your Guide to Walking in Camden Cut the fat and sugar Camden outdoor gyms	Steps chart Printed weight graph (Rate your plate)
5	8	Taking charge of your environment: Review progress, explain importance of cues and discuss ways of changing the environment to make losing weight the 'easy' option.	Your Environment Goals & Rewards Eat Well on the Cheap	(Rate your plate) (Steps Chart) Printed weight graph
6	10	Eating when out and about: Review progress, explain keys to making healthy choices when out and about and discuss alcohol if appropriate.	Healthy choices Alcohol and your diet Eating when out and about	(Rate your plate) (Steps chart)
7	12	Tip the calorie balance: Review progress at 3-month stage of programme; explain energy balance equation, importance of healthy eating, being active, social support and action planning.	Tipping the calorie balance Individual printed weight graph	(Steps Chart) (Rate your plate)
8	15	Positive thinking: Review progress and introduce ways to stop negative thoughts and 'talk back' with positive ones.	Positive Thinking Camden Walk4Life maps	(Food diary) (Activity diary) (Steps chart)

				(Rate your plate) (Behaviour Change Diary)
9	18	Getting off the slippery slope: Review progress, identify reasons for slips and ways of getting back on course.	Slippery Slope Camden Walk4Life maps BHF 'Healthy meals, Healthy Heart' or 'Food should be fun & healthy' menus Individual printed weight graph	
10	21	Social eating: Review progress, discuss social settings where it may be difficult to stay in control of eating healthily and ways to overcome this and enjoy healthy social eating.	Social eating Individual printed weight graph	
11	27	Staying on course: Review progress, identify successful changes made and identify situations where participant not in control and discuss ways of overcoming barriers.	Staying on course Healthy snacking 100 Calorie portions Meal plans- Indian/ Minimum cooking Individual printed weight graph	(Rate your plate) (Food diary) (Steps chart) (Activity Diary)
12	31	Staying active: Review progress; discuss additional changes made and how further activity can be added into lifestyle.	Staying active Individual printed weight graph	(Activity Diary) (Steps chart)
13	35	Managing stress: Review progress; discuss how stress affects weight and ways to manage stress.	Day to day stress Individual printed weight graph	(Activity Diary) (Steps chart) (Rate your plate) (Food Diary)
14	47	Reshaping habits: Review progress since start of programme; discuss ways of continuing to lose/ maintain changes in the long term.	Reshaping habits Cancer Research UK's Ten top tips Camden architecture & walking guide Travel Camden: Camden walking map; Belsize walk; Jubilee Walk Individual printed weight graph Certificate of Achievement	(Rate your plate) (Food Diary) (Steps chart) (Activity Diary)

References

1 Whitlock G, Lewington S, Sherliker P, et al. Body-mass index and cause-specific mortality in 900,000 adults: collaborative analyses of 57 prospective studies. *Lancet* 2009;**373**:1083-96**.**

2 *Global Health Risks. Mortality and burden of dieases attributable to selected major risks.* Geneva, World Health Orgainisation, 2009.

3 Finucane MM, Stevens GA, Cowan MJ, et al. National, regional, and global trends in body-mass index since 1980: systematic analysis of health examination surveys and epidemiological studies with 960 country-years and 9·1 million participants. *Lancet* 2011;**377**:557-567**.**

4 Whitlock G, Lewington S, Mhurchu CN. Coronary heart disease and body mass index: a s ystematic review of the evidence from larger prospective cohort studies. *Semin Vasc Med* 2002;**2**:369-81.

5 Haslam DW, James WP. Obesity. *Lancet* 2005;**366**:1197-209.

6 Foresight. *Tackling Obesities: future Choices*. London, Government Office for Science 2007.

7 The NHS Information Centre, Lifestyles Statistics. Statistics on obesity, physical activity and diet: England, 2012 http://www.ic.nhs.uk/statistics-and-data-collections/health-and-lifestyles/obesity/statistics-on-obesity-physical-activity-and-diet-england-2012 (accessed March 2012).

8 Perri MG, Limacher MC, Durning PE, et al. Extended-care programs for weight management in rural communities: the treatment of obesity in underserved rural settings (TOURS) randomized trial. *Arch Intern Med* 2008;**168**:2347-54.

9 Perri MG, Sears SF Jr, Clark JE.Strategies for improving maintenance of weight loss. Toward a continuous care model of obesity management. *Diabetes Care* 1993;**16**:200-9.

10 Kinmonth AL, Wareham NJ, Hardeman W, et al. Efficacy of a theory-based behavioural intervention to increase physical activity in an at-risk group in primary care (ProActive UK): a randomised trial. *Lancet* 2008;**371**:41-8.

11 Wing RR, Phelan S. Long-term weight loss maintenance. *Am J Clin Nutr* 2005;**82**:222S-225S.

12 Aucott L, Poobalan A, Smith WC et al. Weight loss in obese diabetic and non-diabetic individuals and long-term diabetes outcomes--a systematic review. *Diabetes Obes Metab* 2004;**6**:85-94.

13 Poobalan A, Smith WC, Avenell A, et al. Effects of weight loss in overweight/obese individuals and long-term lipid outcomes--a systematic review. *Obes Rev* 2004;**5**:43-50.

14 A Avenell A, Broom J, Brown TJ, et al. Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement. Health Technol Assess 2004;**8**:1–182.

15 Norris SL, Zhang X, Avenell A, et al. Long-term effectiveness of weight-loss interventions in adults with pre-diabetes: a review. *Am J Prev Med* 2005;**28:**126-39.

16 Norris SL, Zhang X, Avenell A, et al. Long-term effectiveness of lifestyle and behavioral weight loss interventions in adults with type 2 diabetes: a meta-analysis. *Am J Med* 2004;**117:**762-74.

17 Potter MB, Vu JD, Croughan-Minhane M. Weight management: what patients want from their primary care physicians. *J Fam Pract* 2001;**50**:513-8.

18 Nanchahal K, Townsend J, Letley L, et al. Weight-management interventions in primary care: a pilot randomised controlled trial. *Br J Gen Pract* 2009;**59**:e157-66.

19 Davies MJ, Heller S, Skinner TC, et al. 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 controlled trial. *BMJ* 2008;**336**:491-5.

20 Trueman P, Haynes SM, Felicity Lyons G, et al. Long-term cost-effectiveness of weight management in primary care. *Int J Clin Pract* 2010;**64**:775-83.

21 Wardle J, Johnson F. Weight and dieting: examining levels of weight concern in British adults. *Int J Obes Relat Metab Disord* 2002;**26**:1144-9.

22 Campbell M, Fitzpatrick R, Haines A, et al. Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000;**321**:694-6.

23 Jones LR, Wadden RA. State of the science: behavioural treatment of obesity. *Asia Pac J Clin Nutr* 2006;**15**(Suppl):30-9.

24 Bandura A. Health Promotion by Social Cognitive Means. *Health Educ Behav* 2004;**31**:143-64.

25 Locke EA, Latham GP. Building a practically useful theory of goal setting and task motivation : A 35-year odyssey. *Am Psychol* 2002;**57**:705-17.

26 Alemi F, Neuhauser D, Ardito S, et al. Continuous self-improvement: systems thinking in a personal context. *Jt Comm J Qual Improv* 2000;**26**:74-86.

27. NICE clinical guidance 43 Obesity: Quick reference guide 2 for the NHS. London, National Institute for Health and Clinical Excellence 2006.

28 Koenigsberg MR, Bartlett D, Cramer JS.Facilitating treatment adherence with lifestyle changes in diabetes. Am Fam Physician 2004;**69**:309-16.

29 Michie S, Rumsey N, Fussell A, et al. *Improving Health: Changing Behaviour NHS Health Trainer Handbook.* Department of Health 2008.

30 Kellow J, Costain L, Walton R. *The Calorie, Carb and Fat Bible.* Peterborough: Weight Loss Resources 2009.

31.British Heart Foundation. *So You Want to Lose Weight... For Good*. London: British Heart Foundation 2005.

32 NHS Camden. *Annual Report & Accounts 2009/10.* Camden Primary Care Trust 2010. Available at http://www.camden.nhs.uk/downloads/012522A1_CNHS_Annual%20Report_LR.pdf

33 Forward Planning Service London Borough of Camden Camden Profile 2010. London Borough of Camden Forward Planning Service. Available at http://www.camdendata.info/AddDocuments1/Forms/DispForm.aspx?ID=131

34 Patrick DL, Bushnell DM, Rothman M. Performance of Two Self-Report Measures for Evaluating Obesity and Weight Loss. *Obes Res* 2004;**12**:48-57.

35 Olssøn I, Mykletun A, Dahl AA. The Hospital Anxiety and Depression Rating Scale: a cross-sectional study of psychometrics and case finding abilities in general practice. *BMC Psychiatry* 2005;**5**:46.

36 Rosenberg M. *Society and the Adolescent Self Image*. Princeton, NJ: Princeton University Press 1965.

37 Broadhead WE, Gehlbach SH, de Gruy FV, et al. The Duke-UNC Functional Social Support Questionnaire: measurement of social support in family medicine patients. *Med Care* 1988;**26**:709-723.

38 Karlsson J, Persson LO, Sjöström L, et al. Psychometric properties and factor structure of the Three-Factor Eating Questionnaire (TFEQ) in obese men and women. Results from the Swedish Obese Subjects (SOS) study. *Int J Obes Relat Metab Disord* 2000;**24**:1715-25.

39 Besson H, Brage S, Jakes RW, et al. Estimating physical activity energy expenditure, sedentary time, and physical activity intensity by self-report in adults. *Am J Clin Nutr* 2010;**91**:106-14.

40.Department for Communities and Local Government. *The English Indices of Deprivation 2010*. London 2010. Available at http://www.communities.gov.uk/documents/statistics/pdf/1871208.pdf

41 Glasgow RE, Wagner EH, Schaefer J, et al. Development and validation of the Patient Assessment of Chronic Illness Care (PACIC). *Med Care* 2005;**43**:436-44.

42 Schmittdiel J, Mosen DM, Glasgow RE, et al. Patient Assessment of Chronic Illness Care (PACIC) and improved patient-centered outcomes for chronic conditions. *J Gen Intern Med* 2008;**23**:77-80.

43 Scott NW, McPherson GC, Ramsay CR, et al. The method of minimization for allocation to clinical trials: a review. *Control Clin Trials* 2002;**23**:662-74.

44 Douketis JD, Macie C, Thabane L, et al. Systematic review of long-term weight loss studies in obese adults: clinical significance and applicability to clinical practice. *Int J Obes (Lond)* 2005;**29**:1153-67.

45 Carpenter JR and Kenward MG. Missing data in clinical trials – a practical guide. National Health Service Coordinating Centre for Research Methodology: Birmingham 2008. Downloadable from

http://www.haps.bham.ac.uk/publichealth/methodology/docs/invitations/Final_Report_RM04_JH17_mk.pdf.

46 Rubin DB. *Multiple Imputation for Nonresponse in Surveys*. Wiley-Blackwell 1987.

47 Kenward MG, Carpenter J. Multiple imputation: current perspectives. *Stat Methods Med Res* 2007;**16**:199-218.

48 Royston P. Multiple imputation of missing values. *STATA Journal* 2004;**4**:227-241.

49 Nanchahal K, Hession M,Power T, et al. Challenges in recruitment to clinical trials and lessons learned from a randomized controlled trial of a weight management intervention in general practice. *Obes Rev* 2010;**11**(Suppl S1):P214.

50 McConnon A, Kirk SF, Cockroft JE, et al. The Internet for weight control in an obese sample: results of a randomised controlled trial. *BMC Health Serv Res* 2007;**7**:206.

51 Counterwweight Project Team. Evaluation of the Counterweight Programme for obesity management in primary care: a starting point for continuous improvement. *Br J Gen Pract* 2008; **58**:548-54.

52 Jebb SA, Ahern AL, Olson AD, et al. Primary care referral to a commercial provider for weight loss treatment versus standard care: a randomised controlled trial. *Lancet* 2011;**378**:1485-92.

53 Jolly K, Lewis A, Beach J, et al. Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: Lighten Up randomised controlled trial. *BMJ* 2011;**343**:d6500.

54 Inelmen EM, Toffanello ED, Enzi G, et al. Predictors of drop-out in overweight and obese outpatients. *Int J Obes (Lond)* 2005;**29**:122-8.

55 Thomas E, Croft PR, Paterson SM, et al. What influences participants' treatment preference and can it influence outcome? Results from a primary care based randomised trial for shoulder pain. *Br J Gen Pract* 2004;**54**:93-6.

56 McCambridge J, Kypri K. Can Simply Answering Research Questions Change Behaviour? Systematic Review and Meta Analyses of Brief Alcohol Intervention Trials. *PLoS One* 2011;**6**:e23748.

57 Woodcock J, Edwards P, Tonne C, et al. Public health benefits of strategies to reduce greenhouse-gas emissions: urban land transport. *Lancet* 2009;**374**:1930-43.

58 *Managing Obesity in Primary Care CD-ROM*. National Obesity Forum 2004.

59 Byoni Ltd. *Perfect Diet Tracker Software*. Available from http://www.perfect-diet-tracker.com/

60 Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. *Health Psychol* 2008;**27**:379-87.

61 Miller WR, Rose GS. Toward a theory of motivational interviewing. *Am Psychol* 2009;**64**:527-37.

62 Foreyt JP, Poston WS. What is the role of cognitive-behavior therapy in patient management? *Obes Res* 1998;**6**(Suppl 1):18S-22S.

63 Moore H, Summerbell CD, Greenwood DC, et al. Improving management of obesity in primary care: cluster randomised trial. *BMJ* 2003;**327**:1085.

64 Ahern AL, Olson AD, Aston L, et al. Weight Watchers on prescription: An observational study of weight change among adults referred to Weight Watchers by the NHS. *BMC Public Health* 2011;**11**:434.