A pragmatic randomised controlled trial 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
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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.

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

THEORETICAL

Social Cognitive Theory[24]

Social support, self-regulation, monitoring, goal

Goal Setting Theory[25]

Specific Measurable Attainable Relevant Time-bound goal setting, goal commitment,

Systems Thinking[26]

Environmental changes, long-term changes in

Treatment adherence[28]

Short-term behaviour targets, self-monitoring

***Behaviour Change Techniques**[58]

NICE Guidelines[27]

Multi-component intervention with tailored advice on physical activity, eating behaviour, healthier eating, & lifestyle changes

ADVISOR TRAINING

Drivers of weight change

The CAMWEL intervention

Behaviour change techniques[58]

Talking about weight change[59, 60]

Role Play

National Obesity Forum CD-

The Calorie, Carb and Fat Bible[56]

The 100 calories kit[Δ]

Perfect Diet Tracker Software[57]

Adams Portion Pot[Ω]

Pedometer[β]

CAMWEL INTERVENTION

- **S1: Getting Started:** *elicit personal reasons for losing weight, commitment to programme.*
- **S2: Changing Habits:** *importance of changing habits permanently.*
- **S3: Healthy Eating:** *regular meals, portion sizes, easy food swaps.*
- **S4: Let's Get Active:** *incorporating PA into daily lifestyle.*
- **S5: Taking Charge of your Environment:**

- **S8: Positive Thinking:** *ways to stop negative thoughts.*
- **S9: Getting off the Slippery Slope:** *slips, and getting back on course.*
- **S10: Social Eating:** *difficult social settings and how to control eating*
- **S11: Staying on Course:** *identify successes, how to stay on course*
- **S12: Staying Active:** *additional physical activity to be added to routine.*

* 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.*

Figure 2 Flow of participants through the trial

Enrolment

Assessed for eligibility (n=392)

Excluded (n=11)
- ♦ Not meeting inclusion criteria (n=8)
- ♦ Declined to participate (n=3)

Randomized (n=381)

Allocation

Allocated to CAMWEL intervention (n=191)
- ♦ Received allocated intervention (n=184)
- ♦ Did not receive allocated intervention (n= 7)
  - Could not be contacted (n=5)
  - Refused intervention (n=2)

Allocated to Usual Care control (n=190)

Follow-Up

6 MONTHS: (n=134)

  Lost to follow-up (n=57)
   - Could not be contacted (n=41)
   - Personal illness (n=4)

   - Family illness (n=4)

   - Moved house (n=4)

   - No time to attend (n=4)

12 MONTHS: (n=103)

  Lost to follow-up (n=88)

   - Could not be contacted (n=31)

   - Declined to attend (unspecified reason) (n=21)

ONTHS: (n=129)

  Lost to follow-up (n=61)
   - Unknown (n=61)

12 MONTHS: (n=114)

  Lost to follow-up (n=76)

   - Could not be contacted (n=30)

   - Declined to attend (unspecified reason) (n=9)

   - DNA appointment (n=15)

Analysis

Analysed (n=103 plus imputed data for participants lost to follow-up)
- ♦ Excluded from analysis (give reasons) (n=0)

Analysed (n=114 plus imputed data for participants lost to follow-up)
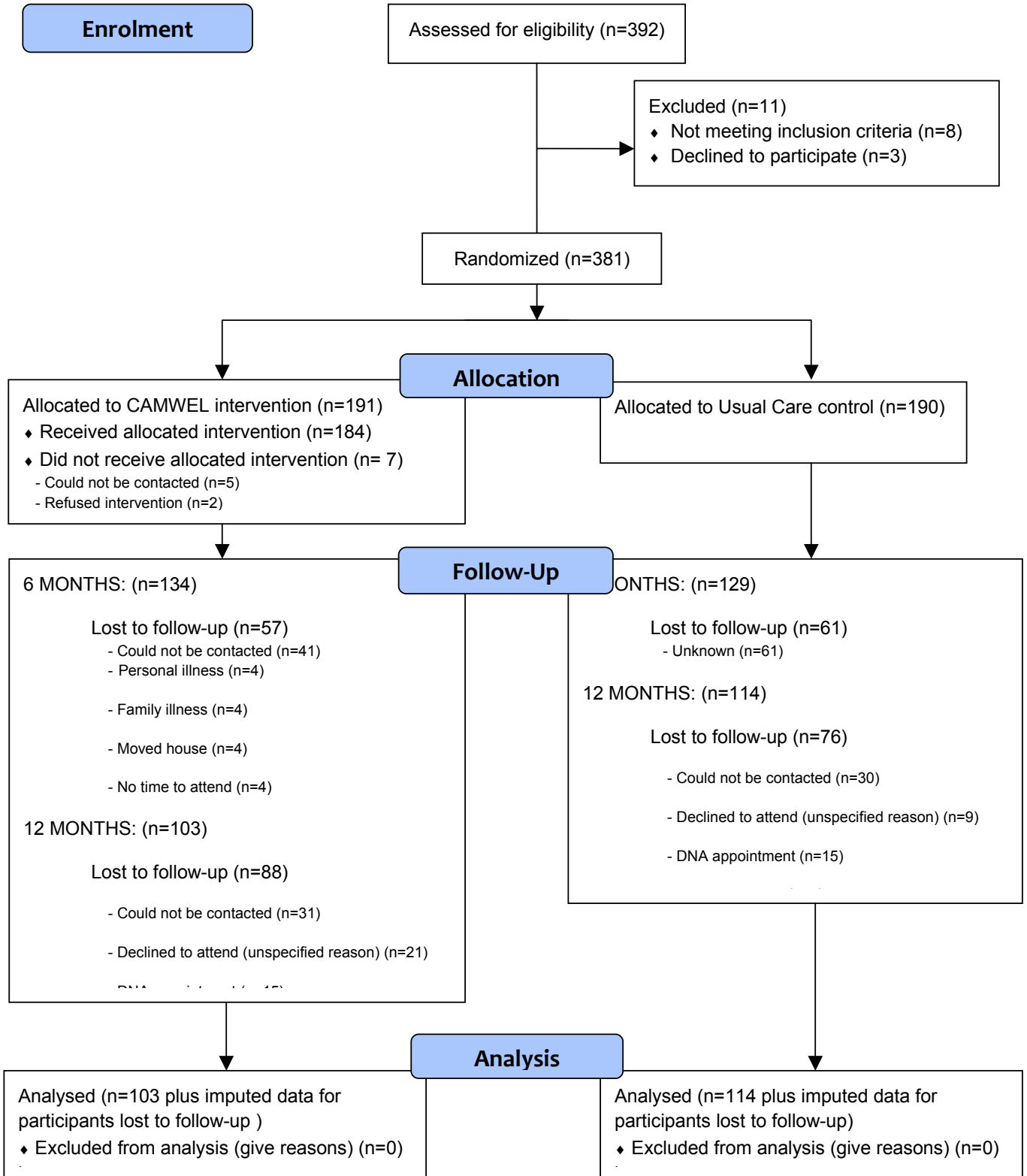- ♦ Excluded from analysis (give reasons) (n=0)

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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
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[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	Jubilee walkway map[66]	21.2	(41.2)	11/52
Camden Belsize walk map[65]	29.6	(46.1)	16/54	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 (N=41) | | No (N=111) | | (Yes – No) | |
	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 (Rate your plate) Healthy snacking (Food diary) 100 Calorie portions (Steps chart) Meal plans- Indian/ Minimum cooking Individual printed weight graph (Activity Diary)
12	31	Staying active: Review progress; discuss additional changes made and how further activity can be added into lifestyle.	Staying active (Activity Diary) Individual printed weight graph (Steps chart)
13	35	Managing stress: Review progress; discuss how stress affects weight and ways to manage stress.	Day to day stress (Activity Diary) Individual printed weight graph (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 (Rate your plate) Cancer Research UK's Ten top tips (Food Diary) Camden architecture & walking guide (Steps chart) Travel Camden: Camden walking map; (Activity Diary) Belsize walk; Jubilee Walk Individual printed weight graph Certificate of Achievement

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