HEALTH TECHNOLOGY ASSESSMENT

VOLUME 20 ISSUE 79 OCTOBER 2016
ISSN 1366-5278

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National Institute for Health Research

DOI 10.3310/hta20790

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Declared competing interests of authors: Sandra Eldridge is a member of the Health Technology Assessment clinical trials board.

Published October 2016
DOI: 10.3310/hta20790

This report should be referenced as follows:

McRobbie H, Hajek P, Peerbux S, Kahan BC, Eldridge S, Trépel D, *et al*. Tackling obesity in areas of high social deprivation: clinical effectiveness and cost-effectiveness of a task-based weight management group programme – a randomised controlled trial and economic evaluation. *Health Technol Assess* 2016;**20**(79).

Health Technology Assessment is indexed and abstracted in *Index Medicus*/MEDLINE, *Excerpta Medica*/EMBASE, *Science Citation Index Expanded* (SciSearch®) and *Current Contents®*/ Clinical Medicine.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.058

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 09/127/34. The contractual start date was in December 2011. The draft report began editorial review in September 2015 and was accepted for publication in April 2016. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

Tackling obesity in areas of high social deprivation: clinical effectiveness and cost-effectiveness of a task-based weight management group programme – a randomised controlled trial and economic evaluation

Hayden McRobbie,[1] Peter Hajek,[1] Sarrah Peerbux,[1]* Brennan C Kahan,[2] Sandra Eldridge,[2] Dominic Trépel,[3] Steve Parrott,[3] Chris Griffiths,[4] Sarah Snuggs[1] and Katie Myers Smith[1]

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Background: An increasing number of people require help to manage their weight. The NHS recommends weight loss advice by general practitioners and/or a referral to a practice nurse. Although this is helpful for some, more effective approaches that can be disseminated economically on a large scale are needed.

Objective: To assess whether or not a task-based weight management programme [Weight Action Programme (WAP)] has better long-term effects than a 'best practice' intervention provided in primary care by practice nurses.

Design: Randomised controlled trial with cost-effectiveness analysis.

Setting: General practices in east London, UK.

Participants: Three hundred and thirty adults with a body mass index (BMI) of ≥ 30 kg/m^2 or a BMI of ≥ 28 kg/m^2 plus comorbidities were recruited from local general practices and via media publicity. Those who had a BMI of > 45 kg/m^2, had lost $> 5\%$ of their body weight in the previous 6 months, were currently pregnant or taking psychiatric medications were excluded. Participants were randomised (2 : 1) to the WAP or nurse arms.

Interventions: The WAP intervention was delivered in eight weekly group sessions that combined dietary and physical activity, advice and self-monitoring in a group-oriented intervention. The initial course was followed by 10 monthly group maintenance sessions open to all participants in this study arm. The practice nurse intervention (best usual care) consisted of four one-to-one sessions delivered over 8 weeks, and included standard advice on diet and physical activity based on NHS 'Change4Life' materials and motivational support.

Main outcome measures: The primary outcome measure was weight change at 12 months. Secondary outcome measures included change in BMI, waist circumference and blood pressure, and proportion of participants losing at least 5% and 10% of baseline body weight. Staff collecting measurements at the 6- and 12-month follow-ups were blinded to treatment allocation. The primary outcome measure was analysed

according to the intention-to-treat principle, and included all participants with at least one recorded outcome at either 1, 2, 6 or 12 months. The analysis employed a mixed-effects linear regression model, adjusted for baseline weight, age, sex, ethnicity, smoking status and general practice. The European Quality of Life-5 Dimensions-5 Levels questionnaire was completed and used to estimate quality-adjusted life-years (QALYs) within the cost-effectiveness analysis.

Results: There were 330 participants (WAP arm, $n = 221$; nurse arm, $n = 109$; 72% women). A total of 291 (88%) participants (WAP arm, $n = 194$; nurse arm, $n = 97$) were included in the main analysis for the primary outcome. Weight loss at 12 months was greater in the WAP arm than in the nurse intervention arm [–4.2 kg vs. –2.3 kg; difference –1.9 kg, 95% confidence interval (CI) –3.7 to –0.1 kg; $p = 0.04$]. Participants in the WAP arm were more likely than participants in the nurse arm to have lost at least 5% of their baseline body weight at 12 months (41% vs. 27%; odds ratio 14.61, 95% CI 2.32 to 91.96; $p = 0.004$). The incremental cost-effectiveness ratio for WAP over and above the nurse arm is £7742 per QALY.

Conclusions: A WAP delivered in general practice better promotes weight loss over 12 months than a best usual practice nurse-led weight loss programme.

Limitations: The trial recruited mostly women. Research is needed into factors that would make weight loss programmes more attractive to men.

Trial registration: Current Controlled Trials ISRCTN45820471.

Funding: This project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 20, No. 79. See the NIHR Journals Library website for further project information.

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AE	adverse event
BMI	body mass index
BOCF	baseline observation carried forward
CI	confidence interval
EQ-5D-5L	European Quality of Life-5 Dimensions-5 Levels
GCP	good clinical practice
GP	general practitioner
ICER	incremental cost-effectiveness ratio
IQR	interquartile range
MET	metabolic equivalent
NICE	National Institute for Health and Care Excellence
PCTU	Pragmatic Clinical Trials Unit
QA	quality assurance
QALY	quality-adjusted life-year
R&D	research and development
RCT	randomised controlled trial
SAE	serious adverse event
SD	standard deviation
SSS	Stop Smoking Service
SWAP	Peer-Support Weight Action Programme
WAP	Weight Action Programme

Plain English summary

An increasing number of people in the UK require help to manage their weight. The NHS currently offers advice in general practice, sometimes accompanied by slimming medications and a referral to the practice nurse or dietitian. Although this is helpful for some patients, more effective approaches are needed that can be disseminated economically on a large scale, possibly in parallel with the successful Stop Smoking Service (SSS).

The Weight Action Programme (WAP) is a weight loss intervention that provides participants with tools to lose weight and maintain a long-term healthy lifestyle. In the eight weekly sessions, participants are equipped with tools to maintain a healthy lifestyle, with weekly individualised tasks and peer-support group sessions. The initial course is followed by 10 monthly maintenance sessions.

The trial was designed to see if the WAP provides long-term benefits over and above the effect of a 'best practice' weight management intervention provided in primary care by practice nurses.

The nurse intervention consisted of four one-to-one sessions delivered at fortnightly intervals over 8 weeks that included standard advice on diet and physical activity based on NHS 'Change4Life' materials and motivational support.

A total of 330 obese adults who wanted to lose weight were randomly assigned to the WAP or the nurse intervention. All participants were followed up at 2, 6 and 12 months.

One year after the start of the programme, participants who received the WAP had lost significantly more weight (4.2 kg) than those who received help from a practice nurse (2.1 kg). Economic analysis conducted in this study suggests that the WAP may represent value for money if implemented in the NHS. Both groups found their weight loss programme helpful.

Scientific summary

Background

An increasing number of people in the UK require help to manage their weight. The NHS currently offers advice in general practice, sometimes accompanied by slimming medications and a referral to the practice nurse or dietitian. Although this is helpful for some patients, more effective approaches are needed that can be disseminated economically on a large scale, possibly in parallel with the successful UK specialist Stop Smoking Service (SSS).

Objective

To assess whether or not a task-based weight management programme [Weight Action Programme (WAP)] has a long-term effect over and above the effect of a 'best practice' weight management intervention provided in primary care by practice nurses.

Methods

Overview

We conducted a randomised controlled trial with 12 months' follow-up between September 2012 and February 2015. The primary outcome measure was weight change at 12 months post randomisation.

Participants

Participants were recruited from six general practitioner (GP) surgeries across the London boroughs of Tower Hamlets and Hackney, both areas with high levels of social deprivation, via GP referrals, mailshots from GP databases and self-referrals facilitated by posters and leaflets. Recruitment was also facilitated by advertisements in the local newspaper, community venues and word of mouth. Those who met the self-reported eligibility criteria assessed during a telephone call were invited to one of two GP surgery sites for the initial screening session.

Participants were eligible if they were aged $\geq$ 18 years, wanted to lose weight and had an objectively measured body mass index (BMI) of $\geq$ 30 kg/m^2 or a BMI of $\geq$ 28 kg/m^2 plus comorbidities. Those who were unable to read/write/understand English, had a BMI of > 45 kg/m^2, had lost > 5% of their body weight in the previous 6 months, were currently pregnant, were taking psychiatric medications, were not registered with a GP in the participating borough areas or were involved in a current research project were excluded.

Following baseline measurements, eligible participants were randomised to the WAP or the nurse arm in a 2 : 1 ratio (WAP to nurse). Treatment in both arms started within 2 weeks of randomisation. All participants were invited to attend 6- and 12-month follow-up appointments to assess outcomes.

Nurse arm

The practice nurse intervention was modelled on a best-practice intervention in primary care, derived from discussions with GPs and practice nurses, and incorporating national guidelines and NHS materials.

Participants received the intervention from a trained study nurse in four one-to-one sessions delivered over 8 weeks. The initial session lasted 20–30 minutes; the follow-up sessions were briefer, as per usual practice. The intervention included advice on diet and physical activity based on NHS 'Change4Life'

material, and motivational support. Participants were encouraged to lose around 1 lb (0.45 kg) per week and were weighed at each session to assess their progress.

Weight Action Programme arm

The WAP is a group-based weight loss programme developed via extensive client feedback and piloting with underprivileged groups since 2002. The WAP aims to provide participants with tools to lose weight and to maintain a long-term healthy lifestyle.

It is delivered over eight weekly group sessions that combine standard cognitive–behavioural interventions, dietary advice and self-monitoring with group-oriented interventions aimed at increasing participant retention, involvement and adherence to weekly tasks. The initial course is followed by 10 monthly maintenance sessions. These maintenance sessions were 'open' groups, with participants at different stages of the intervention attending the same once-a-month session. The target weight loss was 1 lb (0.45 kg) per week. Two advisors (research health psychologists) conducted the WAP sessions in groups of 10–20 participants (one advisor conducted the maintenance sessions).

Both arms, as per standard care, received information about local exercise provision and, where appropriate, participants were given information about orlistat and advised to see their GP if they wished to use it as part of their weight loss programme.

Outcome measurements

Trained study staff assessed weight, waist circumference and blood pressure objectively, following standard protocols. Other secondary outcomes were self-reported: changes in physical activity using the International Physical Activity Questionnaire; changes in healthy eating using the Food Knowledge Assessment questionnaire; and changes in food craving using the Food Craving Questionnaire.

Participants were asked to report adverse events (AEs) at every session. All measurements at 6 and 12 months were collected by a researcher who was blind to treatment allocation.

Sample size

We hypothesised that the WAP would increase annual weight loss by 2.6 kg compared with best usual practice (WAP 3 kg vs. usual care 0.4 kg) for participants available for follow-up at 1 year, and that there would be no difference in weight loss between treatment groups for participants not available for follow-up. Assuming that 50% of participants in both treatment groups were available for follow-up at 1 year, the difference in weight loss between arms would be 1.3 kg (WAP 1.5 kg vs. usual care 0.2 kg). Assuming a standard deviation (SD) of 3 in both arms, and a 5% two-sided significance level, we would require 112 participants in each arm to detect this mean difference with 90% power. To account for potential clustering effects because of group treatment in the WAP arm, assuming a mean cluster size of 18 and an intracluster correlation coefficient of 0.05, a total of 208 individuals were required in the WAP arm. The same power was calculated as achievable with 108 in the nurse arm and 216 in the WAP arm, which was increased to 110 in the nurse arm and 220 in the WAP arm to give an allocation ratio between the two arms (2 : 1), expressed in whole numbers. Thus, we required a total of 330 individuals for the entire study.

Statistical analyses

The main analysis for the primary outcome (change in weight at 12 months) was performed in accordance with the intention-to-treat principle, whereby all participants with at least one recorded weight measurement at either 1, 2, 6 or 12 months were included in the analysis, and were analysed according to the treatment group to which they were randomised. *p*-values were two-sided, with the significance level set at 5%. The primary outcome measure (change in weight) was analysed using a mixed-effects linear regression model, and included a random intercept for cluster, where cluster was defined as the specific nurse delivering care to control arm participants and the WAP group that intervention arm participants belonged to. An unstructured correlation matrix for weight at different follow-up time points (1, 2, 6 and 12 months) was used. The analysis was adjusted for baseline weight, age, sex, ethnicity, smoking status and GP practice.

Two sensitivity analyses were undertaken to assess the robustness of our primary analysis to different assumptions regarding the missing data. These were (1) a complete-case analysis, including only patients with recorded data at 12 months; and (2) an analysis that assumes data missing at 12 months are not missing at random.

Cost-effectiveness analysis

Cost-effectiveness analysis was undertaken to examine whether or not the WAP represents value for money to the NHS.

In order to estimate the cost-effectiveness of the WAP (intervention group) versus nurse-led weight management (representing usual care), a within-trial cost–utility analysis was undertaken. The costs were estimated from the NHS and social services perspectives. To inform the estimation of quality-adjusted life-years (QALYs), participants completed the European Quality of Life-5 Dimensions-5 Levels questionnaire.

The incremental cost-effectiveness ratio (ICER) was calculated. Costs and outcomes were bootstrapped (using 10,000 replications) and the data used to construct cost-effectiveness acceptability curves to show the probability that the WAP is a more cost-effective intervention than routine care.

Base-case analysis makes three key assumptions regarding the cost of the WAP intervention: (1) the prior history of health-care use should not influence results; (2) group sessions are conducted by a band 5 (hospital dietitian); and (3) the cost of the WAP assumes attendance of 15 participants for all sessions. These three assumptions are subject to sensitivity analysis.

Results

Study population

Of 1018 potential participants registering an interest, 389 were ineligible (reasons include use of psychiatric medication, lost > 5% of body weight in the last 6 months, a BMI of < 28 kg/m^2 or < 30 kg/m^2 without comorbidities), 283 declined to participate and 16 could not be randomised because the study sample size target had been reached. The remaining 330 were randomly allocated in a 2 : 1 ratio to the WAP ($n = 221$) and nurse ($n = 109$) arms.

Participants were, on average, in their mid-forties (WAP arm, mean 46.6 years; nurse arm, mean 45.1 years) and weighed, on average, 95.5 kg and 98.3 kg, in the WAP and nurse arms respectively. The majority (72%) were women, and 48% were from black or other ethnic minority communities. Most (59%) were entitled to free prescriptions, reflecting the low income of the population, and 38% had left school before the age of 16 years.

Primary outcome

A total of 291 participants (WAP, $n = 194$; nurse, $n = 97$) were included in the analysis of the primary outcome. Weight loss at 12 months was significantly greater in the WAP arm than in the nurse arm [–4.2 kg vs. –2.3 kg; difference –1.9 kg, 95% confidence interval (CI) –3.7 to –0.1 kg; $p = 0.04$]. In the sensitivity analyses, under the assumption that, on average, the weight of those lost to follow-up showed no change from baseline, the results are unaffected (difference –2.4 kg, 95% CI –4.3 to –0.5 kg). The complete-case analysis showed similar results.

Secondary outcomes

Participants in the WAP arm were significantly more likely than those in the nurse arm to have lost at least 5% of their baseline body weight at 12 months (41% vs. 27%; odds ratio 14.61, 95% CI 2.32 to 91.96; $p = 0.004$).

Reduction in waist circumference at the 12-month follow-up was also greater in the WAP arm ($n = 149$) than in the nurse arm ($n = 83$), although the difference was not significant (–4.0 vs. –2.0 cm; difference –2.0 cm, 95% CI –4.1 to 0.2 cm; $p = 0.07$).

There were no significant differences between groups in changes in blood pressure, physical activity, time spent sitting or knowledge of caloric content of food from baseline to the 12-month follow-up.

Adverse events were reported by 25 (11%) participants in the WAP arm and six (6%) in the nurse arm (odds ratio 2.19, 95% CI 0.86 to 5.58; $p = 0.1$). There were three serious AEs (all in the WAP arm), but none related to study procedures.

Cost-effectiveness

The total cost of providing the WAP intervention (up until the end of maintenance) was £195 per participant, or approximately £10 per session attended. The nurse intervention cost £176 per participant. The mean (SD) unadjusted QALYs gained as a result of the WAP and the nurse intervention was 0.389 (0.072) and 0.404 (0.079), respectively. The cost-effectiveness analysis, which controls for baseline utility and age, shows that the increase in QALYs (WAP vs. nurse) is not statistically significant (0.0104, 95% CI –0.0015 to 0.0224; $p = 0.088$). The ICER for the WAP over and above the best-practice nurse-led intervention is £7742 per QALY, which falls below the nominal threshold of £20,000–30,000 used by the National Institute for Health and Care Excellence.

Conclusions

A WAP delivered in general practice better promotes long-term weight loss than a best usual practice nurse-led weight loss programme.

Implications for health care

A possible model for weight management services along the lines of the SSS.

Recommendations for research

1. We recommend ongoing follow-up of this study cohort, which would enable investigation of whether or not the WAP is able to support weight loss in the long term.
2. The WAP treatment programme is delivered over 8 weeks, with ongoing maintenance sessions. With demands on staff and patient time in addition to financial restraints, research is needed on the added benefit, if any, of longer programmes.
3. Research is needed into factors that would make weight loss programmes more attractive to men.
4. The efficacy of the WAP delivered through electronic media should be investigated.
5. The ICER provides initial evidence that the WAP represents value. However, to address uncertainties in economic evaluations of this health-care programme, future research should conduct a sample size and power calculation for cost-effectiveness analysis.

Trial registration

This trial is registered as ISRCTN45820471.

Funding

This study was funded by the Health Technology Assessment programme of the National Institute for Health Research.

Chapter 1 Introduction

Background

Recent estimates show that over one-third of the world's adult population is overweight or obese, which is equivalent to more than 2.1 billion people globally.[1] By 2030 the proportion of adults who are overweight or obese is expected to rise to > 40%.[1] In terms of health risk, the World Health Organization estimates that around 2.8 million deaths per year, worldwide, are directly attributable to excess body weight or obesity.[2]

In England, the proportion of men who are classified as overweight [body mass index (BMI) of ≥ 25 kg/m^2)] has increased from 58% to 67% in the last decade, with a similar magnitude increase (49% to 57%) in women. Current rates of obesity (BMI of ≥ 30 kg/m^2) are 26% and 24% for men and women, respectively.[3] However, modelling has indicated that these rates could rise to 60% and 50% in men and women, respectively, by 2050.

Ill health resulting from obesity is responsible for approximately 10% of morbidity and mortality in the UK.[4] A summary of illnesses associated with high BMI is shown in *Box 1*. Weight loss has been shown to improve many of these illnesses[6] and reduce all-cause mortality.[7]

In 2002, the direct annual health-care costs associated with the treatment of obesity were around £1B. In 2007, the costs were estimated to have increased to £4.2B, and they are predicted to increase further, to £10B, by 2050.[5] The costs to society are far greater. Obesity currently accounts for 3–8% of health costs in different parts of Europe,[8] with the overall impact on health-care costs estimated to range from €59B (direct) to €118B–236B (indirect), because obesity is linked to a range of comorbidities. In the UK, obesity is second to smoking in terms of economic loss, costing the country around £45B in 2012.[9] This equates to 3% of gross domestic product.

Obesity has links to health inequalities, and the proportion of obese people is particularly high in the lower socioeconomic groups.[3] There are also ethnic differences; for example, the highest obesity rates are reported in African-Caribbean and Irish men.[3] Rates are also high in Bangladeshi women, with 17% classified as having a BMI of ≥ 30 kg/m^2. This proportion rises to 50% when obesity is defined using the waist-to-hip ratio.[10]

BOX 1 Summary of health risks associated with a high BMI

- Type 2 diabetes mellitus.
- Abnormal blood lipids (e.g. increased low-density lipoprotein).
- Cardiovascular disease (e.g. high blood pressure, stroke, myocardial infarction, congestive heart failure).
- Obstructive sleep apnoea.
- Cancer (e.g. cancers of the endometrium, breast, colon and gallbladder).
- Reproductive disorders (e.g. ovulatory dysfunction).
- Osteoarthritis.
- Liver and gall bladder disease (e.g. fatty liver and gallstones).

Source: adapted from *Reducing Obesity: Future Choices*.[5]

Given the high prevalence of obesity, there is a need to investigate the effectiveness of simple, pragmatic and cost-effective interventions that have the ability to reach the large number of obese and overweight individuals in the UK.

Weight management strategies

In 2011, the Department of Health published a policy paper that called for efforts to reduce the proportion of adults with excess weight by 2020.[11] A range of strategies will be required if the UK is to reduce its obesity rates.[9] These strategies include personal health-care interventions, such as weight management programmes and weight loss medicines, as well as education and environmental changes.

The menu of evidence-based interventions currently available for people unable to lose weight on their own is relatively limited. A stepped-care approach is currently the recommended approach for weight management depending on the severity of the patient's obesity. Current pharmacological treatments have modest effects that can be beneficial but are likely to be lost once the medication is stopped.[12] Surgical interventions are more successful but are currently expensive and unsuitable for large-scale use, and are usually indicated for the morbidly obese or those with coexisting conditions.[13,14] Dietary interventions on their own have only modest effects[15] and brief routine interventions within primary care have generally reported disappointing results.[16]

More intensive behavioural interventions generate a small but sustainable weight loss,[17] which can engender significant and clinically worthwhile long-term health benefits.[18] Despite the fact that some of the initial weight lost is regained, interventions that lead to at least a 5% reduction in body weight can lead to health improvements (e.g. a decreased risk of type 2 diabetes mellitus).[19–22]

Obesity is a chronic condition that requires lifelong management, as weight is often regained, but achieving changes in behaviour is challenging.[23] Weight management in overweight individuals who seek help normally requires changes to their habitual lifestyle, which are difficult to implement and maintain without specialist input, structure and support.[24,25] The National Institute for Health and Care Excellence (NICE) guidance on *Managing Overweight and Obesity in Adults* recommends multicomponent interventions as the treatment of choice (*Box 2*).[26] These interventions should include behaviour change techniques to increase people's physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person's diet, and reduce energy intake. Several systematic reviews have demonstrated that the combination of diet, exercise and behavioural approaches are effective management strategies.[27] However, few studies have specifically targeted primary care patients.

Intensive weight management programmes can make considerable demands on staff expertise and budgets, and they also face the challenge of participant retention. The programmes usually include, as one of their core active ingredients, assignment and monitoring of tasks. These are difficult to implement for most participants and the participant dropout is usually large.[28]

Primary care interventions

Similar to smoking cessation, primary care has the potential to play a key role in helping overweight and obese people to achieve a healthy weight because of its unique role in the health-care system.

General practice is potentially an ideal location for running weight management services. People trust the advice of their general practitioner (GP) team, their GP practice is often local and convenient, and large GP practices now have multidisciplinary teams and physical space to operate weight management services. Some patients, especially those from ethnic minority groups, may be less likely to use commercial providers.[29–31] GPs have also been incentivised via the Quality and Outcomes Framework to maintain a register of patients (aged $\geq$ 16 years) with a BMI of $\geq$ 30 kg/m^2 as part of routine care.[32]

Current guidelines recommend that primary care physicians in England should identify people with obesity and offer clinical management, although few options for treatment exist. In 2013, the Royal College of

BOX 2 The NICE recommendations: core components for effective weight loss and prevention of weight regain

- They are multicomponent (i.e. they address dietary intake, physical activity levels and behaviour change).
- They are developed by a multidisciplinary team.
- They focus on lifelong lifestyle change and the prevention of future weight gain.
- They last at least 3 months, and sessions are offered at least weekly or fortnightly and include a 'weigh-in' at each session.
- Achievable goals for weight loss are agreed for different stages.
- Specific dietary targets are agreed (e.g. for a clear energy intake or for a specific reduction in energy intake), tailored to individual needs and goals.
- Discussions take place about how to reduce sedentary behaviour and the type of physical activities that can easily be integrated into everyday life and maintained in the long term.
- Programmes are tailored to support the needs of different groups.
- Weight, indicators of behaviour change and participants' personal goals are monitored throughout the programme.
- A respectful, non-judgemental approach is adopted.
- They foster independence and self-management (including self-monitoring).
- Opportunities for ongoing support once the programme or referral period has ended are discussed.
- The importance of maintaining new dietary habits and increased physical activity levels in the long term to prevent weight regain is stressed and strategies to overcome any difficulties in maintaining the new behaviours are discussed.
- They encourage dietary habits that will support weight maintenance and are sustainable in the long term.
- They promote ways of being more physically active and less sedentary that are sustainable in the long term (e.g. walking). The wider benefits of physical activity should also be emphasised.

Source: adapted from NICE guidance on *Managing Overweight and Obesity in Adults*.[26]

Physicians published a report on how the NHS should adapt to deal with the rising rates of obesity.[33] This report highlighted the role of GPs and the practice team, recommending that GPs should deal with excess weight and obesity as an important risk factor for non-communicable diseases. Although most obesity management in the UK takes place in primary care, the approach is not co-ordinated or consistent.[34]

Despite the advantages of targeting obesity in primary care, the effectiveness of interventions in this setting has not been widely evaluated. Where studies have been conducted, the results can be disappointing (*Box 3*).[34–36] If research evaluations showed little impact then real-life impact is likely to be worse.

Several recent systematic reviews have suggested that weight loss interventions in primary care yield small reductions in weight that are not likely to be clinically significant.[42,43] In the USA, a recent review concluded that obesity treatment delivered in primary care has limited effectiveness.[44]

One strategy that has shown modest effectiveness is primary care referral to evidence-based commercial programmes for weight loss treatment.[36]

The NICE guidelines recommend that GP practices raise the issue of weight loss with overweight patients and refer them to weight management services, where these exist.[26] These guidelines also recommend referring people to a group rather than an individual programme if they express no preference because, on average, group programmes tend to be more cost-effective.

BOX 3 Examples of weight loss trials that have included a primary care arm

The Lighten Up trial (2011)[35]

A total of 740 obese adults were randomised to one of six weight loss interventions or a control group. Three were commercial programmes [Weight Watchers® (New York, NY, USA), Slimming World (Alfreton, UK) and Rosemary Conley (Markfield, UK)], one was a NHS group-based programme (Size Down) and the last two were delivered either by GPs or pharmacists who had received weight loss advice training from dietitians. GP and pharmacist interventions were no better than the minimal intervention control, achieving a weight loss of 1 kg at 1 year.

Jebb *et al.* (2011)[36]

In a trial that compared the effects of a referral to Weight Watchers with weight loss advice from a primary care professional at the local GP practice, weight loss at 12 months was significantly lower in participants in the GP arm than in those who used Weight Watchers (1.6 kg vs. 4.0 kg).

POWER-UP trial (2011)[37]

A US primary care study randomised 390 obese patients to usual care (quarterly GP visits during which 5–7 minutes was devoted to reviewing the patients' weight change), brief lifestyle counselling (quarterly visits plus 10- to 15-minute appointments with a health-care assistant) or enhanced brief lifestyle counselling [monthly visits supplemented by participants' choice from orlistat, sibutramine (Meridia; Abbott Laboratories, Chicago, IL, USA) or meal replacements]. At the 12-month follow-up the weight loss in the three groups was 2.3 kg, 3.4 kg and 7.1 kg, respectively, with only the weight loss in the enhanced condition significantly greater than in the other groups.

Appel *et al.* (2011)[38]

In this randomised controlled trial, participants from six primary care practices were randomly assigned to weight loss advice delivered by telephone, internet and e-mail (remote support), in-person support during individual and group sessions (in-person support) and to a self-directed weight loss programme (control group). At 2 years, weight loss was similar in the groups that received in-person support (5.1 kg) and remote support (4.5 kg), and significantly greater than in the control group.

CAMWEL (2012)[23]

Participants were recruited in 23 general practices in a borough in London, UK. A total of 381 adults were randomised to the control group (usual weight management advice from the GP) or to the intervention condition (a structured one-to-one programme delivered in 14 visits over 12 months). At the 12-month follow-up, the difference in mean weight change between the intervention and control groups was not statistically significant (2.39 vs. 1.31 kg).

Think Health! (2012)[39]

Two interventions were tested in five primary care practices in the USA. A total of 261 participants were randomised to either usual care (four visits with a primary care provider over 1 year) or usual care supplemented by monthly lifestyle coaching provided by administrative staff. At 1 year, there was no significant difference in weight loss between the groups (1.61 kg in the intervention group and 0.62 kg in the control group).

BOX 3 Examples of weight loss trials that have included a primary care arm (*continued*)

The Counterweight Programme (2005, 2008)[40,41]

This has been promoted as a programme that could be implemented in primary care, and some results from a prospective cohort study have been reported. Practice nurses provided nine treatment sessions and mean weight loss of < 3 kg at 12 months was reported. However, this weight loss was was achieved in the 45% of enrolled patients who attended for follow-up. Without accounting for those lost to follow-up, and in the absence of a control group, the efficacy of the programme is difficult to appraise.

In the field of health behaviour modification, group approaches can dramatically reduce the costs of treatments and increase their reach.[45] They may also have potential to improve participant retention. Social support has been associated with positive change in a number of areas, including weight management.[46] Some potentially useful pointers can be derived from the field of smoking cessation, which shares a number of key features with weight management. Interaction-oriented groups have been shown to improve attendance and participant retention,[47] mutual linking of individual tasks improves treatment compliance and short-term outcome,[48] and on a national scale group treatments seem to be yielding results superior to individual treatment.[49] Current group weight management programmes usually have a strongly didactic focus, with limited efforts to utilise social support and to link the progress of individual participants. It is likely that the mutual support-oriented group approach, which has proved useful in smoking cessation, can be used here as well.

Several types of such programmes have been commissioned by local councils, but their efficacy is generally not known. With previous evidence suggesting that obesity interventions in primary care have had little impact, there is a need for evidence-based public domain weight management programmes that are clinically effective and cost-effective, and readily accessible and attractive for patients from diverse ethnic and socioeconomic backgrounds.

Trial objectives

The trial objective was to determine whether or not a promising task-based weight management programme [Weight Action Programme (WAP)] targeting underprivileged groups has a long-term effect that is over and above the effect of a 'best practice' weight management intervention provided in primary care by practice nurses.

Primary objective

To determine whether or not the WAP can generate better-sustained weight loss over 12 months in overweight adults than a best practice intervention delivered by nurses in general practice.

Secondary objective

To determine the cost-effectiveness [in terms of costs of interventions and quality-adjusted life-years (QALYs) derived from the European Quality of Life-5 Dimensions-5 Levels (EQ-5D-5L) questionnaire] of the two interventions.

Chapter 2 Methods

Overview of trial design

We conducted a randomised controlled trial (RCT) between 2012 and 2015 in two NHS general practices. Eligible adults were recruited primarily from these practices, supplemented by wider advertising, and randomised to the intervention or control arm in the ratio of 2 : 1 (WAP arm to nurse arm). Participants in the WAP and nurse arms started treatment within 1 week after randomisation. All participants were invited to attend 6- and 12-month follow-up appointments. To maximise retention, home and work visits were conducted for those unable to attend the follow-up appointments.

Changes to trial design

We initially intended to randomise 116 participants to the control arm and 214 to the intervention arm. However, we realised that for statistical and logistical reasons it was simpler to randomise 110 and 220 to the nurse and WAP arms, respectively. This change did not affect the total sample size ($n = 330$) and made little difference to the power. This major amendment was submitted and approved by the trial sponsor and ethics committee before the trial commenced recruitment. Protocol amendments are summarised in *Table 1*.

Participants

Inclusion criteria

Participants were eligible if they were aged ≥ 18 years, wanted to lose weight and had a BMI of ≥ 30 kg/m^2 or ≥ 28 kg/m^2 plus comorbidities.

Exclusion criteria

Those who were unable to read/write/understand English, had a BMI of > 45 kg/m^2, had lost > 5% of their body weight in the previous 6 months, were pregnant, were taking psychiatric medications, were not registered with a GP in the local areas or were involved in a current research project were excluded.

The decision to exclude participants on psychiatric medication, including antidepressants, was based on the fact that these medications can have a significant effect on weight, and that psychiatric illness often makes follow-up and adherence to long-term programmes more difficult. We did not exclude people with a history of psychiatric illness if they were no longer taking psychiatric medication.

We did not exclude any other comorbidities to ensure that the study addressed NHS needs and that the results are generalisable. Clients who were unable to exercise were not excluded as both the nurse and the WAP interventions are multimodal and do not rely solely on exercise.

TABLE 1 Summary of protocol amendments

Version	Date	Summary
1.0	5 December 2011	Original protocol
2.0	17 May 2012	Change in randomisation procedure (conducted by the Sheffield Clinical Trials Unit rather than a PCTU statistician); clarification of the primary and secondary outcomes; and procedures relating to confidentiality and quality assurance processes clarified
3.0	22 January 2015	See *Change from planned analysis*, clinic address updated

PCTU, Pragmatic Clinical Trials Unit.

Recruitment

Box 4 lists the strategies that we used to recruit participants.

Recruitment commenced in September 2012 with the first participant enrolled at the Barkantine Practice, London, UK, on 24 September 2012. The first participant was screened at the Lawson Practice, London, UK, on 18 October 2012.

We encountered some difficulties in recruiting our sample in the short time frame that we had set. These are discussed in *Chapter 5*, *Recruitment barriers and facilitators*.

All publicity (except GP fax referrals) invited potential participants to contact the study team by telephone. A researcher would explain the study, assess interest and eligibility, and invite the potential participant to attend the initial screening session.

Setting

We wrote to all practices in the two boroughs with a brief explanation of the study and an invitation to contact the study team if interested in participating as a host site. The chairperson of the Trial Steering Committee helped facilitate site identification in Hackney.

The interventions were delivered in two GP practices, one in the London borough of Tower Hamlets and one in Hackney. Recruitment of participants was primarily from these two practices, but participants were

BOX 4 Trial recruitment strategies and publicity

General practitioner-based recruitment

Posters/flyers (*Figure 1*) in reception area and consultation rooms; adverts on GP practice website and boards; text and letter mailshots to potential participants identified via GP database searches; GP fax/telephone referrals (*Figure 2*); 'comments' box on GP reception allowing potential participants to express their interest; newsletters for practice patients and staff providing feedback on current participants; and attending regular clinical meetings to ensure GP staff were aware of the purpose of the study and how to refer onto it. Several GP practices throughout Tower Hamlets, Hackney and the City were contacted.

Publicity in media

Newspapers

Local papers: *East End Life* (on 4 February 2013, 3 June 2013 and 14 October 2013).

Other

Community venues

Posters and leaflets were distributed in various community venues throughout Tower Hamlets, including the Osmani Trust. Stalls were also held at various health promotion events in the Tower Hamlets area.

Workplace venues

Posters and leaflets were distributed in various locations throughout Queen Mary University and the Royal London Hospital.

(a)

(b)

FIGURE 1 Leaflets (a) and posters (b) used to promote the study.

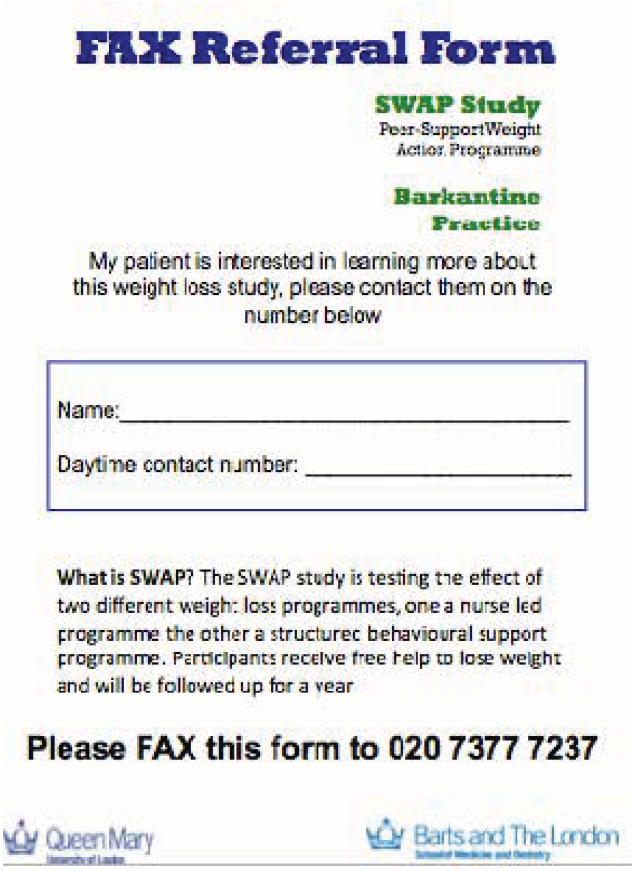

FIGURE 2 General practitioner fax referral form.

also referred from four other neighbouring practices to facilitate recruitment. Hackney is ranked as the most deprived borough in England and Tower Hamlets is ranked third.[50]

In the London borough of Tower Hamlets it is estimated that 47% [95% confidence interval (CI) 42.3% to 52.1%] of adults are classified as overweight or obese. In Hackney, the figure is similar (49%, 95% CI 43.7% to 53.7%).

The Barkantine Practice is a large GP practice and walk-in centre in Tower Hamlets. It has approximately 18,000 patients on its list. The practice staff comprises 13 doctors, two nurse practitioners, three nurses, three health-care assistants, two health visitors and administrative staff.

The Lawson Practice is a large GP practice in the centre of Hackney. It has approximately 13,000 patients on its list. The practice staff comprises 13 doctors, one nurse practitioner, one nurse, three health-care assistants, two health visitors and administrative staff.

Study procedures

Screening procedures

Participants were either invited to telephone the study team if recruited by posters or leaflets, or telephoned by the study team if referred by GP fax referral.

At the initial screening telephone call, a good clinical practice (GCP)-trained member of staff provided the participant with information on the study. If interested, participants were screened for eligibility over the telephone. Eligible participants were booked onto the next available screening session and were posted or e-mailed the participant information sheet, baseline questionnaire and letter of invitation in advance of this. Participants who were not eligible but still interested in losing weight were either offered the option to attend the standard care clinic or advised to visit their GP for further advice on weight management.

Informed consent procedures

Participants were provided with detailed trial information and allowed sufficient time (at least 24 hours) to consider whether or not they wanted to participate in the trial. All participants were provided with a participant information sheet with more details of the study.

All participants provided written informed consent at the baseline (first) screening session, prior to being randomised to the study arms.

Written informed consent was obtained by an appropriately GCP-trained member of staff delegated by the investigator as documented on the site delegation log, prior to any participation/study-specific procedures.

Randomisation procedures

If eligible, participants were invited to attend the randomisation session a few days later. At this session, participants completed further questionnaires and had their weight, waist circumference and blood pressure recorded. They were then randomised (see *Randomisation* for more detail of randomisation procedure) to the WAP or nurse (weight loss intervention from a trained GP practice nurse) arms. The first session of the WAP and the nurse intervention were provided within 7 and 14 days of the randomisation session. *Table 2* summarises the main purpose of the study visits. All visits were held face to face.

Interventions

Practice nurse intervention

We standardised the nurse intervention to ensure that participants received a consistent standard of care. The nurse intervention was modelled on the best practice intervention in primary care, derived from

TABLE 2 Study visits

Visit number	Time point	Top-level tasks
1	Week –1	Screening
2	Week 0	Randomisation[a]
3–10	Weeks 1–8	WAP – eight weekly sessions
		Nurse – four fortnightly sessions
11–20	Months 3–12	WAP – 10 monthly follow-up sessions
		Nurse – 6- and 12-month follow-up sessions only

a Time to all follow-up sessions was taken from this time point.

discussions with GPs and practice nurses, and incorporating national guidelines at the time[51] and NHS materials (*Your Weight, Your Health: Raising the Issue of Weight in Adults*[52]).

In 2011, when we were designing this project, we conducted a survey of weight management interventions in a range of general practice surgeries. GPs typically provided brief advice followed by referral to a practice nurse. A minority of practices used dietitians but this was slowly being phased out. Some practice nurses had received 1-day training in weight management and provided one-off sessions or sessions with a degree of follow-up, either optional or scheduled, over 2–8 weeks. In about half of the practices, the nurses also referred patients to local community-based physical activity programmes.

We modelled the nurse intervention on the more intensive end of the spectrum, which is still routinely practicable across GP surgeries. Participants received weight management intervention from a practice nurse who had been given training in the study procedures by the research team. The nurses provided the intervention in four sessions delivered over 8 weeks.

The intervention included advice on (1) diet (instructions on understanding food groups, food labels and calories; eat at least five portions of a variety of fruit and vegetables each day in place of foods higher in fat and calories; eat breakfast; watch the portion size of meals and snacks; and replace high-calorie food with healthier options); and (2) activity (make enjoyable physical activities part of everyday life; minimise sedentary activities; build activity into the working day; and take up one of the local exercise opportunities). *Table 3* shows a summary of the control intervention. Each session lasted up to 30 minutes. Participants received information about local exercise provision and 'exercise on prescription', and received relevant vouchers and referrals. This advice was supported with written materials. Participants received a:

- *Drink Swap: How to Cut Down on Calories in Drinks without Having to Say 'No'* leaflet[53]
- *Portion Swap: How Smaller Plates and Portions Help Prevent us Eating too Many Calories* leaflet[54]
- *Snack Swap: How to stay Healthy Without Giving Up all Snacks* leaflet[55]
- *Walk 4 Life: Tips to Get Walking Every Day* leaflet[56]

TABLE 3 Session content of the nurse intervention

Session	Content description
1	Introduction, dietary advice (food labels, 5 a day, easy switches), opportunities for exercise and information on orlistat
2	Discuss progress, provide encouragement
3	Discuss progress, provide encouragement
4	Discuss progress, provide encouragement and discuss plans for continuing

- *The Eatwell Plate* leaflet[57]
- *5 a Day: What Counts?* leaflet[58]
- *Food Labels* leaflet (created by the Health and Lifestyle Unit, Wolfson Institute of Preventive Medicine, London, UK – available on request)
- calorie guide (created by the Health and Lifestyle Unit, Wolfson Institute of Preventive Medicine, London, UK – available on request)
- exercise guide (created by the Health and Lifestyle Unit, Wolfson Institute of Preventive Medicine, London, UK – available on request).

Where appropriate, participants were given an information sheet about orlistat (based on the information provided on the NHS Choices website[59]) and advised to see their GP if they wished to use it as part of their weight loss programme.

Participants' weight was recorded at all treatment and follow-up visits. Participants were not restricted from using any other weight loss intervention (including pharmacological treatment if their GP agreed it was appropriate) during the study. They were, however, asked to report on the use of such interventions during the study period.

Weight Action Programme group intervention

The WAP is a multimodal health behaviour modification intervention developed at the Wolfson Institute of Preventive Medicine via extensive client feedback and piloting with underprivileged groups since 2002. The programme is a multicomponent service utilising evidence-based behaviour change techniques in the context of group support targeted to individual needs that aims to provide participants with tools to lose weight and to maintain a long-term healthy lifestyle.

The evidence-based strategies and contents include:

1. self-regulation through the use of (1) food diaries to monitor caloric intake; (2) self-monitoring of weight; and (3) goal-setting and contingent reinforcement
2. motivational components incorporating the standard elements of cognitive–behavioural interventions aimed at encouraging and improving self-efficacy, facilitated by a range of concrete and verifiable tasks agreed individually with each participant (e.g. participants agree incremental pedometer targets)
3. fostering a non-judgemental support network strengthened by shared experience, outcome expectations, positive reinforcement and information on coping with lapses and long-term support
4. dietary advice, information on healthy eating and caloric content of food, cue management, provision of opportunities for exercise and close monitoring of exercise levels.

Participants commit to implementing each of a series of concrete and verifiable tasks for at least 1 week (see *Box 8* for a full description). They can drop the task after that if they find it unhelpful.

Another innovative feature of the programme consists of the use of group-oriented interventions aiming to increase participant retention, involvement and adherence to weekly tasks. For example, 'buddy pairs' of participants are made responsible for each other's completion of the weekly task and weight loss of 1 lb (0.45 kg) between the pair. The group format also makes the programme more cost-efficient. Facilitator-led group support creates an environment in which participants can discuss their progress, identify patterns of behaviour and develop coping strategies to facilitate weight loss and maintenance.

The programme was initially implemented within NHS Tower Hamlets, and then modified in the light of participants' feedback to make it suitable for underprivileged groups, including ethnic minorities. Where information is imparted, it is mostly in a pictorial and easily understandable format.

The WAP has been evaluated in two pilot studies of 162 overweight adults (mean BMI of 35 kg/m^2) from multiethnic areas of high deprivation.[60] The average weight loss was 2.8 kg at the end of treatment and

4.5 kg at the 3-month follow-up (with 24% of participants attending follow-up losing ≥ 5% of their body weight). Limited promotion via GP practices and local adverts generated a large volume of interest. The client retention was at least as good as in comparable programmes conducted in research settings with more traditional clients (59% completed the 6-week treatment) and the programme received very high approval ratings. Clients also demonstrated significant improvements in knowledge of healthy eating, and in their exercise levels, as measured by pedometer monitoring. Clients considered the group support essential in helping them to stick to their tasks and to lose weight.[60] In its current form, the WAP also includes information on orlistat.

The version of WAP used in the trial comprised eight weekly sessions, followed by monthly follow-up visits lasting up to 1 hour each. The content of the programme is summarised in *Table 4*. The target weight loss was 1 lb (0.45 kg) per week. Two advisors conducted the WAP sessions in groups of 10–20 participants.

Participants were provided with an Oregon pedometer PE980 (Oregon Scientific, Tualatin, OR, USA).

As in the control intervention, participants were not barred from using any other weight loss intervention (including pharmacological treatment from their GP). They also received information about local exercise

TABLE 4 Session content of the WAP

Session	Content description and key tasks
1	Content: introductions, explanation of the course and setting positive and accurate expectations
	Tasks: wear pedometer and record steps daily, keep a food diary on at least 3 days, monitor 'screen time' and do not make any changes yet
2	Content: understanding calories
	Tasks: pedometer reading to reach agreed level and food diary to include calories
3	Content: 5 a day, orlistat and triggers for overeating
	Tasks: pedometer reading to reach agreed level, 5 a day and obtain orlistat from GP if interested and eligible
4	Content: exercise
	Tasks: pedometer reading to reach agreed level and 2 × 10–30 minutes of exercise/moderate-intensity activity
5	Content: awareness of unnecessary eating, 'buddy' up participants and importance of regular weigh-ins
	Tasks: pedometer reading to reach agreed level, 3 × 20–30 minutes of exercise, 'say no' to unnecessary eating and monitor weight
6	Content: calories recap and monitor hunger
	Tasks: pedometer reading to reach agreed level, 3 × 30 minutes of moderate-intensity activity, 'say no' to unnecessary eating and monitor weight
7	Content: avoiding triggers to eating and easy switches
	Tasks: pedometer reading to reach agreed level, 3 × 30 minutes of moderate-intensity activity, 'say no' to unnecessary eating, monitor weight and easy switches
8	Content: recap of 8-week course, feedback and discuss plans for continuing
	Tasks: pedometer reading to reach agreed level, 3 × 30 minutes of moderate-intensity activity, 'say no' to unnecessary eating and monitor weight
9–18	Content: maintenance sessions, monitor progress and reinstate interventions as needed
	Tasks: pedometer reading to reach agreed level, 3 × 30 minutes of moderate-intensity activity, 'say no' to unnecessary eating and monitor weight

provision and where 'exercise on prescription' was available, they received relevant vouchers and referrals. Participants were asked to report on the use of such interventions during the study period.

To help improve replication and further evidence synthesis, *Table 5* summarises the content of the WAP according to the CALO-RE (Coventry, Aberdeen, London – Refined) taxonomy of behaviour change techniques for changing physical activity and healthy eating behaviours.[61]

TABLE 5 Behaviour change techniques used in the WAP

	Session number								
Behaviour change techniques[61]	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9–18**
Providing information on consequences of behaviour in general	✗	✗	✗	✗	✗	✗	✗	✗	✗
Providing information on consequences of behaviour to the individual	✗	✗	✗	✗	✗	✗	✗	✗	✗
Providing information about others' approval	✗				✗	✗	✗	✗	✗
Providing normative information about others' behaviour	✗	✗	✗	✗	✗	✗	✗	✗	✗
Goal-setting (behaviour)		✗	✗	✗	✗	✗	✗	✗	✗
Goal-setting (outcome)		✗	✗	✗	✗	✗	✗	✗	✗
Action-planning		✗	✗	✗	✗	✗	✗	✗	✗
Barrier identification/problem-solving		✗	✗	✗	✗	✗	✗	✗	✗
Setting graded tasks	✗	✗	✗	✗	✗	✗	✗	✗	✗
Prompting review of behavioural goals		✗	✗	✗	✗	✗	✗	✗	✗
Prompting review of outcome goals		✗	✗	✗	✗	✗	✗	✗	✗
Prompting rewards contingent on effort or progress towards behaviour					✗	✗	✗	✗	
Providing rewards contingent on successful behaviour					✗	✗	✗	✗	
Shaping									
Prompting generalisation of a target behaviour		✗	✗	✗	✗	✗	✗	✗	✗
Prompting self-monitoring of behaviour		✗	✗	✗	✗	✗	✗	✗	✗
Prompting self-monitoring of behavioural outcome		✗	✗	✗	✗	✗	✗	✗	✗
Prompting focus on past success	✗								✗
Providing feedback on performance		✗	✗	✗	✗	✗	✗	✗	✗
Providing information on where and when to perform the behaviour	✗	✗	✗	✗	✗	✗	✗	✗	✗
Providing instruction on how to perform the behaviour	✗	✗	✗	✗	✗	✗	✗	✗	✗
Modeling demonstrating the behaviour	✗	✗	✗	✗	✗	✗	✗	✗	✗
Teaching to use prompts/cues									
Environmental restructuring			✗				✗		
Agreeing behavioural contract					✗	✗	✗	✗	
Prompting practice		✗	✗	✗	✗	✗	✗	✗	✗
Use of follow-up prompts									
Facilitating social comparison		✗	✗	✗	✗	✗	✗	✗	✗
Planning social support/social change					✗	✗	✗	✗	✗
Prompting identification as role model/position advocate									✗

TABLE 5 Behaviour change techniques used in the WAP (*continued*)

Behaviour change techniques[61]	Session number								
	1	2	3	4	5	6	7	8	9–18
Prompting anticipated regret									
Fear arousal		✗			✗	✗	✗	✗	✗
Prompting self-talk			✗	✗					
Prompting use of imagery									
Relapse prevention/coping planning								✗	✗
Stress management/emotional control training			✗						
Motivational interviewing									
Time management									
General communication skills training								✗	✗
Stimulating anticipation of future rewards									

Staff training

All staff delivering the WAP were trained by shadowing Professor Hajek or Professor McRobbie delivering the programme, and were supervised and mentored when delivering the WAP themselves.

Monitoring of intervention fidelity

For the WAP intervention, the chief investigator (Professor McRobbie) attended five sessions led by each advisor (two in the early phase of the trial and then quarterly) and formally checked the conduct of the session against the counselling protocol to provide feedback to the advisors and record fidelity of the intervention. Professor McRobbie also attended five sessions of the control intervention (two in the early phase of the trial and then quarterly) and checked the conduct of the session formally against the counselling protocol to provide feedback to the nurse and record fidelity of the intervention. Professor Hajek attended one session at each practice and provided feedback.

Outcomes

Primary outcome

The primary outcome is the change in weight (in kg) at 12 months post randomisation.

Secondary outcomes

We recorded the following secondary outcomes:

- change in weight (in kg) at 1, 2 and 6 months post randomisation
- change in BMI at 1, 2, 6 and 12 months post randomisation [BMI is calculated as weight (in kg) divided by the square of height (in metres); the height measured at screening was used for each follow-up assessment]
- change in waist circumference (in cm) at 2, 6 and 12 months post randomisation
- change in systolic blood pressure (in mmHg) at 2, 6 and 12 months post randomisation
- change in diastolic blood pressure (in mmHg) at 2, 6 and 12 months post randomisation

- change in the Food Craving Inventory score (frequency domain) at 1, 2, 6 and 12 months post randomisation
- change in the Food Craving Inventory score (strength domain) at 1, 2, 6 and 12 months post randomisation
- change in Food Knowledge Assessment Questionnaire score at 2, 6 and 12 months post randomisation
- change in the Three-Factor Eating Questionnaire score (cognitive restraint domain) at 2, 6 and 12 months post randomisation
- change in the Three-Factor Eating Questionnaire score (uncontrolled eating domain) at 2, 6 and 12 months post randomisation
- change in the Three-Factor Eating Questionnaire score (emotional eating domain) at 2, 6 and 12 months post randomisation
- change in the International Physical Activity Questionnaire score [metabolic-equivalent (MET) minutes/week domain] at 2, 6 and 12 months post randomisation
- change in the International Physical Activity Questionnaire score (sitting domain) at 2, 6 and 12 months post randomisation
- proportion of participants losing 5% of body weight at 2, 6 and 12 months post randomisation
- proportion of participants losing 10% of body weight at 2, 6 and 12 months post randomisation.

Measurements

Baseline

The following variables were collected at baseline:

- Demographics: includes age, sex, ethnicity, employment and level of education.
- Health and lifestyle: includes smoking status, alcohol consumption and general health.
- Weight loss history: includes number of past weight loss attempts, methods used, most weight ever lost and regular monitoring of weight.
- Concurrent medications: all current medications are recorded.
- Height and weight: measured in centimetres and kilograms respectively, BMI was calculated from these. Height was measured, without shoes, on a Seca 2013 portable stadiometer (Seca, Birmingham, UK). Weight was measured on an Omron HBF 400 Body Fat Monitor and Scale (Omron Healthcare UK Ltd, Milton Keynes, UK), with participants wearing light clothing and no shoes. Accuracy was ensured by calibration against standard weights.
- Waist circumference: measured in centimetres.
- Blood pressure: resting blood pressure recorded using an Omron 705IT BP monitor (Omron Healthcare UK Ltd, Milton Keynes, UK) using an appropriately sized cuff.

The following questionnaires were also administered at baseline:

- International Physical Activity Questionnaire[62]
- Food Craving Inventory[63]
- Three-Factor Eating Questionnaire [64]
- EQ-5D-5L questionnaire[65]
- Use of Health Services Questionnaire (see *Appendix 1*).

We also administered a picture-based food knowledge assessment at baseline and at follow-up. This was developed by the Health and Lifestyle Unit, Queen Mary University of London, to measure basic knowledge of caloric content of different food groups.

Scoring details for the Food Craving Inventory, the Food Knowledge Assessment Questionnaire, the Three-Factor Eating Questionnaire and the International Physical Activity Questionnaire are available in *Appendix 2*.

Timing of measurements
The study sessions are summarised in measurement schedule shown in *Table 6*.

Adverse events
We used the sponsor's definition of an adverse event (AE), defined as any untoward medical occurrence in a subject to whom the intervention has been administered, including occurrences that are not necessarily caused by or related to the intervention.

At every visit all participants were asked whether or not they had experienced any AEs since their last contact with the research team.

All AEs were categorised by a member of the research team, blinded to treatment group, according to their severity and whether or not they were related to participation in the Peer-Support Weight Action Programme (SWAP). When possible, serious adverse events (SAEs) and any AEs for which relatedness to participation in SWAP was not clear were followed up by a telephone call to the participant. AEs that occurred before the baseline measurement period were not recorded.

Serious adverse events
A SAE was defined as an adverse event meeting at least one of the following criteria:

- fatal
- life-threatening
- necessitating inpatient hospitalisation or prolongation of existing hospitalisation
- resulting in persistent or significant disability/incapacity
- a congenital anomaly/birth defect
- otherwise considered medically significant by the investigator.

Any SAEs were reported immediately to the chief investigator, the sponsor and the Research Ethics Committee. A report of all SAEs was provided at every Trial Management Committee and Trial Steering Committee meeting.

Follow up
The following variables were collected during follow-up visits: weight, waist circumference, blood pressure, International Physical Activity Questionnaire,[62] Food Knowledge Assessment, Food Craving Inventory, Three-Factor Eating Questionnaire,[64] EQ-5D-5L,[65] Use of Health Services Questionnaire (see *Appendix 1*), AEs, participant feedback (see *Appendix 3*) and use of any concomitant weight loss treatment.

In the intervention arm, the following were collected during the 8-week intervention phase: pedometer use, food diary use and adherence to weekly tasks (e.g. increase in fruit and vegetable intake, increase in exercise, monitoring television and computer use).

The 6- and 12-month follow-ups
The 6- and 12-month follow-up sessions for both arms were held at each GP practice. To maximise retention at each follow-up, participants were (1) telephoned 3–4 weeks prior to the visit to schedule a suitable time and explain the importance of attending; (2) sent a confirmation letter/e-mail 1–2 weeks before the scheduled visit; (3) sent a text reminder on the day of the appointment; (4) offered a home/work visit if attending the GP practice was difficult; and (5) offered £10 as a contribution towards travel expenses. The sample size calculation assumed that 50% of participants would be lost to follow-up at 12 months; however, the study team implemented a range of strategies to ensure that as many participants as possible completed the final follow-up (*Box 5*).

TABLE 6 Study measures and assessment schedule

Measure	Time																		
	Week –1	Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Informed consent	✓																			
Demographics	✓																			
Weight loss history	✓																			
Height	✓																			
Weight[a]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Waist circumference		✓								✓				✓						✓
Blood pressure		✓								✓				✓						✓
Randomisation		✓																		
Comorbidities	✓																			
Concurrent medications	✓													✓						✓
Pedometer use[b]			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
International Physical Activity Questionnaire[62]	✓									✓				✓						✓
Food diary use[b]			✓	✓	✓	✓	✓	✓	✓	✓										
Weekly tasks[b]				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Food knowledge assessment	✓									✓				✓						✓
Food Craving Inventory[63]		✓				✓				✓				✓						✓
Three-Factor Eating Questionnaire [64]		✓								✓				✓						✓
EQ-5D-5L[65]		✓												✓						✓
Use of Health Services Questionnaire		✓												✓						✓
Participant feedback										✓				✓						✓
AEs			✓	✓	✓	✓	✓	✓	✓	✓	✓[b]	✓	✓[b]	✓	✓[b]	✓	✓[b]	✓	✓[b]	✓

a Weight measured at months 3–5 and 7–11 in the intervention group only.
b Intervention group only.

BOX 5 Follow-up strategies used and suggestions for future research

Follow-up strategies used

The implementation of multiple follow-up routes (e.g. telephone, text, letter, e-mail).

Calls made to participant at different times of the day (e.g. early mornings/late evenings).

All contact attempts documented, so study team could quickly assess which route to try next.

Involving staff affiliated with the study team (i.e. not involved in the intervention) to make contact with participants to invite them to attend for follow-up so as not to put participant off if they speak to the researcher involved in leading the intervention.

Flexible appointments offered (e.g. evening/weekend/home visits).

Stressing the importance to participants at end of treatment to attend for follow-up, even if they feel that they have gained weight.

Potential strategies for future research

Consider ways of keeping participants 'involved' in the study, even if they stop attending from an early stage (e.g. newsletters/interim texts/e-mails).

Send feedback forms to those participants who did not attend to better capture reasons for drop out.

Consider detailing in protocol plans to contact GP to capture data collected at surgery where participants do not attend follow-up.

Consider the use of using self-captured data.

Incentivise follow-up.

Weight, BMI, waist circumference and blood pressure outcomes were measured by researchers who were blind to treatment arm. These researchers were affiliated with the trial team, but were involved only in collecting outcomes during follow-up and had no role in providing the intervention, and no contact with patients other than while collecting follow-up measurements.

Data management

Data collection

All data were collected in the paper clinical record form, questionnaires, and on participant diaries and task cards. All data were kept in accordance with GCP and data protection requirements.[66]

Data entry

Data were entered into Oracle Database version 11 (Oracle Corporation UK Ltd, London, UK), an online database hosted at the Barts Cancer Centre. The electronic data capture forms are web based and built using Java, with data validation in JavaScript (Java framework Struts 2; Oracle Corporation UK Ltd, London, UK).

Data quality

When recruitment and follow-up were completed, the study team cleaned the data. Source data verification was also conducted by taking a random sample of 10% of case report forms. A member of the quality assurance (QA) team (based at the Pragmatic Clinical Trials Unit; PCTU) compared all written entries with those entered onto the main study database. The prespecified data quality target was a $\leq 2\%$ discrepancy rate between entries in the case report form and the electronic database, which was met.

Process measures

The process measures included attendance throughout the programme, duration of involvement in the programme (time to dropout), results of knowledge tests, participant feedback on components of treatment at 2, 6 and 12 months (e.g. weekly tasks, new information, group discussion, buddy system), and use of concomitant treatments. Some of these process measures were available only in the WAP arm.

Sample size determination

A clinically significant effect can be achieved with 3–5 kg of weight loss in obese people.[67] We assumed that the WAP would increase weight loss by 2.6 kg compared with usual care (WAP 3 kg vs. nurse 0.4 kg) among participants available for follow-up at 1 year, and that there would be no difference in weight loss between treatment arms among participants not available for follow-up. Assuming that 50% of participants in both treatment arms were available for follow-up at 1 year, the difference in weight loss between arms would be 1.3 kg (WAP 1.5 kg vs. usual care 0.2 kg). Assuming a standard deviation (SD) of 3 in both treatment arms, and a 5% two-sided significance level, we would require 112 participants in each arm to detect this mean difference with 90% power. Our estimate of 50% loss to follow-up is conservative and based on international experience in this field and existing data from similar underprivileged and highly mobile populations and interventions.

To account for potential clustering effects due to group treatment in the WAP arm, assuming a mean cluster size of 18 and an intracluster correlation coefficient of 0.05, a total of 208 individuals will be required in the WAP arm. The same power can be achieved with 108 in the nurse arm and 216 in the WAP arm, which we increased to 110 in the nurse arm and 220 in the WAP arm to give an allocation ratio between the two arms (2 : 1) that can be expressed in whole numbers. Thus, we required a total of 330 individuals for the entire study.

Randomisation

After providing written, informed consent, eligible participants were randomised in a 2 : 1 ratio (WAP to nurse) using permuted blocks with randomly varying sizes of 18, 21 and 24, stratified by study site (Barkantine or Lawson). Randomisation was conducted using an internet-based application produced by the Sheffield Clinical Trials Unit, University of Sheffield. The randomisation sequence was generated by a statistician from epiGenesys, a wholly owned subsidiary of the University of Sheffield (www.epigenesys.org.uk/).

The study staff randomising the participant accessed the randomisation program remotely when the patient was with them, entering their ID number into the program. The ID number was specific to study site. No other information was entered, as there were no other stratification factors. The allocation was immediately provided by the program.

Investigators randomising participants were unaware of the allocation until after they performed the randomisation (allocation concealment), but were then unblinded after the randomisation had been performed. Researchers who collected measurements at 6 and 12 months' follow-up were blinded to treatment allocation.

Treatment masking (blinding)

Participants and study staff providing the interventions and collecting data at the 1- and 2-month follow-up were not blinded. However, the study staff collecting the measurements (including weight, BMI, waist circumference and blood pressure) at the 6- and 12-month follow-up were blinded to treatment allocation.

All members of the trial team remained blinded to outcome data, summarised according to treatment arm until the statistical analysis plan was signed off.

Statistical methods

Change from planned analysis

In version 1.0 of the trial protocol we specified that we would use a baseline observation carried forward (BOCF) approach for dealing with patients with missing weight data during follow-up. This approach assumes that all those who were lost to follow-up returned to their exact baseline weight. Although this approach has been commonly used in other RCTs, it is problematic because it will provide biased estimates of the treatment effect when this assumption is incorrect (i.e. when participants do not return to their exact baseline weight when they fail to show up to their 6- or 12-month appointment).[68] In addition, BOCF will often lead to an inflated type I error (false-positive) rate as it tends to underestimate the standard error for the treatment effect (as a result of ignoring the within-patient variability in weight when imputing using BOCF).[68] This is particularly problematic in the SWAP trial, as it is unlikely that all participants who are lost to follow-up will return to their baseline weight; in many cases, we would expect them to gain weight. Cross-sectional and prospective cohort studies show that individuals gain weight over time, with an average weight gain per year of 0.5–1 kg.[69]

We therefore decided to use a mixed-effects linear regression model for the primary analysis. This analysis method provides unbiased estimates of treatment effect and correct type I error rates, provided that the data are missing at random. That is, the probability that a participant is lost to follow-up depends on their previous weight measurements (e.g. their weight at baseline and 6 months if they are lost to follow-up at 12 months) and baseline patient characteristics.[70]

This strategy of analysis has been widely recommended in the presence of missing outcome data.[68] The decision to change analysis methods was made before we had any access to the trial data or ongoing trial results and, therefore, there was no risk of bias associated with this decision.

The statistical analysis plan is provided in *Appendix 4*.

General analysis principles

All analyses were performed using intention-to-treat principles, meaning that all participants with at least one recorded outcome during follow-up were included in the analysis, and participants were analysed according to the treatment group to which they were randomised.[71] More information on which participants were included in each analysis is available in *Missing data for outcomes*. All *p*-values are two-sided, and the significance level was set at 5%.

All analyses accounted for clustering by group in the WAP arm and clustering by nurse in the nurse arm.[72,73] Each participant has been defined as belonging to a cluster, by which group they belonged to if they were in the intervention arm and by which nurse they were treated by if they were in the control arm. This variable has been included as a random intercept in a mixed-effects regression model. This analysis assumes that the intraclass correlation coefficient is the same between groups in the intervention arm as it is between nurses in the control arm. The Kenward–Roger degree of freedom correction was used for all linear mixed-effects models.[74]

All analyses were adjusted for baseline weight, age, sex, ethnicity (white British, white other, black, Asian, mixed or other), smoking status (smoker vs. non-smoker) and GP practice (Lawson vs. Barkantine) as covariates in a regression model.[75–77] Outcomes that were measured at baseline were also adjusted for the value of the outcome at baseline (this includes weight, BMI, waist circumference, systolic and diastolic blood pressure, Food Craving Inventory, Food Knowledge Assessment, Three-Factor Eating Questionnaire, and International Physical Activity Questionnaire). Continuous covariates (baseline weight and age) were assumed to have a linear association with outcome. Binary and categorical covariates (sex, ethnicity, smoking status and GP practice) were included in the regression model using indicator (dummy) variables. Missing baseline data were accounted for using mean imputation.[78]

Missing data for outcomes

For outcomes that are measured at multiple time points during follow-up, we based our analysis strategy on that proposed by White *et al.*[71] To deal with incomplete data (i.e. when patients have missing data at one of the follow-up time points) we:

- attempted to follow up all randomised patients even if they withdrew from the study
- performed a main analysis of all observed data that are valid under a plausible assumption about the missing data
- performed sensitivity analyses to explore the effect of departures from the assumptions made in the main analysis
- accounted for all randomised participants, at least in the sensitivity analyses.

In the analyses we:

- Included all patients with at least one post-randomisation assessment (i.e. if they have recorded data for at least one follow-up time point) in the analysis. This allows data from patients who dropped out before 12 months to contribute to the treatment effect estimate at 12 months (e.g. patients with recorded data at 1 month but who dropped out after that would still contribute towards the 12-month analysis).
- Used a mixed-effects model adjusted for baseline covariates, which assumes that the data are missing at random (i.e. they are missing based on their observed outcome at other time points, and other patient characteristics, *Box 6*).
- Performed sensitivity analyses under other missing data assumptions (e.g. that patients who were lost to follow-up gained more weight than patients who remained in the trial).

Analysis of primary outcome

The primary outcome (change in weight at 12 months post randomisation) was analysed using a mixed-effects linear regression model. The model included change in weight at 1, 2, 6 and 12 months as outcomes.

The model included a random intercept for 'cluster' (group or nurse, depending on treatment arm). The correlation between observations at different time points from the same patient (1, 2, 6 and 12 months) was modelled using an unstructured correlation structure. The model was estimated using restricted maximum likelihood. Treatment arm, time point (month 1, 2, 6 or 12) and the interaction between treatment arm and time point were included in the model as fixed factors. Time point was included as an indicator variable. The covariates listed in *General analysis principles* were also included in the model as fixed factors.

This analysis approach meant that any participant who had a recorded weight for at least one follow-up session (at either 1, 2, 6 or 12 months) was included in the analysis for the primary outcome. So, for example, a participant who lost 0.5 kg at 1 month but had no further weight measurements at 2, 6 or 12 months would still be included in the primary analysis, and would contribute towards the estimated treatment effect at 12 months. Their 12-month weight would be estimated based on their weight at

BOX 6 Definition of assumptions about missing data

Missing completely at random

Data are assumed to be *missing completely at random* if being lost to follow-up (LTFU) is not dependent on any baseline covariates or outcomes. This would be the wrong assumption to make about missing data in this study, as LTFU is highly likely to be related to outcome (i.e. those not losing weight are more likely to drop out).

Missing at random

Data are assumed to be *missing at random* if LTFU is dependent on observed data, including those data collected during follow-up (e.g. those who have not lost weight at early follow-up points are more likely to be lost to follow-up later). Missing at random is a reasonable assumption for missing data in this trial.

Missing not at random

Data are assumed to be *missing not at random* if LTFU is dependent on both observed and unobserved outcomes. Missing not at random is a reasonable assumption for missing data in this trial.

Source: Wood AM, White IR, Hillsdon M, Carpenter J. Comparison of imputation and modelling methods in the analysis of a physical activity trial with missing outcomes. *Int J Epidemiol* 2005;**34**:89–99.[70]

1 month, their treatment group and their baseline factors, such as baseline weight, age, sex, ethnicity, smoking status and GP practice. This analysis approach provides unbiased estimates of treatment effect provided the reason the participant's weight data at 2, 6 and 12 months are missing is based upon their observed weight at 1 month or their baseline characteristics (e.g. participants with lower weight loss at 1 month are more likely to be lost to follow-up at 12 months).[79]

Sensitivity analyses for primary outcome

Missing data

We performed two sensitivity analyses to assess the robustness of our primary analysis to different assumptions regarding the missing data. These sensitivity analyses were performed only for the primary outcome (change in weight at 12 months):

1. a complete-case analysis, where only patients with recorded data at 12 months are included
2. an analysis that assumes data missing at 12 months is missing not at random (*Box 7* and see *Figure 6*).

Participants who became pregnant or had bariatric surgery during follow-up

We performed a sensitivity analysis to assess the impact on results of patients who became pregnant or underwent bariatric surgery during follow-up. Patients who became pregnant or underwent bariatric surgery during follow-up were excluded from the analysis. This analysis was performed using the same methods as for the primary analysis.

Analyses of secondary outcomes

Change in weight at 1, 2 and 6 months were included as outcomes in the same analysis model as change in weight at 12 months.

BOX 7 Sensitivity analysis where missing weight data at 12 months is assumed to be missing not at random

Where we assumed data to be missing not at random we used the following formula:

$$\Delta = \Delta_{CC} + Y_1 P_1 - Y_2 P_2. \quad (1)$$

- Δ is the treatment effect under the missing not at random scenario.
- Δ_{CC} is the treatment effect from a complete-case analysis.
- Y_1 and Y_2 are the assumed mean change in weight at 12 months for participants with missing 12-month weight data in treatment groups 1 and 2, respectively.
- P_1 and P_2 are the proportion of participants with missing weight data at 12 months in groups 1 and 2, respectively.
- Groups 1 and 2 represent the intervention and control groups, respectively.

The standard error for Δ is assumed to be approximately equal to the standard error for Δ_{CC}.

Y_2 was varied between –10, –5, –2.5, 0, 2.5, 5 and 10. Negative values indicate that the participant lost weight at 12 months, positive values indicate that they gained weight and a value of 0 indicates that there was no change from baseline. For each value of Y_2, Y_1 was set to $Y_2 - 5$, Y_2 and $Y_2 + 5$.

For example, for $Y_2 = 10$, this would indicate an assumption that patients in treatment arm 2 (the control arm) who were lost to follow-up at 12 months, had gained 10 kg, on average, at 12 months. Y_1 would vary between 5, 10 and 15, indicating the assumption that patients in treatment arm 1 (the intervention arm) who were lost to follow-up had gained 5 kg, on average, at 12 months (5 kg less than those in the control arm), 10 kg (the same amount as those in the control arm) or 15 kg (5 kg more than those in the control arm).

Cross-sectional and prospective cohort studies show that individuals gain weight over time, with an average weight gain per year of 0.5–1 kg.[69] Therefore, those lost to follow-up are unlikely to gain > 5 kg in 1 year.

The analyses for change in BMI, waist circumference, systolic and diastolic blood pressure, and the Food Craving Inventory, Food Knowledge Assessment and Three-Factor Eating Questionnaires all used the same method of analysis as the primary outcome, with the exception of which baseline covariates were included in the analysis. These differences are summarised in *Table 7*.

The analysis of the proportion of patients losing 5% of their body weight used a mixed-effects logistic regression model. The model included as outcomes whether or not participants had lost 5% of their body weight at 2, 6 and 12 months. The model included three levels. The top level included a random intercept for 'cluster' (group or nurse, depending on treatment arm). The second level included a random intercept for patient and a random slope for time point. The third level included patient's visit (i.e. whether it was the patient's 2-, 6- or 12-month visit). Treatment arm, time point and the interaction between treatment arm and time point were included in the model as fixed factors. The fixed effect for time point was included as an indicator variable. This analysis adjusted for the same baseline covariates as that of the primary outcome.

The proportion of patients losing 10% of their body weight was analysed separately at 6 and 12 months (the analysis at 2 months was not performed because of the small number of events at this time point). The analysis at 12 months used a mixed-effects logistic regression model, with a random intercept for 'cluster' and adjusted for the same baseline covariates as in the analysis of the primary outcome. The analysis at 6 months also used a mixed-effects logistic regression model, but adjusted only for baseline weight (as the model did not converge when the other covariates were included).

TABLE 7 Analyses of secondary outcomes

Outcome	Difference to analysis method for primary outcome
Change in BMI at 1, 2, 6 and 12 months	Baseline BMI was included as a covariate in the regression model and baseline weight was not
Change in waist circumference at 2, 6 and 12 months	Baseline waist circumference was included as a covariate in the regression model and baseline weight was not
Change in systolic blood pressure at 2, 6 and 12 months	Baseline systolic blood pressure was also included as a covariate in the regression model
Change in diastolic blood pressure at 2, 6 and 12 months	Baseline diastolic blood pressure was also included as a covariate in the regression model
Change in Food Craving Inventory (frequency domain) at 1, 2, 6 and 12 months[a]	The baseline Food Craving Inventory (frequency domain) score was also included as a covariate in the regression model
Change in Food Craving Inventory (strength domain) at 1, 2, 6 and 12 months[a]	The baseline Food Craving Inventory (strength domain) score was also included as a covariate in the regression model
Change in Food Knowledge Assessment at 2, 6 and 12 months	The baseline Food Knowledge Assessment score was also included as a covariate in the regression model
Change in Three-Factor Eating Questionnaire (cognitive restraint domain) at 2, 6 and 12 months	The baseline Three-Factor Eating Questionnaire (cognitive restraint domain) score was included as a covariate
Change in Three-Factor Eating Questionnaire (uncontrolled eating domain) at 2, 6 and 12 months	The baseline Three-Factor Eating Questionnaire (uncontrolled eating domain) score was included as a covariate
Change in Three-Factor Eating Questionnaire (emotional eating domain) at 2, 6 and 12 months	The baseline Three-Factor Eating Questionnaire (emotional eating domain) score was included as a covariate
Change in International Physical Activity Questionnaire (MET-minutes/week domain) at 2, 6 and 12 months	The baseline MET-minutes/week domain score was included as a covariate
Change in International Physical Activity Questionnaire (sitting domain) at 2, 6 and 12 months	The baseline sitting domain score was included as a covariate

a Treatment effect estimates will only be presented at 6 and 12 months; data from month 2 is included in the model to increase power and to make the missing at random assumption more plausible.

Subgroup analyses

No subgroup analyses were performed.

Other data summaries

Data summaries are also provided for:

1. number of participants on both treatment arms who used orlistat
2. weight change at 12 months in participants who used orlistat versus those who did not
3. participant feedback (mean and SD, number and per cent) in both treatment arms at 2, 6 and 12 months.

Statistical software

All analyses were implemented in Stata version 14 (StataCorp LP, College Station, TX, USA).

Departures from the statistical analysis plan

- Sensitivity analysis: patients who became pregnant or had bariatric surgery.
  - The statistical analysis plan stated that for this sensitivity analysis patients who became pregnant or had gastric surgery would be excluded from the point at which they had surgery or became pregnant (i.e. their follow-up data from before pregnancy or surgery would be included in the analysis). However, the date of pregnancy was unavailable for a number of patients. Therefore, this analysis completely excluded patients who became pregnant or had gastric surgery.

- Secondary outcome: proportion of patients losing ≥ 10% of their body weight.
  - The statistical analysis plan stated that this outcome would be analysed in the same way as the proportion of patients losing ≥ 5% of their body weight (i.e. using a three-level mixed-effects logistic regression model). However, this analysis model did not reach convergence. We therefore tried to refit the model after removing the random slope for time point, but the model still did not reach convergence. We therefore analysed this outcome separately at 6 and 12 months (i.e. separate logistic regression models were used at each time point); we did not analyse this outcome at 2 months because of the small number of events. The analysis at 12 months was performed using a mixed-effects logistic regression model with a random intercept for cluster and adjusted for the same baseline covariates as the analysis of the primary outcome. However, this model did not converge for the 6-month analysis; we therefore removed all baseline covariates from the model except for baseline weight.

Ongoing public and patient involvement

The Trial Steering Committee included the lay member Julie Griffiths, an ex-service user who, in addition to providing general feedback to the study team regarding the progress of the study, contributed to the redrafting of the recruitment and follow-up strategies, providing invaluable suggestions to improve participant retention based on her previous experience of participating in the WAP. For example, Julie suggested that in telephone conversations with participants who failed to attend follow-up appointments, it would be helpful if the study team reasserted the importance of attending. Julie was also key in assisting the study team with the design of the study to help ensure that the delivery of the intervention and control conditions was as practicable as possible. Study documents, including questionnaires, information sheets and invitation letters, were reviewed by Julie, who provided useful feedback.

Two participants (both in the intervention condition) attended several general practice meetings with a member of the study team to encourage regular referral onto the study. Participants presented their first-hand experience of taking part in the WAP, presenting the advantages and challenges faced, providing practice staff with direct feedback from active participants. Several general practice staff members informed the study team that such presentations were not only useful in helping them to remember to offer the study to their patients but also reassuring, as they felt more comfortable offering the study to their patients upon hearing the honest feedback from participants.

Ex-service users are involved in regular panels held at the Health and Lifestyle Research Unit, during which potential study ideas are discussed as well as ways to improve the WAP in its current format.

Quality control and quality assurance

The PCTU was responsible for monitoring and audit of the study. The PCTU QA manager drafted a monitoring/audit plan prior to study initiation, which consisted of a combination of remote and on-site monitoring. A risk assessment of the study was conducted by the PCTU QA manager and chief investigator, which informed the frequency of monitoring and audit visits.

Approvals

This study was sponsored by the Joint Research Management Office, Queen Mary University of London, and received ethics approval from the London – Central Ethics Committee on 3 February 2012 (reference number 12/LO/0122).

Trial committees

Members of the Trial Steering Committee and Trial Management Committee are shown in *Table 8*.

TABLE 8 Members of the trial committees

Committee	
Trial Steering	**Trial Management**
Dr Vicky Hobart (chairperson, public health consultant)	Professor Hayden McRobbie
Dr Simon Coppack (consultant physician)	Professor Peter Hajek
Dr Clare Grace (obesity research dietitian)	Dr Katie Myers Smith
Professor Luke Vale (health economist)	Mrs Sarah Snuggs
Dr John Stapleton (independent statistician)	Dr Amanda Bunten (City and Hackney PCT)
Professor Hayden McRobbie (chief investigator)	Mr Mike Waring (data manager)
Professor Peter Hajek (co-investigator)	Mrs Anitha Manivannan (QA manager)
Ms Julie Griffiths (lay member and service user)	Professor Sandra Eldridge
	Dr Brennan Kahan (trial statistician)
	Miss Sarrah Peerbux

PCT, primary care trust.

Chapter 3 Results

Participant flow

Figure 3 shows participant flow through the trial.

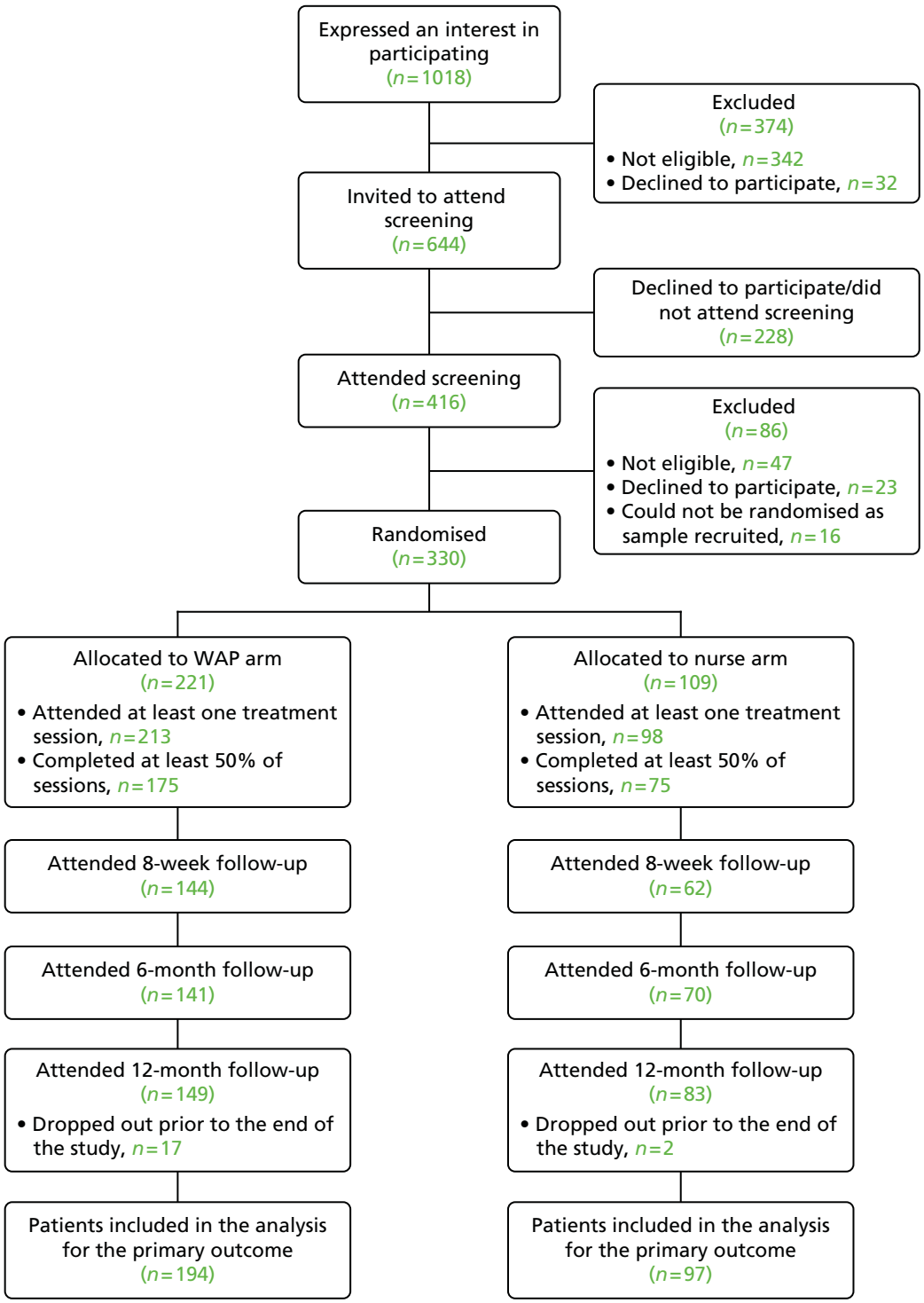

FIGURE 3 Consolidated Standards of Reporting Trials diagram.

Losses and exclusions

Of the 1018 people registering an interest during the recruitment period, 435 were excluded from the trial (55 decided against participation, 389 were not eligible and 16 could not be randomised as the sample size target had been reached). Of the 389 participants excluded from taking part, 87 participants (22%) were excluded because they were taking psychiatric medication (*Table 9*). A total of 221 participants were randomly allocated to the intervention group and 109 to the control group.

Recruitment

It was originally planned to recruit approximately 30 participants per month over a 12-month period starting in October 2011. However, because of delays in research and development (R&D) approvals and contracting, the project plan was revised to start recruitment in July 2012, recruiting 40 participants per month over a 9-month period.

Despite this revised timetable, the start of recruitment was delayed until September 2012 and was slower than anticipated (*Figure 4*). This led us to further revise our strategy and timetable, extending recruitment until January 2014 (*Figure 5*). The barriers to recruitment, and our strategies to remedy this, are discussed in *Chapter 5*.

The were a total of 15 waves of recruitment, eight at the Barkantine Practice and seven at the Lawson Practice (*Table 10*).

Four practice nurses were allocated a median of 24 participants [interquartile range (IQR) 17–38 participants]. The 15 groups contained a median of 15 participants (IQR 13–18 participants). Of the intervention group, 120 (54%) were from the Barkantine Practice and 101 (46%) from the Lawson Practice (*Table 11*). The Barkantine nurses saw 58 (53%) control group participants and the Lawson nurse saw 51 (47%) participants.

Retention was good for weight management programmes, with 96% of the WAP participants and 90% of the nurse participants attending at least one of the treatment sessions. Seventy-nine per cent of

TABLE 9 Reasons for exclusion

Reason for exclusion	Number of participants
BMI of < 30 kg/m^2 or < 28 kg/m^2 plus comorbidities	58
BMI of > 45 kg/m^2	6
Lost > 5% of their body weight in the previous 6 months	66
Currently pregnant	14
Taking psychiatric medications	87
Not registered with a GP in the local areas	21
Involved in a current research project	8
Aged < 18 years	5
Unable to commit to the sessions/unavailable for follow-up	54
Other[a]	23

a Include being unable to understand English and taking part in another weight management programme.

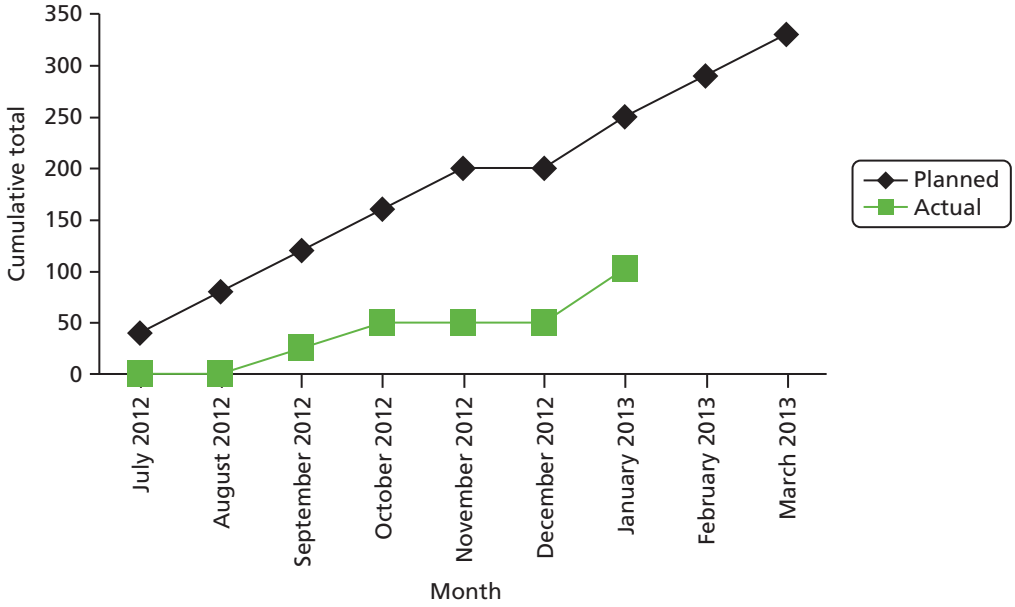

FIGURE 4 Initial recruitment targets.

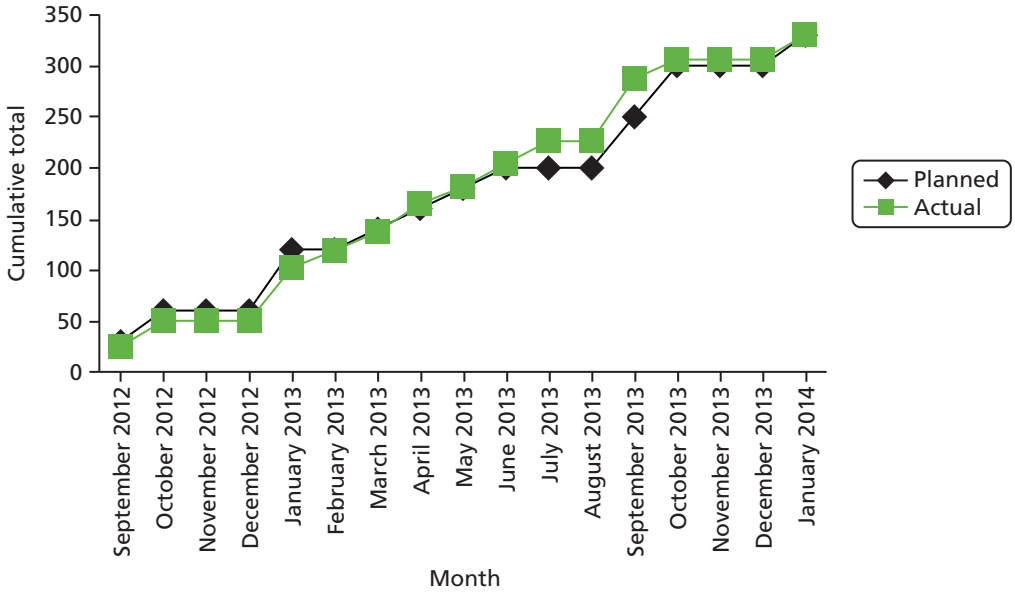

FIGURE 5 Revised recruitment targets.

participants in the WAP arm attended at least half of the prescribed sessions, compared with 69% in the nurse arm.

The first 6-month follow-ups were conducted in March 2013. The first 12-month follow-ups were conducted in September 2013 and the final 12-month follow-up was conducted in February 2015.

Overall, 70% of participants completed the 12-month follow-up, with the follow-up rates being slightly higher in the nurse arm than in the WAP arm (*Table 12*).

Follow-up rates were similar at the two study sites (*Table 13*).

TABLE 10 Summary of recruitment and randomisation by practice

Clinic	Number of participants					
	Booked for a screening visit	Who attended a screening visit	Who attended a randomisation visit	Randomised	Randomised to the WAP	Randomised to the nurse arm
Barkantine wave 1	34	29	25	25	16	9
Barkantine wave 2	49	31	29	29	18	11
Barkantine wave 3	39	21	17	17	13	4
Barkantine wave 4	51	34	28	28	19	9
Barkantine wave 5	48	31	25	23	17	6
Barkantine wave 6	61	40	33	33	21	12
Barkantine wave 7	37	23	19	19	13	6
Barkantine wave 8[a]	35	24	20	4	3	1
Lawson wave 1	41	31	25	25	15	10
Lawson wave 2	50	28	23	23	16	7
Lawson wave 3	42	23	19	18	13	5
Lawson wave 4	28	19	16	16	10	6
Lawson wave 5	37	26	22	22	14	8
Lawson wave 6	57	32	28	28	19	9
Lawson wave 7	35	24	20	20	14	6
Total	644	416	349	330	221	109

a A total of four participants were randomised onto the study before the sample size of 330 participants was achieved. As a result, the WAP arm comprised three randomised participants and a further 16 non-randomised participants (totalling 19 WAP participants for Barkantine wave 8).

TABLE 11 Characteristics of clusters

Clusters	Arm	
	Nurse ($n = 109$)	WAP ($n = 221$)
Number of nurses/groups	4	15
Number of participants per nurse/group, median (IQR)	24 (17–38)	15 (13–18)

TABLE 12 Attendance at follow-up appointments

	Arm, *n* (%)	
Follow-up	Nurse (*N* = 109)	WAP (*N* = 221)
1 month	74 (68)	164 (74)
2 months	62 (57)	144 (65)
6 months	70 (64)	141 (64)
12 months	83 (76)	149 (67)

TABLE 13 Attendance at 12-month follow-up by study site

		Attended follow-up, *n* (%)		
Site	Number of participants randomised	Nurse	WAP	Total
Barkantine	178	45 (76)	79 (66)	124 (70)
Lawson	152	38 (75)	70 (69)	108 (71)
Total	330	83 (76)	149 (67)	232 (70)

Baseline data

Table 14 shows demographics of participants. The majority (72%) of participants were women, as is fairly typical of weight management programmes. Participants were middle-aged (mean age 45 in the nurse arm and 47 years in the WAP).

Almost half (48%) of participants were from black and ethnic minorities, which reflects the population of the study setting. Forty per cent were white British and 12% were classified as 'white other'. Approximately one-third of participants were single and 43% were married or living with their partner. Three measures (entitlement to free prescriptions, employment status and educational qualification) provided an indication of the socioeconomic status of participants. Overall, 59% were entitled to free prescriptions, 51% had no higher education and 52% did not have paid employment.

On average, alcohol consumption was within recommended limits. Sixteen per cent of participants reported that they were current smokers.

Baseline data related to weight, physical activity and eating behaviours are shown in *Table 15*. The mean weight of both groups was > 95 kg (98.3 kg in the nurse arm and 95.5 kg in the WAP arm). The average BMI for both groups was > 35 kg/m^2, indicating that participants were obese. Approximately one-third of participants reported being overweight or obese as children and one-third reported having an overweight or obese mother. Fewer participants (16%) reported that their father was overweight or obese.

The median number of previous weight loss attempts was three, with participants claiming to have lost a significant amount of weight in past attempts (median amount of weight lost was 9.3 kg and 10.9 kg in the nurse and WAP arms, respectively).

Although participants reported sitting for approximately 6.5 hours per day, self-reported baseline levels of physical activity were high in both the nurse and WAP arms (mean 1815 and 1919 MET-minutes per week, respectively).

TABLE 14 Sample characteristics

Variable	Arm		Missing data (number in nurse arm, number in WAP arm)
	Nurse ($N = 109$)	WAP ($N = 221$)	
Age (years), mean (SD)	45.1 (14.2)	46.6 (15.0)	0, 0
Female, *n* (%)	75 (69)	161 (73)	0, 0
Marital status, *n* (%)			0, 0
Single	40 (37)	72 (33)	–
Separated or divorced	13 (12)	33 (15)	–
Married or living with partner	49 (45)	92 (42)	–
Other	7 (6)	24 (11)	–
Ethnicity, *n* (%)			1, 3
White British	46 (43)	85 (39)	–
White other	11 (10)	27 (12)	–
Black	26 (24)	53 (24)	–
Asian	16 (15)	27 (12)	–
Mixed	1 (1)	11 (5)	–
Other	8 (7)	15 (7)	–
Educational qualification, *n* (%)			1, 0
None	15 (14)	36 (16)	–
GCSE or equivalent	25 (23)	49 (22)	–
A-Level or equivalent	12 (11)	30 (14)	–
Degree or equivalent	41 (38)	71 (32)	–
Other	15 (14)	35 (16)	–
Employment status, *n* (%)			0, 0
In paid employment	57 (52)	103 (47)	–
Unemployed	18 (17)	38 (17)	–
Looking after the home	6 (6)	15 (7)	–
Retired	17 (16)	34 (15)	–
Full-time student	3 (3)	10 (5)	–
Other	8 (7)	21 (10)	–
Entitled to free prescriptions, *n* (%)			0, 0
Yes	62 (57)	133 (60)	–
No	45 (41)	81 (37)	–
Not known	2 (2)	7 (3)	–
Baseline comorbidities, *n* (%)			
Heart disease	6 (6)	21 (10)	1, 1
Diabetes mellitus	9 (8)	21 (10)	0, 0
At least one comorbidity	66 (61)	135 (61)	0, 0
Current smoker, *n* (%)	18 (17)	35 (16)	0, 0
Units of alcohol consumed per week, mean (SD)	7.6 (11.7)	7.2 (10.3)	55, 104

A-Level, Advanced Level; GCSE, General Certificate of Secondary Education.

TABLE 15 Physical and questionnaire-based baseline measurements

Variable	Arm		Missing data (number in nurse arm, number in WAP arm)
	Nurse ($N = 109$)	WAP ($N = 221$)	
Weight (kg), mean (SD)	98.3 (16.6)	95.5 (15.8)	0, 0
BMI (kg/m^2), mean (SD)	35.7 (4.3)	35.0 (4.2)	0, 0
BMI categories (kg/m^2), *n* (%)			
25–29.9	9 (8)	16 (7)	–
30–34.9	44 (40)	112 (51)	–
35–39.9	35 (32)	60 (27)	–
40–45	21 (19)	33 (15)	–
Waist circumference (cm), mean (SD)	114.2 (10.1)	113.4 (10.7)	0, 0
Systolic blood pressure (mmHg), mean (SD)	134.8 (15.9)	134.5 (16.7)	0, 0
Diastolic blood pressure (mmHg), mean (SD)	80.6 (8.6)	81.3 (10.5)	1, 0
Food Craving Inventory score, mean (SD)			
Frequency domain	9.6 (3.8)	9.1 (3.8)	0, 0
Strength domain	8.9 (4.0)	8.5 (3.9)	0, 1
Food Knowledge Assessment Questionnaire score, mean (SD)	6.6 (1.7)	6.6 (1.7)	0, 0
Three-Factor Eating Questionnaire score, mean (SD)			
Cognitive restraint domain	2.3 (0.6)	2.4 (0.6)	1, 2
Uncontrolled eating domain	2.2 (0.7)	2.2 (0.7)	4, 3
Emotional eating domain	2.5 (0.9)	2.6 (1.0)	1, 2
International Physical Activity Questionnaire, mean (SD)			
MET-minutes/week domain	1815 (2355)	1919 (2508)	12, 28
Sitting domain	391 (197)	382 (219)	13, 38
Overweight or obese as a child, *n* (%)	36 (33)	84 (38)	0, 0
Mother overweight or obese, *n* (%)	30 (30)	78 (39)	9, 22
Father overweight or obese, *n* (%)	19 (21)	34 (18)	20, 29
Number of previous attempts at weight loss, median (IQR)	3 (2–5)	3 (1–5)	8, 12
Greatest previous amount of weight loss (kg), median (IQR)	9.3 (5.0–19.1)	10.9 (6.0–19.1)	9, 20

Numbers analysed

As specified in the statistical analysis plan, we followed the recommended guidance for applying intention-to-treat principles in the presence of missing data,[68] and have included all participants with at least one follow-up measurement (e.g. who had their weight recorded at at least one of their 1-, 2-, 6- or 12-month visits) in the analysis of the primary outcome.

The numbers of participants available for analysis of each of the clinical outcomes are shown in *Table 16*. For the primary outcome, weight loss at 12 months, we used data from participants who provided weight measurements at least once during follow-up. Therefore, data were available for 88% ($n = 291$) of participants, with almost identical rates in both arms (89% nurse, 88% WAP). For the secondary measures, data available at each follow-up point were used; therefore,12-month data for the other clinical outcomes were available for 76% of participants in the nurse arm and 67% of participants in the WAP arm.

Table 17 shows the numbers of participants available for analysis of questionnaire data.

Primary outcome: weight at 12 months

A total of 291 participants (nurse, $n = 97$; WAP, $n = 194$) were included in the model and so contributed data to the estimated treatment effect at each time point. At 12 months, participants in the WAP arm had lost more weight (4.2 kg) than those in the nurse arm (2.3 kg). This 1.9-kg difference was statistically significant (95% CI –3.7 kg to –0.1 kg; $p = 0.04$). Except at 1 month post randomisation, participants in the WAP arm lost significantly greater amounts of weight than those the nurse arm (*Table 18*).

TABLE 16 Availability for clinical outcomes

Variable	Arm, *n* (%)	
	Nurse (*N* = 109)	WAP (*N* = 221)
Weight/BMI		
1 month	74 (68)	157 (71)
2 months	62 (57)	140 (63)
6 months	70 (64)	141 (64)
12 months	83 (76)	149 (67)
Measured at least once during follow-up	97 (89)	194 (88)
Number of measurements per patient		
0	12 (11)	27 (12)
1	13 (12)	26 (12)
2	23 (21)	39 (18)
3	14 (13)	33 (15)
4	47 (43)	96 (43)
Waist circumference		
2 months	60 (55)	140 (63)
6 months	70 (64)	141 (64)
12 months	83 (76)	149 (67)
Measured at least once during follow-up	92 (84)	182 (82)
Number of measurements per patient		
0	17 (16)	39 (18)
1	18 (17)	36 (16)
2	27 (25)	44 (20)
3	47 (43)	102 (46)

TABLE 16 Availability for clinical outcomes (*continued*)

Variable	Arm, *n* (%)	
	Nurse (*N* = 109)	WAP (*N* = 221)
Blood pressure		
2 months	60 (55)	140 (63)
6 months	70 (64)	141 (64)
12 months	83 (76)	149 (67)
Measured at least once during follow-up	92 (84)	182 (82)
Number of measurements per patient		
0	17 (16)	39 (18)
1	18 (17)	36 (16)
2	27 (25)	44 (20)
3	47 (43)	102 (46)
Lost 5% or 10% of body weight		
2 months	62 (57)	140 (63)
6 months	70 (64)	141 (64)
12 months	83 (76)	149 (67)
Measured at least once during follow-up	92 (84)	182 (82)
Number of measurements per patient		
0	17 (16)	39 (18)
1	18 (17)	36 (16)
2	25 (23)	44 (20)
3	49 (45)	102 (46)

TABLE 17 Availability of questionnaire scores

Questionnaire	Arm, *n* (%)	
	Nurse (*N* = 109)	WAP (*N* = 221)
Food Knowledge Assessment		
2 months	47 (43)	144 (65)
6 months	70 (64)	140 (63)
12 months	83 (76)	147 (67)
Measured at least once during follow-up	90 (83)	180 (81)
Number of measurements per patient		
0	19 (17)	41 (19)
1	18 (17)	33 (15)
2	34 (31)	43 (19)
3	38 (35)	104 (47)

continued

TABLE 17 Availability of questionnaire scores (*continued*)

Questionnaire	Arm, *n* (%)	
	Nurse (*N* = 109)	WAP (*N* = 221)
Food Craving Inventory frequency domain		
1 month	66 (61)	161 (73)
2 months	61 (56)	143 (65)
6 months	70 (64)	140 (63)
12 months	83 (76)	147 (67)
Measured at least once during follow-up	97 (89)	192 (87)
Number of measurements per patient		
0	12 (11)	29 (13)
1	14 (13)	24 (11)
2	22 (20)	36 (16)
3	22 (20)	33 (15)
4	39 (36)	99 (45)
Food Craving Inventory strength domain		
1 month	63 (58)	160 (72)
2 months	57 (52)	140 (63)
6 months	70 (64)	140 (63)
12 months	83 (76)	146 (66)
Measured at least once during follow-up	97 (89)	192 (87)
Number of measurements per patient		
0	12 (11)	29 (13)
1	15 (14)	25 (11)
2	24 (22)	36 (16)
3	22 (20)	35 (16)
4	36 (33)	96 (43)
Three-Factor Eating cognitive restraint domain		
2 months	62 (57)	140 (63)
6 months	69 (63)	140 (63)
12 months	83 (76)	146 (66)
Measured at least once during follow-up	91 (83)	179 (81)
Number of measurements per patient		
0	18 (17)	42 (19)
1	18 (17)	32 (14)
2	23 (21)	47 (21)
3	50 (46)	100 (45)
Three-Factor Eating uncontrolled eating domain		
2 months	59 (54)	140 (63)
6 months	69 (63)	138 (62)
12 months	80 (73)	147 (67)

TABLE 17 Availability of questionnaire scores (*continued*)

Questionnaire	Arm, *n* (%)	
	Nurse (*N* = 109)	WAP (*N* = 221)
Measured at least once during follow-up	90 (83)	179 (81)
Number of measurements per patient		
0	19 (17)	42 (19)
1	18 (17)	33 (15)
2	26 (24)	46 (21)
3	46 (42)	100 (45)
Three Factor Eating emotional eating domain		
2 months	63 (58)	142 (64)
6 months	70 (64)	140 (63)
12 months	83 (76)	146 (66)
Measured at least once during follow-up	92 (84)	180 (81)
Number of measurements per patient		
0	17 (16)	41 (19)
1	18 (17)	33 (15)
2	24 (22)	46 (21)
3	50 (46)	101 (46)
International Physical Activity Questionnaire MET-minutes/week domain		
2 months	53 (49)	113 (51)
6 months	58 (53)	118 (53)
12 months	72 (66)	123 (56)
Measured at least once during follow-up	87 (80)	161 (73)
Number of measurements per patient		
0	22 (20)	60 (27)
1	24 (22)	34 (15)
2	30 (28)	61 (28)
3	33 (30)	66 (30)
International Physical Activity Questionnaire sitting domain		
2 months	49 (45)	114 (52)
6 months	59 (54)	116 (52)
12 months	62 (57)	113 (51)
Measured at least once during follow-up	78 (72)	159 (72)
Number of measurements per patient		
0	31 (28)	62 (28)
1	18 (17)	36 (16)
2	28 (26)	62 (28)
3	32 (29)	61 (28)

TABLE 18 Mean weight loss over a 12-month period in the intention-to-treat population

Time point	Arm, mean (SD)[a]		Treatment effect (95% CI)[b]	*p*-value
	Nurse ($n = 109$)	WAP ($n = 221$)		
1 month	–1.0 (1.6)	–1.0 (1.7)	–0.1 (–0.6 to 0.5)	0.81
2 months	–2.2 (2.6)	–3.2 (2.7)	–1.0 (–1.7 to –0.3)	0.009
6 months	–2.1 (4.3)	–5.0 (5.4)	–2.5 (–3.8 to –1.2)	< 0.001
12 months	–2.3 (6.6)	–4.2 (7.3)	–1.9 (–3.7 to –0.1)	0.04

a The summary statistics (mean and SD) were calculated based on the number of participants with a recorded outcome at 1, 2, 6 and 12 months, which were as follows: for the nurse arm, 74, 62, 70 and 83, respectively; and for the WAP arm, 164, 144, 141 and 149, respectively.
b Treatment effects are presented as a difference in means (estimated from a mixed-effects regression model) between the two arms. Calculation is based on data from 97 participants in the nurse arm and 194 participants in the WAP arm.

Sensitivity analyses on primary outcome

We performed two sensitivity analyses to assess the robustness of our primary analysis to different assumptions regarding the missing data.

Figure 6 shows the results for different missing not at random assumptions. These scenarios assume that participants were lost to follow-up because of their weight, and that those lost to follow-up (non-responders) had different weight values at 12 months than those who provide data (responders). The values along the *x*-axis represent the mean change in weight from baseline for non-responders in the nurse arm (usual care). Then, each colour (black, green or blue) represents the mean change in weight for non-responders in the WAP arm (black indicates that non-responders in the WAP arm lost, on average, 5 kg more at 12 months than non-responders in the nurse arm; green indicates that they lost the same amount; and blue indicates that WAP non-responders gained 5 kg more, on average, than the nurse arm non-responders). The points and bars in the graph indicate the treatment effect and 95% CI for each scenario.

The outcome here is that results are not materially affected unless we assume that non-responders (patients who were lost to follow-up at 12 months) in the WAP arm gained more weight than non-responders in the nurse arm, or if we assume that non-responders in both arms gained a large amount of weight (i.e. 10 kg). Under the assumption that, on average, non-responders in both arms had no change from their baseline weight, the results are unaffected (difference –2.4 kg, 95% CI –4.3 to –0.5 kg).

Table 19 shows the results of the two other sensitivity analyses. One is the complete-case analysis, where only patients with recorded data at 12 months are included, and the other excludes women who fell pregnant and participants who had bariatric surgery, after randomisation. The treatment effect is not substantially altered.

Secondary outcomes

Changes in body mass index

As expected, change in BMI followed change in weight, with participants in the WAP arm showing a greater reduction in BMI than those in the nurse arm (*Table 20*).

Changes in waist circumference

Table 21 shows that participants in the nurse arm had a greater reduction in waist circumference than those in the WAP arm at the end of treatment (–7.7 vs. –3.9 cm; $p = 0.001$), but this was reversed at 6-month follow-up (–1.5 vs. –5.0 cm; $p = 0.004$). By 12 months, the difference had narrowed (–2.0 vs. –4.1 cm) and the difference was no longer significant ($p = 0.07$).

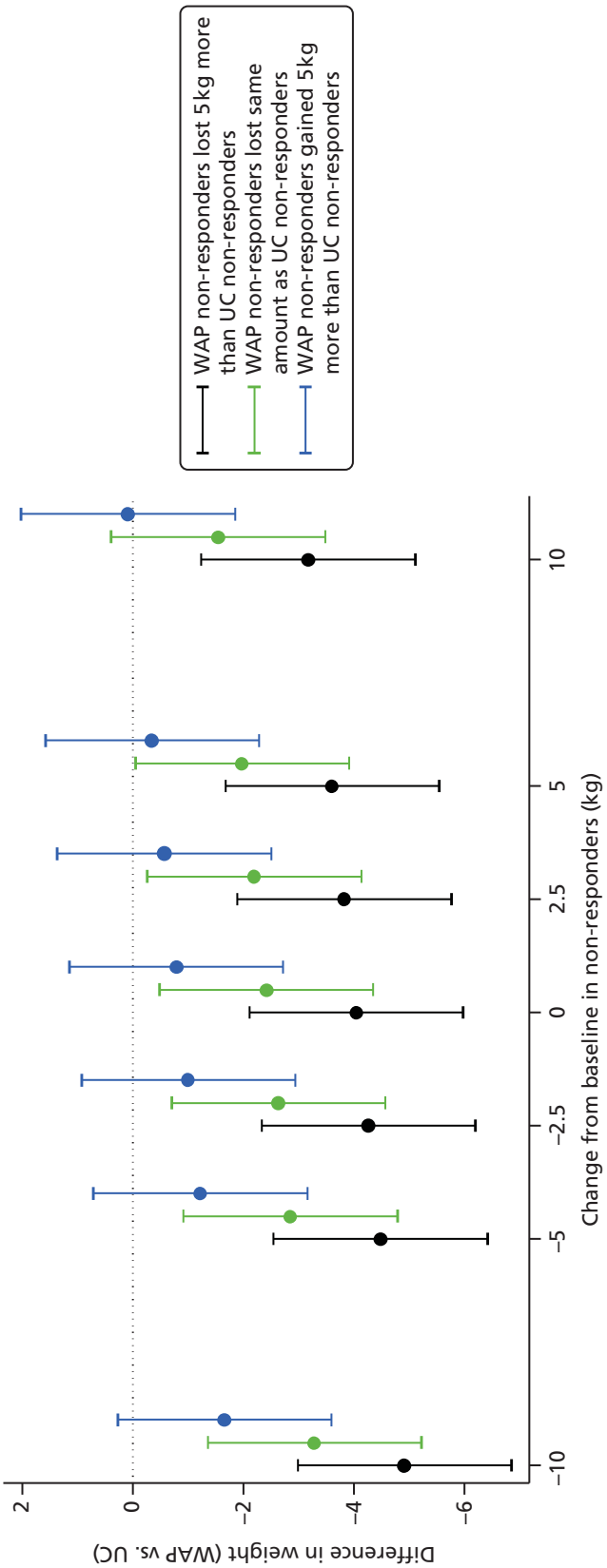

FIGURE 6 Treatment effect and 95% CI for change in weight at 12 months under the assumption that non-responders are missing not at random. UC, usual care.

TABLE 19 Sensitivity analyses for primary outcome

Sensitivity analysis	Arm, mean (SD)		Treatment effect (95% CI)
	Nurse	WAP	
Complete-case analysis ($n = 232$)	–2.3 (6.6)	–4.2 (7.3)	–2.4 (–4.9 to 0.1)
Excluding patients who had bariatric surgery or became pregnant during follow-up[a] ($n = 221$)	–2.1 (5.7)	–4.2 (7.3)	–2.1 (–3.9 to –0.4)

a Eleven patients were excluded from this analysis because of gastric bypass (control, $n = 1$; intervention, $n = 0$) or being pregnant (control, $n = 5$; intervention, $n = 5$).

TABLE 20 Change in BMI (kg/m^2)

Time point	Arm, mean (SD)[a]		Treatment effect (95% CI)[b]	*p*-value
	Nurse ($n = 109$)	WAP ($n = 221$)		
1 month	–0.4 (0.6)	–0.4 (0.6)	0.0 (–0.2 to 0.2)	0.73
2 months	–0.8 (0.9)	–1.2 (1.0)	–0.4 (–0.6 to –0.1)	0.005
6 months	–0.7 (1.5)	–1.8 (1.9)	–0.9 (–1.4 to –0.5)	< 0.001
12 months	–0.8 (2.3)	–1.5 (2.6)	–0.7 (–1.3 to 0.0)	0.04

a The summary statistics (mean and SD) were calculated based on the number of participants with a recorded outcome at 1, 2, 6 and 12 months, which were as follows: for the nurse arm, 74, 62, 70 and 83, respectively; and for the WAP arm, 164, 144, 141 and 149, respectively.
b Treatment effects are presented as a difference in means (estimated from a mixed-effects regression model) between the two arms. Calculation is based on data from 97 participants in the nurse arm and 194 participants in the WAP arm.

TABLE 21 Change in waist circumference (cm)

Time point	Arm, mean (SD)[a]		Treatment effect (95% CI)[b]	*p*-value
	Nurse ($n = 109$)	WAP ($n = 221$)		
2 months	–7.7 (7.3)	–3.9 (4.9)	3.9 (2.0 to 5.7)	0.001
6 months	–1.5 (6.2)	–5.0 (6.7)	–3.1 (–5.1 to –1.2)	0.004
12 months	–2.0 (7.3)	–4.1 (7.9)	–2.0 (–4.1 to 0.2)	0.07

a The summary statistics (mean and SD) were calculated based on the number of participants with a recorded outcome at 2, 6 and 12 months, which were as follows: for the nurse arm, 60, 70 and 83, respectively; and for the WAP arm, 140, 141 and 149, respectively.
b Treatment effects are presented as a difference in means (estimated from a mixed-effects regression model) between the two arms.

Proportion of participants losing at least 5% or 10% of their baseline body weight

At the 12-month follow-up the proportion of participants who had lost at least 5% of their body weight was significantly greater in the WAP arm than in the nurse arm (41% vs. 27%; $p = 0.004$). Similarly, the proportion of participants who lost 10% of their baseline body weight was higher in the WAP arm than in the nurse arm (participants in the WAP arm were twice as likely as those in the nurse arm to have lost 10% of their weight), but the difference was not significant (*Table 22*).

TABLE 22 Participants losing 5% and 10% of baseline body weight

Time point	Arm, *n* (%)[a]		Odds ratio (95% CI)[b]	*p*-value
	Nurse (*N* = 109)	WAP (*N* = 221)		
Participants losing 5% of their body weight				
2 months	10 (16)	32 (23)	2.41 (0.69 to 8.46)	0.17
6 months	14 (20)	65 (46)	31.60 (6.52 to 153.18)	< 0.001
12 months	22 (27)	61 (41)	14.61 (2.32 to 91.96)	0.004
Participants losing 10% of their body weight				
2 months	0 (0)	2 (1)	–[c]	–
6 months	3 (4)	26 (18)	5.10 (1.48 to 17.56)	0.01
12 months	7 (8)	25 (17)	2.50 (0.99 to 6.32)	0.05

a The summary statistics (*n* and %) were calculated based on the number of participants with a recorded outcome at 1, 2, 6 and 12 months, which were as follows: for the nurse arm, 74, 62, 70 and 83, respectively; and for the WAP arm, 164, 144, 141 and 149, respectively.
b Calculation is based on data from 97 participants in the nurse arm and 194 participants in the WAP arm.
c There were only two events at 2 months; therefore, we did not perform an analysis at this time point.

Changes in blood pressure

The only significant change in blood pressure between the arms was a greater drop in systolic blood pressure in the nurse arm at the end of treatment (–9.6 mmHg vs. –2.1 mmHg; $p = 0.02$). At the 12-month follow-up there was no significant difference in blood pressure between participants in the nurse and WAP arms (*Table 23*).

Changes in food knowledge

Participants in the WAP arm showed a significant increase in their knowledge of the calorie content of foods compared with participants in the nurse arm at the end of treatment and at the 6-month follow-up (*Table 24*). By the 12-month follow-up this effect had disappeared.

TABLE 23 Change in blood pressure

Time point	Arm, mean (SD)[a]		Treatment effect (95% CI)[b]	*p*-value
	Nurse (*n* = 109)	WAP (*n* = 221)		
Change in systolic blood pressure (mmHg)				
2 months	–9.6 (14.4)	–2.1 (13.7)	5.6 (1.0 to 10.3)	0.02
6 months	–5.1 (13.0)	–5.1 (14.6)	0.4 (–4.4 to 5.1)	0.88
12 months	–3.5 (16.0)	–2.8 (15.0)	0.6 (–4.3 to 5.4)	0.81
Change in diastolic blood pressure (mmHg)				
2 months	–0.6 (8.9)	–1.5 (7.7)	–0.3 (–3.0 to 2.4)	0.81
6 months	–2.0 (9.2)	–3.6 (8.4)	–0.9 (–3.8 to 1.9)	0.51
12 months	–0.4 (10.2)	–1.7 (9.1)	–0.7 (–3.6 to 2.1)	0.59

a The summary statistics (mean and SD) were calculated based on the number of participants with a recorded outcome at 2, 6 and 12 months, which were as follows: for the nurse arm, 60, 70 and 83, respectively; and for the WAP arm, 140, 141 and 149, respectively.
b Treatment effects are presented as a difference in means (estimated from a mixed-effects regression model) between the two arms.

TABLE 24 Changes in food knowledge, craving and eating

Time point	Arm, mean (SD)[a]		Treatment effect (95% CI)[b]	*p*-value
	Nurse	WAP		
Change in Food Knowledge Assessment Questionnaire score				
2 months	0.1 (1.7)	1.1 (1.7)	1.1 (0.6 to 1.6)	< 0.001
6 months	0.2 (2.0)	0.8 (1.7)	0.5 (0.1 to 1.0)	0.03
12 months	0.4 (1.9)	0.6 (2.0)	0.1 (–0.3 to 0.6)	0.61
Change in Food Craving Inventory score (frequency domain)				
1 month	–2.2 (3.8)	–2.1 (3.6)	–0.3 (–1.4 to 0.7)	0.53
2 months	–1.8 (3.8)	–2.0 (3.8)	–0.6 (–1.7 to 0.5)	0.25
6 months	–1.2 (4.1)	–1.7 (3.7)	–0.8 (–1.9 to 0.3)	0.13
12 months	–0.9 (3.7)	–1.5 (4.0)	–0.8 (–1.9 to 0.2)	0.12
Change in Food Craving Inventory score (strength domain)				
1 month	–2.3 (4.4)	–2.0 (3.4)	0.1 (–0.9 to 1.1)	0.85
2 months	–2.2 (4.0)	–1.7 (3.9)	–0.1 (–1.1 to 0.9)	0.85
6 months	–1.2 (3.7)	–1.3 (4.0)	–0.3 (–1.4 to 0.7)	0.48
12 months	–1.4 (3.8)	–1.3 (4.2)	–0.2 (–1.2 to 0.9)	0.75
Change in Three-Factor Eating Questionnaire score (cognitive restraint domain)				
2 months	0.2 (0.6)	0.4 (0.6)	0.2 (0.0 to 0.3)	0.05
6 months	0.2 (0.5)	0.4 (0.7)	0.1 (0.0 to 0.3)	0.07
12 months	0.2 (0.6)	0.3 (0.6)	0.1 (0.0 to 0.3)	0.10
Change in Three-Factor Eating Questionnaire score (uncontrolled eating domain)				
2 months	–0.2 (0.5)	–0.1 (0.5)	0.1 (–0.1 to 0.2)	0.35
6 months	–0.2 (0.5)	–0.2 (0.5)	0.0 (–0.1 to 0.1)	0.93
12 months	–0.3 (0.6)	–0.2 (0.6)	0.0 (–0.1 to 0.2)	0.66
Change in Three-Factor Eating Questionnaire score (emotional eating domain)				
2 months	–0.3 (0.8)	–0.2 (0.7)	0.1 (–0.1 to 0.3)	0.32
6 months	–0.3 (0.7)	–0.2 (0.7)	0.1 (–0.2 to 0.3)	0.59
12 months	–0.3 (0.7)	–0.2 (0.7)	0.1 (–0.1 to 0.2)	0.54

a The summary statistics (mean and SD) were calculated based on the number of participants with a recorded outcome at each time point.
b Treatment effects are presented as a difference in means (estimated from a mixed-effects regression model) between the two arms.

Changes in food craving

All participants showed a decrease in the frequency and strength of food craving at the 1-, 2-, 6- and 12-month follow-up points (see *Table 24*). There were no significant differences between the groups.

Changes in Three-Factor Eating Questionnaires

Changes in the scores of the domains of the Three-Factor Eating Questionnaire were minimal (see *Table 24*). Participants in both arms showed a small increase in cognitive restraint scores, but the increase was greater in the WAP arm than in the nurse arm at the end of treatment (0.4 vs. 0.2; $p = 0.05$). Participants, on average, showed small decreases in uncontrolled and emotional eating scores. There were no significant differences in the changes between study arms.

Changes in levels of physical activity

Participants in both arms increased their levels of physical activity above baseline across the duration of the study to the same extent (*Table 25*) (818 MET-minutes/week vs. 264 MET-minutes/week; $p = 0.09$).

Participants reported reducing their sitting time by 1 hour at the end of treatment, but no significant differences between groups was observed.

Adverse events

Table 26 provides a summary of all AEs. There were more AEs in the WAP group, although this difference was not statistically significant (WAP arm 11% vs. nurse arm 6%; odds ratio 2.19, 95% CI 0.86 to 5.58; $p = 0.10$).

Three SAEs were reported (shortness of breath, myalgia and gastrointestinal complaints) and resulted in participants being hospitalised overnight. These were all in the WAP arm and were not related to study procedures.

TABLE 25 Changes in International Physical Activity Questionnaire scores

Time point	Arm, median (IQR)[a]		Treatment effect (95% CI)[b]	*p*-value
	Nurse	WAP		
MET-minutes/week				
2 months	264 (–347 to 1030)	818 (0 to 2517)	923 (–167 to 2014)	0.09
6 months	336 (–240 to 1644)	415 (–258 to 1584)	–441 (–1380 to 497)	0.33
12 months	215 (–763 to 1589)	359 (–385 to 1750)	613 (–312 to 1537)	0.18
Minutes spent sitting/day				
2 months	–60 (–120 to 0)	–60 (–150 to 60)	–12 (–93 to 69)	0.77
6 months	0 (–90 to 30)	–60 (–150 to 0)	–5 (–71 to 61)	0.87
12 months	–60 (–120 to 60)	0 (–120 to 60)	19 (–51 to 89)	0.57

a The summary statistics (median and IQR) were calculated based on the number of participants with a recorded outcome at each time point.
b Treatment effects are presented as a difference in means (estimated from a mixed-effects regression model) between the two arms.

TABLE 26 Summary of AEs

AEs	Arm, *n*	
	Nurse ($N = 109$)	WAP ($N = 221$)
Number of AEs[a]	8	45
Number of patients with at least one AE	6	25
Number of AEs per patient		
0	103	196
1	5	16
2	0	5
3	1	1

continued

TABLE 26 Summary of AEs (*continued*)

AEs	Arm, *n*	
	Nurse (*N* = 109)	WAP (*N* = 221)
4	0	0
5	0	2
6	0	1
Number of SAEs	0	3
Systems affected by AE		
Gastrointestinal	5	21
Nervous system	0	7
General disorders	0	6
Musculoskeletal and connective tissue	0	6
Psychiatric	0	2
Respiratory, thoracic and mediastinal	1	1
Infections and infestations	2	0
Blood and lymphatic	0	1
Skin and subcutaneous tissue	0	1
AE category		
Arthralgia	0	4
Bloating	0	2
Bruising	0	1
Constipation	1	2
Diarrhoea	1	6
Dizziness	0	4
Dry skin	0	1
Flatulence	0	2
Flu-like symptoms	0	6
Generalised muscle weakness	0	1
Headache	0	2
Haemorrhoids	1	0
Insomnia	0	2
Lung infection	2	0
Memory impairment	0	1
Myalgia	0	1
Steatorrhoea	0	7
Stomach pain	1	1
Voice alteration	0	1
Vomiting	1	1
Wheezing	1	0

a Some patients experienced more than one AE.

Chapter 4 Economics evaluation methods and results

Overview

Obesity-related illness is responsible for about 10% of morbidity and mortality in the UK and costs the NHS about £7B annually.[80] In order to estimate the cost-effectiveness of the WAP (intervention group) versus nurse-led weight management (representing usual care), a within-trial cost–utility analysis was undertaken. The costs were estimated from a NHS and Social Services perspective.[81] To inform the estimation of QALYs, participants completed the EQ-5D-5L questionnaire. As already mentioned (see *Chapter 2*, *Overview of trial design*), participants were randomised to treatment groups prior to receiving a weight loss intervention (when baseline data were also collected). The impact of treatment was measured by following up participants at 6 and 12 months post randomisation.

Methods

An incremental cost-effectiveness analysis was conducted to estimate the cost per QALY of the WAP over and above the best practice nurse-led intervention.

Valuation of resource use

The NHS health-care costs were estimated using UK unit costs applied from national sources such as *NHS Reference Costs*[82] and the Personal Social Services Research Unit's *Unit Costs of Health and Social Care 2013*.[83]

The costs in each study arm were calculated, including the time spent by health-care professionals delivering care, equipment and materials used in the interventions, and overhead costs. Patients completed a service-use questionnaire to record their use of NHS resources including hospital and primary care services [see *Appendix 4* (*Appendix 1: Timing of data collection*)].

All costs were valued in pounds sterling, according to the price year representing the mid-point of the trial (2012/13). Any costs occurring in prior price years were inflated using the Hospital and Community Health Services pay and prices index.[83] As the trial follow-up was 12 months post randomisation, no discounting will be required. Quantities of services were multiplied by the relevant unit costs to estimate total cost.

Outcome measures

Health-related quality of life was measured using the EQ-5D-5L[84] at baseline, and at the 6- and 12-month follow-up in the SWAP trial, and forms the primary cost-effectiveness end point, following NICE guidance.[85]

Responses were then converted to utility scores (a scale where death is equal to 0 and full health is equal to 1) using the population-based EQ-5D-5L value sets study[86] and preliminary reported results.[87]

Quality-adjusted life-years for patients receiving the WAP and usual care were derived from utility scores using the area under the curve method over the follow-up period.[88] This enables cost–utility analysis expressing the value of the WAP as the incremental cost per QALY.

Cost-effectiveness analysis

The incremental cost-effectiveness ratio (ICER) was calculated using the formula below where Δ represents change, *C* represents the costs, *E* represents the effects and I and C refer to the intervention and control, respectively:

$$\text{ICER} = \frac{\Delta C}{\Delta E} = \frac{\bar{C}_I - \bar{C}_C}{\bar{E}_I - \bar{E}_C}. \quad (2)$$

Incremental costs of the WAP intervention over and above routine care were calculated and combined with the incremental effectiveness to compute the ICER. In order to allow for the skewness typically encountered with cost data, both costs and outcomes were bootstrapped (using 10,000 replications) and the data used to construct cost-effectiveness acceptability curves to show the probability that the WAP is a more cost-effective intervention than routine care.

Base-case analysis makes three key assumptions regarding the cost of the WAP intervention: (1) the prior history of health-care use should not influence results; (2) that group sessions are conducted by a band 5 (hospital dietitian); and (3) that the cost of the WAP assumes attendance of 15 participants for all sessions. These three assumptions are subject to sensitivity analysis (further explanation is provided in *Results*).

Results

Resource utilisation and costs

Weight Management Programme intervention

The resources required to deliver the WAP intervention consisted of two research health psychologists per session delivering group sessions over eight weekly group sessions. As reported in *Table 11*, the mean group size per session was 15 participants (IQR 13–18 participants), thus indicating a staff-to-participant ratio of 2 : 15 in the base-case estimate cost of the intervention. In the trial, the WAP intervention was delivered by two health research psychologists (grade 6). However, for the base-case analysis, staff costs were based on a NHS band 5 hospital dietitian (see *Table 28*). Further details of the within-research costs are provided in *Appendix 5*, *Table 41*.

Further to the staff costs of running the WAP sessions, equipment costs (including pedometers, materials, digital scales, blood pressure monitors, batteries, measuring tapes, stationery and venue) are included in the cost of the intervention (for full details see *Appendix 4: Appendix 5 – Costs*).

Following the initial 8-week course, 10 further monthly group sessions were provided during the maintenance sessions; again these were assumed to take place with a staff-to-participant ratio of 2 : 15.

Each group session lasted 2 hours and for the direct contact per group session both intervention staff further required 1 hour for pre-session preparation (preparing materials, photocopying, scheduling text messages) and 2 hours post session (checking/filing forms, contacting participants for missing information, following up non-attenders).

Based on the above information, and assuming a constant group size of 15, the cost per participant is calculated to be £10.33 per session. It was further assumed that a participant prescribed the WAP would receive eight initial treatment sessions (£82.64) and a further 10 sessions in the maintenance phase (£103.30) and would account for a proportion of equipment costs (£8.69). This indicates that the cost per participant in the WAP was £194.63.

Nurse intervention (control)

The control group intervention was based on best usual care, consisting of four sessions lasting 1 hour each delivered over 8 weeks by a practice nurse. The cost of the control intervention also includes equipment costs (materials, digital scales, blood pressure monitors, batteries, measuring tape, stationery and venue). The cost per participant of the nurse intervention is £180.90. For further details of costs related to nurse intervention, see *Appendix 2*, *Table 42*.

In addition to the direct cost of providing weight management interventions, the economic analysis considers consequences of intervention on wider NHS resources. *Table 27* provides observations of the resource utilisation (by study group), as measured using the resource-use questionnaire in four categories. The first category indicated contacts with general practice and community nursing services. The second widens the perspectives to consider contacts with social services. The third considers contact with psychiatric services (both hospital and community). The fourth, and final, category considers other in-hospital services, NHS Direct, paramedics and prescriptions. All statistics on resource use are reported as mean and SD, based on the final available sample for the complete-case cost-effectiveness analysis (WAP arm, $n = 116$; nurse arm, $n = 63$).

Examining the profile of resource use at baseline, there are small differences evident between the two study groups across the four categories. In the category *General practice and community nursing services* (see *Table 27*), across all subcategories rates of service contact was higher in the nurse arm. Social work and psychiatric services others displays a pattern of large magnitudes of service use in the nurse arm compared with the WAP arm. These patterns may indicate potential selection bias. Differences in service use are most commonly explained by individuals' health status (at baseline) or by differences in the age distribution between groups. Baseline health-state utilities are presented later in this chapter (see *Table 30*). Differences in age distribution by study group are presented in *Figure 7*. Observations would suggest there exists some potentially influential difference in the age distributions between groups and, therefore, is it important that cost-effectiveness analysis controls for age when explaining both costs and outcomes.

Follow-up data were collected at 6 and 12 months and these visits represent NHS contacts following the intervention. The most frequently reported service contact in the post-intervention period was contact with a GP in the surgery. The mean number of contacts by group at 6 months was 1.90 (SD 2.675) in the WAP arm and 1.89 (SD 2.057) in the nurse arm. At 12 months, the mean number of contact in the WAP arm was 1.53 (SD 2.019) and in the nurse arm was 1.87 (SD 1.806). Observing this pattern over time may suggest that the nurse arm shows reduced service use at 6 months (compared with the WAP arm), but by 12 months the mean number of GP surgery visits was lowest in the WAP group (potentially attributable to an effect of the available maintenance phase for up to 12 months with the WAP arm).

At baseline, the mean number of nurse contacts within the surgery setting was comparable between the WAP (1.08, SD 1.434) and nurse arms (1.11, SD 1.45), and the magnitude of variance was the same in both trial arms. At the 6-month follow-up, the mean number of service contacts in the WAP arm (0.56, SD 1.01) was lower than in the nurse arm (0.77, SD 1.453), and variance was also reduced. This trend seems to have been sustained to 12 months in the WAP arm (0.59, SD 1.059); however, by this time, the mean number of nurse visits in the nurse arm (0.53, SD 1.004) was comparable to that in the WAP arm.

The home help variable demonstrates a significant amount of variance from baseline in both the WAP (1.67, SD 15.806) and nurse arms (1.97, SD 15.494). A small number ($n = 3$) of influential outliers reported very high levels of home help (ranging between 24 and 168 visits from home help during the 6-month period).

The mean number of calls to GP at baseline was lower in the WAP arm (0.58, SD 1.026) than in the nurse arm (1.10, SD 2.133). By 12 months, the average number of calls decreased in both the nurse arm (0.64, SD 1.319) and the WAP arm (0.38, SD 0.96); similar to surgery contact, this may be attributed to the maintenance phase within the WAP.

TABLE 27 Resource utilisation. Available sample to inform complete-case analysis (WAP arm, $n = 116$; nurse arm, $n = 63$)

	Time point											
	Baseline				6 months				12 months			
	WAP arm		Nurse arm		WAP arm		Nurse arm		WAP arm		Nurse arm	
Type of service	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
General practice and community nursing services												
GP (surgery)	2.696	2.381	3.097	3.308	1.904	2.675	1.887	2.057	1.53	2.019	1.871	1.806
GP (home)	0.009	0.093	0.081	0.635	0.009	0.093	0	0	0.035	0.263	0	0
GP (telephone)	0.583	1.026	1.097	2.133	0.513	1.165	0.581	0.915	0.383	0.96	0.645	1.319
Nurse (surgery)	1.078	1.434	1.113	1.45	0.565	1.01	0.774	1.453	0.591	1.059	0.532	1.004
Nurse (home)	0	0	0.661	5.08	0	0	0	0	0	0	0.016	0.127
Counsellor (surgery)	0.148	1.086	0.629	4.331	0.052	0.292	0.129	0.64	0.348	2.347	0.097	0.469
Other practice contacts[a]	0.104	0.502	0.033	0.256	0.052	0.346	0.048	0.216	0.035	0.227	0.177	1.274
Social services												
Social worker	0.052	0.475	0	0	0.07	0.588	0	0	0.052	0.346	0.016	0.127
Home help	1.67	15.806	1.968	15.494	0	0	0	0	0.209	2.238	0	0
Care assistant	0	0	0	0	0.73	7.833	0	0	0.887	9.324	0.032	0.254
Day centre (visit)	0	0	0	0	0	0	0	0	0	0	0	0
Other social service contacts[a]	0.017	0.187	0.161	1.27	0.07	0.434	0	0	0.017	0.187	0.194	1.524
Psychiatric hospital and community services												
Psychiatrist (hospital)	0.035	0.227	0.129	1.016	0.026	0.208	0.129	1.016	0.009	0.093	0.048	0.381
Psychiatrist (home)	0	0	0	0	0	0	0	0	0	0	0	0
Psychologist	0.009	0.093	0.161	1.27	0.009	0.093	0.161	1.27	0.009	0.093	0.403	2.036
Psychiatric nurse	0.017	0.131	0	0	0.009	0.093	0	0	0.009	0.093	0	0
Other psychiatric service contacts[a]	0	0	0	0	0	0	0.5	2.702	0.209	1.899	0	0

	Time point											
	Baseline				6 months				12 months			
	WAP arm		Nurse arm		WAP arm		Nurse arm		WAP arm		Nurse arm	
Type of service	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Other services												
Hospital (day case)	0.043	0.205	0.952	6.109	0.017	0.131	0.048	0.216	0.061	0.305	0.032	0.254
Hospital (A&E)	0.165	0.494	0.323	0.647	0.104	0.36	0.129	0.527	0.13	0.45	0.065	0.248
Hospital (outpatient)	0.443	1.371	0.71	1.712	0.522	1.629	0.419	0.967	0.487	1.334	0.419	0.95
Hospital (inpatient)	0.096	0.577	0.113	0.483	0.026	0.208	0.081	0.635	0.017	0.131	0.016	0.127
Other hospital contacts[a]	0.165	0.794	0.129	0.461	0.061	0.404	0.032	0.178	0.07	0.508	0.113	0.483
NHS Direct	0.096	0.418	0.081	0.329	0.009	0.093	0.048	0.216	0.061	0.483	0	0
Ambulance or paramedic	0.043	0.244	0.097	0.433	0.026	0.16	0.081	0.417	0.07	0.472	0.016	0.127
Prescriptions received (6 months)	2.991	5.905	4.048	6.759	2.757	4.26	2.29	3.659	2.252	3.541	2.613	4.451

A&E, accident and emergency.
a Full details of other services, as specified by participants, are available on request.

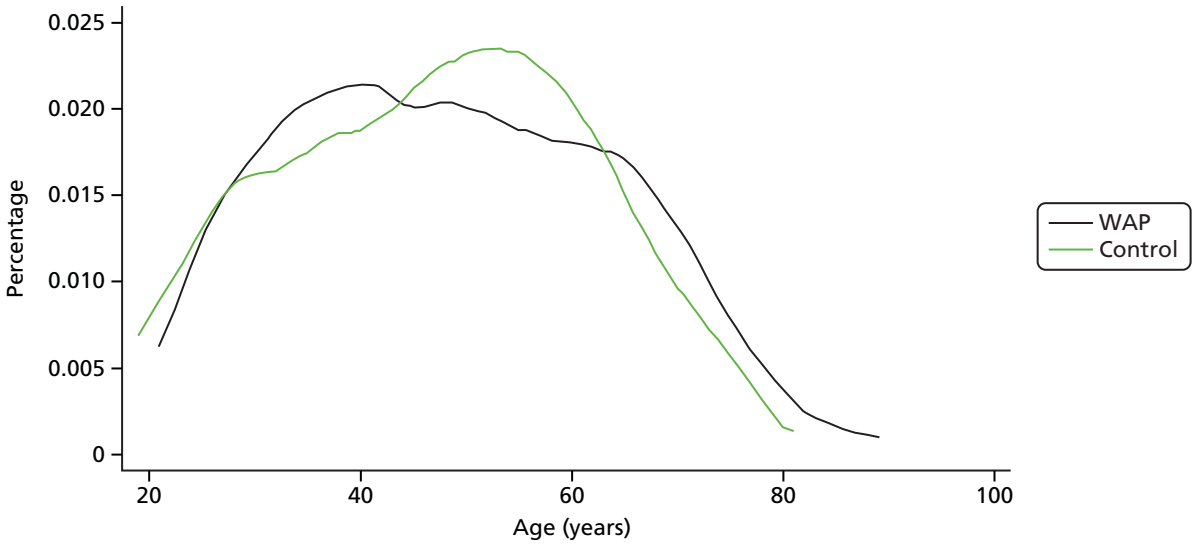

FIGURE 7 Age distribution by study arm.

To assign a monetary value to the above resource consequences, *Table 28* presents the identified units per item of resource use. *Table 29* multiplies the quantity of resource use by the unit cost to obtain cost consequences to the NHS.

The main variable to inform the relative cost consequences of intervention and to inform cost-effectiveness analysis is the total cost. First, it should be noted that, at baseline, the mean total cost in the nurse arm (£1681, SD £4411) is effectively double the cost in the WAP arm; hence there may exist significant differences in the overall resource requirement between the two study groups.

To conduct the cost-effectiveness analysis, only cost consequence after intervention (i.e. at the 6- and 12-month follow-ups) would be incorporated within a base-case cost-effectiveness. However, the assumption that retrospective differences in total costs may not be of relevance raises important questions regarding the validity of the base-case estimate on value for money; implications of potential differences (as indicated by baseline total costs) are explored using a sensitivity analysis (see *Sensitivity analysis 1*).

Outcomes

Health-related quality of life using the EQ-5D-5L is measured to enable the estimation of QALYs. *Table 30* presents the EQ-5D-5L mean (SD) utility scores at each time point and the group QALY.

The difference in baseline utility scores between groups is 0.011, indicating that we should control for baseline utility. The unadjusted QALY for the WAP arm is 0.404 (SD 0.079) and in the nurse arm is 0.389 (SD 0.072), indicting that the unadjusted incremental QALY (i.e. the difference between the WAP and nurse arm) is 0.015.

Cost-effectiveness analysis: base-case analysis

To inform the base-case estimation of cost-effectiveness, a seemingly unrelated regression is utilised to jointly explain the change in total cost and QALYs (*Table 31*). As outlined above, group differences were observed in both group baseline utility and age distributions, and hence it is necessary to control for age and baseline utility in the regression analysis. This provides adjusted estimates of the effect of the WAP on the incremental QALY and incremental total cost.

Adjusting for age, the WAP is associated with a mean incremental total cost of £80 (95% CI –£505 to £667). This suggests no significant difference in cost between the two arms of the trial. The level of significance on the age coefficient confirms the importance to control for group differences in age distribution.

TABLE 28 Unit costs

Item	Unit cost (£)	References	Price year
Interventions			
WAP session	10	PSSRU 2013:[83] two hospital dietitians (band 5). Attendance: 15 participants per session. Indirect time per session: 3 hours	2012–13
Practice weight loss	44	PSSRU 2013:[83] nurse (GP practice), per hour of face-to-face contact,	2012–13
General practice and community nursing services			
GP (surgery)	45	PSSRU 2013:[83] 'per-patient contact lasting 11.7 minutes'	2012–13
GP (home)	114	PSSRU 2013:[83] 'per out-of-surgery visit lasting 23.4 minutes'	2012–13
GP (telephone)	27	PSSRU 2013:[83] 'per telephone consultation lasting 7.1 minutes'	2012–13
Nurse (surgery)	13	PSSRU 2013:[83] £52 per hour. Face-to-face contact, duration of contact 15.5 minutes	2012–13
Nurse (home)	60	PSSRU 2013:[83] community nurse (includes district nursing sister, district nurse). Cost per hour of home visiting	2012–13
Counsellor (surgery)	63	PSSRU 2013:[83] counselling services in primary medical care. Cost per hour of client contact	2012–13
Social services			
Social worker	159	PSSRU 2013:[83] social worker (adult services). Cost per hour of face-to-face contact	2012–13
Home help	24	PSSRU 2013:[83] home care worker. Cost per hour (weekday)	2012–13
Care assistant	30	PSSRU 2013:[83] senior 'home care worker'. Cost per hour (weekday)	2012–13
Day centre (visit)	38	PSSRU 2013:[83] local authority social services day care for people with mental health problems. Cost per user session	2012–13
Psychiatric services			
Psychiatrist (hospital)	261	PSSRU 2013:[83] consultant – psychiatric. Cost per hour (face-to-face contact)	2012–13
Psychiatrist (home)	261	PSSRU 2013:[83] consultant – psychiatric. Cost per hour (face-to-face contact)	2012–13
Psychologist	134	PSSRU 2013:[83] clinical psychologist. Cost per hour of client contact	2012–13
Psychiatric nurse	65	PSSRU 2013:[83] nurse (mental health). Cost per hour of face-to-face contact	2012–13
Other services			
Hospital (day case)	697	PSSRU 2013:[83] Day cases HRG data (weighted average of all stays)	2012–13
Hospital (A&E)	956	PSSRU 2013:[83] 'outpatient and A&E (all service users)'	2012–13
Hospital (outpatient)	135	PSSRU 2013:[83] outpatient procedures (weighted average of all outpatient procedures)	2012–13
Hospital (inpatient)	598	PSSRU 2013:[83] non-elective inpatient stays (short stays)	2012–13
NHS Direct	52	PSSRU 2013:[83] £52 per hour of telephone contact with nurse specialist	2012–13
Ambulance/paramedic	221	National Audit Office 2011[89] (£213.5 mid-point of cost per incidence in range £176–251). Applied annual rate of 3.5%	2012–13
Prescriptions	44.64	PSSRU 2013:[83] prescription costs per consultation (net ingredient cost)	2012–13

A&E, accident and emergency; HRG, Healthcare Resource Group; PSSRU, Personal Social Services Research Unit.

TABLE 29 Cost consequences. Available sample to inform complete-case analysis (intervention, $n = 116$; control, $n = 63$)

	Time point											
	Baseline				6 months				12 months			
	WAP		Nurse		WAP		Nurse		WAP		Nurse	
Type of service	Mean (£)	SD (£)	Mean (£)	SD (£)	Mean (£)	SD (£)	Mean (£)	SD (£)	Mean (£)	SD (£)	Mean (£)	SD (£)
General practice and community nursing services												
GP (surgery)	121	107	139	148	86	120	84	92	69	90	83	81
GP (home)	1	11	9	72	1	11	0	0	4	30	0	0
GP (telephone)	16	28	29	57	14	31	15	25	10	26	17	35
Nurse (surgery)	15	19	15	19	8	15	10	19	8	14	7	13
Nurse (home)	0	0	7	50	0	0	0	0	0	0	0	1
Counsellor (surgery)	8	56	39	271	6	48	7	39	22	148	12	73
Other practice contacts	1	8	0	0	1	9	0	0	1	7	1	5
Social services												
Social worker	3	27	0	0	10	74	0	0	8	55	0	3
Home help	79	755	46	369	0	0	0	0	15	160	0	0
Care assistant	0	0	0	0	43	468	0	0	104	1114	0	4
Day centre (visit)	0	0	0	0	0	0	0	0	0	0	0	0
Other social service contacts	1	8	0	0	1	9	0	0	1	7	1	5
Psychiatric hospital and community services												
Psychiatrist (hospital)	9	59	33	263	7	54	33	263	2	24	12	99
Psychiatrist (home)	0	0	0	0	0	0	0	0	0	0	0	0
Psychologist	1	12	21	169	1	12	21	169	1	12	51	270
Psychiatric nurse	1	7	0	0	1	6	0	0	1	6	0	0
Other psychiatric service contacts	2	14	0	0	2	14	0	0	1	8	1	8

	Time point											
	Baseline				6 months				12 months			
	WAP		Nurse		WAP		Nurse		WAP		Nurse	
Type of service	Mean (£)	SD (£)	Mean (£)	SD (£)	Mean (£)	SD (£)	Mean (£)	SD (£)	Mean (£)	SD (£)	Mean (£)	SD (£)
Other Services												
Hospital (day case)	30	142	653	4225	12	91	33	150	42	211	22	176
Hospital (A&E)	157	471	303	615	99	342	121	500	124	428	61	235
Hospital (outpatient)	64	190	94	230	76	226	56	130	69	182	56	127
Hospital (inpatient)	57	344	66	286	15	124	47	377	10	78	9	75
Other hospital contacts	9	89	0	0	9	89	0	0	1	4	2	12
NHS Direct	1	4	1	7	0	2	1	7	1	12	0	0
Ambulance or paramedic	10	54	21	95	6	35	18	91	15	104	4	28
Prescriptions received (6 months)	134	264	178	300	127	193	101	163	104	162	117	197
Total cost (at time point)	716	1219	1681	4411	523	957	548	933	613	1485	455	576

A&E, accident and emergency.

TABLE 30 Unadjusted EQ-5D-5L mean (SD) utility scores and QALYS by group (WAP arm, $n = 116$; nurse arm, $n = 63$)

	Time point			
Arm	Baseline	6 months	12 months	QALY
WAP (intervention)	0.849 (0.153)	0.868 (0.157)	0.868 (0.173)	0.404 (0.079)
Nurse (control)	0.838 (0.148)	0.838 (0.178)	0.841 (0.171)	0.389 (0.072)

TABLE 31 Seemingly unrelated regression of change in total cost (from an NHS perspective) and QALYs explained by the WAP adjusted for age and baseline utility

Coefficients	Total costs (£) (95% CI)	QALY (95% CI)
WAP	80 (–505 to 667)	0.0104 (–0.0015 to 0.0224)*
Age	33 (14 to 52)***	–0.0004 (–0.0008 to 0.000)*
Baseline utility	–	0.4228 (0.3836 to 0.4619)***
Constant	2191 (1804 to 2578)***	0.280 (0.267 to 0.290)***

*$p < 0.1$; **$p < 0.01$; ***$p < 0.001$.
Correlation of QALYs and costs = –0.0689; Breusch–Pagan $\chi^2 = 0.851$.

Controlling for age and baseline, intervention with the WAP with an adjusted mean incremental QALY is 0.0104 (95% CI –0.0015 to 0.0224; $p = 0.060$). The estimated magnitude of the change in QALY indicates that there remains some uncertainty in the health gains from the WAP.

The following formula shows the calculation of the adjusted ICER based on the estimated mean incremental total cost and QALY is:

$$\begin{aligned} \text{ICER} &= \frac{\Delta C}{\Delta E} = \frac{\bar{C}_I - \bar{C}_C}{\bar{E}_I - \bar{E}_C} \\ &= \frac{\bar{C}_{WAP}}{\bar{E}_{WAP}} \\ &= \frac{£80.85}{0.010433} \\ &= £7,742/\text{QALY}. \end{aligned} \tag{3}$$

An ICER of £7742 per QALY would suggest that the WAP would represent a cost-effective intervention with respect to the cost per QALY threshold of £20,000, as used by NICE. However, assuming that a decision-maker may be risk averse, it is also important to consider uncertainty in the ICER.

We can demonstrate the uncertainty surrounding the ICER (and to address skewness resulting from the count nature of cost data) by initially bootstrapping the cost and outcome data using 10,000 bootstrap replications. *Figure 8* presents the results of the bootstraps on both a cost-effectiveness plane and cost-effectiveness acceptability curve. Presenting the result of the bootstrap on the cost-effectiveness plane helps to illustrate uncertainty in probabilistic terms as they relate to decisions related to each quadrant. The first observation is the uncertainty in whether the WAP will cost more or less than best usual care, and bootstrap results suggest a 38% probability that the WAP will cost less than usual care, of which 36% also have a positive health gain. Despite the low level of significance surrounding the adjusted mean incremental QALY, the results suggest a 96% probability of a positive health gain from the WAP. However, the most probable scenario is that the WAP will be more effective and will, overall, cost more to the NHS (60%).

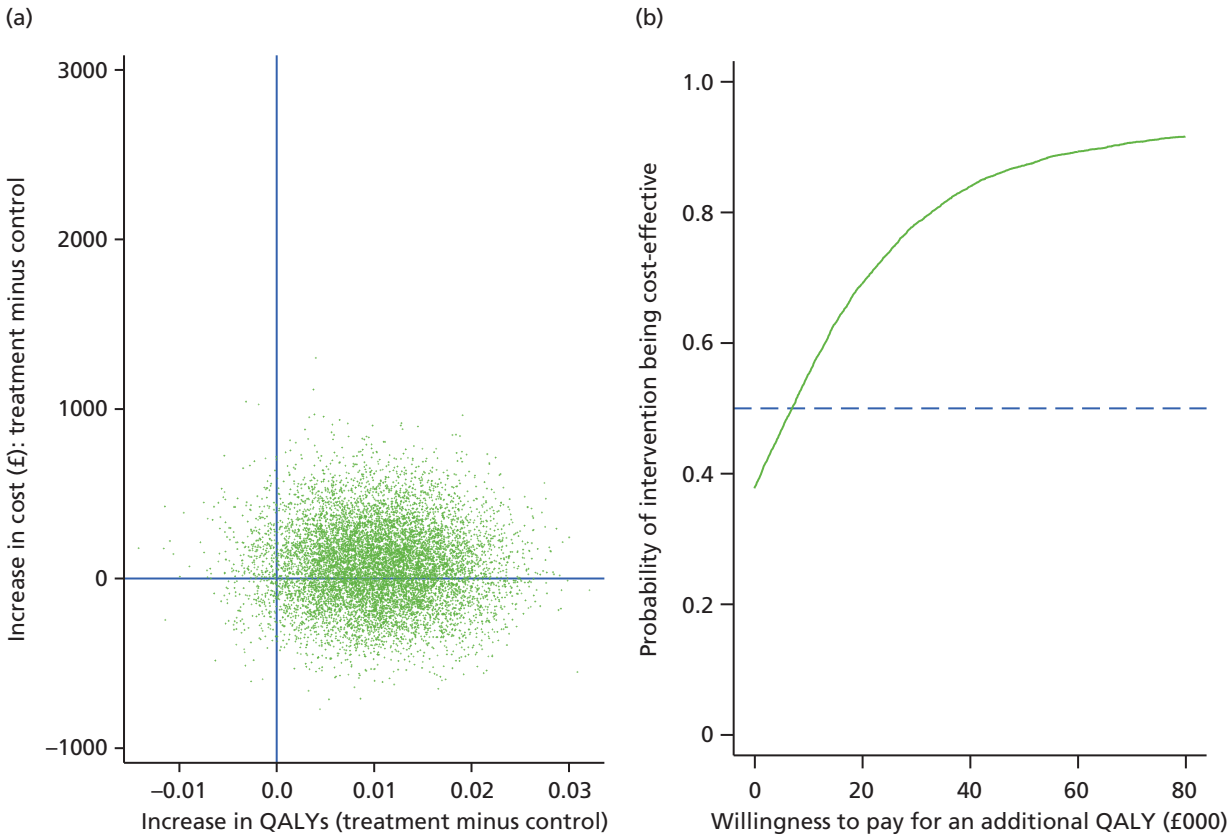

FIGURE 8 Cost-effectiveness plane (a) and cost-effectiveness acceptability curve (b).

To further explore the decision in the context of uncertainty, bootstrap results are utilised to form a cost-effectiveness acceptability curve. This plot demonstrates how the probability that an intervention is cost-effective increases as the decision-makers willingness to pay increases. First, it can be observed from the cost-effectiveness acceptability curve that should a decision-maker not be willing to pay any more than usual care, there is a 0.38 probability that the WAP will be cost-effective. Decision-makers must make decisions in the context of uncertainty. The probabilities that the WAP falls within the NICE willingness-to-pay threshold of £20,000–30,000 are $p(\text{ICER} < 20{,}000/\text{QALY}) = 0.6826$ and $p(\text{ICER} < 30{,}000/\text{QALY}) = 0.7746$.

Given the available information (in addition to base-case required assumptions), the base-case cost-effectiveness analysis suggests that the WAP may represent value for money to the NHS.

To explore the implication of underlying assumptions, the following three sensitivity analyses aim to explore the implications of assumptions of the base-case findings.

Sensitivity analysis 1

The first assumption was that the two populations have a difference in profiles of health service use in the 6 months preceding randomisation and, controlling for baseline total costs, will influence estimates of cost-effectiveness. *Table 32* repeats the base-case seemingly unrelated regression alongside a second equation in which the regression of total cost controls for baseline total cost.

The results suggest that future health-care use (i.e. cost consequences over the 12-month follow-up period) is related to use in the previous 6 months and controlling for this may improve the estimation of the treatment effect given potential heterogeneity in the available complete-case sample. The effect of the WAP on total cost (having controlled for baseline total costs) compared with the base-case assumption suggests that the incremental costs related to the WAP may increase. This finding may suggest that there is merit in obtaining further evidence on the treatment effect of the WAP (e.g. additional trials or future meta-analysis).

TABLE 32 Seemingly unrelated regression of change in total cost and QALYs explained by the WAP controlling for age, baseline total cost and baseline utility sensitivity analysis

	Regression coefficients (95% CI)	
Variables	Base case	Controlling for baseline total cost
Total costs		
WAP	60 (–532 to 653)	244 (–338 to 826)
Age	33 (14 to 52)	28 (9 to 46)
Baseline total costs	–	0.1804 (0.0809 to 0.2798)
Constant	–337 (–1337 to 664)	–397 (–1367 to 572)
QALY		
WAP	0.0115 (–0.0005 to 0.0235)	0.0115 (–0.0005 to 0.0235)
Age	0.4293 (0.3897 to 0.469)	0.4285 (0.3889 to 0.4681)
Baseline utility	–0.0003 (–0.0007 to 0.0000)	–0.0004 (–0.0007 to 0.0000)
Constant	0.0446 (0.0016 to 0.0877)	0.0454 (0.0024 to 0.0884)
Statistics		
n	177	177
Correlation matrix of residuals: QALY to total costs	–0.0611	–0.0855
Breusch–Pagan test of independence	0.660 ($p = 0.4165$)	1.293 ($p = 0.2555$)

Sensitivity analysis 2

Sensitivity analysis was repeated on the assumption that a band 5 hospital dietitian is the correct competency level and associated pay scale should the WAP be deployed in the NHS. To examine the implication, *Table 33* presents the following scenario, which examines the implications of varying NHS band on cost-effectiveness estimates (assuming that treatment effect is not related to NHS band).

TABLE 33 Implications of the WAP staff cost on cost-effectiveness estimates

NHS staff band	Salary (£)	Per hour (£)	Session cost (£)	ICER (£)	p(ICER < 20,000)	p(ICER < 30,000)
3[a]	18,264	24	8	3726	0.7285	0.8037
4[a]	21,122	27	9	5450	0.7104	0.7926
5 (base case)[b]	23,441	31	10	7742	0.6826	0.7746
6[c]	31,752	42	14	14,068	0.5962	0.7081

PSSRU, Personal Social Services Research Unit.
a Based on generic NHS bands reporting in PSSRU 2013.[83] Total staff cost includes salary on costs, overheads and capital.
b Base case: hospital dietitian, PSSRU 2013.[83]
c Nurse specialist, PSSRU 2013.[83]

In the current trial the intervention was delivered by two grade 6 research psychologists (equivalent to band 6) and it may be argued that a dose–response relationship was evident in that greater effectiveness was a consequence of the higher level of training. The cost of someone on band 6 is £42 per hour, compared with £31 per hour for someone on band 5; adjusting most to band 6 hourly rates shows a substantial change in ICER [$ICER_{(band\ 6)} = £14{,}068$ vs. $ICER_{(band\ 5)} = £7742$]. As there is uncertainty around cost-effectiveness estimates, this illustrates an important parameter should a decision rule such as 'approval with research' be considered.[90]

It may also be the case that potential cost savings could be realised should the NHS utilise NHS staff below band 5. However, this analysis suggests that there is limited added value in going below band 5 [$ICER_{(band4)} = £5450$ or $ICER_{(band\ 3)} = £3726$].

Sensitivity analysis 3

The final sensitivity analysis considered the effect of the assumption that group size is assumed static (i.e. a mean group size is 15). Proportions attending sessions during the intervention and maintenance phase (see *Figure 9*) are utilised to estimate overall session attendance (based on the assumption that each group aims to obtain 20 participants at onset). *Table 34* presents results comparing the base case to adjusted estimates based on the observed data.

The results suggest that the mean number of attendances per session is 14.7 during the intervention period and 6.96 in the maintenance phase. Specifically, low attendance during maintenance doubles the attendance cost per session, from £10 (base case) to £20 (based on observed proportions). This is because group interventions are subject to decreasing average cost functions when cost is plotted against attendance. This may substantially elevate the ICER and reduces the probability of falling within the NICE reimbursement threshold. Should the WAP be implemented, commissioners may wish to consider incentive structures based on providers ensuring adherence in the longer term.

Summary of within-trial cost-effectiveness findings

1. The total cost of the WAP is £195 per person (or £10 per group session attended), compared with £176 for best usual care.
2. Controlling for baseline utility and age, the incremental QALY gain is 0.0104 (95% CI –0.0015 to 0.0224; $p = 0.088$).
3. The mean incremental total cost was not significantly different from the cost of best practice, nurse-led usual care £80 (95% CI –505 to 667; $p = 0.787$).
4. In the base case, the ICER is estimated at £7742 per QALY, with a probability that the WAP is the most cost-effective intervention of 68.26% when a QALY is valued at £20,000 and of 77.46% when a QALY is valued at £30,000.

TABLE 34 Implications of variation in attendance

Scenario	Mean number attending		Session cost (£)	ICER (£)	p(ICER < 20,000)	p(ICER < 30,000)
	Session	Maintenance				
Base case	15	15	10	7742	0.6826	0.7746
Observed	14.7	6.96	20	24,935	0.4339	0.5755

Chapter 5 Process evaluation: methods and results

Introduction

This chapter explores the processes involved in the study, from recruitment to delivery of treatment, follow-up and participant satisfaction.

The focus in this section is on exploring the many components of the WAP. We do not explore in any detail the components of the nurse-based intervention, but provide a summary of participant feedback on the overall helpfulness of the programme.

The WAP is a multicomponent programme that includes a range of concrete and verifiable tasks agreed individually with each participant (*Box 8*). Tasks varied in their ease to complete and the additional resources that they required (e.g. regular weighing required participants to have access to scales).

The WAP also includes monthly 'maintenance' sessions that aim to improve participant motivation, allowing participants to discuss the challenges they have faced since the last session, and to anticipate challenges of the month ahead. Owing to the flexible nature of the monthly sessions, participants were able to elect what they would like to discuss at the next session. For example, one group requested that they go over calorie counting and take the calorie test again. Participants were encouraged to make changes to their diet and physical activity that they could sustain, while the importance of self-monitoring

BOX 8 Tasks in the WAP arm

Pedometer use

Participants were provided with an Oregon PE980 pedometer at the first session and received a demonstration on how to use it. Participants were advised to wear the pedometer all day, every day, as they went about their usual activities and to make a note on their task card of the number of steps displayed on the pedometer at the end of every evening.

After the first 'baseline' week, WAP facilitators assigned the participant with a daily step count target, which was increased until an agreed level was reached. Opportunities to help achieve the step count target were discussed (e.g. getting off at a bus stop earlier and walking the rest of the journey).

All participants were informed of the recommendations to walk 10,000 steps per day and those who were able to achieve this were encouraged to do so.

Television/screen time use

During the first week, participants were advised to monitor their 'screen time' (i.e. the number of hours spent watching television or using the computer for leisure purposes) and to write down the amount of time spent engaged in screen-time activities on their task card each day. During the second week, participants were asked to continue monitoring and those who identified spending > 4 hours per day engaged in screen time activities were asked to reduce this by half.

BOX 8 Tasks in the WAP arm (*continued*)

Food diary use

During the first week, participants were advised to keep a food diary (paper copies provide by the study team) for at least 3 days, and write down everything that was consumed (both food and drink), without changing their usual eating habits. Participants were advised against keeping the food diary retrospectively and were instead advised to write items down as they ate. Participants were advised to tick when they had completed the task on their task card. From week 3 onwards, the task of keeping a food diary was optional.

Counted calories

At the second session, participants were introduced to 'calorie counting', taught how to read food labels and provided with a calorie booklet and directed to a range of resources, including MyFitnessPal (MyFitnessPal Inc., San Francisco, CA, USA). Participants were provided with an individual daily calorie plan (using the Harris–Benedict equation) and were asked to keep a food diary and to count calories. Participants were advised to tick when they had completed the task on their task card.

5 a day

At the third session, participants were introduced to the 5-a-day task (to consume five portions of fruits or vegetables a day) and provided with a leaflet providing examples of how to achieve this. The 5-a-day task remained a task throughout the programme. Participants were advised to tick when they had completed the task on their task card.

Exercise

At the fourth session, participants were introduced to the importance of regular physical activity and were set the task of conducting two short bouts of moderate-intensity activity (10–20 minutes in length). Participants were provided with information on opportunities for exercise in their local areas. The frequency and length of the exercise was increased gradually until participants were able to achieve at least three bouts lasting 30 minutes each, with the goal of five 30-minute bouts per week. Participants were advised to tick when they had completed the task on their task card.

No junk

At the fifth session, participants were advised to monitor their hunger and say no to junk/unnecessary eating. Participants were advised to tick when they had completed the task on their task card.

Scales

At the fifth session, the importance of regular weigh-ins was discussed and participants were advised to buy a set of scales for their home if they did not already have a set. Participants were given the task to weigh themselves at least once a week, at the same time of day. Participants were advised to tick when they had completed the task on their task card.

Removed triggers/avoiding temptations

At the seventh session, the importance of removing triggers from home and work environments was discussed. Participants were encouraged to identify opportunities to do this and given the task of removing triggers from sight on at least one occasion over the next week. Participants were also advised to replace any tempting foods on display with healthier alternatives (e.g. a fruit bowl instead of a biscuit tin). Participants were advised to tick when they had completed the task on their task card.

BOX 8 Tasks in the WAP arm (*continued*)

Food swaps/easy switches

At the seventh session, participants were asked to identify any 'food swaps' (adoption of healthier alternatives) that they had made while attending the WAP. Participants were then given a leaflet that provided further examples of food swaps and asked to think about any more swaps that could be made.

Thinking about reasons for overeating

At the third session, participants were provided with a list of common reasons why people overeat (e.g. boredom, stress) and were asked to choose the two main reasons that applied to them. A group discussion followed, allowing participants to explain their choice and provide examples of instances where overeating occurs. Participants were then asked to identify alternative behaviours (other than overeating) that could be conducted (e.g. if eating because food is there, the participant identified that food could be moved out of sight).

Buddying

Introduced at the fifth session, the task of buddying was introduced, in which participants were paired up and had the option to place small bets/pledges (of monetary value). If the pair lost 1 lb per week between them, the pair would have the option to either have their money back or roll it over to the following week. If the pair failed to lose 1 lb per week between them, they would lose their money (which would be donated to charity). Participants were also given 'buddy cards' with the contact details of their buddy and encouraged to contact their buddy at least once each week (via telephone, text or e-mail).

Hunger thoughts

At the second session, participants were asked to monitor their hunger and to ask themselves if they were hungry before they ate. If participants decided that they were not hungry, they were advised not to eat. Participants were asked to report back on their experience of this at the third session.

Food recall

At the eighth session, participants were asked to think about their last meal every time they were about to eat to see if this would influence how much they ate at their next meal.

was reasserted at each session. In instances where weight gain had occurred, participants were asked to identify the strategies that had helped to facilitate weight loss in the past and to consider adopting these again (e.g. returning to keeping a food diary and monitoring the effect of this on weight loss). The monthly sessions also allowed for discussions around learning how to deal with setbacks.

Methods

We followed the process evaluation recommendations in the *Standard Evaluation Framework for Weight Management Interventions*[91] for weight management interventions.

We collected data on the number of participants responding to the various recruitment strategies, the number invited to attend screening and the number enrolled into the study. We also summarised some of the problems we encountered during the study set-up and recruitment phases.

Participant attendance was recorded at each session.

At each session, participants were given a task card detailing their pedometer target (from session 2) and tasks for the week ahead. At the start of the following session, the task cards were collected so that we could measure adherence to each task.

At the end of the treatment (8 weeks) participants completed an anonymous feedback questionnaire that asked them to rate the helpfulness of the programme and how likely they would be to recommend it to others (both scored out of 10). Participants were also provided with a list of the various components of the WAP (e.g. keeping a food diary) and asked to rate the helpfulness of each aspect and how likely they were to continue with each aspect. Participants were also required to choose the three main aspects that they found most useful. Participants were able to rate the convenience of the programme in terms of location and timing, and suggest alternative timings if preferred. Finally, all participants were invited to offer any advice or suggestions they might have on how to improve the programme. Participants were required to complete the same questionnaires at the 6- and 12-month follow-ups.

People who dropped out of treatment were called, and if reached were asked their reasons for dropping out.

For the nurse arm, participant attendance was recorded and participants were asked to provide feedback via a questionnaire that asked them to rate the helpfulness of the programme and how likely they would be to recommend it to others. Participants were also provided with a list of the three main aspects of the nurse arm and asked to rate the helpfulness of each aspect before choosing the aspect they found the most useful. Participants were able to rate the convenience of the appointments in terms of location and timing and suggest alternative timings if preferred. Finally, all participants were invited to offer any advice or suggestions they might have on how to improve the programme. Participants were required to complete the same questionnaires at the 6- and 12-month follow-ups.

Analysis

We summarised the data on attendance and adherence to each of the tasks. Participant feedback on the helpfulness of the components of both the WAP and nurse interventions was also summarised. The mean scores of overall helpfulness of the programmes and how likely participants would be to recommend it to others were compared between arms. Descriptive feedback from participants, where available, was themed.

Results

Study set-up

Recruitment of practice nurses

It was initially decided to have just one nurse at each of the two GP sites who would provide the nurse-based intervention for all participants. The practices were agreeable to this and allocated a nurse to the task. Senior study staff trained the nurses to deliver the nurse-based intervention and carry out the study procedures (measurements, questionnaires, etc.). We did, however, encounter some minor problems that we had not anticipated, but were able to find solutions for these (*Table 35*).

Recruitment

Our primary avenue for recruitment was via GP practices. However, posters were displayed in a small range of other community venues and workplaces.

TABLE 35 Problems encountered in nurse intervention arm

Problem	Description	Solution(s)
GCP training	The study sponsor requires all research staff to be GCP trained. Although the sponsor offers GCP training, free of charge, the nurse could not attend this during normal practice hours	Nurses completed GCP training online
Demand on nurse time	Concerns were raised by both practices over the amount of nurse involvement the study required	An additional nurse was trained at one practice, so workload could be shared. Appropriate spacing of recruitment waves was necessary so that nurses were not overloaded with appointments
Nurse turnover	Two nurses left one practice during the study period	Identification and training of additional nurses

We asked GP practices to query their patient database for potentially eligible participants. Owing to data protection issues, practices had to perform all database queries and printing of letters in-house. The processing of the letters (i.e. folding, stuffing envelopes and franking) took considerable time and effort. Later, practices offered to send text messages instead to their patients who were potentially eligible for participation. This method was significantly easier and less costly, although it relies on people having an up-to-date mobile phone number. We sent out approximately 3800 letters and 6500 text messages.

The most frequently reported route into the study was via GP text and mailshots to potential participants (*Figure 9*).

Recruitment barriers and facilitators

It was originally planned to recruit approximately 30 participants per month over a 12-month period starting in October 2011. However because of delays in R&D approvals and contracting, the project plan was revised to start recruitment in July 2012, recruiting 40 participants per month over a 9-month period.

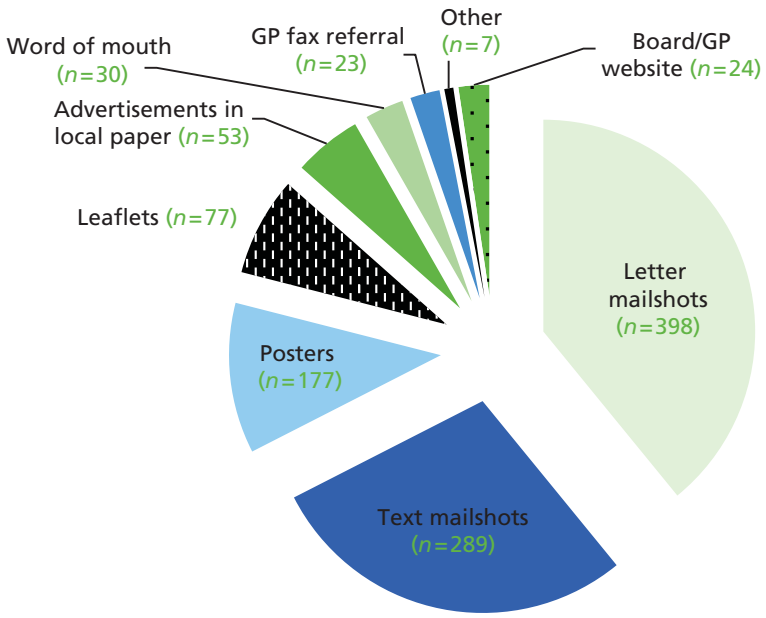

FIGURE 9 Number of volunteers contacting the study by source.

Despite this revised timetable the start of recruitment was delayed until September 2012 and was slower than anticipated (see *Chapter 3, Recruitment*).

One of the barriers to recruitment was our reliance on the GP team completing referral forms that we asked the practice to fax to us. To try to increase the profile of the study, the research team attended GP team meetings on a fortnightly basis to remind GP staff of how to refer. We had participants from our early waves who wanted to share their success with their GP practice and so attended some of these meetings. However, although staff were interested and hugely supportive, we did not see an increase in GP referrals.

Plans for improving recruitment were discussed during the Trial Management Committee and Trial Steering Committee meetings. The recruitment targets were revised in February 2013 (see *Chapter 3, Recruitment*), extending the recruitment period to January 2014, adding an additional 10 months to the recruitment period and extending the 12-month follow-up to January 2015. These changes were presented at a Health Technology Assessment monitoring meeting in July 2013 and a 6-month no-cost extension was approved to enable these changes.

The recruitment strategy was redrafted in November 2012 to include mobile phone text mailshots, advertising on websites and boards in practices, producing newsletters on study progress to staff and GP patients, and holding stalls to advertise the study to potential participants.

It was also agreed that participants could be recruited from neighbouring practices. This, however, was not straightforward. Practice managers proved difficult to get hold of and often did not return calls. The process was extremely time-consuming, requiring study staff to explain the study and answer any questions posed. In the end, 15 surgeries were contacted via telephone, letters and e-mails, nine replied expressing an interest and four participated, referring 290 participants to the study. We also needed to find a process by which participants from outside the practice could attend for their weight management appointments without mistakenly being turned away because they were not registered with the practice.

Learning points

Owing to the steadily increasing burden of research regulation, R&D delays are increasingly common and are now practically a norm. Research timetables need to include contingency time of several months for unexpected bureaucratic delays.

We had also initially overestimated our ability to recruit from primary care, despite initial assurances that the practices would be able to do this. We had based our assumptions that the most would be GP fax referrals on our work in smoking cessation as the majority of referrals to smoking cessation from GPs come in this way. However, this system has been in place for approximately 10 years.

In terms of recruitment from the additional practices, we found benefit in working with network managers (where available) rather than individual practice managers. The network managers are often in charge of a number of surgeries in their local area partnership and can co-ordinate letter/text mail-outs for these GP surgeries.

In hindsight it would have been wise to employ a broad range of recruitment strategies from the beginning, instead of a stepwise approach.

Screening sessions

Our experience in clinical practice with running smoking cessation and weight management clinics is that approximately half of people invited to attend the first session do not attend. We therefore double-booked all appointments for the first session. We did, however, have a lower did-not-attend rate (35%) than expected, which meant that some screening sessions were busy and participants were required to wait for up to 30 minutes longer than usual.

Weight Action Programme groups

Over the course of the study a total of 15 groups were run. The size of the groups ranged from 10 to 21 participants. *Table 36* shows the times and days of the week that these groups were run. A greater number of evening clinics (17.30–18.30 hours) were offered, as this tended to be when most people were able to attend. We tried running one clinic between 14.00 and 15.00 hours, but this was not repeated as it clashed with collecting children from school.

Participant attendance at treatment sessions

More than two-thirds of participants in both study arms completed at least half of all treatments sessions (*Table 37*). Session attendance generally declined over time (*Table 38* and *Figure 10*).

TABLE 36 Summary of the WAP group operating times and group size

WAP group	Day of week	Session time	Group size
Barkantine group 1	Monday	12.30–13.30	16
Barkantine group 2	Monday	17.30–18.30	18
Barkantine group 3	Tuesday	14.00–15.00	13
Barkantine group 4	Tuesday	17.30–18.30	19
Barkantine group 5	Tuesday	17.30–18.30	17
Barkantine group 6	Tuesday	17.30–18.30	21
Barkantine group 7	Tuesday	12.30–13.30	13
Barkantine group 8	Tuesday	17.30–18.30	19
Lawson group 1	Thursday	17.00–18.00	15
Lawson group 2	Wednesday	17.30–18.30	16
Lawson group 3	Wednesday	11.30–12.30	13
Lawson group 4	Wednesday	17.30–18.30	10
Lawson group 5	Wednesday	11.30–12.30	14
Lawson group 6	Wednesday	17.30–18.30	19
Lawson group 7	Wednesday	11.30–12.30	14

TABLE 37 Participant attendance at treatment sessions

	Arm	
Attendance	Nurse ($N = 109$)	WAP ($N = 221$)
Attended at least one session, *n* (%)	98 (90)	213 (96)
Attended half or more of the sessions,[a] *n* (%)	75 (69)	175 (79)
Number of sessions[a] attended per participant, median (IQR)	3 (1–4)	7 (5–8)

a Participants in the WAP were invited to attend eight group sessions. Participants in the nurse arm were invited to attend four sessions.

TABLE 38 Adherence to different tasks at the WAP treatment sessions

	Session, *n* (%)							
Attendance and task	1	2	3	4	5	6	7	8
Attendance	202 (91)	193 (87)	174 (79)	164 (74)	153 (69)	140 (63)	133 (60)	144 (65)
Completed task card	170	144	147	126	111	117	98	47
Pedometer use	146 (86)	128 (89)	132 (90)	115 (91)	103 (93)	108 (92)	84 (86)	31 (66)
Television/screen time	149 (88)	116 (81)	–	–	–	–	–	–
Food diary use	131 (77)	–	–	–	–	–	–	–
Counted calories	–	94 (65)	–	–	–	–	–	–
5 a day	–	–	88 (60)	74 (59)	69 (62)	76 (65)	62 (63)	34 (72)
Exercise	–	–	–	84 (67)	69 (62)	73 (62)	60 (61)	30 (64)
No junk	–	–	–	–	68 (61)	68 (58)	65 (66)	28 (60)
Scales	–	–	–	–	55 (50)	63 (54)	56 (57)	27 (57)
Removed triggers	–	–	–	–	–	–	6 (6)	–

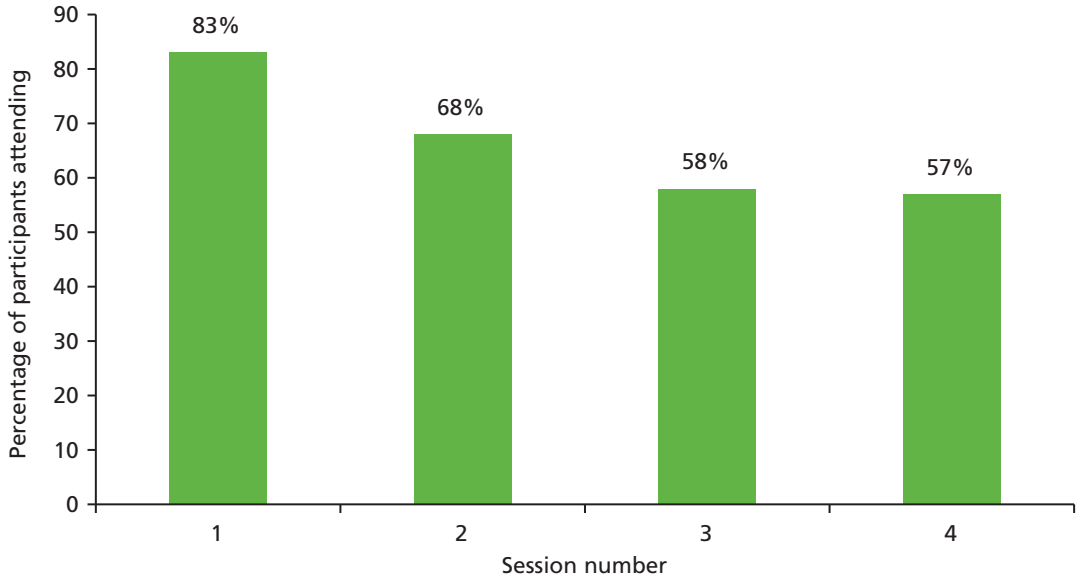

FIGURE 10 Proportion of participants in the nurse arm attending each session. Sessions 1–4: fortnightly treatment sessions over 8 weeks.

Not everyone who dropped out of the WAP provided a reason for doing so. Among those who did, inability to attend because of inconvenient times was the most common reason (*Figure 11*). Although participants were informed of the clinic times at the very first contact, it was often because life circumstances had changed (e.g. changes in work rota or child care).

Participant attendance at maintenance sessions

Attendance at each session is shown in *Figure 12*. Participation declined over time, with only around one in five participants attending maintenance sessions in the last 6 months. The maintenance sessions were held as 'open sessions', with participants at different stages of the intervention attending the same maintenance session.

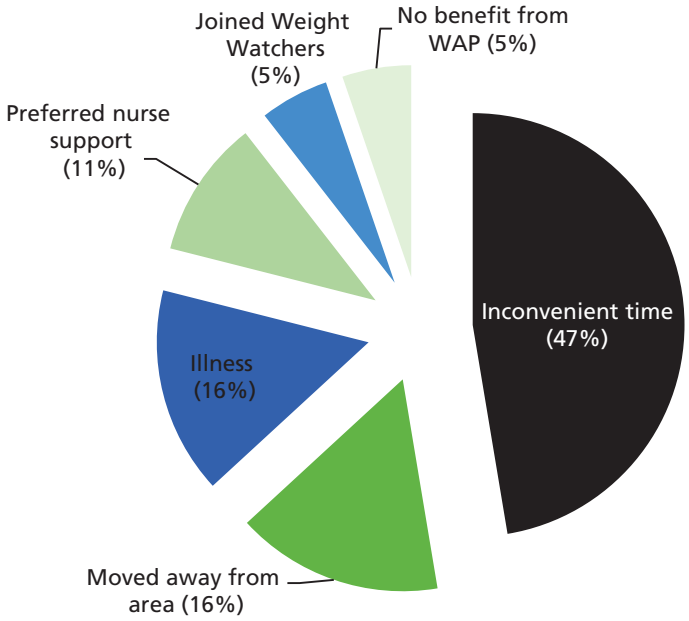

FIGURE 11 Reasons given for dropping out of the WAP treatment ($n = 19$).

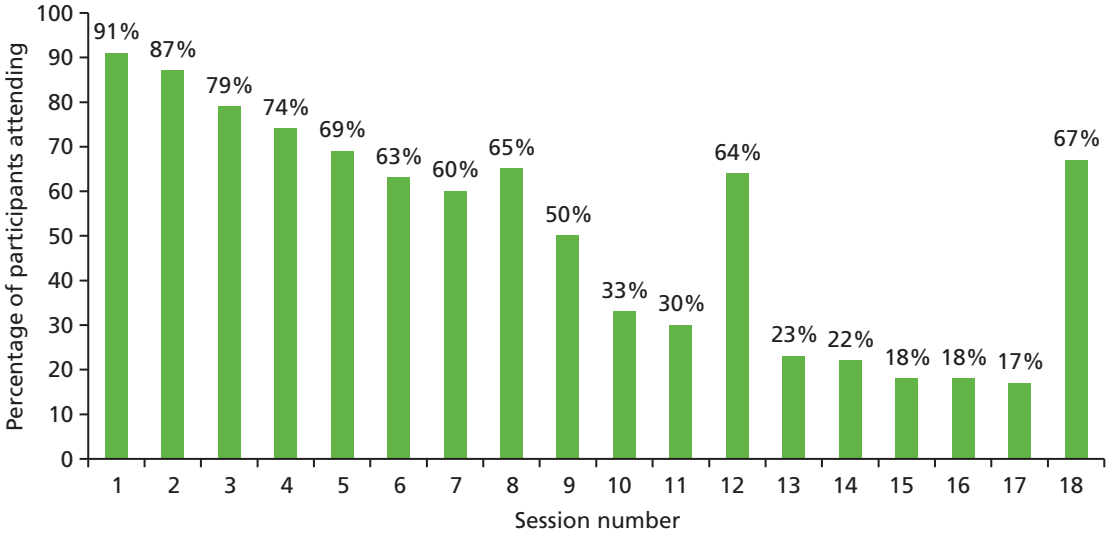

FIGURE 12 Proportion of participants in the WAP arm attending each session. Sessions 1–8: weekly treatment sessions; sessions 9–18: monthly maintenance sessions.

Follow-up rates

We implemented a number of strategies for minimising loss to follow-up (*Box 9*). Follow-up rates were higher than predicted (70% vs. 50% predicted at 12 months). There was no difference in follow-up rate by study site, but the proportion of participants followed up at 12 months was greater in the nurse arm (76%) than in the WAP arm (67%).

Participant adherence to Weight Action Programme tasks

Of all tasks, pedometer use was the most likely to be adhered to, with close to 90% of participants who handed in task cards reporting to use these devices daily. Approximately half of participants weighed themselves regularly (50–57%) and around 60% adhered to the 5-a-day task. Removal of triggers to eat was the least used tool (6%).

BOX 9 Examples of strategies used to minimise loss to follow-up

Stress the importance of attending at the end of treatment, even if participants feel that they have gained weight.

Multiple follow-up routes (telephone, GP practice, text, letter, e-mail).

Flexible appointments offered (evening/weekend/home visits). Calls made to participant at different times of the day (early mornings/late evenings).

All contact attempts documented so study team could quickly assess which route to try next.

Involving staff affiliated with the study team (i.e. not involved in the intervention) to make contact with participants to invite them to attend for follow-up so as not to put participant off if they speak to the researcher involved in leading the intervention.

Use of orlistat

During the planning stage we were alerted to the fact that people were offered orlistat as part of standard care. We therefore included information about orlistat at the third WAP session. All participants were given an information sheet about orlistat. Among those who expressed an interest in using orlistat, eligibility was checked by study staff, to prevent participants making an unnecessary visit to their GP. Those who were eligible were advised to make an appointment with their GP to obtain a prescription and bring the medication back to the session the following week, during which participants were given a recap on how to use orlistat.

All eligible participants were prescribed a 1-month course of orlistat in the first instance, with continued prescriptions contingent on weight loss, as per NICE guidelines. At subsequent sessions, participants were asked about their orlistat usage.

At total of 75 (23%) participants opted to use orlistat as part of their weight loss attempt. Participants in the WAP arm were significantly more likely to use orlistat than participants in the nurse arm (31% vs. 6%; odds ratio 6.50, 95% CI 2.78 to 15.59; $p < 0.001$). Weight loss at 12 months was greater in those who used orlistat (mean –5.4 kg, SD 8.1 kg) than in those who did not (mean –2.9 kg, SD 6.6 kg), with the difference (–2.5 kg) being statistically significant (95% CI –4.5 to –0.4 kg; $p = 0.02$).

Participant feedback

Participants in both arms provided feedback on the helpfulness of the weight loss intervention they received at the end of treatment (*Table 39*) and at the 12-month follow-up (*Table 40*). Ratings of helpfulness in losing weight were high in both arms, but significantly greater from participants who used the WAP (9.1 vs. 8.0; $p < 0.001$). The WAP participants were also more likely to recommend the programme to others (9.3 vs. 8.1; $p < 0.001$). Ratings were only slightly lower at the 12-month follow-up, but remained significantly greater in the WAP arm (see *Table 40*).

Participants also ranked their top three most useful aspects from each of the treatment programmes (nurse and WAP). Few participants ($n = 5$) in the nurse arm responded, but at the end of treatment all highly ranked advice from the nurse.

TABLE 39 Helpfulness of programme at the end of treatment

Question	Arm, mean[a] (SD)		Difference (95% CI)	*p*-value
	Nurse (*n* = 48)	WAP (*n* = 129)		
How helpful was the programme?	8.0 (2.1)	9.1 (1.4)	1.1 (0.6 to 1.6)	< 0.001
Would you recommend the programme to others?	8.1 (2.2)	9.3 (1.3)	1.2 (0.6 to 1.7)	< 0.001

a Responses are scored from 1 to 10, with higher values indicating more helpfulness or more likely to recommend.

TABLE 40 Helpfulness of programme at 12-month follow-up

Question	Arm, mean[a] (SD)		Difference (95% CI)	*p*-value
	Nurse (*n* = 48)	WAP (*n* = 129)		
How helpful was the programme?	7.2 (2.9)	8.4 (2.3)	1.3 (0.5 to 2.0)	0.001
Would you recommend the programme to others?[b]	7.8 (2.7)	8.8 (2.2)	1.0 (0.3 to 1.7)	0.004

a Responses are scored from 1 to 10, with higher values indicating more helpfulness or more likely to recommend.
b Two participants with missing responses (one in each arm).

Of the respondents in the WAP arm, the component most frequently ranked in the 'top 3' at the end of treatment was 'monitoring with a pedometer' (30%; *Figure 13*). This was followed by 'having weight regularly monitored' (14%) and 'coming to group sessions' (13%). 'Avoiding temptation', 'leaflets provided', 'exercise programmes' and 'buddy system' were not seen as particularly helpful.

In their feedback, some participants provided written comments about what they liked about the WAP. These comments were collapsed into three themes.

(1) Group-based treatment format

There are a number of advantages of running a group-based treatment programme. Participants get to learn from others' experience. This is often vicarious learning, but also includes learning of a normative experience. Groups also provide support, encouragement and motivation from others. This is type of support is often more relevant when it comes from peers going through the same experience, as opposed to a trained facilitator:

> *Group aspects were good and raised my awareness.*
>
> *It was good hearing other participants' experiences during sessions.*
>
> *I've found it helpful and although know how to lose weight; it's good to have support and encouragement.*

(2) Specific tasks

In general, participants appreciated the different tasks they were given. The pedometer/walking task was well liked. The information and tasks provided on calories and food was also noted as helpful:

> *The information on calories for food, discussions on eating times, the pedometer were all very useful tools as were the report backs when we had to measure results and discuss. The messages and info have made me more aware and altered my habits.*
>
> *The programme was very helpful, helped me with my walking and taught me to count calories.*

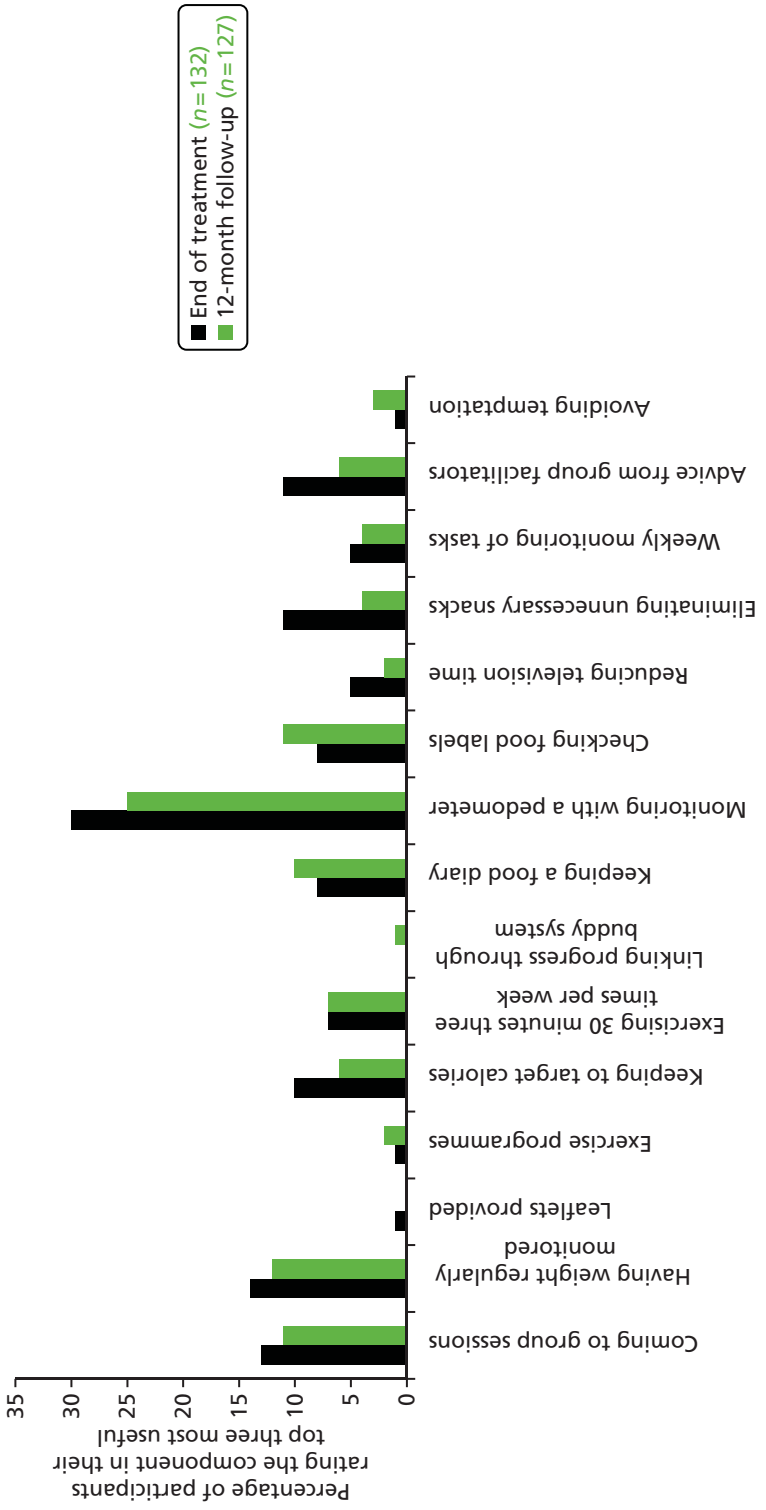

FIGURE 13 Percentage of participants rating each component of the WAP treatment in their top three most useful.

(3) General comments

The ratings of helpfulness of the programme were high, which is reflected in these general comments:

> *The programme has been very interesting and for most people, effective.*

> *Staff were lovely and helpful and I'm grateful for the opportunity of attending the programme.*

Participants were also given the opportunity to comment on how the WAP could be improved. These comments also fell into three main themes.

(1) Group-based treatment format

To some extent the success of group-based treatment relies on an element of group pressure, that is, participants are accountable to each other for meeting their targets and losing weight. Two participants commented that this element could have been strengthened in their groups:

> *In the group we are too nice to each other – we should be more encouraging and tougher on each other about keeping to targets. I would rather I was more accountable for not losing weight – maybe a tougher GP for people who need a bit more pressure.*

> *It may be different in the different groups of people, but I did feel that a lot of the people already knew the basics. Might be better to focus on areas of motivation rather than just weekly 'confessions'. Maybe more team time to make you feel closer to the group and more accountable for your results.*

One component of the WAP is to ask people to pair up (or buddy up) with others (see *Box 8*). The purpose of this task was to foster the experience of social support outside of the weekly sessions in the hope that this would encourage motivation and self-efficacy. This type of task is used in smoking cessation groups where buddies work together to remain abstinent from smoking, and generally it works well.[92,93] However, it did not rate highly with participants overall (see *Figure 13*) and was specifically mentioned by one participant:

> *It was good hearing other participants' experiences during sessions but I really didn't like/want to participate in the 'buddy' scheme.*

(2) Specific tasks

Three comments related to two specific tasks. One concerned the need for more advice on choosing healthy food:

> *Maybe more advice on food labelling and healthy food.*

In general, the advice on calories and choosing healthy options was well received. Although many people had a good general knowledge of calories and could determine which food options were more calorific than others, there was, anecdotally, some confusion over food consumption and weight loss. For example, in one of the groups a participant who did not have a particularly healthy diet lost weight by eating smaller portions of his usual foods. Some participants could not understand how weight loss was possible when he was eating 'unhealthy' foods.

The other two comments concerned exercise and the programme's instructions about how to exercise. The WAP does not give specific advice on the type of exercise to do and how this might be tailored to individual need. Instead it provides goals and general information on the types of exercise that counts as moderate intensity and options for structured exercise programmes in the local areas:

> *Health and safety issues/advice before exercising, explanation regarding vigorous vs. moderate exercise, invite local exercise group leaders to attend one session to advertise what is available.*

> *I think for me, with my disability it was difficult to engage with some of the activities recommended.*

(3) Clinic times

Although we tried to offer a range of different options for clinic times, some participants still found the groups difficult to attend:

> *I would have loved if the class was a little later, possibly 6, as I had to leave work early to attend which was not too convenient. The sessions were helpful and informative but felt a little bit too long at times. Perhaps would have been good to do the programme in the summer.*

> *I've enjoyed the programme. I would prefer if the sessions were held at 6 p.m. as allow time for me to attend straight from work.*

> *It's always difficult to find a regular time to be available between work. A longer period of sessions would have helped me only because I was away a lot.*

> *If you can do some at the weekends.*

Chapter 6 Discussion

Key results

The WAP helped people lose almost 2 kg more, on average, than the nurse-based intervention at 12 months. This difference was statistically significant and was robust across different sensitivity analyses. In the WAP arm, 41% of participants lost at least 5% of their baseline body weight, compared with 27% in the nurse arm ($p < 0.001$). At the end of treatment both arms rated the weight loss programme they received as very helpful and were likely to recommend the programme to others.

The health economic analysis showed that that the cost of the WAP is £195 per participant (or £10 per group session attended), compared with £176 per participant for best usual care. Controlling for baseline utility and age, the incremental QALY gain is 0.0104 (95% CI –0.0015 to 0.0224; $p = 0.088$). Mean incremental total cost was not significantly different from the cost of best practice nurse-led usual care at £80 (95% CI –£505 to £667; $p = 0.787$).

In the base case, the ICER is estimated at £7742 per QALY, with a probability that the WAP is the most cost-effective intervention of 68.26% when a QALY is valued at £20,000 and of 77.46% when a QALY is valued at £30,000. With respect to the explicit decision threshold stipulated by NICE, these results would suggest that the WAP is likely to represent value for money to the NHS.

Study limitations

There are several limitations of the trial worth noting. Although we exceeded our expected retention rates, we were unable to measure weight in 30% of participants at 1 year. High attrition rates in trials of weight loss are well recognised and estimated to range between 30% and 60%.[94] Missing data pose problems for weight loss and most other behaviour change trials. A traditional approach has been to use the last observation carried forward, but as people often stay in treatment while they are doing well and drop out when they put on weight, and most initially successful dieters regain at least some of their initial weight loss during the follow-up period, this approach is likely to overestimate treatment effects, and in controlled trials this generates noise that may obscure real treatment effects. We used a mixed-effects model approach that is currently the preferred approach, although it does not completely resolve the problems associated with missing data. It is reassuring that the various sensitivity analyses confirmed the main result.

We were unable to blind staff taking measurements of weight, waist circumference and blood pressure to participant allocation throughout the treatment phase, but staff collecting these measurements at the key 6- and 12-month follow-ups were blind to participant allocation.

Participants were recruited from six general practices in two London boroughs. This reduces the generalisability of the results somewhat, although there is little reason to assume that patients in other parts of London or the country would be markedly different. We also only provided treatment at two sites; in reality, not all GP practices would have the facilities to run the WAP and referring patients to neighbouring GPs would be the most likely solution.

Participants in the WAP arm had more treatment contact time than the nurse arm. This could, in theory, generate better follow-up rates via greater participant involvement and thus generate a potential bias. This fortunately did not happen: follow-up rates were slightly better in the nurse arm than in the WAP arm.

The trial attracted mostly women (72%). This is the norm in weight management research and clinical practice.[35,37–39] As obesity is no less prevalent in men than in women, there is a need to explore factors that would make such programmes more attractive to men.

Obesity management guidelines typically consider 5% weight loss to be clinically meaningful, and behavioural intervention can help a proportion of clients to achieve this. However, there is an increasing acceptance among weight management experts that a weight loss target of 5% is no longer sufficient for many of the patients being treated in primary care. Currently, the only proven life-transforming treatment for patients with severe obesity is bariatric surgery. Lifestyle modification programmes of the type we evaluated, however, can improve weight, health and fitness in people who have not reached morbid obesity levels. Such programmes may also stop further weight gain in people who would reach morbid obesity in future, though evidence for this is lacking to date.

One of the strengths of the trial was its inclusiveness. There were few exclusion criteria. Many weight management studies recruit primarily middle-class clients, which limits generalisability to clinical populations. Our trial enrolled participants from a diverse range of ethnic and socioeconomic backgrounds. Only 62% had completed a high school education, compared with > 90% reported in similar trials,[38,39] and participants were also less likely to be employed (48%) than those in other studies.[38,39]

Interpreting study findings

When interpreting the main finding, it is important to note that the positive result was not an artefact of the control group doing poorly. The nurse intervention did better than expected,[27] so the benefit seen with the WAP was not the result of having an inferior comparator.

Participants in the WAP group had a greater reduction in waist circumference at the 6- and 12-month follow-ups, although the difference did not reach statistical significance at 12 months. At the end of treatment, participants in the nurse arm had a significantly greater reduction in waist circumference, but achieved less weight loss. These contradictory findings may have been related to errors in measurement of waist circumference, which are a well-recognised problem,[95,96] and related to site of measurement, time since last meal and phase of respiration.[97] Nurses were trained to measure waist circumference at the end of treatment, but at baseline and other follow-up points the study team measured this. Similar to other studies,[37,38] we did not find any significant change in blood pressure. In a meta-analysis of data from 34 trials, systolic blood pressure did not change with weight loss in 18 trials and diastolic blood pressure did not change with weight loss in 21 trials.[98]

A greater proportion of participants in the WAP arm than in the nurse arm reported AEs, although this difference was not statistically significant. This may have been a consequence of the fact that participants in the WAP arm were asked about AEs more frequently, and so there is potential for recall bias.

The WAP relies primarily on the group format, focusing on encouraging attendance and adherence to programme tasks. There remains the question, however, of the different effects of different tasks. The study was not set up to allow dismantling of the WAP effects and determining which parts of the programme were responsible for its effect. However, the WAP does not rely on any one specific task or advice. The key innovative element of the WAP is that it encourages participants to try a range of strategies, insisting that each new behaviour is not just considered but practically implemented for at least 1 week. After that participants can decide whether or not to carry on with it. Unlike most other approaches that insist on adherence to some core recommendation, the expectation here is that none of the tasks will be adopted by 100% of the participants, but that there is a sufficient variety to allow as many participants as possible to find and adopt one or more strategies that work for them. Seeing other group members adopting such strategies and benefiting from them may increase willingness to try and

maintain such new behaviours as well. The use of pedometers appeared to be a task that was liked by the majority of participants.

Orlistat use provides another good illustration of the group effect. Participants in the WAP arm were more likely to use orlistat and orlistat use contributed to weight loss. Most clients react to the offer of orlistat with uncertainty, mostly related to the drug's unpleasant side effects. The group format seems to have provided additional encouragement and reassurance via social learning. In most groups there would be one or two people who had benefited from orlistat in the past, or are benefiting from it during treatment, and report this at the WAP sessions, which encourages others to consider using the medication.

Interpretation in relation to other studies

The WAP group programme surpassed the effects of nurse intervention and enabled > 40% of participants to lose ≥ 5% of their body weight and maintain this over 1 year. This tallies with previous findings showing the popularity and efficacy of group programmes for weight loss.[35,38]

The WAP differed from the nurse intervention in two procedural variables: contact frequency and group format. Some studies suggest that more frequent contact promotes better weight loss,[35,36,99,100] but a recent meta-analysis found no evidence of this.[101] The advantages of group support are the more likely explanation of our finding, but both elements may have contributed.

The finding generates the obvious question of whether or not, and how, such a treatment could be disseminated on a larger scale.

The reason for relying on practice nurses to help primary care patients lose weight is largely pragmatic. Most people see their GP at least once per year and obese patients often present with obesity-related problems. GPs are thus uniquely placed to trigger weight loss attempts. However, apart from offering a prescription for orlistat (which without further support is likely to have only limited effects) GPs do not have the tools, training or time to engage in weight management treatments. A referral to a practice nurse is the obvious solution. Our earlier survey showed that practice nurses would mostly provide one-off advice, sometimes suggesting to patients to arrange proactively further sessions if they want to. This is likely to generate less weight loss than the relatively intensive and well-structured intervention used in our trial and it may not be the best use of the precious primary care time.

There is a close parallel with how stop-smoking interventions used to be delivered prior to the establishment of the NHS Stop Smoking Service (SSS) in 1999. GPs were prescribing nicotine replacement treatments and referring smokers to practice nurses for behavioural support. This was time-consuming and therefore expensive, and had limited efficacy. The idea behind the SSS was to take this burden and expense away from primary care. GPs were expected to simply refer smokers to trained full-time advisors who provide a more effective, intensive multisession treatment.

In theory, the WAP could help to translate some of the most useful features of the SSS into the new tier 2 and tier 3 weight management services that are currently being set up across the country.

The initial model of stop-smoking services assumed that smokers would be treated in groups, as this is by far the most cost-efficient approach, and there is growing evidence that it is also more effective.[49,102,103] In practice, however, recruitment of smokers into the service proved difficult, and only a few services have large enough throughput to be able to run groups. This is not an issue in weight management where the interest in treatment is much greater and group approaches are much more widespread.

Another important feature of the SSS was that the service included compulsory objective and standard monitoring of its throughput and outcome. This generated data essential for service evaluation and

improvements, and for establishing service standards. The services also had access to standard training and were mandated to provide evidence-based treatments.

Weight management services have followed a different trajectory. Primary care remains the key source of weight management advice. In addition to this, public health services, which are now placed with local councils rather than the NHS, are now responsible for commissioning tier 2 and tier 3 weight management services. These should be based on evidence, but unlike the SSS there has been a relative lack of clear guidance. Commercial providers are being commissioned with no request to provide evidence of their outcomes and no mandated monitoring of weight loss achieved. It is likely that much of the investment will generate limited benefits, if any.

To be successful, any healthy lifestyle programme must be able to be integrated into existing GP practice systems and convenient to patients.[104] We found that practices were very willing to refer patients, but in practice few were referred. This, in part, may have initially been because of the referral mechanism we asked them to use that was outside their normal systems. Other factors that may have contributed to low referral are lack of time, limited understanding about weight management and fear of damaging the relationship with the patient by raising a potentially sensitive topic.[105] This finding is supported by a recent study.[106] Of the 91,413 overweight and obese patient records analysed, 90% had no weight management intervention recorded, and 59% of patients with morbid obesity had no intervention recorded.

Sending letters or text messages to patients who met inclusion criteria generated a lot of interest, with little effort from busy practice staff. The WAP groups were run in meeting rooms within the practice at times when these were available. Running this outside of usual practice hours (e.g. 17.30–18.30 hours) ensured that space was more likely to be available and was more convenient for participants. Running WAP clinics within GP practices was also convenient for participants.

Cost-effectiveness

Obesity-related illness costs the NHS about £7B annually through the increased likelihood of mortality and morbidity. The economic analysis in this report finds the WAP group intervention to be the cost-effective option with respect to best routine care. The cost of providing the WAP is similar to nurse-led routine care, however, the group format allows for a longer-term treatment phase with sustained maintenance. Undoubtedly, the structured approach to long-term weight management is associated with the observed improvement in health-related quality of life. On aggregate, the results of cost-effectiveness analysis fall below explicit reimbursement thresholds (£7742 per QALY), suggesting that the WAP represents good value for money.

A programme like the WAP seems suitable for adoption in such services for several reasons. There is evidence of its efficacy: it is based on an inclusive pragmatic trial; its group format with 15–20 participants per group means that it is much more cost-efficient than approaches requiring individual contact; it is based on multiple strategies to allow participants to identify those suitable for their individual needs, which means that it can incorporate and roll out new methods, techniques and medications as they are discovered; it includes standard monitoring of objective outcomes that could be collated across services; and it is easy to teach and disseminate.

Given that a commitment was already made to fund tier 2 and 3 services for people seeking help with weight management at each individual borough in the country, there now exist structures and funding that could incorporate the WAP on a large scale. In theory, Public Health England and NICE could consider how best to encourage these services to consider the results of this trial before this large investment settles with the current mixture of programmes with dubious rationale and efficacy, and with no standard outcome checks.

Further research

Although we report on 12-month data, which give a sound indication of the effectiveness of weight loss programmes, ongoing follow-up of this study cohort would enable investigation of whether or not the WAP is able to support weight loss in the long term.

The WAP treatment programme is delivered over 8 weeks, with ongoing maintenance sessions. NICE guidelines[51] recommend that weight management programmes should be 12 weeks in length. With demands on staff and patient time in addition to financial restraints, research is needed on the added benefit, if any, of longer programmes.

Overall, individual-level non-surgical interventions for obesity tend not to be highly effective, and more research on obesity prevention through community-level interventions may be required.

Like other studies in this field, a minority of participants were men. Given slightly higher rates of obesity in men compared with women, research is needed into factors that would make weight loss programmes more attractive to men.

Further research may explore incentive structures based on providers ensuring patient adherence to the WAP over the course of treatment and within a continuous maintenance phase.

Finally, the efficacy of the WAP delivered through electronic media should be investigated. Some of the components of the WAP have already been modified for delivery via mobile text messages and websites,[107] and tested in a feasibility study.[108] Further work is needed on how the group-based aspect of treatment can be utilised, perhaps using existing social media applications [e.g. Facebook (Facebook, Inc., Menlo Park, CA, USA; www.facebook.com) and Twitter (Twitter, Inc., San Francisco, CA, USA; www.twitter.com)].

Chapter 7 Conclusions

The group-based WAP intervention delivered in a general practice setting was more effective at helping obese patients lose weight at 1 year than weight loss advice delivered by a practice nurse.

The WAP intervention was also more cost-effective than nurse-based treatment, although both would be deemed highly cost-effective based on the current NICE recommendations. However, as the WAP is delivered in a group format, it is a more cost-efficient way of treating patients.

The WAP can be relatively easily implemented within primary care. It can be delivered by auxiliary staff, such as health trainers, with just 2 days of training and with relatively little specialist or costly equipment.

Future research should focus on longer-term follow-up, how to make weight management programmes more attractive to men and explore whether or not the programme, or parts of the programme, could be delivered via electronic media. Further work should confirm its effectiveness when implemented outside the setting of a RCT. As with most weight management studies, further attention needs to be given to increasing retention rates.

Acknowledgements

We would like to acknowledge the following groups and individuals:

Our Trial Steering Committee members, in particular the chairperson Dr Vicky Hobart and our lay member Julie Griffiths.

All the people who participated in the study.

Our National Institute for Health Research project managers, Alexa Cross and Hazel Church.

Staff at the Barkantine Practice, including Mostafa Farook (practice manager), Shahzad Firoz (assistant practice manager) and Dr Stuart Bingham (lead GP).

Staff at the Lawson Practice, including Lauren Stephenson (practice manager) and Dr Deborah Colvin (lead GP).

Staff at the North Central London Research Consortium who were involved in awarding NHS support costs.

Dr Dunja Przulj, Miss Celine Homsey, Miss Elizabeth Rock, Miss Anna Phillips, Miss Rebecca Anderson, Miss Kirsten McAlpine, Mr Ronnie Troughton, Miss Danielle Cornwall, Miss Dawn Lindsay and Miss Lizzie Carter-Fox from the Health and Lifestyle Research Unit, Queen Mary University of London, who collected data at follow-up points and contributed to data entry.

Mike Waring, data manager from the PCTU, who was responsible for the set-up and monitoring of the database.

Professor Cliona Ni Mhurchu, National Institute for Health Innovation, University of Auckland, New Zealand, who provided feedback on the initial grant application and project plan.

We are grateful to the four practice nurses who provided the intervention in the nurse arm. They are Alexandra Truelove, Maria Marco, Abbie McFarlane and Barbara Curran.

Contributions of authors

Dr Hayden McRobbie (Professor of Public Health Interventions) co-wrote the original grant application, co-developed the intervention, co-designed the trial, co-wrote the statistical analysis plan, trained staff, interpreted the findings and led the drafting of this report. He was the chief investigator of the trial and was a grant holder on this project.

Professor Peter Hajek (Professor of Clinical Psychology) co-wrote the grant application, co-developed the intervention, co-designed the trial, trained staff, helped interpret the study findings and contributed to the drafting of this report. He was a grant holder on this project.

Miss Sarrah Peerbux (Research Health Psychologist) co-ordinated the study between October 2013 and February 2015, delivered the intervention, contributed to data collection, co-wrote the statistical analysis plan, helped interpret the study findings and contributed to the drafting of this report.

Dr Brennan C Kahan (Lecturer in Medical Statistics) co-wrote the statistical analysis plan, undertook the statistical analyses and contributed to writing this report.

Professor Sandra Eldridge (Professor of Biostatistics) contributed to the original grant application, advised on statistical methods and analyses, advised on study governance and management and contributed to writing this report. She was a grant holder on this project.

Dr Dominic Trépel (Senior Lecturer in Health Economics) conducted the health economic analysis in the report and wrote *Chapter 4*.

Dr Steve Parrott (Reader in Health Economics) contributed to the initial research proposal, the health economics analysis plan, and supervised and contributed to the writing of the health economic analysis.

Professor Chris Griffiths (Professor of Primary Care) contributed to the original grant application, advised on standard weight management practice in primary care, advised on engagement with general practice and contributed to writing this report. He was a grant holder on this project.

Sarah Snuggs (Research Health Psychologist) was involved in the study set-up, recruitment and delivering the WAP treatment. She also contributed to writing this report.

Dr Katie Myers Smith (Research Fellow) co-wrote the original grant application, co-developed the intervention, co-designed the trial, trained staff, interpreted the findings and led the drafting of this report. She co-ordinated the study between September 2012 and October 2013, led the approvals process and governance aspects, delivered the intervention, contributed to data collection and helped to interpret the study findings. She was a grant holder on this project.

Data sharing statement

Data can be obtained from the corresponding author.

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Appendix 1 Use of health services questionnaire

Date:

Use of health and social-service questionnaire
We would like to know whether you have had any contacts with the social services listed below, and, if so, the number of times you have had contacts with them in the last 6 months. Please put the number of times in the appropriate boxes. Please put '0' if you had no contact.

Type of service	**Number of times** *If '0' move down the table to the next question*	**Time spent at the service**
General practice and community nursing services		
Number of times you saw a GP at the surgery		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO
Number of times you saw a GP at your home		How many hours did you normally spend with each visit? ……hours
Number of times you spoke to a GP on the telephone		How many hours did you normally spend with each call? ……hours
Number of times you saw a practice nurse at the surgery		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO
Number of times you saw a district nurse at your home		How many hours did you normally spend with each visit? ……hours
Number of times you saw a counsellor at the surgery		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO

Number of contacts with <u>anyone else from the practice</u> **Who did you see?** **.....**		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO
Social Services		
Number of times you <u>saw a social worker</u> **Where did you see the social worker?** **.....**		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO
Number of times you <u>saw a home help</u>		How many hours did you normally spend with each visit? ……hours
Number of times you <u>saw a care assistant</u>		How many hours did you normally spend with each visit? ……hours
Number of times you <u>visited a Day Centre</u>		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO
Number of contacts with <u>anyone else from Social Services</u> **Who did you see?** **.....**		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO

Psychiatric Hospital and Community Services		
Number of times you <u>saw a psychiatrist at the hospital clinic</u>		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO
Number of times you <u>saw a psychiatrist at your home</u>		How many hours did you normally spend with each visit? ……hours
Number of times you <u>saw a psychologist</u>		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO
Number of times you <u>saw a community psychiatric nurse</u>		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO
Number of contacts with <u>anyone else from the psychiatric services</u> Who did you see? ……		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO
Other Services		
Number of times you <u>attended a Day Hospital</u>		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO
Number of times you <u>went to the Accident and Emergency Department</u>		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work

		to accompany you? (please circle) YES NO
Number of times you went to a hospital clinic		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO
Number of nights you spent on a hospital ward		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO
Number of contacts with anyone else from the hospital **Who did you see?** **.....**		How many hours did you normally spend with each visit? ……hours Did you have to take time off work? (please circle) YES NO Did someone else have to take time off work to accompany you? (please circle) YES NO
Number of times you contacted NHS Direct		How many hours did you normally spend with each call? ……hours
Number of times you called for an Ambulance or paramedic		
Number of prescriptions you have received from a doctor in the last 6 months		

Appendix 2 Questionnaire scoring

Food Knowledge Assessment score

The Food Knowledge Assessment score is scored on an 11-point scale (range 0–10), with higher scores indicating more knowledge. It contains 10 questions and each question is scored either 0 or 1. The overall score is calculated by summing the scores of the individual questions.

The scores for the individual questions are shown in *Table 41*. Each question has four possible answers (a, b, c or d); the table indicates which of the four answers results in a score of 1 (all other answers result in a score of 0).

Food Craving Inventory score

Each of the five food types (fatty foods, carbohydrates and starches, sweet foods, savoury snacks and fruit) is assigned a score from 0 to 5 on both frequency and urge of craving. The frequency domain is then calculated by summing the scores of the individual questions related to frequency; the strength domain is calculated in a similar manner. The overall scores from both domains range from 0 to 25, with higher scores indicating more frequent or stronger urges.

International Physical Activity Questionnaire

Metabolic-equivalent minutes/week domain

This score represents the total MET-minutes/week, and is expressed on a continuous scale with a minimum score of 0. It is calculated as:

$$\begin{aligned}\text{MET} - \text{minutes/week} = {} & 3.3 \times (\text{walking intensity minutes}) \times (\text{walking intensity days}) + 4.0 \\ & \times (\text{moderate intensity minutes}) \times (\text{moderate intensity days}) + 8.0 \\ & \times (\text{vigorous intensity minutes}) \times (\text{vigorous intensity days}).\end{aligned} \quad (4)$$

TABLE 41 Food Knowledge Assessment scores

Question	Score = 1, if answer is:
1	A
2	A
3	C
4	B
5	D
6	B
7	C
8	B
9	B
10	A

Sitting domain

This score represents the number of minutes per day spent sitting. It is calculated directly from question 4.

Three-Factor Eating Questionnaire

The Three-Factor Eating Questionnaire contains 18 questions, each of which is scored from 1 to 4, with higher values indicating a higher level of the behaviour. Domain scores (cognitive restraint, uncontrolled eating and emotional eating) are calculated as the mean of all the questions within a domain.

Table 42 indicates which questions are included in which domain.

Table 43 indicates how each question is scored.

TABLE 42 Three-Factor Eating Questionnaire domains

Domain	Questions included in domain
Cognitive restraint	2, 11, 12, 15, 16, 18
Uncontrolled eating	1, 4, 5, 7–9, 13, 14, 17
Emotional eating	3, 6, 10

TABLE 43 Three-Factor Eating Questionnaire scores

Question	Scoring system
1–13	Definitely true = 4
	Mostly true = 3
	Mostly false = 2
	Definitely false = 1
14	Almost always = 4
	Often between meals = 3
	Sometimes between meals = 2
	Only at meal times = 1
15	Almost always = 4
	Usually = 3
	Seldom = 2
	Almost never = 1
16	Very likely = 4
	Moderately likely = 3
	Slightly likely = 2
	Unlikely = 1

TABLE 43 Three-Factor Eating Questionnaire scores (*continued*)

Question	Scoring system
17	At least once a week likely = 4
	Sometimes likely = 3
	Rarely likely = 2
	Never = 1
18	Answer 7–8 = 4
	Answer 5–6 = 3
	Answer 3–4 = 2
	Answer 1–2 = 1

Appendix 3 Participant feedback questionnaire

WAP Group

WEIGHT ACTION PROGRAMME: FEEDBACK QUESTIONNAIRE

On a scale of 1 to 10, where 1 is the lowest and 10 is the highest rating:

- How would you rate the help the program provided?

(1 = not helpful, 10 very helpful)

☐

- How likely would you be to recommend the program to others?

(1 = very unlikely, 10 = very likely)

☐

- Please indicate how helpful you found each aspect of the programme and how likely you are to carry on with it. Please circle one answer in each box

	How helpful did you find this?	How likely are you to carry on with it?
Avoiding temptations (removing snacks from sight, less time in kitchen, etc.)	Not at all	Not at all
	Somewhat	Somewhat
	Very much	Very much
Coming to group sessions every week	Not at all	
	Somewhat	
	Very much	
Having my weight regularly monitored	Not at all	Not at all
	Somewhat	Somewhat
	Very much	Very much
The leaflets I was provided with	Not at all	
	Somewhat	
	Very much	
The exercise programme/s I was referred to	Not at all	
	Somewhat	
	Very much	
	n/a	
Keeping to my target calories	Not at all	Not at all
	Somewhat	Somewhat
	Very much	Very much
Exercising for at least 30 min at least 3 times a week	Not at all	Not at all
	Somewhat	Somewhat
	Very much	Very much
Linking my progress with other people through the group and buddy system	Not at all	Not at all
	Somewhat	Somewhat
	Very much	Very much

Keeping a food diary	Not at all	Not at all
	Somewhat	Somewhat
	Very much	Very much
Monitoring how much I walk with a pedometer	Not at all	Not at all
	Somewhat	Somewhat
	Very much	Very much
Checking food labels	Not at all	Not at all
	Somewhat	Somewhat
	Very much	Very much
Reducing time spent watching TV	Not at all	Not at all
	Somewhat	Somewhat
	Very much	Very much
Eliminating unnecessary snacks	Not at all	Not at all
	Somewhat	Somewhat
	Very much	Very much
Weekly monitoring of my task card	Not at all	Not at all
	Somewhat	Somewhat
	Very much	Very much
Advice from group facilitators	Not at all	Not at all
	Somewhat	Somewhat
	Very much	Very much

- Please circle three things in the table above that you found most useful.

Compared to how you were before you joined the programme,

- Are you now eating more healthily?

Yes No N/A – have always eaten healthily

- Are you more active?

Yes No N/A – have always been active

- Do you have a better understanding of calories and weight?

Yes No N/A – have always known about these

- Do you check the labels on food more often?

Yes No N/A – have always checked labels

- Are you eating more regularly and snacking less?

Yes No N/A – have always eaten regular meals

Regarding the clinic

- How convenient was the location of the clinic for you? (circle one)

Not convenient Reasonably convenient Very convenient

- How convenient were the clinic times for you?

Not at all convenient Reasonably convenient Very convenient

- If they were not convenient, what time slots would be better for you? *(circle one)*

Morning (9-11am)	Midday (11.30am-1.30pm)	Afternoon (2pm-4.30pm)	Evening (4.30pm-6pm)

Please write in the box below any advice or suggestions on how to improve the programme

Nurse Group

WEIGHT ACTION PROGRAMME: FEEDBACK QUESTIONNAIRE

On a scale of 1 to 10, where 1 is the lowest and 10 is the highest rating:

- How would you rate the help the program provided?
  (1 = not helpful, 10 very helpful)

  ☐
- How likely would you be to recommend the program to others?
  (1 = very unlikely, 10 = very likely)

  ☐
- Please indicate how helpful you found each aspect of the programme and how likely you are to carry on with it. Please circle one answer in each box

	How helpful did you find this?
The leaflets I was provided with	Not at all Somewhat Very much
The exercise programme/s I was referred to	Not at all Somewhat Very much n/a
Advice from the nurse	Not at all Somewhat Very much

- Please circle the thing in the above table that you found most useful.

Compared to how you were before you joined the programme,

- Are you now eating more healthily?
  Yes No N/A – have always eaten healthily
- Are you more active?
  Yes No N/A – have always been active
- Do you have a better understanding of calories and weight?
  Yes No N/A – have always known about these
- Do you check the labels on food more often?
  Yes No N/A – have always checked labels
- Are you eating more regularly and snacking less?
  Yes No N/A – have always eaten regular meals

Please write below any advice or suggestions on how to improve the programme

_____
_____
_____
_____
_____

1. How convenient was the location of the clinic for you? (circle one)

Not convenient Reasonably convenient Very convenient

2a) How convenient were the clinic times for you?

Not at all convenient Reasonably convenient Very convenient

2b) If they were not convenient, what time slots would be better for you? *(circle one)*

Morning (9-11am)	Midday (11.30am-1.30pm)	Afternoon (2pm-4.30pm)	Evening (4.30pm-6pm)

Appendix 4 Statistical analysis plan

A peer-support weight action programme to supplement brief advice in general practice (SWAP)

Statistical Analysis Plan

Version: 2.0
Date: 14th April, 2015

Person(s) contributing to the analysis plan	
Name(s) and position(s)	Hayden McRobbie (Chief Investigator) Brennan Kahan (Statistician) Sarrah Peerbux (Research Health Psychologist) Sandra Eldridge (Statistician)
Authorisation	
Position	**Chief or principal investigator**
Name	**Hayden McRobbie**
Signature	
Date	
Position	**Senior trial statistician**
Name	**Brennan Kahan**
Signature	
Date	
Position	**Independent statistician**
Name	**Richard Hooper**
Tick once reviewed	
Date	

1. INTRODUCTION

Purpose of statistical analysis plan

The purpose of this document is to provide details of the statistical analyses and presentation of results to be reported within the principal paper(s) of the SWAP trial. Subsequent papers of a more exploratory nature (including those involving baseline data only) will not be bound by this strategy but will be expected to follow the broad principles laid down in it. Any exploratory, post hoc or unplanned analyses will be clearly identified in the respective study analysis report.

The structure and content of this document provides sufficient detail to meet the requirements identified by the International Conference on Harmonisation (ICH) and the PCTU SOP (PCTU/07).

Members of the writing committee

Brennan Kahan and Hayden McRobbie were primarily responsible for writing the Statistical Analysis Plan, with input from other members of the Trial Management Group.

This document has been finalised before any members of the Trial Management Group had access to the trial data, or were unblinded to trial results.

Summary

The SWAP trial aims to determine whether a group-based weight management programme (Weight Action Programme; WAP) targeting underprivileged groups is superior to 'best practice' weight management that is provided in primary care by practice nurses.

Background to the Weight Action Programme

Weight Action Programme (WAP) is a multi-modal health behaviour modification intervention developed at the Wolfson Institute of Preventive Medicine via extensive client feedback and piloting with underprivileged groups since 2002. The programme is a multi-component service that aims to provide participants with tools to lose weight and maintain a long-term healthy lifestyle. The contents include the standard elements of cognitive behavioural interventions, dietary advice, self-monitoring, information on healthy cooking and eating and caloric content of food, cue management, provision of opportunities for exercise and close monitoring of exercise levels, and a range of concrete and verifiable tasks agreed individually with each participant. Participants are asked to wear a pedometer in order to record daily number of steps at baseline. Throughout the course, individual pedometer step targets are gradually increased until an optimal sustainable level is reached. An innovative

feature of the programme consists of the use of group-oriented interventions aiming to increase participant retention, involvement and adherence to weekly tasks. This also makes the programme more cost-effective. The focus of the WAP course is to help participants to maintain a healthy lifestyle after the programme finishes.

The programme has been developed to cater specifically for underprivileged groups including ethnic minorities. Where information is imparted, it is mostly in pictorial and easily understandable format.

WAP has been evaluated in two pilot studies of 162 overweight adults (mean BMI of 35 kg/m2) from multi-ethnic areas of high deprivation.[61] The average weight loss was 2.8kg at end of treatment and 4.5kg at 3-month follow-up (with 24% participants attending follow-up losing 5% or more of their body weight). Limited promotion via GP practices and local adverts generated a large volume of interest. The client retention was at least as good as in comparable programs conducted in research settings with more traditional clients (59% completed the 6-week treatment) and the program received very high approval ratings. Clients also demonstrated significant improvements in knowledge of healthy eating, and in their exercise levels as measured by pedometer monitoring. Clients considered the group support essential in helping them to stick to their tasks and to lose weight.[61] WAP also includes information on orlistat.

We recruited from and conducted the interventions in two GP practices, one in the London borough of Hackney and the other in Tower Hamlets. Both boroughs have a high level of deprivation.

Changes from planned analysis in the protocol

In the original trial protocol we specified we would use a baseline-observation-carried-forward approach (BOCF) for dealing with patients with missing weight data during follow-up. This approach assumes that all those who were lost to follow-up returned to their exact baseline weight. Whilst this approach has been commonly used in other randomised controlled trials, it is problematic because it will provide biased estimates of the treatment effect when this assumption is incorrect (i.e. when participants do not return to their exact baseline weight when they fail to show up to their 6 or 12 month appointment). In addition, BOCF will often lead to an inflated type I error (false-positive) rate as it tends to underestimate the standard error for the treatment effect (due to ignoring the within-patient variability in weight when imputing using BOCF).

We have therefore decided to use a mixed-effects linear regression model for the primary analysis. This analysis method provides unbiased estimates of treatment effect and correct type I error rates provided the data is missing-at-random (MAR);

that is, that the probability that a participant is lost to follow-up depends on either their previous weight measurements (e.g. their weight at baseline and 6 months if they are lost-to-follow-up at 12 months), and baseline patient characteristics (See section 5 for variables we are adjusting for). [72]

This strategy of analysis has been widely recommended in the presence of missing outcome data. We made the decision to change analysis methods before we had any access to the trial data, or ongoing trial results, and therefore there is no risk of bias associated with this decision.

Changes from SAP version 1.0

Version 2.0 of the SAP specifies that all linear mixed-effects models will employ the Kenward-Roger degree-of-freedom correction. This decision was undertaken prior to any member of the trial team having access to unblinded data, or ongoing trial results.

2. STUDY OBJECTIVES AND ENDPOINTS

Study objectives

Primary objectives

To determine if WAP can generate a better sustained weight loss over 12 months in overweight adults than best-practice intervention that is routinely provided by nurses in general practice.

Secondary objectives

a) To determine the cost-effectiveness (in terms of costs of interventions and QALYs derived from the EQ-5D) of the two interventions

Outcome measures

Primary outcomes

The primary outcome measure is the change in weight (in kg) at 12 months post-randomisation.

Secondary outcomes

- Change in weight (in kg) at 1, 2, and 6 months post-randomisation.
- Change in BMI at 1, 2, 6 and 12 months post-randomisation. BMI is calculated as weight (in kg) divided by the square of height (in metres). The height measured at screening will be used for each follow-up assessment.
- Change in waist circumference (in cm) at 2, 6 and 12 months post-randomisation.
- Change in systolic blood pressure (mmHg) at 2, 6 and 12 months post-randomisation.
- Change in diastolic blood pressure (mmHg) at 2, 6 and 12 months post-randomisation.
- Change in the Food Craving Inventory score (Frequency domain) at 1, 2, 6, and 12 months post-randomisation.
- Change in the Food Craving Inventory score (Strength domain) at 1, 2, 6, and 12 months post-randomisation.
- Change in Food Knowledge Assessment Questionnaire score at 2, 6, and 12 months post-randomisation.
- Change in the Three Factor Eating Questionnaire score (Cognitive Restraint domain) at 2, 6, and 12 months post-randomisation.
- Change in the Three Factor Eating Questionnaire score (Uncontrolled Eating domain) at 2, 6, and 12 months post-randomisation.
- Change in the Three Factor Eating Questionnaire score (Emotional Eating domain) at 2, 6, and 12 months post-randomisation.
- Change in the International Physical Activity Questionnaire (IPAQ) score (MET-minutes/week domain) at 2, 6, and 12 months post-randomisation.
- Change in the International Physical Activity Questionnaire (IPAQ) score (Sitting domain) at 2, 6, and 12 months post-randomisation.

- Proportion of participants losing 5% of body weight at 2, 6, and 12 months post-randomisation.
- Proportion of participants losing 10% of body weight at 2, 6, and 12 months post-randomisation.

Scoring details for the Food Craving Inventory, the Food Knowledge Assessment Questionnaire, the Three Factor Eating Questionnaire, and the International Physical Activity Questionnaire are available in Appendix 2.

Weight, BMI, waist and blood pressure outcomes were measured by researchers who were blind to treatment arm. These researchers were affiliated with the trial team, but were involved only in collecting outcomes during follow-up, and had no role in providing the intervention, and no contact with patients other than whilst collecting follow-up measurements.

3. STUDY METHODS

Overall study design and plan

Target for randomisation:	220 intervention and 110 control participants
Date of first randomisation:	27/09/2012
Date of last randomisation:	30/01/2014
Trial design:	Individually randomised, parallel group
Who is blinded:	Researchers affiliated with the study team conducting measurements at 6 and 12-month follow-up. Patients and those delivering the intervention are aware of the patient's treatment allocation.
Randomised Interventions:	Intervention (WAP) vs. control (Nurse counselling)
Allocation ratio:	2:1

Selection of study population

The study population was selected from people responding to letters and text messages sent from their GP surgery, posters in surgery waiting areas, direct referrals from GP staff and advertisements in local papers.

Participants were eligible to take part if they were age 18 years and older, wanted to lose weight, and had a BMI of 30 kg/m^2 or over, or a BMI of 28 kg/m^2 or over with co-morbidities.

Participants were excluded from participating if they could not read, write, or speak English, had a BMI over 45 kg/m2, had lost more than 5% of their body weight in the previous 6 months, were pregnant, currently taking psychiatric medications, were not registered with a GP, or currently involved in another research project.

Method of treatment assignment and randomisation

Participants were randomly allocated to the two treatment arms in a 2:1 ratio (intervention:control) by means of an independent web-based randomisation service. Allocation was via random permuted blocks stratified by GP Practice (Lawson vs. Barkantine) with randomly varying block sizes of 18, 21, and 24.

Randomisation was undertaken within each GP practice. Study staff accessed the web-based randomisation programme developed by the Sheffield Clinical Trials Unit, University of Sheffield and entered the participant ID number into the programme. No other information was entered. The allocation was immediately provided by the programme and participants were given instruction on what to do for the next sessions. Neither participant nor study staff were blind to the allocation after this point.

Treatment masking (Blinding)

Participants and study staff providing the interventions were not blinded. However the study staff collecting the measurements at 6 and 12-month follow-up (the primary endpoint) were blinded to allocation.

The statistician (and all other staff who have access to outcome data) remained blinded until the database was finalised and Statistical Analysis Plan is signed off.

Sample size determination

A clinically significant effect can be achieved with 3-5 kg weight loss in obese people.[69] We assumed that WAP would increase weight loss by 2.6kg compared with usual care (WAP 3kg vs. usual care 0.4kg) for participants available for follow-up at one year, and that there would be no difference in weight loss between treatment groups for participants not available for follow-up. Assuming that 50% of participants in both treatment groups were available for follow-up at one year, the difference in weight loss between groups would be 1.3kg (WAP 1.5kg vs. usual care 0.2kg). Assuming a standard deviation of 3 in both treatment groups, and a 5% two-sided significance level, we would require 112 participants in each group to detect this mean difference with 90% power. Our estimate of 50% loss to follow-up is conservative and based on international experience in this field and existing data from similar underprivileged and highly mobile populations and interventions.

To account for potential clustering effects due to group treatment in the intervention arm, assuming a mean cluster size of 18 and an intra-cluster correlation coefficient of 0.05, a total of 208 individuals will be required in the intervention arm. The same power can be achieved with 108 in the control arm and 216 in the intervention arm which we have increased to 110 in the control arm and 220 in the intervention arm to give an allocation ratio between the two arms (2:1) which can be expressed in whole numbers. Thus we require a total of 330 individuals for the entire study

4. DATA COLLECTION

Baseline

The following variables were collected at baseline

- ***Demographics:*** includes age, sex, ethnicity, employment, level of education
- ***Health and lifestyle:*** includes smoking status, alcohol consumption, and general health
- ***Weight loss history:*** includes number of past weight-loss attempts, methods used, most weight ever lost, and regular monitoring of weight.
- ***Concurrent medications:*** all current medications are recorded.
- ***Height and weight:*** measured in centimeters and kilograms. BMI calculated from these.
- ***Waist circumference:*** measured in centimetres.
- ***Blood pressure:*** resting blood pressure recorded.

The following validated questionnaires are also administered at baseline:

- International Physical Activity Questionnaire [63]
- Food knowledge assessment
- Food craving inventory [64]
- Three Factor Eating Questionnaire [65]
- EQ-5D
- Use of health services questionnaire

Follow up

The following variables were collected during follow-up visits: weight, waist circumference, blood pressure, International Physical Activity Questionnaire [63], Food knowledge assessment, Food craving inventory, Three Factor Eating Questionnaire [65], EQ-5D, use of health services questionnaire, adverse events, participant feedback and medication use.

In the intervention arm the following were collected during the 8-week intervention phase: pedometer use, food diary use, and adherence to weekly tasks (e.g. increase fruit and vegetable intake, increase exercise, monitoring television and computer use).

Timing of data collection

The recruitment period was: September 2012– January 2014 (17 months) and the study sessions were conducted as follows:

Week -1: Screening

Week 0:	Randomisation
Weeks 1-8:	Intervention group – 8 weekly sessions
	Control group – 4 fortnightly sessions
Months 3-12:	Intervention group – 10 monthly follow-up sessions
	Control group – 6 and 12 month follow-up sessions only

Database

Description

Data were entered into the online database, 'Oracle Database version 11', hosted at the Barts Cancer Centre. The Electronic Data Capture forms are web based and built using Java with data validation in JavaScript (Java framework Struts 2).

Data quality

When recruitment and follow-up are complete, the study team will clean the data in the following way: values for each variable will be sorted, and those at the extremes will be checked to ensure that they are within the expected range.

Source data verification will also be conducted: a random sample of 10% of CRFs will be selected, and a member of QA team (PCTU) will compare all written entries with those entered onto the main study database. The pre-specified data quality target is ≤ 2% discrepancy rate between entries in the CRF and the electronic database. If an error is found in >2% of entries, the quality target for data entry will not have been met, and all CRF data will be cross-checked against data in the study database. (This would be done by counting up the maximum number of data items that could be entered for a patient on each of the CRFs, ignoring free text fields. Errors will be tallied and these would include any items that were inadvertently missed out.)

Derived and computed variables

All derived and computed variables will be documented in the analysis programmes.

5. GENERAL ISSUES FOR STATISTICAL ANALYSIS

General analysis principles

The main analysis for each outcome will use intention-to-treat (ITT) principles, meaning that all participants with a recorded outcome will be included in the analysis, and will be analysed according to the treatment group to which they were randomised. More information on which participants will be included in each analysis is available in the section below. All p-values will be two sided, and the significance level is set at 5%.

Analyses for all outcomes will be presented as:

- The number of participants included in the analysis, by treatment group;
- A summary measure of the outcome, by treatment group (e.g. mean (SD) for continuous outcomes, number (%) for binary outcomes);
- A treatment effect, with a 95% confidence interval;
- A two-sided p-value.

All analyses will account for clustering by group in the intervention arm, and clustering by nurse in the control arm. Each patient will be defined as belonging to a cluster, defined by which group they belonged to if they were in the intervention arm, and which nurse they were treated by if they were in the control arm. This variable will be included as a random intercept in a mixed-effects regression model. This analysis assumes the intraclass correlation coefficient is the same between groups in the intervention arm as it is between nurses in the control arm. The Kenward-Roger degree-of-freedom correction will be employed for all linear mixed-effects models.

All analyses will adjust for baseline weight, age, gender, ethnicity (White British, White other, Black, Asian, Mixed, or other), smoking status (smoker vs. non-smoker) and GP practice (Lawson vs. Barkantine) as covariates in a regression model. Outcomes which are measured at baseline will also be adjusted for the value of the outcome at baseline (this includes weight, BMI, waist circumference, systolic and diastolic blood pressure, Food Craving Inventory, Food Knowledge Assessment, Three Factor Eating Questionnaire, and IPAQ). Continuous covariates (baseline weight, age) will be assumed to have a linear association with outcome. Binary and categorical covariates (gender, ethnicity, smoking status, and GP practice) will be included in the regression model using indicator (dummy) variables. Missing baseline data will be accounted for using mean imputation.

Missing data for outcomes

For outcomes that are measured at multiple time points during follow-up, we have based our analysis strategy on that proposed by White et al 2011[73]. To deal with incomplete data (i.e. when patients have missing data at one of the follow-up time points) we will:

1. Attempt to follow up all randomised patients even if they withdraw from the study
2. Perform a main analysis of all observed data that are valid under a plausible assumption about the missing data
3. Perform sensitivity analyses to explore the effect of departures from the assumptions made in the main analysis
4. Account for all randomised participants, at least in the sensitivity analyses

We will therefore (a) include all patients with at least one post-randomisation assessment (i.e. if they have recorded data for at least one follow-up time point) in the analysis; (b) use mixed-effects models adjusted for baseline covariates, which assumes that the data are missing-at-random (i.e. they are missing based on their observed outcome at other time-points, and other patient characteristics); and (c) perform sensitivity analyses under other missing data assumptions (e.g. that patients who were lost-to-follow-up gained more weight than patients who remained in the trial).

Analysis of primary outcome

The primary outcome (change in weight at 12 months post-randomisation) will be analysed using a mixed-effects linear regression model. The model will include change in weight at 1, 2, 6 and 12 months as outcomes.

The model will include a random intercept for ‘cluster’ (group or nurse, depending on treatment arm). The correlation between observations at different time points from the same patient (1, 2, 6, and 12 months) will be modelled using an unstructured correlation structure. The model will be estimated using restricted maximum likelihood (REML). Treatment arm, time point (month 1, 2, 6, or 12), and the interaction between treatment arm and time point will be included in the model as fixed factors. Time point will be included as an indicator variable. The covariates listed in section 5 will also be included in the model as fixed factors.

The analysis will be implemented in Stata as follows:

```
mixed outcome treatment##time covariates || cluster_id:, || ///
        patient_id:, noconstant residuals(unstructured, t(time)) stddev reml
dfmethod(kroger)
```

If this model fails to converge, we will run the model again using the correlation structure

residuals(ar 2 , t(time)). If the model still fails to converge, we will use *residuals(ar 1 , t(time))*.

Sensitivity analyses for primary outcome

Missing data

We will perform two sensitivity analyses to assess the robustness of our primary analysis to different assumptions regarding the missing data. These sensitivity analyses will be performed for the primary outcome (change in weight at 12 months).

- A complete case analysis, where only patients with recorded data at 12 months are included
- An analysis which assumes data missing at 12 months is missing-not-at-random.

We will perform the second sensitivity analysis (where data missing at 12 months is assumed to be missing-not-at-random) using the formula $\Delta = \Delta_{CC} + Y_1P_1 - Y_2P_2$, where Δ is the treatment effect under the missing-not-at-random scenario, Δ_{CC} is the treatment effect from a complete case analysis, Y_1 and Y_2 are the assumed mean responses for participants with missing data in treatment groups 1 and 2 respectively, P_1 and P_2 are the proportion of participants who were excluded from the analysis in groups 1 and 2 respectively, and groups 1 and 2 represent the intervention and control groups respectively. The standard error for Δ is assumed to be approximately equal to the standard error for $\Delta_{CC.}$ Y_2 will be varied between -10, -5, -2.5, 0, 2.5, 5, and 10. Negative values indicate the participant lost weight at 12 months, positive values indicate they gained weight, and a value of 0 indicates there was no change from baseline. For each value of Y_2, Y_1 will be set to Y_2 - 5, Y_2, and Y_2 + 5.

For example, for $Y_2 = 10$, this would indicate an assumption that patients in treatment arm 2 (the control arm) who were lost to follow-up at 12 months, had gained 10kg on average at 12 months. Y_1 would vary between 5, 10, and 15, indicating the assumption that patients in treatment arm 1 (the intervention arm) who were lost to follow-up had gained 5kg on average at 12 months (5kg less than those in the control arm), 10kg (the same amount as those in the control arm), or 15kg (5kg more than those in the control arm).

Patients who became pregnant or had bariatric surgery during follow-up

We will perform a sensitivity analysis to assess the impact of patients who became pregnant or underwent bariatric surgery during follow-up on results. This analysis will be performed for the primary outcome. This sensitivity analysis will involve including only weight measurements collected prior to pregnancy/bariatric surgery in the analysis; weight measurements collected after pregnancy/bariatric surgery will be set to missing. This analysis will be performed using the same methods as for the primary analysis.

Analysis of secondary outcomes

Change in weight at 1, 2, and 6 months

This outcome will be included in the same model as the primary outcome.

Change in BMI at 1, 2, 6 and 12 months

These outcomes will be analysed using the same method as change in weight at 6 and 12 months, with the exception that baseline BMI will be included as a covariate in the regression model, as opposed to baseline weight. BMI measurements at 1, 2, 6, and 12 months will be included in the model.

Change in waist circumference at 2, 6 and 12 months

These outcomes will be analysed using the same method as change in weight at 6 and 12 months with the exception that baseline waist circumference will be included as a covariate in the regression model, as opposed to baseline weight. Waist circumference measurements at 2, 6, and 12 months will be included in the model.

Change in systolic blood pressure at 2, 6 and 12 months

These outcomes will be analysed using the same method as change in weight at 6 and 12 months. The baseline value of systolic blood pressure will also be included as a covariate in the model. Systolic blood pressure measurements at 2, 6, and 12 months will be included in the model.

Change in diastolic blood pressure at 2, 6 and 12 months

These outcomes will be analysed using the same method as change in weight at 6 and 12 months. The baseline value of diastolic blood pressure will also be included as a covariate in the model. Diastolic blood pressure measurements at 2, 6, and 12 months will be included in the model.

Change in Food Craving Inventory (frequency domain) at 1, 2, 6 and 12 months

These outcomes will be analysed using the same method as change in weight at 6 and 12 months. The baseline value of the Food Craving Inventory (frequency domain) will also be included as a covariate in the model. Frequency domain measurements at 2, 6, and 12 months will be included in the model.

Treatment effect estimates will only be presented at 6 and 12 months; data from month 2 is included in the model to increase power, and to make the missing-at-random assumption more plausible.

Change in Food Craving Inventory (strength domain) at 1, 2, 6 and 12 months

These outcomes will be analysed using the same method as change in weight at 6 and 12 months. The baseline value of the Food Craving Inventory (frequency domain) will also be included as a covariate in the model. Strength domain measurements at 2, 6, and 12 months will be included in the model.

Change in Food Knowledge Assessment at 2, 6 and 12 months

These outcomes will be analysed using the same method as change in weight at 6 and 12 months. The baseline value of food knowledge will also be as a covariate in the

model. Food Knowledge Assessment measurements at 2, 6, and 12 months will be included in the model.

Change in Three Factor Eating Questionnaire (Cognitive Restraint domain) at 2, 6 and 12 months

These outcomes will be analysed using the same method as change in weight at 6 and 12 months. The baseline value of the Three Factor Eating Questionnaire (Cognitive Restraint domain) will also be included as a covariate in the model. Cognitive Restraint domain measurements at 2, 6, and 12 months will be included in the model.

Change in Three Factor Eating Questionnaire (Uncontrolled Eating domain) at 2, 6 and 12 months

These outcomes will be analysed using the same method as change in weight at 6 and 12 months. The baseline value of the Three Factor Eating Questionnaire (Uncontrolled Eating domain) will also be included as a covariate in the model. Uncontrolled Eating domain measurements at 2, 6, and 12 months will be included in the model.

Change in Three Factor Eating Questionnaire (Emotional Eating domain) at 2, 6 and 12 months

These outcomes will be analysed using the same method as change in weight at 6 and 12 months. The baseline value of the Three Factor Eating Questionnaire (Emotional Eating domain) will also be included as a covariate in the model. Emotional Eating domain measurements at 2, 6, and 12 months will be included in the model.

Change in International Physical Activity Questionnaire (MET-minutes/week domain) at 2, 6 and 12 months

These outcomes will be analysed using the same method as change in weight at 6 and 12 months. The baseline value of the MET-minutes/week domain will also be included as a covariate in the model. MET-minutes/week domain measurements at 2, 6, and 12 months will be included in the model.

Change in International Physical Activity Questionnaire (sitting domain) at 2, 6 and 12 months

These outcomes will be analysed using the same method as change in weight at 6 and 12 months. The baseline value of the sitting domain will also be included as a covariate in the model. Sitting domain measurements at 2, 6, and 12 months will be included in the model.

Proportion of participants losing 5% of body weight at 2, 6, and 12 months

These outcomes will be analysed using a mixed-effects logistic regression model. The model will include whether the participant had lost 5% of their body weight at 2, 6 and 12 months as outcomes.

The model will include three levels: the top level will include a random intercept for 'cluster' (group or nurse, depending on treatment arm). The second level will include a random intercept for patient, and a random slope for time point. Treatment arm, time point, and the interaction between treatment arm and time point will be included

in the model as fixed factors. Time point will be included as an indicator variable. The covariates listed in section 5 will also be included in the model as fixed factors.

The analysis will be implemented in Stata as follows:

```
meqrlogit outcome treatment##time covariates || cluster_id:, || ///
        patient_id: time, cov(exch)
```

If this model fails to converge, we will run the model again after removing the random slope for time at the second level.

Proportion of participants losing 10% of body weight at 2, 6, and 12 months
These outcomes will be analysed using the same methods as the proportion of participants losing 5% of body weight at 2, 6, and 12 months.

Subgroup analyses
No subgroup analyses will be performed.

Other data summaries

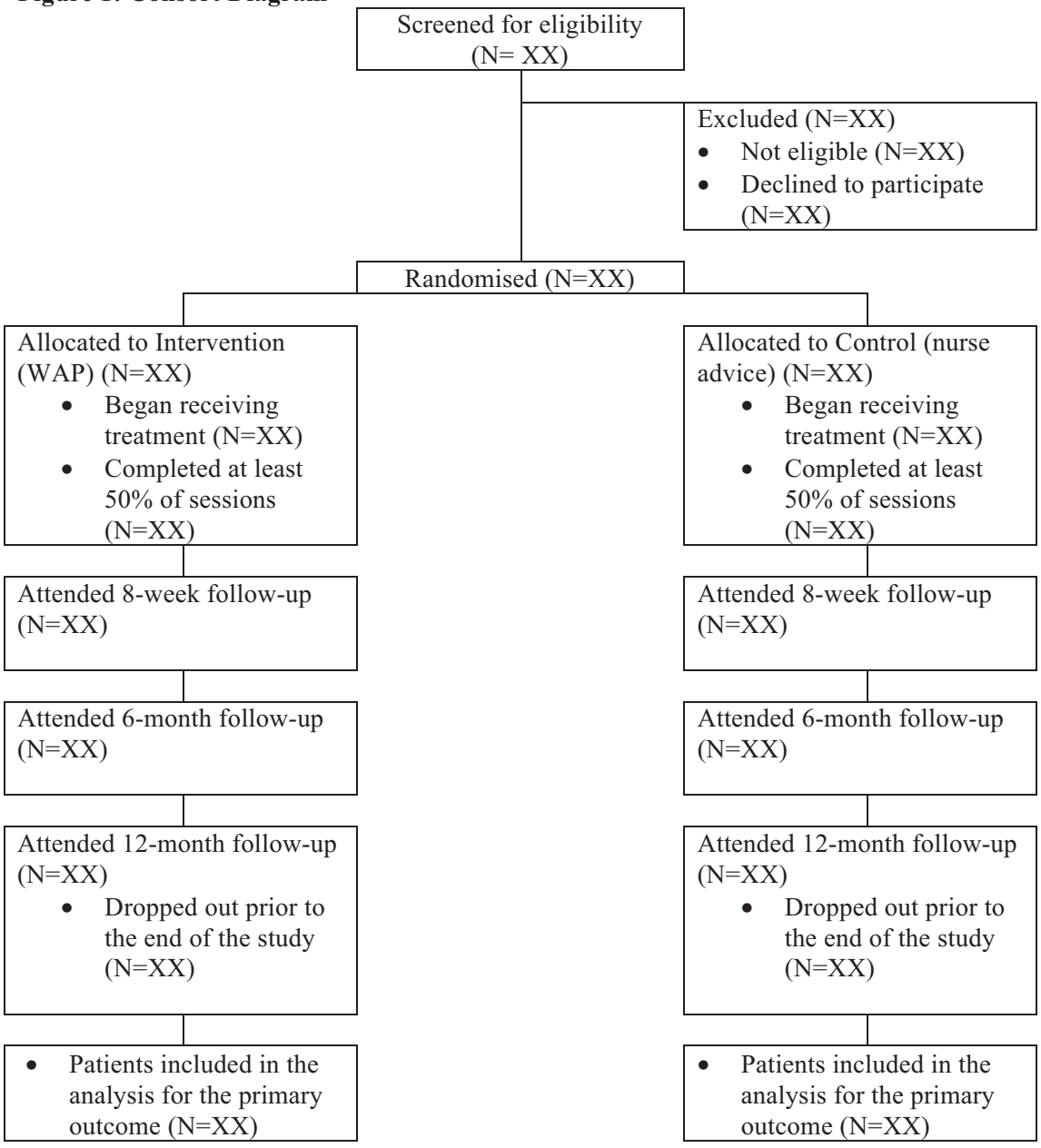
- Number of participants on both treatment arms who began taking orlistat during follow-up
- Compare weight change at 12 months in participants who received orlistat during follow-up vs. those who did not
- Summary measures for the feedback questionnaire form (mean and SD, number and percent) in both treatment arms for Q1, Q2, and Q4

6. Figures

Participant flow

Participant throughput will be summarized in a CONSORT diagram (see figure 1).

Figure 1: Consort Diagram



Other figures

For certain outcomes, we will produce two graphs. The first graph will show the mean outcome within each treatment group (i.e. the mean outcome in the intervention arm, and the mean outcome in the control arm) at each time-point of follow-up. The mean outcome at each time point will be presented with a 95% confidence interval. The second graph will show the estimated treatment effect (with a 95% CI) at each time point.

These graphs will be produced for the following outcomes:

- Change in weight at 1, 2, 6, and 12 months
- Change in BMI at 1, 2, 6, and 12 months
- Change in waist circumference at 2, 6, and 12 months
- Change in systolic blood pressure at 2, 6, and 12 months

7. Tables

Table 1 - Baseline measurements

	Usual care (n=…)	WAP (n=…)
Weight (kg) – mean (SD)		
BMI – mean (SD)		
Waist circumference – mean (SD)		
Systolic blood pressure – mean (SD)		
Diastolic blood pressure – mean (SD)		
Age (years) – mean (SD)		
Female – no. (%)		
Food Craving Inventory score – mean (SD)		
Frequency domain		
Strength domain		
Food Knowledge Assessment Questionnaire score – mean (SD)		
Three Factor Eating Questionnaire score – mean (SD)		
Cognitive Restraint domain		
Uncontrolled Eating domain		
Emotional Eating domain		
International Physical Activity Questionnaire – mean (SD)		
MET-minutes/week domain		
Sitting domain		
Centre – no. (%)		
Lawson		
Barkantine		
Marital status – no. (%)		
Single		
Separated or divorced		
Married or living with partner		
Other		
Ethnicity – no. (%)		
White British		
White other		
Black		
Asian		
Mixed		
Other		
Educational qualification – no. (%)		
None		
GCSE or equivalent		
A-Level or equivalent		
Degree or equivalent		
Other		
Employment status – no. (%)		

In paid employment		
Unemployed		
Looking after the home		
Retired		
Full time student		
Other		
Entitled to free prescriptions – no. (%)		
Smoking status – no. (%)		
Smoker		
Non-smoker		
Units of alcohol consumed per week – mean (SD)		
Family history of being overweight or obese – no. (%)		
Mother		
Father		
Themselves		
Number of previous attempts at weight loss – median (IQR)		
Greatest previous amount of weight loss – median (IQR)		

Table 2 – Characteristics of intervention groups and patient adherence

	Usual care (n=…)	WAP (n=…)
Number of intervention groups or nurses (usual care)		
Number of participants per group – median (IQR)		
Number of sessions attended per participant – median (IQR)		
Attended more than half the sessions – no. (%)		

Table 3 – Number (%) of participants included in the analysis for each outcome

	Usual care (n=…)	WAP (n=…)
Change in weight		
Change in BMI		
Change in waist circumference		
Change in systolic blood pressure		
Change in diastolic blood pressure		
Food Craving Inventory score		
Frequency domain		
Strength domain		
Food Knowledge Assessment Questionnaire score		
Three Factor Eating Questionnaire score		
Cognitive Restraint domain		
Uncontrolled Eating domain		
Emotional Eating domain		
International Physical Activity Questionnaire		
MET-minutes/week domain		
Sitting domain		
Participants losing 5% of their body weight		
Participants losing 10% of their body weight		

Table 4 – Results for primary and secondary outcomes

	Usual care (n=…)	WAP (n=…)	Treatment effect* (95% CI)	P-value
Change in weight (kg) – mean (SD)				
1 month				
2 months				
6 months				
12 months				
Change in BMI – mean (SD)				
1 month				
2 months				
6 months				
12 months				
Change in waist circumference (cm) – mean (SD)				
2 months				
6 months				
12 months				
Change in systolic blood pressure – mean (SD)				
2 months				
6 months				
12 months				
Change in diastolic blood pressure – mean (SD)				
2 months				
6 months				
12 months				
Change in Food Craving Inventory score (Frequency domain) – mean (SD)				
1 month				
2 months				
6 months				
12 months				
Change in Food Craving Inventory score (Strength domain) – mean (SD)				
1 month				
2 months				

6 months				
12 months				
Change in Food Knowledge Assessment Questionnaire score – mean (SD)				
2 months				
6 months				
12 months				
Change in Three Factor Eating Questionnaire score (Cognitive Restraint domain) – mean (SD)				
2 months				
6 months				
12 months				
Change in Three Factor Eating Questionnaire score (Uncontrolled Eating domain) – mean (SD)				
2 months				
6 months				
12 months				
Change in Three Factor Eating Questionnaire score (Emotional Eating domain) – mean (SD)				
2 months				
6 months				
12 months				
Change in International Physical Activity Questionnaire (MET-minutes/week domain) – mean (SD)				
2 months				
6 months				
12 months				
Change in International Physical Activity Questionnaire (Sitting domain) – mean (SD)				
2 months				
6 months				
12 months				
Participants losing 5% of their body weight – no. (%)				
2 months				

6 months				
12 months				
Participants losing 10% of their body weight – no. (%)				
2 months				
6 months				
12 months				

*Treatment effects are presented as a difference in means (estimated from a mixed-effects regression model) between the two groups (WAP vs. control) for all outcomes apart for the number of participants who lost 5% or 10% of their body weight, where the treatment effect is presented as an odds ratio.

Table 5 – ICC values for group or nurse at 6 and 12 months

	6 months	12 months
Change in weight		
Change in BMI		
Change in waist circumference		
Change in systolic blood pressure		
Change in diastolic blood pressure		
Food Craving Inventory score		
Frequency domain		
Strength domain		
Food Knowledge Assessment Questionnaire score		
Three Factor Eating Questionnaire score		
Cognitive Restraint domain		
Uncontrolled Eating domain		
Emotional Eating domain		
International Physical Activity Questionnaire		
MET-minutes/week domain		
Sitting domain		
Participants losing 5% of their body weight		
Participants losing 10% of their body weight		

Table 6 – No. (%) of participants in the WAP group using different process measures at each session

Process measure	S1 (n=…)	S2 (n=…)	S3 (n=…)	S4 (n=…)	S5 (n=…)	S6 (n=…)	S7 (n=…)	S8 (n=…)
Pedometer use	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
TV/screen time use	No. (%)	No. (%)	-	-	-	-	-	-
Food diary use	No. (%)	-	-	-	-	-	-	-
Counted calories	-	No. (%)	-	-	-	-	-	-
5/day	-	-	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
Exercise	-	-	-	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
No junk	-	-	-	-	No. (%)	No. (%)	No. (%)	No. (%)
Scales	-	-	-	-	No. (%)	No. (%)	No. (%)	No. (%)
Removed triggers	-	-	-	-	-	-	No. (%)	-

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Appendix 1

Timing of data collection

Source of data	Data collected
Baseline questionnaire	Age Sex Marital status Ethnicity Educational qualification Employment status Entitlement to free prescriptions Smoking status Alcohol Consumption Eating Habits Weight Loss history Concurrent illnesses/ medications
CRF – screening session	Weight (kg) Height (cm) BMI Eligibility checked against inclusion criteria
CFR – randomisation session	Weight (kg) Waist circumference (cm) Blood pressure MPSS Motivation scale Use of other weight loss methods
CRF – control group treatment sessions	Weight (kg) Waist circumference (cm) (Session 4 only) Blood pressure (Session 4 only) MPSS Motivation scale (Session 1 only) Use of other weight loss methods AEs
CRF – intervention group treatment sessions	Weight (kg) Waist circumference (cm) (Session 8 only) Blood pressure (Session 8 only) MPSS Motivation scale (Session 1 only) Use of other weight loss methods AEs
Task cards (intervention group only)	Pedometer readings (reported and actual) Step target Screen time

	Completion of food diary Calorie counting 5/day Exercise 'Said no' to unnecessary food Self monitoring on weighing scales
CRF – 6 month follow-up	Weight (kg) Waist circumference (cm) Blood pressure Concurrent illness/medications MPSS Use of other weight loss methods AEs
CRF – 12 month follow-up	Weight (kg) Waist circumference (cm) Blood pressure Concurrent illness/medications MPSS Use of other weight loss methods AEs

Appendix 2

Scoring of questionnaires

Food Knowledge Assessment score

The Food Knowledge Assessment score is scored on an 11 point scale (range 0-10), with higher scores indicating more knowledge. It contains 10 questions, and each question is score either 0 or 1. The overall score is calculated by summing the scores of the individual questions.

The scores for the individual questions is shown in the table below. Each question has four possible answers (a, b, c, d); the table indicates which of the four answers results in a score of 1 (all other answers result in a score of 0).

	Score=1 if answer is
Q1	A
Q2	A
Q3	C
Q4	B
Q5	D
Q6	B
Q7	C
Q8	B
Q9	B
Q10	A

Food Craving Inventory score

Each of the five food types (fatty foods, carbohydrates and starches, sweet foods, savoury snacks, and fruit) is assigned a score from 0 to 5 on both frequency and urge of craving. The frequency domain is then calculated by summing the scores of the individual questions related to frequency; the strength domain is calculated in a similar manner. The overall scores from both domains range from 0 to 25, with higher scores indicating more frequent or stronger urges.

International Physical Activity Questionnaire

MET-minutes/week domain

This score represents the total MET-minutes/week, and is expressed on a continuous scale with a minimum score of 0. It is calculated as:

MET-minutes/week = 3.3*(walking intensity minutes)*(walking intensity days) +
4.0* (moderate intensity minutes)*(moderate intensity days) +
8.0* (vigorous intensity minutes)*(vigorous intensity days)

Sitting domain

This score represents the number of minutes per day spent sitting. It is calculated directly from question 4.

Three Factor Eating Questionnaire

The Three Factor Eating Questionnaire contains 18 questions, each of which is scored from 1 to 4, with higher values indicating a higher level of the behaviour. Domain scores (Cognitive Restraint, Uncontrolled Eating, and Emotional Eating) are calculated as the mean of all the questions within a domain.

The table below indicates which questions are included in which domain:

Domain	Questions included in domain
Cognitive Restraint	2, 11, 12, 15, 16, 18
Uncontrolled Eating	1, 4, 5, 7, 8, 9, 13, 14, 17
Emotional Eating	3, 6, 10

The table below indicates how each question is scored:

Question	Scoring system
Q1 to Q13	Definitely true = 4 Mostly true = 3 Mostly false = 2 Definitely false = 1
Q14	Almost always = 4 Often between meals = 3 Sometimes between meals = 2 Only at meal times = 1
Q15	Almost always = 4 Usually = 3 Seldom = 2 Almost never = 1
Q16	Very likely = 4 Moderately likely = 3 Slightly likely = 2 Unlikely = 1
Q17	At least once a week likely = 4 Sometimes likely = 3 Rarely likely = 2 Never = 1
Q18	Answer 7-8 = 4 Answer 5-6 = 3 Answer 3-4 = 2 Answer 1-2 = 1

Appendix 5 – Costs

Table 41: WAP intervention costs (price year 2012/3)

Resource	Cost	Notes
Staff 1 (Research Health Psychologist)	£69,778	Total from 09/12-02/15. Runs the 8 week programmes and monthly Follow-ups (FU)
Staff 2 (Research Health Psychologist)	£69,778	Total from 09/12-03/14. Co-runs the 8 week programmes only
Pedometer	£1,071	Total spent (£4.50 per unit)
Materials	£332.6	Total spent. Includes printing and photocopying costs (posters, leaflets, task cards, questionnaires etc)
Digital scales	£80	Total spent (£40 per scale)
BP monitor	£140	Total spent (£70 per monitor)
Batteries	£10	Total spent
Measuring tape	£2	Total spent (£1 per item)
Stationary	£284	Total spent. Clipboards, pens etc
Venue	0	Covered by GP Practices

Table 42: Nurse led usual care costs (price year 2012/3)

Resource	Cost	Notes
Staff (Practice Nurse)	£41,342	Total spent. £20671 Invoiced per practice (Barkantine/Lawson) for 50% nurse time
Materials	£166.30	Total spent. Includes printing and photocopying costs (leaflets, questionnaires etc)
Digital scales	£80	Total spent (£40 per scale)
BP monitor	£140	Total spent (£70 per monitor)
Batteries	£5	Total spent
Measuring tape	£1	Total spent
Stationary	£142	Total spent. Clipboards, pens etc
Venue	0	Run from the GP surgery

Table 43: Staff cost components including indirect costs (price year 2012/3)

Cost and unit estimation	Unit cost	Notes
Wages/salary	£29,120	Average salary of Research Health Psychologist whilst on the project
Salary on-costs	£6,912	
Salary (total inc. overheads)	£50,546	
Working time	37.5 hours per week, 45 weeks per year	30 days annual leave, 1 week college closure
Length of sessions	2 hours per session	Each session lasted 1 hour + 1 hour set up time
Indirect time	1 hour per session	Admin pre-session (preparing materials, photocopying, scheduling text messages) 1 hour per session
Indirect time	2 hour per session	Admin post-session (checking/filing forms, contacting participants for missing data, following up DNAs) 2 hours per session

EME
HS&DR
HTA
PGfAR
PHR

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