Study Title: A feasibility study testing the acceptance and recruitment methods of weight loss intervention referrals to help inform the development of a larger trial.

Internal Reference Number / Short title: A brief GP intervention for weight loss: The BWeL-B feasibility trial

Ethics Ref:

Date and Version No: Version 1 15th February 2018

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Sponsor: University of Oxford

Funder: NIHR Oxford Biomedical Research Centre

Chief Investigator Signature:

A handwritten signature in black ink, appearing to read 'Paul Aveyard', is written over a horizontal line. To the right of the signature is a vertical yellow line.

Paul Aveyard and Susan Jebb have conducted independent research funded by weight loss companies but have received no personal financial payments. Kate Tudor has nothing to declare.

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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1. SYNOPSIS

Study Title	An uncontrolled trial to test the effect of a GP offering a referral to a weight management programme at cost to the patient with an embedded randomised controlled trial of two ways of describing the cost - BWeL-B feasibility trial.	
Internal ref. no. / short title	A brief GP intervention for weight loss: The BWeL-B feasibility trial	
Study Design	Randomised controlled trial (RCT)	
Study Participants	Adults who are obese in England attending their GP for reasons other than weight management. General Practitioners delivering the intervention.	
Planned Sample Size	65 participants divided into the following groups: Group 1 (Patient participants receiving Script 1) = 30 Group 2 (Patient participants receiving Script 2) = 30 Group 3 (GP participants) = 5	
Planned Study Period	6 months	
	Objectives	Outcome Measures
Primary (Group 1 and 2 only)	1) To determine whether participants will attend a weight management programme within 3 weeks of a GP recommendation, to help inform the development of a larger trial.	1) Participants' self-reported attendance to a weight management programme referral at 3 week follow up.
Secondary	2) To examine patient participants' acceptability of a GP referral to attend a weight management programme that requires their own payment. 3) To examine patient participants' thoughts and feelings about the opportunistic intervention, (and the script specifically) that was delivered when they visited for reasons other than their weight.	2) Acceptance of GP referral immediately after the appointment, specifically whether they planned to attend the weight management programme in the immediate future (recorded immediately after the referral). 3) Participants' thoughts about the opportunistic intervention, (and the script specifically) that was delivered when they visited for reasons other than their

	<p>4) To examine GPs' views of delivering the opportunistic intervention both before and after giving the opportunistic intervention</p> <p>5) To examine the effect of two types of brief intervention scripts (basic cost vs cost comparison) on patient reaction to, acceptance of, and attendance at a commercial weight management programme.</p>	<p>weight. and whether other styles may have resulted in a different reaction than the one experienced.</p> <p>4) GPs thoughts and attitudes about the two brief intervention scripts. This will include exploring: why GPs felt as they did; whether other brief interventions might be more or less acceptable than the one they gave; and whether these interventions might be suitable for all people who are obese, or only those with relevant medical conditions.</p> <p>5) Comparison of the proportion of participants who attend a weight management programme in each treatment arm (basic cost vs cost comparison).</p>
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2. ABBREVIATIONS

BMI	Body Mass Index
BOCF	Baseline Observation Carried Forward
CI	Chief Investigator
CRF	Case Report Form
CTRG	Clinical Trials & Research Governance, University of Oxford
CWMS	Commercial Weight Management Service
DPA	Data Protection Act
GCP	Good Clinical Practice
GP	General Practitioner

HRA	Health Research Authority
MI	Motivational Interviewing
NHS	National Health Service
NRES	National Research Ethics Service
OXTREC	Oxford Tropical Research Ethics Committee
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
PCT(s)	Primary Care Trust(s)
PC-CTU	Primary Care Clinical Trials Unit
RC	Rosemary Conley
REC	Research Ethics Committee
QALY	Quality Adjusted Life Years
QOF	Quality and Outcomes Framework
RCT(s)	Randomised Controlled Trial(s)
SOP	Standard Operating Procedure
SSA	Site-Specific Assessment
SOP	Standard Operating Procedure
SW	Slimming World
SWAT	Study Within A Trial
UK	United Kingdom
TSC	Trial Steering Committee
WW	Weight Watchers

3. BACKGROUND AND RATIONALE

Obesity is an increasing problem in the UK, affecting around 25% of the adult population and the prevalence is projected to double in the next half century.¹ It is a major cause of morbidity and chronic disease, particularly increasing the risk of type II diabetes, cardiovascular disease and some cancers.² In addition, the direct economic cost in England is estimated at £4.2 billion per year. There is good evidence that moderate weight loss (5-10% of initial body weight) among adults who are obese leads to beneficial clinical outcomes, particularly reducing the risk of diabetes.³ While high priority should be given to prevent future cases of obesity, there is also a pressing need to identify effective intervention to treat established obesity.

In a recent randomised trial ('BWEL') we showed that physician led 30-second opportunistic interventions to motivate action on weight are highly acceptable to patients, lead to effective action in

many patients, and lead to long-term weight loss.⁴ Specifically, 83% of consecutive patients attending 137 GPs agreed to enrol in the trial and 1882 were randomised to one of two interventions. In the control group ('advice'), physicians advised patients to lose weight to improve their health. In the intervention group ('support'), physicians advised patients that the best way to lose weight was to attend a commercial weight management group that was available on the NHS and referred patients to it if they agreed. 77% of all patients agreed to attend the group, 40% did so, and the mean weight loss across the whole population of people in the intervention group was 2.4kg versus 1kg in the control, difference 1.4kg (95% confidence interval) (0.9, 2.0). 1 in 500 people thought the GP intervention was inappropriate and unhelpful, while over 80% thought it appropriate and acceptable. The intervention is acceptable, practicable, and scalable.

Modelling over 20 years, we examined the change in prevalence of obesity using data from previous Health Surveys for England to project the trend forward. In 20 years, the prevalence of obesity is expected to rise to 33%. We then calculated the incidence of obesity-related disease, its impact on length of quality of life, and the costs of treating those diseases using a Markov model microsimulation cohort based on the population of England. We compared the impact of this scenario with two others: one in which GPs gave the advice brief intervention and one in which they gave the support intervention. We assumed GPs did this to every person who was obese that consulted them and did so once a year on average, about one in five consultations. In these scenarios, the prevalence of obesity dropped: to 27% in the advice condition and 16% in the support condition. These two strategies would generate 0.037 QALYs/person and save 0.23% of the NHS budget in the advice condition and 0.083 QALYs /person and save 0.48% of the NHS budget. Achieving these gains is tantalisingly attainable. It would take a fulltime GP three hours per year to deliver this intervention to her or his population to achieve these outcomes and cost-savings.

The support intervention offers the best health gain and reduces costs the most and therefore looks to be the best strategy and is dominant over advice. However, there is a problem that may limit implementation. The intervention strategies do not reduce overall NHS costs until year seven of the implementation programme. In the meantime, overall NHS and public health costs must rise if we are to implement this plan. To deliver the support intervention, the NHS and public health must spend an additional £200 million annually, with almost no offset of costs recouped in the first year or two. Moreover, most of the costs of the programme fall to the local authority public health budget, which is under greater financial pressure than the NHS, and most of the benefits of the programme fall to the NHS. This is because the major cost is the £50/person for each referral taken up at a weight management programme, which the local authority pays, much higher than the £2/person costs to the NHS of delivering and supporting the brief intervention. Unless the Government earmarks money to implement this programme, it is unlikely to be implemented.

One solution to the problem is for the brief intervention to be modified slightly. Instead of informing patients that the intervention is the best way to lose weight and is free on the NHS, GPs could instead say that it is the best way but has to be paid for by the patient themselves. In fact, many areas of the country have ceased to commission these programmes or have never had GP referral schemes in place, so in many areas of the country now, this is all GPs can say if they are to implement our brief intervention. Unless there were to be a massive ring-fenced uplift in local authority money for public health, any large-scale implementation of this plan would require GPs giving brief interventions to say

this too. The scale of provision of weight management referral places, even where available, is way below the demand that would be generated.

The major difficulty with this proposition is that basic economic theory would suggest that offering something at a cost (of around £5/week) will reduce demand relative to offering something cost-free. It may deter initial uptake and the likelihood of persistence with the programmes, which we know is related to weight loss. There is evidence of this.⁵ In a trial in which participants were randomised to either 12 weeks or 52 weeks of Weight Watchers provided free, an additional 1 in 10 participants in the 52-week condition were still attending Weight Watchers at one year compared with the 12-week condition. However, this difference may not entirely be due to cost. It could be that having been referred for 12 weeks or 52 weeks by a GP created expectations about how long the participants 'should' attend.

An obvious difficulty with this approach is that it could widen health inequalities. While many people could afford £5/week, some could not do so easily. However, in an exploratory analysis from the BWeL trial, we divided participants in both arms into those that took 'effective action' or not. 'Effective action' meant attending a commercial weight management programme as other options (such as medication) were very rarely used. In the advice condition (the control group), participants were more likely to take effective action in the three months after enrolment than in the three months prior to it, which may have been prompted by the physician's advice. Participants in this arm paid for enrolment into a weight management programme because they were not referred by the GP. In the advice arm, the most deprived group who paid for themselves to attend achieved very large weight losses, higher than the affluent group who paid for themselves and greater than the group who were referred. While these results are exploratory, it raises the hypothesis that paying for and attending a weight loss programme when money is scarce may lead to greater commitment to the programme.

We therefore propose conduct a trial testing an intervention where GPs endorse, offer, and facilitate a referral to a commercial weight loss programme that requires patients to pay for the service. We have undertaken PPI work to establish people's thoughts about the idea of GPs recommending people pay for their own CWMS. 56% of PPI panel members (n=32) states that it was appropriate for GPs to recommend people pay for themselves to attend a CWLS (28% reported they were unsure, and 16% stated it was inappropriate). Furthermore, 66% said it was reasonable for doctors to do this, and 58% said it they would be willing to pay £5/6 out of their own money. These PPI findings are promising, suggesting that the majority of patients would find the referral acceptable.

Before developing a trial that utilises the same recruitment process, and follow up processes that proved successful in the first BWeL trial, we intend to test whether people will accept a referral that requires their own payment when offered by the GP and whether people will actually attend. We will be able to compare these proportions to the corresponding proportions in BWeL, where 77% and 40% respectively accepted and attended a referral when the GP offered this at no cost. If these proportions are low, then a future trial is not likely to show a benefit because the difference between arms in BWeL was driven by take-up of the weight loss programme.

On the basis of these previous findings, we plan to conduct a small randomised trial to gather reactions to two different versions of the GP script where the GP describes the cost of the intervention. To inform

this, our PPI work aimed to find the best way to make the cost of CWMS attendance seem appropriate to people, for example by comparing it with other costs for discretionary purposes that people would not think twice about paying. To do so, we conducted a focus group with PPI participants, with variable feedback regarding the best GP script. While some PPI participants suggested ideas for discretionary items (predominantly, coffee or alcoholic beverages) some panel members suggested that this approach would be ineffective. We therefore resolved to test the acceptability of a straight description of the price or comparing this to everyday purchases.

4. OBJECTIVES AND OUTCOME MEASURES

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
<p>Primary objective (Group 1 and 2 only)</p> <p>1) To determine whether participants will attend a weight management programme within 3 weeks of a GP recommendation, to help inform the development of a larger trial.</p>	<p>1) Participants' self-reported attendance to a weight management programme referral at 3 week follow up.</p>	<p>3 week follow up phone call.</p>
<p>Secondary Objectives</p> <p>2) To examine patient participants' acceptability of a GP referral to attend a weight management programme that requires their own payment.</p> <p>3) To examine patient participants' thoughts and feelings about the opportunistic intervention, (and the script specifically) that</p>	<p>2) Acceptance of GP referral immediately after the appointment, specifically whether they planned to attend the weight management programme in the immediate future (recorded immediately after the referral).</p> <p>3) Participants' thoughts about the opportunistic intervention (and the script specifically) that was delivered when they visited for reasons other than their weight, and whether other</p>	<p>Baseline visit, immediately after the referral. Recorded by the investigator.</p> <p>3 week follow up phone call.</p>

<p>was delivered when they visited for reasons other than their weight.</p> <p>4) To examine GPs' views of delivering the opportunistic intervention both before and after giving the opportunistic intervention</p> <p>5) To examine the effect of two types of brief intervention scripts (basic cost vs cost comparison) on patient reaction to, acceptance of, and attendance at a commercial weight management programme.</p>	<p>styles may have resulted in a different reaction than the one experienced.</p> <p>4) GPs thoughts and attitudes about the two brief intervention scripts. This will include exploring: why GPs felt as they did; whether other brief interventions might be more or less acceptable than the one they gave; and whether these interventions might be suitable for all people who are obese, or only those with relevant medical conditions.</p> <p>5) Comparison of the proportion of participants who attend a weight management programme in each treatment arm (basic cost vs cost comparison).</p>	<p>Before conducting first intervention and (up to one week) after completing their last intervention.</p> <p>After last final participants 3 week follow up call.</p>
<p>Tertiary Objectives Please add if applicable</p>		

5. STUDY DESIGN

Study design: A pragmatic RCT to compare two delivery approaches of a brief intervention for adults who are obese attending their GP for reasons other than weight management.

Study duration: The total study duration will be 6 months. Table 1 illustrates the sequence and duration of all study periods.

Participant participation: Each participant in Group 1 and 2 (i.e. patient participants) will be enrolled on the day of recruitment and followed up at 3 weeks (see *Appendix A* for the study flow diagram). Participants in Group 3 will complete the questionnaires on the day of the intervention and be interviewed on the same day or up to one week later (see *Appendix B* for the study flow diagram).

Table 1. Study Timeline

<i>Study Task</i>	<i>Month</i>	<i>-5-0</i>	<i>1</i>	<i>2-3</i>	<i>4-6</i>
<i>Document Preparation</i> <i>e.g. ethics</i>		<i>Nov 2017-Mar 2018</i>			
<i>Preparation (START 1st April. 2018)</i> <i>e.g. practice recruitment, GP & staff training</i>			<i>Apr 2018</i>		
Group 3 (i.e. GPs) complete pre-intervention questionnaire.			<i>Apr 2018</i>		
<i>Patient recruitment & data collection (Visit 1)</i>				<i>May 2018- Jun 2018</i>	
Group 3 (i.e. GPs) complete post-intervention questionnaire.				<i>Jun 2018</i>	<i>Jul-Aug 2018</i>
Group 3 (i.e. GPs) complete interview.				<i>Jun 2018</i>	<i>Jul-Aug 2018</i>
<i>Group 1 and 2 participants. 3 week follow up (telephone)</i>				<i>Jun 2018</i>	<i>Jul-Aug 2018</i>
<i>Finalisation</i> <i>e.g. data cleaning and verification, analysis and write up</i>					<i>Aug 2018</i>

Measurement of Outcomes: Please see section 7.2, Baseline Assessments and Subsequent Visits for outcome measurement information.

6. PARTICIPANT IDENTIFICATION

6.1 Study Participants

65 (in total).

60 participants (Patient Participants Groups 1 and 2) will be adults who are obese in England attending their GP for reasons other than weight management; 30 participants will be randomised

into each of the two intervention groups (see section 9.2, Number of Participants for more information).

5 participants (Group 3) will be GPs who have delivered the brief intervention to patient participants.

6.2 Inclusion Criteria (All groups)

- is ≥ 18 years of age.
- Participant is willing and able to give informed consent for participation in the study and comply with study procedures.

6.3 Inclusion Criteria (Group 1 and 2 only)

- is identified with a body mass index BMI ≥ 30 (or ≥ 25 for South Asian population groups) and excess body fat.

6.4 Exclusion Criteria (All groups)

The participant may not enter the study if any of the following apply:

- unable to understand and speak English sufficiently to give informed consent and complete the research assessments.

6.5 Exclusion Criteria (Group 1 and 2 only)

- pregnant or imminently intending to become pregnant.
- persons with pacemakers or other electronic medical implants.
- currently or within the past three months participated in a weight management programme (including pharmacotherapy or bariatric surgery).
- visiting the GP for weight management.
- the GP deems it inappropriate to make an opportunistic intervention on weight management. This includes personal medical reasons known to the GP, such as an eating disorder, or reasons related to the consultation e.g. the patient has become distressed and it would seem insensitive to make such an intervention at this time. If the GP does not consider it appropriate, then the patient will not be enrolled and randomised into the trial (see section 7.5 Randomisation, blinding, and code breaking).

7. STUDY PROCEDURES

7.1 Recruitment of GP practices

We will invite one GP practice from an area without referral schemes for weight loss to participate in the trial. It is not ethical to conduct the trial, where patients are requested to pay for a service which they could receive free of charge, within an area where local authorities commission GP referral schemes. In

some areas, such as Birmingham however, local authorities have ceased to commission GP referral schemes to commercial weight management programmes.

7.2 Recruitment of Participants (including screening, eligibility and baseline assessment)

Screening and Eligibility (Group 1 and 2 only)

On arrival at the practice, the receptionist will provide a leaflet to each patient (i.e. potential participants for Group 1 and 2) attending for a GP consultation during that recruitment session. The leaflet will inform patients that everyone visiting the GP that session will be asked, by an investigator, to take some measurement before their GP appointment to see if they are eligible to take part in a short study. The leaflet will state that to be eligible for the study, we need to take height, weight, and body fat measurements and that if patients were eligible, would be asked to provide informed consent before taking part. In practices where patients' check-in for their appointment via an automated computer system upon arrival, rather than seeing a receptionist, the leaflet will be positioned by the check-in system, and the on-screen message will be programmed to ask the patient to take one.

Following this, the researcher will approach the patient and ask if they would like to be assessed for eligibility. If the patient agrees, both the researcher and patient will go into a private consultation room. Here, the researcher will measure height and weight and percentage body fat of willing patients in a vacant consultation room using medically approved and validated weighing scales (Tanita portable body composition analyser, model SC 240 MA); the researcher will ask participants to remove excess clothing, e.g. coats and large jumpers, and shoes to increase accuracy of body weight, body fat, and height.

If the patient is not eligible to take part in the study, the researcher will state this, thank them for their time, and tell the patient that any information collected up until this point will be passed to clinical staff to update GP records if they wish, and subsequently destroyed. The researcher will invite patients meeting the trial eligibility criteria (see sections 6.2/6.4, Inclusion and Exclusion Criteria), to participate "in a study about people's responses to GP's discussion of their weight"; the researcher will explain the trial to the interested patients and answer any questions they may have, as well as provide them with a trial Patient Information Sheet (PIS) for future reference. If the patient is willing to participate, the researcher will seek immediate written informed consent to participate in the trial (i.e. trial consent) prior to their appointment with the GP. It is inherent in the nature of brief opportunistic advice that patient participants cannot be given warning of this, or it ceases to be opportunistic.

We will ask to keep the anthropometric and demographic data of patients who are eligible but decline to participate in the trial, however will destroy these at the first opportunity if the patient states they do not want these measures kept by the researcher. The researcher will record evidence of verbal consent for this on the Trial Screening Form.

Recruitment of GPs (Group 3)

Participants for Group 3 will be recruited when a researcher visits the practice to conduct training. GPs who will be delivering the brief intervention to patient participants (Group 1 and 2) will be receiving training on this day and by default, all will be eligible for participation in the study.

Table 2. Data to be collected by researcher during baseline visit (pre-GP consultation).
<p>Form 1 – BWeL-B Trial Screening form <i>(These data are to identify potential participants).</i></p> <ul style="list-style-type: none"> • Name <i>(to identify the record)</i> • Date of birth <i>(to establish age and for identification)</i> • Ethnic group ([optional] for trial purposes) • Height, weight and percentage body fat <i>(to assess eligibility for the trial and to update GP medical records)</i> • Gender <p>Form 2 – Written evidence of consent <i>(for eligible and willing patient participants [i.e. groups 1 and 2] only).</i></p> <p>Form 3 – BWeL-B Participant Contact Sheet <i>(these data will only be collected for patients who are eligible and consent to be part of the trial).</i></p> <ul style="list-style-type: none"> • Address, including postcode • Telephone number(s) • Email addresses(s)

7.4 Informed Consent

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants detailing no less than: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; the known side effects and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal.

Patient participants (Groups 1 and 2) will be given the opportunity to ask the researcher any questions about the study to inform their decision of whether to participate. However, written informed consent to participate in the trial (i.e. trial consent) will be conducted prior to their appointment with the GP. It is inherent in the nature of brief opportunistic advice that patient participants consent prior to their GP appointment, or it ceases to be opportunistic. Written Informed Consent will be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site. One point of the Informed Consent form is whether patient participants are happy for the part of their GP consultation relevant to the study can be audio-recorded. It is possible for patient participants to consent to the trial however not consent to their consultation being audio-recorded. If this is the case, a sticker will be placed by the researcher onto the Randomisation Card (that the GP will open) which clearly states “Do Not Audio-record. This patient has not consented to recording. Please ignore any prompt to record the brief intervention”.

Written informed consent to participate in the trial will be conducted with GP participants (i.e. group 3) when the researcher visits the GP practice to provide training for the intervention.

7.5 Randomisation, blinding and code-breaking

Participants in Group 1 and 2 will be randomised to a treatment arm at the baseline visit, which will be conducted at their GP practice. After informed consent is obtained, the researcher will give eligible patients who are willing to participate in the trial an opaque A4 sealed envelope, which will contain a colour coded randomisation card. The envelopes will be numbered in sequence. We will use block randomisation of randomly sequenced blocks of 2 and 4 stratified by GPs, which will balance individual consulting styles. The trial statistician will be responsible for the production of randomisation schedule, prior to recruitment.

The researcher will ask patient participants to give the sealed envelope to their GP upon entering their consultation. The card inside the sealed envelope will reveal to the GP, but not the patient, which intervention to deliver. We will ask GPs not to open the randomisation envelope until they are satisfied that it is suitable for the patient participant to be included in the trial, i.e. after they have addressed the patients primary reason for visiting them and feel that it would be clinically appropriate to offer a brief intervention at this time to this patient (see section 6.3, Exclusion Criteria); once the randomisation envelope is opened then the patient has been enrolled in the trial. It would undermine the ability of the study to detect differences between the arms if we enrolled participants who did not receive an intervention. Attached to the outside of each randomisation card envelope will be a detachable 'patient withdrawal card'. The researcher will discretely write the patient participant's weight and BMI on the back of the withdrawal card before handing the sealed envelope to them so that the GP will be aware of their up-to-date measurement, if required, during the consultation. Furthermore, there will be a tick box option on the card for GPs to select, if they did not randomise the patient to the trial, indicating that the person has not been randomised and therefore not enrolled. The tick box will indicate the reason for non-enrolment, i.e. clinically inappropriate, not appropriate in the consultation, or special reasons. If 'special reasons' is selected, the GPs will be asked to state why, if they can without breaking patient confidentiality, in the space provided. The sealed envelope and withdrawal card would be returned to the patient participant after their consultation who will return to the researcher and the envelope will then be replaced at the top of the randomisation envelope pile for use by the next appropriate potential participant.

To examine the fidelity of the intervention, only the brief research component of consultations by each GP will be audio-recorded. Anonymised transcripts of these audio recordings may be used in future qualitative research. A card will be attached to the randomisation card inside the randomisation envelope reminding the GP to turn on the audio-recorder at the appropriate time during the consultation. If a participating patient (i.e. groups 1 and 2) has not consented to audio-recording of the brief intervention, the GP will be alerted to this by a sticker on the randomisation envelope.

7.6 Baseline Assessments

Group 1 and 2

There are four key purposes of this visit. First is the identification of potential participants, which is detailed above (see 7.2, Recruitment of Participants). At this point we will ask to record personal information from all potential patient participants, primarily to assess eligibility for the trial, but also if they agree to update medical records as an additional benefit to the general practice.

Second, is to invite eligible patients to join the trial. If a patient is willing to participate, written consent to participate in the trial and randomisation will take place immediately, as detailed above (see sections 7.2 and 7.4, Recruitment of Participants and Informed Consent, respectively).

Thirdly, the researcher will ask all participants, upon exit of their appointments for their randomisation card and envelope (and withdrawal card if applicable). Subsequently, the researcher will provide the patient participant with information about their local weight management service and ask if they would like to book their first appointment (Outcome #2).

Fourth, is to measure patient participants' reactions to the GP discussing weight management, immediately after their GP appointment, when they visited for reasons other than their weight (Outcome #3). The randomisation card will ask participants to rate the helpfulness and the appropriateness of the GP's very brief intervention on five-item Likert-type scales that the researcher will ask the participant to complete; this will be carried out confidentially in the investigator's room.

Where patients have not been randomised, the researcher would explain that the GP does not feel it is suitable for them to be involved with the trial at this time and therefore, they have not been enrolled; GPs will be asked to record why the patient was not randomised (see section 7.5 for details).

Group 3

Baseline assessment for GP participants will be conducted either on the day of training by the Chief Investigator or on the first day they begin delivering the intervention to patient participants. GPs will be asked to complete a questionnaire examining their views of delivering these types of opportunistic interventions to their patients who are obese (Objective #4). GPs will be asked to complete a second similar questionnaire after conducting their final opportunistic intervention in the study, which will also explore their attitudes towards each intervention script

7.7 Subsequent Visits

Follow up telephone call at three weeks (after enrolment);

A researcher will contact all patient participants (Group 1 and 2) via telephone (or by alternative methods such as email, post or text message if telephone contact is not possible) 3 weeks after their initial appointment to assess whether they attended the commercial weight loss service they were advised to attend at the appointment (Outcome #1). Following the follow up call of the final recruited participant, we will compare the attendance rates of participants randomly allocated to each intervention script (Outcome #5).

Additionally, the researcher will ask open-ended questions about participants' thoughts about the opportunistic intervention (and the script specifically) that was delivered and whether other styles may have resulted in a different reaction than the one experienced (Outcome #3).

The subsequent visit for Group 3 (GP participants) will be the conduct of a brief questionnaire and interview. The questionnaire will take approximately 5 to 10 minutes and will be conducted within the practice (i.e. GPs do not take the questionnaire away with them). Interview questions will examine participants' thoughts about the brief intervention, exploring why GPs felt as they did and whether other brief intervention scripts might be more or less acceptable than the two compared in the trial (Outcome #4). The researcher will attempt to do the interview immediately after the GP has completed the second questionnaire (face-to-face). If this is not possible, due to time restrictions, the researcher will agree a time to telephone the GP (up to one-week later) to conduct the interview over the phone. In either case (face-to-face or over the phone) the interviews will be audio-recorded and transcribed verbatim.

7.8 Discontinuation/Withdrawal of Participants from Study

Group 1 and 2

At the time of consent (see section 7.2, Recruitment of Participants), participants will be given a PIS to keep, which will provide details of what they should do if they no longer want to take part in the trial. The PIS will state that participants are free to withdraw from the trial without it affecting their care and that they would not be contacted again by the research team. The PIS will include a telephone number for participants to contact the researchers for this or other reasons. Participants who have withdrawn will not be replaced but we will use their data up to the point that they withdrew unless they request that we do not do so. There are no withdrawal criteria other than a self-request to withdraw.

Treatment withdrawal: The treatment is a referral to a commercial weight management service from the GP, delivered using two different scripts. Patient participants (groups 1 and 2) cannot withdraw from receiving the intervention as it is a natural part of the consultation. Of course, it is possible that participants may choose not to attend a weight management intervention or, having initially attended, may choose not to complete a course of treatment. Such decisions will have no effect on the follow-up of participants in the trial.

Group 3

GPs participating in the study (i.e. group 3) will also be given a PIS to keep which will provide details of what they should do if they no longer want to take part in the study. The PIS will state that GP participants are free to withdraw from the study. The PIS will include a telephone number for GP participants to contact the researchers for this or other reasons. GP participants who have withdrawn will not be replaced but we will use their data up to the point that they withdrew unless they request that we do not do so.

7.9 Definition of End of Study

The end of study is the date of the last date of follow up for the last patient participant (in either Group 1 or 2). The trial will be closed in accordance with the PC-CTU standard operating procedure.

8 INTERVENTIONS

After GPs have dealt with the participating patient's original presenting complaint(s), and have confirmed the appropriateness of proceeding, they will briefly deliver one of two treatments, which the participant is randomly allocated to. The treatments include: A referral to a CWMS stating the cost (basic cost), and referral to a CWMS stating the cost compared to the weekly cost of an item that people commonly buy but could choose not to (cost-comparison).

Consistent with the assistance orientated treatment arm of the BWeL trial ⁴, the GPs brief intervention is aimed to last no more than a few seconds. For example, in the 'basic cost' arm: *"Did you know that the best way to lose weight is to go to Slimming World or Weight Watchers? It costs about £5/6 per week but can really boost your weight loss. We can book an appointment today if you would be willing to give it a go."* The cost-comparison arm will have a relatively minor difference: *"Did you know that the best way to lose weight is to go to Slimming World or Weight Watchers? It costs about the same as two cups of coffee a week but can really boost your weight loss. We can book an appointment today if you would be willing to give it a go"* The choice of weight management service will mainly be determined by availability in the local area.

If the person agrees to referral to the CWMS, the GP will ask the participant to make an appointment at reception and to return in a month: "I know it can be difficult to lose weight, so I'd like you to return in a month to see how you are getting on". If the participant wants to try weight loss without assistance, the GP might say: "Its fine for you to try to lose weight on your own but I know it's hard. Would you like to make an appointment to return in a month to see how you are getting on?" This provides an opportunity to re-refer those who accepted referral but did not attend, refer those who tried to lose weight on their own but did not do well, prescribe orlistat to those who have followed the treatment programme but not succeeded (in line with NICE guidance), and it lets the patient participant know their doctor is taking this seriously. ⁸ If the participant wants to discuss this with their GP, the GP will encourage the participant to make another appointment to do so. (English GPs have 10 minutes per consultation).

Outside the context of the trial, we would envisage that the GP would make a referral to the weight management service in the same way s/he makes referrals to other services. We could envisage a system of direct booking, where the availability and days/times of local services are shown online on the GP receptionist's computer. However, because referral to weight management is uncommon, our GPs and patient representatives advised us it would be better to ask the research team to do this. The investigator in the practice will hold details of local groups that are available and make a booking immediately, to capitalise on the participating patient's impulse to act. If this is not possible, we will arrange to telephone the participant at the earliest convenience with details of the options available.

Commercial weight management services encourage weight loss via a healthy lifestyle such as increased physical activity, a reduced fat diet and offer group counselling for motivation and behaviour change, with target setting for weight, activity, and energy intake. Full details of the behavioural change techniques used by the three common services are available in the Lighten Up trial protocol. ⁹

8.1 Treatment Providers

As noted above, the primary treatment is delivery of a brief intervention of recommending attendance to a CWMS by the participants' GP. All GPs will receive trial specific training prior to commencing the study at their practice. We will train GPs using academic detailing methods, an established evidence-based technique for changing behaviour.¹⁰ The principal method of delivery will be face-to-face training by the research team. Training will address the evidence on the effectiveness of the commercial providers in the NHS referral schemes. We will also aim to address the lack of knowledge and hence confidence to intervene on weight management. This will be addressed by reassuring GPs that we are not expecting them to undertake nutritional and physical activity assessments. Nevertheless, we recognise that patient participants might ask their GP for specific weight loss advice and our GP advisors were struggling to say more than "eat less, do more". The training will advise GPs to deflect detailed questions about nutrition. We are not aiming to get GPs involved in behavioural change strategies or give particular or detailed advice, only allay concern that might arise from offering participating patients a 10-minute review to discuss weight management. If there is any uncertainty about treatment delivery (e.g. intervention content and methods of delivery) then GPs will be able to contact the research team for clarification.

Training will be supplemented via a video-tutorial that was designed for the BWeL trial, which will be available to GPs on a dedicated website before and during the trial. We will utilise the approach developed for the BWeL trial. The training video will be a module: 'The case for intervening in obesity'. This is designed to address GP's perceived barriers to intervene in weight management. These are that weight management is ineffective, which we will address by showing evidence that health risk is continuously associated with degree of overweight and that reduced weight reduces risk, even if the visible change is imperceptible.

To examine the fidelity of the interventions, we will seek the permission of both participants and GPs to audio-record the brief intervention component of a proportion of consultations by each GP in the practice. Most GPs will be familiar with recording their consultations as part of their training and most patients agree to this. Fidelity of both treatment arms will be assessed by recording whether a CWMS was recommended to the patient and whether or not there was supporting discussion e.g. encouragement to attend, advice on the superiority of the service over trying alone.

All patient participants will be recommended to attend an evidence-based CWMS (e.g. SW or WW). Immediately after the GP appointment, a researcher at the GP practice will provide the intervention group participants with their weight management referral packs and assist booking the participants' first appointment if they wish one.

9 STATISTICS AND ANALYSIS

9.1 Description of Statistical Methods

Descriptive analyses will be done for the primary outcome: self-reported CWMS attendance at 3-week follow up. The primary outcome will be presented as a frequency and compared to the proportion of participants that attended CWMS in the BWeL trial (i.e. 40%). Additionally, descriptive analyses will be done for the secondary outcome: participant accepting the GPs referral to a CWMS immediately after their appointment, which will be compared to the proportion of participants who accepted in the BWeL

trial (i.e. 77%). Frequencies for the primary and secondary outcomes will be presented as frequencies and compared to the BWeL outcomes using a chi-square / t-test.

GPs' reaction to raising the issue of weight management opportunistically and giving the two types of brief intervention will be summarised by presenting the frequencies of each response to question 1, 2 and 7 of GP post-trial questionnaire part 2 in a bar chart. Total score will be calculated by summing questions 3 and 4 for GP's reaction to advice to lose weight and summing questions 5 and 6 for GPs' reaction to offering support. These two total scores will be compared to the results of the BWeL trial using a paired t-test.

The qualitative data on responses to the intervention, as identified in section 8.1, will be analysed using framework analysis. This approach is a relatively quick method of qualitative enquiry that allows deductive exploration based on the aims and objectives of the interview. A thematic framework for analysis will be constructed prior to interview and unanticipated themes arising during interview will be added to the framework as appropriate. Data will be sorted and summarised under theme and subtheme headings from which the range and diversity of attitudes and experience will be summarised and explanatory linkages explored.

Fidelity of the intervention will be assessed using a rating scale for key elements in the brief intervention types and summarised as a score. These are descriptive process data and will not be compared by arm.

9.2 The Number of Participants

It is hoped that 65 participants will be recruited to this study. 60 of these will be patient participants randomized into each of the two intervention groups (30 per group). The remaining 5 participants will be GP's in a single designated GP practice. These numbers are based on the likely number of GPs that will be delivering the opportunistic intervention throughout the trial.

The trial is underpowered to detect differences between arms and the aim of this is mainly to examine responses in an exploratory manner together with qualitative data. The primary outcome measure is participants' self-reported attendance to a weight management service at a three week follow up. Given that in BWeL, 40% attended, we might expect a slightly lower proportion here. If we expect that this may be around 33%, then the 95% confidence intervals around the proportion would be +/-12%. This provides sufficient precision for us to proceed to the main trial. We will not proceed if the 95% confidence interval for attendance drops below 15%.

On average, GPs consult with 9 patients per session (session refers to morning and afternoon session). In the BWeL trial, approximately 69% of patients who were screened by the researcher were eligible for the study and randomly assigned to treatment. Based on the recruitment rate of the BWeL trial, approximately 6 patients would be eligible for the study and recruited per session. To achieve a sample size of 60 would require the researcher to be recruiting during 10 GP sessions. With the staffing available this could be achieved in two weeks.

10 DATA MANAGEMENT

10.1 Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

10.2 Data Handling, Record Keeping and Retention

The trial is being run as part of the portfolio of trials in the PC-CTU. The data management will be run in accordance with the trials unit SOPs, which are fully compliant with the DPA and Good Clinical Practice (GCP). The source documents for Group 1 and 2 participants (i.e. patient participants) will be the Trial Screening Form and Participant Contact Sheet (see Baseline Assessments, section 7.6), Case Report Forms (CRFs) and questionnaires. The source documents for Group 3 participants will be questionnaires. All documents will be securely held in locked, fire and protected storage facilities. These will be transferred from the site of the research visits to the university, and consent will explicitly be sought from participants to do so. The study database will be securely held and maintained by the PC-CTU. On completion of the trial and data cleaning, the study documentation, including patient participant identifiable information will be transferred to a secure, GCP compliant, external archiving facility. Here, the identifiable information will be held; either until the end of the trial and then destroyed or indefinitely after the end of the trial. Doing this will allow participants to be recruited into further studies or additional follow-up, and patient participants will be asked to consent to either of these options. The database will be anonymised and a secure compact disc containing the link between identification number and patient participant identifiable information will be stored in a secure archiving facility until the end of the study and then destroyed. Anonymised data will be kept securely for 5 years. (Note: there is no identifiable information taken from GP participants).

The audio-recordings of GP interviews will be transcribed verbatim within two weeks of collection. During those two weeks the Dictaphone will be securely held in locked, fire and protected storage facilities. These will be transferred from the site of the research visit and consent will be explicitly sought to do so. There will be no identifiable information on the transcribed documents. Following transcription, the audio-recordings will be deleted from the Dictaphone. Anonymised transcribed data will be kept securely for 5 years.

10.3 Data Access and Quality Assurance

Data will be kept in accordance with the Data Protection Act. The SOPs of the trials unit will be followed, which are designed to protect participants' confidentiality. Participant identifiable information will be available to the researcher conducting follow up as it is important that these data are known to them. Direct access to data will be granted to authorised representative from the Sponsor and host institution

for monitoring and/or audit of the study to ensure compliance with regulations. The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

10.4 Case Report Forms

The secure online database will incorporate an online CRF, however there will also be a paper copy of CRFs. In the context of the GP surgery it will not be possible to use an online CRF. In this case the paper CRF will be completed and data will be copied to the online version at a later date. As previously mentioned, paper CRFs will be securely held in locked, fire and protected storage facilities at the Nuffield Department of Primary Health Care Sciences building at Oxford University.

11 STUDY MANAGEMENT

The management of the study will be conducted by researchers in the Behavioural Medicine team at the University of Oxford. All members of the research team are familiar with the BWeL trial and therefore sufficiently trained to conduct this very similar study.

11.1 Study Personnel

See *Appendix E* for study personnel details.

12 QUALITY CONTROL

The study will be conducted in accordance with the current approved protocol, GCP, relevant regulations and PC-CTU SOPs. A proportion of the data will be monitored by a member of the research team who is not affiliated with the study to ensure accuracy in relation to the source documents. The investigators have received appropriate training in GCP and trial procedures.

13 ETHICAL AND REGULATORY CONSIDERATIONS

13.1 Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

13.2 Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

13.3 Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and HRA for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

13.4 Participant Confidentiality

Group 1 and 2

Participant identification will be required for the registration process. The research team will preserve the confidentiality of all data obtained; in compliance with the Data Protection Act (DPA; 1998) and PC-CTU SOP DM 01 04 “Data Management”, 23-03-2012; this includes data of trial participants. No personal identification data will be kept for patients who are eligible but refuse to participate; the research team will only keep their non-identifiable data to compare the characteristics of those who are eligible and do take part with those who are eligible and do not take part. The trial management team will monitor confidentiality. Consent will be sought from all participants for the study sponsor or their delegates, members of the study team, regulatory authorities and the PCT to have direct access to research data. If the individual agrees, all data obtained from participants who are not eligible to participate in the study will be provided to the GP practice only, if the individual agrees; the research team will not keep any of these data as they are not needed.

Group 3

With regard to GP participants, identification is not required for the registration process. However, the research team will store all data in compliance with the Data Protection Act (DPA; 1998) as described above. All information collected will be anonymised using a unique code and stored in a locked storage facility at the University of Oxford.

13.5 Other Ethical Considerations

The only ethical consideration is that patient participants (i.e. groups 1 and 2) may view their GP broaching the subject of weight opportunistically as inappropriate or unacceptable. However, in a similar study (BWeL trial) only 1 in 500 people thought the GP intervention was inappropriate and unhelpful.

14 FINANCE AND INSURANCE

14.1 Funding

The study will be funded the NIHR Oxford Biomedical Research Centre.

14.2 Participant Payments

Participants will not be compensated for their time.

14.3 GP Payments

GPs practices will be paid, through NHS service support costs, for their time to deliver the intervention, which currently is not part of standard routine. These reimbursements are on a scale determined by the Primary Care Research Network. GP participants (i.e. Group 3 participants) will not be reimbursed individually.

14.4 Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London). NHS Indemnity operates in respect of the clinical treatment that is provided.

15 PUBLICATION POLICY

The results of the current feasibility trial will be presented for publication in a peer reviewed journal. The funders have no contribution to make on decisions on publication.

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by NIHR Biomedical Research Centre. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

15.1 Dissemination plan

The purpose of this trial is to inform the development of a larger scale randomised-controlled trial and the results will be presented for publication.

Findings will be disseminated to Group 1 and 2 participants via email address where provided or via post where not available. GP participants, who were involved in the trial will also be provided with an email providing a summary of the results and how these will be used to inform the development of the larger scale trial. We will also send the results to the GP surgery to display to patients.

Disseminating research to participants and clinicians, without whom the research would not have been possible, is often overlooked and is seen as being a low priority.¹¹ There are many potential benefits to providing research results to participants including providing context for the participant on their role within the research, reducing any notion of deception or exploitation by the researcher, sharing knowledge that could lead to better quality of life or reduce the risk of future harm; provide information that is more up to date and generally more accurate than is generally available in lay information leaflets.¹² In addition, research tells us that participants agree to take part in research because they understand that the research might help future patients who are in a similar situation to them.¹³ A comprehensive dissemination strategy allows the investigators to fulfil this expectation and it shows that investigators have respect for those individuals who contributed to the research¹⁴. Despite the evidence showing its benefit, little is known about how to disseminate research findings effectively for a heterogeneous audience outside of an academic environment.

Research tells us that clinicians (those that are not recruited as participants in the study) are split on when they would prefer results to be disseminated with 30% suggesting after the trial had closed would be appropriate while 24% were happy to wait until the trial results were published¹⁵. We don't know how participants feel about this but we do know that 88.5% of participants want to be told trial results with 70.4% happy to receive an overall summary of those results¹⁶. To reflect this, we have based both of our dissemination strategies on providing a summary of the main results, rather than providing a personalised response outlining what the results might mean for a particular individual. We know much less about how research results are actually disseminated to those who participated, both clinicians and participants, and whether those receiving results thought that the information was presented in an appropriate format, whether the format had an impact on how the participant reacted to the results once known and whether the format has an effect on participants' satisfaction with their experience of taking part in the research. It is reasonable to assume that clinicians, GP participants, and patient participants will respond in different ways to the two methods of dissemination but how their reactions will be different is unknown and so research looking for differences between participant and clinician responses is needed. This will allow research teams to tailor their dissemination plans to specific audiences in the future.

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17 APPENDIX A: STUDY FLOW CHART GROUP 1 AND 2

18 APPENDIX B: STUDY FLOW CHART GROUP 3

19 APPENDIX B: SCHEDULE OF STUDY PROCEDURES GROUPS 1 AND 2*Optional* Alter as required, delete if not wanted

Procedures	Visits (insert visit numbers as appropriate)				
	Visit timing e.g. Day 0	Day 21			
	Screening + baseline	Follow up phone call.			
Informed consent	1				
Demographics	1				
Eligibility assessment	1				
Randomisation	1				
Brief opportunistic GP intervention	1				
Short interview		1			

20 APPENDIX C: SCHEDULE OF STUDY PROCEDURES GROUP 3

Procedures	Visits (insert visit numbers as appropriate)				
	Visit timing e.g. Day 0				
	Screening + baseline	Follow up questionnaire (post-trial i.e. max 4 months)	Follow up interview (post-trial i.e. max 4 months)		
Informed consent	1				
Pre-Trial Questionnaire	1				
Post-Trial Questionnaire		1			
Short interview			1		

21 APPENDIX D: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made

22 APPENDIX E: STUDY PERSONNEL

Personnel	Name	Address	Telephone	E-mail
Sponsor	The University of Oxford	The University of Oxford, Joint Research Office, Block 60, Churchill Hospital, Old Road, Headington, OX3 7LE	01865 572224	ctr@admin.ox.ac
Chief Investigator	Kate Tudor	Primary Care Health Sciences, The University of Oxford, Radcliffe Observatory Quarter,	[insert trial phone number here]	Kate.tudor@phc.ox.ac.uk

		Woodstock Road, Oxford, OX2 6GG		
Investigator	Prof. Paul Aveyard	Primary Care Health Sciences, The University of Oxford, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG		Paul.aveyard@phc.ox.a c.uk
Investigator	Prof. Susan Jebb	Primary Care Health Sciences, The University of Oxford, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG		Susan.jebb@phc.ox.acu k