# Study Protocol

**Study Title:**

**Testing the short-term effectiveness of Online Weight loss programmes: OWL**

**Short title:**

Online Weight Loss (OWL)

**Ethics Ref:**

19-SC-0210

**Trial Registration Number:**

ISRCTN 14859844

**Date and Version No:**

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**IRAS Ref:** 263985

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**Sponsor:**
University of Oxford

**Funder: NIHR Oxford Biomedical Research Centre (BRC)**

*Signature:* Susan A-Jebb — *Chief Investigator* — *Date* 11th Dec 2019

*Signature:* — *Statistician* — *Date* 16 Dec 2019

The investigators declare there are no conflicts of interest for this study.

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## 1. KEY TRIAL CONTACTS

| | |
|---|---|
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| **Funder:** | Internal funding through BRC grant and weight loss programmes provided by Slimming World, Rosemary Online and NHS Choices. |

## 2. SYNOPSIS

| | | |
|---|---|---|
| **Study Title:** | Testing the short-term effectiveness of Online Weight loss programmes: OWL | |
| Internal ref. | OWL | |
| Trial Design | Individually randomised four-arm controlled superiority trial | |
| Trial participants: | Adults (≥18 years) with a BMI ≥30kg/$m^2$ | |
| Planned Sample Size | 528 participants | |
| Intervention | Online weight loss programmes | |
| Comparator | No intervention | |
| Treatment duration | 8 weeks | |
| Final outcome | 8 weeks | |
| Planned Trial Period | 01/06/2019 to 31/05/2020 | |
| | Objectives | Outcome Measures |
| Primary Outcome | To determine the effectiveness of an online programme for weight loss compared with no intervention | Change in participants' weight from baseline to 8 weeks |
| Process Measures | • To examine engagement with the programme<br>• To examine the demographic profile of participants | • Data will be collected from the online programmes.<br>• Data will be collected by questionnaire |

## 3. ABBREVIATIONS

| | |
|---|---|
| BMI | Body Mass Index |
| CRF | Case report Form |
| CTRG | Clinical Trials & Research Governance, University of Oxford |
| CRF | Case Report Form |
| DMP | Data management Plan |
| ECRF | Electronic Case Report Form |
| GCP | Good Clinical Practice |
| GP | General Practitioner |
| HRA | Health Research Authority |
| ICF | Informed Consent Form |
| NHS | National Health Service |
| PI | Principal Investigator |
| REC | Research Ethics Committee |
| SAE | Serious Adverse Event |
| SAR | Serious Adverse Reaction |
| SOP | Standard Operating Procedure |
| TSC | Trial Steering Committee |

## 4. BACKGROUND AND RATIONALE

### Background

A quarter of all adults in the UK are obese and three-quarters of these people are seeking to lose weight, but mostly without professional support (1). While self-management interventions can be effective, the magnitude of weight loss is small and evidence suggests it is less than formal weight management programmes (2, 3).

There are a number of formal weight management programmes that lead to successful weight loss (4, 5). The most commonly used approach is a community-based behavioural weight management group, and referral to these schemes is the mainstay of publicly-funded weight management services in the UK. Randomised controlled trials suggest absolute weight losses averaging 3-7 kg at one year among individuals motivated to take action to lose weight (6, 7). But uptake of these programmes is only about 10-15% of the eligible population and there is significant interest in other approaches to weight loss.

Online programmes offer some potential advantages over traditional face to face programmes. First, they may boost overall engagement of participants. Second, face-to-face group-based interventions attract mainly women, with only one in 20 attendees being men in typical UK referral schemes, and even fewer among people who choose to fund their own attendance at these groups (8). The lack of male attendees is a deterrent to other men attending who would otherwise have chosen behavioural support to lose weight. An online programme provides a way that men could access behavioural support in a way that may be more acceptable than attending a group in person. Finally, an increase in the scale of provision of face to face behavioural weight loss programmes leads to an almost linear increases in marginal costs, whereas online provision could be more cost-effective. At a time of reduced spending on public health in many countries, this would be a major advantage.

However, the evidence pertaining to online weight loss programmes is relatively limited. A Cochrane review in 2012 included only 14 weight loss studies with a total of 2537 participants. It reported that computer-based interventions led to greater weight loss than minimal interventions (mean difference -1.5 kg; 95% confidence interval (CI) -2.1 to -0.9; two trials) but less than in-person treatment (mean difference 2.1 kg; 95% CI 0.8 to 3.4; one trial) (9). A recent review of 84 eHealth studies found a mean difference of -2.7 kg (95% CI -3.33 to -2.08) post-intervention compared with control, but of these, less than half were delivered solely through eHealth technologies and most included face to face support, sometimes from a health professional (10). In a recent trial of the WeightWatchers Online programme (11) participants were randomized to one of three groups, control or two online weight loss groups, one of which received an additional activity tracking device. Weight loss among participants in the online treatment group was significantly greater than control at 3 months (2.7 kg (95% confidence interval (CI), 2.0-3.5 kg), but not at 12 months. There was no significant difference in weight compared to the group with additional activity tracking.

One of the challenges for commissioners of weight-loss programmes is that there are a great many online programmes with differing characteristics, and the effectiveness may relate to a particular component of the intervention. It is challenging for public health researchers to evaluate all the possibilities in high-quality randomised controlled trials. A high-quality randomised controlled trial to provide evidence of a suitable standard to inform clinical guidelines by NICE or other authoritative bodies would need to follow participants for a minimum of 1 year. From our previous experience, we know that the costs of such a trial will be in excess of £500k. Before embarking on the considerable investment needed to conduct a definitive trial of the effectiveness of a weight loss programme we propose to conduct a short-term study to check whether or not these programmes lead to additional weight loss

beyond self-management. We consider the appropriate control to be a person's own self-directed efforts to lose weight, because if the intervention is no more effective than this, there is no case for the NHS to offer the additional support, and NHS intervention could be limited to encouraging self-management. This is important since these programmes will only be accessed by people with some motivation to seek weight loss support and we need to establish if referral to an online programme is more effective than self-management.

Accordingly, our aim here is to conduct a short-term, pragmatic assessment of weight loss over 8 weeks and to compare each to a single control group and not to compare programmes with each other. There is good evidence that weight loss at 8 weeks is a very good predictor of longer-term outcomes (12) in behavioural weight loss interventions. The goal of the present study is to identify programmes that might be effective in the short term which we will then take forward into a high-quality definitive trial to test the effectiveness of online programmes as an option for weight loss treatments offered in primary care.

In selecting programmes to test we have focused on those offered by the providers of group-based face to face weight loss programmes that are known to be effective, namely Slimming World and Rosemary Conley Online. These programmes are designed to be used without additional support from a health professional, are available at scale and underpinned by a business model which means they could be rapidly offered through the NHS if shown to be clinically effective. We have excluded WeightWatchers Online since there is already a trial showing weight loss at three months, and we are in discussion with the company to run a definitive trial of an enhanced version of their online programme. In addition, we will also consider the effectiveness of an online weight loss programme provided by NHS Choices since this is available at no cost and, if clinically effective, will be the best option for the NHS. However, it lacks many of the features of commercial programmes which provide more personalised support and there are concerns that it may be less effective.

## 5. OBJECTIVES AND OUTCOME MEASURES

The primary outcome is change in weight from baseline to eight weeks between each of the intervention and control groups. This will be self-reported by the participant at baseline and eight weeks.

**Process Measures**

We propose to examine the engagement of participants with the programme by assessing several process measures that may influence or explain the effectiveness of the programmes. For example, this may include the number of times participants access the website, frequency of recording of body weight and the use of programme features which vary from programme to programme. We will examine the proportion of people who are continuing their weight loss attempt at 8 weeks. We will also ask participants about weight control practices, if any, that they are using. We will also describe the population that take part in the trial in terms of gender and ethnicity, since there is evidence that face to face programmes are more commonly attended by men and people of white ethnicity.

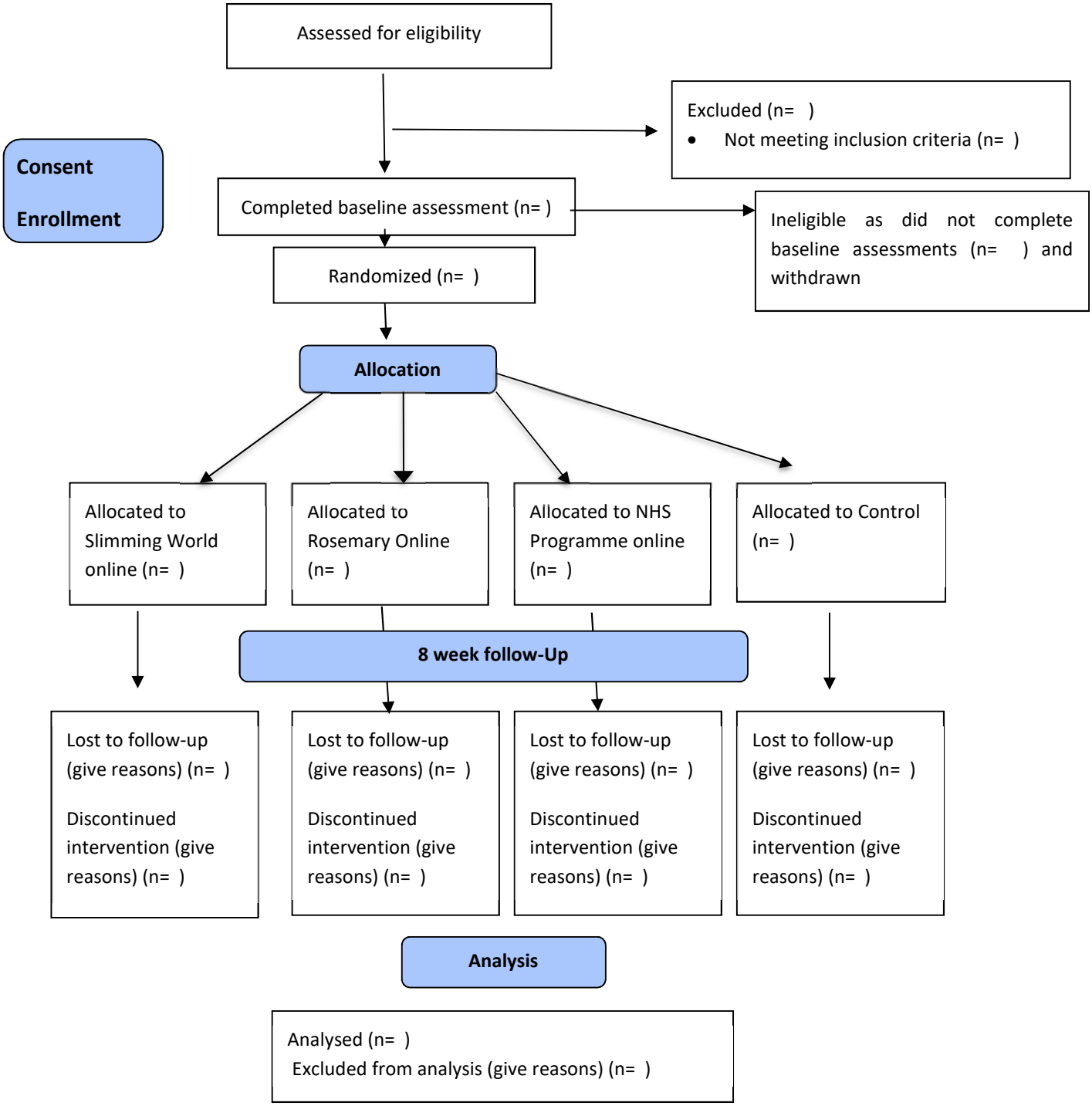
| | **Objectives** | **Outcome** |
|---|---|---|
| Primary | To determine the effectiveness of a referral to an online programme for weight loss compared with no intervention | Change in participants' weight from baseline to 8 weeks |
| Process Measures | • To examine engagement with the programme<br>• To examine the demographic profile of participants | • Data will be collected from the online programmes (for example: the number of times participants access the website, frequency of recording of body weight and the use of programme features)<br>• Demographic data collected by questionnaire |

## 6. TRIAL DESIGN

Participants will be randomised 1:1 with simple randomisation and no stratification to one of three intervention groups or control. Participants will be enrolled for 8 weeks at which point the primary outcome will be assessed. The trial design is a superiority trial between each of the intervention arms and the control arm. Participants have a 75% chance of being randomised to an intervention which is thought to be effective.

A flow diagram showing the trial design is given in Figure 1.

**Figure 1: CONSORT flow diagram:**



## 7. PARTICIPANT IDENTIFICATION

### 7.1. Trial Participants

Five hundred and four adults who are classified as obese (BMI ≥30kg/$m^2$) will be recruited. The study setting will be online.

**Inclusion Criteria**

- Aged 18 years or above
- Body Mass Index ≥30 kg/$m^2$
- Participant is able and willing to complete the baseline questionnaire in a single session
- Able to use and have access to a mobile phone, the internet and own weighing scales

**Exclusion Criteria**

- Unable to understand the study materials and interventions
- Currently following a weight loss programme (defined as a structured, prescribed and monitored programme and not a self-regulated diet)
- Pregnant, breastfeeding, or planning to become pregnant during the course of the study

## 8. TRIAL PROCEDURES

Table 1 provides an outline of the trial procedures and time points

**Table 1: Schedule of Procedures**

| Activity/Assessment | Screening | Consent | Baseline | Randomisation | On-line weight loss programme | Follow-up |
|---|---|---|---|---|---|---|
| **Months** | -1 to 0 | -1 to 0 | -1 to 0 | 0 | 8-week duration | 8 weeks (- 1 week, +4 weeks) |
| **Setting** | Online | Online | Online | Online | Online | Online/ Phone |
| **Length of assessment** | 3 mins | 3 mins | 15 mins | 1 mins | 8 weeks | 5 mins |
| **Initial eligibility screening** | X | | | | Intervention groups only | |
| **Informed Consent** | | X | | | | |
| **Weight** | X | | | | | X |
| **Height** | X | | | | | |
| **Demographic questionnaire** | | | X | | | |
| **Questionnaires**<br>• Morning/eveningness questionnaire | | | X | | | |
| **Weight Control questionnaire** | | | | | | X |
| **Engagement with online programmes** | | | | | | X |

### 8.1. Recruitment

We aim to recruit 528 participants. Participants will be recruited through a variety of means including the following: 1. GP practices: Based on a conservative response rate of 10% from similar previous studies, we will approach approximately 9000 eligible individuals from approximately 25 GP practices in England (5). The primary care provider will search their electronic registers for eligible individuals (BMI ≥30 kg/$m^2$ in the past 12 months, aged ≥ 18 years) and GPs will screen out those to whom it would be inappropriate to send a letter. The letter from their GP will invite the patient to consider taking part in the study and the patient will be directed to the study website for more information or to contact the study research team for questions. Practices will be participant identification centres only.

2. Other healthcare providers: We will also consider recruiting participants through other healthcare providers. These could include hospital doctors or private healthcare providers for example.

3. Community: We will advertise the study through online and offline social networks, online and paper newsletters and newspapers, and electronic mailing lists. We will also advertise through public facilities (including community boards, advertisement boards, notice boards in coffee shops or other communities/locations where permission for this was given) and through established personal networks.

All participants will be directed to a website which has the details of the Patient Information Sheet and the contact details of the research team if participants have further questions. If a participant wishes to take part they will click on a link that will take them to the initial eligibility assessment.

### 8.1. Initial Eligibility Assessment

Potential participants will complete an eligibility assessment online that asks them about the inclusion/ exclusion criteria. As part of the initial eligibility assessment participants will be asked to report their height and weight to calculate BMI. The reported body weight will also be used as their baseline weight. If the participant is ineligible a pop-up will explain that they do not meet the eligibility criteria for this study. If they are eligible they will be asked to provide their full name and email so that the research team can contact them. They will also be asked to create a four-digit access code for the online consent.

### 8.2. Informed Consent

As detailed above (section 8.1) participants will visit a website to read the Participant Information Sheet online and able to print out if they wish to. The participant will be allowed as much time as they wish to consider the information and have the opportunity to call the research team to ask any questions before they decide whether they will participate in the study. Following their initial eligibility assessment (section 8.1), eligible participants will be sent an email with a link to the online database where consent is taken. They will log in with their full name and access code given previously at the initial eligibility assessment (section 8.1). They will then agree to each statement of the consent form and then sign the consent form by putting their full name and access code. Once consent has been given, participants will click on a link to the electronic data capture system database which will be activated following their consent to complete the baseline assessment. Participants will be able to download a copy of the consent form to keep for their records.

### 8.3. Baseline Assessment

To assess whether people are motivated to take part and ensure that participants can use a computer, participants will be asked to complete a baseline questionnaire (Morningness/eveningness questionnaire). Only those who complete the questionnaire will be randomised. Participants will be informed in the Participant Information Sheet that they will only be able to enter the study after completing the questionnaire fully in one attempt as the system will not allow them to go back into the questionnaire to answer the remaining questions later.

We have selected a questionnaire which does not include information usually considered sensitive, which has some relationship to weight control, but which is unlikely to act as an intervention in its own right by alerting people to specific weight control behaviours. The 19-item Morningness/Eveningness Questionnaire (MEQ) (14) will assess participants' chronotype. Eating a greater proportion of food late at night, typical or "evening" people and reduced sleep are associated with weight gain. Results from this questionnaire will not be reported in the trial paper as it is used here as a method of assessing the ability to use the internet and complete trial procedures, however, the data may be used in an anonymised form for future research as described in the participant information sheet.

Participants will also be asked to complete a brief questionnaire to provide demographic information.

### 8.4. Randomisation and blinding

All eligible participants will be individually randomised to one of four arms:

1. Control; 2. NHS online weight loss programme; 3. Slimming World online; 4. Rosemary Online for eight weeks. The randomisation will be conducted using the Redcap inbuilt randomisation software. This ensures full allocation concealment as information on future allocations is not accessible to the person randomising.

The trial statistician will be blind to allocation until after the completion of the final analyses. The participants will be aware that they will be randomised to one of several online weight loss programmes or control, therefore no blinding can take place.

### 8.5. Follow-up at week 8

At week 8 all participants will be asked to report their weight and complete a Weight Control questionnaire about weight control behaviours they use. Participants will be sent a link to the questionnaire via email. If they don't complete the questionnaire online, the research team will follow them up via email, phone or text. Participants will be classified as loss to follow-up if data is not collected within 6 weeks of the 8-week follow-up point.

### 8.6. Other Study Procedures

For participants in the intervention group, engagement with the online programmes will be received from the online programmes under appropriate agreements with the companies. These include as examples: the number of times participants access the website, frequency of recording of body weight and the use of programme features which vary from programme to programme.

### 8.7. Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the trial at any time.

If a participant decides to withdraw from treatment, we will seek to retain them in the trial for follow-up by explaining the value to the trial of collecting follow up data from all participants by speaking with the participants. However, if the participant wishes to withdraw from follow up we will use their data up to the point that they withdraw unless they request that we do not do so. The reason for withdrawal will be recorded in the electronic case report form (ECRF). Participants that withdraw from the trial will not be replaced.

### 8.8. Definition of End of Trial

The end of study is the date the last participant reports their 8-week weight or their data on engagement with online programmes, whichever comes last.

## 9. INTERVENTIONS

### 9.1. Control group

Participants randomised to the control group will receive no intervention.

### 9.2. Intervention group

Participants randomised to the intervention group will receive an email explaining how to access the online programme and a voucher code that will provide access to the programme for eight weeks. The online weight loss programmes involve diet, physical activity and behaviour change components.

**Table 2: A brief description of the interventions**

| Name | Link | Features |
|---|---|---|
| **NHS weight loss plan** | http://www.nhs.uk/Livewell/weight-loss-guide/Pages/losing-weight-getting-started.aspx | Group help features<br>12-week plan<br>0.5kg – 1kg weight loss per week.<br>Easy meals apps<br>Links to other items. |
| **Slimming World** | http://www.slimmingworld.co.uk/joining-online/what-to-expect.aspx | -recipes<br>-food diaries<br>-Regular weight recording<br>-group sessions<br>-live chat support<br>- body magic challenges |
| **Rosemary Online** | https://www.rosemaryconley.com/#membership_plans | - Tracking tools e.g. weight monitoring, food and exercise diary<br>- Exercise ideas/ videos<br>- Blogs, videos and articles<br>- Access to online coaching<br>- Recipes<br>- Online community support<br>- Mobile friendly (includes App)<br>- Daily motivational reviews<br>- Coaches are nutritionally trained |

## 10. SAFETY REPORTING

This intervention is very low risk and due to this, we will not be collecting information about adverse or serious adverse events.

## 11. STATISTICS

The study results will be reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) 2010 statements (11). A full analysis plan (will be prepared and finalised before any data analysis.

### 11.1. Description of Statistical Methods

The primary statistical analysis of efficacy outcomes will be carried out on the basis of intention-to-treat (ITT). This is, after randomisation, participants will be analysed according to their allocated intervention group irrespective of what intervention they actually receive. We will endeavour to obtain full follow-up data on every participant to allow full ITT analysis, but we will inevitably experience the problem of missing data due to withdrawal, loss to follow up, or non-response to questionnaire items.

We will analyse the primary continuous outcome with a linear mixed effects model adjusting for baseline value of the relevant variable where relevant. We will analyse the proportions achieving 5% and 10% weight loss by arm through the use of a logistic mixed effects model with similar adjustments as for the primary analysis. For exploratory analyses, we will use analogous models, but interpret the data in an exploratory manner rather than confirmatory.

### 11.2. The Number of Participants

To detect a treatment difference 2 kg at eight weeks with a standard deviation for weight change of 3.9kg, a sample size of 105 per treatment arm would be required with power of 90%. This would allow for 3 comparisons between the intervention arms and the control arm, maintaining an overall type one-error rate of 5%. We will randomise 528 participants to allow for a 20% drop out rate at eight weeks follow-up.

### 11.3. The Level of Statistical Significance

The results from the trial will be prepared as comparative summary statistics (difference in proportions or means) with 95% confidence intervals. All the tests will be done at a 5% two-sided significance level.

### 11.4. Procedure for Accounting for Missing, Unused, and Spurious Data.

We will assess the sensitivity of the analysis to different assumptions about missingness using a variety of imputation methods commonly used in obesity trials. These are completer only analysis, standard baseline observation carried forward, last observation carried forward, and multiple imputation (an alternative method which assumes missing at random).

In the case of unusual outliers in the primary outcome (defined as individuals with weight change more than three standard deviations away from the mean) a sensitivity analysis will be performed excluding each of these individuals from the analysis to determine the sensitivity of the result to these individuals' outcomes.

### 11.5. Inclusion in Analysis

After randomisation, participants will be analysed according to their allocated intervention group irrespective of what intervention they actually receive. Every effort will be made for full follow-up data on every participant to allow full ITT analysis. As the participants are not blinded to their allocation, all participants will be included in the final analysis.

We will conduct a separate sensitivity analysis examining those participants that engage with the programme and also conduct completer's analysis.

### 11.6. Procedures for Reporting any Deviation(s) from the Original Statistical Plan

As far as possible, any amendments to the protocol will be reflected by complementary amendments in the statistical analysis plan prior to data lock. Where deviations from the original statistical plan are required, these will be fully justified and explained in the final analysis report.

## 12. DATA MANAGEMENT

### 12.1. Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections.

### 12.2. Data Recording and Record Keeping

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 Good Clinical Practice (GCP). A trial specific Data Management Plan (DMP) will be developed for the OWL trial outlining in detail the procedures that will be put in place to ensure that high-quality data are produced for statistical analysis.

A unique trial specific number and/or code in any database will identify the participants. All data will be directly entered online by the participant unless followed- up by the research team, using phone calls, text messages or email. There will be two databases as all information is collected online and therefore identifiable information is also collected. Only the trial team will be able to have access to the database. Trial data will be kept in compliance with the relevant Sponsor's policy, in particular: the University of Oxford: Data Protection Checklist: https://researchsupport.admin.ox.ac.uk/policy/data/checklist and **Practical: Consideration: https://researchsupport.admin.ox.ac.uk/policy/data/practical**

The data will be stored in Sentry and REDCAP and both are held on University secure servers and the University IT team provide security through Firewalls and backups of the systems are taken daily.

The trial management file and any paper CRFS (if used) will be secured in a locked cabinet in a locked room in the Department of Primary Care Health Sciences.

On completion of the trial and data cleaning, the trial documentation will be transferred to a secure, GCP compliant archiving facility, where they will be held for five years. Participants' identifiable information will be destroyed at the end of the trial. Prior to database lock, the Data Manager and the Trial Statistician will undertake a dataset review. The anonymised dataset will be stored on a University secure server with access held by the Senior Data Manager. Procedures in relation to data transfer are documented within the PC-CTU_SOP_DM108 and in accordance with the Information Governance Policy.

## 13. QUALITY ASSURANCE PROCEDURES

The trial will be conducted in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

Regular monitoring will be performed according to GCP. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents. Following written standard operating procedures, the monitors will verify that the clinical trial is conducted and data are generated, documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements.

A Trial Management Group (TMG) will provide oversight of all matters relating to participant safety and data quality. The study is not blinded, carries low risk with no rules for early termination and the trial protocol would not be modified based on interim data. Therefore it is felt that it is neither necessary nor appropriate to have a specific Data Monitoring and Ethics Committee in addition to the TMG.

## 14. ETHICAL AND REGULATORY CONSIDERATIONS

### 14.1. Declaration of Helsinki

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

### 14.2. Guidelines for Good Clinical Practice

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

### 14.3. Approvals

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

### 14.4. Reporting

The CI shall submit once a year throughout the clinical trial, or on request, an Annual Progress Report to the REC, HRA (where required), host organisation and Sponsor. In addition, an End of Trial notification and final report will be submitted to the HRA, the REC, host organisation and Sponsor.

### 14.5. Participant Confidentiality

The trial staff will ensure that the participants' anonymity is maintained and an ID number will identify participants. There will also be a secure trial management system where participant's identifiable information will be kept to contact participants throughout the trial. This will be destroyed at the end of the trial. All documents will be stored securely and only accessible by trial staff and authorised

personnel. The trial will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which requires data to be anonymised as soon as it is practical to do so.

### 14.6. Expenses, Benefits and Retention

Participants will receive a £10 voucher when they provide data at 8-weeks follow-up. This is to reimburse participants time and encourage retention for the study. Participants may benefit from taking part in this study as they may lose weight and some participants will receive free access to a treatment that would usually incur a fee. We will share the results of the trial by making them available on our website.

### 14.7. Intellectual property

Ownership of IP generated by employees of the University vests in the University. The protection and exploitation of any new IP is managed by the University's technology transfer office, Oxford University Innovations.

## 15. FINANCE AND INSURANCE

### 15.1. Funding

The study will be funded by through an NIHR Oxford Biomedical Research Centre (BRC) research grant to the Nuffield Department of Primary Care Health Sciences. The research funding will be administered by the University of Oxford.

### 15.2. 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).

## 16. PUBLICATION POLICY

The trial results will be published and all who meet the criteria for authorship will be listed as authors. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. The funders will have no role in decisions on publication.

Other dissemination methods may be used including press releases and social media; the Investigators will be involved in reviewing drafts of such items as well as the relevant media teams.

Participants will be informed of the trial results through an information sheet prepared for a lay audience that will be made available via email and made available on the department website.

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## 18. APPENDIX A: AMENDMENT HISTORY

| Amendment No. | Protocol Version No. | Date issued | Author(s) of changes | Details of Changes made |
|---|---|---|---|---|
| 1 | 2.0 | 10/06/19 | Michaela Noreik | • Pg 12. 8.1 Initial Eligibility Assessment and pg. 22 flow-diagram: Participants will be asked to provide four-digit access code instead of the research team creating it.<br>• Pg. 22 flow-diagram: Group allocation email will be sent by the database.<br>• Typing errors have been corrected throughout the document. |
| 2 | 3.0 | 25/07/19 | Michaela Noreik | Adjustment of recruitment target after noticing error in calculation of attrition rate. |
| 3 | 3.1 | 02/10/19 | Michaela Noreik | Change of statistician from Nerys Astbury to Ly-Mee Yu. Addition of trial registration number. |

## 19. APPENDIX B: GANTT CHART

| | FEB 2019 | MAR | APR | MAY | JUN | JUL | AUG | SEP | OCT | NOV | DEC | JAN 2020 | FEB | MAR | APR | MAY |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Finalise protocol | | | | | | | | | | | | | | | | |
| Finalise IRAS application | | | | | | | | | | | | | | | | |
| Patient facing documents complete | | | | | | | | | | | | | | | | |
| Review by CTRG | | | | | | | | | | | | | | | | |
| HRA submission | | | | | | | | | | | | | | | | |
| HRA approval | | | | | | | | | | | | | | | | |
| Advertising study | | | | | | | | | | | | | | | | |
| Set up of practices as PICs | | | | | | | | | | | | | | | | |
| Recruitment | | | | | | | | | | | | | | | | |
| Follow-up | | | | | | | | | | | | | | | | |
| Close of study | | | | | | | | | | | | | | | | |
| Analyses | | | | | | | | | | | | | | | | |
| Archiving | | | | | | | | | | | | | | | | |
| Writing up | | | | | | | | | | | | | | | | |

## APPENDIX C: PARTICIPANT FLOW DIAGRAM