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Online weight loss

Submission date	Recruitment status	[X] Prospectively registered
12/08/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/09/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/10/2021	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and aims
Online weight loss programmes offer advantages over traditional face-to-face programmes in so far as they can be delivered at scale at a fraction of the cost of in-person programmes and may appeal to people who are unable or unwilling to attend face to face programmes.

However, there is limited evidence on the acceptability or effectiveness of online weight loss programmes for routine weight loss treatment. The aim of this study is to explore the short-term effectiveness of a number of online weight loss programmes to inform which options warrant further investigation in a definitive longer-term randomised controlled trial.

Who can participate?
All adults with a BMI >30kg/m2 with access to a computer connected to the internet and a mobile phone and weighing scales can take part in this study.

What does the study involve?
Participants will be asked to complete questionnaires online which include demographic and current weight before being randomised to one of four conditions, access to one of three online weight loss programmes for 8 weeks: NHS weight loss programme, Slimming world online or Rosemary online, or a control group who are asked not to make any changes to their usual diet and physical activity. After 8 weeks they will be asked to send a weight measurement via an online questionnaire.

What are the possible benefits and risks of participating?
This is a very low-risk study, some participants report feeling tired during weight loss attempts but we do not expect other adverse events.

The participants randomised to the active online treatments will receive 8 weeks of free access to the programmes.

Where is the study run from?
The study is being run by the University of Oxford (Principal Investigator Prof Susan Jebb)

When is the study starting and how long is it expected to run for?
The study will begin to recruit in September 2019 and is expected to run for approximately 12 months.

Who is funding the study?
The study is funded by the National Institutes of Health Research Biomedical Research Centre Oxford.

Who is the main contact?
The main study contact is Dr Michaela Noreik, Trial Manager michaela.noreik@phc.ox.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Michaela Noreik

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
19/SC/0210

Study information

Scientific Title
Testing the short-term effectiveness of Online Weight Loss programmes

Acronym
OWL

Study objectives

Active online weight loss interventions will result in greater weight loss at 8 weeks compared with the control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/08/2019, the South Central- Oxford A Research Ethics Committee (South Central – Oxford A Research Ethics Committee, Bristol Research Ethics Committee Centre, Whitefriars, Level 3 Block B, Lewins Mead, Bristol, BS1 2NT; 0207 104 8210; nrescommittee.southcentral-oxforda@nhs.net), ref: 19/SC/0210.

Study design
Randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied
Obesity

Interventions
Participants will be randomised to one of four groups in a 1:1:1:1 ratio using simple randomisation (no stratification or blocking) to receive one of three online weight loss programmes, or a control (no intervention).

NHS weight loss plan
Participants will be provided with online access to the 12-week plan, which guides participants to achieve a weight loss of 0.5kg – 1kg per week. It includes easy meals apps and links to other items.

Slimming World
Participants will be provided with 8-weeks free of charge access to the online programme which features recipes, food diaries, Regular weight recording, group sessions, live chat support body magic challenges

Rosemary online
Participants will be provided with 8 weeks free of charge access to the online programme which

includes tracking tools e.g. weight monitoring, food and exercise diary, Exercise ideas/ videos, Blogs, videos and articles, - Access to online coaching, Recipes, Online community support, Mobile friendly (includes App), Daily motivational reviews, Coaches are nutritionally trained.

All study arms (intervention and control) will be contacted after 8 weeks to send a self-reported weight measurement and completed a questionnaire online.

Intervention Type
Behavioural

Primary outcome measure
Change in self-reported weight from baseline to 8 weeks.

Secondary outcome measures
1. Engagement with the programmes is measured using data 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).
2. Demographic data is collected using a self-reported questionnaire at baseline.

Overall study start date
01/01/2019

Completion date
04/03/2020

Eligibility

Key inclusion criteria
1. Aged 18 years or above.
2. Body Mass Index ≥30 kg/m2.
3. Able and willing to complete the baseline questionnaire in a single session.
4. Able to use and have access to a mobile phone, the internet and own weighing scales.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
528

Total final enrolment
528

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

Date of first enrolment
23/09/2019

Date of final enrolment
05/12/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Nuffield Department of Primary Care Health Sciences
Radcliffe Primary Care,
Woodstock Road
Oxford
United Kingdom
OX2 6GG

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical trials and Research Governance
Joint Research Office
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United Kingdom

OX3 7GB
01865 0000000
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Sponsor type
University/education

Website
https://researchsupport.admin.ox.ac.uk/ctrg

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal in 2020.

Intention to publish date
30/12/2021

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request after publication of the results from Prof. Susan Jebb (susan.jebb@phc.ox.ac.uk). A data-sharing agreement will need to be signed prior to anonymised data being made available.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/10/2021	20/10/2021	Yes	No
HRA research summary			28/06/2023	No	No