ISRCTN14407868 https://doi.org/10.1186/ISRCTN14407868

Optimising a digitally-delivered weight loss intervention

Submission date
04/01/2024

Recruitment status
No longer recruiting

Registration date
05/01/2024

Overall study status
Completed

Last Edited
11/03/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Digitally-delivered weight loss programmes can provide a convenient, potentially lower-cost, and scalable treatment option for people who may need to lose weight. However, outcomes are often inferior to in-person interventions. This trial aims to optimise the effectiveness of a commercial digital behavioural weight loss programme (Second Nature). The aim of this trial is to identify a combination of four intervention components that enhance weight loss, beyond the core programme, over a 24-week period. Using a factorial trial design allows us to test whether these components work independently and whether some of them work better when combined with others. We will also explore which components contribute to improvements in participant retention and engagement with the programme.

Who can participate?
Adults (aged 18 years and over) with a body mass index (BMI) of over 21 kg/m², who are signed up to the Second Nature programme. People cannot self-refer to this study and are only invited to participate after enrolment in the programme.

What does the study involve?
The study will use a factorial design that tests all possible combinations of four intervention components. Participants will be assigned to groups and will undergo the programme within these groups. Follow-up in the trial will last for 24 weeks.

Each group will be cluster randomised to one of 16 experimental conditions. Users who have registered to privately access the Second Nature behavioural weight loss programme during the recruitment window will be eligible to participate in the trial. The four new intervention components will be tested as adjuncts to the core Second Nature programme.

Participants will not be required to attend or complete any research-specific follow-up assessments, the majority of the data will be routinely collected as part of the Second Nature programme using their app and website. An acceptability questionnaire will be sent as part of the end-of-programme feedback. At baseline, all participants will complete a questionnaire to collect socio-demographic information as part of the Second Nature enrolment process. Weight data will either be automatically collected using the Bluetooth weighing scales provided at the

start of the programme (for those who opt to use them) or can be manually inputted into the app. Data for all participants will be retrieved from Second Nature's database at baseline, and three further time points following the start of the start of the programme: 4, 16, and 24 weeks.

This trial will be conducted online using the Second Nature app. Second Nature is one of the digital weight management service provider's weight loss programmes commissioned by NHS England and local commissioning groups. It is a 16-week digitally-delivered behavioural intervention designed to support people to increase their physical activity and create sustainable healthy eating habits to thus achieve weight loss.

What are the possible benefits and risks of participating?
Participants may receive useful advice about losing weight and will be prompted to weigh themselves four times throughout the trial period. There is no plausible mechanism for the intervention to increase the occurrence of any adverse events. Participants will be able to discuss any changes in wellbeing with their designated health coach. All participants will benefit by receiving the core Second Nature programme, which has been shown to be effective for weight loss in previous studies. The majority of participants will also receive at least one of the additional components which will likely confer additional benefits beyond the core programme. We do not anticipate any risks from these additional components.

Where is the study run from?
University of Oxford in collaboration with Second Nature (UK)

When is the study starting and how long is it expected to run for?
January 2023 to March 2025

Who is funding the study?
UK Medical Research Council

Who is the main contact?
Gina Wren
gina.wren@phc.ox.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
Ms Gina Wren

ORCID ID
https://orcid.org/0000-0001-9262-7043

Contact details
Nuffield Department of Primary Care Health Sciences, Radcliffe Observatory Quarter,
Woodstock Road
Oxford
United Kingdom

OX2 6GG
+44 1865 617855
gina.wren@phc.ox.ac.uk

Type(s)
Principal investigator

Contact name
Prof Susan Jebb

Contact details
Nuffield Department of Primary Care Health Sciences, Radcliffe Observatory Quarter, Woodstock Road
Oxford
United Kingdom
OX2 6GG
+44 1865 617826
susan.jebb@phc.ox.ac.uk

Additional identifiers

Study information

Scientific Title
Optimising a digitally-delivered behavioural weight loss programme: a factorial trial

Study objectives
Whilst digitally-delivered weight loss programme are promising, outcomes are inferior to in-person interventions and there are often issues with long-term engagement and retention in such programmes. Thus, the primary aim of the study is to identify a set of new components that improve weight loss in a commercial digital behavioural programme. All participants will receive a core app-based digital behavioural weight loss programme (Second Nature) and up to four of the new intervention components. The components that will be tested in this trial are: 1) a health coach introductory call, 2) coaching drop-in sessions, 3) goal setting statements, and 4) food diary review & feedback. The four selected components target supportive accountability which proposes that added human support may increase adherence to digital interventions through accountability to another person. These components are hypothesised to improve weight loss, either directly or in part, through enhanced engagement with the programme, we also hypothesise that there will be some synergistic interaction between components.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/12/2023, Medical Sciences Interdivisional Research Ethics Committee, University of Oxford (Research Services, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, United Kingdom; +44(0)1865 616575; ethics@medsci.ox.ac.uk), ref: R89540/RE001

Study design
Randomized factorial trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Weight loss

Interventions
Current interventions, as of 08/01/2024:

The study will use a factorial design that tests all possible combinations of the four intervention components. Participants will be assigned to groups of 28-32 and will undergo the programme within these groups. Follow-up in the trial will last for 24 weeks.

Each group will be cluster randomised to one of 16 experimental conditions. The four new intervention components will be tested as adjuncts to the core Second Nature programme.

The intervention components are:
1. Health coach introductory call - Participants will be offered one call from their health coach within their first week of the programme. Each call will last approximately 20 minutes. The purpose of the call is for the health coach to introduce themselves, including their qualifications as a registered dietitian or nutritionist, and for the participant to ask any specific questions they may have about the programme.
2. Coaching drop-in time – Participants will either be offered a designated 30-minute time slot each week where their health coach will be 'live' in the private chat. This provides a platform for participants to receive timely responses to questions, seek guidance, and receive personalised support, as well as providing regular, ongoing accountability. These drop-in sessions will occur once a week for the first month and then fortnightly thereafter.
3. Goal setting statement – Participants will be asked to complete a goal setting statement alongside regular reflection. Participants will be asked to complete a template where they will be prompted to set an outcome goal, a process goal, and commit to performing 1-2 actions of their choice. Participants will then be prompted on a weekly basis to answer a series of reflection questions which allows them to reflect on their progress and adjust their strategies accordingly. On a monthly basis, the health coach will prompt the participant to review and adjust their goal if they wish.
4. Food diary review & feedback – Participants will be prompted to complete a weekly food diary and will be offered a review of their food diary entries by their health coach. At the beginning of weeks 3, 6, and 10, the health coach will offer to offer to review and provide personalised feedback on 1 weeks' worth of entries for that week.

Randomisation:
A computerised algorithm will be used to randomly allocate the groups with a minimisation algorithm to ensure sex and age are balanced across the experimental conditions.

———

Previous interventions:

The study will use a 24 factorial design that tests all possible combinations of four intervention components. Participants will be assigned to groups of 28-32 and will undergo the programme within these groups. Follow-up in the trial will last for 24 weeks.

Each group will be cluster randomised to one of 16 experimental conditions. The four new intervention components will be tested as adjuncts to the core Second Nature programme.

The intervention components are:
1. Health coach introductory call - Participants will be offered one call from their health coach within their first week of the programme. Each call will last approximately 15 minutes. The purpose of the call is for the health coach to introduce themselves, including their qualifications as a registered dietitian or nutritionist, and for the participant to ask any specific questions they may have about the programme.
2. Coaching drop-in time – Participants will either be offered a designated 30-minute time slot each week where their health coach will be 'live' in the private chat. This provides a platform for participants to receive timely responses to questions, seek guidance, and receive personalised support, as well as providing regular, ongoing accountability. These drop-in sessions will occur once a week for the first month and then fortnightly thereafter.
3. Goal setting statement – Participants will be asked to complete a goal setting statement alongside regular reflection. Participants will be asked to complete a template where they will be prompted to set an outcome goal, a process goal, and commit to performing 1-2 actions of their choice. Participants will then be prompted on a weekly basis to answer a series of reflection questions which allows them to reflect on their progress and adjust their strategies accordingly. On a monthly basis, the health coach will prompt the participant to review and adjust their goal if they wish.
4. Food diary review & feedback – Participants will be prompted to complete a weekly food diary and will be offered a review of their food diary entries by their health coach. At the beginning of weeks 3, 6, and 10, the health coach will offer to offer to review and provide personalised feedback on 1 weeks' worth of entries for that week.

Randomisation:
A computerised algorithm will be used to randomly allocate the groups with a minimisation algorithm to ensure sex and age are balanced across the experimental conditions.

Intervention Type
Behavioural

Primary outcome(s)
Weight measured using bluetooth weighing scales or manual self-report in the app at 4, 16, and 24 weeks

Key secondary outcome(s))
1. Engagement with the programme measured using the number of interactions with the 3 main app functions at 4, 16, and 24 weeks
2. Drop-out of programme measured using the proportion of people who cancelled the programme at 4, 16, and 24 weeks

Completion date
31/03/2025

Eligibility

Key inclusion criteria
1. Signed up to privately access the Second Nature programme
2. Aged ≥18 years
3. BMI >21 kg/m²
4. Able to access the internet with a smartphone or laptop and be willing to install the Second Nature app on their device

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1418

Key exclusion criteria
1. Past or present diagnosis of an eating disorder
2. Currently pregnant

Date of first enrolment
08/01/2024

Date of final enrolment
16/09/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Second Nature Healthy Habits Ltd
483 Green Lanes
London
United Kingdom
N13 4BS

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the data being owned by the collaborating company.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		13/07/2024	16/07/2024	Yes	No