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Rethinking approaches to excess weight in adolescents (RENEWAL)

Submission date
10/02/2023

Recruitment status
No longer recruiting

Registration date
28/02/2023

Overall study status
Completed

Last Edited
25/04/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Approximately one in three adolescents aged 13 to 17 years is above a healthy weight. Excess weight in adolescents can lead to both physical and mental health concerns and often persists into adulthood. Behavioural weight management interventions are currently regarded as best practice in obesity treatment for children and adolescents. Unfortunately success on these programmes is limited and often non-existent when delivered at scale or over the long term. Therefore a new and novel approach is needed to treat excess weight in adolescents.
Digital interventions are interventions delivered virtually either through a website, computer programme, virtual coach or mobile app. Studies in other fields have shown promise results when using digital interventions for work with adolescents and preliminary studies using digital interventions for weight loss also show promise. Despite this there are no studies based in the United Kingdom showing the use of a digital intervention for weight management in adolescents.
Our study aims to test whether it is possible to use a mobile app for treating excess weight in overweight and obese adolescents. We will monitor the impact of the intervention on weight, nutrition, physical activity and self-esteem as well as monitoring engagement levels and satisfaction. If successful, we will progress to a bigger study to investigate whether this intervention can support adolescents to reach a healthy weight.

Who can participate?
Any young person between the ages of 13 and 17 years who is deemed above a healthy weight by a health care professional. Participants must have access to a smart phone or tablet and must not have any other significant physical or mental illnesses.

What does the study involve?
Young people will be randomised to either the intervention or the control groups (2:1). The control group will receive a 1:1 with a dietitian where they will review current behaviours, set smart goals and be signposted to further resource. The intervention group will gain access to the Second Nature app and be encouraged to use it for 12 weeks with dietitian check-ins at weeks 3 and 7. Both groups will undergo pre and post-intervention assessment and post-intervention progress, or lack thereof, will be reported to the referring HCP.

What are the possible benefits and risks of participating?
Whilst participants may lose weight and increase their health by taking part in this study, we do not know what the outcome will be which is why we are conducting this research. Participants will learn more about healthy eating, exercise and sleep for weight loss and be able to discuss their needs with a dietitian. It is hoped that the results of this study will support young people to better manage their weight in the future. This is a low-risk public health intervention therefore the disadvantages and risks to taking part are minimal. However all participants will be monitored for signs of disordered eating and mental wellbeing and will be referred back to local health services should the need arise.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
January 2022 to July 2025

Who is funding the study?
National Institute for Health and Care Research Applied Research Collaboration Oxford and Thames Valley (UK)

Who is the main contact?
Melissa Little, melissa.little@phc.ox.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
316058

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 54848, IRAS 316058

Study information

Scientific Title
REthiNking Approaches to Excess Weight in AdoLescents (RENEWAL): a randomised feasibility trial to assess a digital Intervention for managing excess weight in adolescents with overweight and obesity

Acronym
RENEWAL

Study objectives
When compared to a brief weight management intervention, the digital intervention will promote a reduction in BMI Z-score, among adolescents with excess weight.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/11/2022, Health Research Authority and Health and Care Research Wales (Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; hra.approval@nhs.net), ref: 22/NS/0143

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Summary: this is an individually randomised controlled feasibility trial. Participants, recruited via hospitals, local authorities and NHS trusts, will be randomised 2:1 to intervention group or control group. The control group will receive a brief intervention for weight management and the intervention group will receive the use of the digital intervention (app) for 12 weeks. Most study procedures will be conducted online or remotely (by telephone) including: eligibility assessment, informed consent, baseline assessment, randomisation, engagement with the app-

based intervention (or brief intervention for the control group) and 2 dietitian check-in appointments. The final appointment, a post-intervention assessment, will be done by the research team in person at a mutually acceptable location.

Baseline Assessment: Once consent has been obtained a member of the research team will support the participant virtually to complete the baseline assessments. These will include three questionnaires (Adult Eating Behaviour Questionnaire, Adolescent Food Habits Checklist, Rosenberg Self-Esteem Questionnaire) as well as obtaining basic demographic data. Participants will only be randomised once they have fully completed the questionnaires.

Randomisation: Once consent and baseline assessments have been completed, all eligible participants will be individually randomised to one of two arms in a 2:1 ratio: Intervention (12-week, app-based support), or control (brief intervention on weight management). The randomisation will be conducted using an online randomisation programme such as OxMar trying to balance gender and deprivation level across the two groups. Due to the nature of the intervention, it will not be possible to blind participants or the research team.

Intervention group: Participants randomised to the intervention group will receive an email explaining how to download and access the app-based intervention, and a voucher code that will provide access to the programme for 12 weeks. The intervention, provided by Second Nature, involves diet, activity and behaviour change components. It comprises a 3-month remote behavioural change programme with mentoring from a registered dietitian or nutritionist (health coach), peer group support, structured education articles and activity tracking technology. These elements are accessed via a smartphone or web-based application. Participants will also be asked to complete a virtual 'check-in' with the dietitian at 3 and 7 weeks. The purpose of these sessions will be to review the participants' progress, provide support, answer any questions regarding the intervention and troubleshoot any issues.

Control Group: Participants randomised to the control group will be informed of their weight status and provided with brief advice. Participants and the dietitian will work together to suggest healthy behaviour changes and set some SMART goals to work on including signposting to online resources such as the NHS Healthier Families website and Change4Life resources. The control group will not be contacted again until the end of the 12-week trial period.

Post-intervention Assessment: All participants will be asked to attend a post-intervention assessment appointment. The appointment will be done in-person at a mutually acceptable location where weight and height will be recorded by the research team. Participants will be asked to complete the same questionnaires that they completed at the baseline assessment.

Interviews: After the 12-week post intervention visit the research team will conduct qualitative interviews with all participants in the intervention group to learn more about their views on the intervention. Interviews will last approximately 30 minutes. With participants consent this will be audio-recorded. The interview will be conducted by a trained member of the study team and will be audio-recorded and then transcribed.

Intervention Type
Behavioural

Primary outcome(s)
1. Engagement (user contact with the intervention) measured using amalgamated number of contact points with the app throughout the Intervention.
2. Retention (user completion of the intervention) measured using proportion of people

attending their 12 week post-intervention appointment at the end of the intervention.
3. Recruitment (length of time to complete recruitment for the study) measured using Average number of people recruited to the intervention per month during the recruitment phase.

Key secondary outcome(s))
Measurements at baseline and follow-up:
1. BMI Z-score measured using mean difference in BMI z-score between follow-up and baseline.
2. Eating behaviours measured using mean difference in score on the Adult Eating Behaviours questionnaire between follow-up and baseline and mean difference in score on the Adolescent Food Habits Checklist between follow-up and baseline.
3. Physical activity levels measured using mean difference in steps between follow-up and baseline and number of self-record exercises done through app.
4. Self-Esteem measured using mean difference in score on the Rosenberg Self Esteem Scale between follow-up and baseline.

Completion date
01/07/2025

Eligibility

Key inclusion criteria
1. Young people aged 13-17 years living in the United Kingdom
2. BMI z-score >91st centile for BMI using the UK 1990 growth reference.
3. Participant has access to an appropriate device to install and use the app.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 years

Upper age limit
17 years

Sex
All

Key exclusion criteria
1. Participants with a mental illness or significant mental health problems that would interfere with adherence to the intervention or trial protocol.
2. Participants with a learning delay that would interfere with adherence to the intervention or trial protocol.
3. Participants with any other illness that would interfere with adherence to the intervention or trial protocol.

Date of first enrolment
01/02/2023

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR CRN: Thames Valley and South Midlands
Nuffield Department of Primary Care
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OX3 9DU

Sponsor information

Organisation
University of Oxford

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research Applied Research Collaboration Oxford and Thames Valley

Alternative Name(s)
NIHR ARC Oxford and Thames Valley, NIHR Applied Research Collaboration Oxford and Thames Valley, Oxford and Thames Valley NIHR Applied Research Collaboration, NIHR Oxford and Thames Valley Applied Research Collaborative, National Institute for Health and Care Research (NIHR) Oxford and Thames Valley Applied Research Collaboration, NIHR Applied Research. Collaboration (ARC) for Oxford and the Thames Valley, ARC OTV, OTV ARC, NIHR ARC OTV, NIHR ARC-OxTV, ARC OxTV

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Competent youth version 1.1	15/11/2022	24/02/2023	No	Yes
Participant information sheet	Parent version 1.1	15/11/2022	24/02/2023	No	Yes
Participant information sheet	Young person version 1.1	15/11/2022	24/02/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes