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PARTICIPANT INFORMATION SHEET (Competent Youth)

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

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

Currently 1 in 3 young people in the UK are overweight or obese. Carrying excess weight can lead to issues with both physical health, such as high blood pressure or diabetes, and mental health, such as anxiety or depression. It is therefore important that we try to support young people who would like to lose weight. Unfortunately current approaches to weight loss in this age group are often not successful and are not designed around the needs and lifestyles of young people. Second Nature is a an app which is used in adults to supports them to make changes to their eating, exercise and sleeping habits, the intension of this study is to compare this app with routine care in adolescents to see how successful young people are in using the app and whether it may be a helpful tool in supporting them to maintain a healthy weight.

Why have I been invited?

You have been invited to take part in this study because you are between the ages of 16-17 and are considered to be above a healthy weight range. We are hoping to involve thirty teenagers, all above a healthy weight, to take part in this study.

Do I have to take part?

No, it is up to you whether you take part or not. You are free to withdraw from the study at any time without giving a reason. A decision to withdraw from the study will not affect the usual care you receive from your GP or practice nurse or other healthcare professional.

What will happen if I decide to take part?

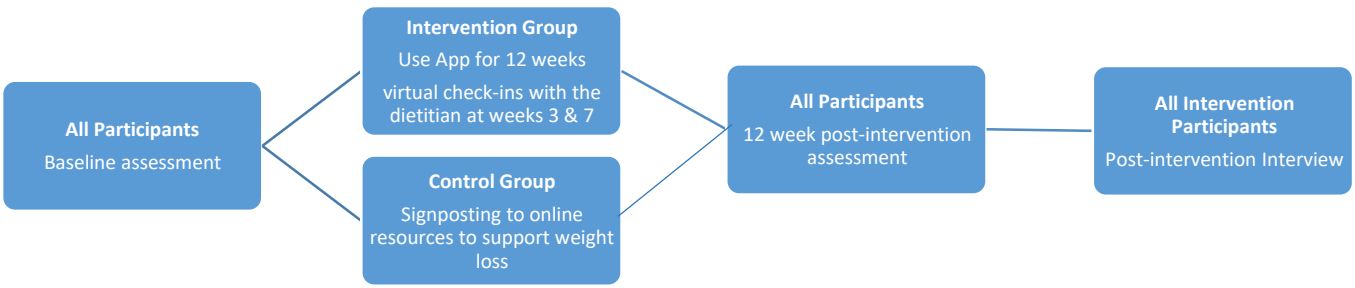
If you choose to take part in the study a research assistant will schedule a time to do a baseline assessment with you over MS Teams. Before the assessment starts we will ask you detailed questions on whether or not you agree to take part in the study, and ask you to consent to each question; this will be recorded as oral consent, or a "spoken agreement" to take part. Once consent

has been obtained we will email you a copy of the completed form for your records. After this we will conduct the baseline assessment which will involve answering some questions about eating habits and self-esteem. We will also take some demographic details such as age, gender, ethnicity and post-code.

Once the baseline assessment is complete you will be assigned to either the intervention or a control group. This will be done through randomisation which means participants will be allocated a group at random by a computer programme. If you are in the control group, you will receive a 30-60min 1:1 with a dietitian. You and the dietitian will work together to suggest healthy behaviour changes and set some SMART goals for you to work on. The control group will not be contacted again until the end of the 12 week trial period. If you are assigned to the intervention group you will be given access to an app called Second Nature that supports healthy eating and physical activity. You will be asked to use this app for the next 12 weeks in a way that works around your lifestyle. You will also be asked to do a virtual check-in with a dietitian at week three and week seven where you will discuss how you are getting on and any questions you may have.

After 12 weeks participants in both the control group and the intervention group will be asked to complete another assessment with the research team. This assessment will be done in person at a mutually acceptable venue so that measurements can be taken. Participants will be asked answer all the same questions as the baseline assessment and weight and height will be recorded.

Once the intervention is complete participants in the intervention group will be asked to take part in a 30 minute telephone interview to discuss what they thought of the app and their experiences using it. The discussion will be audio recorded and direct anonymous quotes may be used in study outputs.



What should I consider?

In order to take part in this study you must be aged 13-17 years and have a BMI z-score above the 91st centile as diagnosed by a health and care professional. Participants must also speak English, must not have any significant learning delays and must not be undergoing treatment for any current mental health issues. They must also have access to a device where they can download and regularly use the app.

If you agree to take part in the study, you would need to:

- Follow your allocated treatment to the best of your ability
- Complete questionnaires, which we will provide

- Attend 4 appointments with the dietitian or research team; 3 virtual and 1 in person

Are there any possible disadvantages or risks from taking part?

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. It is also possible that a safeguarding issue may arise during the course of the study. The lead researcher has completed both NHS and University safeguarding training and understands the protocol that must be followed in such a situation.

What are the possible benefits of taking part?

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.

Will my General Practitioner/family doctor (GP) be informed of my participation?

No, your GP will not be informed of your participation in the research study as participation in the study should not have any effect on your clinical care.

Will my taking part in the study be kept confidential?

Data collected throughout the study, will be recorded onto secure electronic Case Report Forms (CRFs), incorporated in the study's electronic database. The database will be password-protected and kept on a secure University server with access limited to members of the research team. Second Nature, a third party who are designing and delivering the digital intervention, will also have access to identifiable data and have been vetted to ensure they follow all university data protection procedures.

Information which can identify you will not be recorded on any study data collection forms (paper or electronic), apart from the main study consent form and the contact details sheet. Instead, any information recorded about you in this study will be assigned a study code (pseudonymised). A code sheet linking your study code with your personal data, will be kept separately and securely in the archiving facilities of the University of Oxford's Nuffield Department of Primary Care Health Sciences.

Qualitative interview sessions will be audio-recorded, encrypted and kept securely in a password-protected University server. They will be transferred in an encrypted manner to a University of Oxford approved transcriber (a third party) following secure University approved procedures. The transcriptions will be pseudonymised using the participant ID number. Following transcription, the original audio-recording will be deleted immediately. The pseudonymised transcriptions will be securely stored in a password-protected University server.

Following study completion, the study's electronic database, CRFs and other study documentation will remain pseudonymised with the participant study code for 5 years after the end of the study.

Responsible members of the University of Oxford and the relevant NHS Trusts may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

This study's procedures have been designed in a way that most assessments and intervention sessions are done virtually or by phone. This is to minimise your burden with regards to the time and effort needed to attend visits. You will only be asked to attend two face-to-face visits, one when you are recruited to the study, and one post-intervention to record your weight and height.

We will offer to all participants a £20 gift card at the 12-week post-intervention appointment to compensate for the time and inconvenience of attending. Participants taking part in the qualitative interviews will be offered an extra £20 gift card for their time.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study, based in the United Kingdom, is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information, name and contact details, for a year after the end of the study. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford's Nuffield Department of Primary Care Health Sciences, for 5 years after the end of the study and will then be destroyed. Please see the section on confidentiality for more information on exactly how your data will be used and stored.

Qualitative interviews, until transcription, will be encrypted and kept in a password protected University server. They will be transferred in an encrypted manner to a university approved transcriber following secure University approved procedures. The transcriptions will be psuedonymised using the participant study code. Following transcription, the original audio-recording will be deleted immediately. The de-identified transcriptions will be securely stored in a password-protected University server for 3 years before being deleted.

If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be

limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights. You can find out more about how we use your information by contacting Melissa.little@phc.ox.ac.uk.

What will happen if I don't want to carry on with the study?

Participation is voluntary and you can withdraw at any time; your current or future care will not be affected by this decision. We will give you the opportunity to tell us the reason for withdrawing if you would like to. If you request to withdraw from the study, we will use the data that we have collected from you up to that point unless you ask us not to in which case we will permanently delete your data.

What will happen to the results of this study?

We are hoping that the findings from this research will be written up in an academic publication and potentially presented at academic conferences. You will not be identifiable in any of the research outputs. Some of the research being undertaken will also contribute to the fulfilment of a doctoral thesis a copy of which will be deposited both in print and online in the Oxford University Research Archive where it will be publicly available to facilitate its use in future research; a URL address will be available to you should you wish to access it. All participants will be sent a summary of the study findings via email or post. Information about publication arrangements will be included in the participant information sheet as well as the summary sheet of the results. Participants will have been made aware since the recruitment stage that we intend to keep their contact information for up to a year after the end of the study, and this will enable us to send them the results.

What will happen at the end of the study?

This intervention has not yet been demonstrated to be effective nor is it widely available for routine NHS use and as such no arrangements have been made for continued provision of the intervention to study participants as this would not be feasible or appropriate at this stage.

What if we find something unexpected?

Should the research uncover unexpected clinical findings you will be referred, with your consent, to an appropriate health care professional for further investigation.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. Additionally, NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Melissa Little on 01865 219385 or Melissa.little@phc.ox.ac.uk or you may contact the University of Oxford Research Governance, Ethics and Assurance (RGEA) office on 01865 616480, or the head of RGEA, email ctrg@admin.ox.ac.uk.

How have patients and the public been involved in this study?

Members of the public helped to shape the ideas for this research, and to decide the questions that we are trying to answer. In designing this study we have taken into account patient opinions on the schedule of appointments that you will be asked to attend and the patient information sheets.

Who is organising and funding the study?

This research is jointly funded by the National Institute of Health Research (NIHR) and the Oxford-Wolfson-Marriott NDPCHS Graduate Scholarship. The University of Oxford is responsible for the design, conduct and publication of results from this study. No personal information about you will be shared with the funder or included in any future publication.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by North of Scotland Research Ethics Committee 2.

Participation in future research:

We would like to keep your contact details on file for participation in future research. Your contact details would be held separately from this study on a secure, password protected computer in the Nuffield Department of Primary Care. All contact will come from your research team in the first instance and agreeing to be contacted does not oblige you to take part in future research; you can be removed from this register at any time you wish.

Further information and contact details:

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Melissa Little
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Oxford University telephone number: 01865 289315
Oxford University e-mail: Melissa.Little@phc.ox.ac.uk

Thank you for taking the time to read this information sheet