

People REgulating themselVes to Achieve weIght Loss (PREVAIL) Online

Participant Information Sheet

We would like to invite you to take part in this research study, which may help you lose weight. Joining the study is entirely up to you. Before you decide we would like you to understand why this research is being done and what it would involve for you. Please take the time to read this information and discuss it with others if you wish. If anything is unclear, or if you would like more information, please contact the researchers on prevailonline@phc.ox.ac.uk. They will be more than happy to address any questions you may have.

Purpose of the Research

The aim of this study is to test whether an online weight loss intervention helps people to lose weight.

Who are we looking for?

We are looking for people living in the UK who are overweight and want to lose weight with the help of a mobile phone app.

Do I have to take part?

Taking part is entirely voluntary. You can ask questions about the study before deciding whether or not to participate by contacting the researchers on prevailonline@phc.ox.ac.uk. If you do agree to participate, you may withdraw yourself and your data from the study at any time, without giving a reason and without penalty, by advising the researchers of this decision.

What would taking part involve?

You will be invited to complete four assessments online over 12-months, for which you will be reimbursed for your time. The first assessment will occur when you have agreed to take part, then again after 12, 26, and 52 weeks. During each assessment you will be asked to weigh yourself on your own digital weighing scale and report your weight. You will also be asked to upload a photograph of your weight displayed on the scales for verification purposes, and to complete two short questionnaires. The first assessment will take approximately 20 minutes to complete. The subsequent assessments will take approximately 15 minutes.

Following the first assessment, you will be randomly assigned by a computer programme to an online weight loss programme, or a control group which will receive no treatment. We cannot predict which group you will be assigned, and it would not be a fair test of the benefits of the app if we took your preference into account. If you are randomised to the intervention group, you will be asked to download the PREVAIL app from the Apple or Android store on your mobile device, and access this using a unique code and password. This app will contain a guided weight loss programme, which will help you find weight loss strategies that work for you and fit with your lifestyle. It involves logging on every day for some weeks to allow you to try out the strategies. The app also gives you feedback

on how you are doing and helps you build a collection of useful weight loss strategies personalised to you. Once you have found what works for you, you can move to weekly check-ins.

What are the possible benefits of taking part?

We know that this approach helps people lose more weight in the short-term than trying to lose weight without support. What we need to know is whether it works in the long-term. Half the people who take part will get access to the app. Regardless of whether this helps you personally, taking part in this research helps us learn more about the science of weight loss and this can help other people wanting to lose weight in the future.

Will I be reimbursed for taking part?

You will receive financial reimbursement for your time within the study on three occasions: when you complete the study assessments at the 12-week (£5), 26-week (£8), and 52-week (£12) follow up.

What are the potential disadvantages and risks of taking part?

There are no known risks from taking part. Some people worry that weighing oneself regularly may cause undue concern about weight and food. However, research suggests that there are no negative long-term consequences of regular weighing, but we will check this through the study.

What happens if I don't want to continue with the study after I consent?

If you change your mind, you can of course stop taking part in the study. At any time, you can request your account to be deleted on the study app, and for any data collected about you to be withdrawn.

How will my information be kept confidential?

When the study is finished, your responses will be anonymised. This means it won't be possible to know that the data came from you. Any information that is collected about you during the course of the research will be kept strictly confidential. The data will be stored on a secure University server and will only be accessible to the study team.

What will happen to my data?

All data will be collected through the study specific website and app that have been developed by us in collaboration with a team of app developers. These developers been checked thoroughly by the University to make sure they follow all relevant data protection guidelines. Our website and app are hosted on secure University servers. All data will be kept confidential, accessible only to the research team.

Once all follow-up assessments are completed, we will destroy information that could identify you. The de-identified research data and records will be stored securely for up to 30 years and then deleted. Relevant members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations. At all times personal data collected from you will be held in compliance with the requirements of the GDPR and the Data Protection Act 2018.

What will happen to the results of this study?

The results will be published in scientific journals or presented at research meetings. Your individual data will never be made publicly available. However, anonymised data may be shared through secure, private channels with other researchers in the interest of open and transparent science. We will also send you a summary of the study results at the end of the study.

Who is organising and funding the research?

This study has been funded by the National Institute for Health Research (NIHR) as part of the Oxford and Thames Valley Applied Research Collaboration (ARC).

Who has reviewed this study?

This project was reviewed by and received ethics approval through the University of Oxford Central University Research Ethics Committee (Reference number: TBC).

Who do I contact if I have a concern about the study or I wish to complain?

If you have a concern about any aspect of this project, please contact the research team on prevailonline@phc.ox.ac.uk. The research team should acknowledge your concern within 10 working days and give you an indication of how they intend to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Medical Sciences Interdivisional Research Ethics Committee at the University of Oxford: Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD.

Thank you for taking the time to read this information sheet. You can download a copy of this information [here](#). If you are interested in participating in this study, please click [here](#), where you will be taken to the consent form hosted on a secure University of Oxford website.