



If you have any questions after reading this information please contact us at: **01865 617131** or **owl@phc.ox.ac.uk**



The Online Weight Loss study

Testing the short-term effectiveness of Online Weight loss programmes: OWL

PARTICIPANT INFORMATION SHEET

We'd like to invite you to take part in this research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. 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 using the contact details at the top of this page.

WHAT IS THE PURPOSE OF THE STUDY?

Research shows that community-based weight management groups are currently the most effective way for people to lose weight. These weight management services are also provided online, however we don't yet know how effective these are. The aim of this study is to find out whether participating in an online weight management programme is effective in supporting people to lose weight. For 8 weeks some participants will be asked to follow an on-line weight loss programme and some will continue their normal routine. We will measure the changes people record in their weight over an eight week period.

WHY HAVE I BEEN INVITED?

Either:

- You have seen an advert and you are interested in taking part.

Or:

- Your GP has told you about the study as their records suggest it may be beneficial for your health to lose weight based on your height and weight recorded.

Taking part in the study will not affect the usual care you receive from your GP. If you were sent a letter from your GP inviting you to take part The University of Oxford did not have access to any of your personal or medical information.

We are aiming to recruit 528 people.

WHAT SHOULD I CONSIDER?

To take part in the study you need to meet the following criteria:

- Aged 18 years or above
- Body Mass Index ≥ 30 kg/m²
- Able to use and have access to a mobile phone, the internet and own weighing scales and willing and able to complete questionnaires using an online programme.

Unfortunately you cannot take part if:

- you are currently following a weight loss programme
- you are pregnant, breastfeeding or planning pregnancy in the next eight weeks

DO I HAVE TO TAKE PART?

It is up to you whether you take part or not, it is entirely voluntary. If you do decide to take part in the study you will be asked to complete an online consent form. You are free to withdraw 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.

WHAT WILL HAPPEN NOW IF I WANT TO TAKE PART?

1. If you decide that you want to take part, please carry on reading and at the end you will find a link to some questions to assess whether you are eligible to take part. If you have any questions you can call or e-mail us - our contact details are at the top of the first page. If you are eligible to take part you will be asked by the programme to provide your full name and email address and provide a four digit study access code which you will be required to write down and keep in a safe place. If you are ineligible you will be told this immediately when you complete the eligibility assessment and you will not receive any further correspondence from the study team. This will take about 3 minutes to complete.
2. The study team will send you an email with a link to the consent form. Please, check your junk mail folder in case our e-mail may be re-directed there. You will be asked to agree to the items in the consent form and enter your full name and access code to consent to the study. You will be able to download a copy of the consent form, as well as this Participant Information Sheet to keep for your records. At the end of the consent form you will be asked to provide phone numbers, your address and post code so that we can contact you about the study and at the end of the study send your voucher in the post.
3. Once you have completed the consent form you will be given a link to complete one questionnaire which will take no longer than 15 minutes. If you don't complete the questionnaire you will not be able to continue in the study. You will have to complete the questionnaire fully in one attempt as the system will not allow you to go back into the questionnaire to answer later. These questions ask you about your demographics and sleep patterns.

4. Once you have completed this questionnaire you will be randomly (that is, as if by chance, like tossing a coin) assigned to one of four study groups: three groups will be following an online weight programme and one will be continuing their normal routine.
5. If you are assigned to one of the online weight loss groups, we will send you an email explaining how to access the online weight management programme and a voucher code that will provide access to the programme free of cost for eight weeks. The online programme involves nutrition, physical activity and behaviour change strategies to support you to manage your weight. If you are assigned to a group which does not receive a weight loss programme we will email you to let you know this and ask you to continue your normal routine.
6. After eight weeks we will send an e-mail to all participants, no matter which group they were assigned to with a link to a follow-up questionnaire. You will be asked to complete this brief questionnaire about your experiences of taking part in the study (2-7 minutes). We will also ask you to weigh yourself and send us an update of your weight. If we don't hear from you, we may write, text or phone you to collect the information.
7. If you have been allocated to a group who receive the online programme then we will be sent data from the weight loss provider about your engagement with the programme, such as how many times you access the programme and which parts you access so that we can look at what is helpful for weight loss.

ARE THERE ANY POSSIBLE DISADVANTAGES OR RISKS FROM TAKING PART?

We do not anticipate any risks from taking part in the study.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Taking part in the study may help you to lose weight and improve your overall health. We will share the results of the study by making them available on our website.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Any information that is collected about you during the course of the research will be kept strictly confidential. We will use codes to avoid identification of participants by their names. We have two separate databases, the first will record your identifiable data (i.e. contact details and consent form) and for the second database we will use an ID number and data for the study will be collected. Data will be stored on University secure servers with only the trial team having access. Any data collected on paper will be stored in a locked cupboard in a locked room.

Responsible 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 the appropriate regulations.

WILL I BE REIMBURSED FOR TAKING PART?

When you complete the follow-up questionnaire at 8 weeks we will send you a £10 gift voucher as a thank you for taking part in the study.

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 data

controller and is responsible for looking after your information and using it properly. We will follow the same standard procedures that the University of Oxford's Primary Care Clinical Trials Unit have set up to store all your information securely, including your contact details and a copy of the online consent form. We will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 3-6 months after the study has finished. As this study is online, your IP address is collected and stored and you will also be asked to provide phone numbers and your address so that the study team can contact you about the study but all this data will be deleted at the end of the study.

We will store the anonymised research data and your consent form securely at the University of Oxford for 5 years after the end of the study. We may use the anonymised data for future studies outside the remit of this study, however you will not be able to be identified.

Once you electronically agree, you will be able to download the consent form.

If you are allocated to a weight loss programme we will ask the weight loss programme to provide us with information about your engagement with the programme during the 8 weeks you have access to the programme so that we can look at what is helpful for weight loss. This will be given to us securely using identification codes rather than identifiable information. As you will be enrolled with one of three providers of online weight-loss programmes, they might also collect some of your data. Please refer to their privacy policy for details about what happens to the data they hold.

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at <http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>

You can find out more about how we use your information by contacting the CI or study team email: susan.jebb@phc.ox.ac.uk or owl@phc.ox.ac.uk or the University data protection team: data.protection@admin.ox.ac.uk or 01865 280299.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

Your participation is voluntary. If you decide you do not want to take part in the research at any point that is fine, and you can withdraw at any time without giving a reason. Your future medical care will not be affected. If you would like to withdraw please contact the study team on the details at the top of the page.

WHAT WILL HAPPEN TO THE RESULTS OF THIS STUDY?

We will publish the results so that scientists and doctors know whether it is effective for people to use online weight management services. We will publish a summary of the results of our study on the website and if you would like to receive a full copy you can contact us. You will not be personally identifiable in any publication.

WHAT IF THERE IS A PROBLEM?

The University of Oxford, as Sponsor, has appropriate insurance in place in the very unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the study team on 01865 617131 or owl@phc.ox.ac.uk; or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrig@admin.ox.ac.uk.

WHO IS ORGANISING AND FUNDING THE STUDY?

The present study is funded by the National Institute for Health Research (NIHR) Biomedical Research Centre (BRC) in Oxford and the weight loss programmes are providing the services free of charge. The University of Oxford Nuffield Department of Primary Care Health Sciences is responsible for the design, conduct and publication of results from this study. No personal information about you will be shared with the funder.

WHO HAS REVIEWED THE STUDY?

All research in the NHS is reviewed by an independent group of people called the Research Ethics Committee, who protect your rights, safety, wellbeing and dignity. This study has been reviewed and given favourable opinion by the NRES Committee South Central – Oxford A REC Number 19-SC-0210.

FURTHER INFORMATION AND CONTACT DETAILS:

If you want to discuss the study in more detail please contact us, our details are at the top of the page.

Thank you for taking the time to read this information sheet