MRC | Epidemiology Unit

UNIVERSITY OF CAMBRIDGE

Participant Information Sheet

Supporting Weight Management (SWiM) Feasibility Study

SWIM
SUPPORTING WEIGHT MANAGEMENT

We invite you to take part in a research study

- Before you decide whether or not you wish to take part please take the time to read the following information carefully, it explains why the research is being done and what it will involve. Discuss it with friends, relatives and your GP/practice nurse if you wish.
- You are free to decide whether or not to take part in this research. If you choose not to take part, this will not affect the care you get from your GP.
- Ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information sheet.

Key information

- We want to test a new intervention to help people maintain weight after a weight loss programme.
- Two thirds of the people in the study will be offered a web-based intervention called "SWiM" (Supporting Weight Management).
- One third will be offered standard care in the form of a booklet of hints and tips for weight loss maintenance.
- You can stop taking part in the study at any time, without giving a reason.
- Your confidentiality will be maintained at all times. All information collected about you will be stored securely by the University of Cambridge.

Contents

How to contact us

If you have any questions about this study please talk to:

Jenny Woolston
MRC Epidemiology Unit
University of Cambridge

Tel: 01223 613420
Email: swim.study@mrc-epid.cam.ac.uk

About this study

After weight loss, people find it difficult to maintain their new weight and many regain the weight they lost. We are doing this study to find out the best way to help people maintain their weight loss, improve their health and reduce their risk of developing weight-related health problems.

What interventions are we looking at?

The SWiM feasibility study will test two interventions which are designed to help people maintain weight loss after completing a weight management programme.

Two thirds of participants will receive a new web-based weight loss maintenance intervention called "Supporting Weight Management" (SWiM) and 4 telephone support calls with a coach.
One third of participants will receive standard care which is a booklet of helpful hints and tips for weight loss maintenance.

What do we hope to find out?

We will look at whether the two intervention options help participants to maintain their weight loss. We will also get feedback from participants about their experience of the intervention options and the study in general.

How is it decided who gets the new intervention?

A computer programme will choose which group you are assigned to – this is called 'randomisation'. This is a bit like throwing a dice, we can't control which group is selected.

The rest of this leaflet explains how you might be involved in our research study.

2 Why am I being asked to take part?

You are being invited to take part because you have recently completed a weight loss programme. We are inviting 60 people in the UK to take part.

Do I have to take part?

No, it is up to you to decide whether or not to take part in the study. You are free to withdraw at any time without giving a reason. This will not affect the standard or type of care you receive.

3 What will happen and how will I be involved?

If you are interested in taking part in the study, please contact us by email or telephone. Contact details can be found on the front and back pages of this leaflet.

We will explain the study in more depth. We will then ask you some questions to check that you are able to take part. This will include questions about your current weight and your recent experience of weight loss programmes.

If you are eligible and would like to take part, we will send you a weblink to an electronic consent form for you to complete.

Online study visits

We will ask participants to complete two online questionnaires – one at the start of the study and another 6 months later. These questionnaires will include a question about your weight, so you will be asked to measure your weight at home. At the end of the study we will compare changes in weight and other outcomes between the two groups to see if the intervention has helped you or not. The questionnaires should take approximately 30 minutes to complete.

The interventions

Group 1: The standard care group: participants will receive a booklet (via email) with information to help you plan your weight loss maintenance.

Group 2: The Supporting Weight Management (SWiM) intervention is a web-based platform with a series of sessions for you to work through to help with weight loss maintenance. There are weekly web-based 'SWiM sessions' for the first 13 weeks with a follow up session at 17 weeks. You can work through these at your own pace. You will also get 4 telephone support calls from a coach over the course of the 4.5 months. The web-based platform also includes a weight tracker so that you can continue to track your weight over time.

Taking part in this study will not limit the usual care provided by your GP. You will still be able to receive other treatment from your GP during the study. After the study ends you will return back to standard care.

Interviews

At the beginning and end of the study, participants will also be asked to take part in one-to-one or online group discussions with one of the study teams' researchers about their experiences of taking part in these interventions. Participants will be selected from both intervention groups for the interviews and focus groups; weight and demographic data will also be considered in the selection. 10 participants will be invited to take part in the interviews. Four focus groups (total of 20 participants) will be held.
The discussions will be digitally recorded.

4 Possible benefits and disadvantages of taking part

Benefits of taking part

The information you provide in this study will help our research into the prevention and treatment of weight related health problems. You will be part of a unique study that may be helpful in providing better support for weight management in the UK. You will receive one of two interventions which may help to improve your health.

As a thank you for taking part, you will receive a £10 high street voucher for completing the first questionnaire and a £20 high street voucher for the 6 month questionnaire. If you take part in an interview at the end of the study you will receive a £20 voucher.

Disadvantages or risks of taking part

Other than the time it takes you to complete the online questionnaires, there should be very little risk or disadvantage to taking part.

5 If you have any questions or concerns

Questions about the study

Contact the study team:
01223 613420
Email: swim.study@mrc-epid.cam.ac.uk

If you have a formal complaint

Contact the University of Cambridge Clinical School Secretary:
Tel: 01223 333543
Email: SchoolSec@medschl.cam.ac.uk

6 How will my information be looked after?

What will happen to information about me that is collected during the study?

Information we collect during the study will be kept strictly confidential.

With your permission, information we collect will be stored in a pseudonymised form at the MRC Epidemiology Unit, University of Cambridge. You will be assigned a unique code when you first take part in SWiM. This code will be used to label all data collected during the study and is used in place of personal information. Personal identifiable information, such as the contact details we use to keep in touch with you, will be kept separate from any other data we collect. The database containing personal information is on a secured network drive at the MRC Epidemiology Unit, University of Cambridge. Interviews and focus groups will be transcribed by an external company under an appropriate confidentiality agreement and your data

will be kept anonymous and later stored on the secured network drive at the MRC Epidemiology Unit.

The SWiM intervention has been developed by a company called Cauldron Science Ltd. The SWiM platform is stored on a secure Microsoft Azure database. If you are allocated to receive the web – based intervention, your name and email address will be stored on this platform. The only people with access are the research team and the technical team at Cauldron Science Ltd. The University of Cambridge holds a data confidentiality agreement with Cauldron. They will only access the platform to provide technical support, they will not access or share data for any other purpose.

Pseudonymised data may be used to support other research in the future and may be shared with other researchers, with appropriate credentials, including those overseas or in the commercial sector. This will be solely for the purposes of research.

The University of Cambridge and the Cambridgeshire and Peterborough Clinical Commissioning Group are co-sponsors for this study based in the United Kingdom. The University of Cambridge will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Cambridge will keep identifiable information about you for 20 years after the study has finished and it will then be destroyed.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information
https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data/

What will happen to the results of the study?

When the study is completed, the results will be presented at scientific meetings and published in scientific journals. If published, your identity and personal details will be kept confidential. No information that could identify you, like your name, will be published in any report about this study. We will also continue to provide you with a summary of our findings from the study through our newsletters.
The results of this feasibility study will help us to improve the SWiM intervention, and to plan for a larger study, where we can test whether it is an effective treatment option that offers value for money for the NHS.

Who is organising and funding the study?

This study is organised by the MRC Epidemiology Unit, part of the University of Cambridge.

The study is funded by the National Institute for Health Research (NIHR). The study is co-sponsored by the University of Cambridge and NHS Cambridgeshire and Peterborough CCG.

Who has reviewed the study?

The Study has been reviewed and approved by the Health Research Authority (HRA) UK, and the Cambridge South Research Ethics Committee (REC Ref: 21/EE/0024).

Occasionally our studies may be monitored by our Sponsors. This is to ensure our research is conducted soundly and in the best interests of the participants. Your research records may be made available for this purpose to inspectors from the University of Cambridge, and NHS Cambridgeshire and Peterborough CCG.

It has already been reviewed by the NHS National Institute of Health Research, who awarded the funding for this study.

7 Contact for further information

If you would like to take part in the SWiM study, please call or email the study team.

Study Coordinator

Jenny Woolston
MRC Epidemiology Unit
University of Cambridge

Tel: 01223 613420
Email: swim.study@mrc-epid.cam.ac.uk

Chief Investigators

Dr Amy Ahern
Senior Investigator Scientist
University of Cambridge

Prof Simon Griffin
Professor of General Practice
University of Cambridge

SUPPORTING WEIGHT MANAGEMENT