

# Participant Information Sheet

## Supporting Weight Management

### During COVID-19 (SWiM-C)

## Study



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 and relatives 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 support adults with a self-help intervention that can help people prevent weight gain and support their emotional wellbeing during the COVID-19 pandemic.
- Half of the people in the study will be offered a web-based programme called “SWiM” (Supporting Weight Management).
- The other half will be offered standard care in the form of advice on diet, physical activity and mood.
- 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 and Cauldron.

### Contents

- 1 About this study
- 2 Why am I being asked to take part?
- 3 What will happen and how will I be involved?
- 4 Possible benefits and disadvantages of taking part
- 5 If you have any questions or concerns
- 6 How will my information be looked after?
- 7 Contact for further information

### How to contact us

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

**Jenny Woolston**  
MRC Epidemiology Unit  
University of Cambridge

Email: [swimcovid.study@mrc-epid.cam.ac.uk](mailto:swimcovid.study@mrc-epid.cam.ac.uk)  
Phone: 01223 613420

---

## About this study

---

Coronavirus (COVID-19) has had a huge impact on all our lives. Social distancing and isolation measures have disrupted our usual routines and habits and many people are feeling more anxious or stressed. This can make managing our weight challenging, and can have negative impacts on both our physical and mental health. Adults with overweight or obesity are at a higher risk of weight gain and the negative impacts on health.

### What treatments are we looking at?

Half of the participants will receive a new web-based weight loss maintenance programme called “Supporting Weight Management” (SWiM).

The other half of participants will receive standard advice on diet, physical activity and mood. At the end of the study participants who received standard advice will have the opportunity to try the SWiM website, and those who received SWiM will receive the standard advice materials.

### What do we hope to find out?

We will look at whether a new online self-help programme or standard advice is better at helping people to prevent weight gain and support their emotional wellbeing.

### How is it decided who gets which 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 have contacted us to show your interest in this

research. We are looking for a total of 360 people 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 phone or email. 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.

If you are eligible and you 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 4 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.

### The programmes

**Group 1:** The Supporting Weight Management (SWiM) programme is an online programme designed to help you prevent weight gain and to support good physical and mental health. The website includes weekly sessions in which you will learn new skills and create healthy habits. It also includes a weight tracker so that you can monitor your weight over time. You will receive a call from your SWiM coach after completing the week 4 session to see how you are getting on with the programme. After the study has

finished, these participants will receive the standard advice materials.

**Group 2:** The standard care group: participants will receive a booklet (via email) that will give you advice on diet, physical activity and mood. Participants in this group will receive access to the SWiM website after the study has finished.

***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 no longer have access to the intervention and will return back to standard care.***

## Interviews

At the end of the study, we will interview a small sample of participants over the telephone to find out what you thought of the two interventions and whether they helped with your weight management during this unique period.

We will also interview the SWiM coaches to learn about their experience as a coach. Any information discussed in these interviews will be kept confidential.

---

## 4 Possible benefits and disadvantages of taking part

---

### Benefits of taking part

The information you provide in this study will help us to understand how to help people to manage their weight and support their wellbeing during social distancing and isolation.

You will be part of a unique study that may be helpful in providing better support for weight management and wellbeing in the UK during this unique time. It will also inform interventions to support people with weight management in other situations. You will receive one of two treatments 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 online

survey and a £20 high street voucher for the 4 month survey.

## Disadvantages or risks of taking part

Other than the time it takes you to complete the online surveys, 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:

Phone: 01223 613420

Email: [swimcovid.study@mrc-epid.cam.ac.uk](mailto:swimcovid.study@mrc-epid.cam.ac.uk)

### If you have a formal complaint

Contact the University of Cambridge Clinical School Secretary:

Email: [SchoolSec@medschl.cam.ac.uk](mailto: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 anonymously at the MRC Epidemiology Unit, University of Cambridge. You will be assigned a unique code when you first take part in SWiM-C. 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.

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 programme, 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.

Anonymised 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 are the sponsor for this study based in the United Kingdom. The University of Cambridge will be using information from you and 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.

## **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 Medical Research Council and the National Institute for Health Research (NIHR). The study is sponsored by the University of Cambridge.

## **Who has reviewed the study?**

The Study has been reviewed by the University of Cambridge Psychology Research Ethics Committee (PREC) (REC Ref: PRE.2020.049 COV19).

Occasionally our studies may be monitored by our Sponsor. 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.

---

## **7 Contact for further information**

---

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

### **Study Coordinator**

Jenny Woolston

MRC Epidemiology Unit  
University of Cambridge  
Level 3 Institute of Metabolic Science  
Addenbrooke's  
Cambridge Biomedical Campus  
Cambridge  
CB2 0QQ

Phone: 01223 613420

Email: [swimcovid.study@mrc-epid.cam.ac.uk](mailto:swimcovid.study@mrc-epid.cam.ac.uk)

### **Chief Investigator**

Dr Amy Ahern

Senior Investigator Scientist  
University of Cambridge

**Thank you for taking the time to  
consider taking part in this study.**