

Participant Information Sheet

Supporting Weight Management (SWiM 2.0) 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, relatives and your GP 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 standard or type of care you receive.
- 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 if our intervention helps people maintain weight loss and improves their physical and psychosocial well-being after participating in a weight loss programme.
- Half of the people in the study will be offered a 14-week intervention with coach support called “SWiM” (Supporting Weight Management). This involves weekly sessions accessed on the SWiM web-platform, or using a paper-based workbook, and 4 telephone support calls with a coach.
- The other half will be offered standard care in the form of a leaflet 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.

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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 375399

Email: swim2.study@mrc-epid.cam.ac.uk

About this study

After completing a weight loss programme, people often 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. There is evidence to suggest that a type of psychological therapy called Acceptance and Commitment Therapy (ACT) can support long term weight management. We worked with patients and health professionals to develop a guided self-help programme based on ACT to support weight management after weight loss. This intervention is called SWiM (Supporting Weight Management).

What approaches are we looking at?

We want to test whether the SWiM intervention can help people to prevent weight regain and to improve their health and wellbeing after completing a weight management programme.

Half of the participants will receive the SWiM intervention, a 4-month guided self-help programme that includes telephone support calls with a coach.

The other half of participants will receive standard care and a leaflet of helpful hints and tips for weight loss maintenance.

What do we hope to find out?

We want to know which of these two approaches is best at helping people to manage their weight in the longer term and to improve their health and wellbeing. We also want to know which approach offers best value for money for the NHS. We want to understand the experiences of different groups of people taking part in the study so that we can improve the interventions and tell the NHS how they can be used nationally to help as many people as possible.

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 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 looking for 1,840 people in the UK to take part.

Unfortunately, we can only have one person per household take part in the study to avoid confusion over data from the weighing scales and the potential for a participant in the intervention group to influence a participant in the control group.

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, but we will keep information about you that we already have. This will not affect the standard or type of care you receive outside of the study.

The research team upholds the right to withdraw your participation should they feel you do not comply with study requirements or the study protocol.

3 What will happen and how will I be involved?

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

In the form, you will be asked to fill out some questions to check if you are able to take part. This will include questions about your current weight and your recent experience with weight loss programmes.

If you are eligible and would like to take part, you will be able to give electronic consent and fill out your details to receive the scales and finger-prick test.

If you prefer, you can give permission for your weight management professional to pass on your contact details to the study team who will then contact you.

Study measures

We will ask you to complete the following study measures at the start of the study and at 6 months, 12 months, and 24 months after you start the study:

Online questionnaires - about your health and wellbeing, diet, physical activity, sleep, and how you use healthcare services. These can be completed on a computer or mobile device and should take approximately 30 minutes to complete. If you cannot complete the online questionnaires, you can complete the survey over the phone.

Digital scales - Following the completion of the first questionnaire, we will send you a set of scales by Withings. You can use these scales as often as you like, but you will be asked to stand on the scales at the baseline, 6 months, 12 months and 24 months timepoints. The results will be sent via cellular data (mobile networks) to the research team database. This measure should take approximately 2 minutes to complete. The same scales will be sent to all participants so that we are capturing the exact same data from everyone. If you complete the study, you will be able to keep these scales at the end of the study.

Blood testing kit - We will also ask you to complete a finger prick blood test using a home testing kit to analyse your blood sugar levels which should take approximately 10 minutes to complete. Once the sample has been analysed, it will be disposed of.

At the end of the study, we will use these measures to compare whether the SWiM group or the Standard

Care group was better at improving the health and wellbeing of participants.

Study groups

Group 1: If you are put in the standard care group, you will receive a leaflet (via email) with information to help you plan your weight loss maintenance. You will also receive any standard care that you would normally receive after completing a weight loss programme.

Group 2: If you are put in the SWiM intervention group, you will take part in a 4-month guided self-help programme with telephone coach support which will build on what you have learned in your previous weight loss programme and will teach you new skills and strategies to support long term weight management. There are weekly 'SWiM sessions' to complete during the first 13 weeks with a follow up session at 17 weeks. You can work through each weekly session at your own pace on the SWiM web-platform or using a paper-based workbook. We estimate that each session takes about 20-30 minutes to complete. We will ask you to practice your new skills and strategies between sessions. You will also get 4 scheduled telephone support calls from a coach over the course of the 4 months, each lasting 20-30 minutes. There are also 3 optional coach calls that you can request when you need them. The web-based platform and workbook also include a weight tracker so that you can continue to track your weight over time. You will continue to have access to the SWiM workbook materials after the study ends.

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

Interviews

At 6 months and at the end of the study at 24 months, some Group 2 participants will be invited to take part in an optional online video or telephone interview with one of the study team's researchers about their experiences of taking part in this intervention. We will use the data we have collected on participants characteristics and use of the intervention to make sure

we invite people with a range of different backgrounds and experiences. A minimum of 15 participants will be invited to take part in the interviews. The discussions will be digitally recorded.

We will need to verify that your location, email address and phone number matches those from the consent stage of the study. If you don't want your interview to be video recorded, we will need you to turn the camera on at the beginning, prior to recording, for verification.

Health records

With your consent, we will follow up on your health after the study has finished to assess the longer-term effects of the two programmes. This health record follow up is optional.

We will use national data sources that hold data on your health, such as hospital attendance and whether you develop any serious health conditions such as cancer or heart disease. We will use these data sources to find out information about your health and to see what health and social care resources you have used.

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.

You will receive a set of digital scales for the baseline assessment and you can keep these for the duration of your study participation and at the end of the study. As a thank you for taking part, you will receive a £10 gift voucher for completing the 6 month assessment and a £20 gift voucher for completing the 12 and 24 month

assessments. If you take part in an interview, you will receive a £20 voucher.

Disadvantages or risks of taking part

Other than the time it takes you to complete the questionnaires, there should be very little risk or disadvantage to taking part. When completing the finger prick sample there is a small risk of bruising.

5 If you have any questions or concerns

Questions about the study

Contact the study team:

01223 375399

Email: swim2.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?

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

The University of Cambridge and the Cambridgeshire and Peterborough Integrated Care Board (ICB) are the joint sponsors for this study based in the United Kingdom.

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your:

- Name
- Date of birth
- Contact details
- NHS Number
- Your answers to questionnaires

- Your weight
- Your blood measurements

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Cambridge is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Collaborators
- Your weight loss service provider
- NHS England (for health registry data)

We will keep all information about you safe and secure by:

- Storing data securely on a secure computer network accessible only by the study team.
- All data will be held confidentially on our Secure Research Drive (SRD) which is password protected and accessed by 2 Factor Authentication.

International transfers

We may share or provide access to data about you outside the UK for research related purposes:

- For additional analyses by other researchers

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Research organisations

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law.

We will make sure your data is safe outside the UK by doing the following:

- Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.
- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/>
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/report-a-breach>

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 20 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records. If you do not want this to happen, tell us and we will stop.
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- by asking one of the research team
- by sending an email to swim2.study@mrc-epid.cam.ac.uk
- by ringing us on 01223 375399
- on the 'How we use your personal information (for medical research participants)' page on the University website
<https://www.information-compliance.admin.cam.ac.uk/data-protection/medical-research-participant-data>

Who else will see your data?

The SWiM web platform 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 SWiM 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 Science Ltd. They will only access the platform to provide technical support, they will not access or share data for any other purpose.

The cellular-scales are manufactured by a company called Withings who will be sending the scales directly to you. The research team will therefore need to share your name, address and contact details with Withings, as well as some data necessary to configure the scales (height, weight, gender, and date of birth). The University of Cambridge holds a data transfer agreement with Withings. They will only use your personal details to set up the scales and post them to you, they will not be used for any other purpose.

The data the cellular-scales send back to us will be held on secure servers at Withings and at the University of Cambridge, and will not have your name or contact details associated with them.

With your permission, we will verify that you completed a weight loss programme with the provider you are recruited from. We will need to share data with each other, including your name, date of birth, programme outcomes and study outcomes. This will be done via a secure file transfer process.

To obtain data on your health, we may also share your information with NHS England, the national provider of information and data for health and social care, the National Cancer Registry, the Healthcare Quality Improvement Partnership, and the Office of National Statistics. We will use a secure web portal to send some of your identifiable data (name, date of birth, NHS number) to these organisations. They will use this information to find the data that we requested and send this data to us in a link-anonymised form so that we can combine it with the other data we have collected as part of this study. This part of the study is optional. Your health records will be accessed after the main study has finished.

If you give us permission to, we will share data on your progress in SWiM 2.0 with your original weight loss provider, so they can find out what happens to their participants.

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 secure network drive at the MRC Epidemiology Unit.

Who is organising and funding the study?

This study is organised by the University of Cambridge.

The study is funded by the National Institute for Health Research (NIHR). The study is sponsored by the University of Cambridge and NHS Cambridgeshire and Peterborough Integrated Care Board.

Who has reviewed the study?

The study has been reviewed and approved by the Health Research Authority (HRA) UK, and the East Midlands- Derby Research Ethics Committee (REC Ref: 25/EM/0104).

Occasionally our studies may be monitored by our Sponsors. This is to ensure our research is conducted appropriately 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.

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

Chief Investigator

Dr Amy Ahern

Principal Research Associate and Programme Leader
University of Cambridge



SUPPORTING WEIGHT MANAGEMENT

Thank you for taking the time to consider taking part in 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 375399

Email: swim2.study@mrc-epid.cam.ac.uk