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Supporting Weight Management (SWiM) Study

Submission date
17/06/2025

Recruitment status
Recruiting

Registration date
17/06/2025

Overall study status
Ongoing

Last Edited
16/07/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Behavioural weight management programmes can help people lose weight and improve health outcomes, but this weight is often regained. We previously developed an intervention to support weight loss maintenance called SWiM (Supporting Weight Management). This trial aims to evaluate whether SWiM can prevent weight regain and improve long-term physical and mental health outcomes.

Who can participate?
We will recruit 1840 adults with overweight or obesity who have completed a behavioural weight management programme or a behaviour change programme to prevent or treat type 2 diabetes.

What does the study involve?
Participants will be randomly allocated to either the SWiM programme or standard care:
i) SWiM is delivered via a website, with 14 modules delivered over 4 months. It also involves telephone calls with a trained, non-specialist health coach. Participants can use a paper-based version of SWiM if preferred.
ii) The standard care group will receive no additional structured support.

At baseline, 6 months, 12 months and 24 months, we will measure weight (using “e-scales” that send us the data automatically when participants step on the scales), average blood glucose (using at-home fingerpick tests) and other physical and mental health outcomes and health economics outcomes like health resource use (using self-report questionnaires).

Our analyses will test whether SWiM is better than standard care at reducing weight regain, blood glucose, and health care costs, and improving other physical and mental health outcomes over two years. We will test whether SWiM works equally well in different groups. We will also interview a subset of participants and people involved in delivering SWiM to understand what worked, what didn’t, and why. We will then examine whether SWiM is good value for money.

What are the possible benefits and risks of participating?
Benefits of taking part
The information participants provide in this study will help our research into the prevention and treatment of weight-related health problems. Participants will be part of a unique study that

may be helpful in providing better support for weight management in the UK. Participants will receive one of two interventions which may help to improve their health.
Participants will receive a set of digital scales for the baseline assessment and can keep these for the duration of their study participation and at the end of the study. As a thank you for taking part, participants 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 participants take part in an interview, they will receive a £20 voucher.

Disadvantages or risks of taking part
Other than the time it takes 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.

Where is the study run from?
MRC Epidemiology Unit, University of Cambridge (UK)

When is the study starting and how long is it expected to run for?
November 2024 to October 2029

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Principal investigator: Amy L. Ahern, amy.ahern@mrc-epid.cam.ac.uk
Study coordinator: Jenny Woolston, Jenny.Woolston@mrc-epid.cam.ac.uk

Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
336794

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR206801, CPMS 59543

Study information

Scientific Title
Supporting Weight Management (SWiM): Evaluating the effectiveness, equity, and cost-effectiveness of using acceptance-based guided self-help to improve long-term outcomes of weight management interventions

Acronym
SWiM

Study objectives
We aim to evaluate the effectiveness, equity, and cost-effectiveness of the SWiM programme (an ACT-based guided self-help programme that addresses the specific challenges of weight loss maintenance) relative to standard care in people who have recently completed a behavioural weight loss programme.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/05/2025, East Midlands - Derby Research Ethics Committee (2 Redman Place, London, EC20 1JQ, United Kingdom; +44 207 104 8154; derby.rec@hra.nhs.uk), ref: 25/EM/0104

Study design

Pragmatic randomized single-blinded parallel group trial with 1:1 randomization

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Weight loss maintenance in adults with overweight or obesity who have recently completed one of a range of UK-commissioned standard behavioural programmes for the prevention and treatment of obesity and type 2 diabetes.

Interventions
Participants will be randomly allocated to one of two groups (intervention or control) in a 1:1 allocation using block randomisation (block size 6) stratified by prior weight loss programme and weight loss medication use. Randomisation lists will be generated by the trial statistician using Stata statistical software and incorporated into the study database by the data manager. The randomisation lists will be unknown to all other personnel, including study coordinators, outcome assessors and investigators.

Intervention
SWiM (Supporting Weight Management) is a guided self-help programme that uses acceptance-based strategies to support weight maintenance following weight loss. It aims to help people who have lost weight reflect on what has worked (and not worked) in the past, build on what works for them, and learn new strategies to overcome challenges that typically derail weight loss maintenance. The intervention includes access to an online web platform with 14 modules (SWiM sessions) consisting of psychoeducational content, reflective exercises, and behavioural experiment. Participants will also be provided with the option to receive an adapted paperbased workbook version of the module content. SWiM is intended to be a 4-month intervention, with weekly sessions for the first 3 months followed by a one-month break, and a final module at week 17. To guide them through the programme, participants receive 4 telephone support calls from a trained, non-specialist “SWiM coach” over the 4-month programme. Calls are scheduled for week 1 (activation call), week 3, week 8, and week 17. There will also be 3 optional calls that can be used at any time should the participant need additional coach support.

Control
No additional structured support will be offered, but participants will be free to use Local Authority- or NHS-commissioned services offered as standard care or self-fund their own methods.

All participants in both study arms will be asked to complete online assessments at baseline (0 months), 6, 12, and 24 months. All study procedures (measurements and interventions) are done remotely via internet.

Intervention Type
Behavioural

Primary outcome(s)

Weight (kg) is measured using a set of weighing cellular-scales (provided to all participants by the study team) at baseline, 6 months, 12 months and 24 months. The primary outcome is change in weight from baseline to 12 months.

Key secondary outcome(s))
1. 6 and 24-month change from baseline in weight (kg) measured using weighing cellular-scales

6, 12 and 24-month change from baseline in:
2. HbA1c measured using freepost finger prick home testing kits (provided and analysed by The Doctors Laboratory (TDL), United Kingdom, accredited to the international standard for medical laboratories, ISO15189)
3. emotional eating measured using the 21-item version of the Three-Factor Eating Questionnaire (TFEQ-R21)
4. binge eating measured using the Binge Eating Scale (BES)
5. psychological flexibility measured using the Acceptance and Action Questionnaires, Weight Related (AAQWR)
6. anxiety symptoms measured using the 7-item Generalized Anxiety Disorder scale (GAD-7)
7. depression symptoms measured using the 8-item Patient Health Questionnaire (PHQ-8)
8. stress measured using the 4-item Perceived Stress Scale (PSS-4)
9. wellbeing measured using the Short Warwick–Edinburgh Mental Well-being Scale (SWEMWBS)
10. physical activity using the International Physical Activity Questionnaire (IPAQ) - Short Form
11. diet measured using the Rapid Prime Diet Quality Score Screener (rPDQS)
12. sleep quality measured using the Brief version of the Pittsburgh Sleep Quality Index (B-PSQI)

Health Economic Outcomes
13. Health-resource use measured using the Modular Resource-Use Measure (MODRUM)
14. Self-reported out-of-pocket costs and loss of productivity measured using selected modified MODRUM depth questions
15. Quality-adjusted life-years (QALYs) based on HRQoL (EQ-5D-5L)
16. Work productivity measured using the Work Productivity and Impairment Questionnaire (WPAI)
(all measured at baseline, 6 months, 12 months and 24 months)

Completion date
31/10/2029

Eligibility

Key inclusion criteria
We will recruit UK adults (N=1,840) with obesity or overweight who have, in the previous 6 months, completed at least 60% of one of 5 weight loss programmes currently commissioned by the UK NHS or local authorities:
1. Tier 2 weight management programme
2. Tier 3 weight management
3. NHS Diabetes Prevention Programme
4. NHS Digital Weight Management Programme
5. NHS Diabetes Remission Programme

Other inclusion criteria
1. Age ≥18 years

2. Capable of giving informed consent
3. Good understanding of the English language (the intervention and study materials are not tailored to support non-English language speakers)
4. Willing to be randomised
5. Willing to complete study measurements
6. Able to access the web-based platform from home

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Current use of insulin
2. Previous or planned bariatric surgery
3. Current or planned pregnancy
4. Current diagnosis of eating disorder
5. A same household partner

The Study Team reserves the right to withdraw a participant at any time if they don't follow the protocol.

Date of first enrolment
15/07/2025

Date of final enrolment
15/11/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Epidemiology Unit, University of Cambridge
Institute of Metabolic Science
Cambridge Biomedical Campus

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Sponsor information

Organisation
University of Cambridge

ROR
https://ror.org/013meh722

Organisation
Cambridgeshire and Peterborough Integrated Care Board (ICB)

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Individual participant data will not be publicly available. Participant consent will allow for data to be shared in future analyses with appropriate ethical approval, and the host institution has an access policy (https://www.mrc-epid.cam.ac.uk/wp-content/uploads/2019/02/Data-Access-Sharing-Policy-v1-0_FINAL.pdf) so that interested parties can obtain the data for replication or other research purposes that are ethically approved. Data access will be available upon reasonable request (datasharing@mrc-epid.cam.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.0	08/04/2025	17/06/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes