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Supporting weight management (SWiM) feasibility study

Submission date	Recruitment status	[X] Prospectively registered
04/03/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/03/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/06/2023	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

The cost-effectiveness and long-term impact of behavioural weight management programmes depends on weight loss maintenance. Systematic reviews show that most weight is regained within 3-5 years, even after specialist-led behavioural programmes. Extended use of traditional behavioural strategies (e.g. self- monitoring, problem solving) can improve weight loss maintenance to some extent, but new approaches are needed to maximise the benefits of behavioural weight management programmes.

There is growing evidence to suggest that interventions based on acceptance and commitment therapy (ACT) may be more effective for longer-term weight control and can improve some psychological determinants of weight loss maintenance. However, to date most studies have been conducted in a US setting and the cost-effectiveness of this type of intervention has not been evaluated. Acceptance-based programmes are usually psychologist-led and the cost and scarcity of psychologists specialising in obesity could limit their use in countries with a national health care system. There is currently insufficient evidence on cost-effectiveness or the importance of facilitator expertise and mode of delivery to recommend scalable implementation of acceptance-based interventions, particularly in the context of weight loss maintenance.

We developed the SWiM (Supporting Weight Management) programme as a guided self-help programme that uses acceptance-based treatment and specifically focusses on supporting post-treatment weight loss maintenance. SWiM uses digital technology and non-specialists to minimise resources needed to deliver an acceptance-based programme at scale. SWiM is intended to be used after someone has completed a standard behavioural weight management programme, and seeks to reinforce what helped people to lose weight and teach new skills and strategies for the longer term. The current study is designed to assess the feasibility and acceptability of the SWiM intervention and to inform the development of a protocol for a full scale trial examining its cost-effectiveness compared to standard care.

Who can participate?

Persons aged 18 years or older, who have completed a weight loss programme in the last 3 months.

What does the study involve?
The SWiM feasibility study will test two programmes 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 programme 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. We will ask participants to complete two online questionnaires – one at the start of the study and another 6 months later. At the end of the study we will compare changes in weight and other outcomes between the two groups to see if the programme has helped participants or not.

What are the possible benefits and risks of participating?
BENEFITS: 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 treatments which may help to improve your health.
RISKS: Other than the time it takes you to complete the online questionnaires, there should be very little risk or disadvantage to taking part.

Where is the study run from?
MRC Epidemiology Unit (UK)

When is the study starting and how long is it expected to run for?
September 2020 to December 2022.

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

Who is the main contact?
Dr Amy Ahern, amy.ahern@mrc-epid.cam.ac.uk

Study website
https://www.mrc-epid.cam.ac.uk/research/studies/swim (under construction)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
279784

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 48220, IRAS 279784

Study information

Scientific Title
Acceptability and feasibility of an acceptance and commitment therapy-based guided self-help programme for weight loss maintenance in adults who have previously completed a behavioural weight loss programme: the SWiM feasibility study

Acronym
SWiM

Study objectives
The aim of this study is to evaluate the feasibility and acceptability of the SWiM intervention and to inform the development of a future trial which evaluates effectiveness and cost effectiveness by minimising uncertainties about trial parameters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/03/2021, Cambridge South Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8104; cambridgesouth.rec@hra.nhs.uk), ref: 21/EE/0024

Study design
Randomized; Both; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Weight loss in obesity and overweight

Interventions
Current intervention as of 24/01/2022:
Following informed consent, participants will be asked to complete online assessments at 0 and 6 months. This will include:
- Self-measured height and weight
- Questionnaires

Interventions
Following baseline measurements, the study team will notify the participant of their intervention group (randomly allocated using a computer-generated sequence) and will talk them through the intervention materials.

1. Supporting Weight Management (SWiM) programme
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 to 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 experiments. SWiM is intended to be a 4 month intervention, with weekly sessions for the first 3 months followed by a month break, then a final session at week 18. Participants are encouraged to weigh themselves weekly and to record their weight at the start of each session. Between sessions, participants are asked to complete more reflective exercises and behavioural experiments as 'SWiM Practice'. To guide them through the programme, participants receive 4 telephone support calls from a "SWiM coach" over the 4 month programme. Calls are scheduled for after session 1 (activation call), session 3, session 8 and session 14. The coach's role is to help the participant take ownership of their weight management and the calls are scripted and manualised. Automated email reminders are sent to participants to
remind them to complete sessions and calls.

2. Control Intervention
Participants who are randomised to the control arm will receive a booklet about weight loss maintenance which helps them to make a personalised weight maintenance plan and is similar to that implemented in tier 2 weight management services.
Participants will complete a series of self-report questionnaires, which will be completed online. This will include:
- Demographics questionnaire
- Quality of life and wellbeing
- Economic evaluation
- Psychosocial factors
- Intervention evaluation and intervention adherence

Participants will be given a participant specific web link to complete the questionnaire. The study coordinator will send email/phone reminders to participants if a completed questionnaire has not been received after 7 days.

Previous intervention:
Following informed consent, participants will be asked to complete online assessments at 0 and 6 months. This will include:
- Self-measured height and weight
- Questionnaires

Interventions
Following baseline measurements, the study team will notify the participant of their intervention group (randomly allocated using a computer-generated sequence) and will talk them through the intervention materials.

1. Supporting Weight Management (SWiM) programme
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 to 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 experiments. SWiM is intended to be a 4 month intervention, with weekly sessions for the first 3 months followed by a month break, then a final module at week 17. Participants are encouraged to weigh themselves weekly and to record their weight at the start of each session. Between sessions, participants are asked to complete more reflective exercises and behavioural experiments as 'SWiM Practice'. To guide them through the programme, participants receive 4 telephone support calls from a "SWiM coach" over the 4 month programme. Calls are scheduled for week 1 (activation call), week 3, week 8 and week 17. The coach's role is to help the participant take ownership of their weight management and the calls are scripted and manualised. Automated email reminders are sent to participants to
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Intervention Type
Behavioural

Primary outcome measure

Current primary outcome measure as of 24/01/2022:
1. Feasibility and acceptability outcomes:
1.1. Number and characteristics of those invited measured using data from weight management services collected during the recruitment period
1.2. Number and characteristics of the following measured using study database records collected during the recruitment period:
1.2.1. Recruited participants (by recruitment method and by study group)
1.2.2. Respondents (by recruitment method and by study group
1.2.3. Participants who withdraw or have missing data (by study group)
1.3. Recruitment rate (per month, per weight management service, and by study group) measured using study database records collected during the recruitment period
1.4. Proportion of missing data (by outcome measure) measured using study database records collected throughout the study period
1.5. Experience of participants and coaches in terms of participating in, and supporting the delivery of, the study, respectively. measured by qualitative telephone/video interviews conducted at 3 months and 6 months
1.6. Views and experiences of participants who withdraw from the study measured by qualitative telephone/video interviews conducted throughout the study period
2. Outcomes for assessment of effectiveness:
2.1. Clinical outcomes:
2.1.1. Height (cm) measured by self-report at baseline
2.1.2. Weight (kg) measured by self-report at baseline and 6 months
2.2. Quality of Life and Wellbeing:
2.2.1. Health-related quality of life measured using the EQ-5D-5L questionnaire at baseline and 6 months
2.2.2. Capability/Wellbeing measured using the ICEpop CAPability measure for Adults (ICECAP-A) at baseline and 6 months
2.3. Economic Evaluation:
2.3.1. Health/ Social Care Use measured using a bespoke resource use questionnaire at baseline and 6 months
2.3.2. Out of pocket costs measured using a bespoke resource use questionnaire at baseline and 6 months
2.4. Psychosocial factors:
2.4.1. Disinhibition measured using the Three-Factor Eating Questionnaire (TFEQ) at baseline and 6 months
2.4.2. Psychological Flexibility measured using Acceptance and Action Questionnaires (Food-related, Weight-related) at baseline and 6 months
2.4.3. Depression measured using the Patient Health Questionnaire 8-item (PHQ-8) at baseline and 6 months
2.4.4. Anxiety measured using the Generalized Anxiety Disorder 7-item (GAD-7) scale at baseline and 6 months
2.4.5. Stress measured using the Perceived Stress Scale (PSS-4) at baseline and 6 months

Previous primary outcome measure:
1. Clinical outcomes:
1.1. Height (cm) measured by self-report at baseline
1.2. Weight (kg) measured by self-report at baseline and 6 months
2. Quality of Life and Wellbeing:
2.1. Health-related quality of life (EQ-5D-5L) at baseline and 6 months
2.2. Capability/Wellbeing (ICECAP-A) at baseline and 6 months

3. Economic Evaluation:
3.1. Health/ Social Care Use (bespoke resource use questionnaire) at baseline and 6 months
3.2. Out of pocket costs (bespoke resource use questionnaire) at baseline and 6 months
4. Psychosocial factors:
4.1. Disinhibition (TFEQ) at baseline and 6 months
4.2. Psychological Flexibility (Acceptance and Action Questionnaires (Food-related, Weight-related)) at baseline and 6 months
4.3. Depression (Patient Health Questionnaire 8-item (PHQ-8)) at baseline and 6 months
4.4. Anxiety (Generalized Anxiety Disorder 7-item (GAD-7) scale) at baseline and 6 months
4.5. Stress (Perceived Stress Scale (PSS-4)) at baseline and 6 months

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/09/2020

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Age >=18 years
2. Completed a weight loss programme in the last 3 months
3. Capable of giving informed consent
4. Have a good understanding of the English language (for the pilot study, materials are not tailored to support non-English language speakers)
5. Willing to be randomised
6. Willing to complete study measurements
7. Able to access the web-based platform from home
8. Who own a set of scales that they can weigh themselves with during the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
61

Key exclusion criteria
1. Using insulin
2. Previous/planned bariatric surgery
3. Current/planned pregnancy
4. Current diagnosis of eating disorder

Date of first enrolment
01/05/2021

Date of final enrolment
11/11/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Epidemiology Unit
University of Cambridge
Box 285, Institute of Metabolic Sciences
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
University of Cambridge

Sponsor details
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+44 (0)1223769291
cad50@medschl.cam.ac.uk

Sponsor type
University/education

Website
http://www.cam.ac.uk/

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0216-20010

Funder Name
National Institute for Health Research (NIHR) (UK)

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 5.0	12/07/2022	04/10/2022	No	No
HRA research summary			28/06/2023	No	No
Plain English results			30/06/2023	No	Yes