ISRCTN12107048 https://doi.org/10.1186/ISRCTN12107048

Supporting weight management during COVID-19

Submission date
27/05/2020

Recruitment status
No longer recruiting

Registration date
28/05/2020

Overall study status
Completed

Last Edited
14/11/2022

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 15/06/2021:

Background and study aims
The social distancing and isolation measures imposed during the Coronavirus (COVID-19) pandemic mean adults with overweight and obesity may be vulnerable to weight gain and the associated negative impacts on health. The SWiM-C study is trying to find the best way to help people with overweight and obesity prevent weight gain and support good physical and mental health.
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.

Who can participate?
We are currently recruiting adults (aged over 18 years) with overweight/obesity (BMI > 25 kg/m²) and access to weighing scales at home.

What does the study involve?
We will recruit participants and randomly assign them into one of two groups: one group receives 'SWiM'; and one group receives standard advice materials. We will ask all participants to complete an online questionnaire at the beginning of the study, at 4 months, and 12 months so we can measure changes in weight and other outcomes. After the study ends, we will also interview a small sample of participants over the telephone to find out about their experience of the SWiM programme and the study.

What are the possible benefits and risks of participating?
BENEFITS:
The information provided 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. Participants 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. Participants will receive one of two treatments which may help to improve your health.
RISKS:

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

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?
April 2020 to September 2021

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

Who is the main contact?
Jenny Woolston, jenny.woolston@mrc-epid.cam.ac.uk

Previous plain English summary:

Background and study aims
The social distancing and isolation measures imposed during the Coronavirus (COVID-19) pandemic mean adults with overweight and obesity may be vulnerable to weight gain and the associated negative impacts on health. The SWiM-C study is trying to find the best way to help people with overweight and obesity prevent weight gain and support good physical and mental health.
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MRC Epidemiology Unit, University of Cambridge (UK)

When is the study starting and how long is it expected to run for?
April 2020 to February 2021 (updated 06/04/2021, previously: April 2021)

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

Who is the main contact?
Jenny Woolston, jenny.woolston@mrc-epid.cam.ac.uk

Study website
https://www.mrc-epid.cam.ac.uk/research/studies/swim-feasibility/

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 2.0 18.05.2020

Study information

Scientific Title
An acceptance and commitment therapy-based programme for weight management during the COVID-19 pandemic in people with overweight and obesity

Acronym
SWiM-C

Study objectives
Current study hypothesis as of 15/06/2021:

To evaluate the effect of SWiM on weight at 4 months and 12 months follow-up, compared to standard advice on diet, physical activity and mood.

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Previous study hypothesis:

To evaluate whether SWiM reduces weight gain over 4 months compared to standard advice on diet, physical activity and mood

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/04/2020, Cambridge Psychology Research Ethics Committee (School of the Biological Sciences, 17 Mill Lane, Cambridge, UK; +44 (0)1223 766894; Cheryl.Torbett@admin.cam.ac.uk), ref: PRE.2020.049 COV19

Study design
Pragmatic randomized single-blind parallel-group two-arm single-centre trial

Primary study design
Interventional

Secondary study design

Randomised parallel trial

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
Can be downloaded as a PDF from the link at the bottom of the following page http://www.mrc-epid.cam.ac.uk/research/studies/swim-c/information-for-participants/

Health condition(s) or problem(s) studied
Overweight and Obesity

Interventions
Current intervention as of 15/06/2021:
Participants will be randomised to either the SWiM intervention or to a standard advice wait list control using a computer-generated sequence with 1:1 allocation stratified by sex and BMI classification. If they have been allocated to the SWiM intervention, they will receive access to an online web platform with 12 modules (SWiM sessions) consisting of psychoeducational content, reflective exercises, and behavioural experiments. SWiM is intended to be a 12 week intervention, with 1 session completed per week. It also includes a weight tracker and remote support from a SWiM Coach via telephone after completing the week 4 session and via email after completing week 10 session. If allocated to standard advice waitlist control, they will be emailed a PDF of the European Association for the Study of Obesity (EASO) guidance on diet, physical activity and mood during the COVID 19 pandemic. At the end of the study participants who received standard advice will receive access to the SWiM website, and those who received SWiM will receive standard advice materials.
Participants will complete outcome assessments online at baseline, 4 months and 12 months.

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Previous interventions:

Participants will be randomised to either the SWiM intervention or to a standard advice wait list control using a computer-generated sequence with 1:1 allocation stratified by sex and BMI classification. If they have been allocated to the SWiM intervention, they will receive access to an online web platform with 12 modules (SWiM sessions) consisting of psychoeducational content, reflective exercises, and behavioural experiments. SWiM is intended to be a 12 week intervention, with 1 session completed per week. It also includes a weight tracker and remote support from a SWiM Coach via telephone after completing the week 4 session and via email after completing week 10 session. If allocated to standard advice waitlist control, they will be emailed a PDF of the European Association for the Study of Obesity (EASO) guidance on diet, physical activity and mood during the COVID 19 pandemic. At the end of the study participants who received standard advice will receive access to the SWiM website, and those who received SWiM will receive standard advice materials.
Participants will complete outcome assessments online at baseline and the end of the 12 week programme.

Intervention Type

Behavioural

Primary outcome measure
Current primary outcome measure as of 15/06/2021:

Self-reported weight (kg) at baseline and 4 and 12 months follow up

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Previous primary outcome measure:

Self-reported weight (kg) at baseline and 4 months

Secondary outcome measures
Current secondary outcome measures as of 15/06/2021:

At baseline 4 months, and 12 months:
1. General health measured using the Patient Health Questionnaire 8-item (PHQ-8)
2. Anxiety measured using the Generalized Anxiety Disorder 7-item (GAD-7) scale
3. Stress measured using the Perceived Stress Scale (PSS-4)
4. Weight-related thoughts and feelings measured using the Acceptance and Action Questionnaire Weight-Related (Revised) (AAQW-R)
5. Eating behaviour measured using the Three-Factor Eating Questionnaire (TFEQ-R21)
6. Physical activity measured using the International Physical Activity Questionnaire (IPAQ)
7. Health related quality of life measured using EQ-5D-L
8. Wellbeing measured using ICECAP-A
9. Website Usage (data analytics)
10. Demographics and intervention engagement

Previous secondary outcome measures:

At baseline and 4 months:
1. General health measured using the Patient Health Questionnaire 8-item (PHQ-8)
2. Anxiety measured using the Generalized Anxiety Disorder 7-item (GAD-7) scale
3. Stress measured using the Perceived Stress Scale (PSS-4)
4. Weight-related thoughts and feelings measured using the Acceptance and Action Questionnaire Weight-Related (Revised) (AAQW-R)
5. Eating behaviour measured using the Three-Factor Eating Questionnaire (TFEQ-R21)
6. Physical activity measured using the International Physical Activity Questionnaire (IPAQ)
7. Health related quality of life measured using EQ-5D-L
8. Wellbeing measured using ICECAP-A
9. Website Usage (data analytics)
10. Demographics and intervention engagement

Overall study start date
07/04/2020

Completion date
30/09/2021

Eligibility

Key inclusion criteria
1. Adults (Age ≥ 18 years)
2. Overweight or obesity (BMI ≥ 25kg/m²)
3. Good understanding of written English (materials are not suitable for non-English language speakers)
4. Willing to be randomised to either intervention and to complete outcome assessments online
5. 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
360

Total final enrolment
388

Key exclusion criteria
1. Bariatric surgery in the last 2 years

Date of first enrolment
08/06/2020

Date of final enrolment
07/09/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Epidemiology Unit
University of Cambridge School of Clinical Medicine
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Sponsor information

Organisation
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Sponsor type
University/education

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

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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

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

Intention to publish date
30/04/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from MRC Epidemiology Unit, University of Cambridge. Dr Amy Ahern, amy.ahern@mrc-epid.cam.ac.uk Data will become available following analyses completed by the PI and collaborators. Data request forms will need to be completed and sent to the PI for discussion with the other Principle Investigators. Consent will be obtained from participants and all data anonymised.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version V5	10/03/2021	17/03/2021	No	No
Results article		13/04/2022	14/04/2022	Yes	No
Statistical Analysis Plan	12-month analysis version 3.1	16/03/2022	20/06/2022	No	No
Protocol file	version 5.0	25/05/2021	28/09/2022	No	No
Results article	qualitative results	13/09/2022	17/10/2022	Yes	No
Results article	12-month follow up	11/11/2022	14/11/2022	Yes	No