Supporting Weight Management during COVID-19 – The SWiM-C Randomised Controlled Trial

Scientific title	An acceptance-based programme for weight management during the COVID-19 pandemic in people with overweight and obesity (SWiM-C Study).
Lay title	Supporting Weight Management during COVID-19 (SWiM-C)
Trial Registration	ISRCTN12107048
REC Reference	PRE.2020.049 COV19
Funding reference	NIHR-PGfAR RP-PG-0216-20010
Sponsor	Carolyn Read, Research Governance Officer University of Cambridge, School of Clinical Medicine, Box 111, Cambridge Biomedical Campus, Cambridge, CB2 0SP
Principal Investigator (contact for scientific queries)	Dr Amy Ahern MRC Epidemiology Unit University of Cambridge Box 285, Institute of Metabolic Sciences, CB2 0QQ 01223 769138 Ala34@cam.ac.uk
Study Coordinator (contact for public queries)	Mrs Jenny Woolston MRC Epidemiology Unit, University of Cambridge, Box 285, Institute of Metabolic Sciences, CB2 0QQ 01223 769204 Jenny.Woolston@mrc-epid.cam.ac.uk
Co-Investigators	Dr Rebecca Richards, University of Cambridge Ms Marie Stubbings, University of Cambridge Ms Fiona Whittle, University of Cambridge Ms Rebecca Jones, University of Cambridge Mr Jack Birch, University of Cambridge Professor Simon Griffin, University of Cambridge Mr Stephen Sharp, University of Cambridge Professor Andrew Hill, University of Leeds Dr Robbie Duschinsky, University of Cambridge Professor Stephen Morris, University of Cambridge Dr Carly Hughes, The Fakenham Medical Practice Professor Alan Brennan, University of Sheffield Dr Francesco Fusco, University of Cambridge Mrs Jennifer Bostock, PPI Representative

Protocol Signatures

I give my approval for the attached protocol entitled "An acceptance-based programme for weight management during the COVID-19 pandemic in people with overweight and obesity (SWiM-C randomised controlled trial)" version 5.0, dated 25/05/2021

Principal Investigators

Name: Dr Amy Ahern

Signature: _____

Date: _____

PROTOCOL REVISION CHRONOLOGY

Version	Date	Details
1.0	17/04/2020	Original protocol
1.1	24/04/2020	PHQ-9 is replaced with the PHQ-8. SWiM participants receive control materials after study ends.
2.0	18/05/2020	Follow up changed to 4 months
3.0	26/06/2020	Addition of social media advertising as method of recruitment

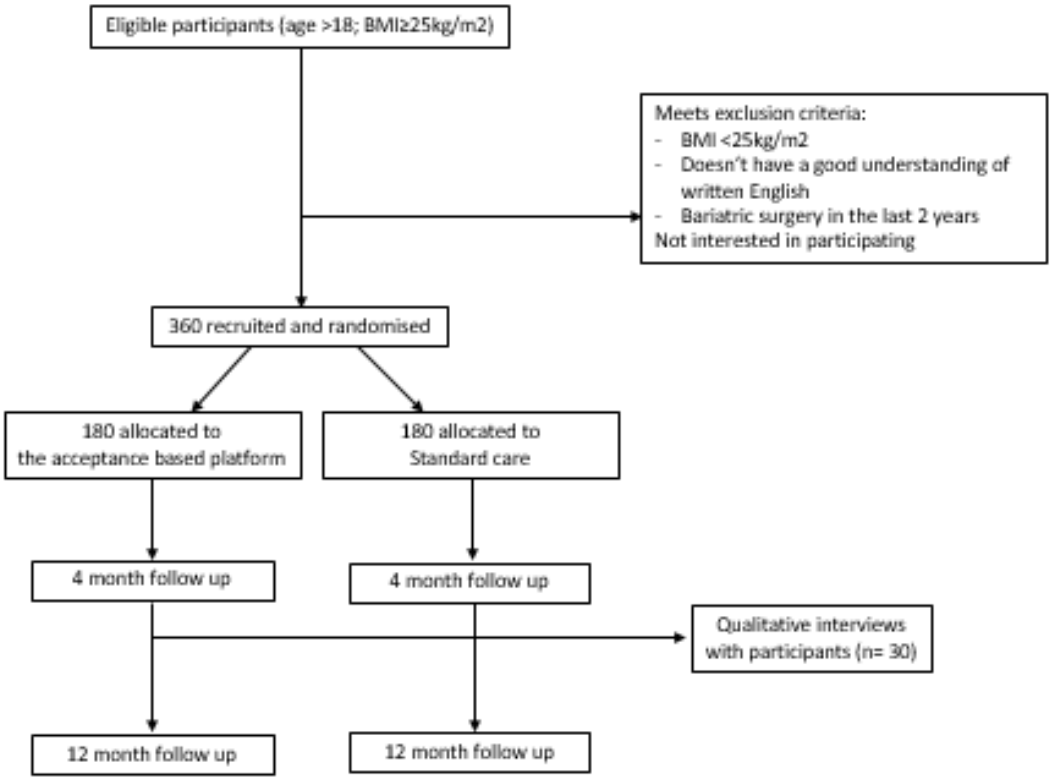
4.0	03/08/2020	Addition of qualitative SWiM coach interviews
5.0	25/05/2021	Addition of a 12 month follow up

LIST OF CONTENTS

Acronyms and abbreviations

ACT	Acceptance and Commitment Therapy ACT is an action-based approach to behavioural therapy that encourages accepting thoughts and feelings, rather than fighting or avoiding them, or trying to change them. ACT encourages responding to thoughts in a more helpful way in order to move towards one's goals that are in line with core values. Another core message of ACT is accepting what is outside of one's personal control and committing to action to change things that are within one's control.
COVID-19	A new illness, caused by a virus called coronavirus, that can affect your lungs and airways.
EASO	European Association for the Study of Obesity EASO is a federation of professional membership associations from 34 European countries. It is the voice of the European obesity community, representing scientists, health care practitioners, physicians, public health experts and patients. EASO is in official relations with the World Health Organisation (WHO) Regional Office for Europe and is a founding member of the EU Platform on Diet, Physical Activity and Health.
SWiM	Supporting Weight Management during COVID-19 A web-based supported self-help intervention that aims to support adults with overweight and obesity to prevent weight gain by helping them to manage their eating behaviours, be more physically active and protect their emotional wellbeing.
- SWiM Sessions	Weekly modules delivering educational material, reflective exercises and behavioural experiments based on Acceptance and Commitment Therapy (ACT) and habit theory.
- SWiM Coach	A trained member of the SWiM team providing telephone and email-based support to intervention participants.
- SWiM Practice	Reflective exercises and behavioural experiments assigned at the end of SWiM Sessions for participants to complete between sessions.
- SWiM Aids	A feature of the SWiM platform that collates the core exercises and concepts from each SWiM Session, providing the participants with easy access to the core intervention components.

Figure 1: TRIAL FLOW CHART



1. BACKGROUND

The social distancing and isolation measures imposed during the COVID-19 pandemic beginning March 2020, including the closure of community weight management programmes and services, mean that adults with overweight and obesity in the UK are at increasing vulnerability to weight gain, and associated negative impacts on physical health and mental wellbeing. Usual habits and routines are disrupted, stress and anxiety are likely to be high, usual coping mechanisms may be limited, and people are likely to respond by developing unhealthy habits such as comfort eating and sedentary behaviour and may experience increased low mood resulting from this. We have previously shown that preventing weight gain can reduce diabetes incidence amongst people with type 2 diabetes, even among people who already have overweight or obesity.(1) Other studies show that annual weight gain can typically be attributed to discrete periods of time (e.g. holidays) and that this weight gain is typically not compensated for.(2,3) Thus, weight gain during social distancing could have a significant impact on the health and wellbeing of people with overweight and obesity.

There is good evidence that interventions based on acceptance and commitment therapy (ACT) are effective for weight management and may improve mental wellbeing and psychological determinants of weight control.(4) However, acceptance-based programmes are usually psychologist-led and the cost and scarcity of psychologists specialising in obesity mean it is not possible to support everyone who would benefit from this type of intervention. It is possible to deliver self-help versions of acceptance-based programmes.(5) However, there is currently insufficient evidence on mode of delivery or cost-effectiveness to recommend scalable implementation of self-help versions of acceptance-based interventions, particularly in the context of weight management.(4)

We have developed a supported self-help intervention (SWiM; Supporting Weight Management during COVID 19) that aims to help adults with overweight and obesity to manage their weight and eating behaviour, be more physically active, and protect their emotional wellbeing. This intervention is adapted from the SWiM programme, which was originally developed to help people to maintain weight after weight loss. The adaptations speak specifically to the restrictions associated with COVID 19, including outside access, social distancing, and isolation. The 12-week intervention is based on ACT, targets known psychological determinants of weight management and is delivered via an online platform with remote support from a guide or coach. The current study compares the effectiveness of SWiM with standard written materials giving advice on diet, physical activity and mental health during the COVID-19 pandemic.

The COVID19 crisis represents a unique situation of unknown duration, but some form of social distancing is likely to last for many months and could reoccur. If the SWiM intervention proves to be effective it could be rolled out on a larger scale to support people through the current crisis. Findings may also be generalisable to other situations involving high levels of stress, reduced access to resources, and/or low levels of mobility. Qualitative interviews with participants will give insight into the extent to which findings from this study are context dependent and give insight into how the intervention could be adapted for other contexts.

2. AIMS AND OBJECTIVES

2.1 Aim

To evaluate the effect of the SWiM intervention on weight, eating behaviour, physical activity and wellbeing compared to current standard advice for people with overweight and obesity. Primary Objective

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.

2.2 Secondary Objectives

To evaluate the effect of SWiM on eating behaviour, physical activity and psychological wellbeing compared to standard advice.

To evaluate the cost-effectiveness of the SWiM intervention compared to standard advice.

To understand the experience of participants and the extent to which the programme meets their needs.

To explore potential causal mechanisms, and contextual factors that may be associated with variations in outcome.

3. STUDY DESIGN

This is a pragmatic, randomised, single-blind, parallel group, two-arm trial. 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. Participants will complete outcome assessments online at baseline, at 4 months and at 12 months follow-up.

4. PARTICIPANTS

Participants (N=360) will be adults with overweight or obesity (Age ≥18 years; BMI≥25kg/m2) who have a good understanding of written English (materials are not suitable for non-English language speakers), are willing to be randomised to either intervention and to complete outcome assessments online, and who own a set of scales that they can weigh themselves with during the study. Participants will be excluded from taking part if they have had bariatric surgery in the last 2 years.

4.1 Recruitment

Participants will be recruited online through obesity and weight management organisations, volunteer databases and social media. Recruitment adverts have been reviewed by patient and public involvement representatives to ensure sensitivity. Adverts and email invitations will include a link to a secure web form which will be used to provide participant information, confirm eligibility, and obtain informed consent. Once informed consent is given, baseline data will be collected.

4.2 Randomisation

Once baseline data have been collected, eligible participants will be allocated to one of the two intervention arms in a 1:1 allocation using block randomisation (block size 6) stratified by BMI classification (25-30, 30-40, 40+) and sex (male, female). The randomisation sequence will be computer-generated by the trial statistician and incorporated into the trial database by the data manager. The sequence will be unknown to all other personnel, including study coordinators, outcome assessors and investigators.

Randomised allocation will be revealed to the participant by phone or email, which will provide detail of the allocated intervention. If they have been allocated to SWiM, they will receive a web link to access the website with instructions for getting started. 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.(6)

5. PLANNED INTERVENTION AND CONTROL

5.1 Supporting Weight Management during the COVID-19 pandemic (SWiM) programme

SWiM is a supported self-help programme that uses acceptance-based strategies to support adults with overweight and obesity to manage their weight and eating behaviour, be more physically active, and protect their emotional wellbeing. The intervention includes access to an online web platform with 12 modules (SWiM sessions) consisting of psychoeducational content, reflective exercises, and behavioural experiments. Content is described in Table 1. SWiM is intended to be a 12 week intervention, with 1 session completed per week. 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 known as 'SWiM Practice'. Automated email reminders are sent to participants to remind them to log in and complete sessions each week. After the participant has completed the week 4 session, they will receive a telephone call from their SWiM Coach. This will be a 20 minute call to check in and see how the participant is getting on with the intervention and to ensure they understand the content. A

tailored email will also be sent at week 10. At the end of the study, participants will then receive the same standard advice materials as the control group.

Session	Content
Welcome to SWiM	What is SWiM?
	Let's take a tour around SWiM!
	Meet the SWiM Team
Session 1: Eating Well During Lockdown	1.0 Tracking Your Progress
	1.1 Eating Well During The Lockdown
	1.2 Alcohol and COVID19
	1.3 SWiM Practice: Planning Your Meals
Session 2: Staying Active During Lockdown	2.0 Checking in
	2.1 Physical Activity and COVID19
	2.2 Physical Activity Recommendations
	2.2 Tips for Staying Active
	2.3 SWiM Practice: Your Physical Activity Plan
Session 3: Planning and Goal-Setting	3.0 Checking in
	3.1 Your Weight Maintenance Plan
	3.2 SMART Goals and Plans
	3.3 SWiM Practice: Goal Setting
Session 4: Control and Acceptance	4.0 Checking in
	4.1 Control and Acceptance
	4.2 What Matters to You?
	4.3 SWiM Practice: Values, Goals and Actions
Session 5: Being Willing	5.0 Checking in
	5.1 Values and Goals
	5.2 Being Willing
	5.3 SWiM Practice: 'Even If…' Thoughts
Session 6: Overcoming Obstacles	6.0 Checking in
	6.1 Identifying Your Obstacles
	6.2 Planning for Obstacles
	6.3 How to Deal with a Lapse
	6.4 SWiM Practice: Being BOLD
Session 7: Emotional Eating	7.0 Checking in
	7.1 What is Emotional Eating?
	7.2 Breaking the Cycle
	7.3 SWiM Practice: Emotional Responses Diary
Session 8: Stress Management	8.0 Checking in
	8.1 Stress and Weight Gain
	8.2 Control What You Can, Accept What You Can't
	8.3 Defusion: Unplugging the Sink
	8.4 Mindful Breathing
	8.5 How to get a good night's sleep
	8.6 SWiM Practice: Practising Defusion
Session 9: Urges and Cravings	9.0 Checking in
	9.1 We All Have Urges and Cravings
	9.2 Recapping Defusion
	9.3 Urge Surfing

	9.4 SWiM Practice: Learning to Surf
Session 10: Habits and Being Flexible	10.0 Checking in
	10.1 Forming Helpful Habits
	10.2 Breaking Unhelpful Habits
	10.3 Being Flexible
	10.4 SWiM Practice: Breaking Unhelpful Habits
Session 11: Weight Stigma and Self-Acceptance	11.0 Checking in
	11.1 The Impact of Weight Stigma
	11.2 How to Deal with Weight Stigma
	11.3 Self-Acceptance
	11.4 SWiM Practice: Practicing Self-Acceptance
Session 12: Friends and Family	12.0 Checking in
	12.1 Friends and Family
	12.2 How to Get the Support You Need
	12.3 Breaking Unhelpful Food Rules
	12.4 SWiM Practice: Rule Breaking and Being Assertive
	12.5 Going Forward – Maintaining Motivation

TABLE 1: SWiM Intervention Outline and Content

Web Platform

On the SWiM web platform, intervention content is divided into SWiM sessions, which are each divided into activities. Progress through the sessions is presented as a 'journey' using a map-like graphic. Star icons "light up" when activities/sessions are competed (figure.2). As participants complete core skills exercises, these are stored in "SWiM Aids" where they can be accessed without revisiting specific sessions. The web platform is designed to allow participants to revisit past sessions and skills, and it is intended that future roll out would include indefinite access to the website.

Figure 2: Screenshot of participant 'journey' page of SWiM website

The web platform includes a weight tracker, which tracks weight over time, displayed in a visual graphic display. The weight tracker generates a line graph that automatically updates as data is inputted by the participant. As part of the first session, participants are asked to enter their current weight. The weight tracker automatically sets a weight maintenance target range with a boundary of +/-3kg that they are encouraged to stick within. This boundary can be adjusted if required as weight changes over time. Each session starts with a reflection on the previous session and SWiM practice and entry of weight data into the tracker.

5.2 Control Intervention

Participants who are randomised to the control arm will receive standard advice from the European Association for the Study of Obesity (EASO) on diet, physical activity and mood during the COVID 19 pandemic.(6) They will also be wait-listed to receive access to the SWiM website after the study ends.

6. OUTCOMES AND MEASURES

6.1 Primary Outcome

Self-reported weight at 4 months.

6.2 Secondary Outcomes

Patient Health Questionnaire 8-item (PHQ-8) (7,8)

Generalized Anxiety Disorder 7-item (GAD-7) scale(9)

Perceived Stress Scale (PSS-4)

Acceptance and Action Questionnaire Weight Related (Revised) (AAQW-R) (10)

Three-Factor Eating Questionnaire (TFEQ-R21) (11)

International Physical Activity Questionnaire (IPAQ) (12)

Health related quality of life and wellbeing (EQ-5D-L ; ICECAP-A) (13)(14)

Website Usage (data analytics)

They will also complete bespoke questionnaires on demographics and intervention engagement (adapted from Perski et al., 2020)(15)

7. MEASUREMENTS AND DATA COLLECTION

7.1 Visit Schedule

Participants will complete online assessments at 0,4 and 12 months. Details of which measures will be taken at each time point are summarised in Table 4. Participants will be given an honorarium for completing (£10 for baseline and £20 for the 4 and 12 month visit). Honoraria for assessment completion are not dependent on intervention engagement/completion.

TABLE 4: Schedule of Enrolment, Interventions, and Assessments

	STUDY PERIOD			
	Enrolment	Baseline	Follow Up	
TIMEPOINT**	$-t_1$	0	4 months	12 months
ENROLMENT:				
Online screening	X			

Informed consent		X		
Randomisation		X		
INTERVENTIONS:				
Supporting Weight Maintenance (SWiM)		←	———	→
Standard Advice		X		
ASSESSMENTS:				
Height		X		
Weight		X	X	X
Demographics		X		
Eating Behaviour		X	X	X
Physical Activity		X	X	X
Quality of Life /Wellbeing		X	X	X
Intervention Engagement			X	X

7.2 Outcome Assessments

All outcomes will be assessed via online self-report questionnaires. Participants will be asked to weigh themselves on the day that they complete the outcome assessment so that they can report a self-measured weight. At 12 months, intervention and control participants will complete the intervention engagement questionnaire, since control participants received access to the SWiM website after the 4-month follow-up. This will allow us to control for intervention engagement in analyses, and to compare intervention experiences between intervention participants who received the website in conjunction with support by a coach, and control participants who received only the website without coach support.

Participants will complete a demographics questionnaire at baseline based on Progress-Plus(16) factors.

The study coordination team will send email/phone reminders to participants if a questionnaire has not be completed after 7 days.

7.3 Website analytics

Engagement and intervention usage will be assessed through website analytics. Reports on web-traffic, frequency and duration of visits will be available via secure download directly from the SWiM online platform. Access will be limited to authorised members of the research team.

8. STATISTICS AND QUANTITATIVE DATA ANALYSIS

8.1 Statistical analysis

A detailed statistical analysis plan will be developed and signed off by the Trial Steering Committee (TSC) prior to analysis. Participants will be analysed in the group to which they were randomised, based on the intention-to-treat principle. The primary analysis will estimate the baseline-adjusted difference between intervention groups in change in weight from baseline to 4 months, using a linear regression model including randomisation group, baseline weight, and the randomisation stratifiers (sex, BMI classification). Participants with missing values of weight at 4 months will be excluded (ie, a complete-case analysis which assumes outcome data are missing at random conditional on covariates in the model). If there are >5% of participants with missing values of weight, a sensitivity analysis will be performed using multiple imputation by chained equations – this makes the missing at random assumption but provides increased precision compared with a complete-case analysis. Linear regression will be used to estimate the baseline-adjusted difference between intervention groups in change in weight from baseline to 12 months and 4 months to 12 months. Since the control group was waitlisted and therefore received access to the SWiM website after the 4-month follow-up, analyses at 12 months will need to account for intervention usage in the control group. Regression models for the 12-month follow-up will therefore include intervention engagement (as measured using the intervention engagement questionnaire and/or website analytics) as a covariate. Full details of this analysis will be provided in the statistical analysis plan. Continuous secondary outcomes will be analysed using the same method.

8.2 Sample size calculation

Based on previous trials of weight gain prevention over similar periods, we designed the study to have 90% power to detect a difference between randomised groups in mean change in body weight from baseline to 4 months of 1kg as significant at the 5% level. Based on our previous studies in similar populations, we assumed a SD of 6kg for weight and a correlation between repeated measures of 0.9. Allowing for a 20% drop out, 360 participants (180 per group) would be required.

8.3 Cost-effectiveness analysis

A cost-effectiveness analysis (CEA) will be undertaken, comparing the incremental costs and effects of the SWiM programme (i.e. acceptance-based weight maintenance) versus standard care.

The outcomes used in the cost-effectiveness analysis will be the change in weight over time and the health-related quality of life (HRQOL), which will be expressed in Quality Adjusted Life Years (QALYs). Although the current value set for the 5 levels version of the EuroQol EQ-5D questionnaire (EQ-5D-5L) suffer from low quality and reliability issues, we anticipate that these problems will be solved by the time the analysis will be performed. (17) In the absence of high-quality and reliable value set for the EQ-5D-5L, the analyses will be conducted using the cross-walk algorithm developed by van Hout et al as conform with the NICE position statement. (17,18)

Missing data in outcomes is anticipated, and it will be handled using multiple imputation methods.

The imputed mean cost and mean effectiveness in each arm will be used to obtain an incremental cost-effectiveness ratio (ICER), which is calculated by dividing the mean cost difference by the mean effectiveness difference. These mean differences will be ascertained by using regression methods and will be adjusted by the prespecified subgroups accordingly to the statistical analysis plan. Additionally, these regressions will be adjusted by the HRQOL, costs and any other unbalanced variable observed at randomisation. The uncertainty around the incremental cost and incremental effectiveness estimates will be calculated using non-parametric methods and presented as cost-effectiveness probabilities. A non-parametric bootstrapping will simulate an appropriate number of pairs of mean cost and effectiveness differences, which will be plotted on the cost-effectiveness plane. Estimating the proportion of the bootstrapped cost and effectiveness pairs with corresponding ICERs below the cost-effectiveness threshold will allow estimating the cost-effectiveness probability. Although NICE has identified a range of acceptable ICERs for an additional cost per additional QALYs (i.e. NICE thresholds: £20-30,000 per QALY), a similar threshold for bodyweight loss measures is not available yet. Therefore, the cost-effectiveness probabilities will be computed by varying the maximum acceptable ICER and each time re-calculating the proportion of plotted points with ICERs below this figure. The so obtained probabilities will enable the construction of the cost-effectiveness acceptability curve. Besides the ICER, we will present the results of the analysis using quality of life data by calculating the net monetary benefits (NMB) of each intervention. NMB will be computed by using the NICE cost-effectiveness thresholds to transform the health benefits in their health care costs equivalent. Therefore, the costs observed during the study will be subtracted to these monetary estimates of the health benefits to obtain the

respective NMB for each arm. The intervention with the highest NMB will be considered cost-effective.

9. QUALITATIVE STUDY

The qualitative component of this feasibility study aims to explore participants' experiences of the intervention programme and the study, and the individual and contextual factors that influenced their engagement. We will also explore how well the intervention supports people's weight management and emotional wellbeing and how the programme could be improved to provide better support.

The qualitative component will further explore the SWiM coaches' experiences of delivering the intervention programme, engaging with participants, and supporting participants with weight management and emotional wellbeing. We aim to explore how the programme could be improved in the future.

9.1 Data collection

Individual semi-structured interviews (n~30) will be conducted at the end of the study. Participants will be purposively sampled using outcome data (broad demographic, range of adherence and weight outcomes) in participants from both trial arms (2:1 ratio, intervention: control). Questions will focus on participants' experiences of SWiM, including the benefits and challenges experienced, their remaining needs at the programme end, and the extent and manner of programme implementation. Participants will receive a £20 gift voucher as an honorarium for taking part in the qualitative interview.

All SWiM coaches (n=7) will be invited to take in individual semi-structured interviews. Questions will focus on coaches' experiences of delivering SWiM-C, including the engaging with participants, supporting participants' needs, and the programme acceptability. Participants will receive a £20 gift voucher as an honorarium for taking part in the qualitative interview.

9.2 Analysis

Qualitative analysis will explore the perceived feasibility and acceptability of the programme; individual and contextual factors that influence implementation and effectiveness; what participants experienced as key facilitators or barriers to weight control during the pandemic; the impact the intervention had on emotional wellbeing, and any needs they felt were not met.

Data pertinent to different groups (intervention participants, control group participants, and SWiM-C coaches) will be analysed and presented separately. Findings will then be integrated narratively.

Recordings will be transcribed by an experienced external agency and checked for accuracy by the research team. Verbatim transcripts will be coded using NVivo software, retaining a focus on narrative sequences and transitions as well as salient themes. A dual coding approach will be used as follows: a first inductive round based on emerging themes relating to the research questions; a second round sensitised by quantitative findings. In the first inductive stage, open codes will be generated based on line-by-line scrutiny of verbatim transcripts uploaded into NVivo. Inconsistencies between coders will be resolved through discussion.

10. DATA MANAGEMENT

10.1 Data Security

The MRC Epidemiology Unit has an over-arching data management policy (DMP) that encompasses the standards and processes applied to all research and operational activities in the Unit. The PIs will ensure that all data generated, stored and shared from this trial will be handled in compliance with the DMP and the General Data Protection Regulations. The data controller will be the University of Cambridge. The legal basis for holding and processing the data as outlined in the protocol is to enable the team to conduct health research in the public interest.

All electronic data will be held on the Unit's secure networks, collated in version controlled uniquely identified databases.

Participation will be under full informed e-consent, including for the storage and use of data collected. At any point, participants can choose to opt out of any aspect of data collection or processing. As stated on the information sheet, any data collected up until the point of withdrawal will continue to be held by the study team.

Personal identifiable data will be held in the Study Database developed by the MRC Epidemiology Unit Data Manager in SQL server. It will have secure encrypted transmission. This will only be accessed by the core study team at the University of Cambridge using designated usernames and passwords. The database will be kept on the unit's private network which is used for the storage of identifiable data. It is automatically backed up to ensure no loss of data. All systems are run by professional IT staff and data handling and back-up processes are managed to standards equivalent to those defined in the MRC Information Security Policy and meet the University of Cambridge Data Security Policy. The Study Coordinator and Data Manager will monitor the accuracy of the database

with validation checks against the data collection forms. All resulting datasets will be anonymised and stored securely. The study database will also be used to record study data, including randomisation group, eligibility criteria met and attendance at appointments. Questionnaire webforms will be held in separate link-anonymised data files, and will be linked to other data sources for analysis using a link file stored in the study database.

The SWiM web-platform has been developed by Cauldron Science Ltd and is stored securely on Microsoft Azure which is a secure cloud based web host. All data is stored in a Microsoft Azure SQL database; this is stored in two different data centres both located within the European Union. Data inputted into the SWiM web-platform, including name and email address are stored securely in the Azure SQL database, which is encrypted at rest and only accessible with both the correct credentials and a whitelisted IP address. The University of Cambridge and Cauldron Science Ltd hold a data confidentiality agreement. The web platform is stored in accordance with the University of Cambridge data standards and such data is only accessible to the study team and Cauldron as the technical providers. All content is the intellectual property of the University of Cambridge. The study team at MRC Epidemiology will be responsible for downloading the research data via a secure download directly from the SWiM platform.

The qualitative interviews will be carried out by phone or using zoom (chats will be password protected to ensure privacy) and will be recorded using an Epidemiology Unit Dictaphone. The recordings will be transferred to the Unit's secure network as soon as they have been recorded.

Recordings will be transcribed by an experienced external agency and checked for accuracy by the research team. Verbatim transcripts will be coded using NVivo software, retaining a focus on narrative sequences and transitions as well as salient themes. This will help us understand participants' accounts of what mattered for their weight control and how these aspects fit within the context of their everyday lives. A dual coding approach will be used: a first inductive round based on emerging themes relating to the research questions; a second round sensitised by quantitative findings. In the first inductive stage, open codes will be generated based on line-by-line scrutiny of verbatim transcripts uploaded into NVivo. Inconsistencies between coders will be resolved through discussion.

10.2 Link Anonymisation

Participants will complete an online screening questionnaire and will be assigned an anonymised participant ID number which will be unique to them. The Database Manager will have programmed a

series of ID numbers into the database which will be assigned to participants in sequence. The ID number and participant's personal details will need to be linked in a separate database to enable us to contact participants for further follow up visits, but access to this information will be restricted to the database manager and the study coordinator. At the point the participant has been assigned an ID number, this will be used thereafter on all Case Report Forms and questionnaires; the only form to include the participants name will be the consent form which will be kept separately to the other study documents. Link-anonymised ID numbers will also be used to access online questionnaires.

Participant details will only be used when we mail out study information (eg. Newsletters) and questionnaires.

10.3 Data Sharing during the Trial

Data sharing will be kept to the minimum required for the trial conduct and patient safety. Personal identifying information and outcome data will be kept separate at all times. Any data transfer will be encrypted and shared via a secure FTP server with appropriate data sharing agreements and consent in place.

Anonymised data sets may be shared with collaborators for research purposes. Each data request from outside the research team undergoes review by the PIs for scientific merit and integrity before any releases are made.

10.4 Data Forms and Data Entry

Online questionnaires will be completed via a dedicated programme that has been set up by the Data Team at the University of Cambridge. Online questionnaires will be exact copies of the paper forms. Data will be exported from the software programme by the study coordinator and saved on the secure network where 10% sense checks will be carried out. The Database Manager and the Study Coordinator will be responsible for data entry, quality and checking procedures.

10.5 Data Storage and Archiving

The Principal Investigators and Sponsor will take overall responsibility for data archiving with day to day responsibility delegated to the Database Manager and Study Coordinator. All data sets will be kept securely with no access from unauthorised personnel. Data will be stored so that it can be accessed, used and understood by subsequent users. When the investigators have completed their planned analyses, the anonymised data will be made available for use by others and will be shared under appropriate data sharing agreements. Primary data and the Trial Master File will be retained securely in their original form for a minimum of 10 years**.**

The MRC Epidemiology Unit will be responsible for archiving all documentation relating to the trial which will include consent forms, participant forms (screening questionnaires, CRFs, questionnaires), data, the study database, and results and associated files.

MRC policy is that: (i) primary research data are kept in original form for a minimum of 10 years from study end after which review will be carried out regularly to review retention; (ii) where consent has been taken, the original records covering the protocol, consent procedure, recruitment log and adverse event reports will be kept for 30 years after the end of the study in both digital and original form; and (iii) for clinical or public health studies, all records (other than those relating to consent) will be kept for 20 years to enable review and / or re-appraisal.

11. ADVERSE EVENTS

It is unlikely that we will experience adverse events as this is an online randomised controlled trial but in the event that we do, they will be reported according to unit policy and CETU SOP015 (Recording and reporting adverse events).

12.RESEARCH GOVERNANCE AND APPROVALS

The investigators will ensure that the trial conduct conforms to the principles of the Declaration of Helsinki (2008), ICH notes for Guidance on Good Clinical Practice and the Data Protection Act. All research participation will be done under written informed consent.

The protocol, participant information sheets, and e-consent form will be submitted for to the University of Cambridge Psychology Research Ethics Committee (PREC). No participants will be recruited until relevant approvals have been received. Where needed, the Investigators will submit any proposed substantial and non-substantial amendments to the protocol or other approved documents to the PREC for approval. Substantial amendments will not be implemented until relevant approvals have been given.

13. ROLES AND RESPONSIBILITIES

The MRC Epidemiology Unit, University of Cambridge is the lead institution. All Investigators contributed to the design of the protocol and the application for funding.

As Joint Principal Investigators, Dr Amy Ahern and Professor Simon Griffin have joint responsibility for the design and conduct of the trial and for the analysis and dissemination of results.

As the Study Coordinator, Jenny Woolston will take responsibility for the day-to-day management of the trial at the MRC Epidemiology Unit. This will include day-to-day responsibility for: recruiting participants, monitoring recruitment and uptake, retention and online study completion; creating standard operating procedures; preparing reports for the sponsor, ethics committees and funders as appropriate; ensuring that the trial is running in a timely manner and in accordance with good clinical practice guidelines.

The Trial Statistician, Mr Stephen Sharp, is responsible for overseeing the work of a dedicated Research Associate who will write and implement the statistical analysis plan.

Professor Stephen Morris is responsible for leading the economic evaluation, including the establishment of the data collection methods used, conducting the quantitative analyses and publication and appropriate dissemination of findings.

Dr Robbie Duschinsky and Dr Rebecca Richards will lead the qualitative evaluation, including the establishment of the data collection methods used, conducting the qualitative analyses outlined in Section 9, and publication and appropriate dissemination of findings.

14. PATIENT AND PUBLIC INVOLVEMENT

The ideas for this study were developed in response to requests for support with eating behaviour and weight management from the European Patient Council on Obesity, who then reviewed the initial outline of the study and strongly supported its aims. Substantial PPI input was included in the development of the SWiM intervention. The initial ideas and research proposal were reviewed by 22 men and women attending the Fakenham Weight Management Service in Norfolk and 6 members of the University of Cambridge PPI Panel. Once funding was awarded a Patient User Group Panel (PUGP) was formed, comprising members with diverse experiences of weight loss and weight maintenance. This group helped in development and refinement of the logic model, the intervention outline, and different prototype iterations. Regular meetings were convened during the development phase, in order to consult on progress and to feedback to the panel on how their input was incorporated. A series of 'Think aloud' user testing sessions were completed for the alpha version of the web platform with feedback requested on content, design and functionality. To get feedback on the content from a wider and more diverse audience, remote user testing of the web platform has been conducted with the PUGP members and participants from the WRAP study from around the UK.

To maximise participant engagement and retention, and minimise burden, PPI representatives have also reviewed the content, design, and delivery of participant-facing materials. They will also advise on the content and methods of qualitative interviews and focus groups to ensure sensitivity and to maximise participant engagement.

A member of the PUGP will review the transcripts of the qualitative interviews, providing input to the analysis and interpretation of the findings. They will be included as a co-author on the qualitative results paper.

A PPI representative (Jennifer Bostock) is a member of our Investigator team and has contributed to the design of the protocol and chairs the PUGP. She will also contribute to designing and delivering PPI training, preparing ethics and R&D submissions, co-authoring journal articles and the final report, disseminating findings to a wide range of audiences, and supporting other PPI members.

Two PPI representatives are members of the Trial Steering Committee. They will review the final study reports and contribute to the writing of specific sections, such as the lay summary.

Including PPI perspectives in plans for dissemination will ensure that we access an appropriate range of audiences and communicate messages effectively. PPI representatives will advise on content and methods of dissemination and will review public facing documents such as newsletters and press releases.

PPI representatives will be reimbursed for their time and expenses in a timely manner and tailored PPI training will be provided to suit the specific needs of the individual and their role. We will use the INVOLVE Standards for PPI as a guide. All meetings will be virtual and tailored to individual needs as Covid-19 recommendations and regulations dictate.

15. PROGRAMME STEERING COMMITTEE

An independent trial steering committee will be established to ensure that the project is conducted to the rigorous standards set out in the UK Policy Framework for Health and Social Care Research and the Guidelines for Good Clinical Practice. The TSC will consist of at least 3 independent academics with relevant experience and 2 patient and public representatives. They will provide advice to the Investigators on all aspects of the trial and will review and agree the trial protocol, the statistical analysis plan, and any amendments to the protocol. This is a low risk trial with no rules for early stopping and participants and study coordinators are not blind to intervention allocation. Thus a separate data monitoring committee was not deemed to be necessary.

16. DISSEMINATION

At the end of the trial we will present our findings to our PPI representatives and our stakeholder panel and to identify appropriate ways to communicate findings to participants and other non-academic audiences. Co-authorship & co-presenting with our PUGP members will be sought where possible and the results will be made available to participations.

All specified analyses will be written up as scientific papers and submitted for publication in peer-reviewed open-access journals. Members of the research team will be involved in reviewing drafts of the manuscripts, abstracts, and any other publications arising from the trial. The Principal Investigators will have final approval on all publications and press releases. Authorship will be determined using ICMJE criteria.

In all papers or reports for publication the following statement (which incorporates a disclaimer in view of the independence of the research) should be used, amended accordingly, depending on the type of output:

"This paper/article/abstract presents independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research Programme (Reference Number RP-PG-0216-20010) and the MRC Epidemiology Unit. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health."

As a condition of NIHR funding, the Investigators must give 28 days' notice of intention to NIHR prior to submitting a research paper and 14 days' notice prior to the host institution or publisher or collaborator issuing a press release together with the draft manuscript.

17. REFERENCES

1. Feldman AL, Griffin SJ, Ahern AL, Long GH, Weinehall L, Fhärm E, et al. Impact of weight maintenance and loss on diabetes risk and burden: a population-based study in 33,184 participants. BMC Public Health. 2017;17(1).
2. Schoeller DA. The effect of holiday weight gain on body weight. Physiol Behav. 2014;
3. Yanovski JA, Yanovski SZ, Sovik KN, Nguyen TT, O'Neil PM, Sebring NG. A prospective study of holiday weight gain. N Engl J Med. 2000;
4. Lawlor ER, Islam N, Bates S, Griffin SJ, Hill AJ, Hughes CA, et al. Third-wave cognitive behaviour therapies for weight management: A systematic review and network meta-analysis. Obesity Reviews. 2020.
5. Cavanagh K, Strauss C, Forder L, Jones F. Can mindfulness and acceptance be learnt by self-help?: A systematic review and meta-analysis of mindfulness and acceptance-based self-help interventions.

Clinical Psychology Review. 2014.

6. European Association for the Study of Obesity. EASO Guidance on COVID [Internet]. Available from: https://easo.org/what-you-need-to-know-about-obesity-and-covid-19-a-guide-for-patients/

7. Kroenke K, Spitzer R, Williams J. The PHQ-9: Validity of a brief depression severity measure. J Gen Intern Med. 2001;16(02):606–13.

8. Wu Y, Levis B, Riehm KE, Saadat N, Levis AW, Azar M, et al. Equivalency of the diagnostic accuracy of the PHQ-8 and PHQ-9 : a systematic review and individual participant data meta-analysis ‡. 2019;

9. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: The GAD-7. Arch Intern Med. 2006;

10. Palmeira L, Cunha M, Pinto-Gouveia J, Carvalho S, Lillis J. New developments in the assessment of weight-related experiential avoidance (AAQW-Revised). J Context Behav Sci. 2016;

11. Karlsson J, Persson L-OO, Sjöström L, Sullivan M. Psychometric properties and factor structure of the Three-Factor Eating Questionnaire (TFEQ) in obese men and women. Results from the Swedish Obese Subjects (SOS) study. Int J Obes Relat Metab Disord [Internet]. 2000;24(12):1715–25. Available from: http://www.nature.com/doifinder/10.1038/sj.ijo.0801442

12. Activity IP. International Physical Activity Questionnaires Ipaq : Short Last 7 Days Self-Administered Format. Self. 2002;

13. Devlin NJ, Shah KK, Feng Y, Mulhern B, van Hout B. Valuing health-related quality of life: An EQ-5D-5L value set for England. Heal Econ (United Kingdom). 2018;27(1):7–22.

14. Al-Janabi H, Flynn TN, Coast J. Development of a self-report measure of capability wellbeing for adults: The ICECAP-A. Qual Life Res. 2012;21(1):167–76.

15. Perski O, Blandford A, Garnett C, Crane D, West R, Michie S. A self-report measure of engagement with digital behaviour change interventions (DBCIs): Development and psychometric evaluation of the “DBCI Engagement Scale.” Transl Behav Med. 2020;10(1):267–77.

16. O’Neill J, Tabish H, Welch V, Petticrew M, Pottie K, Clarke M, et al. Applying an equity lens to interventions: Using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. J Clin Epidemiol. 2014;67(1):56–64.

17. National Institute for Health and Care Excellence (NICE). Position statement on use of the EQ-5D-5L value set for England (updated October 2019). [Internet]. [cited 2020 Feb 25]. Available from: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/technology-appraisal-guidance/eq-5d-5l

18. Van Hout B, Janssen MF, Feng YS, Kohlmann T, Busschbach J, Golicki D, et al. Interim scoring for the EQ-5D-5L: Mapping the EQ-5D-5L to EQ-5D-3L value sets. Value Heal. 2012;