SWiM 2.0 Study Protocol

Full 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

IRAS Number:

REC Number:

ISRCTN:

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Funder: National Institute for Health and Care Research (NIHR)

Sponsor: University of Cambridge and Cambridgeshire and Peterborough Integrated Care Board (ICB)

This protocol adheres to HRA guidance

Protocol Signature:

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate, and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

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Date: 08/04/2025

PROTOCOL REVISION CHRONOLOGY

Version	Date	Details
1.0	08/04/2025	Original protocol

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LIST OF ABBREVIATIONS

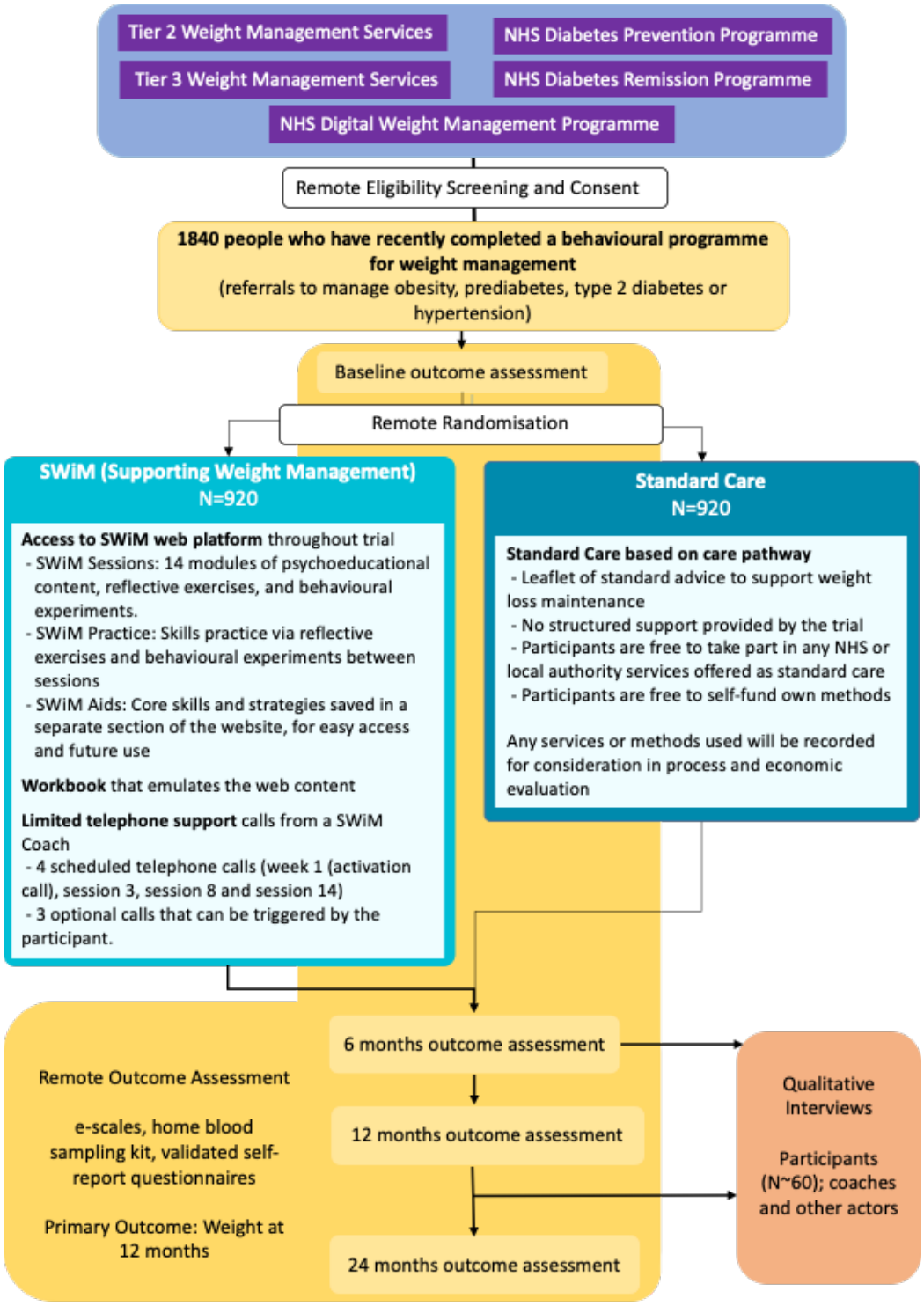
Abbreviation	Full name
2-FA	Two Factor Authentication
ACT	Acceptance and commitment therapy
AE	Adverse Event
CETU	Cambridge Epidemiology & Trials Unit
CI	Chief Investigator
eConsent	Electronic Consent
eCRF	Electronic Case Record Form
eTMF	Electronic Trial Master File
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
ID	Identifier
IT	Information Technology
MRC	Medical Research Council
NBL	Nutritional Biomarker Laboratory
Non_CTIMP	Non-Clinical Trial of an Investigational Medicinal Product
PI	Principal Investigator
PID	Participant Identifiable Data
PPI	Participant and Public Involvement
REC	Research Ethics Committee
SAE	Serious Adverse Event
sFTP	Secure File Transfer Protocol
SOP	Standard Operating Procedure
SRD	Secure Research Domain
T2D	Type 2 diabetes
WLP	Weight loss programme

STUDY SUMMARY

Study 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
Short title	SWiM 2.0
Study Design	A randomised, single-blinded, parallel-group trial with 1:1 randomisation.
Study Participants	The study will recruit 1,840 UK adults with overweight or obesity who have recently completed a behavioural weight management programme. Participants will be recruited from five different UK-commissioned weight loss programmes (WLPs): 1. Tier 2 weight management programme 2. Tier 3 weight management programme 3. NHS Diabetes Prevention Programme 4. NHS Digital Weight Management Programme 5. NHS Diabetes Remission Programme Eligibility Criteria Inclusion Criteria: • Age ≥18 years • Capable of providing informed consent • Good understanding of English • Willing to be randomised • Willing to complete study measurements • Able to access the web-based platform from home Exclusion criteria • Current use of insulin • Previous or planned bariatric surgery • Current or planned pregnancy • Current diagnosis of an eating disorder Participants will be recruited in collaboration with WLP providers, with targeted efforts to ensure diversity in recruitment. Oversampling will be used to ensure adequate representation of underserved groups, including men, people from minority ethnic backgrounds, and those from lower socioeconomic backgrounds.

Research Question/Aim(s)	Primary Research Question: • Does the SWiM intervention improve long-term weight maintenance, physical health, and mental well-being compared to standard care in adults who have recently completed a weight loss programme? Secondary Research Questions: • What is the impact of SWiM on long-term weight outcomes, glycaemic control, and psychological well-being, including depression, anxiety, emotional eating, and quality of life? • Does the effectiveness of SWiM differ by initial weight loss programme? • What are the barriers and facilitators to engagement with SWiM, and how do they vary across demographic and socioeconomic groups? • What is the cost-effectiveness of SWiM compared to standard care in maintaining weight loss and preventing type 2 diabetes and other obesity-related complications? • How can SWiM be adapted for people using GLP1-RA pharmacotherapy or bariatric surgery to support long-term weight maintenance?
Summary of study procedures	This is a randomised, single-blinded, parallel-group trial with 1:1 allocation to the SWiM intervention or standard care. • Recruitment: Participants who have completed a behavioural weight management programme within six months will be identified and enrolled. • Randomisation: Stratified by weight loss programme and weight loss medication use. • Intervention: The SWiM group will access a web-based self-help programme with behavioural exercises and telephone coaching. A paper workbook will also be available. • Control: Standard care with no additional structured support. • Assessments: Conducted remotely at baseline, 6, 12, and 24 months, measuring weight, glycaemic control, mental health, eating behaviours, and quality of life. • Process evaluation and economic analysis: A mixed-methods evaluation, including participant interviews, to assess engagement, feasibility, and cost-effectiveness. • Follow-up: Two years to assess long-term weight maintenance, with potential health record linkage for future outcomes.

STUDY FLOW CHART



1. BACKGROUND

Obesity and type 2 diabetes (T2D) represent significant public health challenges, with substantial impacts on physical and mental health, economic systems, and society.[1,2] While behavioural weight loss interventions have been shown to produce clinically meaningful and cost-effective reductions in weight, sustaining these benefits remains a critical issue.[3,4] Weight regain is common and undermines long-term health improvements, highlighting the need for interventions that support weight loss maintenance.[5,6]

Weight loss maintenance programmes based on self-regulation can achieve modest improvements in long-term weight outcomes.[7,8] However, to date, no UK-based trials have demonstrated effectiveness or cost-effectiveness of a weight loss maintenance programme.[7,9–11] Our systematic review and network meta-analysis found that incorporating strategies from Acceptance and Commitment Therapy (ACT) could have greater effects than standard behaviour change strategies.[12] ACT[13] is a psychological therapy approach that teaches people skills and strategies that directly address some of the core psychological challenges of maintaining weight loss, including acceptance and tolerance of aversive internal experiences (e.g., food cravings, physical discomfort, negative emotions), self-compassion to prevent discouragement following minor lapses, and reductions in negative mood and emotional eating. However, ACT-based interventions are typically used in-person and delivered by Clinical Psychologists, limiting their scalability and affordability in the UK NHS. Some randomised trials of digital ACT-based interventions for lifestyle modification have demonstrated acceptability and feasibility, with positive effects on eating behaviours and psychological flexibility, but their effects on weight and physical activity remain unclear.[14–18]

Using a rigorous theory-, evidence-, and person-based approach,[19–21] we developed an ACT-based guided self-help programme that addresses the specific challenges of weight loss maintenance. The Supporting Weight Management (SWiM) programme is delivered using an online web platform and telephone support from a trained non-specialist coach [22,23]. In our randomised controlled feasibility trial,[24] we found that SWiM was feasible and engaging, and we observed promising effects on weight and psychosocial outcomes. However, a definitive randomised controlled trial is needed to evaluate the effect of SWiM on weight, physical health, and mental well-being following a range of behavioural programmes commissioned in the UK and to identify potential differential effectiveness by weight loss programme (WLP) and demographic groups. Detailed process evaluation is also needed to understand the mechanisms of action and contextual factors influencing the programme's impact. These insights will be critical for refining SWiM and developing guidance for its potential national implementation within NHS weight management services.

2. AIMS AND OBJECTIVES

2.1 Aim

To evaluate the effectiveness, equity, and cost-effectiveness of the SWiM programme relative to standard care in people who have recently completed a behavioural weight loss programme.

2.2 Objectives

Clinical Effectiveness

Primary Objective:

To evaluate the effect of SWiM versus standard care on weight at 12 months

Secondary Objectives:

- To evaluate the effect of SWiM versus standard care on weight at 6 and 24 months
- To evaluate the effect of SWiM versus standard care on body composition, glycated haemoglobin (HbA1c), psychological well-being, and psychosocial outcomes at 6, 12, and 24 months.
- To evaluate whether the effectiveness of SWiM is moderated by demographic characteristics (PROGRSS-Plus criteria)[25] of participants or the weight loss intervention used to lose weight or amount of weight lost before joining the trial.

Process Evaluation Objectives

- To examine how the programme works (i.e., mechanisms of action).
- To explore how SWiM is perceived, experienced, and applied over time across individual contexts.
- To explore why components of SWiM work or do not work, and under what contexts.
- To explore what additional unintended outcomes (positive/negative) are experienced.
- To examine the extent to which SWiM is delivered as intended.
- To understand the contextual factors influencing the delivery of SWiM, by exploring health coaches' perceptions and experiences of delivering SWiM, including barriers and facilitators to delivery.

The NICE NG246 guideline calls for more research on weight management interventions in ethnic minority groups. This study will aim to address this gap by exploring differences in intervention effects across demographic groups.

Cost-Effectiveness Objectives

- To estimate the effect of SWiM versus standard care on health care utilisation, out of pocket spend on weight management services, and work productivity at 6, 12 and 24 months.
- To model the long-term cost-effectiveness of SWiM and its impact on health outcomes and related health care costs
- To evaluate whether the long-term cost-effectiveness of SWiM is different depending on initial weight loss or weight loss programme.
- To evaluate whether the long-term cost-effectiveness of SWiM differs by demographic characteristics.

3. METHODS

3.1 Study design

This is a pragmatic, randomised, single-blinded, parallel group trial with 1:1 randomisation. Participants will be randomised to either the acceptance-based weight maintenance programme (SWiM) or to standard care using a computer-generated sequence with 1:1 allocation stratified by weight loss programme and weight loss medication usage. Participants will complete assessments at baseline, 6, 12 and 24 months using remote measures.

3.2 Eligibility 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

- Age ≥18 years
- Capable of giving informed consent
- Good understanding of the English language (the intervention and study materials are not tailored to support non-English language speakers)
- Willing to be randomised
- Willing to complete study measurements
- Able to access the web-based platform from home

Exclusion criteria

- Current use of insulin
- Previous or planned bariatric surgery
- Current or planned pregnancy
- Current diagnosis of eating disorder
- A same household partner

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

3.3 Procedures

3.3.1 Recruitment

We will collaborate with weight loss programme (WLP) service providers and commissioners to recruit individuals who have completed their WLPs using established recruitment methods and materials.

Potential participants will receive a study information leaflet from the WLP via email or SMS. Those willing to participate will be asked to complete a webform to express their interest in taking part. The webform will assess eligibility and collect contact details. The webform link will be included in the study information leaflet and may also be sent to interested individuals by the WLP via email or text message. Participants can proceed directly to the participant information and e-consent webform or take more time to consider. They can also request the study team to contact them for further information.

The study information leaflet will contain the study team's contact details (telephone and email) so interested individuals can reach out with questions. With participant consent, the WLP may provide contact details to the study team, who will then send the information leaflet and a link to the eligibility screening form.

Service providers will be encouraged to promote the study in person and actively encourage participation. However, they will also conduct blanket SMS or email outreach to all eligible individuals. All providers will receive the same recruitment materials and be asked to follow the same protocols. While opportunistic in-person referrals by coaches or group leaders are encouraged, they are difficult to mandate or monitor. As a result, we rely on the goodwill and motivation of individual service providers to facilitate this aspect of recruitment.

3.3.2 **Consent**

If participants are interested in taking part, they will be sent a secure weblink which will be used to provide participant information, confirm eligibility, and obtain informed e-consent. Once informed consent is obtained, the study team will contact participants to address any follow-up questions, outline next steps, and collect baseline data.

3.3.3 **Study measures**

Participants will complete online assessments at baseline (0 months), 6, 12, and 24 months. Details of which measures will be taken at each appointment are summarised in Table 1. Participants will be given a gift voucher for completing online assessments (£10 for the 6-month assessment, £20 each for the 12- and 24-month assessments). Honoraria for assessment completion are independent of intervention attendance or completion. Where participants are unwilling to complete the full assessment, a reduced amount (£10) will be offered for completion of a minimal data questionnaire (primary outcome and key process data).

Table 1. Schedule of Enrolment, Interventions, and Assessments

	STUDY PERIOD				
	Enrolment	Baseline	Follow Up		
TIMEPOINT**	$-t_1$	0	6 months	12 months	24 months
ENROLMENT:					
Eligibility screen	X				
Informed consent		X			
Randomisation		X (after baseline assessment)			
INTERVENTIONS:					
Supporting Weight Maintenance (SWiM)		←	→		
Standard Care		X			
ASSESSMENTS:					
Height		X			
Weight		X	X	X	X

Self-Report Questionnaires		X	X	X	X
HbA1c		X	X	X	X

Weight

At baseline, participants will be asked to report their height, and measure and report their weight, on the day that they complete the outcome assessment. Participants will be provided with a set of weighing cellular-scales (Withings BodyPro2). The scales are pre-configured before sending, and report weight measures over cellular data networks, and do not require a wi-fi connection or digital literacy to use. When participants stand on the scales, data is sent automatically to Withings' GDPR compliant servers in the EU and then retrieved using the Withings developer API directly to the MRC Epidemiology Unit's secure research data server. Data transfers are secured using HTTPS and OAuth2.0 authentication. Instructions for self-weighing will be provided to reduce measurement bias. Eligibility screening will assess the suitability of the scales. Participants with a pacemaker, defibrillator, or other electronic implant will receive the BodyPro scale instead, as it does not use bioelectrical impedance. Participants living in areas with poor cellular network connectivity or weighing over 200kg will receive a suitable medical-grade scale and will be contacted by the study team to report their weight. All participants will be asked to self-report weight in questionnaires (see Table 2) at each assessment as a back-up.

HbA_{1c}

HbA_{1c} will be measured with 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),) which we used successfully in a previous trial.[26] The kits will include all of the equipment provided for participants to complete the test at home. Kits will then be posted back via freepost to the TDL team to analyse the samples. No identifiable information will be shared with the TDL team.

Questionnaires

Self-reported questionnaires will be collected via REDCap web surveys, with paper or telephone options available for participants requiring them. Self-reported behavioural and psychosocial measures will be collected via validated questionnaires. Health outcomes and use of health care, medications and weight management services will be collected via self-report.

A full list of questionnaires can be found in Table 2.

Table 2. Full list of questionnaires

Domain	Outcome	Measure	Time point
Clinical Outcomes	Height	Self-measured	0m
	Weight	Self-measured	0m; 6m; 12m; 24m
	Body composition	Self-measured	0m; 6m; 12m; 24m
	HbA1c	Self-measured	0m; 6m; 12m; 24m
Quality of Life and Wellbeing	Health-related quality of life	EQ-5D-5L[27]	0m; 6m; 12m; 24m
	Wellbeing	The Short Warwick–Edinburgh Mental	0m; 6m; 12m; 24m

		Well-being Scale (SWEMWBS)[28]	
Economic Evaluation	Health Care Use	MODRUM core module with depth questions for medications[29]	0m; 6m; 12m; 24m
	Out of pocket weight loss management costs	Selected modified MODRUM depth questions	0m; 6m; 12m; 24m
	Work productivity and impairment	Work Productivity and Impairment Questionnaire[30]	0m; 6m; 12m; 24m
Psychosocial factors	Emotional eating	TFEQ-R21[31]	0m; 6m; 12m; 24m
	Binge eating	Binge Eating Scale (BES)[32,33]	0m; 6m; 12m; 24m
	Experiential avoidance/psychological flexibility	Acceptance and Action Questionnaires (Weight Related)[34]	0m; 6m; 12m; 24m
	Depression Anxiety Stress	Patient Health Questionnaire 8-item (PHQ-8)[35] Generalized Anxiety Disorder 7-item (GAD-7) scale[36] Perceived Stress Scale (PSS-4)[37,38]	0m; 6m; 12m; 24m
Other	Physical activity	International Physical Activity Questionnaire (IPAQ) - Short Form Short form[39]	0m; 6m; 12m; 24m
	Sleep quality	Brief version of the Pittsburgh Sleep Quality Index (B-PSQI)[40]	0m; 6m; 12m; 24m
	Diet intake	Rapid Prime Diet Quality Score Screener (rPDQS)	0m; 6m; 12m; 24m
	Weight management questionnaire	Use of weight loss medications and other weight management programmes/activities used in addition to the allocated interventions	0m; 6m; 12m; 24m

	Demographics	Bespoke demographics questionnaire based on Progress-Plus criteria (place of residency, race/ethnicity, occupation, gender/sex, religion, education, socioeconomic status, social capital, age, disability, relationship status, caring responsibilities, car ownership, access to the internet).[25]	0m

The study coordinator will send email or phone reminders to participants if a completed questionnaire is not received within seven days.

Participants will provide consent for future follow-up through routine data sources and national registries. NHS numbers will be obtained to facilitate this process.

3.3.4 **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.

3.3.5 **Referral data**

Aggregate/ anonymised data on number, demographic characteristics, and weight loss of the invited population will be requested from participating service providers. Participants will be asked to consent to the service provider providing data on their attendance and weight loss during the initial weight loss programme.

3.4 **Randomisation**

Participants will be allocated to one of the two intervention arms in a 1:1 allocation using block randomisation (block size 6) stratified by weight loss programme (Tier 2 weight management programme / Tier 3 weight management / NHS Diabetes Prevention Programme / NHS Digital Weight Management Programme / NHS Diabetes Remission Programme) and weight loss medication use (<3 months over the past 6 months, ≥ 3 months over the past 6 months, no weight loss medication use over the past 6 months). 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.

Once eligibility is confirmed and the online baseline assessment is complete, participants will provide their baseline weight before being randomised during a call with the study coordination

team. The study coordinator team will inform participants of their group allocation during the call, and intervention materials will be provided accordingly.

For logistical reasons the study coordinator and the data manager will not be blinded to the allocation group. The trial statistician and investigators will be blinded to intervention allocation until the database is locked and the primary analysis complete.

3.5 Outcomes

3.5.1 Primary Outcome

12-month change from baseline in weight (kg)

3.5.2 Secondary Outcomes

- 6 and 24-month change from baseline in weight (kg)
- 6, 12 and 24-month change from baseline in HbA1c, emotional eating, binge eating, psychological flexibility, anxiety symptoms, depression symptoms, wellbeing, physical activity, diet, sleep quality (all outcomes outlined in Table 2).

3.5.3 Health Economic Outcomes

- Health-resource use over 12 months
- Self-reported out-of-pocket costs and loss of productivity.
- Quality-adjusted life-years (QALYs) based on HRQoL (EQ-5D-5L)
- Work productivity
- Total and incremental costs from NHS and UK society perspectives; incremental net (monetary) benefit; value of information estimates.

4. PLANNED INTERVENTION AND CONTROL

4.1 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 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. Participants will also be provided with the option to receive an adapted paper-based workbook version of the module content. Content is described in Table 3.

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. 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 additional 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. There will also be 3 optional calls that can be used at any time should the participant need additional coach support or be struggling with the intervention.

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. If participants are identified as at risk of disengagement (i.e., they have not attended or rescheduled their coach call), the coach will make up to 3 additional re-engagement calls.

Table 3. SWiM Intervention Outline and Content

Week	SWiM Session	Coach support
1	Welcome to SWiM	
1	Session 1: Planning and Tracking	30-minute scheduled telephone call following completion of SWiM Session 1
2	Session 2: Control and Acceptance	
3	Session 3: Being Willing	30-minute scheduled telephone call following completion of SWiM Session 3
4	Session 4: Overcoming Obstacles	
5	Session 5: Being Active and Willing	
6	Session 6: Emotional Eating	
7	Session 7: Stress Management	
8	Session 8: Forming Helpful Habits	30-minute scheduled telephone call following completion of SWiM Session 8
9	Session 9: Breaking Unhelpful Habits	
10	Session 10: Urges and Cravings	
11	Session 11: The Power of Sleep	
12	Session 12: Friends and Family	
13	Session 13: Weight Stigma and Body Image	
[4-week break to practice skills]		

17	Session 14: Lapses and motivation	30-minute scheduled telephone call following completion of SWiM Session 14.

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 completed (Figure 2). As participants complete core skills exercises, these are stored in "SWiM Tools," 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 rollout would include indefinite access to the website.

Figure 1: 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. The weight tracker generates a line graph that automatically updates as data is entered by the participant.

As part of the first session, participants are asked to enter their prior weight loss so they can see what they have already achieved. The weight tracker automatically sets a weight maintenance target range with a boundary of ±3 kg, which 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 the entry of weight data into the tracker. Participants will be given the option of a printed booklet of the website exercises if they prefer to write their answers down rather than enter the information

online. The "SWiM Tools" and a weight tracker graph will be included at the back of the workbook.

4.2 **Control Intervention**

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. Data on this will be captured at all time points so that we can describe the frequency and nature of weight management behaviours in this cohort by intervention type, weight loss programme, and demographics.

5. STATISTICS AND QUANTITATIVE DATA ANALYSIS

5.1 **Sample Size**

Previous meta-analyses suggest weight gain prevention interventions achieve effects of ~1.5kg at 12 months (less weight gain compared with controls).[41,42] Our feasibility trial observed a -3.86kg (95%CI: -7.83 to 0.11kg, p=0.06) difference in weight at 6 months between SWiM participants and standard care, with SWiM participants losing ~2.2kg whereas standard care participants gained ~2.2 kg. Our expert elicitation workshop identified a potential mean difference of -1.96kg at 12 months with considerable uncertainty. Pre-trial modelling suggests interventions achieving these differences in weight regain after weight loss, and potentially even smaller differences, should be cost-effective.[43–45] Thus, we designed the trial to detect a small overall effect size of ~1kg.

With 1,840 participants there is 90% power to detect a 1.01 kg difference in mean weight between SWiM and standard care as significant at the 2-sided 5% level, assuming a standard deviation at baseline of 22 kg, a 0.967 correlation between baseline and follow up[46] and 30% attrition. The correlation between baseline and follow up is based on the SWiM feasibility study, and is corroborated by data from our previous studies including weight change in the first year after finishing a weight loss programme in the WRAP trial[47] (r=0.96) and 9 month weight change in Fenland COVID[48] (N=1162 adults with overweight/obesity, r=0.972).

Designing the trial to detect a small weight difference in the overall sample should also allow a reasonable level of power to detect differences between SWiM and control within each WLP group (e.g. among only those who lost weight with a tier 3 programme), or within specific demographic groups (e.g. among men). Assuming approximately 368 participants from each WLP, there would be 80% power to detect a 1.96kg difference as significant at the 5% level between SWiM and standard care within each WLP.

5.2 **Analysis Plan**

A detailed statistical analysis plan will be developed, signed off by the Trial Steering Committee and uploaded to the ISRCTN registry prior to analysis. The intervention effect on 12-month weight change will be estimated from a 2-level mixed effects model, using weight measurements at baseline, 6 and 12 months. The model will include timepoint, intervention-by-timepoint interaction, gender and WLP as fixed effects and random intercepts to allow for repeated measures.[49] This model assumes missing outcome data are missing at random. The primary analysis will include all available data; in a sensitivity analysis, we will impute missing values of the outcome using multiple imputation by chained equations.

Similar analyses will be performed for secondary outcomes. We aim to analyse and publish findings as soon as 12-month follow-up is complete to ensure timely communication of findings and enable analyses of inequalities in engagement and effectiveness and other determinants that we can use to understand adaptations needed; therefore 24-month values are not included in the primary analysis but will be analysed and published separately.

The primary analysis will be repeated to identify potential interactions between the intervention effect and WLP by including a three-way interaction (trial intervention x WLP x timepoint). The 12month intervention effect and 95%CI will be estimated within each WLP. Similar methods will be used to identify potential inequalities by PROGRESS Plus criteria[25].

Cost-effectiveness analysis

A detailed Health Economics and Modelling analysis plan (HEDMAP) will be developed and signed off by the Trial Steering Committee. The intervention effect on health-related quality of life will be estimated from a mixed effect model EQ-5D measurements taken at 0, 6 and 12 months.

The intervention effect on health care costs, out of pocket weight management services and work productivity at 12 months will be estimated from a mixed-effects model using measurements taken at 0, 6 and 12 months. Unit costs for health care services will be derived from nationally representative data sources such as the Unit Costs of Health and Social Care Programme[50] and drug tariffs.[51] Total health care costs will be estimated by aggregating the health care and NHS prescribed medications used valued at their unit prices. Scores for absenteeism (work time missed), presenteeism (work impairment), work productivity loss and activity impairment will be calculated using the WPAI scoring system.

Long-term cost-effectiveness analysis will use modelling methods to extrapolate the effectiveness of the intervention on weight and other cardiometabolic risk factors at 12 and 24 months to predict long-term impacts on health and health related costs. Intervention effects on cardiometabolic risks beyond 24 months will be based on existing evidence. The relationships between cardiometabolic risks and obesity related complications, health-related quality of life and healthcare utilisation will be based on evidence from the literature, The analysis will adopt an NHS and Personal Social Services perspective. The analysis will simulate health outcomes and health care costs over the lifetime with costs and health-related quality of life discounted at 3.5%.

6. Process Evaluation

A process evaluation will be conducted to understand what works, how does it work, for whom, in what contexts, and why. We will adopt a mixed-methods convergent parallel design, whereby quantitative and qualitative research methods will be employed simultaneously.

6.1 **Ontological and epistemological positioning**

The process evaluation methodology will be underpinned by a Critical Realist Ontology. Critical Realism posits that an independent reality exists, but such a reality is context-dependent, the result of interacting mechanisms, and that different perspectives on or experiences of this reality exist.[52–54] The quantitative component will be underpinned by a Post-Positivist Epistemology which aims to ascertain objective knowledge whilst acknowledging that research methods and interpretations are inherently limited by the researchers' values and culture.[54,55] The qualitative component will be underpinned by Contextualism, which seeks to ascertain a situated knowledge, understood only by exploring the multiple and subjective perceptions of reality and how these are shaped by human values and context.[54,56]

6.2 **Quantitative component**

The quantitative component will aim to address the following research question:

What works, how does it work, and for whom?

We will report descriptive statistics on key intervention uptake and engagement metrics, such as the number and proportion of participants completing at least the first session, the average

number of sessions completed, and the average number and duration of coach calls completed. In addition to the main statistical analyses described in the above analysis plan, we will examine mediators and moderators of intervention effects informed by our SWiM programme theory (Appendix A). The following variables will be analysed for potential mediating or moderating effects (depending on the programme theory) on the primary outcome: psychological flexibility, depression, anxiety, stress, impulsivity, pain, sleep, diet, physical activity, uncontrolled eating, emotional eating, and number of coach calls attended. We will explore whether intervention effects differ by sociodemographic subgroups by exploring moderating effects of PROGRESS-PLUS criteria, as outlined in section 5.2.

6.3 **Qualitative component**

The qualitative component will aim to address the following research questions:

How is SWiM perceived, experienced and applied over time across individual contexts?

Why do components of SWiM work or not work, and under what contexts?

What additional unintended outcomes (positive/negative) are experienced?

Qualitative data will be collected via longitudinal and cross-sectional semi-structured interviews via zoom or telephone at 6 and 18-months. Stratified, purposive sampling will be employed to ensure; maximum heterogeneity in engagement and 6m weight change and representation across individual characteristics and demographic groups to understand patient journeys. 6 months is chosen to capture intervention completion and 18-months for long-term outcomes. The sample size will be determined by a process of information power, although it is estimated that a sample of 15 (three per each of the five referring weight loss programmes) will be necessary to achieve the desired diversity.[57,58] Co-produced interview schedules will explore how the programme was perceived, experienced and applied across different groups, unanticipated impacts, and long-term sustainability. The interview schedule will be informed by the Client Change Interview. Interview data will be analysed using reflexive thematic analysis[54] with support from a (trained) patient panel member. An abductive approach to coding and theme development will be employed, informed by the revised SWiM programme theory, the Theoretical Framework of Acceptability,[59] and Capability - Opportunity – Motivation – Behaviour Model,[60] whilst also seeking to generate new explanations and extend the programme theory. 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 and/or paper-based coding. Methods to enhance rigour will include the use of a reflective diary throughout data collection and analysis, the involvement of a public panel member, and the progression of coding iterations will be documented to track the evolution of codes and prospective themes. Reflexive discussions will be held amongst the research team to clarify and deepen analytic insights and enhance the quality of the developing analysis.[54,61]
Qualitative and quantitative data will be analysed separately, then integrated using a joint tabular display.[62,63]

7. Delivery Evaluation

7.1 **Fidelity in programme delivery**

A fidelity assessment will be conducted to evaluate whether SWiM is delivered as intended by the SWiM coaches. Underpinned by Ontological Realism and Epistemology Post-Positivism, this assessment will address the following research question:

To what extent is SWiM delivered as intended?

Data will be collected via observations of session recordings. At a minimum, we intend to recruit six coaches for programme delivery and observe a sample of two complete courses (one course ≈ four coach calls) across all six coaches, equating to twelve samples (total *N* = 48 coach calls). If additional coaches are recruited, further observations will be governed by a process of information power.[58] A checklist of core SWiM session parameters (e.g., duration) and content will be developed by the programme development team. The checklist will be assessed for inter-rater reliability using a sample of session recordings, observed and coded by two researchers individually and in duplicate. This will inform checklist refinements before the full-scale fidelity assessment.

All session recordings will be observed and coded against the refined checklist individually and in duplicate by two researchers. Inter-rater reliability will be analysed and reported and all discrepancies between the two coders will be resolved through discussion. Data will be analysed descriptively to report the degree of fidelity.

7.2 **Experiences of health coach delivery**

To understand the contextual factors influencing the delivery of SWiM, a qualitative study will be conducted to explore health coaches' perceptions and experiences of delivering SWiM, including barriers and facilitators to delivery. This will be underpinned by a Critical Realist Ontology and Contextualist Epistemology, aiming to address the following research questions:

How is the delivery of SWiM perceived and experienced by the health coaches?

What are the barriers and facilitators to delivering SWiM with fidelity to the programme theory and coach manual?

Qualitative data will be collected via semi-structured interviews via zoom or telephone between 6 and 12-months into trial recruitment, to allow sufficient time and experience of intervention delivery amongst the coaches. Convenience sampling will be employed, advertising the study to all health coaches delivering SWiM. Interview data will be analysed using reflexive thematic analysis.[54] The sample size will be determined by the number of coaches recruited for SWiM delivery. An abductive approach to coding and theme development will be employed, informed by the Capability – Opportunity – Motivation – Behaviour Model[60] and Theoretical Domains Framework[64], whilst also seeking to generate new explanations and theory of SWiM implementation. 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 and/or paper-based coding. Methods to enhance rigour will include the use of a reflective diary throughout data collection and analysis, and the progression of coding iterations will be documented to track the evolution of codes and prospective themes. Reflexive discussions will be held amongst the research team to clarify and deepen analytic insights and enhance the quality of the developing analysis.[54,61]

8. DATA MANAGEMENT

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.

8.1 **Data Collection tools and source documentation**

The MRC Epidemiology Unit uses a Secure Research Domain (SRD), which is a computer network that has been designed to securely store PID, and which is considered a safe haven for storing

PID by the University of Cambridge. All Participant Identifiable Data (PID) are stored only within the SRD. The SRD has security features and policies to ensure only a minimum number of named, qualified staff have access to this sensitive information. All SRD users have a contract with the Unit and are trained in data security. In addition, all access to the SRD involves 2-Factor Authentication (2-FA) and has a number of security features in place to protect this data.

We will export PID from the SRD under the following circumstances necessary to running the study:

- Transfer of name and email between us and the referring service provider/commissioner to establish contact with participants/check they are not contacted more than necessary. Data transfer via NHS email, sFTP or provider's secure website.
- Transfer of participant name, address, and height and weight to the cellular-scales provider for the purpose of setting up and shipping the cellular-scales. Data transfer via developer API secured by HTTPS and OAuth2.0.
- Transfer of mobile phone number and name to the SMS provider for sending of SMSs between the study team and the participant. Data transfer via sFTP or provider's secure website.
- Transfer of name and email address to Cauldron for set up of participant accounts on the study intervention website. Data transfer via sFTP or provider's secure website.
- Name and address labels for posting finger-prick home kits.
- Transfer of name, date of birth, and NHS number to national registries for linkage of study data to registry data. Data transfer via sFTP or provider's secure website.

All other participant data used in SWiM 2.0 monitoring and analysis will be pseudonymised. This involves assigning a unique study ID to each participant and then removing all data that could allow a participant to be directly identified. The anonymous study ID will also be used for data collection using the REDCap surveys, weight measurements from the cellulare-scales and for the HbA1c result.

The scientists, study team and other members of staff who deal with the participants' data, but who do not need to be in contact with the participant, will only have access to the pseudonymised data, thus allowing them to carry out analysis and other data tasks without compromising the privacy of study participants.

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.

8.1.1 Source data collected at home

Questionnaire data collected remotely via REDCap forms will be linked to the participant using the study ID only (i.e. no identifiable data).

Because the initial expression of interest form is a publicly-available link, we will take extra steps to filter out bots and multiple registrations. We will use a REDCap Captcha module to provide a score for the likelihood that the form has been filled out by a human rather than a bot, add hidden questions to filter out bots, and confirm provided phone numbers by sending an SMS message expecting a reply. We will also filter out entries with duplicate addresses, emails, or phone numbers.

8.1.2 Source data collected via cellular-scales

The cellular-scales will send participants' weight measurements over cellular data to Withings' GDPR compliant servers in the EU and then retrieved using the Withings developer API directly to the Epi Unit's secure research data server. Data transfers are secured using HTTPS and OAuth2.0 authentication. Weight measures will be linked to the participant using the study ID only (i.e. no identifiable data).

8.1.3 Source data collected via HbA1c test

The blood results collected via finger prick will be sent from The Doctors Laboratory directly to the study team in batches. Blood results will be linked to the participant using the study ID only (i.e. no identifiable data).

8.2 Data handling and record keeping

Where possible, on study specific documents and in all places where a participant needs to be referenced, the participant will be referred to by their study ID number, not by name. However, for some documents e.g. informed consent, the participant's name will be present.

All participant level data will be entered and stored on the Unit's SRD to which access is restricted via unique username and password as well as 2-FA. Participant data will be link anonymised (pseudonymised) at the point of data release. Direct quotations about participation in the study will only be used with explicit written permission from the participant unless the quote is anonymised. All data handling, processing, transfer and storage procedures comply with our obligations under the latest Data Protection Act, which incorporates GDPR.

The study database will also be used to record study data, including randomisation group, eligibility criteria met and completion of online assessments.

Any paper documentation, which will be minimal for this study, will be held in access-controlled buildings within lockable rooms in lockable filing cabinets that only authorised personnel can access. All paper data transfers will be sent via recorded delivery or secure courier.

8.3 Access to data

Data will only be accessed and used by those who have permission. Access to data on network storage requires a valid Unit login (username and password). Access to data in the study's databases requires a password protected database account and access to PID is further limited to named users with additional 2-FA.

The data cannot be used or given to any other third party without documented permission of the participant, as explained in the participant information sheet.

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit study-related monitoring, audits and inspections, in line with participant consent.

Anonymised data sets may be shared with external collaborators for research purposes. Studies and analyses of the data collected will be subject to approval by the study investigators. Where external researchers wish to use participant-level data, we will require an agreement to be in place to cover data sharing and security. Where possible we will release data via in-reach to our servers, with a visiting worker agreement and appropriate data security training. Where data needs to be released externally then this will be covered by the study collaboration agreement (for SWIM investigators) or a formal Data Sharing Agreement

8.3.1 Data Protection/GDPR

The Data Protection Act defines "personal data" as any information relating to an identified or identifiable living individual. This is a living individual who can be identified, directly or indirectly, in particular by reference to (a) an identifier such as a name, an identification number, location

data or an online identifier, (b) or one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of the individual.

This study is being conducted by the MRC Epidemiology Unit as part of the University of Cambridge and as such the legal basis to hold and use personal data is covered under the General Data Protection Regulation "Article 6(1) (e) processing is necessary for the performance of a task carried out in the public interest". To hold special categories of personal data our lawful basis is for pursuing scientific research under "Article 9(2) (j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject".

8.4 **Cauldron Science Ltd**

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.

8.5 **Qualitative Interviews**

The qualitative interviews and observations will be recorded on TEAMS, initially as a video/audio mp4 file. The CETU have a shared TEAMs channel configured so that it is only accessible to designated Research staff on that project. The recording will automatically save in the cloud on the University's Microsoft's 365 platform into SharePoint which the Researcher has access to using their RAVEN credentials. The video/audio mp4 file will then be converted into an audio only mp3 file using the software VLC once the file is on the SRD a separate server which requires two factor security authentications to access. Once safely transferred to the SRD, all files will be deleted from TEAMS. Recordings will be transcribed by an experienced external agency and checked for accuracy by the research team.

8.6 **Data Storage and Archiving**

Essential documents are defined as 'those which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced'. Essential documents are primarily held in the eTMF but also includes data held in study databases and source data.

Essential study documents, mostly in electronic form, will be archived in accordance with MRC policy for a minimum of 20 years after the study has ended. The process and monitoring will follow our CETU SOPs and department policies and will be described in detail in the Data Management Plan.

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.

9. MONITORING AND ARCHIVING

9.1 **Risk Assessment**

A risk assessment will be written and approved by the CI before the first participant is invited. The risk assessment will help define all monitoring activities and frequencies.

9.2 **Monitoring**

A monitoring plan, approved by the CI, will describe the frequency and nature of monitoring activities, proportional to the risk identified in the Risk Assessment.

In accordance with the conditions and principles of GCP, an electronic Trial Master File (eTMF) will be established at the beginning of the study and held by the Study Coordinator at the MRC Epidemiology Unit. All essential documents, which together demonstrate the compliance of the study and study personnel with the conditions and principles of GCP and any applicable regulatory requirements, will be stored in the eTMF. The study risk assessment will determine the review frequency of the eTMF as per the CETU TMF Review SOP to confirm adherence to GCP guidelines and any applicable regulations.

Persons from regulatory bodies and representatives of the Unit and the sponsor may require access to participant level data to verify that the conduct of the study is in line with applicable regulations.

Those responsible for undertaking the collection of data from study participants will be subject to appropriate training, review and assessment by the relevant MRC Epidemiology Unit specialist before being deemed competent. Regular monitoring of the level and type of data queries will be performed by the Study Coordinator. This will inform any further training needs. In addition, the Unit's specialist teams will conduct quality control and assurance reviews, on at least an annual basis, in order to maintain a high level of competency and quality in the collection of data

10. SAFETY REPORTING

10.1 **AE/SAE Definitions**

An adverse event (AE) is any untoward occurrence in a participant that occurs as part of a test procedure whether related to that procedure or not. Test procedures include direct measurements, be they at a testing site or in a free-living environment. For example, a participant who faints whilst having a blood sample taken is experiencing an AE. Monitoring these events enables us to improve our test procedures and responses to future events.

A Serious Adverse Event (SAE) is any untoward medical occurrence or event that either:

- Results in death or is life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Consists of a congenital anomaly or birth defect
- Is otherwise considered medically significant by the investigator

10.2 Recording and reporting AEs and SAEs

The Sponsor expects that adverse events are recorded from the point of Informed Consent. Given the remote nature of this study, we do not expect there to be a large number of adverse events.

There are no expected SAEs for this study.

10.3 Reporting Responsibilities

Adverse events experienced by study participants will be recorded, followed-up and reviewed by an investigator as per the CETU SOP for recording and reporting adverse events. The Operational Group will monitor the frequency and type of adverse events during each of their scheduled meetings. In addition, the monthly CETU Steering Group Meeting will receive a report on the numbers of adverse events recorded during the previous month.

All Serious Adverse Events will be reported to the Chief Investigator using the CETU SAE form within 24 hours of awareness of the event. The Chief Investigator is responsible for ensuring the assessment of all SAEs for expectedness and relatedness is completed and the onward notification of all SAEs to the Sponsor if applicable as per CETU SOP for recording and reporting adverse events.

Serious Adverse Events (SAEs) that are related to the study (i.e. those that result from administration of any of the research procedures) and are unexpected (i.e. not listed in the protocol as an expected occurrence) will be emailed to the REC using the Non-CTIMP safety report to REC form. These will be sent within 15 days of the chief investigator becoming aware of the event. There is no requirement for annual safety reports in addition to the information provided through the annual progress report.

11. RESEARCH GOVERNANCE AND APPROVALS

The investigators will ensure that the trial conduct conforms to the principles of the Declaration of Helsinki (2024), 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 HRA approval from the Research Ethics Committee. 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 HRA for approval. Substantial amendments will not be implemented until relevant approvals have been given.

Sponsor:

The study will be sponsored by the University of Cambridge and Cambridgeshire and Peterborough ICB and is funded by the National Institute of Health Research. The University of Cambridge will provide indemnity in the case of negligent and non-negligent harm for research conducted through its Units when it is Sponsor and for employees or others acting on behalf of the University.

Insurance:

The University of Cambridge will arrange insurance for negligent harm caused as a result of protocol design and for non-negligent harm arising through participation in the study.

The University Insurance Manager has advised that insurance for negligent and non-negligent harm under the University's Clinical Trials policy can be arranged if this study is approved by an NHS Research Ethics Committee.

12. 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 Principal Investigator, Dr Amy Ahern has responsibility for the design and conduct of the trial and for the analysis and dissemination of results.

As the Programme Manager, Dr Marie Spreckley will have operational responsibility for the delivery of the trial, ensuring effective communication across the Investigators and Research Staff employed on the trial and effective engagement with other stakeholders.

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; ensuring that the trial is running in a timely manner and in accordance with good clinical practice guidelines.

Dr Julia Mueller will write and implement the statistical analysis plan, with oversight from the Trial Statistician, Mr Stephen Sharp.

Dr Penny Breeze and Prof Alan Brennan are 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 Tamla Evans will lead the qualitative evaluation, including the establishment of the data collection methods used, conducting the qualitative analyses and publication and appropriate dissemination of findings.

Mr Ken Clare and Mrs Hazel Patel will lead the Patient and Public Involvement for the trial.

13. PATIENT AND PUBLIC INVOLVEMENT

Substantial PPI input has already contributed to the development and evaluation of the SWiM intervention, and we will continue to seek PPI input from our Patient User Group Panel (PUGP), which comprises members with diverse experiences of weight loss and weight maintenance.

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 questionnaires and qualitative interviews 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.

Two PPI representatives (Hazel Patel and Ken Clare) are Investigators on the trial, have contributed to the design of the protocol and chair the PUGP. They 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.

One PPI representative will be a member of the Programme Steering Committee. The representative 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.

14. PROGRAMME STEERING COMMITTEE

The Programme Steering Committee (PSC) will provide overall supervision for the SWiM 2.0 Trial on behalf of the Trial Sponsors (University of Cambridge) and Trial Funder (NIHR) and 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 Programme Steering Committee will also take on the role of Trial Steering Committee (this is a low-risk trial, and a separate Data Monitoring and Ethics Committee is not deemed necessary).

The PSC 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. The PSC will be chaired by Professor Lucy Yardley (University of Bristol). Independent members include Dr Iain Timmins (AstraZeneca, Statistician), Dr Edel Doherty (National University of Ireland Galway, Health Economist), and Ms Alison Lake (PPI Advocate). 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.

15. DISSEMINATION

At the end of the trial, we will present our findings to our PPI representatives and our stakeholder panel and identify appropriate ways to communicate findings to participants and other non-academic audiences.

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 Investigator 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 study/project is funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research (NIHR 206801). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.”

The lead author must also give NIHR notice of any media activity (e.g. press release of research) and a copy of the press release at least 3 days before release.

16. REFERENCES

1. Okunogbe, A. *et al.* Economic impacts of overweight and obesity: current and future estimates for 161 countries. *BMJ Glob. Heal.* **7**, 9773 (2022).
2. Soares Andrade, C. A. *et al.* The burden of type 2 diabetes mellitus in states of the European Union and United Kingdom at the national and subnational levels: A systematic review. *Obes. Rev.* **24**, (2023).
3. Hartmann-Boyce, J., Johns, D. J., Jebb, S. A., Summerbell, C. & Aveyard, P. Behavioural weight management programmes for adults assessed by trials conducted in everyday contexts: systematic review and meta-analysis. *Obes. Rev.* **15**, 920–932 (2014).
4. Dombrowski, S. U., Knittle, K., Avenell, A., Araújo-Soares, V. & Sniehotta, F. F. Long term maintenance of weight loss with non-surgical interventions in obese adults: Systematic review and meta-analyses of randomised controlled trials. *BMJ* **348**, (2014).
5. Greaves, C., Poltawski, L., Garside, R. & Briscoe, S. Understanding the challenge of weight loss maintenance: a systematic review and synthesis of qualitative research on weight loss maintenance. *Health Psychology Review* vol. 11 145–163 (2017).
6. Wilding, J. P. H. *et al.* Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension. *Diabetes, Obes. Metab.* **24**, 1553–1564 (2022).
7. Dombrowski, S. U., Knittle, K., Avenell, A., Araújo-Soares, V. & Sniehotta, F. F. Long term maintenance of weight loss with non-surgical interventions in obese adults: systematic review and meta-analyses of randomised controlled trials. *BMJ* **348**, (2014).
8. Dansinger, M. L., Tatsioni, A., Wong, J. B., Chung, M. & Balk, E. M. Meta-analysis: The effect of dietary counseling for weight loss. *Ann. Intern. Med.* **147**, 41–50 (2007).
9. Daley, A. *et al.* A brief behavioural intervention to promote regular self-weighing to prevent weight regain after weight loss: a RCT. *Public Heal. Res.* **7**, 1–66 (2019).
10. Sidhu, M. S., Daley, A. & Jolly, K. Evaluation of a text supported weight maintenance programme 'Lighten Up Plus' following a weight reduction programme: randomised controlled trial. (2016) doi:10.1186/s12966-016-0346-1.
11. Sniehotta Id, F. F. *et al.* Behavioural intervention for weight loss maintenance versus standard weight advice in adults with obesity: A randomised controlled trial in the UK (NULevel Trial). (2019) doi:10.1371/journal.pmed.1002793.
12. Lawlor, E. R. *et al.* Third-wave cognitive behaviour therapies for weight management: A systematic review and network meta-analysis. *Obes. Rev.* **21**, (2020).
13. Lillis, J. & Kendra, K. E. Acceptance and Commitment Therapy for weight control: Model, evidence, and future directions. *J. Context. Behav. Sci.* **3**, 1 (2014).
14. Bradley, L. E. *et al.* Project HELP: a Remotely Delivered Behavioral Intervention for Weight Regain after Bariatric Surgery. *Obes. Surg.* **27**, 586–598 (2017).
15. Mueller, J. *et al.* Supporting Weight Management during COVID-19 (SWiM-C): A randomised controlled trial of a web-based, ACT-based, guided self-help intervention. *Obes. Facts* **15**, 550–559 (2022).
16. Mueller, J. *et al.* Supporting Weight Management during COVID-19 (SWiM-C): twelve-month follow-up of a randomised controlled trial of a web-based, ACT-based, guided self-help intervention. *Int. J. Obes.* **47**, 51–59 (2022).

17. Levin, M. E. *et al.* A randomized controlled trial of online acceptance and commitment therapy to improve diet and physical activity among adults who are overweight/obese. *Transl. Behav. Med.* **11**, 1216–1225 (2021).

18. Berger, E., Garcia, Y., Catagnus, R. & Temple, J. The effect of acceptance and commitment training on improving physical activity during the COVID-19 pandemic. *J. Context. Behav. Sci.* **20**, 70–78 (2021).

19. Lawlor, E. R. *et al.* Cognitive and behavioural strategies employed to overcome "lapses" and prevent "relapse" among weight-loss maintainers and regainers: A qualitative study. *Clin. Obes.* **10**, e12395 (2020).

20. Richards, R. *et al.* Development of a Web-Based, Guided Self-help, Acceptance and Commitment Therapy–Based Intervention for Weight Loss Maintenance: Evidence-, Theory-, and Person-Based Approach. *JMIR Form Res 2022;6(1)e31801 https//formative.jmir.org/2022/1/e31801* **6**, e31801 (2022).

21. Bates, S. E. *et al.* Using health economic modelling to inform the design and development of an intervention: estimating the justifiable cost of weight loss maintenance in the UK. *BMC Public Health* **22**, 1–12 (2022).

22. Lillis, J., Dunsiger, S., Thomas, J. G., Ross, K. M. & Wing, R. R. Novel behavioral interventions to improve long-term weight loss: A randomized trial of acceptance and commitment therapy or self-regulation for weight loss maintenance. *J. Behav. Med. 2021 444* **44**, 527–540 (2021).

23. Forman, E. M. & Butryn, M. L. A new look at the science of weight control: how acceptance and commitment strategies can address the challenge of self-regulation. *Appetite* **84**, 171–180 (2015).

24. Jones, R. A. *et al.* Acceptability and feasibility of an acceptance-based guided self-help programme for weight loss maintenance in adults who have previously completed a behavioural weight loss programme: the SWiM feasibility study (in press). *Obes. Sci. Pract.* (2025).

25. O'Neill, J. *et al.* Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. *J. Clin. Epidemiol.* **67**, 56–64 (2014).

26. Mueller, J. *et al.* Glucose Lowering through Weight management (GLoW): a randomised controlled trial of the clinical and cost effectiveness of a diabetes education and behavioural weight management programme vs a diabetes education programme in adults with a recent diagnosis of type 2 diabetes. *Diabetologia* (2025) doi:10.1007/S00125-024-06355-6.

27. Herdman, M. *et al.* Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual. Life Res.* **20**, 1727–1736 (2011).

28. Ng Fat, L., Scholes, S., Boniface, S., Mindell, J. & Stewart-Brown, S. Evaluating and establishing national norms for mental wellbeing using the short Warwick–Edinburgh Mental Well-being Scale (SWEMWBS): findings from the Health Survey for England. *Qual. Life Res.* **26**, 1129–1144 (2017).

29. Garfield, K., Husbands, S., Thorn, J. C., Noble, S. & Hollingworth, W. Development of a brief, generic, modular resource-use measure (ModRUM): cognitive interviews with patients. *BMC Health Serv. Res.* **21**, 1–12 (2021).

30. Reilly, M. C., Zbrozek, A. S. & Dukes, E. M. The Validity and Reproducibility of a Work

Productivity and Activity Impairment Instrument. *PharmacoEconomics 1993 45* **4**, 353–365 (2012).

31. Tholin, S., Rasmussen, F., Tynelius, P. & Karlsson, J. Genetic and environmental influences on eating behavior: the Swedish Young Male Twins Study. *Am. J. Clin. Nutr.* **81**, 564–569 (2005).

32. Gormally, J., Black, S., Daston, S. & Rardin, D. The assessment of binge eating severity among obese persons. *Addict. Behav.* **7**, 47–55 (1982).

33. Grupski, A. E. *et al.* Examining the binge eating scale in screening for binge eating disorder in bariatric surgery candidates. *Obes. Surg.* **23**, 1–6 (2013).

34. 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.* **5**, 193–200 (2016).

35. Kroenke, K. *et al.* The PHQ-8 as a measure of current depression in the general population. *J. Affect. Disord.* **114**, 163–173 (2009).

36. Spitzer, R. L., Kroenke, K., Williams, J. B. W. & Löwe, B. A brief measure for assessing generalized anxiety disorder: The GAD-7. *Arch. Intern. Med.* **166**, 1092–1097 (2006).

37. Cohen, S., Kamarck, T. & Mermelstein, R. A global measure of perceived stress. *J. Health Soc. Behav.* **24**, 385–396 (1983).

38. Herrero, J. & Meneses, J. Short Web-based versions of the perceived stress (PSS) and Center for Epidemiological Studies-Depression (CESD) Scales: A comparison to pencil and paper responses among Internet users. *Comput. Human Behav.* **22**, 830–846 (2006).

39. Lee, P. H., Macfarlane, D. J., Lam, T. H. & Stewart, S. M. Validity of the international physical activity questionnaire short form (IPAQ-SF): A systematic review. *Int. J. Behav. Nutr. Phys. Act.* **8**, 1–11 (2011).

40. Sancho-Domingo, C., Carballo, J. L., Coloma-Carmona, A. & Buysse, D. J. Brief version of the Pittsburgh Sleep Quality Index (B-PSQI) and measurement invariance across gender and age in a population-based sample. *Psychol. Assess.* **33**, 111–121 (2021).

41. Martin, J. C., Awoke, M. A., Misso, M. L., Moran, L. J. & Harrison, C. L. Preventing weight gain in adults: A systematic review and meta-analysis of randomized controlled trials. *Obes. Rev.* e13280 (2021) doi:10.1111/obr.13280.

42. Graham, H. E., Madigan, C. D. & Daley, A. J. Is a small change approach for weight management effective? A systematic review and meta-analysis of randomized controlled trials. *Obes. Rev.* **23**, e13357 (2022).

43. Wing, R. R. *et al.* Benefits of Modest Weight Loss in Improving Cardiovascular Risk Factors in Overweight and Obese Individuals With Type 2 Diabetes. *Diabetes Care* **34**, 1481–1486 (2011).

44. Hills, A. P., Byrne, N. M., Lindstrom, R. & Hill, J. O. 'Small Changes'' to Diet and Physical Activity Behaviors for Weight Management'. *Obes. Facts* **6**, 228–238 (2013).

45. Lal, A. *et al.* The Modelled Population Obesity-Related Health Benefits of Reducing Consumption of Discretionary Foods in Australia. *Nutrients* **12**, 649 (2020).

46. Borm, G. F., Fransen, J. & Lemmens, W. A. J. G. A simple sample size formula for analysis of covariance in randomized clinical trials. *J. Clin. Epidemiol.* **60**, 1234–1238 (2007).

47. Ahern, A. L. *et al.* Extended and standard duration weight-loss programme referrals for adults in primary care (WRAP): a randomised controlled trial. *Lancet* **389**, 2214–2225

(2017).

48. Mueller, J. *et al.* The relationship of within-individual and between-individual variation in mental health with bodyweight: An exploratory longitudinal study. *PLoS One* **19**, e0295117 (2024).

49. Coffman, C. J., Edelman, D. & Woolson, R. F. To condition or not condition? Analysing 'change' in longitudinal randomised controlled trials. *BMJ Open* **6**, e013096 (2016).

50. Jones, K. C. *et al. Unit Costs of Health and Social Care 2023 Manual. Technical report. Personal Social Services Research Unit (University of Kent) & Centre for Health Economics (University of York), Kent, UK 10.22024/UniKent/01.02.105685. (doi:10.22024/UniKent/01.02.105685)*. (2024) doi:10.22024/UniKent/01.02.105685.

51. NHS Business Services Authority. NHS Electronic Drug Tariff. https://www.drugtariff.nhsbsa.nhs.uk/#/00881924-DC/DC00879352/Home (2025).

52. Pilgrim, D. Some implications of critical realism for mental health research. *Soc. Theory Heal.* **12**, 1–21 (2014).

53. Maxwell, J. A. *A Realist Approach for Qualitative Research*. (SAGE Publications Ltd, 2012).

54. Clarke, V. & Braun, V. Thematic analysis: A practical guide . *London SAGE* (2021).

55. Haraway, D. Situated Knowledges: The Science Question in Feminism and the Privilege of Partial Perspective (1988). *Anthropol. Theory Twenty-First Century a Crit. Approach* 236–240 (2022) doi:10.2307/3178066.

56. Madill, A., Jordan, A. & Shirley, C. Objectivity and reliability in qualitative analysis: Realist, contextualist and radical constructionist epistemologies. *Br. J. Psychol.* **91**, 1–20 (2000).

57. Braun, V. & Clarke, V. To saturate or not to saturate? Questioning data saturation as a useful concept for thematic analysis and sample-size rationales. *Qualitative Research in Sport, Exercise and Health* vol. 13 (2021).

58. Malterud, K., Siersma, V. D. & Guassora, A. D. Sample Size in Qualitative Interview Studies: Guided by Information Power. *Qual. Health Res.* **26**, 1753–1760 (2016).

59. Sekhon, M., Cartwright, M. & Francis, J. J. Acceptability of healthcare interventions: An overview of reviews and development of a theoretical framework. *BMC Health Serv. Res.* **17**, 1–13 (2017).

60. Michie, S., van Stralen, M. M. & West, R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement. Sci.* **6**, 42 (2011).

61. Nadin, S. & Cassell, C. The use of a research diary as a tool for reflexive practice: Some reflections from management research. *Qual. Res. Account. Manag.* **3**, 208–217 (2006).

62. McCrudden, M. T., Marchand, G. & Schutz, P. A. Joint displays for mixed methods research in psychology. *Methods Psychol.* **5**, 100067 (2021).

63. O'Cathain, A., Murphy, E. & Nicholl, J. Three techniques for integrating data in mixed methods studies. *BMJ* **341**, 1147–1150 (2010).

64. Michie, S. *et al.* Making psychological theory useful for implementing evidence based practice: a consensus approach. *Qual. Saf. Health Care* **14**, 26–33 (2005).

17. Appendices

APPENDIX A