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Effectiveness and cost effectiveness of an automated text message intervention for weight management in postpartum women with overweight or obesity: the Supporting MumS Randomised Controlled Trial

The Supporting MumS (SMS) study

Process Evaluation Analysis Plan

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SECTION 1: ADMINISTRATIVE INFORMATION

Process evaluation analysis plan (PEAP) version history:

SAP Version	Protocol Version	PEAP Version	Date	Changes
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Process evaluation analysis plan contributors:

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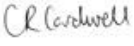
Name: Professor Chris Cardwell Signature: 

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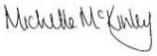
Name: Professor Michelle McKinley Signature: 

Date: 12/09/2024

SECTION 2: INTRODUCTION

2.1 Background and rationale

This trial addresses overweight and obesity trends across the childbearing years. Entering pregnancy with a high body mass index (BMI) increases health risks for these mothers and their babies.(1) Excessive gestational weight gain and postpartum weight retention are common and many women gain further weight across the extended postpartum period, increasing the risk of complications in subsequent pregnancies and contributing to long-term overweight and obesity.(2)

Effective and appropriate weight management interventions in women during the postpartum period, which account for the well-recognised barriers for new mums such as time constraints and childcare, are lacking.(3, 4) Previous intervention studies, often using in-person and structured weight management approaches, are characterised by poor recruitment and high rates of attrition and have not adequately considered the difficulties in reaching this population and specific barriers to health-related behaviour change that come with having a baby.(2, 5) More appropriate ways of recruiting and engaging with postpartum women to achieve sustained behaviour change while considering cost-effectiveness and health inequalities are required.(6)

Mobile technologies can offer a flexible and individualised 'any time, any place' approach to behavioural weight management interventions.(2) Text message interventions have high reach potential, allow for flexible scheduling and interactivity and have been shown to be cost-effective for supporting behaviour change, potentially making them convenient for mums with limited time and helpful for overcoming health inequalities.(7, 8)

The Supporting MumS (SMS) intervention, consisting of a library of text messages, was developed with personal and public involvement to support weight management in the postpartum period.(9) Bidirectional and interactive messages focus on diet and physical activity with embedded behaviour change techniques (BCTs) informed by behaviour change theory and evidence. A previous pilot evaluation demonstrated the feasibility and acceptability of the intervention in a sample of 100 postpartum women from Northern Ireland and determined that pre-specified progression criteria to proceed to a full randomised controlled trial (RCT) were met.(9)

This RCT addresses if this automated 12 month text message intervention, designed to support weight loss and weight loss maintenance for postpartum women with overweight or obesity, is effective and cost-effective for weight loss at 12 months, compared with an active control group receiving text messages on child health and development.

The trial makes a novel and important contribution to the field of behavioural text message interventions as: there are currently few behavioural interventions that are fully automated, where text messaging is the main mode of delivery and two-way messaging is used to encourage engagement and delivery of specific BCTs; there are also few behavioural interventions which consider both weight loss and weight loss maintenance, last 12 months or more and use an active control to minimise disappointment bias. The intervention also offers the opportunity to examine postnatal mental health (PMH) in an ethnically and socioeconomically diverse sample from all four UK countries.

2.2 Objectives

This PEAP addresses in detail the following SMS trial protocol objectives:

- To conduct a process evaluation to explore women's experiences of the intervention, the pathways through which the intervention effects are mediated and contextual factors affecting the outcomes or future implementation of the intervention, including the impact of PMH on intervention engagement and outcomes.
- To conduct interviews with stakeholders to explore scale-up and implementation if warranted.

This process evaluation will have an inequalities focus through consideration of interactions between participant characteristics (including socioeconomic status, ethnicity, and geographical region (e.g. site-specific, urban vs. rural)) and outcomes, as well the intersectionality of these characteristics.

It will also assess specific aspects of trial design namely: fidelity of blinding, acceptability of randomisation, research methods and trial procedures, and contamination between trial groups.

The objectives of the process evaluation are outlined in Table 1.

Table 1: Process evaluation objectives (addressing implementation, mechanisms of impact and context):

Implementation 1. To assess fidelity, reach and dose of intervention delivery including potential for contamination between trial groups.
Mechanisms of impact (satisfaction, mediators, engagement, unintended consequences) 2. To assess level of satisfaction with the intervention. 3. To quantitatively examine if the intervention led to favourable changes in measures of intervention processes specified by the underpinning theory for the intervention and the logic model (mediators) compared with the control group at 6, 12 and 24 months. 4. To quantitatively assess engagement with key components of the intervention and the relationship between level of engagement and intervention outcomes (primary, secondary, exploratory including PMH) at 6, 12 and 24 months. 5. To explore dimensions relevant to mechanisms of impact in qualitative interviews with participants at 6 and 12 months and integrate qualitative analysis with quantitative analysis to provide a comprehensive picture of how women respond to and interact with the intervention, how the intervention produces change, how this relates to the theoretical basis for the intervention and to help refine the logic model if additional mechanisms are identified. 6. To explore if the intervention had any unintended consequences or undesired effects (incl. (including PMH).
Context (moderators, factors related to scale-up and implementation) 7. To examine if contextual moderators affect the strength and direction of intervention effects on trial outcomes (primary, secondary, exploratory including PMH) using quantitative and qualitative methods. 8. To conduct interviews with stakeholders to explore contextual factors related to scale-up and implementation of the intervention.
Trial methods 9. To examine fidelity and acceptability of the trial methods with a range of women from across the UK, to inform future research.

SECTION 3: PROCESS EVALUATION METHODS FOR THE SMS TRIAL

3.1 Description of the intervention and active control group

The intervention group will receive an automated text message intervention focusing on diet and physical activity to support weight loss and maintenance of weight loss for 12 months. An active control will be used, this group will receive automated text messages relating to general childcare and development, but which do not mention the target behaviours (diet or physical activity) and do not contain the active ingredients of the intervention (BCT content related to weight management).

3.1.1 Active Control

As for the intervention messages, the active control messages were developed by the study team with PPI input (see final report (9)). The messages relate to general childcare and development and the content was consistent with evidence based information provided by the NHS Start4life information service for parents (10) and includes a play idea/activity each week and information on specific milestones, home safety, separation anxiety and similar topics. The active control does not mention the target behaviours and does not contain the active ingredients of the intervention (diet and physical activity content and embedded BCTs related to weight loss). There is no bi-directional functionality for the active control messages. Given the study inclusion criteria, the active control messages were developed for mothers with babies from six weeks of age or older (women have to be at least six weeks postpartum to enrol in the study) up to 36 months of age (as women can opt in at any stage up to 24 months postpartum and will receive messages for 12 months). Women will receive three messages each week for 12 months and messages correspond to the age of their baby, i.e. if their baby is six months old when they enrol, they start receiving messages corresponding to this age. Participants can text the word STOP at any time if they no longer want to receive the messages (in that event they would continue in the study unless they also formally withdraw from the study assessments); or they can text the word PAUSE if they want to pause the messages for a period.

3.1.2 Intervention

The intervention group will receive an automated text message intervention about weight loss and maintenance of weight loss for 12 months – full details of the development of the intervention are given in our NIHR final report.(9) The evidence and theory-based intervention consists of a library of text messages focused on diet and physical activity with embedded BCTs known to be positively associated with weight management. Fully automated messages include uni- and bi-directional messages and interactive features as described in brief below.

The intervention is based on the Health Action Process Approach (HAPA)(11) and a systematic review of over 100 behavioural theories which synthesised theoretical explanations for maintenance of behaviour change.(12) Overall, the intervention was designed to encourage a self-guided approach to health-related behaviour change and weight management as supported by the literature.[101-105] In-line with existing evidence, the intervention focused on dietary intake as well as physical activity to address energy balance with BCTs supported by an evidence base and specifically linked to the relevant phases and psychological processes of behaviour change embedded within the text messages alongside specific consideration of barriers for this group (full details can be found in the final report (9)). The messages aimed to adopt a friendly accessible tone including humour to encourage engagement; provide information, advice, practical tips and signpost to external resources; provide encouragement and motivation, discourage guilt and encourage self-reflection.

The number of messages sent varies throughout the 12 month intervention: months 1 and 2: 14-15/week; months 3 and 4: 9-10/week; months 5 and 6: 9-10/week; months 7 to 12: 4-5/week. Participants can text the word STOP at any time if they no longer want to receive the messages (in that event they would continue in the study unless they also formally withdraw from the study assessments); or they can text the word PAUSE if they want to pause the messages for a period.

A core library of text messages was created with additional components:

(i) Messages addressing other weight-related behaviours (smoking and breastfeeding): In addition to the core text messages, women can also opt-in when they register for the intervention to receive messages related to weight management when breastfeeding (n=10) or trying to stop smoking (n=15). The text messages were created to alleviate participant fears or concerns in relation to weight management whilst breastfeeding and to address vulnerabilities around weight gain during smoking cessation.

(ii) A weekly text message asking women to report weight (n=50)

(iii) Bi-directional messages (encourage engagement, self-monitoring, prevent relapses and allow provision of feedback.) – "Yes/No" questions which trigger an automated response to the participant based on their reply as do trigger words designed to address barriers, deal with slip-ups and prevent relapses. Women can text trigger words ('slip-up'; 'crave; 'bad day' or 'tired') at any time and will receive a reply from a bank of messages. During months 7-12, when the focus shifts to maintenance strategies, the weekly message reminding women to weigh themselves asks them to text back their weight and 'up' or 'down' or 'same' in relation to how they did last week which triggers an automated response. Automated responses for these bi-directional messages are sent from a bank of messages that is uploaded to the text message platform; responses are not individually scripted or tailored.

Timing of text messages: Text messages are sent between 10:00 and 23:00 and programmed to arrive at different times during the day to avoid predictability. Participants can choose an additional time of day that they want to be kept message free e.g. 13:00 to 19:00. Following randomisation, the intervention messages will start to be delivered on a Monday so that the message asking participants to weigh themselves is always sent on a Friday.

Social support: Social support is facilitated throughout the intervention using a buddy system (as used previously in txt2stop)(8) where a participant can nominate a friend or family member to receive the same messages they are receiving and so be in a better position to provide support to them. Participants are sent the instructions on how to do this within the messages and can request a friend/ family buddy at any stage and reminders of this facility are sent throughout the intervention period. Messages are also sent to participants to tell them about the value that support can play in weight loss success.

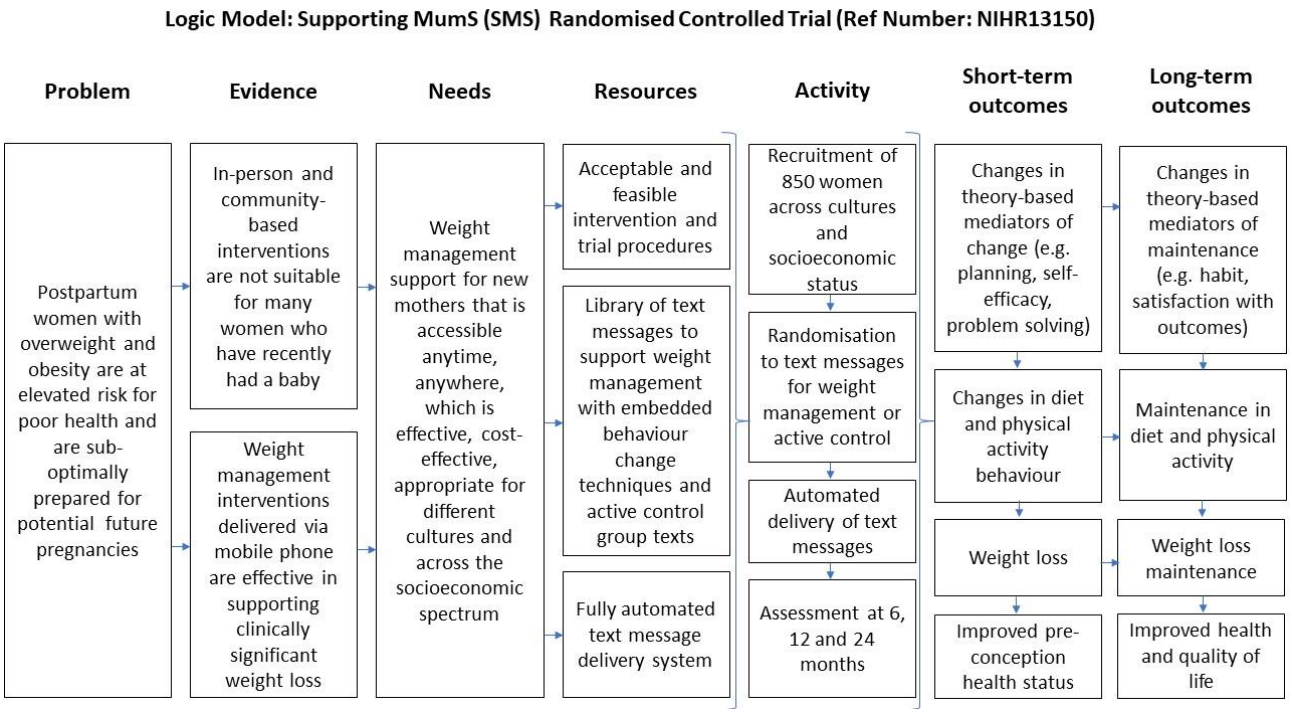
The intervention has been automated using LSHTM's existing text message platform, as used in the pilot study.(9)

3.2 Process evaluation design

A mixed methodology process evaluation, of concurrent qualitative and quantitative data collection, embedded within the SMS trial which is a UK wide multi-site, parallel, two-arm, RCT, comparing weight change in women with overweight or obesity who have had a baby in the last two years and receive an automated text message weight loss intervention for 12 months, with an active control group who receive messages about child health and development for 12 months. Five sites [Scotland, Northern Ireland, Wales, England (Bradford and London)] will recruit and follow-up participants.

The process evaluation is informed by the Medical Research Council (MRC) guidance on process evaluation of complex interventions (13) and will explore participants' experiences of the intervention with a view to understanding if, how and for whom the intervention works and what the mechanisms of impact may be, as well as understanding contextual factors that may be important for implementation. The logic model for the SMS intervention is shown in Figure 1.

Figure 1: Supporting MumS postpartum weight management intervention logic model



3.3 Data sources

Trial assessments are summarised in Tables 2 and 3.

Assessments will take place at baseline (start of intervention), 6 months, 12 months (end of intervention period) and 24 months (12 months after intervention stops) unless otherwise indicated.

Quantitative data from participants will be collected in the trial Case Report Form and questionnaire booklet.

Qualitative data collection will be in the form of telephone interviews with participants at 6 and 12 months and stakeholders at 24 months as described in more detail below.

Other data sources that will be used to address the process evaluation objectives include:

- Trial records kept by the Trial Manager and researchers at each trial site.
- Text message platform data which provides a date and time stamped record of all messages sent and received by each participant for the duration of the intervention. This data will be provided to the process evaluation analysis team by LSHTM after the last participant has completed the intervention.

Table 4 summarises what data sources will be used to address each dimension of the process evaluation and the corresponding objective.

Table 2: Measurement of SMS study outcomes

Outcome collected	Measure used	Time point (month)			
		0	6	12	24
Anthropometric measures and Demographics*					
Height (m)	-	✓			
Body weight (kg) (primary endpoint)	-	✓	✓	✓	✓
Waist circumference (cm)	-	✓	✓	✓	✓
Demographic characteristics**	Study-specific questions	✓			
Acceptability outcomes					
Satisfaction with SMS messages¥	Study-specific questions		✓	✓	✓
Acceptability of intervention, active control and study methods¥	Study-specific questions			✓	✓
Longer-term use of text messages¥	Study-specific questions				✓
Qualitative interviews	-		✓	✓	
Interviews with stakeholders	-				✓
Economic evaluation - Within trial health and social care cost data¥					
Health service resources use	Questions on health resource usage	✓	✓	✓	✓
Medication usage	Questions on over-the-counter medications	✓	✓	✓	✓
Healthy lifestyle-related costs	Questions on personal expenditure	✓	✓	✓	✓
Exercise-related costs	Questions on costs of exercise	✓	✓	✓	✓
Food and drink costs	Questions on weekly cost of groceries, alcohol and smoking products	✓	✓	✓	✓
Employment status	Study-specific questions	✓	✓	✓	✓
Health-related quality of life	EQ-5D-5L(14)	✓	✓	✓	✓
Capability well-being	ICEpop CAPability measure Adults (ICECAP-A)(15)	✓	✓	✓	✓
Secondary outcome measures¥					
Dietary intake	Fat and fibre barometer(16)	✓	✓	✓	✓
Sugar intake	Study-specific questions	✓	✓	✓	✓
Alcohol consumption	Study-specific questions	✓	✓	✓	✓
Physical activity	International Physical Activity Questionnaire (IPAQ) - Short form(17)	✓	✓	✓	✓
Infant feeding	Infant feeding survey(18)	✓	✓	✓	✓
Moderators of intervention effect¥					
Mental health – depression	Edinburgh Postnatal Depression Scale (EPDS)(19)	✓	✓	✓	✓
Mental health - anxiety	Generalised Anxiety Disorder (GAD-7)(20)	✓	✓	✓	✓
Mother and child relationship	Me and My Baby (MaMB)/Me and My Child (MaMC)(21) and Mothers Object Relations Scale (MORS-Baby/Child)(22)	✓	✓	✓	✓
Sleep	Pittsburgh Sleep Quality Index(23)	✓	✓	✓	✓
Confidence/importance/desire for weight loss and maintenance	Study-specific questions	✓	✓	✓	✓
Mediators of intervention effect¥					
Intention and self-efficacy for diet and physical activity	Health Action Process Approach (HAPA) including action and coping planning and self-efficacy(11, 24)	✓	✓	✓	✓
Habit	Self-report behavioural automaticity index(25)	✓	✓	✓	✓
Self-regulation of eating behaviour	Self-regulation of eating behaviour questionnaire(26)	✓	✓	✓	✓
Weight self-monitoring	Study-specific questions	✓	✓	✓	✓
Diet and exercise monitoring	Study-specific questions	✓	✓	✓	✓
Goal-setting for diet and exercise	Study-specific questions	✓	✓	✓	✓
Weight loss motivation	Motivation for weight loss scale(27)	✓	✓	✓	

Taking part in other weight loss programme	Study-specific questions	✓	✓	✓	✓
Weight-related treatments and services engagement	Study-specific questions				✓
Weight management strategies	Study-specific questions				✓
Social support	Social support for eating & exercise [28] plus general social support (Born in Bradford study-specific questions)	✓	✓	✓	✓
Self-esteem	Rosenberg Self-Esteem Scale(29)	✓	✓	✓	✓

*Recorded in case report form (CRF)

**Date of birth, where they heard about the study, NHS number, ethnicity, income, postcode, employment, education, relationship status, weeks postpartum at study entry, parity, medical information (disability status, medication use), infant feeding, weight history, smoking status, alcohol intake, technology usage

¥Recorded in questionnaire booklet

Table 3: Overview of researcher administered measures collected from SMS participants at the baseline and follow-up study visits

	Time point (months)				**Place of assessment**
	0	6	12	24	
Height (m)	✓				At home visit*
Weight (kg) (primary outcome)	✓	✓	✓	✓	At home visit*
Waist circumference (cm)	✓	✓	✓	✓	At home visit*
Demographic questionnaire	✓				At home visit*
Questionnaire booklet	✓	✓	✓	✓	At home visit* after measurements taken, hard copy of questionnaire left for completion and return by post (postage paid)
					Online – Qualtrics
					In person or via telephone with researcher
Telephone interview		✓	✓		Telephone/MS teams

*Or women will have the option of attending another venue of their choice such as a University building or community venue if they prefer

3.4 Qualitative data collection

Interviews with women: At baseline, women will be asked to provide optional consent to be invited for a telephone interview at 6 and 12 months. Women who provide this consent will be asked if they are willing to participate in an interview during the 6 and 12 month follow-up visits. The opt-in semi-structured telephone interviews will be conducted with a sample of approximately 50 women at each time point by a researcher who will not have had any prior contact with the participant and is not responsible for collecting quantitative data from the participant. Participants will be purposively sampled according to study site, randomised group (intervention and control), stage postpartum, parity, ethnicity, SES, engagement with the text messages (intervention group), PMH (as measured in the baseline questionnaires) and weight loss; to gather a range of views in relation to participants'

experiences and allow us to explore any differences across these characteristics. Building on the pilot work which focused on views within a Northern Ireland context, the interview sampling will aim to achieve ethnic, geographic and socio-demographic diversity. We will aim to interview a sample of women who stop the messages. We will also aim to gather information where possible from women who withdraw from the study for a reason other than pregnancy by asking them to provide a reason at the time they withdraw via telephone or via text message (e.g. “Thank you for letting us know you no longer wish to take part in the Supporting MumS study. We will stop the messages, delete your personal information and you will receive no further communication from us. It would be very helpful if you could please tell us the reason you no longer wish to continue by replying to this message. Thank you, the Supporting MumS team.”). This will help us to establish their views of the messages they received and their reasons for discontinuing.

We will collect verbal consent at the start of the interview for audio-recording and for the use of anonymised quotations in publications. Semi-structured interviews at 6 and 12 months will explore women’s views of the intervention and active control text messages they received and contextual factors related to engagement with messages, weight loss (6 month intervention interviews) and weight loss maintenance (12 month intervention interviews), including barriers and facilitators of behaviour change, what elements of the text messages were considered helpful/unhelpful and how they feel the intervention and its components ‘worked’ or did not work for them (mechanism of impact, mediating mechanisms, contextual moderators). We will explore perceived benefits, wider impacts and unintended consequences or undesired effects of the intervention/active control on health or wellbeing, including gathering intervention participants’ views in relation to the theoretical mediators of change as well as the interaction between PMH and intervention engagement/outcomes. Discussions about PMH will be explored with both groups to understand women’s PMH experiences including their views on any support they received, and any further support needed, to inform future service provision. We will gather participants’ suggestions for further refinement of the intervention/active control for implementation purposes. This will allow us to understand how the text messages are being received across the four countries and with a more diverse sample and to explore reasons for non-response (i.e. not engaging with the interactive text messages, not losing weight or not completing trial outcome assessments). We will also explore participants’ motivations for taking part in the study, their views on the acceptability of trial methods (e.g. recruitment, randomisation, data collection visits, measurements), their overall satisfaction with study participation, and any feedback indicating potential for contamination between randomised groups will be explored, to inform future research.

We will use an iterative process for qualitative data collection and analysis whereby findings from early interviews will be incorporated as topics to explore in subsequent interviews. Interviews will continue until it is determined that ‘information power’ to address the research objectives has been achieved.(30)

For women who would prefer to conduct the interviews in a language other than English a translator will be used.

Stakeholder interviews: If the intervention is shown to be effective at 12 months, stakeholder interviews will be conducted to explore factors relevant to implementation including possible facilitators and barriers to wider implementation and scale-up and any further work that is needed to develop a coherent implementation model. The interview guide will be informed by the CICI Framework for implementation (31), the New South Wales Ministry of Health PHRP guide to scaling up population health interventions (32) and the Intervention Scalability Assessment Tool (ISAT).(33) Stakeholders will be identified from research team and trial steering committee (TSC) networks. We will target stakeholders from across the four UK countries, with the aim of conducting 5-10 interviews.

SECTION 4: DATA ANALYSIS

This is a mixed methods process evaluation. Triangulating the findings from the different data sources will take place at the interpretation stage after the qualitative and quantitative analysis described below has been conducted.

In-line with the triangulation protocol methodology,(34, 35) a convergence coding matrix will be constructed to display findings emerging from each component of the process evaluation. Consideration will then be given to where there is agreement, partial agreement, silence, or dissonance between findings from different components of the process evaluation. This integration combines the strengths of both qualitative and quantitative approaches to provide a comprehensive understanding of implementation, mechanisms of impact and context.

Given the timeline of the trial, analysis of qualitative and quantitative data will happen simultaneously, however, data will not be triangulated until all the qualitative and quantitative data has been analysed independently. If there are any unique findings from one methodology identified during triangulation, this may result in additional exploratory analysis.

4.1 Qualitative data analysis

As indicated in Table 4, trial qualitative data is relevant to all trial objectives and will be integrated with quantitative findings at the interpretation stage. Given the trial timeline and the stop/go review included in the trial protocol to review primary outcome data and any other core outcome data required to decide if the trial should progress to stage 3 (24 month follow-up and interviews with stakeholders), we are likely to be aware of some quantitative outcomes before all qualitative analysis has been completed.

Participant interviews: Interviews will be audio-recorded, transcribed verbatim (using pseudonyms); transcripts will be checked by a researcher to ensure maximum data has been transcribed, is accurate and any potentially identifiable information is removed. Thematic analysis techniques (36) which seek to identify and classify the content of qualitative data, will explore patterns and differences across accounts and allowing for the discovery of unexpected concepts in participants' accounts, with the aim of providing explanatory conclusions clustered around themes. The transcripts will be coded then collated into themes and sub-themes according to conceptual similarity of codes. Agreement on concepts and coding will be sought between members of the research team throughout the analysis process to ensure reliability. A proportion of the data (20%) will be coded by two different team members to check for inter-coder reliability. Thematic analysis will be supported by qualitative analysis software (NVivo) and best practice recommendations for ensuring quality in thematic analysis practice and reporting will be followed.(37)

Baseline attributes that may be of interest for comparative purposes in the analysis, including stage postpartum, parity, ethnicity, SES, will be added to all transcripts in Nvivo so that data may be organised and compared by participant characteristics. Additional attributes related to outcomes may be added after the quantitative analysis has been completed if specific hypotheses are generated e.g. around factors related to weight management challenges such as PMH status. The framework matrices function in Nvivo will be used to organise coded data by specific attributes, e.g. to examine if views of the intervention or active control differed by ethnicity.

Stakeholder interviews: The analysis of stakeholder interviews will follow a Framework method,(38) using a deductive approach to code the data in line with ISAT questions.(33) However, as recommended,(38) we will conduct open coding on a few of the transcripts (n=~2-3 depending on total completed) to ensure important aspects of the data are not missed. Codes will be organised into an analytical framework and once all transcripts have been coded, the data will be charted into a framework matrix whereby we will summarise the data from each transcript by category, allowing us to identify possible barriers and facilitators to implementation and scale-up while comparing and contrasting views across different stakeholders. The findings will be summarised then mapped to the

ISAT tool along with other relevant process evaluation findings to determine the extent to which we can assess scalability and what factors would need to be explored in more detail in a future implementation study. This will be presented using the ISAT summary reporting template.

Text message platform data: all data collected by the text message system will be extracted, including details entered at randomisation (including embargo times), messages sent, prompted replies, unprompted replies, 'buddy' system messages and discontinuation of messages. We will examine the sent messages and discontinuation of messages data to determine fidelity of delivery, dose of intervention received and what intervention was received. Prompted and unprompted replies will be examined to determine participants' interactions with the intervention and any indication of unintended consequences/undesired effects in replies will also be recorded. Replies to the text message system will be extracted and analysed by content analysis to allow us to both quantify and categorise the types of replies but also to analyse the meanings, themes and concepts within the replies in relation to how women engage with the intervention and its components. Number and type of prompted and unprompted replies will be reported. Additionally, spontaneous replies to specific core text messages that were designed to prompt self-reflection or evaluation related to specific BCTs or weight management strategies will be categorised and reported as frequencies.

4.2 Quantitative data analysis

Data will be analysed descriptively reporting summary statistics for continuous variables (means, SDs, or medians and range for skewed data) and frequencies for categorical variables.

Tests will be conducted at the 5% significance level (two-sided) and 95% confidence intervals will be presented throughout. As indicated in section 3.5 of the SMS protocol (under 'Exploratory endpoints/outcomes'), as part of the process evaluation, moderator (factors that influence response to intervention) and mediator (possible mechanisms that bring about behaviour change) analyses will be conducted. As per the trial Statistical Analysis Plan (SAP), pre-specified subgroup analyses (including site, socioeconomic status (SES), ethnicity, recruitment method, weeks postpartum (at study entry), BMI (at study entry) and parity) will be explored. All these analyses will be considered exploratory and hence the p-values will not be altered for multiple testing.

4.2.1 Implementation

4.2.1.1 Fidelity – the delivery of the text messages is fully automated once the text message platform, including specific intervention features (e.g. two-way text messages) has been programmed. The text message delivery will be monitored by a member of the trial team who is not involved in data collection to ensure there are no issues with delivery of text messages to participants once the system is live, including monitoring the automated two-way replies and that messages are being sent on correct days and within individual participant embargo times. Any issues with delivery will be resolved with LSHTM, recorded in the trial records by the Trial Manager and reported to the PMG and TSC.

4.2.1.2 Dose – dose received will be assessed by use of the 'Stop' and 'Pause' functions extracted from the text message platform records (date, time, status of message delivery), with collation of reasons for stopping or pausing recorded in Trial Records, if provided by participants. Any other issues related to dose of messages received that emerge from monitoring the text message platform or communication with participants, will be noted in trial records, for example if participants are out of the country for extended periods or block the messages.

4.2.1.3 Reach – the population reach of the intervention will be examined overall and in relation to sites, participant characteristics and randomised group where relevant:

- Participant flow - numbers expressing an interest, screened, eligible, randomised, including reasons for non-participation when known;

- Description of recruitment pathways - numbers recruited by different approaches (including social media analytics where available, e.g. for paid advertisements), analysed by participant characteristics and by site;
- Retention - numbers and reasons for withdrawal (pregnancy vs other reasons) or loss-to-follow-up, analysed by site and randomised group, as well as participant characteristics of retained vs not retained populations.

4.2.1.4 Contamination – any data from trial records or interviews indicating potential for contamination between the randomised groups will be summarised and reported.

4.2.2 Mechanisms of impact

How participants respond to and interact with the intervention and active control and how the intervention produces change will be assessed by examining satisfaction, mediators, engagement and unintended consequences.

4.2.2.1 Satisfaction with the intervention and active control - Acceptability of intervention and active control for a range of women across the UK will be assessed by participant rating of the text messages (questionnaire), alongside data on number of participants in each randomised group who stop the messages. These data will be examined by site, ethnicity and socio-economic status (SES).

4.2.2.2 Mediators - Quantitative testing of the hypothesised mechanisms through which the intervention might work in terms of weight outcomes and related diet and activity behaviours, will be examined at 6, 12 and 24 months. The theory-based mediators of behaviour change are shown in Table 2 (HAPA items including intention, action and coping planning and self-efficacy for diet and physical activity, habit formation indicators (behavioural automaticity), self-regulation of eating behaviour, self-monitoring of diet, activity and weight, goal setting for diet and activity, weight loss motivation, social support, self-esteem). Causal mediation analysis will be conducted using the analysis of covariance approach as recommended.(39) For instance, for continuous mediators, linear regression models will be used to model the mediator at follow-up (on the intervention, mediator at baseline and baseline weight) and the weight at follow-up (on the intervention, mediator at outcome, mediator at baseline and weight at baseline). Direct and indirect effects of the intervention will be determined along with bootstrap 95% confidence intervals. The STATA routine paramed will be used to conduct mediation analyses.(40) We will use the CLIMBR checklist (Column C) to inform the conduct and reporting of the mediation analysis.(41)

4.2.2.3 Engagement

The number of participants who changed the default embargo time for text messages (a tailoring element included to boost engagement) will be recorded for each randomised group, along with reasons for changing the embargo time (if provided).

The LSHTM text message platform captures text messages received from participants. We will examine participant engagement with two-way text messages on a continuous basis across the 12 month intervention to determine adherence.

For the intervention group, the text message platform data will be analysed to calculate the following indicators of engagement with the intervention features:

The calculation of engagement variables will be done at an individual participant level, taking account of dose received e.g. if a participant stopped or paused meaning they did not receive all the Yes/No messages or weight prompts, for months 0-6 and months 7-12 of the intervention, their engagement will be calculated by each participant's number of replies as a proportion of the total number of that type of message that that participant received.

a) Engagement with weekly weight reporting – months 0-6 and months 7-12

b) Engagement with Yes/No replies - months 0-6 and months 7-12

c) Overall engagement (average of a and b above) – months 0-6 and months 7-12

d) Use of trigger words – months 0-6 and months 7-12

e) Use of buddy scheme option

Analysis will be carried out to examine participant characteristics according to engagement variables above, engagement over the 12 month period, and also if engagement is related to change in outcome endpoints (primary, secondary, exploratory) or if engagement varies by site. Level of engagement will be examined as a continuous variable but may also be categorised based on the distribution of the engagement data.

4.2.2.4 Unintended or unexpected consequences – any relevant data captured from trial records, questionnaire (see also mediator analysis re PMH), text message platform replies or negative changes in mediators or moderators such as self-esteem or PMH status, will be collated descriptively.

4.2.3 Context

Context (anything external to the intervention which impedes or strengthens its effects) will be examined to help understand variability in intervention outcomes through a moderator analysis and assessment of factors related to scale-up and implementation, including any modifications that would be needed before scale-up.

4.2.3.1 Moderators

A quantitative moderation analysis will be undertaken to examine for who and under what conditions change occurs. Moderators can interact with the intervention to affect the strength and direction of intervention effects and can identify sub-groups that respond or do not respond to the intervention which is important for implementation and informing context-mechanism-outcome pathways.

As indicated in Table 2, moderators that will be explored are: sleep, mental health (anxiety, depression, mother/child relationship), and confidence, importance, and desire for weight loss. To examine if these moderators measured at baseline affect the strength and direction of intervention effects on trial outcomes (primary, secondary, exploratory), the outcome analysis described in SAP section 6.2 will be repeated for moderator sub-groups. Interaction tests will be conducted, separately, by including interaction terms within analysis of covariance regression models, to test whether the effect sizes differ across sub-groups. No correction for multiple testing will be conducted as these analyses will be considered exploratory. As recommended, all subgroup analyses will be reported. (42)

4.2.3.2 Factors related to scale-up and implementation

Participants' suggestions for further refinement of the intervention gathered during interviews at 6 and 12 months and via free text responses in questionnaires at 6, 12 and 24 months will be collated and used to inform any scale-up plans.

Stakeholder interviews will be analysed as described above and integrated with other relevant data to develop a preliminary scale-up plan using the Intervention Scalability Assessment Tool (ISAT)(33) which has 3 main sections – 'Setting the scene', 'Intervention implementation and planning' and 'Summary of scalability assessment'.

4.2.4 Process evaluation components – trial methods:

4.2.4.1 Fidelity

- Was protocol implemented as intended – any issues or deviations will be recorded in trial records or gathered in participant interviews and reported.

4.2.4.2 Acceptability

- acceptability and willingness to be randomised for a range of women across the UK obtained from participant interviews. Framework matrices will be used to examine women's views on acceptability and willingness to be randomised by specific attributes, including site, ethnicity and SES.
- acceptability of the research methods and trial processes in general for a range of women across the UK– obtained from participant questionnaires and interviews. Framework matrices will be used to examine women's views on acceptability of the research methods and trial processes by specific attributes, including site, ethnicity and SES.

Table 4 Summary of process evaluation components mapped to data sources and relevant objective(s)

Process evaluation component	Dimension	Data source	Relevant objective(s)
IMPLEMENTATION			
Fidelity	Fidelity of intervention delivery	Text message platform data Participant interviews Trial records	1
Dose	Dose of intervention received	Text message platform data Questionnaires Participant interviews	1
Reach	Who received the intervention	Baseline characteristics of the sample population	1
	What intervention was received	Text message platform data Participant interviews	1
Contamination	Contamination between randomised groups	Trial records Participant interviews	1
MECHANISMS OF IMPACT			
Satisfaction	Retention and attrition rates incl. pregnancy exclusion	Trial records	2, 5
	Satisfaction rates and explanations of retention rates	Questionnaires Participant interviews Trial records	2
Mediators	Mediation analysis	Questionnaires Participant interviews	3, 5
Engagement	Participant interactions with the intervention	Text message platform data Participant interviews CRF/ Questionnaires	4, 5
Unintended consequences	Unintended consequences	Participant interviews Text message platform data Questionnaires Trial records	6

CONTEXT			
Moderators	Moderator analysis	CRF/ Questionnaires Participant interviews Engagement data Baseline characteristics of the sample population	7
Explore scale-up	To explore factors relevant for scale-up and implementation	Interviews with stakeholders Feedback from participants (questionnaire and interviews)	8
TRIAL DESIGN AND METHODS			
Fidelity	Protocol implementation Fidelity of blinding	Trial records Participant interviews	9
Acceptability	Acceptability and willingness to be randomised for a range of women across the UK	Questionnaire Participant interviews	9
	Acceptability of research methods and trial procedures for a range of women across the UK	Questionnaire Participant Interviews	9

SECTION 5: RELATED STUDY DOCUMENTS

Supporting MumS_Full trial protocol_v4.0_12042024

Supporting MumS_Statistical Analysis Plan_v1.0_14052024

SMS Study Interview schedule - 6 month intervention Version 4.0_02.03.23

SMS Study Interview schedule - 6 month control Version 3.0_10.11.22

SMS Study Interview schedule - 12 month intervention Version 6.0_06.12.23

SMS Study Interview schedule - 12 month control Version 5.0_11.12.23

SECTION 6: REFERENCES

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