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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

Statistical Analysis Plan

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SECTION 1: ADMINISTRATIVE INFORMATION

Statistical analysis plan (SAP) version history:

SAP Version	Protocol Version	Date	Changes
1.0	4.0	14/05/2024	

SAP contributors:

Prepared by the Trial Statistician (Prof Chris Cardwell), Chief Investigator (Professor Michelle McKinley) and Trial Manager (Dr Dunla Gallagher) and reviewed by the Supporting MumS Project Management Team. This SAP has been written in line with best practice guidelines.(1)

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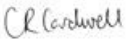
Name: Professor Chris Cardwell Signature: 

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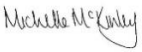
Name: Professor Michelle McKinley Signature: 

Date: 14/05/2024

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.(2) 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.(3)

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.(4, 5) 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 lifestyle behaviour change that come with having a baby.(3, 6) More appropriate ways of recruiting and engaging with postpartum women to achieve sustained behaviour change while considering cost-effectiveness and health inequalities are required.(7)

Mobile technologies can offer a flexible and individualised 'any time, any place' approach to behavioural weight management interventions.(3) 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.(8, 9)

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.(10) Bidirectional and interactive messages focus on adopting a healthier diet and engaging in 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 and determined that pre-specified progression criteria to proceed to a full randomised controlled trial (RCT) were met.(10)

The present RCT examines 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 will make a novel and important contribution to the field of behavioural text message interventions, as: currently, there are few such 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 which consider both weight loss and weight loss maintenance, last 12 months or longer and use an active control to minimise disappointment bias. It also offers the opportunity to examine postnatal mental health in an ethnically and socioeconomically diverse sample from all four United Kingdom (UK) countries.

2.2 Objectives

This SAP addresses the following primary objective from the Supporting MumS trial protocol:

1. To conduct a 2-arm parallel group RCT comparing weight change at 12 months from baseline for postpartum women with overweight or obesity who receive text messages about weight management with an active control.

It also addresses the following secondary objectives from the Supporting MumS trial protocol:

2. To assess differences between groups in secondary outcomes including:
    i. Weight change at 6 and 24 months from baseline;
    ii. Waist circumference at 6, 12 and 24 months from baseline, respectively;
    iii. BMI at 6, 12 and 24 months from baseline, respectively;
    iv. The proportions of women gaining a substantial amount of weight at 12 and 24 months from baseline;
    v. Dietary intake (fat and fibre barometer(11) plus questions on sugar intake) at 6, 12 and 24 months;
    vi. Alcohol consumption at 6, 12 and 24 months;
    vii. Physical activity (IPAQ-SF(12)) at 6, 12 and 24 months; and,
    viii. Infant feeding practices (Infant Feeding Survey(13)) at 6, 12 and 24 months.

SECTION 3: STUDY METHODS

3.1 Trial design

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. Five sites [Scotland, Northern Ireland, Wales, England (Bradford and London)] will recruit and follow-up participants.

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 child health 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).

3.2 Participant Eligibility Criteria

Inclusion criteria

• Women (in accordance with the NICE Postnatal care guideline NG194(14), the term 'woman' used in this trial includes people who do not identify as women but who are pregnant or have given birth)

• Aged over 18 years old

• BMI ≥25 kg/m^2

• Have had a baby within the last two years

Exclusion criteria

• Baby less than 6 weeks old

• No access to a mobile phone to receive personal text messages

• Insufficient English to understand short written messages

• Currently pregnant

• If they have had or plan to have any type of bariatric surgery

• Diagnosis of anorexia nervosa or bulimia from a doctor

• On a specialist diet and receiving dietetic care

• Taking part in another weight management research study currently or in the last 3 months

3.3 Randomisation

Participants will be block randomised and randomisation will be stratified by site. The randomisation sequence will be developed in STATA (using STATA routine ralloc) and sent directly to the text message delivery platform manager at the London School of Hygiene and Tropical Medicine (LSHTM). The randomisation

sequence will be implemented via the LSHTM secure remote web-based system which links directly with the text message platform to deliver the intervention or active control content to trial participants according to the random allocation sequence.

After obtaining informed consent and collection of baseline data, the researcher will register the participant on the LSHTM secure remote web-based system inputting first name, telephone number, recruitment site, and tailoring information for messages. The researchers collecting outcome data will not have access to randomised information and will be blind to treatment group. Participants will become aware of their group allocation when they start to receive the messages. Participants will be requested not to discuss the messages that they are receiving with the researchers, which worked well in the pilot RCT.(10)

3.4 Sample size

In the pilot RCT, between baseline and 12 months, the intervention group lost on average 1.75 kg, whereas the active control group gained 0.19 kg [mean difference in weight change between intervention and active control at 12 months, adjusting for baseline, of -1.67 kg (95% Confidence Intervals (CIs) -4.88 to 1.55)].(10) Based on pilot RCT data from the active control group for mean weight change from baseline to 12 months (SD of the change from baseline to 12 months of 7.5 kg), 594 completing participants (297 participants in each group) gives the study over 90% power to detect a statistically significant difference of 2 kg, at the 5% level, in mean weight change from baseline, between the intervention and active control groups. This mean difference of 2 kg is accepted as being associated with metabolic health benefits and is frequently used to power weight loss studies.(15) In the pilot RCT, a pregnancy exclusion rate of 15% was observed.(10) In more ethnically diverse samples it is anticipated that pregnancy rates could be higher, for example, in the Born in Bradford Better Start cohort, 22% of the South Asian population have a second pregnancy within two years.(16) Therefore, accounting for a loss to follow-up rate of 15% (12% loss to follow-up was experienced in the pilot RCT) and site-specific pregnancy rates, in order to have 119 participants completing at each site (594 participants in total), the following will be recruited per site:

NI, Scotland and Wales: 15% Pregnancy rate + 15% loss to follow-up = recruit 170 women to have 119 completing;

Bradford and London: 22% Pregnancy rate + 15% loss to follow-up = recruit 189 women to have 119 completing.

Therefore, the proposed total sample size for this multi-site RCT would be 444 participants in each of the intervention and active control groups, with a total sample size of 888 women.

3.5 Framework

The primary and secondary outcomes will be compared between groups using a superiority framework.

3.6 Interim analysis

No interim analysis will be conducted.

3.7 Timing of final analysis

Primary outcome analysis will be conducted at 12 months.

3.8 Timing of outcome assessments

Trial assessments are summarised in Tables 1 and 2. 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; analysis of 24 month data is reported in a separate analysis plan) unless otherwise indicated. Researchers will visit women in their homes (or another venue of their preferred choice such as a University building or community venue) for collection of outcome measures. Anthropometric data will be collected using standardised protocols and calibrated scales. To maximise data completeness for weight at 12 months (primary endpoint), when numerous attempts have been made to arrange a face-to-face researcher visit with and a participant and they are unable to complete this, we will attempt to collect self-reported weight from the participant via email, text or phone. All other outcome measures will be collected using self-report questionnaires. Women will have the option of completing these by paper or using an online survey tool (Qualtrics). Either way, questionnaires can be completed by women in one sitting or in smaller blocks of time according to their personal circumstances, which was valued by women in the pilot RCT.(10) Researchers will provide assistance with completion of questionnaires, if required. Method of questionnaire completion – hard copy/online and with/without assistance will be noted in the study case report form (CRF). In the pilot RCT women felt that the questionnaire booklet was clear and easy to complete taking between 20 to 30 minutes.(10)

All participants (intervention and active control group) will be offered a voucher as a token of appreciation for their time committed to completing the measurements at each assessment point (£25 per data assessment point 0, 6, 12 and 24 months; £100 maximum over 24 months). Women will be sent the voucher on receipt of the completed questionnaire, as per the pilot study.(10)

Table 1: 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	✓			
Secondary outcome measures¥					
Dietary intake	Fat and fibre barometer(11)	✓	✓	✓	✓
Sugar intake	Study-specific questions	✓	✓	✓	✓
Alcohol consumption	Study-specific questions	✓	✓	✓	✓

Physical activity	International Physical Activity Questionnaire (IPAQ) - Short form(12)	✓	✓	✓	✓
Infant feeding	Infant feeding survey(13)	✓	✓	✓	✓

*Recorded in 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 2: Overview of researcher administered measures collected 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.

SECTION 4: STATISTICAL PRINCIPLES

4.1 Confidence intervals and P values

Tests will be conducted at the 5% significance level (two-sided) and 95% CIs will be presented throughout. The analysis of weight change at 12 months will be considered the primary analysis. All subsequent tests will be regarded as descriptive/explorative and consequently, there will be no correction for multiple testing.

4.2 Adherence and protocol deviations

Text message delivery is fully automated and centrally delivered via the LSHTM system, which is intended to ensure treatment fidelity. 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. This analysis will inform the study process evaluation (see process evaluation analysis plan) along with qualitative interview data exploring intervention engagement.

Participants in both groups have the ability to pause, stop and restart the messages throughout by sending an automated instruction to the text system e.g., 'STOP', 'START'. Researchers ask women choosing to discontinue the messages to provide any reason for doing so, to inform the process evaluation. Participants discontinuing messages remain in the trial unless they formally withdraw from the trial assessments. Numbers of women discontinuing the intervention and any reasons provided will be reported in the CONSORT flowchart. Dose will be examined as part of the study process evaluation.

All staff undergo training on the protocol, trial processes and standard operating procedures (SOPs) for which they are responsible (as per site delegation log). The Trial Manager monitors trial activities across sites to ensure adherence and consistency to the protocol. There are no planned protocol deviations. If a deviation occurs, it is documented and reported immediately to the Chief Investigator and Sponsor including corrective and preventative actions. Frequent recurrence of protocol deviations is unacceptable, requires immediate action and could be classified as a serious breach i.e. one which is likely to significantly affect the safety or physical or mental integrity of trial participants and/or the scientific value of the trial. Any breach meeting this definition is immediately reported to the Sponsor as per the Sponsor's SOP on 'Matters of non-compliance with study protocol'.

4.3 Analysis populations

The study will be analysed on an intention to treat principle i.e. all individuals in the intervention group will be compared with the active control group regardless of whether individuals in either group continued to receive or interact with the text messages.

SECTION 5: TRIAL POPULATION

We will follow Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting parallel group randomised trials and trial population data will be presented using a participant flowchart.(17)

5.1 Screening and eligibility data

Women expressing an interest in the study are screened according to the participant eligibility criteria (see Section 3) with this process documented using a study screening form. Screening data will be reported as numbers of women eligible and ineligible by total and per site and reasons for study exclusion. Categorical data summarising ethnicity of the screened sample and the way in which women heard about the study will be reported by total and site.

5.2 Recruitment

Dates defining the periods of recruitment and follow-up will be reported and numbers of participants randomised to each group included in the participant flowchart. Reasons for exclusion between screening (determined eligible) and randomisation will be reported.

5.3 Withdrawal/Follow-up

Once consented, participants are advised that they can withdraw from the trial at any time without giving a reason, should they wish. Withdrawals are documented in the CRF along with any reason given for withdrawing. Data collected up to the point of withdrawal is retained for analysis, unless the participant specifies otherwise.

The CONSORT flowchart will be used to report numbers of women completing follow-ups, withdrawn, excluded due to pregnancy or lost to follow-up at each study timepoint by group, along with any reasons provided for losses/exclusions. Following an intention to treat principle any data collected from those withdrawn will be included in analyses.

5.4 Baseline participant characteristics

Tables of baseline characteristics by group will be presented including summary statistics for continuous variables and frequencies for categorical variables. These tables will be reported including only individuals who contribute to the primary analysis and separately including all individuals. The following variables will be included in these tables: age, months postpartum at baseline, parity, employment status, recruitment method, education level, marital status, site, weight at baseline, waist circumference at baseline, BMI, annual household income, postcode deprivation data, ethnicity, smoking and alcohol intake.

SECTION 6: ANALYSIS

6.1 Outcome definitions

The primary outcome is:

1) between-group difference in mean weight change (kg) at 12 months from baseline.

The secondary outcomes are between-group differences in:

1) mean weight change (kg) at 6 months from baseline;

2) mean waist circumference (cm) at 6 and 12 months, respectively;

3) mean BMI (kg/m^2) at 6 and 12 months, respectively;

4) the proportions of women gaining a substantial amount of weight (>5kg) at 12 months;

5) dietary intake (fat and fibre barometer plus questions on sugar intake) at 6 and 12 months, respectively;

7) alcohol consumption at 6 and 12 months, respectively;

8) physical activity (IPAQ-SF) at 6 and 12 months, respectively; and,

9) infant feeding practices (Infant Feeding Survey) at 6 and 12 months, respectively.

Outcomes and analysis at 24 months will be detailed in a separate analysis plan.

6.2 Analysis method

In the primary analysis, weight (kg) at 12 months will be compared, on an intention to treat basis, between the intervention and active control groups using analysis of covariance to adjust for weight at baseline and additionally adjusting for site, recruitment method and ethnicity. The adjusted difference in mean between the intervention and active control groups, and corresponding 95% CIs and P-value, will be reported.

Similar analyses will be conducted for secondary continuous outcome measures. Secondary analysis of binary outcomes will be conducted using logistic regression to compare the intervention and active control groups whilst adjusting for site, recruitment method and ethnicity. Adjusted odds ratios and 95% CIs, and corresponding P-values will be reported.

Assumptions of the regression models for continuous outcomes will be checked by plotting histograms of residuals and scatter diagrams of residuals against fitted values and against other variables in the models respectively.

To understand if there are differential effects of the intervention, subgroup analyses will be conducted stratifying by pre-specified variables including site, socioeconomic status (SES), ethnicity, recruitment method, weeks postpartum (at study entry), BMI (at study entry) and parity. Interaction tests will be conducted separately by including interaction terms within analysis of covariance regression models. No correction for multiple testing will be conducted for subgroup analyses; these analyses will be considered exploratory. As recommended, all subgroup analyses will be reported.(18)

The subgroup analyses are important to examine if the effects of the intervention are generalisable for women from different parts of the UK (sites are based in all four countries of the UK) and from different socio-

economic and ethnic backgrounds. Some previous studies on diet/physical activity and weight management behaviour change have observed that intervention engagement and effectiveness is lower in those from lower socio-economic groups and non-white ethnic groups (19, 20) and it is important to examine this data when possible in trials to guard against widening inequalities. Whilst acceptability to a wide range of women has been carefully considered in the design and development of the SMS intervention, it is important to evaluate if effectiveness is similar across these sub-groups. It is also possible that engagement with the intervention may vary according to the method used for recruitment; for example, those recruited using face-to-face methods or those signposted by a health professional may engage more with the intervention than those recruited via less personal, paid or unpaid social media advertisements. Given the focus on postpartum women, and the increased demands on a mother's time that comes with having one or more children, we will explore if intervention effectiveness is similar for women according to parity, as having multiple children may present additional challenges for women wanting to engage in a behaviour change intervention.(3)

There is a gap in the literature regarding what is the best time to engage women in postpartum weight management.(21) The SMS trial includes women who signed up between 6 weeks and 2 years postpartum and affords an opportunity to see if there is a key time to approach women to maximise effectiveness or if effectiveness is similar across the extended postpartum period. The study inclusion criteria include women with overweight or obesity. Although we do not anticipate major differences in effectiveness for women with overweight compared to those with obesity, it is important to explore if this low intensity intervention has similar effects across all BMI categories.

6.3 Missing data

The frequency and number of missing values for each primary and secondary outcome will be documented. A complete-case approach will be used for the primary analysis, as based upon the pilot we anticipate only around 10% will have missing weight data at baseline or 12 months.(10)

Sensitivity analysis will be conducted to attempt to account for missing data, as follows:

1) include self-reported weight to assess the impact on the primary outcome analysis;

2) using last observation carried forward and baseline observation carried forward;

3) using multiple imputation to impute missing outcome values based upon baseline variables; and,

4) using δ-based methods to explore the impact of worse or better outcomes in the individuals with missing data.

6.4 Additional analyses

Separate plans detail the planned process evaluation analysis, health economics analysis and 24 month follow-up statistical analysis related to the SMS trial.

6.5 Harms

Serious adverse events (SAEs) are recorded by researchers from the time of the participant's consent into the trial until one month after the end of the 12 month intervention period and are reported in line with Good Clinical Practice guidelines and the Sponsor's adverse event reporting procedures. Site Principal Investigators (PIs) review SAEs within 24 hours to determine severity, relatedness and expectedness. The Chief Investigator

(or delegate) is informed of any event evaluated as being severe, related and unexpected, to conduct a second review. The Trial Manager/Chief Investigator is responsible for onward reporting of SAEs categorised as related and unexpected by both the PI and Chief Investigator, to the Sponsor and REC within 24 hours and 15 days respectively. All SAEs are summarised and included in annual reports to the REC and reported during meetings of the PMT and TSC.

SAE data will be summarised by numbers of events reported in total and by timepoint and how events were categorised will be presented as a binary outcome: number of events categorised as severe, related and unexpected vs number of events categorised as unrelated and/or expected. Details of the nature of events will be reported for any categorised as severe, related and unexpected.

6.6 Statistical software

All analysis will be conducted using STATA version 16 software (Statcorp, USA).

6.7 Related study documents

QUB SOP Data Management: Collection, Validation and Storage (Ref: QUB-RGEI-014), v1.0, 20.09.2021.

QUB SOP Delegation of Responsibilities (Ref: QUB-RGEI-005), v1.0, 21.09.2021

QUB SOP Informed Consent for Research (Ref: QUB-RGEI-004), v1.0, 20.09.2021

QUB SOP Matters of Non-compliance with Study Protocol (Ref: QUB-RGEI-016), v1.0, 15.09.2021

QUB SOP Reporting and Managing Research Related Adverse Events (Ref: QUB-RGEI-006), v1.0, 16.09.2021

Supporting MumS_Data Management SOP_v1.0_08062022

Supporting MumS_ Taking Anthropometric Measurements SOP_v1.0_03052022

NICTU Data Management Plan_Supporting MumS, v1.0_16082023

6.8 Trial Master File storage

Hard copy files stored in the Centre for Public Health, Queen's University Belfast and electronic files stored on QUB computer systems- S:\SupportingMumsStudy\FULL SMS TRIAL. Electronic databases and hard copy questionnaires are stored in the Northern Ireland Clinical Trials Unit.

6.9 Statistical Master File

The trial statistician will maintain the Statistical Master File. Hard copy files will be stored in the Centre for Public Health, Queen's University Belfast and electronic files stored on QUB computer systems.

SECTION 7: REFERENCES

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