

# The Supporting MumS (SMS) study: can we use an automated text message intervention for weight management in women after childbirth?

<b>Submission date</b> 10/12/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 10/02/2022	<b>Overall study status</b> Ongoing	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/05/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Many women struggle to lose weight after pregnancy and talk about pregnancy as a time when their weight started to 'creep up'. We need to find ways to help women lose weight after having a baby. Life becomes much busier for women when caring for a baby and going to weight loss groups may not work well for new mums. We have thought about other ways to help women after they have a baby that are more flexible. Nearly everyone has a mobile phone and uses their phone to send and receive text messages. Text messages have been used to help people lose weight so we carried out a small study to see if this might be a useful way to support weight loss after pregnancy.

Women who recently had a baby helped us design our text messages. We recruited one hundred mums from Northern Ireland and they received our weight management messages, or messages about child health and development, for 12 months. More than 4 out of 5 women completed the study. Women rated the messages very highly and felt they were supportive and motivating. Women receiving the weight loss messages lost more weight compared to those receiving the child health messages. The small numbers in our initial study mean we do not know for sure how well the messages work for everyone. We need to test this in a larger study with women from all parts of the United Kingdom.

For this bigger study, we will tell women about the study through social media, mother and baby groups and when they visit the GP for their postnatal check-up or baby immunisations. If women are interested in taking part they will contact the study team through text message, Email or telephone. Women who have had a baby in the last two years will be able to take part. We want to recruit women from a wide range of backgrounds which is why we are doing the study in all parts of the UK (England, Scotland, Wales and Northern Ireland).

### Who can participate?

People aged 18 years or above who have recently given birth and are overweight (have a BMI greater than 25 kg/m<sup>2</sup>)

What does the study involve?

In total, 888 women with excess weight will be entered into the study. Women will be assigned by chance either to receive our weight loss text messages or to receive our text messages about child health and development for 12 months. As it is often difficult to travel to appointments with a baby, researchers will offer to visit the women in their home (or they can come to a research centre if they prefer) to measure weight and waist circumference and ask mums to complete a questionnaire. These visits will happen at the start of the study, at 6 months, 12 months (when the messages end) and at 24 months (12 months after women stop receiving the messages). When attempts to arrange a visit between the researcher and participant at 12 and 24 months have been unsuccessful, as a last resort we will ask women to measure and report their own weight. We will also speak to some women when they have received the messages for 6 months and when they have been receiving the messages for 12 months to see what they think of them. Women will receive a token of appreciation at each visit for the time they have given to the research.

Women have already helped us to write our text messages and chose the name of the study (Supporting MumS). For this bigger study, women will help us to review and edit the messages so they are relevant to women across the UK. We will invite two women to be part of our study team to help us with all aspects of the study.

If the text messages are shown to help women manage their weight after having a baby, they could be made widely available to all women. We will share our findings with a wide variety of audiences including mums, health professionals, politicians, and government departments that could provide the text message service to women.

What are the possible benefits and risks of participating?

By taking part in this research, participants will be helping us find the best ways to support new mums. Some of the messages participants receive may be helpful for the individual and/or their baby by helping them to lose weight or by providing information about child health and development. We do not anticipate any risks from taking part in this study.

Where is the study run from?

Queen's University Belfast (UK)

When is the study starting and how long is it expected to run for?

July 2021 to September 2025

Who is funding the study?

National Institute for Health Research (NIHR) (UK).

Who is the main contact?

Prof McKinley, [m.mckinley@qub.ac.uk](mailto:m.mckinley@qub.ac.uk)

### **Study website**

<https://www.qub.ac.uk/research-centres/CentreforPublicHealth/Research/PublicHealthNutrition/SupportingMumSStudy/>

## **Contact information**

**Type(s)**

Scientific

**Contact name**

Prof Michelle McKinley

**ORCID ID**

<https://orcid.org/0000-0003-3386-1504>

**Contact details**

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[m.mckinley@qub.ac.uk](mailto:m.mckinley@qub.ac.uk)

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

305557

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

IRAS 305557, NIHR131509, CPMS 51568

## Study information

**Scientific Title**

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

**Acronym**

SMS

**Study objectives**

Women randomised to receive the intervention text messages (messages about weight management) will lose significantly more weight compared to women randomised to the active control (messages about child health and development).

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 24/02/2022, West of Scotland REC 4 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 3140213; WoSREC4@ggc.scot.nhs.uk), ref: 22/WS/0003

## **Study design**

Multi-site parallel two-arm interventional randomized controlled trial with embedded process evaluation and cost-effectiveness analysis

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Community, GP practice, Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

A copy of the participant sheet can be requested by emailing [supportingmums@qub.ac.uk](mailto:supportingmums@qub.ac.uk)

## **Health condition(s) or problem(s) studied**

Overweight and obesity in postpartum women

## **Interventions**

Women will be recruited from all four countries in the UK using community based recruitment as well as signposting via routine contact with health professionals. Written informed consent will be obtained, baseline data collected and then participants will be randomised. Participants will be block randomised and randomisation will be stratified by site. The randomisation sequence will be developed in STATA by a statistician who is independent of the study team. The randomisation will be implemented via the London School of Hygiene and Tropical Medicine secure remote web-based system which will link directly with the text message database and will deliver the intervention or control content according to the random allocation sequence. Participants will become aware of their group allocation when they start to receive the messages. Participants will receive the text messages for one year.

The intervention group will receive automated text messages about weight loss and maintenance of weight loss for 12 months. The text messages will focus on diet and physical activity with embedded behaviour change techniques known to be positively associated with weight management.

The control group will receive automated text messages about child health and development for 12 months.

Study assessments will be conducted at baseline, 6 months, 12 months (end of intervention period) and 24 months (12 months after the intervention has ceased) for all participants.

## **Intervention Type**

## Behavioural

### Primary outcome measure

Current primary outcome measure as of 24/02/2024:

Between-group difference in mean weight change (kg) measured using calibrated scales from baseline to 12 months

Previous primary outcome measure:

Weight change from baseline to 12 months (kg), measured using calibrated scales

### Secondary outcome measures

Current secondary outcome measures as of 24/02/2024:

1. Between-group difference in mean weight change (kg) from baseline to 24 months.
2. Between-group difference in mean waist circumference (cm) measured by a flexible measuring tape at baseline, 6, 12 and 24 months.
3. Between-group difference in mean BMI (kg/m<sup>2</sup>) measured at baseline, 6, 12 and 24 months.
4. Health behaviours are measured by: Fat and Fibre Barometer; self-report questionnaire on sugar and alcohol intake; International Physical Activity Questionnaire (IPAQ) - Short form; and self-report questionnaire on infant feeding practices (Infant Feeding Survey) measured at baseline, 6, 12 and 24 months
5. Study acceptability is measured by: recruitment; retention; engagement with the two-way text messages during 12 months; self-reported questionnaire on participant satisfaction with SMS messages (at 6 and 12 months) and rating of intervention (at 12 months); and qualitative interviews (at 6 and 12 months),
6. Economic evaluation outcomes are measured by: self-report questionnaire on health service resources use, prescribed and over-the counter medication usage and lifestyle-related costs; the EuroQol 5-dimension (EQ-5D-5L with visual analogue scale) quality of life questionnaire; and the ICEpop Capability Measure for Adults (ICECAP-A) at baseline, 6, 12 and 24 months
7. Moderators of intervention effect are measured by: Edinburgh Postnatal Depression Scale (EPDS); Generalised Anxiety Disorder (GAD-7); Pittsburgh Sleep Quality Index; and self-report questionnaire on confidence and desire for weight loss and maintenance at baseline, 6, 12 and 24 months
8. Mediators of intervention effect are measured by: Health Action Process Approach (HAPA) for diet and exercise; Self-Report Behavioural Automaticity Index for diet and exercise; Self-regulation of eating behaviour questionnaire; self-report questionnaire on monitoring and goal setting for diet and exercise; Motivation for weight loss scale; Social support for eating & exercise questionnaire; and Rosenberg Self-Esteem Scale at baseline, 6, 12 and 24 months

Previous secondary outcome measure:

1. Waist circumference measured by a flexible measuring tape at baseline, 6, 12 and 24 months
2. Health behaviours are measured by: Fat and Fibre Barometer; self-report questionnaire on sugar and alcohol intake; International Physical Activity Questionnaire (IPAQ) - Short form; and self-report questionnaire on infant feeding practices at baseline, 6, 12 and 24 months
3. Study acceptability is measured by: recruitment; retention; engagement with the two-way text messages during 12 months; self-reported questionnaire on participant satisfaction with SMS messages (at 6 and 12 months) and rating of intervention (at 12 months); and qualitative interviews (at 6 and 12 months),
4. Economic evaluation outcomes are measured by: self-report questionnaire on health service resources use, medication usage and lifestyle-related costs; the EuroQol 5-dimension (EQ-5D) quality of life questionnaire; and the ICEpop Capability Measure for Adults (ICECAP-A) at baseline, 6, 12 and 24 months

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**Overall study start date**

01/07/2021

**Completion date**

30/09/2025

## **Eligibility**

**Key inclusion criteria**

1. Women (as per NICE Postnatal care guideline NG1941, for this trial, the term 'woman' is taken to include people who do not identify as women but are pregnant or have given birth)
2. Aged >18 years old
3. BMI  $\geq 25$  kg/m<sup>2</sup>
4. Have had a baby within the last two years

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

888

**Total final enrolment**

892

**Key exclusion criteria**

Current participant exclusion criteria as of 24/02/204:

1. Baby less than 6 weeks old
2. No access to a mobile phone to receive personal messages
3. Insufficient English to understand short written messages
4. Currently pregnant
5. Recent or planned bariatric surgery

6. Diagnosis of anorexia nervosa or bulimia by a doctor
7. On a specialist diet and receiving dietetic care
8. Taking part in another weight management research study/programme currently, or in the last 3 months

Previous participant exclusion criteria:

1. Baby less than 6 weeks old
2. No access to a mobile phone to receive personal messages
3. Insufficient English to understand short written messages
4. Currently pregnant
5. Recent or planned bariatric surgery
6. Eating disorder
7. On a specialist diet and receiving dietetic care
8. Taking part in another weight management research study currently, or in the last 3 months

**Date of first enrolment**

20/04/2022

**Date of final enrolment**

02/05/2023

## **Locations**

**Countries of recruitment**

England

Northern Ireland

Scotland

United Kingdom

Wales

**Study participating centre**

**Queen's University Belfast**

Centre for Public Health

ICS A, School of Medicine, Dentistry & Biomedical Science

Grosvenor Road

Belfast

United Kingdom

BT12 6BJ

**Study participating centre**

**University of Stirling**

NMAHP Research Unit

Pathfoot Building

Stirling  
United Kingdom  
FK9 4NF

**Study participating centre**

**London School of Hygiene and Tropical Medicine**  
Department of Population Health  
Keppel Street  
London  
United Kingdom  
WC1E 7HT

**Study participating centre**

**Bradford Teaching Hospitals NHS Foundation Trust**  
Better Start Bradford Innovation Hub  
Bradford  
United Kingdom  
BD9 6RJ

**Study participating centre**

**Cardiff University**  
Centre for Trials Research  
Cardiff  
United Kingdom  
CF10 3FT

## **Sponsor information**

**Organisation**

Queen's University Belfast

**Sponsor details**

University Road  
Belfast  
Northern Ireland  
United Kingdom  
BT7 1NN  
+44 2890973861  
p.tighe@qub.ac.uk

**Sponsor type**



University/education

**Website**

<https://www.qub.ac.uk>

**ROR**

<https://ror.org/00hswnk62>

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

30/04/2026

**Individual participant data (IPD) sharing plan**

Current IPD sharing plan as of 24/02/2024:

Following publication of the results, the anonymised participant-level datasets generated during and/or analysed during the current study, along with the statistical code used for generating the results, will be available upon request from the Chief Investigator on reasonable request, as assessed by the Chief Investigator and Project Management Team and subject to any necessary

data sharing agreements. Formal requests to be made in writing to the Chief Investigator (Prof M McKinley; m.mckinley@qub.ac.uk). Data availability will be consistent with timelines for storage of research data.

Previous IPD sharing plan:

Available on request. Formal requests to be made in writing to the CI (Prof M McKinley; m.mckinley@qub.ac.uk).

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 1.0	30/11/2021	10/01/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version 2.0	07/03/2022	28/11/2023	No	No
<a href="#">Protocol file</a>	version 3.0	10/05/2023	29/11/2023	No	No
<a href="#">Protocol file</a>	version 4.0	12/04/2024	07/05/2024	No	No
<a href="#">Protocol article</a>		06/05/2024	09/05/2024	Yes	No
<a href="#">Statistical Analysis Plan</a>	version 1.0	14/05/2024	29/05/2024	No	No