

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

Submission date 10/12/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/02/2022	Overall study status Ongoing	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/05/2025	Condition category 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/m²)

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

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

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Contact details

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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

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/m²) 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 ≥ 25 kg/m²
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

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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?
Protocol file	version 1.0	30/11/2021	10/01/2022	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 2.0	07/03/2022	28/11/2023	No	No
Protocol file	version 3.0	10/05/2023	29/11/2023	No	No
Protocol file	version 4.0	12/04/2024	07/05/2024	No	No
Protocol article		06/05/2024	09/05/2024	Yes	No
Statistical Analysis Plan	version 1.0	14/05/2024	29/05/2024	No	No