ISRCTN90393571 https://doi.org/10.1186/ISRCTN90393571

Text messaging as a way of helping overweight and obese women manage their weight after having a baby - The SMS study

Submission date
02/02/2017

Recruitment status
No longer recruiting

Registration date
24/02/2017

Overall study status
Completed

Last Edited
19/10/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many women are overweight or obese from the start of pregnancy and this puts the mother's and baby's health at risk. If a woman is overweight or obese in pregnancy she is at greater risk of developing gestational diabetes (a type of diabetes that occurs during pregnancy) or pre-eclampsia (a serious condition where blood flow between the baby and placenta is reduced so the baby doesn't get enough nutrients to develop properly). Women are also more likely to need a caesarean section and there is a greater risk of stillbirth and infant death. As well as starting pregnancy too heavy, some women gain too much weight during pregnancy. Many women struggle to lose weight after pregnancy and at the moment the best way to help these women is unknown. The period when women have a baby is a very unique time. On the one hand, it may be a time when women become very aware of the importance of good health and so might be open to changing their diet. On the other hand, women's lives change completely. Their attention becomes focused on caring for the baby rather than themselves. This means that any support provided to women to help them lose weight after pregnancy needs to fit in with their busy and constantly changing lives. Many women are unable to attend scheduled classes or meetings and so it is important to a way to provide support. Text messages have been used to help people stop smoking and some research has shown that they may also help people to lose weight. The aim of this study is to find out whether a weight management programme delivered via text messages can help women lose weight after pregnancy.

Who can participate?
Adult women who have had a baby in the last two years.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive regular text messages on weight loss and how to keep weight off (weight loss maintainance) for 12 months. Those in the second group receive regular text messages about child health and development for 12 months. Women in both groups are visited every three months by study researchers. At each study visit, participants complete some questionnaires about health and lifestyle, have their weight and blood pressure measured and are asked to wear a pedometer

(step counter) for seven days. They are also asked to take part in a short telephone interview twice during the study (at the three and twelve months) to gather views on the text message program.

What are the possible benefits and risks of participating?
Participants may benefit by finding the messages they receive to be helpful and supported. There are no anticipated risks involved with 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?
February 2017 to June 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Michelle McKinley
m.mckinley@qub.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Michelle McKinley

ORCID ID
http://orcid.org/0000-0003-3386-1504

Contact details
Centre for Public Health
School of Medicine, Dentistry & Biomedical Sciences
Queen's University Belfast
Institute of Clinical Science Block B (1st floor)
Grosvenor Road
Belfast
United Kingdom
BT12 6BJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Project: 14/67/20

Study information

Scientific Title
A woman-centred, tailored SMS-delivered multi-component intervention for weight loss and maintenance of weight loss in the postpartum period: a pilot RCT (The SMS Study)

Acronym
The SMS Study

Study objectives
The SMS intervention shows promise as a way to support weight loss and weight loss maintenance in the post-partum period and should be tested in a full trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee, School of Medicine, Dentistry & Biomedical Science, Queen's University Belfast

Study design
Single-centre pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Weight loss and maintenance of weight loss

Interventions
Participants are randomised to one of two groups using the LSHTM’s secure remote web-based system which will link directly with the SMS database and will deliver the intervention or control content according to group allocation.

Interventions group: Participants will receive messages about weight loss and maintenance of weight loss for 12 months.

Control group: Participants will receive messages related to child health and development for 12 months.

In both groups, message delivery will be automated. Messages will be sent out using the London School of Hygiene and Tropical Medicine's (LSHTM) existing messaging technology, via a secure server, as tried and tested in the txt2stop trial.

Study assessments will be carried out at baseline, 3, 6, 9 and 12 months.

Intervention Type
Behavioural

Primary outcome measure
1. Acceptability of the intervention and active control is measured using a satisfaction rating and qualitative views
2. Feasibility of recruitment is measured using study records at the end of the recruitment period
3. Retention rate is measured using study records at 3, 6, 9 and 12 months
4. Attrition rate is measured using study records at 3, 6, 9 and 12 months

Secondary outcome measures
Evidence of positive indicative effects is measured using change in weight and waist circumference at 3, 6, 9 and 12 months.

Overall study start date
22/12/2014

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. Had a baby in previous two years
2. Aged over 18 years
3. Postpartum BMI over 25kg/m2
4. Primiparous or multiparous

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex

Female

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. No access to a mobile phone to receive personal messages
2. Insufficient English to understand messages
3. Pregnancy
4. On a specialist diet
5. Psychiatric disorders
6. Eating disorder
7. Previous/ planned bariatric surgery
8. Type 1 diabetes mellitus

Date of first enrolment
10/02/2017

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Queen's University Belfast
University Road
Belfast
United Kingdom
BT7 1NN

Sponsor information

Organisation
Queen's University Belfast

Sponsor details

University Road
Belfast
Northern Ireland
United Kingdom
BT7 1NN

Sponsor type
University/education

Website
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.

Added 23/10/2019:
The final report is in process with the funder. The first view summary of results is available at:
https://www.fundingawards.nihr.ac.uk/award/14/67/20

Intention to publish date
01/03/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from 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?
Results article	results	01/03/2020	27/11/2020	Yes	No
Protocol (other)		07/03/2022	19/10/2022	No	No