

Participant information sheet

STRICTLY CONFIDENTIAL

Version 1.0 21/09/2016



Participant Information Sheet

Title of study: Supporting MumS (SMS) study

We invite you to take part in a research study by Queen's University Belfast. Before you decide whether to take part, it is important that you understand why we are doing this research and what it will involve. Please take time to read the following information carefully and discuss it with friends/relatives if you wish. If you have any questions, please contact us using the details given at the end of the sheet.

Why are we doing this study?

New mums face many challenges when they have a baby and there may be areas that they could benefit from support. We are interested in finding out how we can support new mums in the first two years after having their baby.

Why have I been asked to take part?

You have been chosen to take part as you are over 18 years old and have had a baby within the past two years.

Do I have to take part?

No, it is up to you whether or not you want to take part. If you do decide to take part, you are free to leave the study at any stage without giving a reason for doing so.

What will happen if I take part?

If you decide to take part we will contact you to explain the study in more detail and answer any further questions you may have.

You will then receive text messages which will be sent to your mobile phone for the next 12 months. The number of text messages you receive each week will change during the study, ranging from 3 per week to 14 per week.

Mums who take part in the study will get text messages on ONE of the two topics shown below. It is important that you understand there is a 50:50 chance you will get texts on either one of these two topics:

1. Information and advice on making healthy food choices and keeping active to help you lose weight.

OR

2. Information and advice on your child's health and development.

What information will you collect from me if I take part?

As well as getting text messages, we would also like to meet with you 5 times (during the 12 month study). These visits will take place at the start of the study, at 3 months, at 6 months, at 9 months and at the end of the study (12 months).



For the visits, the researcher will either visit you at your home or you can come and meet the researcher at the Centre for Public Health in Belfast, whichever is most convenient for you. You will receive a payment of £20 (gift voucher) on completion of each visit in recognition of your time. This will be a total of £100 over the 12 month study if all visits are completed. Each visit will last approximately 1 – 1.5 hours.

At each visit we will collect the following information:

- We will ask you to complete some questionnaires about your health and lifestyle. These will take approximately 50 minutes to complete.
- We will measure your height (just at visit 1) and will ask you to step on the scales to collect information on weight and body fat. We will also measure your blood pressure.
- We will ask you to wear a pedometer (a small piece of equipment that you can put in your pocket or clip onto your clothing to measure the number of steps you take) for 7 days after each study visit and then we will collect it from you or give you a stamped addressed envelope to return it to us.

We would also ask you to consider taking part in a short (approximately 20 minutes) telephone interview twice during the study (at the 3 month visit and the 12 month visit) to help us find out about how you found the text messages, and your thoughts on the information we collected from you for the study. This part is optional.

What are the possible advantages and disadvantages of taking part?

By taking part in this research you will be helping us find the best ways to support new mums. Some of the messages you receive may be helpful for you and/or your baby during the 12 months.

We do not anticipate any risks from taking part in this study.

Is the study confidential?

All data will be treated with the strictest confidence and your details will not be shared with anybody outside of the University, unless there is a serious risk of harm to you or others. Any information collected from you will be stored securely on a password protected file on a computer held at Queen's University Belfast. A back-up copy will be kept in a secure filing cabinet. You will only be identified by a unique ID code.

How will I find out the results of this project?

If you wish, your contact details can be kept securely and when the study is over we can send you some information about the findings from the project. We will ask you whether this is something you would like if you decide to take part in the study.

Who is organising and funding the research?

The work is being organised by researchers at the Centre for Public Health (Queen's University Belfast), and is funded by National Institute of Health Research and Public Health Agency Northern Ireland.

Has this study been approved for safety by an ethics committee?/Is this study safe?

This study has been reviewed and approved as ethically sound by the School of Medicine, Dentistry and Biomedical Sciences Research Ethics Committee.

Contact for Further Information:

Caroline Gallagher, PhD Student, Centre for Public Health, School of Medicine Dentistry & Biomedical Sciences, Institute of Clinical Science Block B, Grosvenor Road, Belfast BT12 6BJ.

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Please ask us if there is anything that is not clear or if you would like more information.

Participant informed consent form

Supporting MumS Study

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CONSENT FORM

Study 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 (SMS Study)

Please initial boxes

1. I confirm that I have read and understand the Participant Information Sheet (version ENTER dated ENTER) for the above study and have a copy to keep. ☐
2. I have had the opportunity to ask questions and have received satisfactory answers to all my questions. ☐
3. I agree to take part in the above study, inclusive of all the procedures mentioned in the Participant Information Sheet (measurement of weight, height and blood pressure, completion of questionnaires and interviews) ☐
- OR*
- I agree to take part in the above study, inclusive of all the procedures mentioned in the Participant Information Sheet (measurement of weight, height and blood pressure, completion of questionnaires) EXCEPT the two telephone interviews. ☐
4. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
5. I give permission for my GP to be informed of my participation and of any medical issues detected during study visits (e.g. elevated blood pressure) ☐
6. I understand that all information collected about me during the course of the research may be looked at by responsible individuals in the study team, Queen's University Belfast and regulatory authorities. All data will be kept strictly confidential as necessary under the Data Protection Act and will be stored securely on University premises. ☐
7. I understand that I will not be identifiable in any data published in relation to this project. ☐

8. At the end of the study, I would like to be informed of the findings and agree for my contact details to be kept for this purpose. ☐
9. I am willing to be contacted in the future about a follow-up to this study. ☐

I am willing to take part in this study. ☐

Consent regarding future research studies (optional):

9. I agree to be contacted by the University about future research studies about diet or lifestyle and health ☐

Name of Participant	Date	Signature
Name of Researcher	Date	Signature
Contact details of researcher		

Letter sent to participants if contacts to arrange follow-up appointments were unsuccessful



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Telephone: 07596 839 285
Email: supportingmums@qub.ac.uk

Participant Name
Address

Date

Dear Name,

I hope this letter finds you well. Unfortunately, we have been unable to get in contact with you to arrange your next research study visit. This would involve a short 15 minute visit at a place convenient to you to take your weight, waist circumference and blood pressure readings. If possible, we would really appreciate it if you could get in contact via text/phone call/email (see contact details above) to let us know if you wish to:

- a) arrange a date for the visit
- b) skip this visit and be re-contacted again when your next visit is due (March 2018)
- c) discontinue taking part in SMS research study visits.

If we don't hear from you we will contact you again to arrange your X month visit (Month).

We really value the time you have given up for the study so far and look forward to hearing from you soon.

Yours sincerely

A handwritten signature in black ink that reads "Michelle McKinley".

Dr Michelle McKinley (Principal Investigator)