



## PARTICIPANT INFORMATION SHEET

### The Supporting MumS (SMS) study



We would like to invite you to take part in this research study which is taking place in Northern Ireland, England, Scotland and Wales.

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 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?

Welcoming a baby brings lots of joy and happiness but being a new mum also means life is a bit busy! There may be areas where mums could benefit from more support. Mums often talk about having a baby as a time when their weight started to creep up and how they would welcome support with this. We are interested in finding out if text messages can help support weight management in the first two years after having a baby.

*For this study, the term 'mum' or 'mother' includes people who do not identify as women but are pregnant or have given birth. The term 'your child' means your youngest child at the time of signing up to the study.*

### 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 and have a body mass index over 25kg/m<sup>2</sup>.

### 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. Your usual health care will not be affected at any time.

### What will happen if I take part?

After you read this leaflet we will contact you to discuss the study in more detail and answer any further questions you may have.

If you decide to take part, you will be asked to sign the consent form for the study and complete some study measurements (described below). You will then receive text messages to your mobile phone for 12 months. The number of text messages you receive each week will vary between 3 and 14 per week. The text messages are delivered to you by a secure text message system owned and operated by the London School of Hygiene and Tropical Medicine.

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 that the topic is randomly chosen for you and that there is a 50:50 chance you will get texts on either topic 1 or topic 2:

1. Information and advice on making healthy food choices and keeping physically 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?

We would meet with you 4 times (during a 24 month period) to collect some measurements and information. These visits will take place at the start of the study, at 6 months, at 12 months (when the text messages stop) and at 24 months (12 months after you stopped receiving the text messages).



For the visits, the researcher will either visit you at your home or you can come and meet the researcher at a convenient location such as a University building or a local community venue; whichever is most convenient for you.

You will receive a £25 voucher on completion of each visit in recognition of your time to complete the research measures. This will be a total of £100 over the 24-month study, if all visits are completed. Each visit will last approximately 1 hour.

At each visit we will collect the following information:

- a) We will measure your height (only at visit 1) and will ask you to step on the scales to collect information on weight and will measure your waist circumference (this will take about 10 minutes).
- b) We will ask you to complete a questionnaire booklet about your health, lifestyle and wellbeing. The booklet will take approximately 30 minutes to complete. You will have the option of:
  - completing a printed questionnaire booklet in your own time and posting it back to us in a stamped addressed envelope we provide; OR
  - completing the questionnaire online by accessing a link we give you; OR
  - completing the questionnaire with the researcher at the study visit or over the phone.

When (a) and (b) above has been collected from you, we will arrange for the £25 voucher to be sent to you.

We would also ask you to consider taking part in a short (approximately 20 minutes) telephone interview twice during the study (at the 6 month visit and the 12 month visit) to help us understand how you found the text messages. *This part is optional.*

### Linking to routine health-related data in the future (this part is optional)

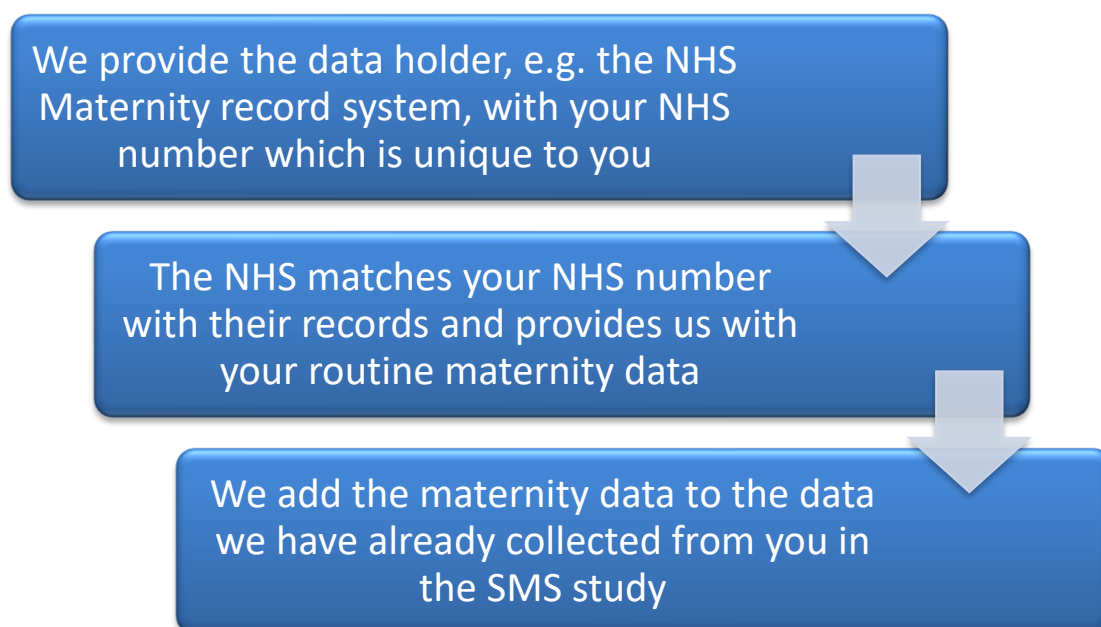
We would also ask you to consider allowing us to collect health-related data about you and your child in the future. We would do this by linking with organisations that collect data about the services they provide to women and children. For example, the NHS keeps records about using health services and any treatment that is provided in GP and dental records, hospital records, maternity and health visiting records and disease registers. This is known as 'routine data'.

Routine data is stored electronically on different systems. To obtain your routine data from other systems, we would share some personally-identifiable details such as name, date of birth, address and NHS number to the organisations that manage these systems and they will send us data back. This will all be done using secure data transfer systems that have been set up carefully to keep your information safe.

Doing this helps us to understand if a study like this has any longer-term benefits and how we might improve health services in the future.

If you consent to us linking to routine health-related data on the consent form, we will ask you for your NHS number. This number will only be stored by QUB and will only be used for this purpose. It will be stored securely, separately from your other data, in a password protected, encrypted file on computers that are only accessible to authorised members of the research team. An example of how we would link your routine data is shown below.

*You do not have to consent to data linkage to participate in this study. This part is optional.*



Example of routine data linkage process

## **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 by helping you to lose weight or by providing you with information about child health and development. We do not anticipate any risks from taking part in this study.

## **How will we use information about you?**

We will need to use information from you for this research project. This information will include your name, address, NHS number, date of birth, telephone number, email address and date of birth of your youngest child. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

## **Will my taking part in the study be kept confidential?**

**Yes**, all your data will be treated with the strictest confidence and your details will not be shared with anybody outside of the research team, unless there is a serious risk of harm to you or others.

Any information collected from you will be stored securely on password protected files on password protected computers that only the research team can access. Hard copies of documents will be kept in locked filing cabinets in locked offices that are only accessible to the research team and are located in a building that is locked outside normal working hours.

Any interviews conducted over the telephone will be audio-recorded and the recording will then be typed up for research purposes. The typed transcript will not contain any,

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names and will be labelled with your unique study number. The recording will be destroyed once the typed transcript is prepared.

Study data will be kept separate from personal information (such as name and address). Only members of the research team will have access to view identifiable data. However, in some instances, inspectors from regulatory authorities may need to access data for checking the quality of the research. All members of the research team and regulatory bodies are trained in data protection and will comply with the requirements of data protection legislation.

Once the study is complete and it is no longer necessary to keep identifiable information or contact details, we will destroy our records of this personal information.

The study questionnaire asks some questions about mental and physical health. If we have any concerns that your responses to such questions may indicate you are at risk of postpartum depression, we will inform you and your GP by letter as part of our duty of care to you. If at any stage we have concerns that you, or someone else, is at risk of harm then we are obliged to tell the relevant services, for example your GP or social services.

### **What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

### **Where can you find out more about how your information is used?**

You can find out more about how we use your information:

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- in our privacy notice from <http://go.qub.ac.uk/SMSstudy> or ask the research team for a copy
- by asking one of the research team
- by sending an email to [info.compliance@qub.ac.uk](mailto:info.compliance@qub.ac.uk), or
- by ringing us on 07341 888415.

**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 your preference about this on the study consent form.

**Who is organising and funding the research?**

For this study we will be recruiting women from all four countries in the UK. The work is being led by Professor Michelle McKinley from Queen's University Belfast. Researchers from Universities in London, Cardiff, Stirling and the Bradford Teaching Hospitals NHS Foundation Trust are leading recruitment in their areas.

Mums have helped us design our text messages and advise on how the study is conducted and will continue to do so.

The study is funded by National Institute of Health Research and the 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 by the West of Scotland Research Ethics Committee 4 and IRAS ID 305557.

**What will happen if I don't want to carry on with the study?**

You can withdraw from the study at any time, without giving a reason by contacting the research team (contact details at the end of this leaflet). If you do decide to withdraw from the study, we will use the data collected up to that point, but we will not collect any more data.

**What if there is a problem?**

If you have a concern about any aspect of this study, you can speak to the researchers who will do their best to answer your questions (contact details on the last page).

Should you remain unhappy and wish to make a formal complaint, you can contact:

Research Governance Team at Queen's University Belfast,  
63 University Road, Belfast  
BT7 1NF

(Telephone: 028 9097 2529; Email: [researchgovernance@qub.ac.uk](mailto:researchgovernance@qub.ac.uk)).

**Contact for Further Information:**

Researchers' Name, Address, Email address, Telephone (site specific)	Dr Dunla Gallagher SMS Trial Manager Centre for Public Health Queen's University Belfast School of Medicine, Dentistry & Biomedical Sciences Institute of Clinical Sciences (Block A) Grosvenor Road Belfast, N.Ireland BT12 6BA Tel: +44 (0)28 90978927 Email: d.gallagher@qub.ac.uk
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**Please ask us if there is anything that is not clear or if you would like more information.**