Supplementary document 10: Participant Information Sheet and Consent Form

Women's interviews at 12 months postnatally – ALL WOMEN

Rec Reference Number: 16/LO/1422

Supporting women with postnatal weight management (SWAN study)

We would like to invite you to take part in an interview about your experience of taking part in the above study. Please take your time to consider this information and discuss it with others if you wish. Please ask us if you need further information.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Part 1 of the information sheet

What is the purpose of the study?

As you kindly agreed to take part in the SWAN study we would now like to ask you about your experiences of taking part. We would like to find out about:

- What you understood about the study, for example, what you thought about the content of the questionnaires we asked you to complete and what you thought about being asked to have your weight checked at 6 and 12 months after having your baby.
- Your diet and level of physical activity since having your baby and any changes to your lifestyle that you may have made since you were pregnant.
- Your experience of and contact with other sources of support which help you to manage your weight.
- Whether or not you think other women would be willing to take part in a future study about postnatal weight management.

Why have I been invited?

You have been invited as you took part in the SWAN study.

Do I have to take part?

No, it is up to you to decide. You can change your mind at any time and withdraw from the study without giving a reason.

What will happen to me if I take part in the interview?

If you are happy to take part:

- You will be asked to sign a consent form to take part when your baby is around 4-6 months old.
- A researcher will contact you by phone to ask a few questions about your experience of taking part in the SWAN study, which will take about 30 to 40 minutes.
- The researcher will ask your permission to audio-record the interview. The interview would be transcribed prior to analysis and we will remove your name and any other identifying information from the typed transcript. Should you wish to review and, if necessary, correct the transcript of your interview, you can request a copy from the Investigator, Professor Debra Bick.

Will my information be confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

All information we collect will be stored securely and kept in locked cupboards in locked offices, only accessible to authorised members of the study team. All study information will be kept in a confidential form, and codes rather than names will be used to identify the interview recording.

We won't use your name or any information that can be used to identify you in any publications. Quotations from the interviews may be used in reports, presentations and papers but will not be traceable to you. All published and unpublished reports will disguise the identity of the individuals.

Your interview transcript will kept for 5 years in a secure location, to allow for any audit of the research that may be required and your interview audio-recording will be destroyed when the study results are published. Only members of the research team will have access to the information you give. The only exception to this will be if you tell us information which suggests a risk of serious danger to yourself or others. In this case, we would inform your health care provider.

What are the possible benefits of taking part?

The information we obtain will help to show how we can best support women with their weight management after having a baby in the future.

What are the possible disadvantages and risks of taking part?

We do not anticipate that there will be any disadvantages or risks in taking part. If answering any questions causes any anxiety about your health, information on who to contact to discuss this is included at the end of this leaflet. If you have any problems or concerns about your health, the researcher will be able to suggest you contact your GP or health visitor.

What will happen to the results of the study?

We will publish the study results in reports required by funders and also in articles published in academic journals. We will also present the results of the study at conferences which may be attended by other parents, those working within maternity services and policy makers. No names of any of the study participants will ever be used in any publication.

Who is organising and funding the study?

The research is being funded by the National Institute for Health Research Public Health Research programme. The sponsor of the study is King's College London.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by London – Camberwell St Giles Research Ethics Committee.

You have been given a copy of this information sheet to keep and when you complete the consent form you will also be given a signed consent form to keep.

Further information and contact details

You can find out more about this study from the funder's website (http://www.nets.nihr.ac.uk/projects)

Is there a contact point where I can seek independent advice about participating in the study?

If you would like more information about the study itself you can ask to speak to the Research Midwife. Their contact details are on the back page of this leaflet. The hospital trust's Patient Advice and Liaison Service (PALS) can also be contacted. They will give you advice about how to contact someone for independent advice. Their phone number is on the back page of this leaflet.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [redacted] If you remain unhappy and wish to complain formally, you can do this through the [redacted]. The PALS team are based in the main entrance on the ground floor at [redacted]

In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against [redacted] but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Where can I find the results of the study?

The results of the study will be published in a medical journal and on the King's College London and the National Institute for Health Research websites when the study has finished. We will send a summary of the study findings to all women who took part in the study when it has finished.

Thank you for taking the time to read this information.

Local contact details: Patient Advice and Liaison Service
[redacted]

Research Lead:
[redacted]

Research Midwives
[redacted]

Study Number:

CONSENT FORM

Name of Researcher:

Please initial box

1. I confirm that I have read and understand the information sheet dated September 17th 2017 (version 7) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my care or legal rights being affected. ☐

3. I agree to the use of audio-taping if I am interviewed, with possible use of verbatim quotes from my interview ☐

4. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of person taking consent	Date	Signature

An original copy of the participant information sheet and completed informed consent form is to be given to the participant, in addition to the original copy that is filed in the investigator file