Supplementary material 3

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Participant Information Sheet and Consent Form for Women with a BMI ≥ 25.

Rec Reference Number: 16/LO/1422

Study of support for women's weight management after giving birth.

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. The Research Midwife will go through the information sheet with you and answer any questions you have. We'd suggest this should take about 10 minutes. Talk to others about the study if you wish and please ask us if there is anything that is not clear or if you would like more 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?

Many women carry excess weight when they become pregnant and this can lead to health problems during and after pregnancy. As women are currently advised that they should not attempt to lose weight in pregnancy, we want to see if it is possible to undertake a study that supports women who carry excess weight to lose this in the months after they have given birth by attending a weight management group. However, before we undertake a large study to find out if the groups would work, we first of all want to undertake a 'feasibility' study to see if women would be prepared to take part in this sort of study after having a baby and complete all stages of the study follow up. If women are happy to take part, we will conduct a much larger study in the future to find out if weight management groups work.

Why have I been invited?

You have been invited as you were identified with a Body Mass Index (BMI) of 25 or over at your first antenatal appointment (or 'booking' appointment).

Do I have to take part?

No. It is up to you to decide. We will describe the study and go through this information sheet. If you agree to take part, we will ask you to sign a consent form but you are free to withdraw from the study, without giving a reason, at any time during the progress of the study. If you no longer wished to take part, it would not affect the standard of care you receive.

What will happen to me if I take part?

If you are happy to take part, you will be asked to sign a consent form when you are around 36 weeks pregnant. The Research Midwife will enter your details into a computer and you will be allocated to either the 'weight management plus usual care' group or the 'usual care only' group. This decision is made by chance, rather like the toss of a coin, and all women will have an equal chance of being in either of the study groups. If you are allocated to the weight management group you will be offered advice on healthy lifestyles and invited to start attending local weight management groups at any time from 8 weeks to 16 weeks after having your baby. You will be invited to attend weekly groups over a total of 12 weeks. You can decide which group you want to attend (for example based on its location in relation to where you live) and the time of day it is held (for example you may prefer an afternoon group or an early evening group). You will also continue to receive any routine contacts with healthcare professionals for you and your baby.

If you are allocated to the 'usual care only' group this means you will continue to have any routine contacts with healthcare professionals for you and your baby.

What would being in the study involve?

After you have signed the consent form, the Research Midwife will ask you to complete a questionnaire on your current health. Information about your pregnancy booking weight and other information on your health in pregnancy will be collected by the Research Midwife from your maternity records. We will also record details of when you and your baby are discharged from the hospital, and details of any treatments you and your baby receive whilst in hospital. If you are allocated to the weight management group, we will also share routinely collected data from the organisation who runs the groups about the number of times you attended, the range of other people who attend the group at the same time and the content of advice offered. These data will be emailed by the organisation to the researchers using a password protected file, with no names used.

At 6 months and 12 months after you have had your baby, you will be asked to complete a questionnaire about your health and your baby's health. You will also be invited at these times to attend an appointment [redacted] with the Research Midwife or you can ask for them to visit you at home, where you will be weighed (and if you want to, you could complete the questionnaire during these visit). We may also ask if you would be interested in taking part in a short interview with one of the researchers to discuss your experiences of weight management after having your baby. This could be done over the phone or [redacted] whichever was more convenient for you.

Expenses and payments

We will provide you with travel expenses for attending the 6 and 12 month appointments with the Research Midwife (or you can ask for the Research Midwife to visit you at home) and a £10 Love2Shop voucher as a 'thank you' for returning each completed questionnaire.

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. We cannot promise the study will help you but your contribution will be extremely important. On completion of the weight groups we offer as part of this study, you will have the opportunity to continue to attend at a reduced fee should you wish to carry on. If you were not allocated to the weight management group, you will be offered the same opportunity to join a group at a reduced fee on completing the study.

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. In some cases, the Research Midwife may call you to discuss your health if you report a particular problem.

What happens when the research study stops?

When the research stops you will continue to receive usual care or services you may have been accessing.

Will my taking part in the study be kept 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 each questionnaire and interview recording (if you are interviewed).

No individual names or details that would identify specific individuals will be included in any publications. Quotations from questionnaires or interviews may be used in reports, presentations and papers but will not be traceable to specific individuals. All published and unpublished reports will disguise the identity of individuals.

If you take part in the study, some parts of your medical records and the data collected for the study may be looked at by authorised persons from the study funders to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant.

Part 2 of the information sheet

What would happen if I change my mind?

You can withdraw from the study at any time without having to provide a reason for this. Any information we have already collected about you may still be used but we would not make any further attempts to contact you.

You mention sending a questionnaire later. What will the questionnaire contain?

The questionnaire will ask about how your health at the time you complete it, and will include questions about your diet, how you are feeling physically and emotionally, how well you are sleeping and about your physical activity. It will also include questions on how often you and your baby have visited the doctors and hospital in the year after giving birth.

The questionnaire will be posted out from the study office at King's College London at 6 and 12 months after you have had your baby. If you would prefer you can complete it at the follow up appointment with the Research Midwife which can take place at your home [redacted] which ever would be better for you. Once completed, it can be returned in a freepost envelope (no stamp required), which is supplied, or returned to the Research Midwife at your planned follow up appointment with them at 6 and 12 months.

What will happen to the results of the research study?

Study results will be published in reports as required by the study funders and in relevant academic and service journals. Findings will also be presented at conferences which may be attended by parents, maternity service clinicians and policy makers, service user representatives and academics. No names of any participants will ever be used in any publication.

Who is organising and funding the research?

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 [redacted]. The PALS team are based in the main entrance on the ground floor at [redacted] and 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] NHS Foundation Trust and/or [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 [redacted] and National Institute for Health Research website 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. You will not be identified in any report or publication.

Thank you for taking the time to read this information.

Local contact details:

[redacted]

[redacted]

[redacted]

Study Number: 16/LO/1422

CONSENT FORM

Postnatal Weight Management Study

Name of Researcher:

Please initial box

1. I confirm that I have read and understand the information sheet dated 04/09/2016 (version 6) 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 understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the study team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to my GP being informed of my participation in the study. YES ☐ NO ☐

5. 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