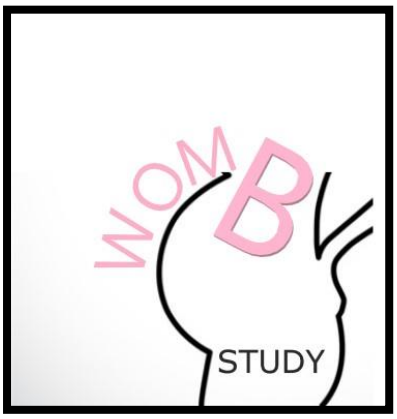
WOMB: **W**earable device to **O**bserve **M**ovements of your **B**aby (WOMB) study



Ethics Ref: 288119

Participant Information Leaflet

Introduction

You are invited to take part in a research trial. Before you decide, it is important that you understand why the research is being done and what it would involve for you.

Please take the time to read the following information carefully and take time to decide whether or not you wish to take part. You are welcome to ask us if there is anything that is not clear or if you would like more information. You might also want to talk to others about the study (for example your family, friends or your GP).

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

PART 1

What is the trial about?

Your baby's movements are reassuring for their health. It can be difficult for some woman to appreciate their baby's movements and this can lead to unnecessary medical intervention.

We are going to test whether a fabric we have developed can accurately pick up a baby's movements. Hopefully this will allow us to create a solution that is easier and more comfortable for longer term monitoring of movement.

Can I take part in the trial?

You would be eligible to participate in the trial if you are pregnant with one baby.

Do I have to take part?

It is entirely up to you to decide. We will describe the study and go through this information sheet, which we will give you to keep. If you choose to participate, we will ask you to sign a consent form to confirm that you have agreed to take part. Your signature is not binding in any way and you will be free to withdraw at any time, without giving a reason. This will not affect you or your care in any way.

If your doctor believes that is in your best interest for you to stop participating in the trial, he or she will discuss this with you.

If any new information regarding your treatment becomes available during the course of the trial, your doctor will discuss this with you as well.

Whether you decide to participate in the trial or not, your decision will not affect your relationship with your doctor.

If you decide not to participate in the trial, you will receive the usual standard of care for your pregnancy.

What will happen to me if I take part?

If you are eligible for the trial and you wish to take part you will first be registered onto the trial. This means you will be asked to provide written informed consent to confirm you wish participate in the trial.

We will ask you to come in for four extra 20 minute scans. During this scan you will be given a button to press when you feel the baby move. The scan operator will also press a foot pedal when they see the baby move. Then after the scan a different independent person will see whether the fabric has picked up the movements that both the mum and person scanning have noticed.

The reason we ask you to come for four scans is so we can see if the fabric works throughout the last 2 months of pregnancy.

8 weeks after the last scan we would telephone you to ask how your pregnancy went and what you thought of the product.

What are the possible disadvantages, side effects, risks and/or discomforts of taking part in this study?

The disadvantage of taking part in the trial is that we would ask you to come in to the hospital for four extra scans between 32 and 38 weeks of pregnancy.

What are the possible benefits of taking part in this study?

Taking part in the trial is not going to be directly beneficial to you personally, although you will get to see your baby on scan a few extra times.

Expenses and payments

Travel expenses up to £30 will be made for participation in this study.

What will happen when the trial ends?

The trial concludes 8 weeks after your last scan and, once you are discharged from hospital care, your GP will continue with your care as normal.

When the last participant has completed the trial, the information we have gathered will be analysed so that we can work out whether our device works to monitor fetal movements.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to your study doctor or nurse who will do their best to answer your questions (see the end of this leaflet for contact details). If you remain unhappy and wish to complain formally, you can do this through the Patient Advice and Liaison Service (PALS). Their full contact details are given in Part 2 of this leaflet.

This concludes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

Who is organising and funding the trial?

This trial is funded by Kymira with a grant from Innovate UK.

Kymira is sponsoring the trial and covering the standard insurance and indemnity costs applicable to research trials.

What will happen if I don't want to carry on being part of the study?

Participation in this study is entirely voluntary. If you decide you do not wish to participate in this trial it will not affect you in any way. If you decide to take part in the study, you will need to sign a consent form, which states that you have agreed to participate. However, you may withdraw from the study at any time without giving a reason and without it affecting you in any way.

You have the right to withdraw from the study completely and decline any further contact by study staff after you withdraw.

Your normal care will not be affected in any way.

Who should I contact if I wish to make a complaint?

If you have a concern or complaint about the Trial which has not been addressed by the study team, you can complain formally through the Patient Advice and Liaison Service (PALS):

Patient Advice and Liaison Service

Email pals@addenbrookes.nhs.uk

Telephone 01223 216756

PALS and Complaints Department,

Box 53,

Cambridge University Hospitals NHS Foundation Trust,

Hills Road,

Cambridge,

CB2 0QQ

Will my taking part be kept confidential?

Once you have agreed to participate, information about you is sent to the WOMB Trial Office which will refer to you only by a unique trial number and your initials so that you cannot be recognised. All information collected about you for this trial is strictly confidential. The information will be securely stored at the WOMB Trial office under the provisions of the 1998 Data Protection Act, and will be accessible only to authorised personnel from the WOMB team.

Occasionally, we may need to access your medical records in order to check that the information provided about you is accurate. This will be done by clinical staff or designated personnel from the Trial Office.

Government regulatory agencies may also require access to your medical records to ensure that the trial is being run in accordance with UK law.

Only the local investigator at your hospital will have access to your personal details and can trace your identity. It will not be available to the team at KYMIRA. Data collected for the trial will be stored for up to 10 years after the end of the trial, as required by UK legislation.

What will happen to the results of the trial?

Once the study is complete the results will be published and a final report will be written. You will not be identified in any reports or publications and none of the data could be traceable to you personally.

What if I want any more information about the study?

If you have any questions about any aspect of the study, or your participation in it which has not been answered by this participant information leaflet, then please contact:

rosieresearch@addenbrookes.nhs.uk
01223769262

Dr Suzi Dunkerton

Thank you for taking the time to read this Participant Information Leaflet.

NHS
National Institute for Health Research