Participant Information Sheet

Study title: The OptiBreech Care Trial: a small randomised trial to determine whether a large trial is possible for women with a breech-presenting baby at term

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Invitation and brief summary

We would like to invite you to participate in this research project. You are being invited to participate in this project because your baby is breech (bottom-down, rather than head-down) at the end of pregnancy, and you were planning a vaginal birth.

Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information.

What is the purpose?

We are conducting a small initial study to see if a larger study is possible.

The ultimate purpose of this study is to identify outcomes for women and birthing people carrying a breech baby at term. Some women choose to try to turn the baby head-down. Some women choose to plan a vaginal breech birth. And some women choose to plan a caesarean section. Women have told us they would like more up-to-date information about the relative safety and effectiveness of each of these options. So we would like to understand more about how each of these choices compare in contemporary maternity services.

We have conducted a small pilot trial and are now looking more closely at a new care pathway that shows some promise in potentially improving outcomes for women and their breech babies at term, known as OptiBreech Care. You will receive further information about this care pathway specifically, but this information sheet will cover participating in the research.

What would taking part involve?

If you choose to participate in this study, we will ask you for consent:

- To access your medical records and those of your baby, so that we can record information about the health services you use and the outcomes of your birth;
- To send you follow up surveys at 1 month, 3 months, 1 year and 2 years;
- To allow us to collect follow-up information on you and your baby, from hospital and community records, for a period of up to 10 years after your birth.

Examples of information we may obtain from your health records include: what kind of birth you had (e.g. vaginal birth or caesarean birth), whether your baby needed any additional care following the birth, how many total appointments you had with healthcare professionals during and after your pregnancy.

You can agree to all of the part of this study, or only the portions you feel comfortable with.

What if I change my mind?

Your choice of treatment is ALWAYS your own. If you are allocated one treatment but upon reflection wish to decline this, you will be supported whichever decision you decide to make.

Data about health service use

In this study, we will collect data about your use of health services during your breech pregnancy. This will include a hand-held record, in which you and your health care providers will record all of your appointments related to your breech pregnancy. This data will help us to determine what it costs to provide different types of care.

In order to collect accurate information about the time it takes to provide different types of care, an additional member of the research team may also take notes during your appointment. This will always be a member of the healthcare team who is also already there to learn. If you prefer not to have learners or students involved in your care, you are welcome to decline this by informing your midwife or doctor.

Surveys and longer-term follow-up

If you participate in the study in any way, we will send you a link to a follow-up survey by e-mail at 1 month, between 3 and 4 months and at 1 and 2 years after you have given birth. This surveys will ask you questions about your experience of care, about you and your baby's use of health services since the birth and about your baby's development. If you do not respond to the e-mail survey, we will telephone you and offer assistance to complete the survey, which could include the use of a telephone translator if you wish. You are under no obligation to continue to participate if you no longer wish to, and the researcher will ask you if you wish to have their assistance to complete the survey via telephone.

The women who contributed to the design of this research indicated that it was important to them to know about the long-term outcomes associated with their birth choices. Therefore, we would like permission to collect information on your health service usage and outcomes, for you and your baby, including from hospital and community health records, for a period of up to 10 years. For example, we may access your baby's health records to determine how many hospital admissions they have had following their birth in breech position. Our follow-up will include information on the outcomes of subsequent pregnancies, as these are often affected by the previous births. If we continue to collect data after 2 years, this will be subject to additional ethics approvals.

Anonymisation

This follow-up will require us to maintain your contact information and NHS numbers, for you and your child. We will also inform your GP about your participation in this study if you give us permission to do this. However, all of your personal information will be kept in a separate secure location from the data we are collecting.

When you enter the study, you will be allocated a code. This will be linked to your personal information and enable you to access the surveys. But when the researchers analyse the information we have collected, your personal details will not be included. Only the Project Lead and Manager will

have access to your personal details, and we will only access them if we need to contact you, or to communicate with your health care service providers in order to collect the data.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and only the parts that you feel comfortable with. You may choose to share your data about birth outcomes but not participate in surveys or long-term follow-up if contacted. Choosing not to take part will not disadvantage you in anyway.

Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

What are the possible benefits of taking part?

Previous studies have shown that participation in clinical trials improves outcomes in women's health compared to non-participation, regarless of whether you are allocated to the new treatment arm or not. The new treatments we are testing are only available through participation in the study, where they are not already part of the hospital's guideline.

What are the possible disadvantages and risks of taking part?

Keeping a record of your appointments and completing follow-up surveys may be time-consuming. The new treatments we are testing may be effective, they may not result in any improvement, or they may introduce new risks we had not anticipated. This study is overseen by a Trial Steering Committee, to whom all serious adverse outcomes are reported and who have the power to stop the trial if the treatments appear to be less effective or to carry additional risk part way through the trial.

How is the project being funded and organised?

This project is being funded by the National Institute for Health Research (NIHR). King's College London is organising the study.

Who else has reviewed the study?

The study has been reviewed by the West London Research Ethics Committee (21/LO/0808).

What will happen to the results of the study?

The results of the project will be submitted for publication. The information reported will not contain any details that would enable you to be identified by someone reading the report. A summary will be posted on the feasibility study's website: https://optibreech.uk/

Involvement of service users in the research

A Patient and Public Involvement (PPI) group has been involved in designing this research, this information and the consent form. If you would like to become a part of this PPI group after you give birth, you can find more information on the study's website: https://optibreech.uk/category/ppi/

The PPI group has also created a private FaceBook group for participants in the study, to enable service users to share experiences and support each other. This can be accessed here: https://www.facebook.com/groups/optibreechinvolvement

Information on the Use of Data

How will we use information about you?

We will need to use information from you and your medical records for this research project.

This information will include your NHS number, name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

We will keep all information about you safe and secure, in a separate place from the data we are analysing.

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 nobody can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time (withdraw), 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. This will be stored on the secure KCL network drive.

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/
- our leaflet available from: www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research
- by asking one of the research team (contact details included below)
- by contacting the Data Protection Officer: (Albert Chan info-compliance@kcl.ac.uk)

King's College London is the sponsor for this study based in the United Kingdom. We will be using information from you and your child in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Our lawful basis for processing your personal data under the General Data Protection Regulation (GDPR) is 'task in the public interest' (as a university, doing research is part of our public task). Similarly, we will be processing your health data (which is a special category of personal data under the GDPR) because it is 'necessary for scientific or historical research purposes'. King's College London will keep identifiable information about you for 10 years after the study has finished.

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.

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 King's College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

What if I wish to make an independent complaint?

The Patient Advice and Liaison Service (PALS) offers confidential advice, support and information on health-related matters, including the NHS compaints procedure. They provide a point of contact for patients, their families and their carers. Local contacts for PALS officers are available from https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/

What if I have further questions?

You are welcome to contact the research team:

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