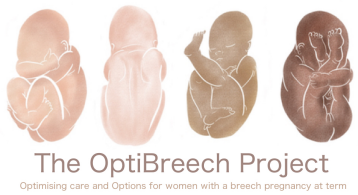
Study title: The OptiBreech Care Pathway: evaluating the feasibility and acceptability of team care for women seeking to plan a vaginal breech birth



Chief Investigator: Dr Shawn Walker, King's College London

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 previously planning a vaginal birth and/or have requested a vaginal breech 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?

The purpose of the project is to explore the feasibility of conducting a large, multi-centre study to determine the safety and cost effectiveness of OptiBreech care.

Optibreech care is what is called in the health services a 'care pathway.' It starts when your baby has first been diagnosed as breech after 36 weeks and follows you through to your birth, whether you choose to try to turn your baby head-down, plan a vaginal breech birth or plan a caesarean section. The most important difference in this potential new care pathway is that care for vaginal breech births, for those who choose this, is delivered by a proficient team, all of which have had enhanced training in physiological breech birth.

We do not know if it will be possible to ensure we can provide care from a proficient team member for vaginal breech births, so we are studying several sites in the UK who would like to try to do this. Following this study, we hope to be able to provide women with accurate information about how often it is possible for a proficient team member to attend their breech birth.

What would taking part involve?

If you choose to take part in this project, there will be no change to the standard of care that you receive. In line with local clinical guidelines, a midwife or obstetrician will counsel you about the research and develop a plan for supporting you during your birth. This will follow your hospital's current guideline. You will be supported to make an informed decision regarding planned mode of birth. If you choose to plan a vaginal breech birth, a member of the breech team will be called to attend your birth. The members of this team will have received enhanced training that conforms to national guidelines. In this study, we would like to interview you about your experiences of the care service you receive.

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 (all participants); AND

- (optional) To interview you approximately 6 weeks after you have given birth about your experience of care for you and your breech-presenting baby;
- (optional) 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.

Interviews

If you agree to be invited, a researcher will contact you approximately 6 weeks after your birth to confirm you are still willing, and if so arrange an interview. This will take place via Microsoft Teams online meeting software. The interview will last approximately 30-45 minutes and be audio or video recorded directly onto a secure data management system. The transcript of the interview will be typed up by a third party with whom KCL has an established contract. Your name and any other identifying details will be removed. Then the research team will read through the interview to understand more about whether and why the service was acceptable to you. We may use direct quotes in our published report, but these will be attributed to a pseudonym of your choice.

If you disclose poor or dangerous practice during your interview, we have a professional duty to raise concerns, to ensure maternity services are as safe as possible. We would inform you and seek your permission if we intend to do this. We would then raise the issue with the local Principal Investigator, who would investigate the concerns via Trust internal governance mechanisms, with a focus on supporting the professional to improve their practice.

Long-term Follow-up

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, from hospital and community health records, for a period of up to 10 years. This 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.

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 interviews 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?

The attendance of a skilled and experienced professional is the only factor associated with a reduction in perinatal mortality in previous, high-quality research. However, very few hospitals offer a plan to increase the likelihood of attendance by a skilled and experienced professional. ***Your breech team cannot offer you an absolute guarantee due to the unpredictable nature of labour,*** by participating in this study, they are agreeing to try their best. Also, although the RCOG guideline supports the use of both supine and upright birthing positions, not all professionals have had fully evaluated training to support upright breech births. All members of your hospital's breech team will have had this training.

Even if you decide to plan a caesarean section, you will receive unrushed, experienced counselling about your options.

If you participate in an interview, some people find it very helpful to review their experience of care during pregnancy and birth. This response is very personal, and every person is different.

What are the possible disadvantages and risks of taking part?

According to the Royal College of Obstetricians and Gynaecologists guideline (RCOG, Impey et al 2017), planning a caesarean section leads to a small reduction in the risk of perinatal mortality (baby's death)

compared with vaginal breech birth. The risk of perinatal mortality is approximately 0.5/1000 with caesarean section after 39+0 weeks of pregnancy; and approximately 2/1000 with planned vaginal breech birth. This compares to 1/1000 with planned head-first birth. You should carefully consider your mode of childbirth with a breech baby at term, and your team will support you regardless of your choice.

If you participate in an interview, sometimes, reviewing your birth experience can make you feel distressed, especially if there were parts of it that were difficult, or where you didn't feel in control. If this happens, the researcher will pause or stop the interview, according to your wishes, and support you to be in touch with a health care professional who can help you talk through these feelings, for your benefit only.

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 Cambridge and Hertfordshire Research Ethics Committee.

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/

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.

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, 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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