Call for Expressions of Interest: Heads Up stepped wedge cluster trial

Expressions of interest are invited for sites to collaborate on an HTA funding bid for a stepped wedge cluster trial of OptiBreech care. We are aiming to submit a funding proposal in August 2023 and if successful, plan to begin work on the trial in summer 2024. We hope to include sites from Scotland, Wales, Northern Ireland and England. The trial will be supported by Imperial Clinical Trials Unit.

Research Team:

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What is OptiBreech collaborative care?

OptiBreech care is a new care pathway for delivering standard care to women and birthing people pregnant with a breech-presenting baby at term. This population is defined as: breech presentation at birth, or at any scan from 35+0 weeks or where a successful external cephalic version (ECV) has been performed.

The service is provided through a dedicated clinic, co-ordinated by a breech specialist midwife, working collaboratively with a breech lead obstetrician. All management options are offered – external cephalic version, vaginal breech birth and elective caesarean birth. ECV attempts are provided by clinic staff in a same-day service where required. Intrapartum care for vaginal breech births follows the OptiBreech physiological breech birth guideline, developed by the OptiBreech Collaborative. The breech lead midwife and obstetrician lead on training throughout the service, including mandatory updates and simulations. The specialist midwife also co-ordinates a continuity of care service, so that whenever possible planned breech births are attended by a member of the team with full OptiBreech training and experience managing complications. Members of the team are also part of an extended OptiBreech community of practice, which provides regular practice updates and opportunities for reflection as they develop competence and expertise.

How does this differ from standard care?

This is a new way of organising care and training for breech presentation at term. Current standard care is characterised by a lack of standardisation and adherence to national guidelines from the RCOG(1) and NICE(2). OptiBreech care promotes standardisation for optimal outcomes. The vaginal breech birth training that is provided is the same training offered on the RCOG Labour Ward Management course, RCOG Vaginal Breech Birth study days and Royal Society of Medicine Maternity and Newborn Forum, which led by clinical members of the research team.

Why do we think a cluster trial is appropriate now?

1. There is strong evidence current standard care pathways do not provide consistent access to all options national guidelines recommend,(3,4) nor do they provide adequate training opportunities for younger obstetricians and midwives.
2. OptiBreech collaborative care is a pathway developed with significant input from service users and clinicians. It is highly acceptable to women and birthing people, regardless of their care choices or ultimate mode of birth.(5)
3. Feasibility work has included two NHS training evaluations,(6,7) an observational implementation evaluation and a pilot trial. All three have demonstrated better outcomes compared to standard care for vaginal breech births. For example, the neonatal serious adverse outcome rate for women planning a vaginal birth has been less than 1%, compared to 5% in the Term Breech Trial,(8) and 7% for actual vaginal births in standard care births included in our training evaluation.(7)
4. The pilot trial demonstrated that women have access to all three guideline-recommended options within the OptiBreech care pathway, but not within standard care (see below).(9)

Pilot trial results: More women planned a VBB when randomised to OptiBreech Care (23.5% vs 0, p = .003, 95% CI =.093,.378). Women randomised to OptiBreech care had: lower rates of cephalic presentation at birth (38.2% vs 54.5%), higher rates of vaginal birth (32.4% vs 24.2%), lower rates of in-labour caesarean birth (20.6% vs 36.4%), lower rates of neonatal intensive care (5.9% vs 9.1%), and lower rates of severe neonatal morbidity (2.9% vs 9.1%). Within the entire cohort, breech presentation on admission to labour/birth (n=44), compared to cephalic presentation (n=38), was associated with: lower levels of neonatal admission (2.3% versus 10.5%), lower levels of severe neonatal morbidity (2.3% vs 7.9%), fewer maternal admissions to HDU (4.5% vs 7.9%) and less severe maternal morbidity (13.6% vs 21.1%). Outcomes for non-British and non-white women were also better than participants from white British backgrounds, which reassures us this service is accessible to minoritised participants. Randomisation was stopped in June 2022 on the advice of the steering committee, at 68 women randomised rather than the planned 104. It was clear 1:1 randomisation would not enable us to compare outcomes for VBB because women were not choosing to plan a VBB within standard care.

We know that the model enables access to a guideline-recommended care option, but we do not know how this will affect outcomes. A definitive trial that is powered on serious adverse neonatal outcomes is urgently needed and could lead to the implementation of OptiBreech collaborative care across the NHS.

What outcomes do we expect to improve with OptiBreech care?

Based on the results of our feasibility work and the available literature, we think that the rate of serious adverse neonatal outcomes (including death, HIE, admission to the neonatal unit >4 days) is about 4.5% for the entire cohort of term breech babies within standard care, as defined above. We think we can reduce this by about 40%, to 2.7%. This is the primary outcome we are seeking to improve.

We also think that OptiBreech care will be more cost-effective and reduce the rate of emergency caesarean birth.

How do we think OptiBreech care will do this?

We expect up to 1-2 women per month at each centre to plan a vaginal breech birth, with no increase in adverse outcomes for these babies. (*Note: This is an estimate of what might happen when services are delivered in this way, but there is no target VBB recruitment rate. Women's choices remain the same*.) Your site will implement the new care pathway for women booked at your service but will not be promoted as an OptiBreech referral site.

Based on available evidence and our feasibility work, we expect a reduction of 0.9% of serious neonatal outcomes will come from increasing skill levels throughout the service, learning from these planned events, and improving mandatory skills training to bring it in line with the most current evidence. We think this will help prevent adverse outcomes in unanticipated vaginal breech births.

In multiple audits and our pilot trial, we have also observed that within this model of care more women choose an elective caesarean birth, and the emergency caesarean birth rate declines. This will result in 0.9% additional improvement in neonatal, maternal and economic outcomes.

How will we evaluate this?

We will evaluate this in a stepped wedge cluster trial, including twenty sites over three years. If your site is chosen to participate, you will implement the care pathway at a point during the three years determined through randomisation. Our research team will analyse outcomes for women receiving care at the sites prior to and after randomisation.

What support would participating sites receive?

If you are one of twenty sites chosen for this trial, your hospital will receive unlimited free physiological breech training. This training is currently provided through the RCOG at a cost of over £360/person. We will train any members of your team you would like to receive full training. We will also train your skills trainers to deliver updates through standard mandatory training activities and periodic simulations.

At this point, we hope to be able to fund one day per week of a Band 7 breech specialist midwife developmental post. This person will be a current Band 6 ready to step up to greater leadership within the service. They would need to be in post for between one to three years, with associated funding between £12,126 and £36,379, depending on your site's starting point in the trial. They would be supported by senior members of your team to develop into a specialist. Your breech specialist midwife will also collect the data for the study, and the time for this will also be funded through the CRN; this is likely to be approximately 0.1 WTE, depending on the size of your service. This is a desirable post for the right person, which we anticipate will contribute to staff satisfaction and retention, in addition to developing your breech service.

We would provide you with a comprehensive job description, guideline and training resources, operational during the time your site is 'live' on the trial. This guideline has been developed by the OptiBreech Collaborative, clinicians who have led the first stages of feasibility work for this trial.

We would provide you with support during the implementation period from an experienced member of our team who has successfully implemented the service we are testing. And we would provide support through our community of practice activities for all members of your team who wish to participate. These include regular practice updates, case reviews and opportunities for reflective supervision with clinicians experienced in supporting physiological breech births. As many new sites will have limited recent experience supporting planned vaginal breech births, this will be re-introduced in a controlled and supported way.

Why else should you consider participating?

If this trial has a positive result, the OptiBreech collaborative care pathway will likely become the standard of care, and you will have already implemented it. If the trial does not demonstrate an improvement in outcomes, your team would still have acquired significant experience in the management of vaginal breech births, which may still bring beneficial skills and knowledge into your service.

Where can I read more about the research supporting OptiBreech care?

The OptiBreech Project Site
Breech Clinics and Specialist Midwives Implementation Toolkit

How can we express an interest in participating?

Please complete this form with your name and contact information. We will contact you with more information about requirements for site selection.

References

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3. Morris SE, Sundin D, Geraghty S. Women's experiences of breech birth decision making: An integrated review. Eur J Midwifery [Internet]. 2022 Jan 25 [cited 2022 Feb 9];6(January):1–14. Available from: http://www.europeanjournalofmidwifery.eu/Women-s-experiences-of-breech-birth-decision-making-An-integrated-review,143875,0,2.html
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5. Dasgupta T, Hunter S, Reid S, Sandall J, Shennan A, Davies SM, et al. Breech specialist midwives and clinics in the OptiBreech Trial feasibility study: An implementation process evaluation. Birth [Internet]. 2022 Oct 26 [cited 2022 Oct 27];00:1–10. Available from: https://onlinelibrary.wiley.com/doi/full/10.1111/birt.12685
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7. Mattiolo S, Spillane E, Walker S. Physiological breech birth training: An evaluation of clinical practice changes after a one-day training program. Birth [Internet]. 2021 Dec 23;48(4):558–65. Available from: https://onlinelibrary.wiley.com/doi/10.1111/birt.12562

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9. Walker S, Spillane E, Stringer K, Trepte L, Davies SM, Bresson J, et al. OptiBreech collaborative care versus standard care for women with a breech-presenting fetus at term: a pilot parallel group randomised trial to evaluate the feasibility of a substantive trial nested within a cohort. In peer review. 2023;

Please send the following information to Shawn.Walker@imperial.ac.uk

Your name:

E-mail:

Hospital/Trust/HealthBoard:

Role:

Please briefly describe the current care pathway within your hospital for breech presentation at term:

Who is your Lead Obstetrician?

Have you discussed this with them yet?*

Who is your Labour Ward Lead Obstetrician?

Have you discussed this with them yet?*

Who is your Director/Head of Midwifery?

Have you discussed this with them yet?*

Does your site have a Consultant Midwife or Clinical Lead Midwife?

If yes, name:

Have you discussed this with them yet?*

Anything else you would like us to know?

**You can still submit an EOI if you have not yet started these discussions. We just want to have a sense of our starting point.*