ISRCTN14521381 https://doi.org/10.1186/ISRCTN14521381

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

Submission date
01/07/2021

Recruitment status
No longer recruiting

Registration date
18/10/2021

Overall study status
Completed

Last Edited
04/01/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Current Plain English summary as of 07/09/2023:
Background and study aims
This study aims to determine whether it is possible to compare care for vaginal breech birth from a skilled and experienced specialist team. This care pathway is called 'OptiBreech care'.

Who can participate?
Women with otherwise healthy pregnancies, who are pregnant with a breech-presenting baby at term (>37 weeks)

What does the study involve?
Women participating in the nested randomised controlled trial (now closed) will be allocated by chance ('randomised') to either OptiBreech care or ECV. They can choose to accept the intervention or decline it, as in standard maternity care. Non-randomised women participating in the prospective observational study will receive OptiBreech collaborative care for a planned vaginal breech birth. The maternity care professionals who provide care will record information about how much and what kind of care women have in pregnancy and during birth. This information will be entered into a database and kept separate from any details that could link it to an individual person, such as name and dates of birth. The study team will send participants follow-up surveys at 1 month, 3-4 months, 1 year and 2 years following the birth.

What are the possible benefits and risks of participating?
Previous studies have shown participation in clinical trials improves outcomes in women's health compared to non-participation, regardless of whether they are allocated to the new treatment. Specialist care for vaginal breech births is available in very few hospitals. Keeping a record of appointments and completing follow-up surveys may be time-consuming. Also, vaginal breech birth where there is no control for the skill and experience of attendants is not as safe as head-first birth. OptiBreech care may or may not change this.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run from?
November 2018 to August 2024

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Shawn Walker
Shawn.Walker@kcl.ac.uk

Previous Plain English summary:
Background and study aims
This study aims to determine whether it is possible to compare care for vaginal breech birth from a skilled and experienced specialist team with trying turning the baby head-down, for women whose baby is breech (bottom-down) at the end of pregnancy. These two care pathways are called 'OptiBreech care' and 'external cephalic version (ECV)'.

Who can participate?
Women with otherwise healthy pregnancies, who are planning a vaginal birth prior to finding out their baby is breech, and have not yet had an attempt at turning the baby (ECV)

What does the study involve?
Participating women will be allocated by chance ('randomised') to either OptiBreech care or ECV. They can choose to accept the intervention or decline it, as in standard maternity care. The maternity care professionals who provide care will record information about how much and what kind of care women have in pregnancy and during birth. This information will be entered into a database and kept separate from any details that could link it to an individual person, such as name and dates of birth. The study team will send participants follow-up surveys at 1 month, 3-4 months, 1 year and 2 years following the birth.

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Who is the main contact?
Dr Shawn Walker
Shawn.Walker@kcl.ac.uk

Study website
https://optibreech.uk/

Contact information

Type(s)
Scientific

Contact name
Dr Shawn Walker

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
303028

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 303028, CPMS 50898

Study information

Scientific Title
The OptiBreech Care Trial: a feasibility study for a pragmatic trial of care for women with a breech-presenting baby at term

Acronym
OptiBreech Care

Study objectives
Current study hypothesis as of 07/09/2023:
It is feasible to conduct a pragmatic trial comparing OptiBreech care with standard care for women with a breech pregnancy at term

Previous study hypothesis:
It is feasible to conduct a pragmatic randomised controlled trial comparing OptiBreech care with external cephalic version for women with a breech pregnancy at term

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/11/2021, West London & GTAC Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)207 1048098; westlondon.rec@hra.nhs.uk), ref: 21/LO/0808

Study design
Two-arm pilot randomized controlled trial, nested within a prospective observational cohort study

Primary study design
Interventional

Secondary study design
Prospective observational cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information material can be found at: https://optibreech.uk/home/information-for-women/

Health condition(s) or problem(s) studied
Breech pregnancy

Interventions
Current interventions as of 07/09/2023:
Pilot trial (Pilot RCT stopped in June 2022 on advice of the Trial Steering Committee, due to lack of planned vaginal breech births among women randomised to ‘standard care,’ prohibiting comparison in 1:1 randomisation): The randomisation schedule will be computer-generated using MedSciNet software. Allocation will be automatic during the enrolment process on the database and revealed to the person who is taking consent and enrolling the participant in the study. Minimalisation factors will include site, parity (0 vs 1 or more previous births), type of

breech presentation (extended/frank vs any other), and gestation at enrolment (<36, 36-38+6, 39+ weeks). Allocation between arms will be equal. The enrolment log will be completed automatically through the database.

Participating women will be randomised to either OptiBreech care (specialist care for vaginal breech birth from professionals who meet minimum proficiency criteria), or external cephalic version (ECV) and offer caesarean if unsuccessful. They can choose to accept the intervention or decline it, as in standard maternity care. The maternity care professionals who provide care will record information about how much and what kind of care women have during pregnancy and during birth. This information will be entered into a database and kept separate from any details that could link it to an individual person, such as name and date of birth. The study team will send participants follow-up surveys at 1 month, 3-4 months, 1 year and 2 years following the birth.
Prospective cohort: Women requesting support for vaginal breech birth will receive OptiBreech collaborative care. That is, professionals with advanced training in physiological breech birth attend VBBs whenever possible. The service is coordinated by a Breech Specialist Midwife with support from a Breech Lead Obstetrician. A small, experienced team provides continuity for women and professionals; their role is to train and support the wider team.

Previous interventions:
The randomisation schedule will be computer-generated using MedSciNet software. Allocation will be automatic during the enrolment process on the database and revealed to the person who is taking consent and enrolling the participant onto the study. Minimalisation factors will include site, parity (0 vs 1 or more previous births), type of breech presentation (extended/frank vs any other), and gestation at enrolment (<36, 36-38+6, 39+ weeks). Allocation between arms will be equal. The enrolment log will be completed automatically through the database.

Participating women will be randomised to either OptiBreech care (specialist care for vaginal breech birth from professionals who meet minimum proficiency criteria), or external cephalic version (ECV) and offer caesarean if unsuccessful. They can choose to accept the intervention or decline it, as in standard maternity care. The maternity care professionals who provide care will record information about how much and what kind of care women have in pregnancy and during birth. This information will be entered into a database and kept separate from any details that could link it to an individual person, such as name and dates of birth. The study team will send participants follow-up surveys at 1 month, 3-4 months, 1 year and 2 years following the birth.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 07/09/2023:
Pilot RCT
1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study by 6 months (randomised) and overall (non-randomised)
2. Acceptance rate recorded as the number of participants randomised to OptiBreech Care who plan a vaginal breech birth, and the number of participants randomised to the control who attempt an ECV, measured at the time of birth (randomised)
3. Attrition rate recorded as the number of participants who consent to participate who remain in the study until the end of follow-up at 4 months after birth
4. Long-term attrition rate recorded as the number of OptiBreech 1 participants who complete 1-year and 2-year follow-up surveys when invited

5. Fidelity to intervention recorded as the number of planned vaginal breech births (VBBs) attended by a proficient team member, measured at the time of birth
6. Costs to deliver the service recorded as the total number of days and nights spent on call to support planned VBBs in the trial by 6 months

Previous primary outcome measures:
1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study by 6 months (randomised) and overall (non-randomised)
2. Acceptance rate recorded as the number of participants randomised to OptiBreech Care who plan a vaginal breech birth, and the number of participants randomised to the control who attempt an ECV, measured at the time of birth
3. Attrition rate recorded as the number of participants who consent to participate who remain in the study until the end of follow-up at 4 months after birth
4. Long-term attrition rate recorded as the number of OptiBreech 1 participants who complete 1-year and 2-year follow-up surveys when invited
5. Fidelity to intervention recorded as the number of planned vaginal breech births (VBBs) attended by a proficient team member, measured at the time of birth
6. Costs to deliver the service recorded as the total number of days and nights spent on call to support planned VBBs in the trial by 6 months

Secondary outcome measures

Current secondary outcome measures as of 07/09/2023:
(Primary outcomes for observational study)
The following potential primary and secondary outcomes for a substantive trial will be feasibility-tested, and incidence rates will be used to inform power calculations for the substantive trial:
1. Admission to higher-level neonatal care, measured as a binary (yes/no) and continuous (number of days/nights) outcome from patients' medical records at 28 days following birth
2. Mode of birth as a categorial measurement to include the following categories: vaginal breech birth, forceps breech, pre-labour caesarean section (CS), emergency CS, cephalic vaginal birth, cephalic forceps, cephalic ventous, from patients' medical records on the day of birth
3. Composite neonatal-perinatal death or serious adverse morbidity including the following: 5-minute APGAR score <4, peripheral nerve injury present at discharge from hospital, skull fracture, spinal cord injury, admission to NICU >4 days, intubation/ventilation >24 hours, convulsions >24 hours, parenteral or tube feeding >24 hours; from patients' medical notes at discharge
4. Composite maternal death or serious morbidity including the following: postpartum haemorrhage >1500 ml, obstetric anal sphincter injury, cervical laceration involving lower uterine segment, vertical uterine incision or serious extension to transverse uterine incision, bladder, ureter or bowel injury requiring repair, dilation and curettage for bleeding or retained placental tissue, manual removal of placenta, uterine rupture, hysterectomy, vulval or perineal haematoma requiring evacuation, wound dehiscence/breakdown, wound infection requiring prolonged hospital stay/readmission/antibiotics, sepsis, disseminated intravascular coagulation; from patients' medical notes at discharge
5. Use of services following referral for breech care, including antenatal and postnatal appointments, total time spent admitted to hospital, number of ECVs, number of ultrasound scans, and professionals present at birth; measured at 28 days following birth
6. Satisfaction with care measured using previously validated survey questions with a 5-point Likert scale, from patients' medical notes at 28 days post-birth
7. Experience of childbirth measured using the Childbirth Experience Questionnaire at 1-month

post-birth
8. Health-related quality of life measured using the PROMIS-10 survey at 1 month, 3-4 months, 1 year and 2 years following the birth

Previous secondary outcome measures:
The following potential primary and secondary outcomes for a substantive trial will be feasibility-tested, and incidence rates will be used to inform power calculations for the substantive trial:
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2. Mode of birth as a categorial measurement to include the following categories: vaginal breech birth, forceps breech, pre-labour caesarean section (CS), emergency CS, cephalic vaginal birth, cephalic forceps, cephalic ventous, from patients' medical records on the day of birth
3. Composite neonatal-perinatal death or serious adverse morbidity including the following: 5-minute APGAR score <7, peripheral nerve injury present at discharge from hospital, skull fracture, spinal cord injury, admission to NICU >4 days, intubation/ventilation >24 hours, convulsions >24 hours, parenteral or tube feeding >24 hours; from patients' medical notes at 28 days following birth
4. Composite maternal death or serious morbidity including the following: postpartum haemorrhage >1000 ml, obstetric anal sphincter injury, cervical laceration involving lower uterine segment, vertical uterine incision or serious extension to transverse uterine incision, bladder, ureter or bowel injury requiring repair, dilation and curettage for bleeding or retained placental tissue, manual removal of placenta, uterine rupture, hysterectomy, vulval or perineal haematoma requiring evacuation, wound dehiscence/breakdown, wound infection requiring prolonged hospital stay/readmission/antibiotics, sepsis, disseminated intravascular coagulation; from patients' medical notes at 28 days following birth
5. Use of services following referral for breech care, including antenatal and postnatal appointments, total time spent admitted to hospital, number of ECVs, number of ultrasound scans, and professionals present at birth; measured at 28 days following birth
6. Satisfaction with care measured using previously validated survey questions with a 5-point Likert scale, from patients' medical notes at 28 days post-birth
7. Experience of childbirth measured using the Childbirth Experience Questionnaire at 1-month post-birth
8. Health-related quality of life measured using the PROMIS-10 survey at 1 month, 3-4 months, 1 year and 2 years following the birth
9. Infant's development measured using the appropriate Ages and Stages Questionnaires at 3-4 months, 1 year and 2 years following the birth

Overall study start date
01/11/2018

Completion date
31/08/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 07/09/2023:
1. Live, singleton pregnancy with a breech-presenting fetus confirmed by ultrasound scan
2. Over 16 years of age
3. Referred for specialist care for breech presentation antenatally from 32 weeks
4. Breech presentation from 37 weeks discovered in labour

5. Requesting or preferring a vaginal birth
6. Giving informed consent to participate in contributing data
7. Consent to randomisation to be offered new treatments that are being tested (only for pilot trial)

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1. Live, singleton pregnancy with a breech-presenting fetus confirmed by ultrasound scan
2. Over 16 years of age
3. Referred for specialist care for breech presentation antenatally from 32 weeks
4. Breech presentation from 37 weeks discovered in labour
5. Requesting or preferring a vaginal birth
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Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
104 (pilot trial); 206 (non-randomised); 273 (overall)

Key exclusion criteria
1. Absolute reason for caesarean section already exists (e.g. placenta praevia major)
2. Requesting a caesarean section prior to recruitment
3. Multiple pregnancy
4. Life-threatening congenital anomaly
5. Not consenting to contribute data to the study
6. Has already had an ECV attempt prior to recruitment
7. Rhesus isoimmunisation
8. Current or recent (less than 1 week) vaginal bleeding
9. Evidence of antenatal fetal compromise, including abnormal electronic fetal monitoring
10. Rupture of the membranes
11. Hyperextended neck on ultrasound
12. Estimated fetal weight less than 2000 g or less than 10th centile at recruitment
13. Estimated fetal weight greater than 3800g or over 95th centile at recruitment
14. Standing/footling presentation at the time of recruitment, defined as hips extended and breech not engaged
15. Any indication at the time of recruitment for induction to be recommended prior to 41 weeks of pregnancy, e.g. gestational diabetes, obstetric cholestasis, advanced maternal age
16. Breech diagnosed for the first time in labour
17. Two or more previous caesarean sections

Date of first enrolment

07/01/2022

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Chelsea and Westminster Hospital
369 Fulham Rd
London
United Kingdom
SW10 9NH

Sponsor information

Organisation
King's College London

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Reza.Razavi@kcl.ac.uk

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Transparency and openness strategy
The researchers have adopted a multi-dimensional dissemination strategy consistent with the Health Research Authority (HRA)'s standards, "Make it Public: Transparency and openness in health and social care research." A dissemination strategy will be operational throughout this project, drawing on patient and public involvement (PPI), professional and policy networks and will involve the Trial Steering Committee (TSC) expert panel made up of service users, midwives, managers, academic collaborators and commissioners, as per the HRA guidance. As each aspect of the study is completed, the PPI group and TSC will be informed and the strategy discussed. Popular social media outputs will be utilised to share knowledge and advertise published findings.

In addition, the study website (https://optibreech.uk) will be used to disseminate updates about study progress and outcomes, including links to published papers and a brief, accessible summary of the findings. During the consent process, participants will be informed about how they will hear of results of the study, e.g. through the OptiBreech website, via the Facebook involvement group or through other means.

Publications
The study report will be used for publication and presentation at scientific meetings. The results of the study and any protocol deviations will be published in writing by the team headed by the Chief Investigator, which will report to the Trial Management Committee. Individual investigators may be able to produce oral reports with the permission of the Trial Management Committee.

Summaries of results will also be made available to Investigators for dissemination within their Trusts.

The entire project will be written up for publication. Findings for each section will be prepared for conference presentations and publication in peer-reviewed journals such as The Lancet, PLoS ONE, Trials, and BMC Pregnancy and Childbirth. A study report and summary will be prepared and submitted to the NIHR.

Intention to publish date
01/10/2024

Individual participant data (IPD) sharing plan
Current IPD sharing plan as of 07/09/2023:
Anonymised raw data will be made available as supplementary material in open-access publications, in accordance with the NIHR publication guidance, and stored in a repository for longer-term availability, in accordance with WHO and ICMJE guidance.
Following the end of the study, anonymised data will be archived on the university's secure Sharepoint site. This will be accessible only to the research team. Anonymised data will be stored in a Microsoft Excel Spreadsheet. All person-identifiable information will be removed or altered. For example, all dates will be converted to time-to-event intervals from the estimated date of birth, or actual data of birth for follow-up surveys. Prospective consent is obtained to use anonymised data in future studies, subject to appropriate ethics and data access approvals. Apply for access via the Chief Investigator Dr Shawn Walker (Shawn.Walker@kcl.ac.uk).

All available data is available on Figshare: https://figshare.com/collections/OptiBreech_Care_IRAS_303028/6386370.

Current IPD sharing plan:
Anonymised raw data will be made available as supplementary material in open-access publications, in accordance with the NIHR publication guidance, and stored in a repository for longer-term availability, in accordance with WHO and ICMJE guidance.
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IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	01/11/2021	04/04/2022	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 1.2	20/06/2022	05/09/2023	No	No
Dataset	Pilot trial data	15/01/2023	07/09/2023	No	No

Results article	Pilot	15/11/2023	16/11/2023	Yes	No
Preprint results		23/11/2023	04/01/2024	No	No