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Birth options feasibility trial

Submission date
15/12/2025

Recruitment status
Recruiting

Registration date
23/01/2026

Overall study status
Ongoing

Last Edited
23/01/2026

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Many women in England have caesarean births – about 42% of all births, and more than half of these are emergency operations. Emergency caesareans can sometimes lead to birth trauma. Women say they want clearer information to help them make choices about how they give birth. This study looks at whether it is possible to run a larger trial comparing three approaches: usual care, a guided conversation about birth options, and a guided conversation plus a tool that predicts the chance of needing an emergency caesarean. In the long term, the study aims to see if these approaches affect how satisfied women feel with their choices and whether emergency caesareans become less common.

Who can participate?
Women who are between 28 and 37 weeks pregnant with their first ongoing pregnancy are invited to take part.

What does the study involve?
Participants fill in a questionnaire between 28 and 36+6 weeks of pregnancy. They are then randomly placed into one of three groups:
1. Usual care
2. A guided conversation about birth options
3. A guided conversation plus a prediction tool for emergency caesarean
The conversation takes place at around 36 weeks. After that, participants can choose vaginal birth, induction, or planned caesarean. The study team collects feedback from participants and their midwives or doctors, and gathers information about pregnancy and birth. Participants also complete short questionnaires about mental health and birth expectations after the conversation, and about experience and mental health at 6 weeks and 6 months after the baby is born.

What are the possible benefits and risks of participating?
Taking part may help participants feel more informed and confident about their birth choices. The study could also improve care for future mothers. There are no major risks from taking part, but the conversations and questionnaires may take some time and could feel sensitive for some people.

Where is the study run from?
University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
January 2026 to September 2027

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

Who is the main contact?
Dr Abi Merriel, BirthOptions@liverpool.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
345836

Central Portfolio Management System (CPMS)
70096

National Institute for Health and Care Research (NIHR)
302530

Study information

Scientific Title
A three-arm randomised feasibility trial of birth options interventions to predict, inform and offer choices to reduce emergency caesarean birth in first pregnancies

Study objectives
Aim:
To establish if it is possible to implement the Birth Options Interventions and recruit and retain participants in the Birth Options feasibility trial

Objectives:
1. What is the recruitment rate to the Birth Options Feasibility Trial?
2. What proportion of women and birthing people complete follow up?
3. Is the Birth Options intervention acceptable to families and clinical staff?
4. What are the reasons for participation/non-participation in the study?
5. How can recruitment to a main trial be optimised?
6. What proportion of women opt for each birth option?
7. Is it feasible to collect the proposed outcome measures for a follow-on trial to evaluate clinical and cost-effectiveness.
8. Exploratory analysis of the proposed outcome measures and characteristics associated with choice of option.
9. What do participants think of the intervention and are any refinements needed?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/11/2025, South East Scotland Research Ethics Committee 01 (Headquarters, Mainpoint, 102 West Port, Edinburgh EH3 9DN, UK; Tel: not applicable; Sandra.Wyllie@nhs.scot), ref: 25/SS/0100

Primary study design
Interventional

Study design
Randomised cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Birth options

Interventions
There are three parts to this study:
1. Randomised feasibility trial
2. Intervention development
3. Alongside recruitment intervention

1. Randomised feasibility trial:

180 women will be recruited across three sites and randomised into either: usual care, clinical conversation or prediction of emergency caesarean plus clinical conversation.

All women will be asked to complete a baseline questionnaire, a questionnaire around 35-37 weeks of pregnancy, a questionnaire at 6 weeks and then 6 months postnatally.

Women in the clinical conversation group will be invited in for a clinical conversation and offer of birth options between 35 and 37 weeks.

Women in the prediction + clinical conversation group will either attend for the prediction results and clinical conversation as per above OR attend for an ultrasound scan if they have not already had one in the study window alongside (ideally at the same attendance)the clinical conversation or will attend a further appointment for a clinical conversation with the prediction model if it cannot be facilitated on the same day. Baseline demographics and outcome data will be collected by the site teams.

2. Intervention development:

This will be for the clinical conversation (60 participants) and clinical conversation + prediction arms (60 participants). After the intervention women will be asked to complete a questionnaire to feedback on the intervention. We will invite 20 women to an interview after the intervention to feedback on it and 20 women to an interview postnatally to feedback in the context of their birth experience.

Alongside this we will ask staff providing the intervention to complete a fidelity questionnaire for each clinical conversation. We will also hold a focus group with staff at each site about the intervention and how to refine it.

3. Alongside recruitment intervention
This is used to try to optimise recruitment processes for a main trial.

We will record recruitment conversations at each site and analyse these to try to identify elements of successful recruitment conversations. Verbal consent will be sought for this.

We will interview upto 20 women who decline participation, 20 who drop out and 20 who complete the study. We will also use the post intervention questionnaires and interviews (mentioned in fidelity section) to understand views on participation/recruitment.

We will also interview recruiting staff and map the study flow at participating sites

Intervention Type
Other

Primary outcome(s)
1. Feasibility of recruitment: do we recruit to time and target, measured using the number of patients recruited to the study at the end of the recruitment period

Key secondary outcome(s)
1. Recruitment rate to the Birth Options Feasibility Trial: number of recruits per month reported at study close
2. Completion of follow-up to the Birth Options Feasibility Trial: number of women completing the study at study close
3. Acceptability of Birth Options intervention to families and clinical staff: examined using surveys post intervention and qualitative interviews post intervention
4. Reasons for non-participation/non-participation: examined using qualitative interviews at the point of declining to participate
5. Optimisation strategies for recruitment to a main trial: identified via qualitative interviews at the time of decline, drop out, completion and with study staff at the end of the trial
6. Proportion of women opting for each birth option recorded after consultation
7. How complete was the collection of proposed outcome measures: number of surveys completed, completeness of case report form at end of study follow-up.

8. Exploratory analysis of the proposed outcome measures and characteristics associated with choice of option: demographic, clinical and experience outcomes reported by intended and actual mode of birth at 6 weeks and 6 months postnatally.
9. What was the feedback on the intervention and suggested refinements: collected via qualitative interviews following intervention and post birth for women and at the end of recruitment for staff.

Completion date
30/09/2027

Eligibility

Key inclusion criteria
Women participating in the trial:
1. From 28+0 weeks – 36+6 completed weeks of pregnancy
2. In first ongoing pregnancy past 22+0 weeks
3. Singleton pregnancy
4. 16 years or older

Staff/clinicians delivering the intervention:
1. Clinical (Doctors and Midwives) staff delivering study intervention or recruiting to the study

Staff recruiting to the study:
1. Research or clinical staff recruiting to the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
99 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Women participating in the trial:
1. Having a pre-existing plan for planned caesarean
2. Having a clinical indication that would likely necessitate a planned caesarean, e.g., placenta

praevia/accreta
3. Multiple pregnancies
4. Less than 16 years old
5. Not in first ongoing pregnancy

Staff/clinicians delivering the intervention:
1. No active participation in the study

Staff recruiting to the study:
1. No active participation in the study

Date of first enrolment
01/02/2026

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liverpool Women's Hospital
Liverpool Womens Hospital
Crown Street
Liverpool
England
L8 7SS

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Other