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Evaluation of a decision aid for women with a breech-presenting baby

Submission date	Recruitment status	[X] Prospectively registered
13/08/2004	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2017	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
211051

Study information

Scientific Title
Evaluation of a decision aid for women with a breech-presenting baby

Study objectives
To evaluate the effectiveness of a decision aid for women with a breech presentation compared with usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. The Central Sydney Area Health Service Ethics Review Committee (ref: X01-0067)
2. The University of Sydney Human Ethics Committee (ref: 3806)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
The study group will receive the ECV Decision Aid which was developed using the Ottawa Decision Support Framework, including a systematic review of the evidence about the benefits and risks of the options for breech pregnancy (attempt ECV or choose planned caesarean section). It comprises an audiotape with a supplementary booklet and worksheet, a format that can be taken home and discussed with a partner.

The control group will receive standard information on management options for breech pregnancy from their usual pregnancy care provider.

At the next antenatal visit, all women will complete a follow-up questionnaire and those in the study group will review their decision aid worksheet with the research nurse.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Knowledge
2. Decisional conflict
3. Anxiety
4. Satisfaction with decision-making

Secondary outcome measures
1. Numbers of ECVs undergone
2. ECV success rate
3. Rates of pregnancy complications
4. Perinatal outcomes:
4.1. Mode of delivery (vaginal, emergency or planned CS)
4.2. Enrolment to delivery interval
4.3. Gestational age
4.4. Birthweight
4.5. Apgar scores
4.6. Perinatal deaths
4.7. Neonatal Intensive Care Unit admission
4.8. Maternal haemorrhage (antepartum or postpartum)
4.9. Length of stay

Overall study start date
01/01/2005

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Women with a single breech-presenting baby at 34 weeks gestation or greater
2. Clinically eligible for external cephalic version (ECV)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
184

Key exclusion criteria
1. Women presenting with a breech in labour
2. Multiple pregnancies
3. Previous Caesarean Section (CS)
4. Severe foetal anomaly
5. Ruptured membranes
6. Indications for CS anyway

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Australia

Study participating centre
Centre for Perinatal Health Services Research
NSW
Australia
2006

Sponsor information

Organisation
Australian National Health and Medical Research Council (Australia)

Sponsor details
Office of NHMRC (MDP 100)
GPO Box 9848
Canberra, ACT
Australia
2601

Sponsor type
Research council

Website
http://www.nhmrc.gov.au/

ROR
https://ror.org/011kf5r70

Funder(s)

Funder type
Research council

Funder Name
Australian National Health and Medical Research Council (Australia) (ref: 211051)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/12/2004		Yes	No
Results article	results	01/03/2007		Yes	No