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

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

#### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

#### Type(s)

Scientific

#### Contact name

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## Additional identifiers

Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

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

#### Key secondary outcome(s))

- 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

#### 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** 

## Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Female

#### 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)

#### **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**

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?
Results article	results	01/03/2007		Yes	No
Protocol article	protocol	20/12/2004		Yes	No