ISRCTN84367722 https://doi.org/10.1186/ISRCTN84367722

# A randomised controlled trial of two decision aids for mode of delivery among women with a previous caesarean section

**Submission date**
21/07/2004

**Recruitment status**
No longer recruiting

**Registration date**
07/09/2004

**Overall study status**
Completed

**Last Edited**
10/02/2010

**Condition category**
Pregnancy and Childbirth

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
N/A

## Study information

## Scientific Title

## Acronym
The DiAMOND trial (Decision Aids for Mode Of Next Delivery)

## Study objectives
Women who have experienced a previous caesarean section are faced with a difficult decision between repeat elective caesarean section and trial of vaginal delivery in subsequent pregnancies. The aim of this study is to investigate two different methods of assisting pregnant women reach a decision about mode of delivery.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Not Specified

## Health condition(s) or problem(s) studied
Pregnancy, with one previous caesarean section

## Interventions
1. Decision analysis
This firstly requires elicitation of utilities (preference values) from women regarding the possible outcomes of both planned vaginal delivery and repeat elective caesarean section. Utilities will be measured via a computerised interview. These utilities will then be combined with probabilities of each outcome in a decision analysis tree. Each woman will be given a computer printout of the outcome of the decision analysis, a recommended 'preferred option' based on maximised expected utility.

2. Interactive information programme
This is an innovative way of providing information about the outcomes and associated risks and benefits involved in the decision. Unlike a videotape or written information, the programme will allow women to more easily tailor the information they view, and sections can be interrupted or repeated as required. The sections viewed are recorded. In addition, women in this group will be given a password that will allow them to access the information programme via the internet as often as they wish. An important difference from the decision analysis intervention is that women¿s preferences are not explicitly sought and there is no recommendation of a 'preferred option' for the individual.

3. Usual care
This will comprise standard care given by the obstetric and midwifery team. Women allocated to

decision analysis or information programme will receive these interventions in addition to usual care.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome(s)
1. Actual mode of delivery
2. Decisional Conflict at 37 weeks gestation

### Key secondary outcome(s))
1. Anxiety
2. Knowledge
3. Perception of shared decision making
4. Satisfaction with decision making process
5. Proportion of women attempting vaginal delivery

### Completion date
31/12/2005

## Eligibility

### Key inclusion criteria
Pregnant women with one previous lower segment caesarean section, no current obstetric problems and delivery expected at ≥37 weeks. Recruitment will take place during the initial booking visit at approximately 12-14 weeks' gestation. Participating centres are maternity units at St Michaels and Southmead Hospitals in Bristol, and Ninewells Hospital in Dundee.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### Key exclusion criteria
Not provided at time of registration

### Date of first enrolment
01/05/2004

### Date of final enrolment

31/12/2005

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Division of Primary Health Care**
Bristol
United Kingdom
BS6 6JL

# Sponsor information

**Organisation**
University of Bristol (UK)

**ROR**
https://ror.org/0524sp257

# Funder(s)

**Funder type**
Charity

**Funder Name**
The BUPA Foundation (UK) (ref 657/G10)

# 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 | 23/06/2007 | | Yes | No |
| Protocol article | protcol | 10/12/2004 | | Yes | No |
| Other publications | economic evaluation | 01/07/2010 | | Yes | No |