

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

<b>Submission date</b> 21/07/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/09/2004	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 10/02/2010	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

## 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  $\geq 37$  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?
<a href="#">Results article</a>	results	23/06/2007		Yes	No
	protocol				

<a href="#">Protocol article</a>		10/12/2004	Yes	No
<a href="#">Other publications</a>	economic evaluation	01/07/2010	Yes	No