

# Improving care at the primary/secondary interface: a trial of community-based support in early labour

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
05/11/2004	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
31/03/2005	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
10/10/2014	Pregnancy and Childbirth	<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Miss Helen Spiby

### Contact details

Mother and Infant Research Unit  
22 Hyde Terrace  
Leeds  
United Kingdom  
LS2 9LN

## Additional identifiers

### Protocol serial number

SDO/40/2003

## Study information

### Scientific Title

### Acronym

### **Study objectives**

In some parts of the UK, women having their first baby have a 40-50% chance of having a caesarean section or instrumental (forceps or ventouse) delivery. These increasing rates are of concern to childbearing women, their families, and to the health services as they are associated with more ill health in women and their babies.

Some existing studies (which are small, or not very rigorous) have suggested that women who attend hospital very early in their labour are more likely to have a range of interventions including artificial rupture of membranes, epidurals, and caesarean and instrumental births. Some 10-33% of women admitted to delivery suite are not in labour, and do not need to be in hospital. This study will test these observations using a large randomised controlled trial. The aim is to examine whether or not a home visit by a community midwife when a pregnant woman thinks she may be in labour will have any impact on the rates of caesarean and other instrumental births, and other outcomes such as use of pain relief, the woman's views, and the health service resources used, compared with normal care. Women expecting their first baby, and whose pregnancy is progressing normally, will be told about the study during their pregnancy, by their own community midwife. If they are interested in participating, and after giving formal consent at around 32 weeks, they will be randomly allocated to one of two groups. Women in the intervention group will be offered a home visit by a community midwife when they think they are in labour, while women in the control group will be asked to telephone the hospital for advice and to go into delivery suite if advised, as is normal practice across the UK. The midwife doing the home visit will offer support to the woman including breathing and relaxation techniques, carry out an assessment to see how labour is progressing, and offer advice about the appropriate time to go to hospital. Information about the two groups will be gathered directly from the women themselves, in pregnancy and 6 weeks after birth, from hospital notes, and from the midwives involved in the study. This information will be used to compare the outcomes for women in the two groups, to examine their views, to calculate the costs to the health services, and to the families. It is already known that caesarean section costs the health services more than twice the cost of a normal birth.

### **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)**

Other

### **Health condition(s) or problem(s) studied**

Pregnancy, labour

### **Interventions**

1. Intervention: support and assessment for nulliparous women at home in early labour by community midwives
2. Control: standard care which usually comprises telephone advice to attend the hospital delivery suite to determine whether labour has established

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Labour

## **Key secondary outcome(s)**

Not provided at time of registration

## **Completion date**

31/12/2005

## **Eligibility**

### **Key inclusion criteria**

Healthy nulliparous women

### **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**

01/01/2005

### **Date of final enrolment**

31/12/2005

## **Locations**

### **Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Mother and Infant Research Unit**  
Leeds  
United Kingdom  
LS2 9LN

## Sponsor information

### Organisation

NHS Service Delivery and Organisation Programme (SDO) (UK)

### ROR

<https://ror.org/02wnqcb97>

## Funder(s)

### Funder type

Government

### Funder Name

NHS Service Delivery and Organisation R&D Programme (UK), Ref: SDO/40/2003

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration