Training Booklet

A study of position during the late stages of labour in women with an epidural

The BUMPES Study

Version 9, May 2012

Contents

1. Introduction to the BUMPES Study

BUMPES is a study of maternal position during the late stages of labour in nulliparous women with an epidural. It is postulated that position during the late stages of labour might affect the chances of a spontaneous vaginal birth however there is little or no evidence of this, which is why the study is being conducted. The maternal positions of interest are either upright or lying down.

This is exciting research, which will provide important information to enhance midwifery practice. The research will provide evidence to support which is the optimal maternal position to promote a spontaneous vaginal birth in women who choose to have an epidural.

BUMPES is a multicentre randomised controlled trial which is taking place across multiple maternity sites in the UK. Recruitment started October 2010 in one site, Birmingham Woman's Hospital, which piloted all the processes before the trial commences in the remaining centres. The study is being co-ordinated by a team at the Clinical Trial Unit, UCL, and will involve midwives, obstetricians and anaesthetists working in the participating units. The study is funded by the Department of Health through the National Institute for Health Research, Health Technology Assessment Programme (NIHR HTA).

Low dose epidural analgesia is the most effective form of pain relief in labour, and is chosen by up to 30% of women in the UK each year. Its uptake is greater in nulliparous women, with up to 40% of women having an epidural in large obstetric units. However randomised controlled trials have shown an association between epidurals and an increased chance of vaginal instrumental births. National Institute of Health and Clinical Excellence, Intrapartum Care Guidelines (NICE, 2007) recognised that epidurals are associated with a longer second stage of labour and increased chance of vaginal instrumental births.

In this study women who consent will be randomly allocated to either the upright or the lying down position in the second stage of labour.

Research objectives

Primary objective

1. To evaluate in nulliparous women who choose a low dose epidural analgesia whether an "upright or lying down position" during the second stage of labour is associated with an increased incidence of spontaneous vaginal birth.

Secondary objectives

2. To evaluate whether there are differences between upright or lying down positions in important clinical outcomes for women and babies around the time of birth and at 12 months postpartum.
3. To evaluate the cost-effectiveness of upright or lying down positions during second stage of labour from an NHS perspective.
4. To measure women's satisfaction with, and experience of labour and birth.

The study aims to recruit 3,000 women over 24 months across participating sites in the UK.

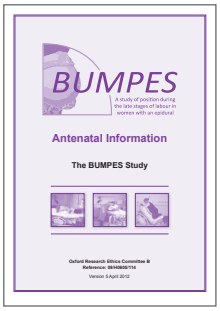
2. Who can be included in the study?

Women in labour who are admitted to a participating labour ward who fulfil all of the following criteria will be eligible to be randomised into the trial, following informed consent:

- 16 years of age or older.
- 37 weeks' gestation or more.
- Nulliparous (no previous delivery of gestation greater than or equal to 24 +0 weeks).
- Singleton cephalic presentation.
- Intend spontaneous vaginal delivery.
- In second stage of labour, confirmed by vaginal examination.
- With a low dose epidural in situ during the first stage of labour, providing effective pain relief.
- Able to understand written and spoken English.

3. How and when will women hear about the BUMPES Study?

There are two information leaflets about the BUMPES Study

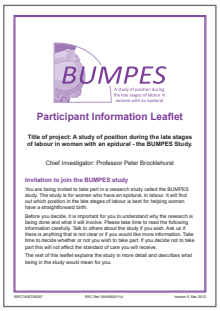


Leaflet 1: Antenatal Information should be offered to nulliparous women at the booking interview and / or at the 20 week anomaly scan or at any convenient opportunity in the antenatal period.

We suggest that the midwife is likely to have an opportunity to discuss the study with a woman during the antenatal period and could introduce the BUMPES Study by explaining that:

"This hospital is one of a group of hospitals taking part in the BUMPES Study. The study aims to find, which is the best position to give birth in for first time mothers who choose an epidural in labour"

It is important that the study is discussed sensitively with women so they do not feel pressurised or that they are expected to have an epidural. However, if in labour an epidural is chosen they may be offered further information and consider taking part in the study.



Leaflet 2: BUMPES Study – Participant Information Leaflet should be offered to women in labour who meet the study eligibility, to ask questions and consider the study prior to consent in either the first stage or second of labour.

4. How and when can women be entered into the study?

Women should be given the opportunity:

- To read the Participants Information Leaflet
- To ask any questions before deciding whether or not they wish to take part in the study.
- To be given an explanation of what the study involves
- To have any questions answered.

All BUMPES information and documentation required for the study will be placed in a large white envelope marked BUMPES Midwife Pack and stored in a convenient location on the delivery unit.

The pack will contain:

- Participant Information Leaflet
- Consent form
- Women and Infant Data Collection Booklet
- Slide rule for Visual Analogue Scale
- Maternal post natal questionnaire titled 'Your labour and birth experience'

If any documentation is missing there should be supplementary supplies available.

Any study documents that have not been used can be put back in the Midwives pack along with completed forms.

5. Obtaining informed consent

What is informed consent?

Informed consent is the process by which a woman voluntarily confirms her willingness to participate. Women must be informed of the benefits and risks of taking part in any study or procedure that they have given consent to and MUST have been offered the opportunity to ask questions about the topic concerned.

a) If a woman does not wish to take part in the study, her care will not be altered in any way and the midwife should follow local guidelines for delivery of women with an epidural. No consent paperwork needs to be completed.

b) A woman may also withdraw at any time and without giving a reason. She must be reassured this will not affect the standard of care she receives.

c) If a woman agrees to take part in the study, the midwife or health care professional must obtain her written consent using the consent form (see page 4) before she is randomised into the study.

When should consent be taken?

Collect the BUMPES Midwife Pack containing all the relevant information.

The BUMPES Participant Information Leaflet should be offered to all women who fulfil eligibility criteria along with a brief introduction to the study when a woman is in labour with an effective epidural. This will allow time for questions and answers before gaining consent. **Consent maybe obtained in first or second stage of labour.**

Who should obtain consent?

Written informed consent can be obtained by a clinician (midwife, obstetrician or anaesthetist). Consent will comprise of a dated signature from the woman and the person who has gained consent.

A copy of her signed consent will be given to the woman and three further carbon copies will be required for:

- The woman's medical notes
- The Principal Investigator
- The Trial Co-ordinating Centre

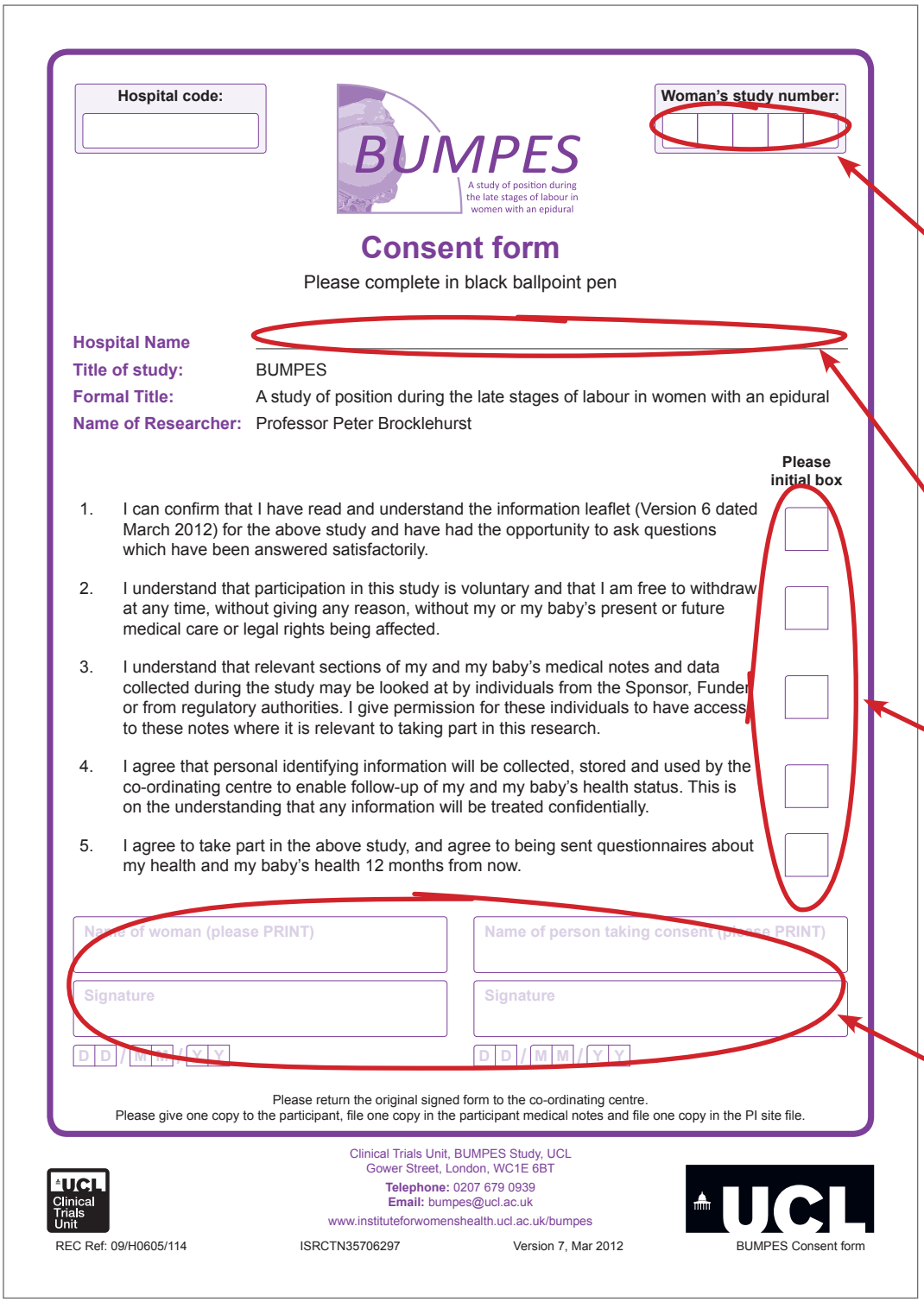
Where should the consent form be stored?

The consent form has 3 carbon copies and will therefore require you both to press firmly. The consenting midwife should place the original signed consent form and one copy with the data collection booklet (when completed) and back in the BUMPES Midwife Pack (the large white envelope) and a designated member of staff will return the contents to the CTU and file the copy in the Principal Investigators Site File.

The consenting midwife will give one copy to the participant and file another copy in her maternity/ medical notes.

Without the CTU receiving a copy of the signed consent form, the woman's data cannot be used in the study, for which she has kindly agreed to take part in.

Completing consent form



Hospital code:

Woman's study number:

BUMPES

A study of position during the late stages of labour in women with an epidural

Consent form

Please complete in black ballpoint pen

Hospital Name _____

Title of study: BUMPES

Formal Title: A study of position during the late stages of labour in women with an epidural

Name of Researcher: Professor Peter Brocklehurst

		Please initial box
1.	I can confirm that I have read and understand the information leaflet (Version 6 dated March 2012) for the above study and have had the opportunity to ask questions which have been answered satisfactorily.	
2.	I understand that participation in this study is voluntary and that I am free to withdraw at any time, without giving any reason, without my or my baby's present or future medical care or legal rights being affected.	
3.	I understand that relevant sections of my and my baby's medical notes and data collected during the study may be looked at by individuals from the Sponsor, Funder or from regulatory authorities. I give permission for these individuals to have access to these notes where it is relevant to taking part in this research.	
4.	I agree that personal identifying information will be collected, stored and used by the co-ordinating centre to enable follow-up of my and my baby's health status. This is on the understanding that any information will be treated confidentially.	
5.	I agree to take part in the above study, and agree to being sent questionnaires about my health and my baby's health 12 months from now.	

Name of woman (please PRINT) | Name of person taking consent (please PRINT)

Signature | Signature

D D / M M / Y Y | D D / M M / Y Y

Please return the original signed form to the co-ordinating centre.
Please give one copy to the participant, file one copy in the participant medical notes and file one copy in the PI site file.

Clinical Trials Unit, BUMPES Study, UCL
Gower Street, London, WC1E 6BT
Telephone: 0207 679 0939
Email: bumpes@ucl.ac.uk
www.instituteforwomenshealth.ucl.ac.uk/bumpes

UCL Clinical Trials Unit

REC Ref: 09/H0605/114 ISRCTN35706297 Version 7, Mar 2012 BUMPES Consent form

UCL

Filling out the consent form accurately

- Ensure you complete the study number.
- Ensure you write the hospital name.
- Ensure all 5 statements are initialled **NOT TICKED** by the woman.
- The woman and the person taking consent must print their names, sign and date the form.

Checklist for obtaining informed consent

1. Have you offered the woman an opportunity to read the BUMPES Participant Information Leaflet? (See section 3)
2. Have you explained, and has the woman understood the aim of the BUMPES Study?

   The study aims to find out which is the best position to give birth for first mothers who choose to have an epidural. (See section 7)
3. Have you explained what the study entails?

   Women who agree to take part in the study will be asked either to be upright or to lie down during the second stage of labour. Their midwife will try to help them find a position that works for them in the group of positions they have been allocated to. We hope that they will be able to maintain positions within this group until the birth.
4. Have you explained what a 'randomised controlled study' is?

   The computer will randomly select the group of positions for the woman to adopt in the second stage of labour i.e. either upright or lying down.
5. Have you explained the potential benefits and risks of taking part in BUMPES?

   The study will provide evidence if either position is associated with increased spontaneous vaginal birth and any differences in longer term health outcomes.

   There are no known or expected risks for the mother or baby in the positions that we are studying. Other than the position that you adopt in the second stage of labour, no other aspects of your clinical care will be altered by your participation in this study.
6. Have you explained that the woman is free to withdraw at any time without having to give a reason and without affecting her midwifery or medical care?
7. Have you explained that there will be a follow up one-year post birth?
8. Check whether the woman considers she has had enough opportunity to ask questions?

   If yes to all of these please ensure that the consent form is signed and dated by the woman and the person taking consent.

   Please randomise as soon as possible once the second stage of labour has been confirmed by vaginal examination

To randomise, see section 6

Summary chart: Information, consent and randomisation for BUMPES

Information offered to all pregnant nulliparous women

Women can be randomised into the study if all of the following apply

- ✓ 16 years of age or older
- ✓ ≥37 weeks gestation
- ✓ nulliparous (no previous delivery ≥ 24 + 0 weeks)
- ✓ singleton cephalic presentation
- ✓ intended spontaneous vaginal birth
- ✓ with a low dose epidural in situ during the first stage of labour, providing effective pain relief

Consent in either first or second stage of labour. Randomise in second stage of labour

Upright position

Data collection in labour and prior to postnatal discharge

Lying-down position

PRIMARY OUTCOME

Incidence of spontaneous vaginal birth

ONE YEAR FOLLOW UP

Mother and infant questionnaire

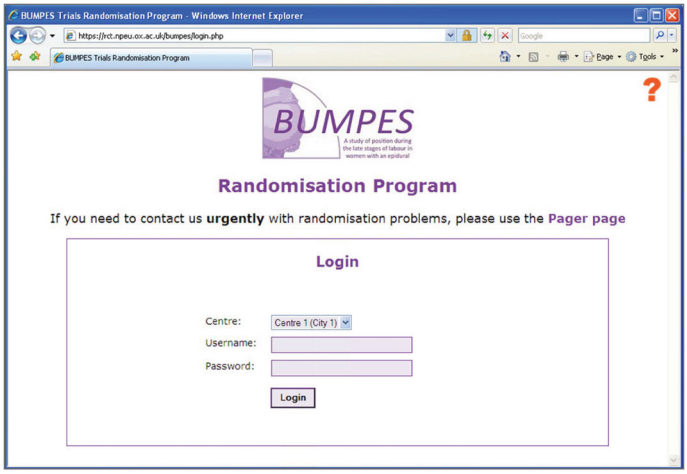
6. How to randomise a woman into the study

Women who fulfil study eligibility criteria will be randomised into the allocated group, either upright or lying down position by a web-based central service (with 24/7 telephone back-up) hosted by the NPEU Clinical Trials Unit, University of Oxford.

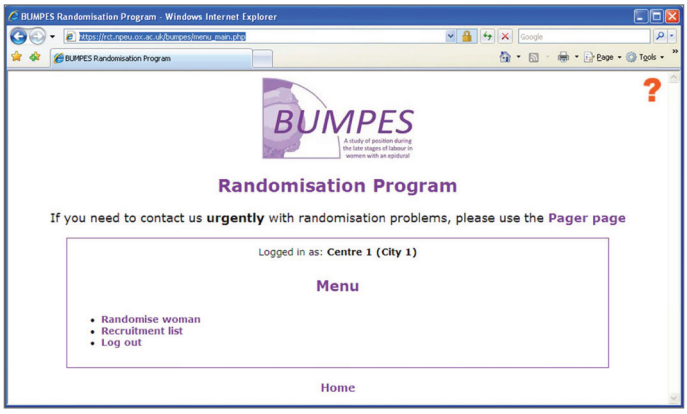
Steps in randomisation

1. Complete eligibility checklist
2. Go to https://rct.npeu.ox.ac.uk/bumpes/ and follow the instructions on the screen.
3. Complete the process and record the study number and group allocation in section 2 (page 3) of the data collection booklet.

Login Page

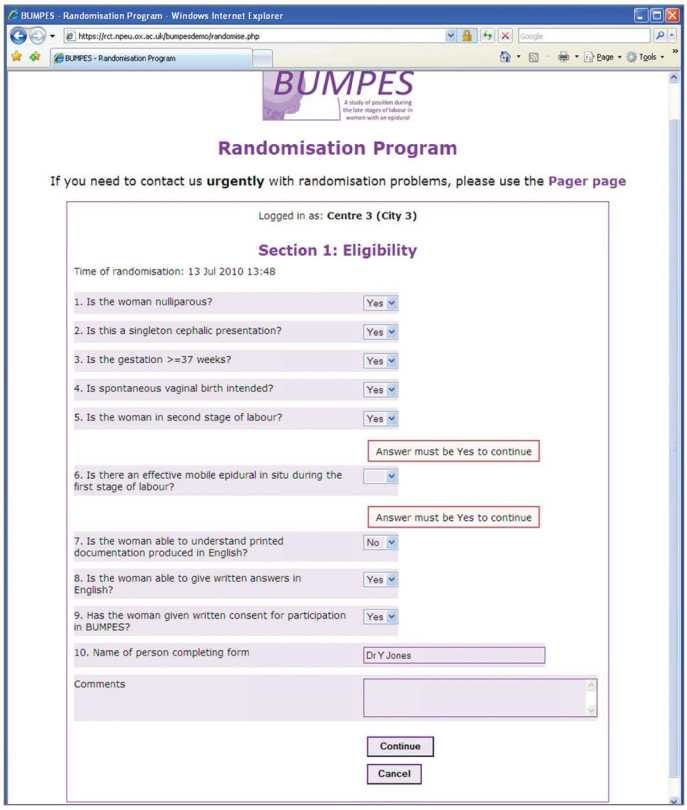


LOGIN: You will be required to select your centre name from the drop down menu and type in your username and password.



There are three different options to choose from. In order to continue with the randomisation you need to select RANDOMISE WOMAN. This will take you to the next stage, ELIGIBILITY.

Eligibility Page

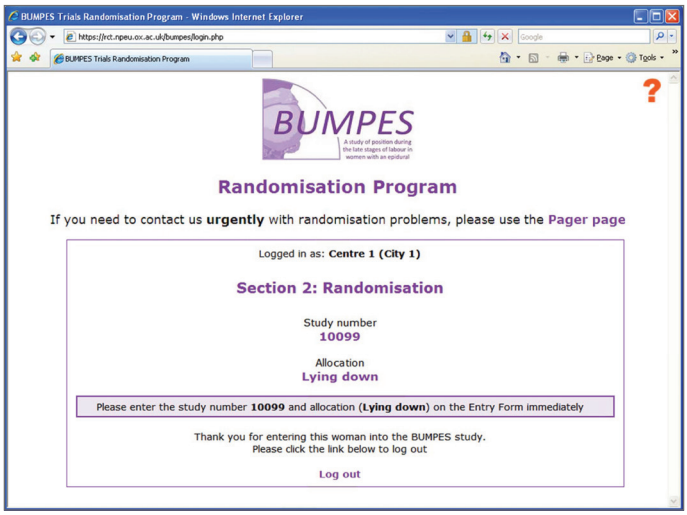


You are now required to answer 10 questions confirming whether the woman is eligible to take part in this study. The first three questions require you to enter the woman's date of birth (day/month/year), the expected date of delivery (EDD) and the woman's hospital number. Questions 4 to 10 require you to choose either YES or NO from the drop down menus. The last box is for your name (First name & Surname).

Please press the 'CONTINUE' button once all information has been entered.

The system automatically checks whether the information entered enables the woman to participate in this study. If the information you entered is contradictory or does not comply with eligibility criteria (woman's age, due date etc.) the system will flag it up and you will be asked to double-check your answers and revise or confirm.

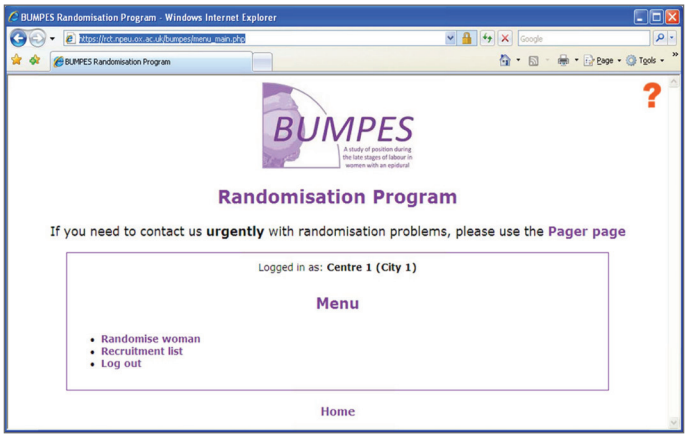
Randomisation Page



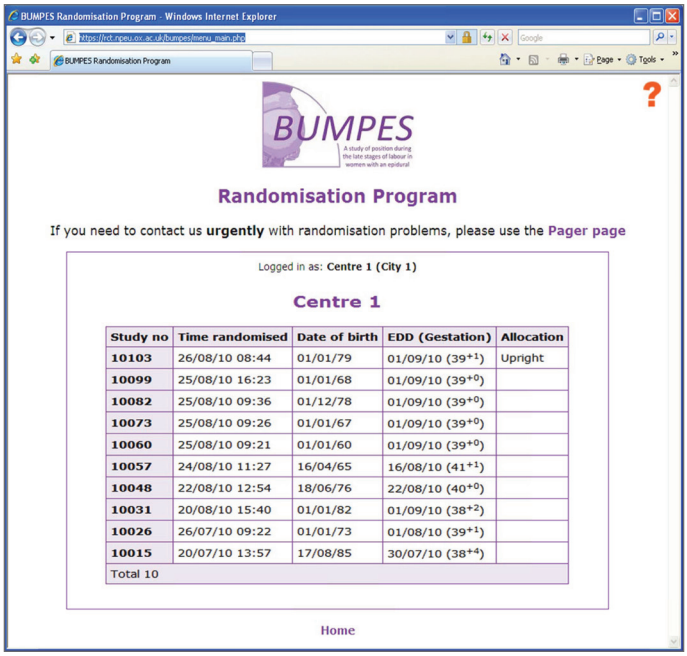
On this page you will be given a unique study number and the allocated position for the woman to adopt during the second stage of labour with the intention of continuing this position until the birth of her baby.

This completes the randomisation process and you can complete the process by pressing log out or you can return to the home page by clicking on the **HOME** button on the screen.

By going back to the 'HOME PAGE' you will be able to view details of all participants recruited in you centre by pressing 'RECRUITMENT LIST'.



Recruitment List



Study no	Time randomised	Date of birth	EDD (Gestation)	Allocation
10103	26/08/10 08:44	01/01/79	01/09/10 (39^{+1})	Upright
10099	25/08/10 16:23	01/01/68	01/09/10 (39^{+0})	
10082	25/08/10 09:36	01/12/78	01/09/10 (39^{+0})	
10073	25/08/10 09:26	01/01/67	01/09/10 (39^{+0})	
10060	25/08/10 09:21	01/01/60	01/09/10 (39^{+0})	
10057	24/08/10 11:27	16/04/65	16/08/10 (41^{+1})	
10048	22/08/10 12:54	18/06/76	22/08/10 (40^{+0})	
10031	20/08/10 15:40	01/01/82	01/09/10 (38^{+2})	
10026	26/07/10 09:22	01/01/73	01/08/10 (39^{+1})	
10015	20/07/10 13:57	17/08/85	30/07/10 (38^{+4})	
Total 10				

The most recent entry is shown first.

Remember to return to home page by pressing home and logout when finished.

Emergency randomisation procedure

If on the rare occasion you are unable to log onto the BUMPES computer and / or use the internet part of the BUMPES website, randomisation can still occur by contacting one of the numbers below.

Before ringing please ensure that you have completed and have with you **Section 1 : Eligibility checklist on page 3 of the Woman and Infant data Collection Booklet.**

Telephone numbers

1. 0207 679 0939 (Office hours 09.00 – 17.00hrs)
2. 0800 138 5451 (Out of hours call centre including weekends and Bank holidays)

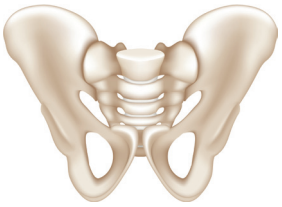
The call centre will be able to support you but will need to identify the help you require. You will be asked, which of the following do you need help with?

1. Randomisation?
2. Do you need to know your username or password for web randomisation?
3. Do you need to know the allocation for the recruit?

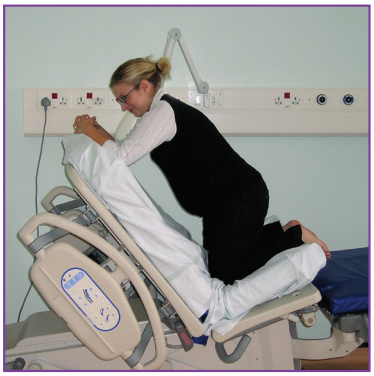
7. Positions to adopt following randomisation

Depending on the allocation, please encourage the women to adopt the relevant position during the second stage of labour as soon as possible after randomisation.

Upright maternal position maintaining the pelvis in as vertical a plane as possible during second stage of labour with the intention of continuing this until the birth.

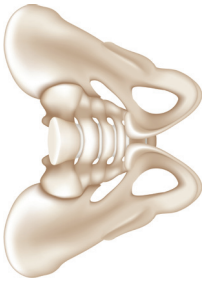


Some suggested positions to maintain the pelvis in a vertical plane



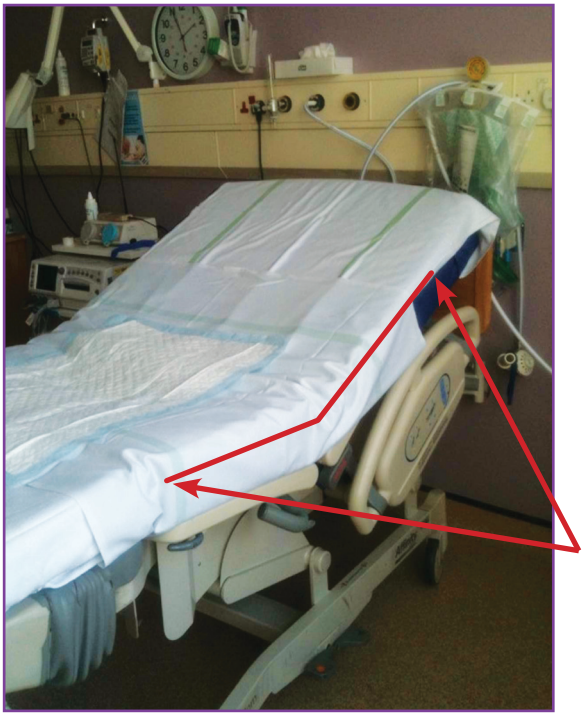
Women allocated to the upright group will be encouraged by the midwife to adopt positions which are as upright a posture as possible (this could include walking, standing, sitting in or out of bed) during the second stage of labour. **(Please note for women who wish to be supported to stand out of bed, midwives will need to ensure that mobility has been assessed by following local policy and by asking the women to perform a 'straight leg raise' (this is to be recorded in the Woman and Infant Data Collection Booklet)**.

Lying down maternal position maintaining the pelvis in as horizontal a plane as possible during the second stage of labour with the intention of continuing this until the birth.



Some suggested positions to maintain the pelvis in a horizontal plane

Women allocated to the lying down position will be encouraged by the midwife to adopt a lying down position which would mean lateral positions or lying down tilted by a wedge on either left or right side in the bed for the second stage of labour but **never** completely on her back.



Back rest can be elevated to a MAXIMUM of 30 degrees

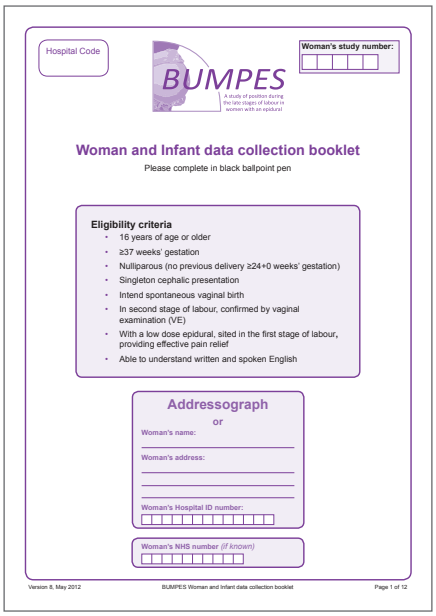
8. Training

The BUMPES Study is an excellent opportunity for midwives, as the study will enhance midwifery practice and is relevant at a National and International level.

There is genuine uncertainty regarding positions in the late stages of labour, it is therefore important for research reliability that midwives support women to remain in the allocated group and accurately record position and any reasons for change. Whilst the woman is comfortable, she is supported in the position(s) that have been allocated at randomisation. In order to monitor adherence the midwife is asked to complete a Maternal and Infant Data Collection Booklet recording which position has been maintained for the previous 15 minutes.

9. How to fill out the Woman and Infant Data Collection Booklet

All study data will be collected using a specific BUMPES Study Woman and Infant Data Collection Booklet for each woman randomised into the trial.


Hospital Code

Woman's study number:

BUMPES

A study of position during the late stages of labour in women with an epidural

Woman and Infant data collection booklet

Please complete in black ballpoint pen

Eligibility criteria

- 16 years of age or older
- ≥37 weeks' gestation
- Nulliparous (no previous delivery ≥24+0 weeks' gestation)
- Singleton cephalic presentation
- Intend spontaneous vaginal birth
- In second stage of labour, confirmed by vaginal examination (VE)
- With a low dose epidural, sited in the first stage of labour, providing effective pain relief
- Able to understand written and spoken English

Addressograph

or

Woman's name:

Woman's address:

Woman's Hospital ID number:

Woman's NHS number *(if known)*

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1. Complete in black ink only.
2. All corrections must be clearly initialled and dated and an explanation provided if appropriate.
3. Correction Fluid must **not** be used

> Please complete page 1 (front cover) with the woman's name, address and hospital number and her NHS number (if known).

The Data Collection Booklet is divided into two parts. Part 1 contains the data that must be collected during the woman's labour, at time of occurrence. Part 2 contains data that can usually be collected retrospectively from the woman's notes. Once completing Part 1 of the booklet you may continue to complete Part 2 if you have time. If not, then this can be placed in the midwives recruitment pack in the designated area for the research midwife to complete later.

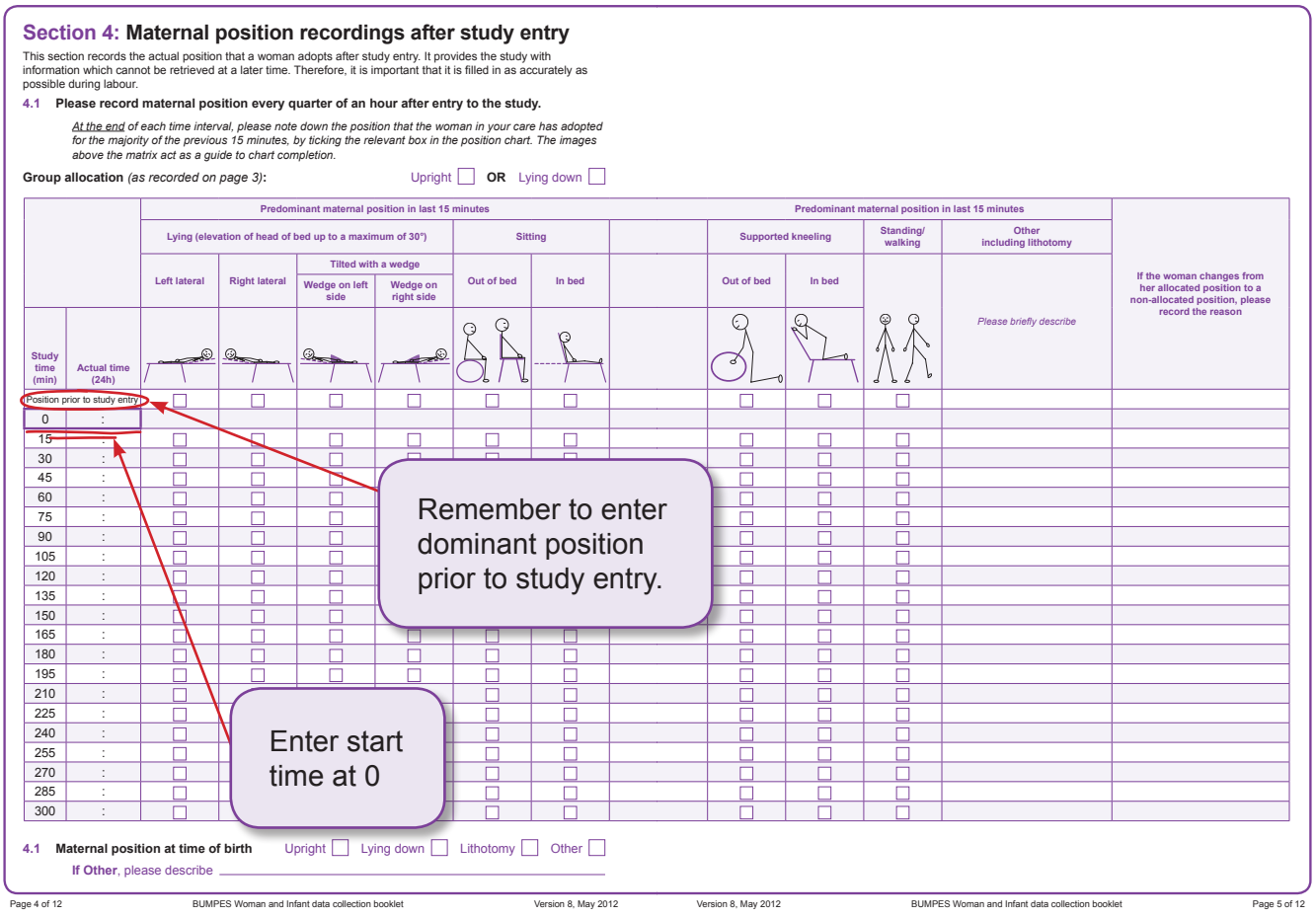
Before randomising a woman please ensure that Part 1, Section 1: Eligibility (page 2) has been completed and signed off.

Once randomisation is completed please record study number and the tick the group allocated **Section 2: Randomisation, page 3**.

> Then go straight to Part 1, Section 4: Maternal Position Recordings After Study Entry (page 4 and 5) and record the woman's position prior to study entry (the top row of the position table).

Once the woman's randomised position is established, please record the study start time in the row marked **'0'**. **See below**.

Part 1, Section 4, page 6 & 7



Section 4: Maternal position recordings after study entry

This section records the actual position that a woman adopts after study entry. It provides the study with information which cannot be retrieved at a later time. Therefore, it is important that it is filled in as accurately as possible during labour.

4.1 **Please record maternal position every quarter of an hour after entry to the study.**

At the end of each time interval, please note down the position that the woman in your care has adopted for the majority of the previous 15 minutes, by ticking the relevant box in the position chart. The images above the matrix act as a guide to chart completion.

Group allocation *(as recorded on page 3)*: Upright ☐ **OR** Lying down ☐

		Predominant maternal position in last 15 minutes											Predominant maternal position in last 15 minutes	
		Lying (elevation of head of bed up to a maximum of 30°)				Sitting			Supported kneeling		Standing/ walking	Other including lithotomy		If the woman changes from her allocated position to a non-allocated position, please record the reason
		Left lateral	Right lateral	Tilted with a wedge: Wedge on left side	Tilted with a wedge: Wedge on right side	Out of bed	In bed		Out of bed	In bed		Please briefly describe		
Study time (min)	Actual time (24h)													
Position prior to study entry		☐	☐	☐	☐	☐	☐		☐	☐	☐			
0	:													
15	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
30	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
45	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
60	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
75	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
90	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
105	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
120	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
135	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
150	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
165	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
180	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
195	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
210	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
225	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
240	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
255	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
270	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
285	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			
300	:	☐	☐	☐	☐	☐	☐		☐	☐	☐			

Remember to enter dominant position prior to study entry.

Enter start time at 0

4.1 **Maternal position at time of birth** Upright ☐ Lying down ☐ Lithotomy ☐ Other ☐

If Other, please describe _____

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Part 1, Section 4 requires the recording of the actual position that a woman adopts during the second stage of labour, immediately prior to study entry and every 15 minutes after entry into the study.

This section provides the study with information that cannot be retrieved later. Therefore it is important that it is filled out as accurately as possible during labour.

It is anticipated that women will be able to remain in the allocated position during the passive stage. However if there is a clinical indication or maternal request to change position in the active or passive phase, please record the reason for change in the right hand column after positions.

Once the maternal position has been established please, return and complete **Part 1, Section 3: Information about the woman at study entry**.

Pain/mobility

In the BUMPES midwife pack there is a slide rule to measure the effectiveness of the epidural at study entry (**Part 1, Section 3**) on a Visual Analogue Scale, this measurement and recording is required again after the birth of her baby **Part 1, Section 5: Pain Assessmentand Pain Relief After Study Entry**.

Please also remember to record PCEA pump reading post birth prior to turning the pump off or disposing of the infusion bag.

Prior to Leaving Delivery Unit

Part 1, Section 6: Maternal Satisfaction Questionnaire titled 'Your labour and birth experience'. Please ask the woman to complete the questions on her experience of her birth as soon as practicable while she is in the delivery suite.

Once Part 1 of the booklet is complete, you can continue to complete Part 2 if you have time. If not, then please place the booklet in the Midwives Pack (large white envelope). Ensure that the completed consent form and maternal satisfaction questionnaire are also enclosed in the Midwives Pack. Seal the envelope, tick the box on the front label and place in the designated area.

At the end of the Data Collection Booklet you will be asked to complete maternal and infant destination after leaving delivery unit. If either mother or baby is transferred to a higher level of care or to another unit there will be supplementary forms to capture this information which will be completed by a designated member of staff.

10. Serious Adverse Events (SAE's)

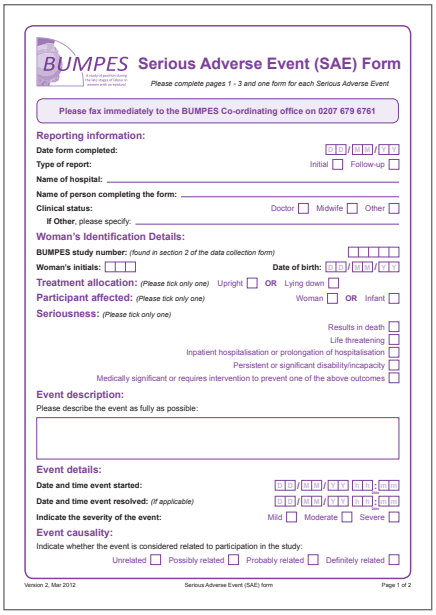
What is an SAE?

A serious adverse event (SAE) is any untoward medical occurrence that:

a) Results in death
b) Is life threatening
c) Requires hospitalisation or prolongation of an existing hospitalisation
d) Results in persistent or significant disability/incapacity
e) Is a congenital anomaly or birth defect

Although no serious adverse events are anticipated, it is possible that these may occur. For example, in the upright group it is possible, though unlikely, that a woman may fall. This will be considered a serious adverse event.

How to report an SAE


BUMPES Serious Adverse Event (SAE) Form

Please complete pages 1 - 3 and one form for each Serious Adverse Event

Please fax immediately to the BUMPES Co-ordinating office on 0207 679 6761

Reporting information:
Date form completed: D D / M M / Y Y
Type of report: Initial ☐ Follow-up ☐
Name of hospital:
Name of person completing the form:
Clinical status: Doctor ☐ Midwife ☐ Other ☐
If Other, please specify:

Woman's Identification Details:
BUMPES study number: (found in section 2 of the data collection form)
Woman's initials:
Date of birth: D D / M M / Y Y
Treatment allocation: (Please tick only one) Upright ☐ OR Lying down ☐
Participant affected: (Please tick only one) Woman ☐ OR Infant ☐
Seriousness: (Please tick only one)
Results in death ☐
Life threatening ☐
Inpatient hospitalisation or prolongation of hospitalisation ☐
Persistent or significant disability/incapacity ☐
Medically significant or requires intervention to prevent one of the above outcomes ☐

Event description:
Please describe the event as fully as possible:

Event details:
Date and time event started: D D / M M / Y Y H H : M M
Date and time event resolved: (If applicable) D D / M M / Y Y H H : M M
Indicate the severity of the event: Mild ☐ Moderate ☐ Severe ☐

Event causality:
Indicate whether the event is considered related to participation in the study:
Unrelated ☐ Possibly related ☐ Probably related ☐ Definitely related ☐

Version 2, Mar 2012 Serious Adverse Event (SAE) form Page 1 of 2

SAE Fax Number: 0207 679 6761

For urgent queries out of hours please contact BUMPES Senior Research Midwife, Lynn Lynch, on 07984497911.

SAE's considered to be related to the trial should be followed up until resolution and subsequent SAE follow up reports should be submitted. Follow up reports will be completed by a designated member of staff.

All serious adverse events occurring during the trial observed by the investigator or reported by the participant, whether or not attributed to the trial, must be reported on the SAE data collection form.

11. Frequently asked questions

Q: What if a woman in the BUMPES Study does not like the position she is in and wants to move?

A: It is anticipated that the woman should be able to remain in her allocated position throughout the passive phase with the intention of maintaining this position until the birth of her baby.

However, if the woman wishes to move from the randomized position or if there is a clinical reason to do so, the midwife should support the decision to change position. In both circumstances the new position and the reason for the change must be recorded in the data collection booklet.

Q: What if the woman is in a different position from the one she was allocated to?

A: The midwife should support and help the woman to try different positions within the allocated group. If the position changes completely for birth the midwife is asked to record position on the Maternal and Infant Data Collection Booklet.

Q: Is the study likely to increase the epidural rate?

A: Only brief information will be given in the antenatal period. Further information will be given following the woman's choice to have an epidural.

Q: What happens if the woman is placed in lithotomy?

A: Lithotomy is not a position included in either the upright or lying down groups. If the woman is placed in lithotomy please record this in the box on the right hand page marked "other including lithotomy" and give a brief description of the reason for lithotomy position.

12. Contact details

BUMPES Postal address:

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Clinical Trials Unit
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Gower St
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WC1E 6BT

BUMPES Co-ordinating centre:

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UCL Rockefeller Building
21 University St
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WC1E 6DE

Telephone: 0207 679 0939
Fax: 0207 679 6761
Email: bumpes@ucl.ac.uk

www.instituteforwomenshealth.ucl.ac.uk/bumpes

Senior Research Midwife:

Lynn Lynch: l.lynch@ucl.ac.uk

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