

**Please retain in maternity notes for medical records**

Participant Information Sheet for **The RETHINK Study Protocol v1.11**

You are being invited to take part in a research project. Before you decide, it is important for you to understand why the research is being carried out and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more help.

**What is the purpose of the study?**

This study aims to see if we can detect those women who may find extra support for early labour useful, to help reduce their chance of a difficult labour and unnecessary intervention. To date research has not shown the best way to support women who are in early labour at home. Some women say they went to hospital during early labour because of their contractions and were looking for support to help them cope with this. Women who stay in hospital during the early stage of labour are more likely to have difficult labours and interventions such as having their waters broken, a hormone drip to speed up contractions, epidural anaesthesia and caesarean sections.

This study will follow participants through pregnancy, labour and birth, and into the postnatal period to see if we can identify those women who might benefit from additional support in early labour to reduce their chance of a difficult labour and unnecessary intervention. To help us do this we would like you to complete two questionnaires, one whilst you are pregnant and the other one after you have had your baby. We will also be asking for your permission for your hospital to tell us some details about your labour and birth.

**Why have I been chosen?**

We would value your views because you are expecting your first baby, you have no known health problems that could affect you or your baby, and you plan to be at home during early labour then to go to hospital to give birth.

We aim to recruit 768 women in this research study.

**What will happen to me if I take part?**

If you decide to take part, you will need to be able to access the study questionnaire online and have an email address for correspondence. We would like you to complete the online questionnaire when you are between 25 and 33 weeks and 6 days pregnant.

Before you start the online questionnaire there are two important steps we would like you to complete. The first involves reviewing five questions to confirm that you are eligible to take part. Second, we ask for you to consent to take part in this study. This involves reviewing seven questions and asks you to consent to each one. Once this is done you will be directed to the questionnaire and included in this study.

Near the end of the questionnaire you will also be asked to provide your email address and the name of your hospital. We would like your email address so that we can contact you to ask you for your full name, your date of birth, and your hospital number or NHS number and so that we can tell your hospital that you are taking part. The information that identifies you is important so that we can ask your hospital for details about your labour and birth. We will also ask for your full postcode. Postcode information is optional, but it can help us to learn more about what affects the group of women who take part in this research. If we do not hear from you in approximately one week after we have sent the email, we will send you one reminder. If you completed the questionnaire with a member of staff from your hospital, they will have asked for this information and you will not be emailed requesting this information again.

When you have finished the first online questionnaire your hospital will be told that you are taking part in this study. If you completed the questionnaire with a member of staff from your hospital, they would already know this. Then when you have had your baby your hospital will look at your hospital records and tell us some details about your labour and birth, such as what pain relief you had, if you had a doctor’s help to give birth, how long you were in labour, if you had your waters broken or a hormone drip, or if you had a caesarean section.

A second online questionnaire will be sent to your email address about 3 weeks after having had your baby, or approximately 3 weeks after when you baby was due.

Each questionnaire should take no more than 20 minutes to complete. The second questionnaire is shorter than the first. The first antenatal questionnaire asks you about your thoughts about your approaching labour and birth, and your thoughts about pain. The second postnatal questionnaire asks you about your labour and birth, and what factors might have influenced your labour and birth choices.

**Do I have to take part?**

It is up to you whether or not you take part in this study. If you decide to withdraw you do not have to give a reason and your care will not be affected in any way.

There are four different ways you can withdraw from taking part in this study.

1. You can withdraw from the study by simply closing the online browser page for the first (antenatal) questionnaire and you will receive no further contact and we will not collect your labour and birth information. If you are completing the antenatal questionnaire with a member of staff from your hospital you will need to inform them of your decision at the time.

2. If you have completed the antenatal questionnaire, or both the antenatal and the postnatal questionnaires, and you do not wish to continue in this study you will need to contact the Chief Investigator to be withdrawn (contact details below).

 If we are informed in time this will also stop us from collecting your labour and birth information and we will not send you an online link to the second questionnaire.

3. If you do not withdraw from this study and you receive the online link to the second questionnaire, but you decide you no longer wish to take part you do not need to do anything. However, the answers you gave on the first questionnaire and your labour and birth information may still be used in this study.

 If you choose not to access the online link you will be sent **one** reminder to complete the postnatal questionnaire before you are withdrawn from this part of the study.

4. You can access the second questionnaire via the online link, and you can tell us here that you do not want to take part in the postnatal section of The RETHINK Study. However, the answers you gave on the first questionnaire and your labour and birth information may have already been collected and may still be used in this study.

If we have already anonymised any of your answers to the questionnaires or your labour and birth information, we will not be able to remove you from this anonymised part of the study.

If you do decide to withdraw from this study your future pregnancy care will not be affected in any way.

**What will happen to my responses and will taking part in this project be kept confidential?**

All the information that you give will be kept strictly private under the General Data Protection Regulations and Data Protection Act 2018. You will not be identified in any reports or in publicly available information.

Bournemouth University is the sponsor for this study based in the United Kingdom. We will be using information from you and your maternity records in order to undertake this study. Bournemouth University is responsible for looking after your information securely and using it properly. Bournemouth University uses BORDaR <http://bordar.bournemouth.ac.uk/> a central secure location for research data. Bournemouth University will keep the research information that identifies you for 5 years after the study has finished. This does not affect the information your NHS hospital must keep about your health care.

By consenting to take part in this study you will be agreeing that your hospital can securely pass on details from your labour and birth records to the Bournemouth University Research Team for purposes of this study. Your hospital has a strict duty to protect your personal information. Your hospital will not pass on any other details other that what you have agreed to for this study.

Certain authorised individuals from Bournemouth University and regulatory organisations may look at the research records to check the accuracy of this study. These research records will be anonymised. This means the authorised individuals and regulatory organisations will not have access to the personal information that identifies you. This activity is required to make sure this study is being conducted properly and to ensure the quality and integrity of the research.

Other than what you agree to we will not collect other information that identifies you such as your Internet Protocol address known as your IP address. Your IP address is like a postal address. It is a long number label given to each device connected to a computer network such as the internet. This address makes it possible to communicate using the internet. The data you provide online will be transferred to Bournemouth University computers. All data collected for this study will be stored in a password protected electronic format on university secure computers. Within three weeks of the close of the data collection period for this study data held online will be destroyed. More information about online surveys can be found here: <https://www.onlinesurveys.ac.uk/gdpr/>

If any of your answers on the questionnaire cause concerns about you or your baby’s safety then the Chief Investigator, who is also a practising midwife, will contact and discuss this with you and share this with your midwife.

Also, if it appears from your responses to the questionnaire that you require extra support, for example for a mental health issue, the Chief Investigator, a member of the research team, or local NHS service will contact you to discuss with you the best person to help you. The best person to help you may be your General Practitioner (GP). We will ask for your consent so that we can refer you to your GP when you access the study online.

You can find out more about how we use your information

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* the leaflet available at [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
* by asking one of the research team
* by sending an email to DPO@bournemouth.ac.uk
* by reading Bournemouth University’s [Research Participant Privacy Notice](https://intranetsp.bournemouth.ac.uk/documentsrep/Research%20Participant%20Privacy%20Notice.pdf) which sets out more information about how we fulfil our responsibilities as a data controller and about your rights as an individual under the data protection legislation. We ask you to read this Notice so that you can fully understand the basis on which we will process your personal information.

**What are the possible disadvantages and risks of taking part?**

There are no expected risks to the health of you or your baby in taking part in this study. You should continue with your usual maternity care. The main disadvantage is that you will be donating around a total of 40 minutes of your time to complete the two questionnaires and 5 minutes to provide your name, address, hospital or NHS number and hospital you have chosen to give birth in, and your postcode.

If you have any health issues that you feel have been caused by taking part in this study, and you would like support with this please contact your 24-hour local maternity service.

**What are the advantages of taking part?**

There are no direct benefits to taking part in this study. However, your participation will be valuable in helping us to understand if we can find women who may require additional support, particularly during early labour. This may be important information to help reduce labour and birth interventions and improve birth experiences for these women.

**Who is organising and funding this study?**

This study is an educational project in part fulfilment of a clinical midwifery doctorate (PhD) programme being undertaken by midwifery researcher Vanessa Bartholomew. It is funded by the Wessex Integrated Clinical Academic Training Programme.

**Who has reviewed this study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The Black Country Research Ethics Committee.

**Can I find out the results of this study?**

Yes, you can find out the results of this study. Results will be posted on the Bournemouth University website available from:

 <https://www.bournemouth.ac.uk/research/projects/rethink-study>

**Contacts**

If you would like to talk to the researchers to help you decide whether or not you would like to take part and answer any questions you may have, then please contact:

Chief Investigator Vanessa Bartholomew vbartholomew@bournemouth.ac.uk

and contact for Faculty of Health and Social Sciences

more information Bournemouth University

about this study: Studland House

 Christchurch Road

 Bournemouth BH1 3NA Tel: 07735 388820

Study Sponsor is: Bournemouth University

Study Identifier: IRAS 270583 Version 1.11 08/05/2021

Sponsor Contact: Suzy Wignall researchethics@bournemouth.ac.uk

Research Development and Support

Studland House

12 Christchurch Road

Bournemouth

Dorset BH1 3NA

**Complaints**

If you wish to complain about any aspect of this research please contact the Chief Investigator or alternatively:

Executive Dean of the Faculty of Health and Social Sciences:

Professor Stephen Tee research governance@bournemouth.ac.uk

Bournemouth University

Studland House

Christchurch Road

Bournemouth BH1 3NA

Alternatively, you can contact your local Patient Advice and Liaison Service (PALS). For details of your nearest PALS office you can go to the NHS website:

<https://www.nhs.uk/common-health-questions/nhs-services-and-treatments/what-is-pals-patient-advice-and-liaison-service/>

OR:

You can also ask your GP surgery, hospital or phone NHS 111

Online link to **THE RETHINK STUDY**:

<https://bournemouth.onlinesurveys.ac.uk/rethink-study-270583>

Email address from which you will receive the request for your personal identification information, the online link to the postnatal questionnaire, and one reminder:

 vanessa.bartholomew@dchft.nhs.uk

You may wish to check how to prevent this email from going to your junk/spam folder with your personal email service. Alternatively, please check your junk/spam folder regularly.

**Thank you very much for considering taking part in this research study.**

For administrative use only: NHS Trust site:

Date and time when the RETHINK Study was introduced:

Staff Signature: Print Name and Designation: