Participant Information Sheet

You are being invited to take part in a research study called "The L-TEL Trial". Before you decide, it is important for you to understand why the research is being done 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 information. Take time to decide whether or not you wish to take part.

Who is organising/funding the research?

The research is a collaborative study between University Hospital Southampton Foundation Trust (UHSFT) and Bournemouth University (BU). It is being led by Rebecca Cousins, a doctoral research student and midwife.

What is the purpose of the research?

"Early labour" is the beginning part of labour after 37 weeks of pregnancy. We know women with low-risk pregnancies have better birth outcomes if they remain at home whilst in early labour. However, existing research suggests that many women do not feel happy or confident to do this. The women who are least confident whilst at home in early labour are mothers expecting their first baby.

The L-TEL Trial will look at a new, early labour website that is not yet publically advertised. The website will offer information and advice about early labour, alongside videos of women who have already had a baby talking about their experiences. The purpose of The L-TEL Trial is to compare a group of women who are given access to the new website during their pregnancy, with a separate group of women who do not have access to the website. Both of these groups will receive all the usual maternity care offered by UHSFT. By comparing these two groups, we hope to see if the early labour website can affect women's experiences of remaining at home in early labour.

Why have I been asked to participate?

You are being asked to participate because you are pregnant with your first baby, you are planning to birth at one of our midwifery-led birthing units and current advice would encourage you to remain at home, if all is well, when you first go into labour after 37 weeks. We would therefore value your involvement in our new research project.

What would taking part involve?

If you chose to take part, you will be emailed a consent form and then asked to fill out an online questionnaire designed to measure your self-efficacy towards childbirth (how confident you are feeling about childbirth). We would also like to collect some personal information about you such as your age, ethnicity, marital status and level of education. This is so we can see how well The L-TEL trial represents the rest of the population. If you do not wish to give out this personal information, there will be an option to leave this part of the questionnaire blank.

The L-TEL trial will be "randomised". This means, after you have completed the online questionnaire, a computer will randomly allocate you to one of two groups. One of these groups will receive the link to the website and one of these groups will not. No one can choose which group you will be put in to. Randomising research participants in this way gives us more accurate results and lets us find out how well something new has worked. You will be told which group you are in (website or no website) via text message and email and we will ask you to reply to let us know you have received this information. If you are in the group who will see the website, you will be sent the link to the website via text and email. You may view this website as much as you wish until you give birth. Both groups will continue to receive all the usual maternity care. In the first couple of weeks after you have given birth, both groups will be sent an online questionnaire looking at your experiences of early labour. The answers you provide in this questionnaire will let us compare the two groups' early labour experiences. In addition, with your permission, we would also like to look at your birth outcomes (such as the type of birth you had, the sorts of pain relief you used). This will be confidentially collected by the researcher from the centralised computer system at the hospital that already routinely collects this data when you have a baby at UHSFT.

Do I have to take part?

This research is completely voluntary and it is entirely up to you to decide whether or not to take part. If you change your mind at any point during The L-TEL Trial about taking part, you can withdraw your consent by contacting the researcher. The information you provide during the trial can only be withdrawn before it is anonymised.

What else should I think about before I decide to take part?

It is important you are able to access the internet in order to complete the forms and questionnaires we will send you. Furthermore, those who receive the link to website will need the internet to access it. It is therefore important to think about whether using the internet during this trial will be of any additional financial cost to you. If so, this may affect your decision to take part in The L-TEL Trial as we are unable to provide any financial reimbursement.

What are the possible benefits of taking part?

This website is not routinely available at any NHS Trust. As this is a new website we do not know how or if the website will affect women's experiences and there are therefore no known benefits for the participants in The L-TEL Trial. We have developed this website with the aim of improving first time mothers' experiences of early labour. Your involvement in The L-TEL Trial will help us see if the website can make a difference to first time mother's experiences for the future.

How will my data be used and kept?

Bu is the sponsor for The L-TEL Trial. We will be using information from you and your medical records in order to undertake the study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. BU will securely keep identifiable information about you for 5 years after the trial has finished. Your rights to access, change or move your information are limited, as we may need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we will use your information by contacting the researcher on the details below. The researcher will collect this information in accordance with our instructions. BU may use your name and contact details to contact you about The L-TEL Trial, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from BU and regulatory organisations may look at your medical and research records to check the accuracy of the research study. UHSFT will pass these details to BU along with the information collected from you. The only people in BU who will have access to information that identifies you will be the researcher and the people who need to contact you about the trial or audit the data collection.

What do I do next if I wish to take part?

Please email the researcher if you wish to discuss The L-TEL Trial further. The researcher will call you to answer any questions you may have and to find out if you wish to take part. Remember your consent is completely voluntary. If you would prefer not to be contacted in this way, please send an email to rcousins@bournemouth.ac.uk stating this. After you have spoken to the researcher on the phone, if you decide to take part, you will be emailed a consent form to complete.

If you have any questions about this research, or are interested to take part please contact the researcher, Rebecca Cousins at rcousins@bournemouth.ac.uk

In case of Complaints

If you have any concerns about this research please contact:

Dr Susan Way - 01202 961821
SueWay@bournemouth.ac.uk

If you still have substantial concerns about this research after having spoken to Rebecca Cousins or Dr Susan Way, please contact researchgovernance@bournemouth.ac.uk

Thank you for taking the time to read this information sheet.