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The Let's Talk Early Labour (L-TEL) Trial

Submission date
22/10/2018

Recruitment status
No longer recruiting

Registration date
22/10/2018

Overall study status
Completed

Last Edited
14/08/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Early labour is the beginning part of a woman's labour. There is substantial research demonstrating that women with low-risk pregnancies have better birth outcomes if they remain at home during this time. In spite of these advantages, many women do not feel confident to cope with early labour pain at home and seek admission to their place of birth; these women are at greater risk of unnecessary obstetric intervention and poorer birth outcomes. The evidence indicates women are not having their needs met during early labour and research is required in an attempt to address this shortfall in maternity care. The aim of this study is to find out whether an educational website affects women's experiences of early labour.

Who can participate?
Women aged 16 and over who are pregnant for the first time with a single baby with no known complications

What does the study involve?
Participants are randomly allocated to receive usual care plus access to an early labour website (intervention) named "Let's Talk Early Labour", or usual care only (control). The website provides evidence-based information about how to cope in early labour, alongside videos of women who have already had babies, talking about their positive experiences of being at home in early labour. Participants' early labour experiences are assessed using a questionnaire at 7-28 days after giving birth.

What are the possible benefits and risks of participating?
As an educational, web-based resource, and as an enhanced version of the pre-existing maternity care, this intervention is considered to be low risk, posing minimal risks to the participants who receive the intervention. All participants receive the standard maternity care and no care is removed from those who receive the intervention. This is a new intervention and whether the website will have a positive impact on participants as expected, remains unknown. However, the website has been developed with the aim to improve the early labour experiences of those who receive it and so those in the intervention group may benefit from this improved experience.

Where is the study run from?
Princess Anne Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2017 to September 2020

Who is funding the study?
Wessex Partnership Scheme (UK)

Who is the main contact?
Miss Rebecca Edwards
edwardsr@bournemouth.ac.uk

Contact information

Type(s)
Scientific

Contact name
Miss Rebecca Edwards

ORCID ID
https://orcid.org/0000-0002-1414-0114

Contact details
Faculty of Health and Social Sciences
Royal London House
Bournemouth University
Christchurch Road
Bournemouth
United Kingdom
BH1 3LT
+44 (0)7805 772081
edwardsr@bournemouth.ac.uk

Additional identifiers

Protocol serial number
39131

Study information

Scientific Title
The Let’s Talk Early Labour (L-TEL) Trial: can an educational website affect nulliparous women's experiences of early labour - a randomised controlled trial

Acronym
L-TEL

Study objectives

The study hypothesis is that those participants who receive access to the website antenatally will score higher overall in a self-reported Early Labour Experience Questionnaire (Janssen and Desmaris 2013) when compared to the study group who will receive only routine care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Health Research Authority: South Central - Hampshire A Research Ethics Committee, 15/10 /2018, ref: 18/SC/0396

Study design
Randomised; Interventional; Design type: Process of Care, Education or Self-Management

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Labour

Interventions
The L-TEL Trial will be an open label, single-centre, pragmatic, randomised control trial (RCT), with a mixed method data collection. Participants will be randomised to receive usual care plus access to an early labour website (intervention) named “Let’s Talk Early Labour”, or usual care only (control). This methodology was deemed most appropriate to assess the effectiveness of the intervention in improving first time mothers' experiences of early labour.

The primary outcome is the total score of the Early Labour Experience Questionnaire (ELEQ) (Janssen and Desmaris 2013). This questionnaire will be completed by participants within 4 weeks following childbirth. The target sample size is 100 participants (50 in each trial arm). This is powered by a 10% difference in the total ELEQ score which has been documented as clinically important for a similar scale (Labour and Delivery Satisfaction Index (Lomas et al 1987)) to which the ELEQ was compared for construct validity during its development. It is estimated that 22% of all births in England are artificially induced (RCM 2016) and participants who have their labour induced will not be able to provide an evaluation of their early labour experiences at home. This has been accounted for in the target recruitment number to ensure the primary outcome can still be met.

Posters advertising the trial will be visible around the NHS Trust's maternity department. These posters will also be posted on Trust based social media (i.e. Facebook page). It is anticipated this will publicise the trial to potential participants in the first half of their pregnancy. Women will be able to self-identify themselves by emailing the researcher and a Participant Information Sheet (PIS) can be emailed to eligible women to read. This will be followed up with a phone call from the researcher to answer questions and discuss the trial and ensure informed, voluntary consent. Women who decide to consent will be sent an online consent form prior to randomisation.

In an attempt to ensure women who may not feel confident to self-identify have information about their ongoing trial, community midwives will also screen women for eligibility. At the routine 25 week appointment, women who are assessed by the midwives to be eligible will be advised that The L-TEL Trial is recruiting and will be given some brief information about what the trial entails. There will be a brief online training package for the midwives providing this information to complete. Eligible women will be offered a Participant Information Sheet and asked if they consent to being contacted by the researcher. With permission, contact details (phone number and email) will be collected by their community midwife and provided to the researcher. At least 24 hours later, the researcher will make telephone contact with women to provide an opportunity to discuss the research in more detail, answer any questions about the research and ensure women are able to provide voluntary and informed consent. Those who wish to consent will be emailed an online consent form to complete prior to randomisation. A copy of this consent form will be emailed to the participant and placed in their clinical notes.

Following recruitment and consent, an online, modified version of the Childbirth Self-Efficacy Inventory (CBSEI) (Lowe 1993) will be emailed to participants for completion. Participants will also be asked to provide some baseline characteristics that will later aid data analysis (year of birth, marital status, ethnicity, education level, and postcode). These baseline characteristics are important as they may have an impact on women's early labour experiences. Provision of these details will be optional.

Following simple computer randomisation, the researcher will email and text the participant to inform them of their trial arm and request a response from the participant to ensure they have received this information.

Those in the intervention group will receive a link via text and email to the "Let's Talk Early Labour" website and will be able to freely use this throughout the remainder of their pregnancy. The intervention group will continue to receive usual antenatal care. The control group will not receive the website link and will continue to receive usual antenatal care as scheduled.

At 7-14 days postnatally, both trial arms will receive an online, modified version of the Early Labour Experience Questionnaire (Janssen and Desmaris 2013) to complete. Questions will be added to the end to measure adherence to the intervention, gauge how the intervention group used the website and what was liked best and least about the website.

The researcher will collect some other maternal and neonatal clinical outcomes (see secondary outcomes section for details) by retrospectively reviewing the computerised, centralised hospital system where this data is already routinely collected. This data will be managed anonymously on a data management form. All data will be kept secure on a university password protected computer.

Research participants will be enrolled on the study for an estimated 21 weeks (≈ 5 months) (the end 17 weeks of their pregnancy and up to 4 weeks postnatally). The trial will end when the last ELEQ response is returned.

Based on the number of women booked to birth at the NHS Trust, it is anticipated the L-TEL trial will run for 14 months.

Intervention Type
Behavioural

Primary outcome(s)

Women’s affective experience as determined by the total score of a pre-validated Early Labour Experience Questionnaire (ELEQ) (Janssen and Desmaris 2013) (modified for online use with the author's permission), measured at 7-28 days postnatal

Key secondary outcome(s))
A number of secondary, maternal and neonatal clinical outcomes will also be retrospectively collected, by the researcher, from the hospital’s centralised computer system during the 6 week postnatal period following a participant's birth. These outcomes will be:
1. Labour phase (as defined by NICE 2014 guidelines) on admission
2. Place of birth
3. Birth mode (i.e. spontaneous vaginal birth, instrumental assisted birth or operative caesarean section birth)
4. Analgesia use
5. Augmentation of labour (artificial rupture of membranes, intrapartum oxytocin infusion use)
6. Neonatal Apgar scores as assessed at 1 minute and 5 minutes of age
7. Neonatal resuscitation required
8. Breastfeeding at discharge from place of birth

Completion date
21/09/2020

Eligibility

Key inclusion criteria
1. Pregnant with a live, healthy, single foetus without known complications
2. Nulliparous (no previous pregnancy >24 weeks gestation)
3. At least 16 years of age at the point of consent
4. Suitable as per Trust guidelines for a spontaneous, vaginal birth at a midwifery-led unit
5. Able to speak and read English for the purpose of informed consent
6. Not requiring antenatal care from a specialist, case-loading midwifery team (a team specifically available for women with complex social needs)
7. Able to access the internet, either on WiFi or on mobile data without unacceptable costs from doing so

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
Female

Total final enrolment

140

Key exclusion criteria
1. Pregnancy with complications (medical, maternal or fetal) that requires birth at the obstetric led unit
2. Multiparous (any previous pregnancy > 24 weeks gestation)
3. Planning for induction or caesarean section birth
4. Unable to speak or read English for informed consent
5. Requiring specialist care from a case-loading midwifery team for complex social needs
6. Unable to access the internet without inappropriate associated costs

Date of first enrolment
22/10/2018

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Princess Anne Hospital
Coxford Road
Southampton
United Kingdom
SO16 5YA

Sponsor information

Organisation
Bournemouth University

ROR
https://ror.org/05wwcw481

Funder(s)

Funder type
Government

Funder Name
Wessex Partnership Scheme

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/08/2023	14/08/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version v2.1	28/09/2018	22/10/2018	No	Yes