Can an educational web-intervention, co-created by service users alongside self-efficacy theory, affect nulliparous women's experiences of early labour? A study protocol for a randomised control trial (the L-TEL Trial)

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Abstract

Background. 'Early labour' refers to the beginning phase of a woman's labour. It is the period of time where there are painful contractions and the cervix changes in preparation for active labour and subsequent childbirth. In UK clinical practice, cervical dilatation of four centimetres is commonly accepted as when active labour begins. Low-risk women, with uncomplicated pregnancies, have less unnecessary medical intervention if they remain at home in early labour. Despite recent efforts to improve labour triage, assessment and diagnosis in an attempt to reduce early-labour admission rates, women remain fearful and under-confident to remain at home during this time and continue to seek admission to their birth place. Thus, further research is required to evaluate new interventions aimed at improving women's experiences of remaining at home in early labour.

Methods. This trial is a pragmatic, randomised control trial with mixed-method data collection. The trial will evaluate the effect of a co-created, educational web-intervention on women's early labour experiences. The trial aims to recruit 140 low-risk, pregnant nulliparous women from a single National Health Service (NHS) Hospital Trust in England. Participants randomised to the intervention group will receive a link to the web-intervention, alongside routine maternity care provisions. The control group will receive only routine maternity care provisions.

Discussion. It is hypothesised that the group that receive the intervention will score higher in the Early Labour Experience Questionnaire (ELEQ, Janssen and Desmarais, 2013), indicating an improved early labour experience when compared with those in the control group. It is anticipated that findings from this trial will contribute to the knowledge base around how to improve first time mothers' experiences of early labour, particularly the time spent at home prior to admission.

Keywords. Pregnancy, childbirth, early labour, latent, self-efficacy, experience, education, website, online, protocol, randomised control trial, evidence-based midwifery

Background

'Early labour' (used interchangeably in the literature with the 'latent phase') is the term used by health care practitioners to refer to the beginning of labour. Generally, the end of the early labour phase is marked by an increased rate of cervical dilatation; this is also the beginning of the more progressive stage of labour referred to as 'active labour'. However, establishing a specific definition of early labour, in particular the point at which early labour transitions to active labour, that academics and practitioners can unanimously agree on has been challenging (Hanley et al, 2016; Hundley et al, 2017). Much of the existing literature agrees that early labour is the time when a woman has contractions, while her cervix effaces and prepares for childbirth; however the numerical dilatation in centimetres that represents the end of early labour varies between two to five (Friedman, 1954; Albers et al, 1996; Zhang et al, 2002; Zhang et al, 2010; Oladapo et al, 2018). The National Institution for Health and Care Excellence (NICE) defined early labour as "a period of time, not necessarily continuous, when there are painful contractions and there is some cervical change, including cervical effacement and dilatation up to four centimetres," (NICE 2014: p18-19). In spite of recent international guidance that recommends five centimetres of cervical dilatation as a better indication to mark the transition between early and active labour (World Health Organization, 2018), the NICE definition remains the most commonly accepted and practised by midwives currently working within the UK.

Women with low-risk pregnancies are less likely to have unnecessary intervention if they remain at home in early labour, coming to their chosen birth place for admission after this phase has finished (Rota et al, 2018). Admission to hospital in early labour increases the risk of obstetric intervention such as oxytocin augmentation of labour, fetal blood sampling, continuous electronic fetal monitoring, epidural analgesia, infection and caesarean section (Hemminki and Simukka, 1986; Holmes et al, 2001; Bailit et al, 2005; Rahnama et al, 2006 Tilden et al, 2015: Mikolajczyk et al, 2016).

There are a number of theories that seek to provide an explanation for these increased risks of intervention:

inherent problems with labour that drive women to seek earlier admission; the impact of the hospital environment on women and their subsequent labour progression; care practitioners' impatience and the notion of predetermined labour timeframes resulting in artificially expedited labour; women's unrealistic expectations once admitted to their birth place; and the challenge of effectively diagnosing the early and active phases of labour (Marowitz, 2014; Hanley et al, 2016).

The complex relationship between the biological, physiological, social, psychological and environmental factors that affect labour progression makes reducing unnecessary interventions after admission challenging. Yet it is widely accepted that avoidable obstetric intervention can have an impact on optimum maternity care and subsequent birth outcomes. This notion is supported by national policy where normalising childbirth, improving outcomes and safety while reducing unnecessary obstetric intervention remains at the forefront of UK maternity care targets (NHS England, 2016). Finding ways to minimise the rates of early labour admission will reduce the number of women at risk of unnecessary obstetric intervention. This is likely to have a positive impact on the provision of optimum maternity care.

A recent evidence review (Kobayashi et al, 2017) concluded that existing assessment and support interventions during early labour have yet to have an impact on mode of birth, a key benchmarker for optimum maternity outcomes and care. So far, research has focused on attempting to improve early labour triage, assessment and diagnosis (McNiven et al, 1998, Janssen et al, 2003; Janssen et al, 2006; Cheyne et al, 2008; Hodnett et al, 2008; Spiby et al, 2008).

McNiven et al (1998) demonstrated that women who were assessed in a separate early labour area (away from the central delivery suite) had less intervention rates and improved satisfaction, confirming that a hospital's delivery suite is not the best place for women in early labour. An algorithm designed to assist midwives' labour assessments did not significantly reduce augmentation or intervention rates but did increase the number of women discharged after assessment (Cheyne et al, 2008).

Spiby et al's (2008) large, multi-centre trial found assessment at home improved maternal satisfaction when compared with telephone triage, but did not reduce obstetric intervention rates. These studies indicate that although early labour assessment should be carried out away from hospital, improving triage methods and midwives' diagnosis of labour has yet to reduce the high rates of intervention associated with early labour admission.

Contrary to improving care, women report that midwives are acting as 'gatekeepers' to their chosen place of birth (Eri et al, 2011) and previous research efforts appear to fall in line with this notion. Many existing studies have primarily focused on developing early labour management pathways that are service-focused, attempting to keep women out of hospital in early labour to improve clinical outcomes. However, qualitative literature in this field indicates that research efforts also need to proactively find woman-centred interventions that aim to meet women's needs in early labour.

Not coping with pain and having low levels of confidence during early labour is cited in the literature as reasons why women seek admission despite professional advice to remain at home (Low and Moffat, 2006; Cheyne et al, 2007). Eri et al's (2015) metasynthesis of women's experiences identified early labour as 'an unknown territory' and concluded women are not having their needs met during this time.

Research efforts may be better focused on improving women's experiences of being at home in early labour as this may aid women to feel more confident to cope and remain out of hospital. Currently, no research has focused on specifically developing and trialling interventions designed to improve women's experiences of this phase. The L-TEL Trial aims to focus on this gap in the literature and offer a woman-focused solution to address the negative experiences associated with being at home in early labour.

Methods

The intervention

The intervention in this trial has been co-created with women who have previously had babies and been cared for within the maternity service. It is a web-based, educational tool developed for use during pregnancy, to provide information about early labour and support for women expecting their first baby.

Antenatal education continues to play a role in how parents prepare for the birth of their baby; participation with antenatal preparation is associated with higher satisfaction and a more positive birth experience (Schrader McMillan et al, 2009). Traditionally, antenatal education was provided by health professionals to groups of pregnant women. However more recently, women are increasingly accessing and valuing online and digital information during pregnancy (Lupton, 2016). In a recent review, 'delivery stages' was identified as one of the most common topics of interest (Javanmardi et al, 2018). Furthermore, the information women are accessing online can be inaccurate and not discussed with their health professionals; consequently there is a great need to provide more accurate and reliable online education (Sayakhot and Carolan-Olah, 2016; Javanmardi et al, 2018).

The web-intervention's development was in line with existing self-efficacy theory (Bandura, 1977). Self-efficacy is defined as one's belief that one will achieve a desired goal or outcome. The existing qualitative literature suggests that in relation to coping at home during labour, women have low levels of self-efficacy. Self-efficacy has been previously shown to be a powerful predictor of how well women cope with labour (Larsen et al, 2001).

In addition, self-efficacy is an important psychological factor in achieving a positive birth experience (Beebe et al, 2007), particularly for first-time mothers (Berentson-Shaw et al, 2009). According to the theory, self-efficacy can be increased though personal mastery, vicarious experience, emotional arousal and verbal persuasion (Bandura, 1977).

In line with this theory, to channel other women's vicarious experiences, the web-intervention's content was shaped by previous users of the maternity service. Involving women in this way has been shown to ensure health and social research

remains focused on relevant, key priorities identified directly by the public (Stanley, 2009).

Women who had previously had babies were identified via an independent, infant-feeding support group on social media and volunteered to speak about their time at home in early labour. Following the provision of an information sheet and a written consent form, the researcher conducted semi-structured interviews with 10 women who had spent time at home while in early labour with their first baby. These interviews were conducted in a private room in a community centre. The interviews focused on drawing out women's coping mechanisms while remaining at home in early labour.

Interviewees were keen to offer emotional arousal and verbal persuasion to other first-time mothers and this fell in line with existing self-efficacy theory (Bandura, 1977). Some women who volunteered to offer their experiences of being at home in early labour did not wish to be interviewed in person and therefore a further 15 women offered their experiences by written response via an online questionnaire. The same questions were used at interview as on the questionnaire. This was to ensure a wide variety of women contributed to the web-intervention's development.

The researcher used the interviews and questionnaire responses to identify topics that women had deemed to be important and these formed the development of the web pages (See box 1).

Box 1 Themes identified through interviews with previous service-users for the intervention

- What does early labour feel like?
- Being at home
- Preparing
- Eating and drinking
- Positioning
- Breathing techniques
- Using water
- TENS
- Distraction
- Hypnobirthing
- Massage
- Reminders from your birth partners
- Being present
- Positive thinking

With permission and consent, the face-to-face interviews were video recorded and edited together using the same topics of interest that had emerged naturally. These videos were embedded within the website and the topics guided the web-intervention's written content, which offers coping mechanisms and motivational techniques. Those women who had been video recorded were invited to view the edited footage to consent to the publication of the videos online and to confirm that the final, edited footage was representative of their original views and experiences.

The existing evidence base, as well as national and local clinical guidelines, supported the written content of the web-intervention. This was reviewed by the Trust's consultant midwife to ensure safe advice was being provided. Furthermore, an independent panel of academics, known for their work in the field of early labour research, peer-reviewed the web-intervention and provided feedback to ensure the provision of safe, credible and evidence-based information.

The web-intervention was then reviewed by an independent group of previous maternity service users to ensure it provided clear information accessible to a wide variety of women. From this review, some adjustments were made to the use of specific words, and definitions of certain terms were added to ensure clarity for the user group.

Research design

This web-intervention will be trialled in a pragmatic randomised control trial (RCT) in a single NHS Trust. The intervention group will receive the link to the web-intervention alongside routine maternity care and the control group will receive only the routine maternity care.

Outcomes and hypothesis

This trial's primary outcome is women's affective experience determined by the total score of the pre-existing, validated, self-report ELEQ (Janssen and Desmarais, 2013). It is hypothesised that on average those in the intervention group will score higher than the control group. If shown to be true, this will illustrate the intervention's likely positive impact on improving women's experiences of remaining at home in early labour. A number of secondary, maternal and neonatal clinical outcomes will also be collected from the hospital's centralised computer system (See box 2).

This trial is not aiming to demonstrate statistical differences in clinical outcomes between the intervention and control group. Instead, it is anticipated that collecting these secondary outcomes may offer context and depth to any findings from this trial. Furthermore, these data may offer insight as to whether a future, larger trial, with higher target recruitment, would be feasible and valuable for measuring clinical outcomes between the trial groups.

Sample Size

The primary outcome for this trial is the total, ELEQ average score. In relation to improving women's experiences, a 10% difference in scores is documented to be clinically important

Box 2 – Secondary outcomes

- Labour phase (as defined by NICE 2014 guidelines) on admission
- Place of birth
- Birth mode (i.e. spontaneous vaginal birth, instrumental assisted birth or operative caesarean section birth)
- Analgesia use
- Spontaneous or induction of labour
- If spontaneous: any augmentation of labour (artificial rupture of membranes, intrapartum oxytocin infusion use)
- Neonatal Apgar scores as assessed at one minute and five minutes of age
- Neonatal resuscitation required
- Feeding at discharge from place of birth

Box 3 – Eligibility criteria

- Pregnant with a live, healthy, single foetus without known complications
- Nulliparous (no previous pregnancy >24 weeks gestation)
- At least 16 years of age at the point of consent
- Planning and professionally assessed as suitable for a spontaneous, vaginal birth at a midwifery-led unit at the specified site
- Able to speak and read English for the purpose of informed consent and access to the intervention
- Not requiring antenatal care from a specialist, case-loading midwifery team (a team specifically available for women with complex social needs)
- Able to access the internet without any inappropriate costs for the research participant

for a similar scale, the Labour and Delivery Satisfaction Index (Lomas et al, 1987). Treating the data as normally distributed (as done so by Janssen and Desmarais, 2013), an independent samples t-test will be used to investigate the difference in score by the two groups. Assuming a two-sided significance level of 0.05 and 90% power, a sample size of 70 (35 in each group) is required.

An increasing number of women are having their labours started artificially; this is referred to as an induction of labour (IOL). It is reported that 33% of labours in England between April 2018 and March 2019 were induced (NHS Digital 2019). The majority of participants who will undergo an IOL will not be able to provide an evaluation of their early labour experiences at home, nor an ELEQ response. Furthermore, it is acknowledged that a number of participants will be lost to follow-up and therefore the L-TEL Trial aims to recruit 140 women (70 per group) to ensure there are adequate ELEQ responses to contribute to the primary analysis. Participants will need to meet the eligibility criteria (See box 3) and recruitment will take place over a 12-month period.

Recruitment Process

Eligible women will be identified by their community midwives and will be provided with a Participant Information Sheet (PIS). If the potential participant agrees, the midwives will pass their contact details to the researcher via an online, secure form. Midwives reported that an online platform for providing these details would have the least impact on their regular work duties. Those midwives involved will receive a short, online training package about this trial and their involvement in the recruitment process.

Eligible participants will also be able to self-identify, via email, to the researcher as trial posters will be visible at the NHS trust and at their antenatal clinics. The researcher will not contact potential participants for at least 24 hours after they have received the PIS to ensure participants can make

an informed, voluntary decision about their involvement. A secure, uniquely password-protected, online consent form will be emailed to participants.

On completion of consent, participants will be provided with an electronic copy of their consent form and asked to fill out the Childbirth Self-Efficacy Inventory (CBSEI, Lowe, 1993). This will give an average, self-efficacy score for both the intervention and control group to determine how group characteristics differ prior to the intervention. Participants will then be randomised via an online randomisation service using randomisation in permuted blocks of four, six and eight to ensure groups are balanced periodically in the relatively small sample group required for this trial. The computerised, randomisation service does not let the researcher know of the details of these blocks. Participants will be notified of their allocation via email.

The intervention group will receive a link to the web-intervention and will be able to use this freely throughout the remainder of their pregnancies. Although forming part of the referral process, individual midwives will not be made aware of a specific participant's involvement or allocation. For safety, midwives providing acute clinical care in the hospital can access information about women's involvement in research without specific detail. Due to the nature of this intervention, neither women nor health care providers will be blinded and some participants may choose to speak to their midwives about their participation in this trial. This is anticipated in both the intervention and control group. As both groups will have continued access to routine maternity care, this is not anticipated to have an impact on the research findings.

Data collection

Between seven and 28 days postnatally, participants will receive a modified, online version of the ELEQ to complete and data analysis will be by intention to treat (ITT) to maintain the balance and advantages generated from the original random allocation (Gupta, 2011). An online version of this questionnaire was deemed by a public involvement group to be the best method for promoting follow-up and minimising the impact on the study population who will be mothers caring for their new-born baby. Additional qualitative questions around both groups' early labour experiences will be collected and descriptively analysed to add context and depth to the quantitative data.

Secondary, clinical outcomes will be collected by the researcher from the existing, centralised hospital system, coded and descriptively analysed. All raw data collected will be anonymised by the researcher before analysis to maintain participant confidentiality. Data sets will be made public after the final data have been collected. Details of where this will be accessible will be available from the corresponding author after data collection has finished. Participants will be made aware of any findings from this trial and where they can access the data.

Adherence to protocol / Contamination bias

Password protecting the web-intervention was considered to minimise contamination bias but after feedback from a public involvement group, it was felt this was more likely to prevent the intervention group successfully accessing the intervention (due to loss of password etc.). Instead, the participants are asked to agree to the trial's terms by not sharing the web-intervention link. Adherence to protocol will be measured as those in the intervention group will be asked how often they accessed the web-intervention. Additionally, contamination bias will be measured as the control group will be asked if they accessed the intervention, despite not being given the link.

Safety

The web-intervention promotes safety and encourages women to call the midwives if they have any concerns. This phone number is clearly displayed on all of the web pages. The web-intervention is a low-risk, educational intervention. However, if during data collection, severe adverse outcomes are noted, a committee made up of risk specialists on the maternity site, will review the case to make a decision about suspension or termination of the trial. Any of these adverse events will be recorded in a confidential incident form and kept in the site file, which is in a locked office on site.

Discussion

More than 600,000 women give birth each year in the UK, of which about 40% are first time mothers (NHS Digital, 2019). The advice offered to many of these mothers when they first commence labour will be to remain at home to minimise the unnecessary intervention associated with early labour admission.

Previous research efforts have focused on improving the diagnostic methods associated with early labour service provision. Currently, there is a lack of research trialling interventions that have been developed specifically to improve women's experiences of the early labour phase at home. This gap in the literature is evident from the dissatisfaction women report with this phase of their labour.

To conclude, it is anticipated that the new educational web-intervention, which has been developed by previous maternity service users in line with self-efficacy theory, may offer a way to improve women's experiences of this phase of labour. Any results from the L-TEL Trial will be published in peer-review journals as well as specifically disseminated to the research participants involved.

Declarations

Registration: Prospectively registered on ISRCTN registry on 22 October 2018: ISRCTN69770712.

Funding: This research is output of the Wessex Clinical Academic Training Programme funded by the Wessex Partnership Scheme.

Ethics approval and consent to participate: Ethical approval was granted on 15 October 2018 by the local research ethics committee and study approval by the Health Research Authority. Any protocol amendments will warrant notification to both these ethical bodies. Fully informed, voluntary consent will be sought and electronically stored securely for each research participant. Blank copies of the PIS, consent forms

and data collection forms can be sought on request from the corresponding author.

Research participants will be able to withdraw their consent, until the point at which data is anonymised, without reason, and this will not affect any aspect of the usual care they receive. While collecting the primary outcome, participants will be supplied with the details for an existing, post-birth aftercare service offered at the site in case participants require any post-trial care.

Data will be kept securely and confidentially on a University approved, password-protected device for five years following the end of the trial, as per University guidelines. Participants are made aware of how the data they provided will be used and stored, in line with General Data Protection Regulations (European Union, 2018), during the consent process.

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