

**Can an educational web intervention,
co-created by service users, affect
nulliparous women's experiences of
early labour? (A randomised control
trial)**

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

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Abstract

Background: Women without complications have lower obstetric intervention if they remain at home whilst in early labour. Many women report dissatisfaction in doing this, describing a disparity between their expectations and the reality of this phase. A dichotomy exists between what is clinically of benefit to women (remaining at home) and what women require emotionally, which is support and reassurance. Previous research has been driven by the needs of the maternity service, focusing on the transition between early and active labour, commonly testing interventions that aim to improve clinical outcomes and the timing of admission. To date, no studies have evaluated interventions specifically developed to improve women's early labour experiences.

Intervention: Using self-efficacy theory as an underpinning framework, a web-based intervention was co-created with women who had previously used maternity services. It provides early labour advice, alongside videoed, real experiences of women who have previously had babies.

Methodology: The primary aim of this study was to evaluate the impact of this intervention on women's self-reported experiences of early labour. The intervention was trialled in a pragmatic, randomised control study at an NHS Trust in England between October 2018 and June 2020. A total of 140 low-risk, nulliparous, pregnant women were randomised to the intervention group (n=69) or the control group (n=71). The intervention group received the web-based intervention antenatally to use at their own convenience and the control group received usual care. Data was collected at 7-28 days postnatally using an online version of the pre-validated, self-report Early Labour Experience Questionnaire (ELEQ). Secondary, clinical outcomes were collected from the existing hospital system, as well as information about the acceptability and usability of the intervention.

Findings: There were no statistically significant differences in the ELEQ scores between trial arms. The intervention group scored more positively in two of the three ELEQ subscale domains (emotional wellbeing and emotional distress) and less

positively in the perceptions of midwifery subscale domain. Participants in the intervention group were less likely to require augmentation during labour.

Discussion: The L-TEL Trial demonstrates that women evaluate different aspects of their early labour experience continuum independently where an improved emotional experience does not necessarily equate to an overall improved experience of this phase. Equipping women to have better emotional experiences at home may negatively impact on their perceptions of midwifery care when it is sought. It is recommended that a larger trial evaluating the intervention is undertaken, which will collect more qualitative data to provide a richer understanding of the relationship between the L-TEL intervention, emotional early labour experiences and the perceptions of midwifery care. A larger trial, with the power to detect differences in augmentation rates is also recommended.

Impact: The L-TEL Trial is the first study to develop an intervention specifically to improve women's experiences of early labour. The co-creation process provided a woman-centred approach, when preceding early labour research has been predominantly service-centred. The trial was well timed, responding to a number of research recommendations about online, digital information, early labour expectation management and support interventions for this specific phase. In this, the L-TEL Trial has made a unique and valuable contribution to this research field.

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<http://www.letstakearlylabour.org/>

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Author's declarations

Chapter 6.0 presents a published paper of this trial's study protocol (Edwards et al. 2019) and is referenced where appropriate and is listed in the reference list.

*“Whenever and however you give birth,
your experience will impact your emotions, your mind,
your body, and your spirit for the rest of your life.”*

-Ina May Gaskin

1.0 Introduction

At the beginning of the last century, almost all women in the UK gave birth at home, commonly with the support of family, friends and the local community (Nove et al. 2008). Few pregnant women at this time had contact with medical practitioners with formal training or qualification, and childbirth was not considered to be something that required hospitalisation (Al-Gailani and Davis 2014). In the aftermath of the Second World War, many no longer had suitable homes in which to birth and so hospital birth became a pragmatic choice for some women (McIntosh 2017). Furthermore the introduction of the National Health Service (NHS) in 1948, alongside substantial developments in antibiotics and sanitation, started the shift towards the medicalisation of childbirth (McIntosh 2013). The movement was further fuelled by public health messages, such as was seen in The Cranbrook Report (Russell 1959), which aimed for 70% of all births to take place in hospital. Continued debate in the medical and obstetric community presented birth as a pathology requiring treatment and there was an ever growing reliance on medical technologies (Oakley 1980). By 1970, The Peel Report made the following national recommendation:

“We consider that the resources of modern medicine should be available to all mothers and babies, and we think that sufficient facilities should be provided to allow for 100% hospital delivery. The greater safety of hospital confinement for mother and child justifies this objective.”

By 1977, homebirth rates were less than 2% (Office for National Statistics (ONS) 2008). There was an initial temporal correlation between the significant shift towards hospital birth (and subsequent medical intervention) and a decline in perinatal and maternal mortality (Reitsma et al. 2020) yet the ability to draw a causal correlation remains contested. Conversely, Tew’s statistical analyses of births throughout the decades of the 1970 and 1980s, found perinatal mortality to be higher when there was increased rates of obstetric intervention, implied by increased hospitalisation, when compared to midwifery care, GP maternity units and homebirth (Tew 1981, 1986). Instead improved maternal health, spanning several generations, is suggested, albeit not proven, to be the catalyst for the mortality reduction (Tew 1986). In spite of this, hospital birth has continued to be the dominant model of care in the UK, and homebirth rates have remained steadily around 2% throughout the last four decades (ONS 2020).

Furthermore, rising trends in obstetric intervention have since continued, without a matched improvement in maternal, fetal or public health outcome (World Health Organization (WHO) 2015). As an example, there has been an exponential increase in

caesarean section rates globally (Visser et al. 2018). When indicated, the procedure can be a lifesaving intervention but the operative birth mode is also associated with both short and long term risks including uterine rupture, abnormal placenta implantation and risk of stillbirth in subsequent pregnancies (Sandall et al. 2018). Whilst the WHO (2015) maintain that caesarean sections should be performed when there is an individual need, rather than to purposefully strive for a specific rate, a caesarean section rate higher than 10-15% has been demonstrated to be of no benefit in reducing mortality rates and may instead present high iatrogenic risk to the population (WHO 2015). Others have found that lowest rates of mortality are achieved with a caesarean rate of around 19% (Molina et al. 2015). However, between 2000 and 2015, global caesarean section rates rose from 12.1% to 21.1% and in some countries it is alarmingly higher still; rates in the Dominican Republic are as high as 58.1% of all recorded births (Boerma et al. 2018). The caesarean section rate in England was 19.7% in 2009-10, but has risen to more than 30% of all births in the last decade (NHS Digital 2020). Consequently, caesarean section rates in England are currently double the optimal rate presented globally for achieving maximum health benefit with minimum iatrogenic risk (WHO 2015).

Furthermore, from the perspective of other obstetric intervention rates, only 57% of babies born in 2019-2020 in England were spontaneous, vaginal births; in addition, in the same period, less than half of all labours started spontaneously, without induction or planned caesarean (NHS Digital 2020). These figures provide more evidence for the ever-growing rates of medical and obstetric intervention in childbirth.

From the perspective of having the potential to reduce unnecessary obstetric intervention, early labour care has received an increasing amount of research attention, particularly in the last decade. Commonly an area of complaint, this early part of the childbirth continuum has been demonstrated to have an impact on rates of unnecessary intervention; more specifically, there is a correlation between women who remain at home in this phase and a reduced rate of intervention (Hemminki and Simukka 1986, Holmes et al. 2001, Bailit et al. 2005, Rahnema et al. 2006, Tilden et al. 2015, Mikolajczyk et al. 2016).

The number of women admitted whilst in early labour is not well recorded, and rates vary widely in the existing literature. Rota et al. (2018) predicted that almost half of women admitted to hospital are in the early phase of labour but this rate has been presented to be higher still at 80% (Bohra et al. 2003). With an urgent global need to

reduce unnecessary intervention in childbirth, so to minimise the maternal-fetal iatrogenic risks, improving early labour management and care to maximise the number of women who can remain at home in this phase, could be of notable benefit to both service users and service providers. Furthermore, women report varying levels of dissatisfaction with this phase of their labour (Eri et al. 2015), which has seen substantially less attention from care providers. There is a continued need for early labour innovation and research, so all efforts can be made to ensure this phase does not contribute any further to the growing concern over rising rates of obstetric intervention, specifically in the UK seen in escalating caesarean section trends and falling numbers of spontaneous vaginal births.

As an integrated thesis, this document will present the work undertaken to make an original contribution to the early labour research field, with support from a peer-reviewed, journal publication (Edwards et al. 2019). Whilst previous efforts in this area have focused on service-provider responses to early labour improvements, the work presented in this thesis has instead adopted a woman-centred approach, focused on developing and evaluating change driven by the needs of the women who use the service.

1.1 Presentation of thesis

Chapter 2.0 presents more detail to the background of this research study. In its entirety, it looks to illustrate the challenges that exist in the early labour phase of the childbirth continuum. The underpinning categorisation of labour is presented and critically appraised, and the subsequent risks for women when admitted in this phase are put forward. It seeks to use the existing literature to provide explanation of these risks and puts them in the realistic context of the labour journey that women must travel to arrive at the birth of their baby. This includes the decisions and options of care pathways that are commonly available within high income maternity care settings. Crucially, it also presents and considers the supporting literature available from the women and their birth partners' perspectives, with an exploration to the challenges that these perspectives bring.

From here, Chapter 3.0 looks to systematically evaluate the existing research evidence base of early labour care provisions and interventions. This detailed scope and critical appraisal looks to gauge what may already be available to women and service

providers in relation to this phase and what, if any, methodological evaluation has been undertaken. In this, a gap in the literature is identified which opens the need for this trial. This ensures original work and a valuable contribution to the wider field.

Following the identified gap, Chapter 4.0 explores the contributing factors that make a positive labour experience leading to childbirth satisfaction. From this, it identified self-efficacy as an important and modifiable aspect to what can make a woman's experience of labour positive. This chapter examines existing self-efficacy theory within the context of maternity and experience, as an adept underpinning framework for the development of a new intervention which aims to improve women's experiences of early labour.

Chapter 5.0 presents the co-creation methods of a novel, web intervention, underpinned by the self-efficacy theory discussed in Chapter 4.0. The merits of co-creating the intervention with women who have previously used maternity services are presented, which justifies why the intervention is uniquely woman focused, rather than driven by the needs of the service.

Following its development, the novel web intervention is evaluated in a randomised control trial (RCT) to establish its impact on early labour experience. Chapter 6.0 provides the trial's study protocol in an integrated, peer-reviewed journal publication (Edwards et al. 2019) and then provides justification of the pragmatic, randomised approach. It also delivers details of the recruitment strategy, data collection and analyses methods and illustrates the ethical and safety considerations that have been paramount throughout this trial's progress.

The findings of the Let's Talk Early Labour (L-TEL) Trial's primary outcome are presented in Chapter 7.0, in both written and visual form, through a comparison between the trial arm and the control arm. This is followed by presentation of the secondary outcomes and the data that were collected regarding the intervention's usability and acceptability.

Chapter 8.0 examines the trial's findings in the broader context of the wider literature and discusses whether the hypothesis can be accepted or rejected. The impacts of the outcomes are considered against the existing knowledge base. The trial's strengths and limitations are discussed and the impact of these on the findings are made

transparent. Lastly, the wider impact of the trial and the implications for future research are examined.

Finally, Chapter 9.0 provides a conclusion to the findings and demonstrates the new knowledge that has been generated by the L-TEL Trial. It illustrates the original contribution that the trial has made to the existing research field and why it differs to the research that has preceded it.

2.0 Background

This chapter sets out the evidence around the phases of labour and childbirth. It looks at the way in which labour is categorised into distinct phases and the impact this has on care providers and the women and families within the service. Importantly it presents the challenges of making distinct definitions between the phases of labour, and why this distinction remains important for women and their care. Finally it offers detail of the metaphorical and physical journey that women must make in early labour, first as they experience this unknown and worrying aspect of their childbirth continuum, and secondly as they decide to seek physical care and support at their chosen place of birth.

2.1 What is labour?

Labour is the transitional process at the end of a pregnancy leading up to, and including, childbirth. Labour describes the process that women undergo to birth a baby. For most, this is characterised by strong and often painful uterine contractions that dilate the cervix and cause the baby to descend through the birth canal to be born (Marshall and Raynor 2020). Cervical dilatation is commonly measured in centimetres determined by health practitioners' digital examinations. During labour, the cervix dilates to 10 centimetres (often referred to as full dilatation) before the baby is born (Downe et al. 2013). Whilst the mechanisms of labour and childbirth are well evidenced, the physiological factors, and external influences, that initiate labour onset are complex, multi-system processes (Hundley et al. 2020). Labour onset is regulated by a complex relationship of biological cues between the mother and fetus, combined with changes in the balance of maternal hormones (Uvnäs-Moberg 2019 et al.). These changes occur over the course of the last few months, weeks and days of a pregnancy and can differ between individual women (Uvnäs-Moberg et al. 2019). In view of this, the biological onset of labour, and subsequent labour progression, is a complex process rather than a specific event that can be determined by an exact timing (McCormick 2003).

In spite of this, labour is routinely categorised into three distinct stages: first (the progression to complete cervical dilatation), second (the period between complete cervical dilatation and full expulsion of the baby) and third (the phase between the baby's birth and the expulsion of the placenta) (Friedman 1954, Zhang et al. 2002, Hutchison et al. 2020). The establishment of labour and birth as three stages was likely a response to an increasing understanding of anatomy and childbirth physiology (Dixon

2011). Additionally, the sub categorisation of the first stage of labour into two further phases, early and active, has been commonplace since the middle of the 20th century, to aid with recognising parameters for normal, expected progression in labour (Friedman 1954, O'Driscoll et al. 1969).

“Early labour” (used interchangeably in the literature with the phrase the “latent phase”) is the term used by health care practitioners to refer to the beginning, less progressive part of labour. The term “active labour” (used interchangeably in the literature with the phrase “established labour”) is used to describe the more progressive part of labour that follows on from the early phase. This thesis will refer to the term “early labour”, as opposed to the “latent phase”. This is because the word “latent” is defined as “existing, but not very noticeable” (Oxford Dictionary 2010). Using a definition of this phase which could imply it to be “not very noticeable”, when there is a plethora of research indicating it to be a challenging and painful time for those experiencing it (Beake et al. 2018, Eri et al. 2015), was inappropriate for this research study. The L-TEL Trial has aimed to provide a woman-centred solution to this part of labour by acknowledging the needs and experiences of the women.

2.2 Labour categorisation

2.2.1 Cervical dilatation

Albeit a professionally constructed concept (Carlsson 2016), the discourse of labour stages, including the early and active phases, has been described in the literature to be something of “common knowledge”, guiding and influencing research, clinical practice and consequently women’s own understanding of childbirth (Dixon 2011). In spite of an overwhelming acceptance of this discourse, differentiating between early labour and active labour, remains an area of wide spread debate and specifically, establishing a distinct definition of early labour that academics and practitioners can unanimously agree upon has been challenging (Hanley et al. 2016). Nonetheless, health professionals continue to report a need to define the onset of labour and the early labour phase because current practice and subsequent care plans are commonly dictated by this definition (Hundley et al. 2017). Uterine contractions and cervical dilatation are the most dominant physical markers in the existing literature for differentiating between labour phases (Hanley et al. 2016). However there remains discrepancy about the point, frequently defined by cervical dilatation, in which the early phase progresses to active labour.

Friedman (1954) originally attempted to distinguish between early and active labour as the point in which the rate of cervical dilatation increases. Friedman's early research dominated the way labour was categorised through the latter half of the 20th century; studies plotting women's labour progression determined early labour as the time before the cervix was between 2 and 3 centimetres dilated (Friedman 1954, 1978). There are numerous limitations to the methodology Friedman's studies employed, including the use of rectal examinations to measure cervical dilatation, a practice no longer used. The study populations in this research included breech presentation and multiple pregnancies which are factors that increase pregnancy associated risk and moreover affect labour progression. Furthermore, population characteristics over the last 70 years have changed, particularly in relation to increasing maternal weight (Centre for Maternal and Child Enquiries (CMACE) 2010), maternal age and fetal weight. In addition, analgesia use, as well as induction and augmentation of labour, are more prevalent today than in the population that informed Friedman's findings (NHS Digital 2020). Maternal age, weight, analgesia use and induction are all noted as variables shown to increase the length of a labour (Albers et al. 1996) therefore cervical dilatation of 2-3 centimetres as the standardised juncture between early and active labour, is not generalisable to today's population.

Friedman (1954) also presented the "labour progression curve" a visual representation of a standardised expected rate of progression during labour. In spite of its noted limitations, the "Friedman curve", as it became known, made using a labour partogram (a standardised chart to recognise slow labour progression and identify the need for subsequent accelerative intervention) commonplace in UK clinical practice, despite a lack of formal evaluation prior to its introduction (Bedwell et al. 2017). Evidence has since indicated that their use may contribute to shorter labours (Javad et al. 2007), although this may translate to increased rates of intervention. Partograms have also been documented as a useful tool for clinical documentation (Bedwell et al. 2017). However, a Cochrane review did not recommend their application routinely as there had not been substantial differences in birth outcomes demonstrated and existing evidence into their impact remains limited (Lavender et al. 2013). The WHO concluded that the use of a partogram alone cannot reliably predict women at risk of adverse birth outcomes and therefore progression outside of these stipulations should not be indication alone for obstetric intervention (WHO 2018).

Commonly, partograms are only commenced at the point in which early labour transitions into active labour, and in support of this practice, Lavender et al. (2013) found increased caesarean section rates when they were utilised in early labour. To concur, Oladapo et al. (2018) dismissed the use of a routine partogram for women in early labour which, as per the more contemporary analysis, was defined to be dilatation prior to 5 centimetres of cervical dilatation. In 2018, the WHO updated their guidance to reflect this more contemporary evidence recommending 5 centimetres of cervical dilatation as the start of active labour.

Similarly, other contemporary research has re-evaluated the “Friedman curve”, and the point in which early labour finishes and active labour commences. A retrospective analysis of 1329 nulliparous women labour progression found that labour accelerated more rapidly after 4 centimetres of cervical dilatation (Zhang et al. 2002), concluding that this was the early-active labour juncture. In 2010, Zhang et al. evaluated a larger cohort of 62,415 cephalic, spontaneous labours and found the rate of accelerative labour progression to be later still, at 6 centimetres of cervical dilatation (Zhang et al. 2010). Whilst there remains some variation in the literature, 4-6 centimetres is accepted by most modern health providers as the end of the early labour phase.

In the UK, the National Institute for Health and Care Excellence (NICE) offer national guidelines for clinical decision making to ensure care is standardised. NICE (2017 p,18) define 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 4 centimetres.”

Active labour is defined when there are painful contractions and there is progressive dilatation from 4 centimetres (NICE 2017). As the L-TEL Trial was undertaken in a UK, NHS setting, this definition will be adopted for the purpose of this study as the point of cervical dilatation in which early labour transitions to active labour, so that the findings of this trial remain generalisable to the wider, intended population outside of this research.

2.2.2 Women's perceptions of labour onset

Research has indicated that using average parameters, from population-level data, does not accurately represent individual women's labour progression, transition from early to active labour, or the variance in individuals' labour durations (Oladapo et al. 2018). Furthermore, standardising the expected cervical dilatation rate using population averages fails to take into account those women's labours that progress at a "slowest-yet-normal" tempo. A more individualised approach, using women's self-report as an indicator for labour onset is becoming more common in early labour research (Hanley et al. 2016, Gross et al. 2004).

Whilst women do not experience the beginning of labour in a standardised way, most women can be reasonably precise about when they believe their labour commenced (Gross et al. 2006), and many can give an exact time and date (Dixon et al. 2013). This distinction however is predominantly made retrospectively, once their baby is born. (Gross et al. 2004). Commonly, the self-reported experiences do not match the clinical measures and signs used to identify labour onset and phases by care providers (Greulich and Tarrant 2010). This provides an additional complexity to the challenge of labour onset recognition and labour phase distinction. Women describe their experiences of labour as a continuous process, rather than one of succinct stages measured by cervical dilatation, and in reality, because they cannot measure their own cervical dilatation, some report stages in relation to this marker to be unhelpful (Dixon et al. 2013). Instead, recurrent contraction pain is most frequently identified by women as the mark of labour onset (Gross et al. 2009), but other signals such as vaginal loss and non-regular pain are also perceived to coincide with the start of labour for some women (Greulich and Tarrant 2010, Hanley et al. 2016). Furthermore, when asked, women are unlikely to spontaneously refer to the titled labour stages and phases in the same way as health practitioners, and are likely to understand them only because they have been provided with their titles during formal antenatal education and preparation (Dixon et al. 2013).

There is evidence that women's perceptions of their own labour onset is predicative of their birth outcomes and that this alone could be useful for practitioners to use so to recognise those in greater need of intervention. Women who indicated that they had been in labour for more than 24 hours prior to admission to their birth place had an increased risk of caesarean (Janssen and Weissinger 2014). Nonetheless, women's perceptions of their own onset are often undervalued, over shadowed by the need to

differentiate the boundaries between each stage and phase of labour, commonly driven by organisational requirement (Gross et al. 2004, Dixon et al. 2013).

2.2.3 Labour categorisation: Why does it matter?

Despite a lack of an internationally evidenced nor practiced definition of early and active labour, low-risk women, without pre-existing medical or pregnancy conditions, who are admitted to their place of birth whilst in early labour are at an increased risk of obstetric intervention (Hemminki and Simukka 1986, Holmes et al. 2001, Bailit et al. 2005, Rahnama et al. 2006, Tilden et al. 2015, Mikolajczyk et al. 2016). When it is required, intervention in childbirth can reduce maternal and fetal morbidity and mortality (Gülmezoglu et al. 2016) but unnecessary intervention increases the risk of complication during childbirth (do Carmo Leal et al. 2014). In the literature, unnecessary intervention is referred to as “too much too soon”; this is when an obstetric intervention is overused without benefit to the mother or baby (Miller et al. 2016). Additionally, a theory known as “the cascade of intervention” refers to the unintended side effect of intervention that triggers further intervention, further unintended side effect and known iatrogenic risk (Tracy and Tracy 2003).

As an example of this, the use of intravenous oxytocin (a synthetic hormone given to induce or accelerate labour) is associated with an increased risk of postpartum haemorrhage (Belghiti 2011), which may require treatment with a blood transfusion. A blood transfusion carries its own risks of infection or reaction which would require further treatment of which carry their own iatrogenic risk. Minimising unnecessary childbirth intervention will reduce unnecessary risks to mothers and babies. Thus a continuing rise in obstetric intervention rates remains of national and global concern (Dahlen et al. 2014).

Admission in early labour has been associated with an increased risk of caesarean section (Holmes et al. 2001, Jackson et al. 2003, Rahmana et al. 2006, Main et al. 2006, Davey et al. 2013, Neal 2014). Women admitted in early labour have increased oxytocin use (Holmes et al. 2001, Davey et al. 2013), increased use of epidural analgesia (Holmes et al. 2001) and higher rates of labour dystocia (Bailit et al. 2005).

2.2.4 Explanations for the increased risk associated with early admission

Women admitted in early labour may be intrinsically predisposed to requiring additional obstetric intervention, experiencing a more challenging early labour phase, thus being driven to seek admission at an earlier time. Rosenbloom et al. (2019) reported a correlation between slower dilatation rates (i.e. longer labours) and risk of caesarean and postpartum complication. Similarly, women who had self-reported to have been in labour for more than 24 hours prior to admission have been shown to be at an increased risk of caesarean (Janssen and Weissinger 2014). It is plausible to suggest that women who experience a lengthier early labour phase will seek admission earlier in their labour (at least defined by their cervical dilatation) because they will have already spent more, or an equal, time at home in labour (Ängeby et al. 2019).

As an example, between 10-34% of babies at labour onset are in the occipito-posterior position (Guittier et al. 2014). This fetal position is associated with longer, more painful labours (Hunter et al. 2007; Simkin 2010), and specifically a longer early labour phase (Tilden et al. 2019) meaning women with babies in this position may be more likely to seek admission at a lower cervical dilatation. This fetal position is also associated with an increased risk of obstetric intervention and instrumental birth (Guittier et al. 2014). In this example, it is perhaps not the earlier exposure to hospital but the fetal position itself which has predisposed the labour to earlier admission and an increased risk of intervention.

Another explanation for the associated risks with early labour admission is that care providers are keen to intervene, provide pain relief or accelerate the labour process following admission. Whilst midwives should look to shield and support those who are admitted in early labour from unnecessary obstetric intervention, instead, there is a professional acceptance that mere presence at hospital yields the requirement for intervention (Eri et al. 2011). In keeping with the previous example, a woman with a baby in an occipito-posterior position may seek admission at a lower cervical dilatation value, because labour thus far at home has been challenging and long (Hunter et al. 2007, Tilden et al. 2019). From this perspective, it is her mere exposure to the hospital environment that provides the increased risk of intervention, rather than the baby's position. In support, it is documented that:

“Hospital staff manage bodies in time... regulating them in ways that contribute to conducting the business of the institution efficiently, as determined by the “experts” who run it” (Simonds 2002, p64).

Hospitals are “managing” women and their labours in a linear fashion, in spite of a lack of evidence detailing normal time parameters of labour, these professional perceptions of time are central to the organisation of maternity care (McCourt 2009). The notion of “a ticking clock” (Simonds 2002) and labour progression corresponding to prescribed time parameters, has led to a medicalised, unrealistic expectation of labour duration which increases the risk of accelerative interventions (Downe and Dykes 2009, p. 64) (such as amniotomy and artificial oxytocic use). Chadwick (2018) describes a clockwork script to which labour is managed.

Throughout the entirety of pregnancy, care is scheduled and structured around a linear time frame and a final, expected due date which may give rise to an “embodied sense of time in the waiting pregnant woman” (Downe and Dykes 2009, p65). It is plausible that health practitioners feel pressured to “help” (i.e. intervene) when women seek early admission, even if clinically it is not indicated. In this theory, it is the so-called “help” and unnecessary intervention that causes the documented risks.

2.3 The early labour journey

Although the safety of homebirth for low risk women is well evidenced (Hollowell et al. 2015, Reitsma et al. 2020), homebirth rates in the UK remain low at 2% (ONS 2020). Consequently, most women must make the journey from home to hospital, often whilst in labour, in order to have their babies. Historically, midwives visited women at home to help decide when they should attend hospital; however this is no longer common practice and so the decision about when to journey from home to hospital is left to the women and their birth partners (Carlsson 2016), often this decision will also involve the midwives or the hospital via telephone conversation (Cheyne et al. 2007).

Once the decision has been made to come to the place of birth, it is recommended nationally, and is common practice, for women to receive a labour assessment (routinely this will consist of a clinical wellbeing assessment of mother and baby, an assessment of contractions and a digital examination to measure cervical dilatation) (NICE 2017). This assessment is to identify the stage of labour and to plan ongoing care based on the findings (NICE 2017). Women and their birth partners then face a number of different consequences:

1. They are assessed, active labour is diagnosed and thus they are admitted.
2. They are assessed, early labour is diagnosed and they are advised to return home to await labour progression.
3. They are assessed, early labour is diagnosed and they are admitted to their place of birth anyway.

The first consequence is the most desirable: care can now be provided by a professional, the request for admission has been met, and the birth is most imminent. The second consequence whilst avoiding early admission does not reliably meet the needs of the woman; this is discussed in further detail in the following Section 2.3.1. The third consequence exposes women to the risks of obstetric intervention associated with early admission as previously discussed. The challenges associated with all consequences and, in particular, the second consequence will now be explored in more detail.

2.3.1 Early labour experiences

Whilst care providers encourage women to remain at home during early labour (Eri et al. 2011, Cheyne et al. 2007), to minimise the risks associated with early admission, there is a plethora of research exploring the negativities that women report whilst at home in this phase (Beake et al. 2018, Allen et al. 2020). Frequently, the expectations of this phase at home do not meet the reality of their experiences (Myhre et al. 2021, Eri et al. 2015, Nolan et al. 2011, Beebe and Humpreys 2006).

Understanding how to prepare effectively for childbirth, and in particular the early labour phase, is challenging for women, especially for those having their first baby (Myhre et al. 2021, Cheyne et al. 2007). As labour onset presents in a variety of ways (Gross et al. 2004), feelings of uncertainty (Eri et al. 2015), and the inability to successfully and adequately prepare for the phase (Cheyne et al. 2007), pervades women's experiences of early labour. Furthermore, many women do not know what to expect during this phase, despite preparation, and even those who do prepare still remain unready for the experience (Beake et al. 2018). Even though preparing for the phase is not without challenge, those without early labour education antenatally are less prepared still; there is a strong association between those who report feeling "very worried" about early labour and those who do not partake in antenatal education (Henderson and Redshaw 2017). Whilst women require realistic information as to what to expect in early labour (Borrelli et al. 2018), this is often not widely available (Beake et al. 2018).

Coping with early labour pain, or the anxiety of impending pain, is often cited as the main reason women seek admission (Low and Moffat 2006, Cheyne et al. 2007). Fear of an inability to cope with labour pain was identified as a key construct in what made women fearful of childbirth (Slade et al. 2019). Furthermore there is a common uncertainty about the level of pain that is to be experienced in labour (Lally et al. 2014), which is likely to further exacerbate the doubts that women associate with early labour, specifically with remaining at home in pain (Lang et al. 2006). Floris and Irion (2015) saw a correlation between women's perceptions of pain and their anxiety in early labour. Whilst women can cope well with labour pain at home (Cheyne et al. 2007), progress in early labour is usually slow and women lose confidence in their abilities to cope (Hanada et al. 2015). Furthermore, many lack confidence to cope and remain at home without assistance from a professional (Carlton et al. 2005).

Women and their birth partners are responsible for identifying the point in which active labour commences, so that they can seek care by journeying to the hospital (Beake et al. 2018). The responsibility of recognising the "right time" to seek admission is documented to be very difficult for women, particularly for first time mothers without previous experiences of being in labour (Beebe and Humphries 2006, Low and Moffat 2006, Carlsson et al. 2009, Nolan and Smith 2010). These women find it particularly difficult causing heightened anxiety (Beake et al. 2018).

Once the decision has been made by the labouring woman that admission may be required, common practice is for contact to be made with the midwives via telephone and this is supported in national guidance (Spiby et al. 2006, NICE 2017). The outcome of this call is to gauge whether it is the appropriate time for the labouring woman to come to her chosen place of birth (Green et al. 2012). It is reported that these telephone interactions can be challenging for women and health practitioners (Cheyne et al. 2007). Midwives are reported to prioritise clinical assessment above the lived experiences of the women to whom they speak (Beake et al. 2018) and that midwives needed to quickly confirm if women are in early or active labour so they can plan and consider ongoing work load from a service management perspective (Eri et al. 2011). Primarily midwives are reported to see the early labour telephone calls as a means of filtering out the women that do not require admission (Spiby et al. 2014). In this, midwives are seen negatively as "gatekeepers" of the labour ward (Vik et al. 2016, Spiby et al. 2014). In this role, midwives can regulate and manage work load and their care focus is entirely on those in women in active labour. However, in this, those requiring support in the early labour phase are not provided with the care they need (Eri

et al. 2015) and these operational issues can impact on midwives' decision making (Allen et al. 2020). There is an apparent lack of team-work and tension between the women at home making decisions about when to seek admission, and the health professionals who "allow" women into the service for care (Henderson and Redshaw 2017). Marowitz (2014 p. 645) cites this tension to be:

"between the goal of delaying admission until active labour in order to decrease the incidence of unnecessary interventions and women's difficulty with managing this part of labour at home".

Whilst women appreciate good telephone advice, many report that they do not feel listened to adequately and that their concerns are not taken seriously by the midwife on the phone (Beake et al. 2018). This may be in part due to the apparent lack of an individualised approach to early labour care and management (Cappelletti et al. 2016).

Some women feel making the decision to call the telephone triage, and then being given permission to journey to hospital, is a "test" they must pass (Nolan and Smith 2010, Nolan et al 2009, Nyman et al. 2011); this is then followed by a "labour assessment" at the hospital. The word "assessment" can commonly be associated with negative connotations of testing and judging (Oxford Dictionary 2010). If women "fail" to identify the correct time to present to hospital, and "fail" the labour assessment, they fear being sent home to await the active phase of labour, which is often described as embarrassing and dissatisfying (Barnett et al. 2008, Eri et al. 2010, Nyman et al. 2011). Current labour definitions common in clinical practice rely on cervical dilatation, and thus a need for a physical examination from a health professional; in this women's intuition and experience are undervalued because they are not able to know what phase of labour they are in without confirmation and input from health professionals (Janssen et al. 2009).

Birth partners' anxiety, and their own need for reassurance, impacts on women's experience of early labour, and birth partners can commonly drive women to seek care earlier (Cheyne et al. 2007, Beebe and Humphreys 2006, Barnett et al. 2008, Nolan and Smith 2010, Nolan et al. 2011, Carlsson et al. 2012). It is well documented that birth partners are keen to play an active and supportive role in the childbirth process (Roberts and Spiby 2020, Premberg et al. 2011) and being engaged, involved and providing support to women is essential to their own satisfaction (Johansson et al. 2015). Whilst at home, birth partners must provide care and support, even if they have had no previous experience of doing this. Many birth partners report they adopt a

passive role (Roberts and Spiby 2020), watching the pain intensify as contractions become stronger and this can create feelings of despair, frustration, helplessness and powerlessness and drive them to want admission for support (Johnson 2002, Premberg et al. 2011, Kululanga et al. 2012). Care providers have the power to confirm experiences as “normal” and without the reassurance, women and their birth partners report to feel uncertain, anxious and powerless at home (Carlsson et al. 2012). Furthermore some mothers describe negotiating “on two fronts” during early labour, firstly with their birth partners about the timing of contact with the hospital, and then again on the phone with the midwife (Eri et al. 2010).

Carlsson (2016) concludes that women need to be “in a safe and thus secure place” during early labour and assuming that for all women this is at home, is, at present, incorrect. In the same paper, a theory is presented which documents the interplay between how women view the discourse of childbirth, and where they would be best placed in early labour. In this, women either see childbirth as a natural event, or a medical one. Those who adopt the former approach may be able to confidently cope well with early labour at home, and those that take the latter view are likely to see hospital as the safest place for early labour (Carlsson 2016). The overwhelming medicalisation of childbirth through the latter part of the 20th century has been described in Chapter 1.0, the low numbers of women choosing to birth at home, and the high rates of hospital birth in the UK infers that the majority of women birthing in the UK adopt a medicalised view of labour and childbirth. For these women, current early labour care provisions, which will routinely send women in early labour home from hospital without support, are not meeting their needs during this phase.

In summary, whilst evidence indicates that women should be at home during early labour to minimise obstetric intervention, many women do not want to follow this pathway of care because of the fear, anxiety, unpreparedness and worry that this phase eludes (Myhre et al. 2021, Eri et al. 2015, Beake et al. 2018). Hormones such as adrenaline, released during periods of anxiety, can cause labour to slow (Buckley 2011, Hundley et al. 2020), which is a reason women are encouraged to remain at home where anxiety levels are anticipated to be low. However, in reality, remaining at home, or being sent home, when women and birth partners require care, reassurance and confirmation of normalcy, worsens anxiety in this phase which has the potential to cyclically delay labour progression.

2.4 Chapter summary

To conclude, finding a unanimous early labour definition remains a challenge when women experience the labour onset process in a variety of ways (Hanley et al. 2016). In spite of this, there is good evidence to suggest that women have less obstetric intervention if they remain at home in early labour. Although true, this leaves women at home, without care and support, at the beginning of an unknown, often painful time where they report feeling underprepared and where their expectations do not meet reality. Women commonly report having to stay at home when actually they desire care and support (Henderson and Redshaw 2017).

To understand what can be done to make improvements to this phase of labour, an evaluation of existing early labour interventions will be undertaken, to establish what research is available. Understanding what is available, and what has already been considered, will enable the identification of service and research gaps, and importantly indicate how this study can rise to meet these gaps.

3.0 Literature review

A literature review is the comprehensive searching, study and interpretation of available evidence; undertaking a literature review is a method to expose and discover what is already known about a topic or issue before further research within the field is designed and implemented (Aveyard 2014).

This chapter details the systematic literature search and subsequent review that was undertaken in 2016, prior to the development of the research trial. This review was then used to inform the succeeding research, to ensure that any new findings contributed to the existing body of knowledge, without duplicating existing research efforts. During the write up period of the research study in 2020, the literature search was repeated, to provide a completeness of knowledge presentation within the subject area.

This chapter will first map out the aim and objectives of the literature review and then look to develop a search question that, when answered, meets said aims and objectives. The search question informed the search strategy, which is also detailed in this chapter. The inclusion and exclusion criteria for the search strategy and the rationale for why these specific criteria were adopted are also illustrated. The search process is presented in an adapted Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart (Moher et al. 2009). Eligible research studies identified in the literature search are then presented in tabular form. These studies are then included in the literature review and are summarised, critiqued and synthesised to determine what is already known about the topic of interest, and where the gaps in the literature exist. The chapter will conclude by detailing the addition of any further research studies that were published between the first and second literature search.

3.1 Literature review aim and search question

Chapter 2.0 identified the multitude of challenges facing women and service providers when managing, caring, coping and journeying through the early phase of labour. The aim of this literature review was: **“To establish, understand and evaluate what has already been studied and presented as a potential solution for these early labour challenges.”**

To achieve this aim, a search question was formed. The search question was: **“How effective are interventions specifically developed for the early phase of labour?”**.

The search question was then more clearly defined using the “Population, Intervention, Comparison, Outcome (PICO) model, as recommended in a comparison study of search tools for systematic reviews (Methley et al. 2014).

- **Population:** Service users (i.e. women) in early labour or service providers providing early labour care
- **Intervention:** Any interventions specifically developed for early labour
- **Comparison:** Not specified
- **Outcome:** Not specified, but a measureable outcome is required to gauge effectiveness of intervention; for example, decreasing unnecessary intervention or improving women’s experiences of care.

3.2 Literature search strategy

To ensure the search question was answered, and to systematically identify all literature of relevance, a comprehensive search strategy was developed.

3.3 Search terms

First search terms were identified and defined. Table 1 outlines the search terms used, rationale for their use and synonyms of each. Synonyms were identified using a thesaurus, the researcher’s own professional knowledge and cross referencing against other key studies. This ensured the search strategy had high sensitivity.

Table 1: Search terms, rationale for term use and synonyms used to conduct literature search

	Search Term	Rationale for Search Term	Synonyms
P	“early labour” ¹	The literature search aimed to identify relevant studies detailing the impact of early labour interventions on both the women and the service providers and for this reason the population was defined only to be “early labour”.	early labour, latent labour, latent phase, prodromal labour, labour onset, start of labour, labour start, labour beginning
I	“intervention”	The literature search aimed to identify available literature about all interventions developed for use with the aim to improve the early labour phase. There was therefore no further specificity required in this search term.	Intervention, treatment, therapy, programme, strategy, training, management, service, education
C	<i>not defined</i>	As this was not defined, there was no need to provide a search term for the “Comparison” because literature with varying comparisons was eligible for inclusion.	Not required
O	<i>not defined</i>	As this was not defined, there was no need to provide a search term for the “Outcome” because literature with varying outcomes was eligible for inclusion.	Not required

¹ The challenge of unanimously defining “early labour” has been previously discussed in the background chapter and there remains a wide variance in practical definitions across clinical practice and in research (Hanley et al. 2016). Therefore, for this search strategy, the term “early labour” was purposefully not defined with any specific markers (i.e. a numerical cervical dilatation value). That was so the search had the potential to identify all research with intervention efforts focused on the “phase of labour prior to the active phase”, regardless of the trial’s specific definition or chosen markers of early labour.

To identify literature which encompassed both search terms, the Boolean operator “AND” was employed; this ensured a high specificity in the search strategy. The synonyms were searched using the Boolean operator “OR” and an asterix ensured different spellings of the same term were included. This ensured a high sensitivity in the search. Table 2 below outlines the search performed.

Table 2: Search terms with Boolean operator used to conduct literature search

Search Term 1	Boolean Operator	Search Term 2
“early lab*r” OR “latent lab*r” OR “latent phase” “prodromal lab*r” OR “lab*r onset” OR “start of lab*r” OR “lab*r start” OR “lab*r beginning”	AND	intervention OR treatment OR therapy OR program* OR strategy OR training OR management OR service OR education

Bournemouth University’s search platform “MySearch” was used to complete an initial search because it encompasses the results and research papers from over 93 existing databases including CINAHL, MEDLINE (EBSCO), the Cochrane Library, PsycINFO, AMED, Scopus, Web of Science and EMBASE which are all known for their robust search abilities in relation to medical, social and psychological research (full details of the search platforms can be found in Appendix 1).

3.4 Inclusion criteria

Study inclusion criteria were specified prior to the search to set predetermined boundaries for the literature identified for review (Tawfik et al. 2019). These are detailed in Table 3, alongside a justification as to why they were applied.

Table 3: Inclusion criteria for literature review and justification for criteria choice

Inclusion criterion	Justification
<p>Date parameter: 1950-present day (2016 at time of literature review)</p>	<p>This date was chosen as was the decade that saw the beginning of labour categorisation into distinct phases and therefore literature from before this decade was not likely to be specific in answering the search question (Friedman 1954).</p>
<p>Language: English</p>	<p>Papers not published or translated to English were excluded due to the limitations of the researcher's language and comprehension. Papers that were initially written in another language, but translated to English are included. Papers with only English abstracts will not be included due to the limitations this presents in being able to judge the quality of the research.</p>
<p>Setting: High income countries (HIC) around the world (as defined by the World Bank).</p>	<p>This inclusion criterion was to only include studies with a research setting similar to that of the UK. This is because the literature review will form a basis for a further piece of research to be undertaken in the UK.</p>
<p>Methods: Qualitative and quantitative, peer reviewed original research papers.</p>	<p>This inclusion criterion was to promote robustness of the research identified. Furthermore, this review will exclude systematic reviews, meta-analyses and secondary or reflective papers in relation to primary research</p>
<p>Focus: Studies looking at the impact or effectiveness of a specific early labour intervention.</p>	<p>This inclusion criterion was to exclude papers that do not measure effectiveness of an intervention (i.e. to exclude papers reporting generically about early labour experience without specific reference to interventions, service evaluations without primary research, service mapping papers, secondary analyses, guidelines).</p>
<p>Population: All service users (women and their families), and service providers (health practitioners including but not limited to hospitals, midwives, obstetricians, other care givers)</p>	<p>This criterion aimed to identify all research of interventions specifically developed for early labour, without a specific outcome measure defined. Eligible research papers can measure outcomes that impact on the services users and the service providers.</p>

The primary literature search was undertaken on 6th May 2016, this was the literature search that identified the relevant literature which subsequently guided the development of the L-TEL Trial. At this time, the Cochrane review by Kobayashi et al. (2017) which investigated the effect of assessment and support interventions during early labour on birth outcomes had not been published. The literature search was undertaken again in October 2020, during this thesis' write-up. A decision was taken to continue with only primary research studies in the review, as all the studies cited within the Kobayashi et al. (2017) review had been included in the first search.

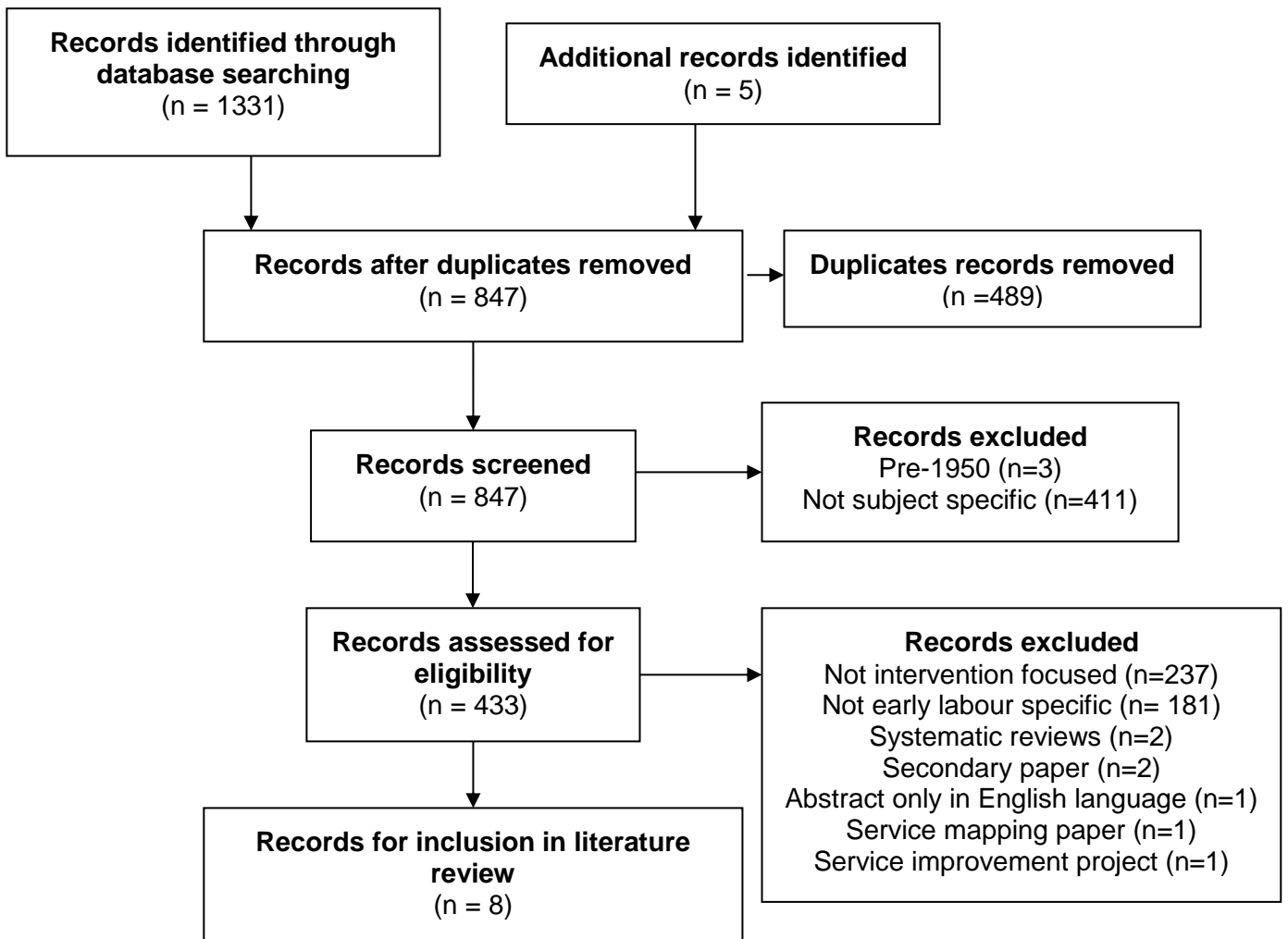
Methodological quality of included studies was assessed using Critical Appraisal Skills Programme (CASP) tool (2013). This was to assess the internal and external validity of the existing research (Zeng et al. 2015).

Given the heterogeneity of the interventions and the study outcomes, a decision was made not to undertake a meta-analysis of the data. This decision will be discussed later and the discussion will draw on the work of Kobayashi et al. (2017). Instead data synthesis involved the production of a descriptive summary of the state of knowledge regarding the effectiveness of interventions for use in early labour.

3.5 Results

The literature search identified 8 studies for inclusion in this review as illustrated in the adapted PRISMA diagram below (Moher et al. 2009) (Figure 1). Using this diagram allows researchers to transparently present their search strategy for identifying evidence and research for inclusion in a literature review; a systematic approach to literature searching minimises the risk of missing existing research which could compromise the quality of the literature review (Liberati et al. 2009). The literature search identified 8 studies for inclusion in this review, details of which can be found in Table 4 below. The 8 studies fall broadly into two distinct themes: antenatal education interventions (i.e. interventions intended for use in the antenatal period) and intrapartum interventions (i.e. interventions intended for use once labour has commenced) and so are presented in this format.

Figure 1: Adapted PRISMA diagram detailing literature search process (Moher et al. 2009)



3.5.1 Studies identified

The details of the included studies can be found in Table 4. Seven of the eight studies were RCTs (one was a cluster RCT) and one was a non-randomised experimental study. The majority of studies were North American, with only three studies considering a UK based population. The studies were considerably varying in sample size and the characteristics of participants were diverse, ranging in ages, ethnicity, education level and country of origin. This variation in eligible participants between studies meant synthesising the data to generalise findings to a UK relevant population was not justifiable. Furthermore the type and timing of the interventions evaluated were on the whole not comparable between trials; two studies trialled interventions that had been developed for use antenatally and six studies' interventions were for use in the intrapartum period. Furthermore two of the eight studies were an intervention developed for the service provider as opposed to the service user. There was further heterogeneity in the outcome measures that the trials evaluated, and in the standard care control to which the intervention was compared. For all of these reasons, the available evidence was judged to be too heterogeneous to undertake a meaningful meta-analysis that would produce findings that could directly and specifically inform future research. Instead the data produced a descriptive summary of the state of knowledge regarding the effectiveness of interventions for use in early labour.

Table 4: Details of studies included in literature review

Source	Type of Study	Location	Participants	Intervention	Comparison	Key findings
Antenatal interventions						
Scrimshaw and Souza 1982	Non-randomised experimental study	US	162	A booklet called "Understanding Labour" given to women in the last month of pregnancy	No booklet provided	<ul style="list-style-type: none"> - No significant differences in the number of trips to hospital between intervention and control groups - Improved women's understanding of labour and improved communication between women and staff for intervention group
Bonovich 1990	RCT	US	208	An educational technique to prepare patients to recognise labour	Routine group education	<ul style="list-style-type: none"> - Reduced number of visits to hospital in intervention group
Intrapartum interventions						
McNiven et al. 1998	RCT	Canada	209	An early labour assessment	Direct admission to hospital	<ul style="list-style-type: none"> - Reduced duration of labour, decreased epidural use and decreased oxytocin use for augmentation in the intervention group - More positive evaluation of labour and birth experience in intervention group - No significant differences in birth mode rates between intervention and control.
Janssen et al. 2003	RCT	Canada	137	Early labour assessment at home	Telephone triage	<ul style="list-style-type: none"> - Reduced arrival to hospital in early labour, decreased narcotic analgesia and decreased neonatal admission in intervention group - More women would recommend the care to a friend in the intervention group
Janssen et al. 2006	RCT	Canada	1459	Early labour assessment at home	Telephone triage	<ul style="list-style-type: none"> - Reduced arrival to hospital in early labour, reduced preadmission visits to hospital in intervention group - Less likely to be evaluated as not coping with labour on arrival in intervention group - No statistical significant differences in analgesia use, neonatal admission or caesarean section rates between intervention and control groups
Cheyne et al. 2008	Cluster RCT	UK	4503	An algorithm for diagnosis of active labour	Usual care (clinical judgement alone)	<ul style="list-style-type: none"> - No significant differences in oxytocin for augmentation, or other intrapartum interventions between the intervention and control group - Higher number of women discharged from hospital after assessment in the intervention group
Hodnett et al. 2008	RCT	US / UK	5002	An hour of a new structured care approach	Usual care (varying between sites)	<ul style="list-style-type: none"> - No significant differences in maternal or neonatal clinical outcomes between intervention and control group - Improved maternal views of their care in the intervention group
Spiby et al. 2008	RCT	UK	3474	Early labour home visiting	Usual care (varying between sites)	<ul style="list-style-type: none"> - No significant differences in birth mode, methods of care, timing of admission or in any maternal and neonatal clinical outcomes - Decreased number of women with preadmission visit to hospital in intervention group - More positive evaluation of experience - Improved maternal evaluation of experience in the intervention group

3.5.1.1 Antenatal interventions

Scrimshaw and Souza (1982) developed an illustrated booklet to teach women to recognise the signs of active labour so to aid their decision about when to come to hospital. The aim of the resource was to reduce early labour admission and multiple visits to hospital. The booklet was tested in a non-randomised, experimental trial in the US which recruited a total of 162 participants. A total of 64 women received the booklet in their antenatal period (intervention group) compared to the control group of 98 women who did not receive the booklet. Following their birth, 50 women from the intervention group, and 69 participants from the control group were interviewed about their knowledge and decision making processes during early labour using a predetermined set of 36 questions. There was no statistically significant difference between the number of trips to hospital between the intervention and the control group. However those who had received the booklet reported a better understanding of why they were being sent home in early labour and reported to have felt calmer as the book told them “to expect that possibility” (Scrimshaw and Souza 1982, p. 1476). The pictorial booklet was found to aid communication between English-speaking care providers and the participants, who were predominantly Spanish-speaking.

There were a number of methodological limitations with Scrimshaw and Souza’s (1982) study. Firstly, the non-randomised recruitment method inhibits knowing if any noted differences can be directly attributed to the intervention. Furthermore, the published paper lacks detail about the participant selection and recruitment process which makes it more challenging to gauge the validity of any noted differences between the trial arms. Rationale is provided for the decision to use two recruitment time periods (one period for the control group and one period for the intervention group); it was hypothesised that there would be a higher chance of contamination between groups if recruited simultaneously, the two distinct time periods employed are however of differing lengths. Additionally, the intervention and control groups sample sizes are not comparable and there is no detail as to whether there was a target recruitment sample size, and if so, whether these targets were met. Both groups saw a comparable, albeit sizeable “drop out” rate between recruitment and data collection. The paper does not detail what obstetric or medical risk factors are present in both groups and there are no detailed eligibility criteria for study inclusion. This makes it problematic to generalise findings to a UK maternity population, where risk assessment to either a midwifery-led model or obstetric-led model of care remains fundamental to the way care is scheduled and provided. Based on these assessments, whilst the importance of providing information in an accessible way is likely to be of value to women, drawing conclusions

from Scrimshaw and Souza's (1982) paper about the effectiveness of the pictorial booklet is very limited.

Bonovich (1990), similarly to Scrimshaw and Souza (1982), developed an educational intervention with the aim of teaching women how to self-recognise early and active labour. The educational intervention was conducted at 37 weeks gestation and was an interactive session, consisting of routine instructions, between the nurse and the participant using positive reinforcement techniques. The intervention taught individuals how to assess and time their contractions and recognise amniotic fluid. The intervention's effectiveness in helping subjects' recognition of early and active labour was evaluated by recording the number of visits made to hospital. Bonovich (1990) trialled the intervention in a randomised control study in the US on a total of 245 participants; 37 participants were lost to follow up, leaving a total of 208 participants to contribute to analysis (intervention=104, control=104). Those in the intervention group had statistically fewer visits to the labour ward that resulted in discharge, compared to the control arm.

The randomisation methods are not detailed in this paper and so it is difficult to assess the robustness of the recruitment process. Furthermore, whilst participant demographics are detailed and comparable between trial arms, they are less comparable to a UK population and thus generalisability of any findings to a UK healthcare setting is limited. Participants in Bonovich's (1990) trial were notably younger (intervention=21.42 years of age vs. control=21.03 years of age) than women having babies in the UK today who are on average 30.7 years of age (ONS 2020). Furthermore study participants were predominantly of Black ethnic origin and unmarried, although there are no further details as to whether "unmarried" equates to supported or unsupported through pregnancy and birth. The homogeneity of this sample group is a notable limitation. Bonovich's (1990) small trial does indicate that an interactive educational intervention could have the potential to reduce the number of trips to hospital that result in discharge, however further, more contemporary research, in a larger, heterogeneous sample, in a more comparable health care setting to the UK, is needed before any robust conclusions can be drawn.

3.5.1.2 Intrapartum interventions

Between 1994 and 1995, McNiven et al. (1998) conducted a RCT in Canada, comparing varying outcomes between women who were directly admitted to hospital (control=104) against women who were assessed at hospital prior to admission (intervention=105). Women in the assessment group, who were found to be in early labour, were encouraged to return home or mobilise. The trial used cervical dilatation of <3 centimetres to define early labour. The percentage of participants who required oxytocin for labour augmentation was significantly reduced in the intervention group (intervention=22.9% vs. control=40.4%). Likewise, the intervention group saw significantly reduced rates of analgesia use and anaesthesia for pain relief (intervention=7.6% vs. control=20%). Whilst the sample size was not large enough to demonstrate any statistically significant difference in birth mode, a slight reduction in caesarean section rate was noted in the intervention group (intervention=7.6% vs. control=10.6%). Furthermore participants in the intervention group evaluated their childbirth experience more positively than those who were directly admitted to hospital. The inability to conceal allocation of trial arm to practitioners may have impacted on the measured outcomes, particularly as the intrapartum interventions that saw a reduction (i.e. anaesthesia analgesia and artificial oxytocin) rely on practitioners to deliver them.

There was a substantial amount of contamination between trial arms, where 16% of participants in the direct admission (control) group, were actually assessed, found to be in early labour and encouraged home (the intervention). Although the paper is transparent about this contamination, it does not detail how many participants from the control group received an assessment and were then admitted. This pathway of care would also be considered part of the intervention and therefore it is conceivable that a higher percentage of participants in the control group may have actually received the intervention than reported. High levels of contamination in this way can invalidate findings attributed to an intervention. No further large scale studies were undertaken in a similarly robust randomised method, to assess if the differences in caesarean section rates seen in McNiven's (1998) trial were significant.

In a Canadian RCT, Janssen et al. (2003) recruited a total of 237 women in early labour to receive either an early labour home assessment (n=117) or to receive telephone advice (n=120). The primary outcome of the trial was differences in epidural analgesia rates between trial arms. Other clinical outcomes, including timing of admission in relation to cervical dilatation, were also collected. There was no difference noted in epidural analgesia rates between the two trial arms, however participants in the

intervention group were significantly less likely to arrive or be admitted to hospital in early labour, require narcotic analgesia and require neonatal admission. Furthermore, more women in the home assessment group recommended this type of care to a friend. Whilst this trial is limited by its small size and single site recruitment methods, home assessment does present a care pathway which is of likely benefit. Within the intervention group, 22% of participants did not receive the allocated home assessment intervention: being able to staff the labour ward, whilst also providing home visiting in early labour, was cited to be the reason for this. Janssen et al. (2003) did analyse data on an intention to treat (ITT) basis, so to preserve the randomised approach, in spite of the relatively large deviation from protocol.

Following the 2003 trial, Janssen et al. (2006) conducted a larger, multi-site RCT with a sample size large enough to detect differences in caesarean section rates. Participants, like the preceding trial, were randomised to receive either early labour assessment at home (n=728) or telephone triage (n=731). The trial recruited low risk, nulliparous women. The two cohorts were comparable in all demographic characteristics, demonstrating a successful randomisation process. In an effort to address the staffing limitation identified in Janssen et al. (2003) and to promote a higher compliance to allocation, a dedicated cohort of staff were employed to support with recruitment and to run the trial. This was successful where 89.8% of the intervention group received a home assessment and all participants in the control group received a telephone triage phone call as allocated. In order to demonstrate a 20% reduction in caesarean section rates, a total sample size of 1634 participants was calculated to be required (817 in each trial arm).

An interim analysis was undertaken when 50% of the planned recruitment was reached and this analysis did not provide evidence of any difference between trial arms. A futility analysis at the enrolment of 1400 participants recommended that further enrolment should be discontinued because there was no chance that trial would show benefit to either arm of the trial, even if target recruitment was met. Whilst no differences in caesarean rates were noted, like seen in Janssen et al. (2003), significantly fewer women were admitted to hospital in early labour (defined to be 3 centimetres of cervical dilatation) in the home visit group. Furthermore, participants in this trial arm were also significantly less likely to require a preadmission to hospital and significantly less likely to be assessed as “not coping” with their labour on arrival to hospital. Those in the home assessment group also spent on average 50 minutes less time in hospital than

the telephone triage group. There were no differences in analgesia use, augmentation of labour or neonatal outcomes.

This trial was of a high quality, with successful randomisation techniques and an improved adherence to protocol when compared to Janssen et al. (2003). Like the earlier trial, Janssen et al.'s (2006) trial indicates home assessment may present a solution to reduce the number of women who present to hospital in early labour but this was not supported by improvements in the measured clinical outcomes.

A UK based, multi-site, RCT also investigated the impact of early labour home visiting (Spiby et al. 2008). Low risk, nulliparous women, from 11 hospital sites, were randomised to receive an early labour home visit by midwives (n=1759) or standard care in hospital (n=1755). A range of outcomes were measured, including birth mode, labour duration, labour interventions, breastfeeding rates, postpartum health and reported pain 6 weeks post birth, as well as participants' and care providers' experiences.

No statistical differences were noted in birth mode, labour interventions, maternal or neonatal clinical outcomes between trial arms in either the ITT or per protocol analysis. Women in the home assessment arm were less likely to report more than one visit to the hospital in early labour, and were thus less likely to report being sent home. Furthermore, women in the home assessment arm were less likely to report feeling they went to hospital too early. Women in the home assessment arm reported a more positive experience, and more satisfaction with the time at home in early labour. There were no reported differences between groups following admission to hospital in labour. The data collected from service providers showed a positive attitude towards the trial but in spite of this, midwives struggled to accommodate the extra work that home assessment required.

Like seen in Janssen et al. (2003), the compliance to intervention in the home assessment group was lower than had been expected in Spiby's (2008) trial. Of the 1759 participants allocated to the home assessment trial arm, 447 received a home assessment (25.4%); in comparison, 97.9% of those allocated to the telephone triage group received their allocated treatment. The low compliance rates seen in the intervention arm is acknowledged in the paper. Following consultation with service users, women and partners expressed a preference to know their group allocation prior

to going into labour. This meant that a large number of women who were eligible at the point of recruitment (commonly between 34-36 weeks), were no longer clinically eligible when in early labour (n=686, 39%). Furthermore, following consultation with recruitment sites, home assessment could only be provided between the hours of 0800 and 2100 and so participants who made contact with the unit outside of these hours, in spite of their trial allocation, could not receive a home assessment (n=559, 31.8%). The impact that this had on Spiby et al.'s (2008) trial is of note. An additional month's recruitment and a further 1000 participants were required to meet the minimum requirements for analysis. Furthermore, although intention-to-treat analyses were undertaken, per protocol analyses were also required to acknowledge the large deviation from protocol allocation. Whilst an ITT analysis is preferable, to preserve the benefits of the original randomisation, in depth consideration was given to any confounding factors that may have had an impact during a per protocol analysis in this study.

Spiby et al. (2008) was the first randomised trial based in the UK to evaluate the impact of home visiting and is of high quality. Whilst it should be commended for its involvement of service providers and users in the development of the trial's methodology, it was also this that challenged the trial's integrity with high levels of non-compliance in the intervention group. A further limitation is in relation to the homogeneity of the sample population, where although demographic characteristics were well matched between trial arms, 91% of participants in both arms reported their ethnic origin as White British. This limits generalisability to the broader UK population, which is increasingly mixed in ethnicity (ONS 2018). Additionally, more than a third of participants reported to have an educational degree. This demonstrates the participant group in Spiby et al.'s (2008) study were predominately well educated.

In a UK based, cluster-randomised trial across 14 maternity sites, Cheyne et al. (2008) assessed the impact of a decision support tool to assist with the diagnosis of active labour on oxytocin for augmentation of labour, other medical interventions, admission management and other birth outcomes. The algorithm was based on key informational cues, for midwives to use in a stepwise fashion to diagnose labour. Participants were nulliparous, low risk women with a term pregnancy. Baseline data was collected from the 7 intervention clusters (n=1029) and the 7 control clusters (n=1291), and again from both trial arms following the implementation of the algorithm in the intervention clusters (intervention n=896, control n=1287).

No significant difference was found between groups in percentage use of oxytocin for augmentation of labour or in the use of other medical interventions in labour. Participants in the algorithm group were significantly more likely to be discharged home after their first labour assessment and thus the algorithm group had significantly more preadmission visits to the hospital prior to admission in labour. This did not result in less time overall spent on the labour ward. The trial was robust, and the use of a cluster design ensured there was no contamination between the intervention and control arms.

Hodnett et al. (2008) conducted a multisite, RCT evaluating the impact of a structured care package (n=2501) against usual care (n=2501) on birth mode. Other outcome measures included labour interventions, women's views of their care and other maternal and fetal wellbeing markers. Eight hospital sites participated in Canada, 10 in the US and 2 in the UK; a total of 505 health practitioners received training to implement the structured care intervention. The content of the training included normalising the birth environment, palpating fetal position, encouraging optimal maternal positioning, assessing the physical, physiological and behavioural markers for labour, pain management, assessment of maternal emotional status, distraction techniques and emotional supportive techniques.

All participants received a labour assessment as per the hospital's usual labour assessment process; those in early labour who consented to participate were randomised to one of the two trial arms. Recruitment only occurred when both intervention and control care was available and so compliance to allocation was high (96.6% in the structured care group and 99.8% in the usual care group). A recruitment strategy that relies on availability is however at more risk of bias where confounding factors (such as staffing or the time of the day) may impact on availability and thus the wider generalisability of results. There were no statistical differences noted in birth mode, or any other maternal or neonatal clinical outcome between trial arms. Women in the structured care group were less likely to report disappointment with the amount of attention received and from the helpfulness of the care providers.

There are some methodological limitations with Hodnett et al.'s (2008) trial; firstly that the risk of contamination between trial arms is high. This is because the practitioners, who were provided with the training to undertake the structured care package, worked alongside practitioners providing the usual care. Furthermore, trained practitioners could also provide care to women not in the trial. Whilst evidence was provided of adherence in the intervention group, there was no measure of what care was provided

in the usual care (control) group. There is a risk that of the 505 practitioners who received the structure care training, some may have imparted knowledge, either consciously or unconsciously, to their colleagues, who were providing the control group with care. A cluster trial study design, as undertaken by Cheyne et al. (2008), would have been a different methodological approach which would have removed this risk.

Secondly, the reporting of the women's experience data is incomplete in the publication, making it problematic to evaluate the robustness of these findings. In relation to "helpfulness of the nurse or midwife", the paper only reports the percentage of responses that were "(something) other than "very helpful"". Reporting in this way infers that different responses were grouped together. More women in the usual care group responded with "(something) other than "very helpful"", which may imply that more women in the structured care group responded with "very helpful" but in reality the truth in this inference is not known due to lack of transparent reporting. The other metric reporting on women's experiences does not group responses together in this way and instead chooses to only report the number of responses that were "unhappy with (the) amount" of attention from staff. More women in the usual care (control) group provided this negative response but it is unclear as to whether this finding equates to more "very happy with (the) amount" of time" responses in the structured care (intervention) group because this response rate is not reported. It would be more transparent to report all responses. Additionally, a negative response in relation to one of the trial arms, does not necessarily equate to a positive response in the other trial arm. Knowing which intervention women evaluate positively may be more useful for drawing conclusions. This lack of reporting transparency could indicate a bias in favour of Hodnett et al.'s (2008) research hypothesis (i.e. the structured care (intervention) group) but it is not possible to know this with the data provided.

3.6 Discussion

3.6.1 Updated literature search

The updated literature search found one further study for consideration in this review (Williams et al. 2020). An Australian pre and post intervention study of 1274 participants evaluated the impact of an "early labour lounge" on rates of epidural use when compared to rates prior to the lounge's introduction. There was no significant difference in epidural rates but the post intervention group saw an increase in amniotomy, meconium stained liquor and neonatal admission. Whilst the two trial arms were comparable in demographic characteristics, the non-randomised methods

employed minimises the ability to gauge the intervention's overall impact. Women admitted to the early labour lounge actually saw less favourable outcomes than those who received the standard care pathway previously. The standard care pathway had been traditionally assessment and if in early labour encouraged home. This study reiterates the notion that women are not best placed in hospital, because of their increased risk of intervention (Rota et al. 2018, Hundley et al. 2020). Providing women with a designated area did not minimise this risk and it would appear in this study that women will continue to have more favourable clinical outcomes if at home in early labour.

The updated literature search also acknowledged Kobayashi et al.'s (2017) Cochrane review. The 2017 meta-analysis only included studies that had already been identified and included in this literature review (Cheyne et al. 2008, Hodnett et al. 2008, Spiby et al. 2008, Janssen et al. 2003, Janssen et al. 2006, McNiven et al. 1996). Bonovich (1990) was excluded from Kobayashi et al.'s (2017) review because the intervention was for antenatal use and was therefore not eligible for inclusion. Scrimshaw and Souza (1998) was not included in Kobayashi et al.'s (2017) review as was not a RCT so did not meet inclusion eligibility. However Kobayashi et al. (2017) did conclude that future reviews could include a broader range of study designs (as well as RCTs) because they could provide a better understanding of the effects and behaviour outcomes of interventions of this nature. Kobayashi et al. (2017) found that to date, assessment and support interventions have not had a clear impact on birth mode, but may impact on reducing analgesia use and on maternal satisfaction with care. The Cochrane review concluded that further high quality trials investigating support and assessment interventions in early labour were required.

Overall, this review found a lack of conclusive evidence to identify what should be done to address the number of challenges associated with the early labour phase. Predominantly, primary outcome measures have been focused on various clinical outcomes (i.e. birth mode, analgesia use and intrapartum intervention rates), and the timing of admission (i.e. the phase of labour at admission and the number of preadmission visits or discharges). These outcomes are to now be explored in more detail.

3.6.2 Clinical outcomes

None of the studies included in this review demonstrated statistically significant differences in clinical outcomes, with the exception of McNiven et al.'s (1998) small RCT which has never been replicated at a larger scale. In this, the body of evidence in which to draw conclusions about how to best improve clinical outcomes via early labour interventions remains extremely limited and warrants further research. There is a body of evidence suggesting that women have less obstetric intervention if they are not admitted during early labour (Hundley et al. 2020, Williams et al. 2020, Rota et al. 2018), and so remains logical to infer that a labour assessment, prior to admission, to exclude admitting anyone in early labour, would be beneficial. This is the stance that has been adopted as common practice in maternity care (NICE 2017) yet large scale, UK based research to back up this standard care pathway is not available. Whilst a preadmission assessment seems a logical way to address rates of early admission, the provision itself gives rise to further challenge. These challenges include defining the phase (Hundley et al. 2017), establishing how to appropriately care and meet the needs of those women who return home, how to appropriately care for those women who remain in hospital in early labour (Bremner and Neerland 2020) and knowing how, when and where labour assessments should take place (Beake et al. 2018). Whilst the common care pathway of assessment followed with admission, or assessment followed by returning home seems logical, it does not solve all the challenges associated with early labour, in reality, this care pathway is accentuating some of the other problems.

3.6.3 Timing of admission

Women admitted in early labour have an increased risk of intervention (Hundley et al. 2020), and so the timing and number of admissions were a common outcome measure in the studies reviewed. Whilst Bonovich (1990) demonstrated a reduced number of visits resulting in discharge for women who were taught to self-recognise active labour, Scrimshaw and Souza (1982) conversely did not see this difference in a similar, antenatal educational intervention. Both studies were of low quality and the heterogeneity in their findings means there remains a lack of conclusive evidence as to the effectiveness of an intervention specifically developed to teach women to recognise labour phases. This too was the conclusion drawn from a Cochrane review investigating interventions for self-diagnosis of labour (Lauzon and Hodnett 2001). This is not a surprising finding when the continued inconclusiveness of the impact of antenatal education on measurable birth outcomes is considered (Gagnon and Sandall 2007). However the sustained, widespread adoption of antenatal education in high

income countries leads to the impression that women and families desire it, even if its impact on clinical outcomes is inconclusive.

Unpreparedness, uncertainty or possessing unrealistic expectations of early labour, is commonly cited as a reason for dissatisfaction in this phase (Beebe and Humphreys 2006, Cheyne et al. 2007, Carlsson et al. 2009) and therefore looking for ways to prepare and manage expectations seems justified. To concur, those who received the antenatal booklet reported a better understanding of why they were being sent home in early labour and reported to have felt calmer as the book told them “to expect that possibility” (Scrimshaw and Souza 1982, page 1476). Based on this, providing information about early labour, as Scrimshaw and Souza (1982) and Bonovich (1990) evaluated, is unlikely to be detrimental and may instead provide women with a way to be more prepared for the phase, particularly in relation to the timing of their admissions.

All 3 studies evaluating home assessment (Janssen et al. 2003, Janssen et al. 2006, Spiby et al. 2008) found that a labour assessment at home reduced the number of women who required a preadmission visit to hospital. Assessing women at home, rather than in hospital, reduced the number of times women needed to be seen at hospital; further implications of this means that less women were sent home following hospital assessment which is a pathway of care described to be particularly dissatisfactory (Eri et al. 2010). This is unsurprising because home assessment removes the possibility of being sent home and hence the negativities associated with this. Instead, it keeps women at all times, in the environment best evidenced as beneficial during this phase and so whilst clinical outcomes were not shown to have been impacted, home assessment could have a positive effect on how admission to hospital is managed.

Home assessment may however offer a less pragmatic solution for high income health care settings because of the additional staffing resource required to safely operate such a service (Spiby et al. 2008). A lack of appropriate midwife was a common reason that participants from the intervention group did not receive a home assessment (Spiby et al. 2008). The Royal College of Midwives (RCM) estimates that the UK is short of 2500 qualified, working midwives (RCM 2019) and so widely implementing a service that is likely to require more qualified staff may be a challenging solution from a resource perspective. Spiby et al. (2008) undertook a cost effectiveness analysis and was not able to conclude that home assessment was more cost effective overall (hospital care

is often accepted to be a more costly solution with regard to resource, capacity and risk of intervention).

Conversely, an algorithm designed to triage labour in hospital saw an increased number of women sent home following assessment (Cheyne et al. 2007). Whilst it would appear that the algorithm did have the ability to improve midwives' diagnosis skills of early labour (inferred from the higher number of women discharged), surprisingly this did not equate to a reduced length of time spent on the labour ward. This indicates that improving labour triage techniques at hospital does not keep women at home for more time, instead it creates a "revolving door" effect (Cheyne et al. 2007). Furthermore, being sent home when women feel they need to be admitted, regardless of their phase of labour, results in women reporting less satisfaction with their care (Beake et al. 2018, Hosek et al. 2014).

To conclude, home environments may offer a good location for labour assessment, but are likely to be too resource intensive to adopt at a wide scale. On the other hand, teaching women to self-recognise labour may be good for preparing women for this phase but further research is required to gauge the true impact on admission timing.

3.6.4 Experiences and satisfaction

Although primary outcome measures focused on clinical outcomes and admission timing, maternal experience and satisfaction were measured in a number of the trials as a secondary outcome (Scrimshaw and Souza 1982, McNiven et al. 1998, Janssen et al. 2003, Hodnett et al. 2008, Spiby et al. 2008). All the research that evaluated women's experiences saw a more positive experience from participants in the intervention group. There are a number of possible reasons for this. Firstly, that there was a bias during reporting from those women allocated the "intervention". In this, they were allocated to the group with their preferred treatment option and thus evaluated their experiences higher because of this. This is plausible because concealment of allocation was not possible in the studies that evaluated experience, due to the nature of the complex and overt interventions on trial. Similarly, participants may have reported a more positive experience because they believed this to be the "right" thing to say because they knew they had received something other than the standard care pathway and so evaluated this well.

Secondly, participants may have actually provided an accurate evaluation of their care (i.e. their reported experiences were not impacted by their preconceived knowledge of trial arm allocation). This theory would instead demonstrate that women prefer anything other than what is “standard care”, this suggests that current care provisions are not meeting women’s needs. Women may have been pleased to have had some care (i.e. an intervention) during this phase, whether that be education (Scrimshaw and Souza 1982), home assessment (Janssen et al. 2003, Spiby et al. 2008) or structured care (Hodnett et al. 2008). It may be that an intervention of any type is better than no care during this phase. To concur, McNiven et al. (1998)’s intervention (an early labour assessment and discharge) was evaluated more positively than direct admission without labour assessment, and yet labour assessment, as well as being sent home, is consistently evaluated poorly in other literature (Beake et al. 2018, Myhre et al. 2021). In this, perhaps neither intervention nor control is satisfactory and so the need for continued research in this area remains paramount.

Early labour interventions are commonly complex with numerous elements to their makeup and so gauging what specifically improves satisfaction is challenging. For example, women in the home assessment arm of Spiby et al.’s (2008) RCT reported a more positive experience overall. This included more satisfaction with the time at home in early labour, greater feelings of being relaxed, safe, having privacy, being treated as an individual and with respect, a greater feeling of being in control and felt more able to adopt comfortable positions. These reports of satisfaction are not specifically in relation to the home assessment (i.e. the clinical assessment of labour), and instead appear to be evaluating the support, personal interaction and emerging positive feelings that exist distinct from the clinical labour assessment. This notion is supported by the wider literature. Women commonly report uncertainty, doubt and fear leading up to childbirth and so being provided with support and effective communication to help guide their experience is likely to have been what was evaluated as more satisfactory to women in this phase (Borrelli et al. 2018, Beake et al. 2018).

The existing evidence base suggests that women will commonly evaluate any intervention in early labour highly. This indicates that some care is likely to be better than no care or standard care. Furthermore what women do value in early labour, such as information, support, coping technique and reassurance is documented to be important (Christiaens and Bracke 2007, Borrelli et al. 2018, Beake et al. 2018). However the specific methods for improving women’s experiences, by addressing their

reported negativities, remains under researched because primary outcomes in existing studies have instead focused on clinical outcomes and admission timing.

3.7 Literature review conclusion

Considering early labour is a significant, often lengthy and painful, phase of the childbirth continuum (Ängeby et al. 2019), it has received notably less research attention than the active phase. This literature review confirmed this in the narrow number of relevant studies identified for inclusion. The literature review set out to be purposefully broad, to seek the available research of any interventions which had been evaluated to improve the early labour phase, yet only eight relevant studies were identified. On the contrary, there is an extensive breadth and depth of existing and continued research focused on improving safety, experience and outcomes in active labour. Whilst it remains unclear as to why the management of this phase remains under researched, it is suggested that early labour is but a prelude to the “real thing” and that it should be something that women can deal with without input from care providers (Janssen et al. 2009). Yet an increasing amount of recent, qualitative literature detailing the dissatisfaction with this phase (Allen et al. 2020) indicates that this is not true and that further research is needed to address this.

The research that is available is inconclusive, without impact on clinical outcomes. Commonly solving one problem in early labour, gives rise to another. Whilst home assessment may offer a way to reduce the number of women being assessed and sent home from hospital, it is likely to be an unrealistic care provision in an already understaffed maternity service. Instead, research efforts should be directed at evaluating pragmatic solutions to the early labour challenges so that improvements to care can be wide spread, effective and equitable.

3.8 Implications of literature review: an identified gap

The existing literature has focused predominantly on attempting to improve clinical outcomes by evaluating interventions that promote the “right” timing of admission. In this, efforts have concentrated on the point in which early labour becomes active labour and have tried to improve the diagnosis of this specific point. Interventions to date have had little success in making these improvements. In reality, existing interventions have

not looked to improve the early phase of labour at all and have instead concentrated on the transition out of the phase.

Existing research efforts have been driven by what is important to the service, commonly evaluating the appropriation and allocation of labour assessment and triage options. This service-centred approach has prioritised clinical outcomes as the most important measure, and yet by keeping women out of hospital, so to improve these outcomes, women are reporting a huge amount of dissatisfaction and negativity (Cappelletti et al. 2016). A dichotomy exists between what women, and what the service, deems to be of priority. Research to date has been driven by the service's priorities, not by the priorities of those using the service. A recent systematic review found "a positive experience that fulfilled or exceeded... prior personal and socio-cultural beliefs and expectations" (Downe et al. 2018, p1) was actually what mattered most to women during childbirth. In addition, Tunçalp et al. (2015) concluded that women's experiences of maternity care should be considered to be as important as clinical care in terms of achieving desired, individualised outcomes. At present, research efforts have not looked to make positive their experiences of early labour, and may have actually indirectly worsened them by only allowing admission at the "right time". The "right time" for the service, and the "right time" for women, does not appear to correlate. In support, Beake et al. (2018) recommended further research into interventions which could reduce anxiety at the onset of labour.

No research to date has developed an intervention specifically to improve the experiences of women in early labour and if this is not addressed, continuing to keep women out of hospital is unlikely to result in the desired improvement in clinical outcomes. Research is needed to look at a service provision which can better meet women's needs so that they are satisfied with care, rather than the needs of the service. For these reasons, the primary outcome for this research will be women's experiences of early labour.

4.0 Self-efficacy: An underpinning framework

This next chapter will present self-efficacy theory and the rationale for its use as the underpinning framework in which a novel intervention will be developed.

The literature review identified a need to develop and evaluate an intervention specifically aiming to address the dissatisfaction women report with their experiences in early labour. Experience is defined to be the process of doing, seeing and of having things happen to an individual, as well as the impression that the process leaves (Oxford English Dictionary 2010). Thereby improving an experience requires both the actual reality of living through that process to be improved, and also a positive, retrospective evaluation of said process (Hodnett 2002).

4.1 What is a positive birth experience?

A positive birth experience can mean childbirth is remembered as an empowering life event (Nilvér et al. 2017, Lundgren 2005); it can also support the transition to parenthood (Nelson 2003). In this, evaluating the experiences of women should be central to any service improvements in healthcare (Nilvér et al. 2017, Fowler and Patterson 2013, Goodman et al. 2004). A positive experience can broadly be translated to being satisfied (Larkin et al. 2009), but defining and understanding what constitutes measurable satisfaction has been cited to be complex (Perriman and Davis 2016, Bramadat and Driedger 1993). Wieggers (2009) is critical of the term satisfaction because it presents only two options for women to choose between: satisfied or dissatisfied. Predominantly women will choose the former and tend to evaluate their childbirth satisfaction highly using formalised tools (van Teijlingen et al. 2003, Porter and MacIntyre 1984), particularly when asked to complete satisfaction surveys by practitioners directly involved in their care (Sawyer et al. 2013).

To make the valuable assessment of satisfaction even more challenging to extract, many of the tools available in the literature to measure distinct metrics of the childbirth experience paradigm lack complete and vigorous testing (Perriman and Davis 2016, Nilvér et al. 2017). Others argue that there is not such a distinct dichotomy between being “satisfied” or “dissatisfied” and instead it is more common for women to evaluate some aspects of their childbirth experiences satisfactory, and others less so (Hodnett 2002). This is because maternal satisfaction will always be a complex psychological, emotional and social response to not only the maternity care that is received, but also

to the occurrence of a very significant life event and so it remains difficult to define and commonly challenging to interpret (Perriman and Davis 2016).

As per satisfaction theory, Day (1977) defines satisfaction to be a feeling that results after positive evaluation of an experience. More specifically to healthcare, Pascoe (1983, p189) defines it to be:

“The health care recipient’s reaction to salient aspects of the context, process and result of their service experiences... (consisting of a) cognitively based evaluation of grading of directly received services including structure, process, and outcome of services... and an affectively based response”

Pascoe (1983) compared patient satisfaction to job satisfaction theories such as Fulfilment Theory. In this theoretical stance, satisfaction is solely impacted through achieving a desired outcome. Fulfilment Theory assumes that the destination is all that is significant to achieving satisfaction. If this theory were true for childbirth, the only influencing factor on pregnancy and childbirth satisfaction would be a healthy baby. There is some literature to suggest that clinical outcomes do impact on women’s evaluation of their experiences; caesarean birth has been associated with a more negative birth experience (Smarandache et al. 2016, Waldenstrom et al. 2004).

Caesarean sections are often as a result of unanticipated complications in labour and experiencing complications may lessen the control that women feel over their birth experience (Smarandache et al. 2016). Interestingly however, many women who have a caesarean birth express a preference for another caesarean in a subsequent pregnancy (Attanasio et al. 2019, Munro et al. 2017); data suggests that 50% of all caesareans performed globally are elective, with many of these being a repeat procedure (Denham et al. 2019). This strengthens the notion that it is not the clinical outcome that impacts on birth experience but the lived experiences that commonly exist alongside certain outcomes (i.e. a loss of control or distrusting relationship between woman and professional) (Karlström et al. 2015). A repeat, elective caesarean may provide the woman with more control and therefore a preferable experience. This is because women evaluate their pregnancy and childbirth experiences not wholly by outcome, having a baby in the UK is likely to be a safe event resulting in a well-baby, but by their psychological, social and emotional lived experiences that occur during the event (Christiaens and Bracke 2007, Wieggers 2009, Berentson-Shaw et al. 2009, Beake et al. 2018).

In support, whilst neonatal admission has shown to negatively impact women's birth experience (Waldenstrom et al. 2004), Bryanton et al. (2008, p29) found that "being together" with the baby following birth was one of the strongest predictors for childbirth experience. Admission of the baby to the neonatal unit removes this important "together" experience which is the aspect of the event that negatively impacts on experience, not the admission itself. To concur, Lisy et al. (2016) found that parental experiences of baby loss could be improved through health professionals support, communication and shared decision making; demonstrating that even in this tragic life event, where the outcome is undoubtedly negative, experience can be adapted for the better.

Discrepancy Theory attributes satisfaction to deviations between expectation and reality; if expectations of an experience are prospectively low but the reality of the lived experience is positive (or at least more positive than had been expected) then retrospective experience is rated satisfactorily (Linder-Pelz 1982). In support of Discrepancy Theory, a meta-analysis of women's experiences of early labour found the disparity between expectation and reality one of the most frequently cited reasons for dissatisfaction (Eri et al. 2010) and this "expectation versus reality" notion is supported in the wider literature about general childbirth satisfaction (Goodman et al. 2004). Similarly, Expectancy-value Theory postulates that prospective expectations affect satisfaction because they have the power to influence subsequent behaviours which, in turn, impact on outcomes and experience (Eccles et al. 1983).

There is a fairly wide literature base identifying the possible main determinants of childbirth satisfaction. Like described in Discrepancy and Expectant-value Theories, the fulfilment of expectations for labour and birth is highly correlated with satisfaction (Green 1993, Slade et al. 1993, Christiaens and Bracke 2007, Hildingsson et al. 2015, Mei et al. 2016, Preis et al. 2019). Control (of self, the environment, birth atmosphere etc.) is cited commonly as a key determinant of childbirth satisfaction (Lavender et al. 1999, Goodman et al. 2004, Tinti et al. 2011, Jafari et al. 2017) and also control during childbirth provides long term benefit for feeling confident in subsequent pregnancy and birth (Humenick 1981). There is some evidence that others prefer to hand over control to health professionals (Snowden et al. 2011) but in doing so this provides a greater level of control to their personal birthing process. This is closely related to the evidence suggesting that women's perceptions of care, such as being treated respectfully, feeling listened to, informed and empathetically cared for, is pivotal to a satisfactory birth experience (Waldenstrom et al. 2011, Hodnett 2002). The relationship between

satisfaction and labour pain is also discussed in the literature. Some studies suggest that experiencing lower levels of pain is associated with higher levels of satisfaction (Kannan et al. 2001, Lowe 2002). Interestingly however, high levels of labour pain do not necessarily preclude an overall positive childbirth experience (Goodman et al. 2004, Hart and Foster 1997). Hodnett (2002) found that pain itself is not a determinant of childbirth satisfaction unless, like Discrepancy theory suggests, the experience of pain is incongruent to the expectations that preceded the birth. Antenatal anxiety is however a factor negatively correlated with satisfaction (Münstedt et al. 2000, Lemmens et al. 2020).

Broadly, the negative experiences reported to be associated with early labour include feeling under prepared for the reality of the experience, uncertainty surrounding the signs of labour, feeling under confidence and under skilled in coping with pain at home, feeling doubtful of the physiological process, seeking approval, advice and validation from professionals but being denied care and the distress of being sent home (Myhre et al. 2021, Borrelli et al. 2018, Beake et al. 2018, Cappelletti et al. 2016, Eri et al. 2010, Barnett et al. 2008, Beebe and Humphreys 2006, Carlsson et al. 2009, Carlsson et al. 2012, Eri et al. 2011). To continue, Carlsson (2016) found that early labour experiences were commonly associated with a wider feeling of disempowerment, where women did not feel in control or knowledgeable about trusting in their bodies, health professionals or in the physiological childbirth process. These feelings of powerlessness during early labour have been shown to be intrinsically linked to levels of self-efficacy and childbirth satisfaction (Carlsson et al. 2009, Carlsson 2016, Fenwick et al. 2003).

Self-efficacy, as well as being another frequently cited determinant of childbirth satisfaction (Christiaens and Bracke 2007, Berentson-Shaw et al. 2009, Sánchez-Cunqueiro et al. 2018), is documented to be “an important psychosocial variable for understanding how to improve a woman’s experience of labour” (Tilden et al. 2016, p7). In addition, Schwartz et al. (2015, p8) states,

“Increasing levels of childbirth self-efficacy may assist women to approach motherhood more positively, improve their general well-being, impact on reducing unnecessary birth interventions, and improve postnatal mental health”.

4.2 Self-efficacy theory

Self-efficacy, rooted in broader social cognitive theory, is defined as one's belief that one will achieve a desired goal or outcome. Self-efficacy theory proposes that a person's belief in their ability to succeed at a specific task will affect their behaviour (Bandura 1977). Self-efficacy is often used colloquially within the same context as self-confidence; however Bandura (1997, p382) identifies the following difference:

“Confidence is a nonspecific term that refers to strength of belief but does not necessarily specify what the certainty is about... perceived self-efficacy refers to belief in one's agentic capabilities that one can produce given levels of attainment”.

Self-efficacy influences the way one will approach goals, tasks and challenges (Luszczynska et al. 2005). With high levels of self-efficacy, people will put increased, persistent effort into mastery of a specific task and these behaviours are more likely to enable their success. A strong sense of self-efficacy promotes accomplishment and personal wellbeing (Bandura 2010), furthermore higher self-efficacy provides the power to face challenge competently, seeing it as a task to accomplish and master, rather than as a threat to avoid. In this, individuals with high self-efficacy approach challenging situations with the conviction that they can control what will happen and this has been linked to success alongside more positive emotions and lower levels of stress (Ebstrup et al. 2011).

A related construct is Rotter's (1966) “locus of control”, which is the degree to which individuals believe that they have control over their lives, as opposed to external forces controlling their lives. Self-efficacy is the related construct used to describe one's personal beliefs that outcome and performance can be controlled by task and action and moreover that those tasks and actions are achievable (Schunk 1991). As an example, an individual with a strong locus of control will believe that studying hard for an exam will result in high grades (Rotter 1966), an individual with high self-efficacy will also believe in their own capability to study and achieve said high grade (Schunk 1991, Bandura 1977) and so perceived control and self-efficacy are closely related.

Since Bandura proposed his original self-efficacy theory (1977), it has been widely accepted that self-efficacy has the potential to affect human function (Porter et al. 2003) and thus choices affecting health. Physical exercise, smoking cessation, contraceptive use and good dental hygiene are related positively to high self-efficacy (Conner and Norman 2015). Furthermore, a systematic review found that high levels of self-efficacy

following self-management programmes were linked to a higher quality of life for patients following a stroke (Fryer et al. 2016). Furthermore, multi-morbidity primary care patients with low self-efficacy had a lower quality of life compared to those with higher self-efficacy (Peters et al. 2019). In this, self-efficacy can change outcome and emotional experiences.

These positive changes in health are because self-efficacy impacts on behaviour choices; generally individuals choose to undertake tasks where self-efficacy is high and tend to avoid tasks when self-efficacy is low (Bandura 1977). Self-efficacy impacts on motivation (Schunk 1991). Broadly speaking, high self-efficacy will mean individuals make more effort to complete a task and will therefore persist for longer. Shin et al. (2011) saw that improving self-efficacy in weight loss patients equated to a greater weight loss. In this, because they believed they would achieve, participants with higher self-efficacy did achieve. This same impact was also observed in a meta-analysis comparing self-efficacy and smoking cessation (Gwaltney et al. 2009). Self-efficacy levels were modest prior to a quit attempt, and stronger post-cessation. This demonstrates that success and completion of a task is intrinsically linked to self-efficacy; self-efficacy can improve the chance of success and success can heighten reported self-efficacy levels. Conversely however, Poggiolini (2019) did not find such a strong correlation between self-efficacy and smoking cessation, whilst they saw higher self-efficacy linked to a strong intention to quit, this was also related to a negative risk perception (i.e. high self-efficacy in this instance, equated to a lower perception of the risks associated with smoking). This resulted in a weakened intention to quit. Finding the optimum balance of self-efficacy will have the most positive impact on behaviour choices; too much self-efficacy can lead to an overestimation in one's ability to complete tasks, conversely low self-efficacy discourages attempts at tasks at all (Bandura 1977).

4.3 Self-efficacy in pregnancy and childbirth

Importantly, self-efficacy as a contributor to a positive and healthy pregnancy and childbirth is receiving increasing attention. Women with high self-efficacy are able to adapt better during pregnancy (Hui Choi et al. 2012). There is also a strong correlation between fear in childbirth and self-efficacy (Beebe et al. 2007, Lowe 2000, Schwartz et al. 2015). Striebich et al.'s (2018) systematic review of approaches to support pregnant women with childbirth fear concluded that strengthening self-efficacy could relieve fear. Sun et al. (2010) documented that higher self-efficacy during pregnancy reduced

discomfort in the final trimester. Women with higher self-efficacy are more likely to attempt a vaginal birth after caesarean in a subsequent pregnancy (Dilks and Beal 1997, Zhang et al. 2018), whereas a previous negative experience can predict the decision for an elective caesarean (Tschudin et al. 2009, Rostampy et al. 2010). Furthermore, self-efficacy has been shown to be a powerful predictor as to how well women cope with labour: high levels of self-efficacy have been demonstrated to reduce perceived levels of pain in labour (Larsen et al. 2001, Stockman and Altmaier 2001, Sánchez-Cunqueiro 2018), increase the time spent coping without pharmaceutical analgesia (Manning and Wright 1983, Slade et al. 2000) and reduce epidural rates (Carlsson et al. 2015). Larsen and Plog (2012) found women with higher self-efficacy were more confident to ask for analgesia in labour when they needed it. In addition, as already discussed, self-efficacy is an important psychological factor in achieving positive birth experience (Beebe et al. 2007, Tilden et al. 2016), particularly for first-time mothers (Berentson-Shaw et al. 2009).

Self-efficacy is a psychosocial variable which can be strengthened during pregnancy and this may have the power to lead to improved outcomes and experiences (Tilden et al. 2016). In support, a number of existing studies have demonstrated a positive modification in self-efficacy levels. Educational interventions, including digital interventions, during pregnancy have shown to be of benefit to self-efficacy levels (Ip et al. 2009, Rahimparvar et al. 2012, Munkhondya et al. 2020). A recent systematic review concluded that antenatal education interventions can make a significant difference to self-efficacy, in both nulliparous and multiparous women (Timmermans et al. 2019). Gau et al. (2011) found that using a birth ball in labour increased self-efficacy and reduced perceived levels of pain. This demonstrates that self-efficacy is not only strongly correlated to a better childbirth experience, but is also a modifiable factor during pregnancy.

4.4 Modifying self-efficacy

Self-efficacy is the personal perception of external social factors (Bandura 1977, Bandura 1988, Mischel and Shoda 1995) and consequently it is theorised that various sources play in to perceived levels of self-efficacy. Bandura (1977) states that it is possible to increase an individual's level of self-efficacy by influencing these external sources and social factors through personal mastery, vicarious experience, verbal persuasion and emotional arousal. Table 5 provides definitions of these, alongside an example.

Table 5: Definitions and examples of how self-efficacy can be modified (theory from Bandura 1977)

	Definition	Example
Personal mastery	This is the notion that previous success at a specific task will improve self-efficacy in regard to this task in the future. This is a particularly influential source of self-efficacy where repeated success and personal mastery will cyclically increase self-efficacy levels.	Multiparous women, who have had given birth previously, have higher levels of self-efficacy when compared to nulliparous women (Schwartz et al. 2015).
Vicarious experience	This is a method of increasing self-efficacy via the observation or social interaction with others who have successfully completed a task. This can be achieved via live modelling (observation of another's actual completion of a task) or via symbolic modelling (symbolic representation of another's actual completion of a task).	Many breast-feeding peer support groups rely on other people demonstrating success and motivating others to believe they can succeed in their breast feeding journeys (Dennis et al. 2002).
Verbal Persuasion	This means of increasing self-efficacy includes suggestion, encouragement, exhortation and instruction from others or from oneself. This is most successful from influential people held in esteem by the individual; this can be friends, family, teachers, coaches, managers or health professionals.	Positive affirming and supportive language from a midwife whilst in labour has been shown to help women cope with pain and overcome feelings of self-doubt (Leap et al. 2010a). Perceived pain is closely linked with self-efficacy (Larsen et al. 2001, Stockman and Altmaier 2001, Sánchez-Cunqueiro et al. 2018).
Emotional Arousal	The state of an individual's emotional arousal can affect perceived self-efficacy when coping in specific situations. Negative emotions such as anxiety and stress may have a negative effect on an individual's self-efficacy. Learning how to control emotions, as well as using relaxation techniques to cope with these negative emotions, is another way of improving self-efficacy towards a specific task.	As an example, hypnobirthing as a technique for coping with labour has become increasingly popular, and although there is only a small number of studies investigating its effect, women evaluate the ability to remain calm and relaxed positively and there is some suggestion that those who use hypnobirthing techniques will require less analgesia overall during labour (Madden et al. 2016).

4.5 Conclusion

Following the gaps identified in the previous chapter by the literature review, this chapter has drawn together the relevant theories in relation to experience and satisfaction and presented self-efficacy as a key component for improving experiences in early labour. It has detailed the impact that self-efficacy is already known to have in the wider health care context, and has also laid out the relevant literature around the significance of self-efficacy within the maternity setting. It has offered relevant, existing research which has positively modified levels of self-efficacy within maternity, and then drawn upon the relevant theory as to how self-efficacy can be best increased. The next chapter will provide details of how the intervention was developed in line with the self-efficacy theory discussed.

5.0 The intervention

The preceding chapters have demonstrated a gap in current literature and existing early labour services where there has been little focus on women's experiences as the primary driver behind existing interventions. Experience and care satisfaction has been explored and self-efficacy and the theory around its positive modification has been identified as a likely key component for the development of a novel intervention aiming to improve women's experiences of early labour.

The first external and modifiable source of self-efficacy was "personal mastery", the concept that previous success at a given task will result in high levels of self-efficacy. This is supported in the wider literature where multiparous women who have previously had babies report higher self-efficacy (Schwartz et al. 2015) and nulliparous women report more worry (Henderson and Redshaw 2017). Furthermore, nulliparous women are more likely to have a longer early labour phase (Ängeby et al. 2019) and so the concerns with nulliparous women's expectations and subsequent experiences of early labour are not only greater, but by definition cannot be addressed using this internal source of self-efficacy. It is for these reasons that this intervention will be developed for use and evaluation by nulliparous women.

The second modifiable source of self-efficacy is "vicarious experience", the notion that other's experiences and successes can impact on how others feel approaching a specific task so to achieve a specific outcome. Peer support, as a more colloquial term for the sharing of vicarious experiences, is the notion that people can provide emotional support, practical guidance, knowledge, education, social interaction, empathetic assistance to others, sometimes for mutual benefit or sometimes for the benefit of one of the parties (Dennis et al. 2002).

Peer support differs to other types of encouragement as it comes from a comparable or similar person with relevant experience, or a person that has been or remains in the same position as the party receiving the support (Solomon 2004). Peer support is used in health promotion and in the management of health conditions with predominantly positive outcomes and there is evidence that peer support can help people feel more knowledge and less anxious (Dennis et al. 2002). In maternity care, peer support is commonplace in the postnatal period, particularly for breastfeeding women (Kaunonen et al. 2012) and has been shown to positively impact on breastfeeding outcomes (Chepkirui et al. 2020, Oakley et al. 2014, Kaunonen et al. 2012). There is also evidence that peer support can help with the transition to parenthood (Bunting and

McAuley 2004, McLeish and Redshaw 2017) and with perinatal mental health (McLeish and Redshaw 2017, Raymond 2009). Research about peer support techniques or the sharing of vicarious experiences to aid with labour preparation, foster self-efficacy and improve experiences is lacking.

It was decided that the intervention should employ the sharing of vicarious experience from other mothers who have been through early labour already. In support, Beake et al.'s (2018, p82) review states:

“It may be useful to consider how multiparous women’s stories about their labour experiences could be used more widely to support those giving birth for the first time, especially as... women valued support from other women”

The aim of this would be for nulliparous women to receive encouragement, support and advice from multiparous women. In this, they would be receiving support from women that were, from a social perspective, their “equal”, as advocated in the literature (Solomon 2004, Dennis et al. 2002). It was also anticipated that the sharing of experiences in this way would provide a realistic account of early labour, so that expectations of this phase could be better managed, which is widely documented in the literature as one of the reasons women report dissatisfaction (Beake et al. 2018, Eri et al. 2010).

5.1 Intervention timing

The literature review identified both antenatal and intrapartum interventions that had been trialled to make improvements to service provisions in early labour. Employing the vicarious experiences of multiparous women to foster self-efficacy, manage expectations and prepare women for early labour has been documented to be important in the development of this intervention and based on this it was decided that this intervention would be best placed for use in the antenatal period.

This decision for an antenatal intervention was supported by Spiby et al.'s (2008) call for the development and assessment of interventions that “address women’s needs for information and their uncertainties in early labour and potentially modify their expectations” and went on to recommend that the intervention should comprise of “education about signs and events in early labour and psychosocial support” (Spiby et

al. 2008, p199). Education and modification of expectation is best placed prior to labour commencing. To continue, Cappelletti (2016, p198) states:

“Midwives should provide clear information and advice about early labour in order to increase women’s confidence and self-efficacy, and decrease their anxiety and fear”.

Beake et al. (2018) also found that lack of appropriate antenatal preparation meant that nulliparous women did not know what to expect and therefore their experiences did not match with their expectations, which had been formed in the antenatal period.

5.2 Intervention delivery

Formalised antenatal education classes have existed since the 1960s in the UK commonly focused on preparation for labour, birth and the transition to parenthood (Koehn 2002). In recent years, birth partners have also been encouraged to access antenatal education alongside the pregnant mother (Ahlden et al. 2012). Antenatal education aims to increase knowledge around the birth process, promote breastfeeding, raise awareness of public health agenda and foster confidence in pregnant women to successfully give birth and become mothers (Brixval et al. 2015). Over time, the models and delivery of antenatal care have varied but most often classes are provided in groups, which can be beneficial for women looking to meet others expecting babies, so to develop social networks (Fabian et al. 2005).

However, there has been a downward trend in the number of women accessing formal NHS education classes (Henderson and Redshaw 2017). In 2006, 37% of women attended NHS provided antenatal education classes but by 2014, this had dropped to 31% with an increasing number of women seeking private antenatal education instead (Henderson and Redshaw 2017). By 2019, a national maternity survey found less than 30% of women had been offered NHS antenatal education classes and 41% of women offered had chosen not to attend (Care Quality Commission (CQC) 2020). There a lack of research investigating why women are choosing not to access antenatal education classes. This further supports the need to develop antenatal education services that are more acceptable and accessible during pregnancy, to ensure women and birth partners receive evidence based preparation for childbirth and parenthood.

A fall in physical attendance of antenatal education may be because women are increasingly accessing and valuing online and digital information during pregnancy (Lupton 2016). The internet has transformed the way information is gathered (Harpel 2018) and it has become the easiest source to access health related information and education (Daniels and Wedler 2015). According to the ONS (2019), more than 99% of all adults less than 44 years of age are now accessing the internet every day and 91% of this population is accessing the internet on-the-go, via smart phones or other portable devices. Based on these data, pregnant women are within the age demographic most likely to be using the internet every day to access information.

In line with this, studies have shown that almost all women are accessing health information during their pregnancy, with the main reason cited to be the need for more knowledge (Bert et al. 2013, Bernhardt and Felter 2004). Pregnant women gather online information to gain reassurance about the normalcy of their pregnancy (Song et al. 2012) as well as information about birth (Weston and Anderson 2014). Women who were pregnant for the first time were also more likely to look for this information (Sayakhot and Carolan-Olah 2016). In a recent review, “delivery stages” (i.e. the phases of labour and birth) were identified as one of the most common topics of interest (Javanmardi et al. 2018). Using the internet allows pregnant women to find answers to their queries quickly and anonymously which is seen to be advantageous (Bert et al. 2013). Seeking online education has also been reported to be virtuous for personal and peer support; it can reduce personal anxiety, promote personal relationships and foster positive energy between new mothers, particularly if they receive knowledge from each other and shared forums online (Javanmardi et al. 2018).

In spite of it being a popular means for women to seek pregnancy related education, health information accessed online is not reliably accurate (Eysenbach et al. 2002, Kunst et al. 2002) yet many studies indicate that women are trusting of it (Gao et al. 2013, Sayakhot and Carolan-Olah 2016) and predominantly they do not choose to speak to their health care providers about the information they acquire (Sayakhot and Carolan-Olah 2016). In light of this, there is a great need to provide accurate and reliable online information, to ensure women and birth partners are accessing true, realistic and valid resources (Sayakhot and Carolan-Olah 2016, Javanmardi et al. 2018).

Beake et al. (2018) reports a growth in websites that report women’s pregnancy and birth stories and personal “mum blogs” yet this information can be misleading and can

also paint a negative picture of childbirth which would be detrimental to nulliparous women, their self-efficacy and subsequent experiences. The same review concludes a need for further research on the impact of web-based information on women's approaches when early labour commences (Beake et al. 2018)

For all of these reasons, the intervention was developed to be an educational, antenatal resource for use on an online platform.

5.3 Co-creation of the web intervention

5.3.1 Background to co-creation

The literature review identified that existing early labour research has traditionally focused on the priorities of service providers and not on the priorities of the women using the service. Furthermore, as detailed in Chapter 4.0, self-efficacy can contribute to a positive childbirth experience and is modifiable using others' vicarious experiences. For these reasons, the intervention was co-created by women who had previously used the maternity service so that the intervention had the strongest potential to positively impact other women's experiences of early labour.

Co-creation is defined as the collaboration between researchers and stakeholders (Greenhalgh et al. 2016). They work alongside one another to ensure research aims and service developments are well aligned to provide significant and valuable societal impact (van Dijk-de Vries et al. 2020). A key stakeholder is the service user (i.e. the woman and her family), who has traditionally been a passive receiver of health care but is now receiving increasingly more traction to be "co-creators" of the health services they use (Zhang et al. 2015). In this pragmatic approach, health care services are designed according to the need of the public, and therefore perform more efficiently and serve more effectively (Spanò et al. 2018). The co-creation methodology has been widely implemented by businesses during product development (Ind and Coates 2013), to ensure private sector output meets the needs and preferences of their consumers, so to generate maximum revenue (Voorberg et al. 2015). Whilst a newer concept in healthcare research, it is becoming an increasingly popular, collaborative approach (Greenhalgh et al. 2016, Bucknall and Hutchinson 2021).

Patient, public and participant involvement (PPI) has commonly held a fundamental role in health research in ensuring research is conducted "with" the public rather than "for"

or “about” them (Bagley et al. 2016, Renedo and Marston 2011). It seeks consultation with public members to make pragmatic decisions about discreet aspects of research methodology ensuring it is conducted in an ethical way producing relevant knowledge (Bagley et al. 2016). However the notion of co-creation goes further than traditional PPI, instead demanding a shared power between the researcher and the public; here the public can influence the direction that is taken, rather than commenting on the direction after it has been taken (Kaisler and Missbach 2020). Involving the public in the development of research has been shown to result in higher quality studies (Staley 2009). However it is not without challenge; it is acknowledged that clear outcomes and objectives are required throughout the co-creation process to ensure that stakeholders and researchers can address gaps in knowledge and the service successfully, whilst still being led by the priorities of the public (Bagley et al. 2016, Leask et al. 2019).

5.3.2 The co-creation process

Women who had previously experienced being at home in early labour were asked to participate in the co-creation process. They took part in videoed, semi-structured interviews, where they were offered the opportunity to speak about their experiences of early labour and offer support, advice and realistic coping techniques for first time mothers facing this aspect of childbirth in the future. The interviews identified key concepts and education topics to directly shape the content and layout of the web intervention. The videoed responses were embedded in the web intervention as vicarious experiences, to foster self-efficacy, as previously discussed in Chapter 4.0.

This co-creation process meant the content, focus and information of the online, antenatal intervention was shaped by the mothers who had previously experienced the maternity service. This ensured the content of the intervention was grounded in real-life, vicarious experience therefore having the strongest potential to benefit the study population and public thereafter (Staley 2009).

5.3.3 Seeking volunteers for the co-creation process

To actively engage relevant women (women who had previously used the maternity services) in the intervention’s co-creation process, a decision was taken to seek volunteers rather than use lay members known to the university; the latter might be considered more knowledgeable in research having participated in a number of studies but would be less representative of the intended target group of the intervention.

Following ethical approval from the researcher's University (see Appendix 2), a breastfeeding peer support page on the social media platform, Facebook, was used with the administrator's permission, for women to self-identify as being interested to receive further information about contributing to the creation of this intervention. Facebook is a platform commonly used by women to share pregnancy experience and advice (Harpel 2018). On this page, an open link to an online, secure survey took those interested to some eligibility screening questions (a. Have you had a baby in the last 10 years? b. When in labour, did you spend any time at home?) (see Appendix 3). Those who screened positively to both questions were given further information and then the choice as to whether they wanted to supply their contact information (an email address and telephone number).

Self-identification was deemed the most ethical method, allowing women to voluntarily seek involvement in the co-creation process. The response rate was high, with 116 individuals taking the survey within a 48 hour period. This not only demonstrated the acceptability of the volunteer recruitment process, but also likely indicated the importance of the research topic to previous service users. The response rate also implies a readiness for women to share their birth experiences with other women, a notion which has been echoed in the literature (MacLellan 2020, Munro et al. 2009). Of the 116 who took the survey, 106 answered "yes" to both the eligibility screening questions. Of this sample, 86 women chose to supply their contact details. Only one woman who chose not to share her contact details provided a reason for this decision, which she listed as "2 babies (and) too busy".

All 86 potential participants were emailed a Participant Information Sheet (PIS) (see Appendix 4) detailing what was required from them in the web intervention's creation. Anyone who did not wish to receive any further correspondence was given the option to opt-out at this point. The researcher made telephone contact, at a convenient time specified by the potential volunteer, as an opportunity for them to ask questions about their involvement. Of the 86 women contacted, 18 women consented via the telephone to participate (68 women either declined to consent or were not contactable). Those who had verbally consented were given an interview time of their convenience. Interviews were carried out in a private, confidential room in a local community hall. Of the 18 women who were verbally consented, 10 confirmed that they would be attending their interview. On arrival to interview, participants were given further opportunities to ask questions and were encouraged to re-read the PIS. All volunteers were asked to

sign a consent form (see Appendix 5) and as the interviews were to be video recorded and published online, a media release form (See Appendix 6), which had been developed in partnership with the Media Department at the University, was provided and signed.

5.3.4 Recording vicarious experiences of early labour

Participants knew they were able to suspend or stop the interview at any point, without giving reason, but no one felt the need to do this. Those that brought babies and children with them were able to attend their needs throughout the interview. Interviews were semi-structured, using open ended questions (see Appendix 7). Interviews lasted approximately half an hour with each volunteer.

To facilitate the recording of the interviews, a second midwife was present with the interviewees' permission. A midwife was deemed the most appropriate person to support in these recordings as had a good understanding of the potential emotional and sensitive subject areas that were in discussion. Additionally, as per the Nursing and Midwifery Code (NMC) (2018), this midwife had an appropriate knowledge of the importance of confidentiality. Video recordings were kept on a password protected university computer.

Some women declined to take part in these interviews because they did not feel comfortable being video recorded. It was recognised that using only women who felt confident to appear on camera was likely to hinder the authenticity of the co-creation process and resulting intervention. The co-creation process had aimed to realistically represent the priorities of all service users. To counteract this recognised limitation, an online, written questionnaire was distributed to those who wished to contribute but did not wish to be videoed. This broadened the sample group as a further 15 participants shared their early labour experiences in writing (alongside the 10 who were video recorded). Consent was granted for the use of these experiences as anonymised, written quotes on the website.

The interviews and written responses gave rise to 15 themes (see Figure 2). The videos were edited together by these identified themes.

Figure 2: Themes identified from co-creation interviews and written responses

<i>Subheadings identified</i>	
<ul style="list-style-type: none">• What it feels like to be in early labour• Being at home in early labour• Preparing for early labour• Eating and drinking• Positioning• Breathing techniques• Using water	<ul style="list-style-type: none">• TENS• Distraction• Hypnobirthing• Massage• Reminders from birth partners• The presence of birth partners• Positive thinking• Positive words

For ease of navigation around the website, the 15 themed videos were placed on the related five subpages:

- 1) Home page: Let's Talk Early Labour
- 2) How can I prepare for early labour?
- 3) What shall I do in early labour?
- 4) How can my birth partner support me in early labour?
- 5) A final word...

5.3.5 Validating the web intervention

5.3.5.1 Validation with co-creation contributors

To ensure the edited videos represented the original contributors' messages, and to validate the subheadings identified by the researcher, those women who had been videoed were provided the opportunity to view the edited videos. This also gave the opportunity for the content to be viewed prior to being published online in the public domain. Prior to their interviews, participants were informed that once the videos had been previewed, validated and published online that withdrawing their participation and videos could only be reviewed on a case by case basis. Furthermore even this could not guarantee the removal of the material from the public domain, which would be outside of the researcher's control. This information was provided on the PIS (see Appendix 4).

Two preview dates were set up at the local maternity hospital, one in the day and one in the evening, to maximise the number of women who could attend at their convenience. All women were satisfied that the videos were representative of their experiences and agreed the subheadings were a good depiction of their early labour

experiences. All women consented to the publication of these videos onto the web intervention.

5.3.5.2 Validation with public involvement review panel

Following the creation and validation of the subheadings and related videos, written content was developed in line with the subheadings to add depth, context and explanation to the video content. This was in line with the existing early labour evidence base, and fell in line with national guidelines (NICE 2017).

To validate and ensure the web intervention's written content was received as intended, and to ensure the safety of future participants in the trial of the intervention, a public involvement review panel meeting was set up at the hospital. Service users (from the Trust's Maternity Voices' Partnership (MVP)) who had had no involvement in the website's development attended, alongside local obstetricians, midwives and an academic researcher from a separate University to that of the researcher. The public involvement review panel deemed the content to be evidence-based and in line with local and national guidelines. Furthermore the panel concluded that the advice was clear, accessible and concise and that the subheadings gave rise to ease of navigation around the intervention. Feedback on the written content was also sought independently from the local Consultant Midwife who specialises in intrapartum care. The public involvement review panel requested one amendment to the intervention where the term "early labour" was deemed to be misleading when viewed without a clear definition. Some of the panel felt "early labour" could be confused with "premature labour" where advice would be different to that published on the website. Therefore a clear definition, on the first landing page of the intervention, distinguishing between the two terms, was added in response to this feedback to promote safety to research participants and the public thereafter.

5.3.5.3 Validation with experts in the research field

Once the web intervention had been developed, it was reviewed in its completeness by a review panel of two experts in this research field (see Acknowledgements); both experts are members of the International Early Labour Research Group. This was to ensure that the web intervention was safe, fit for purpose, in line with existing evidence and peer-reviewed prior to publication. The feedback was positive in relation to the intervention as a whole with specific positive mention to the vicarious experience videos, the subheadings and the content. There was feedback about specifying when

women should be concerned about their baby's movement and so this information was updated. It was advised that the font headings should be "bigger and more interesting" and so this too was adapted prior to its publication.

5.4 Building the website

Graphics for the website were drawn and computerised by a midwife from the local NHS Trust (see Acknowledgements) to ensure original images without copyright issue. Effort was made to ensure these images were diverse and representative of a large demographic of women so the intervention was inclusive. Furthermore it is well evidenced that black and minority ethnic groups are underrepresented in research (Smart and Harrison 2017). See Figure 3 below, which is the graphic used in the logo for the trial and intervention.

Figure 3: Example of an original image (used as the trial's logo) developed for the intervention



The web intervention was then put together by a professional website developer, who had previous experience in developing NHS webpages and supported with the technical side of hosting the web intervention (www.letstalkearlylabour.org).

5.5 Chapter conclusion

This chapter has presented the development of the novel, web intervention. It has demonstrated why the intervention was developed as an antenatal, education tool so to better prepare women to cope in early labour. It has detailed the co-creation process, and documented why it was developed using existing self-efficacy theory. It has illustrated why an online tool, was the most appropriate for the service users of today. Lastly, it has provided details of the safety and ethical considerations that were made during the development of the intervention, and the validation process that was undertaken prior to publication.

The web-based intervention now requires evaluation, to understand its impact on women's early labour experiences. In doing this, it will be possible to understand how the intervention may contribute to the wider research field, and look to address the gaps identified in the literature review.

The next chapter details the methodology of The L-TEL Trial which aims to evaluate the novel web-based intervention described.

6.0 The L-TEL Trial: research methodology

6.1 Introduction

The literature review outlined in Chapter 3.0 identified a gap in existing early labour research: existing studies have focused to improve outcomes by developing and testing interventions that promote the “right” time for admission. These efforts have concentrated on the point in which early labour transitions into active labour. This service centred approach has not recognised women’s experience as a key outcome measure in early labour interventions. Chapter 4.0 examined self-efficacy as a modifiable factor that can positively impact on birth experience and, in line with this framework; Chapter 5.0 detailed the development of a novel, co-created web intervention. To establish if the web intervention has addressed the identified gaps, it requires appropriate testing. This chapter looks to present the methodology of the L-TEL Trial, the trial which aims to test the novel web intervention so to establish if it can improve women’s experiences of early labour.

This chapter starts by presenting the theoretical framework in which the L-TEL Trial was developed. A peer-reviewed publication of the L-TEL Trial’s study protocol (Edwards et al. 2019) is then presented. The chapter then goes on to discuss the rationale and theory behind the pragmatic, experimental design and randomised approach that was adopted. The research setting and population is introduced and discussed, as well as the recruitment strategy and methods of data collection.

6.2 Research philosophy

The trial and research methodology sits within the positivism paradigm. Positivism is the theory that:

“knowledge is statistically generalised to a population by statistical analysis of observations about an easily accessible reality” (Sobh and Perry 2006, p1195).

The L-TEL Trial aimed to generate new knowledge about how the web intervention impacts on nulliparous women’s experiences by taking a representative sample, observing the outcome of the intervention on this sample, in order to statistically analyse and generalise findings to the wider population. The paradigm is useful in the investigation of cause and effect. Specifically for this trial: does the web intervention (the cause) lead to improved early labour experiences (the effect).

6.2.1 A pragmatic approach

The web intervention was evaluated using a pragmatic RCT. The important distinction in adopting a pragmatic approach is to value the difference in trials which measure efficacy of an intervention under laboratory conditions, against those that evaluate effectiveness in the real world (Weinfurt et al. 2017). Both approaches offer new knowledge against accepting or rejecting hypotheses, but a pragmatic approach provides this knowledge already in the context of the real world and existing clinical practice (Patsopoulos 2011). A pragmatic approach constructs the research methodology in the existing reality, as opposed to constructing a new reality for the conduct of the research (James 2017). With consideration of this, it was prudent to adopt a pragmatic approach to evaluate efficacy of the intervention in existing clinical practice as, if effective, it could be widely adopted at the end of the trial period. The L-TEL Trial applied pragmatism in the research setting and the protocol's non-prescriptive use of the intervention, both of which are discussed in more detail later in this chapter.

6.2.2 A randomised design

RCTs are considered the gold standard of experimental research and the most rigorous design in determining effectiveness of a new intervention (Hariton and Locascio 2018). By definition, the design relies on randomly allocating participants to a new intervention (the intervention group) or another form of care (often the existing model) (the control group). The groups are followed to gauge the effectiveness of the new intervention and outcome data are collected to statistically assess any difference in response between the groups. Randomisation is used to reduce the risk of bias and spurious causality as the random allocation minimises confounding factors (both observed and unobserved), meaning the likelihood of the intervention being responsible for any statistical difference in outcome is high (Levin 2007). It is for these strengths that the RCT methodology was best suited for evaluating the web intervention. In addition, non-random methods of allocation cannot offer the attribution of any difference between study groups to the intervention being trialled. Ideally participants, care givers and researchers should not be aware of participants' allocation, as this information could create conscious or unconscious biases (i.e. biases with trial group selection and outcome performance or detection) (Mansournia et al. 2017). In spite of this, it is not always possible to conceal allocation in trials particularly in those that look to assess an intervention with an obvious allocation (i.e. one group receives something and one group does not); this was the case for the L-TEL Trial. A peer-reviewed publication of the L-TEL Trial's study protocol is now presented.

6.3 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. Ethical approval was granted on 15 October 2018 by the local research ethics committee and study approval by the Health Research Authority.

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 bench marker 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 trialing 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 is 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 (Sayakhov 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 through 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 (Staley, 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 using the same questions as were asked at the interviews. 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 Topics identified by previous service users

- 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 for a similar scale, the Labour and Delivery Satisfaction Index

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

(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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6.4 Trial arms

Participants were randomised to either the intervention group or the control group. Flaws in a study's methods, particularly in the randomisation, can invalidate the results of a RCT. Effective randomisation is one of the defining features of a quality RCT requiring transparency and adequate reporting surrounding the study's recruitment process (Schulz et al. 2010). Randomisation for the L-TEL Trial was undertaken via an independent, online randomisation service (www.sealedenvelope.com). An advantage of online randomisation is the assurance that the randomisation process is transparent and has not been amended by the research team. A fully automated randomisation system, based on concealed computer generated random numbers offers a true, unbiased randomisation technique. Random, permuted block randomisation (of 4, 6 and 8) was used to ensure groups were balanced periodically in the small sample group required for the trial. The computerised, randomisation service did not reveal details of these blocks.

The intervention group received a link to the web intervention (details of this intervention are discussed in detail in Chapter 5.0) and also continued to receive the standard care available. The control group did not receive the intervention and continued to receive the standard care available. Standard care included routine midwifery care and advice, and any formal or informal antenatal education that may have been sought by participants. Data were collected in relation to any additional sources of early labour advice that were used.

6.5 Data collection

6.5.1 Primary outcome and outcome measure

The need to evaluate interventions in the context of women's experiences has already been documented and justified in Chapter 3.0. A self-report questionnaire for an experience based evaluation was deemed to be the most accurate way of measuring the primary outcome. Based on this, the primary outcome for this trial was chosen specifically to be women's affective experiences as determined by the scores of the pre-validated, self-reported ELEQ (Janssen and Desmarais 2013a) measured at 7-28 days following birth (see Appendix 8).

The questionnaire was identified as the most suitable tool for the evaluation of this intervention as was the only tool identified to have been specifically developed for self-evaluation of the early labour phase. Furthermore the tool had been developed and piloted on nulliparous women, as was the sample population of the L-TEL Trial. Other tools, prior to the selection of the ELEQ were reviewed (Labour and Delivery Satisfaction Index: Lomas et al. 1987, Intrapartal care in relation to WHO recommendations: Sandin-Bojo et al. 2008, Patient Perception Score: Siassakos et al. 2009) but all were asking for an evaluation of the entire labour and birth, where the L-TEL Trial was looking to focus uniquely on the experiences of the early phase.

Items for the ELEQ were developed in a pilot survey (which included a number of open ended questions prompting qualitative responses) and the existing early labour literature. Clinical experts and an interdisciplinary team examined the initial list of items for face and content validity. The qualitative responses were used to adjust the items to further improve construct and content validity. The questionnaire was then trialled within a population of nulliparous, low risk women (Janssen et al 2003) and was found to have good internal consistency (Cronbach's $\alpha=0.80-0.87$) in regard to both the total score and the individual subscale scores (Janssen and Desmarais 2013a). There was good item homogeneity with subscale scores and with the overall score, and scores were interrelated in the expected direction. Furthermore, participants made use of the full range of scores, suggesting good variability and distribution at item level. Comparison between trial groups within the pilot study offered support for criterion and construct validity. Test-retest reliability was not evaluated. It is theorised that this is because test-retest reliability measures the stability of a score within the same person on separate occasions and a retrospective evaluation of an experience may not remain constant or stable within an individual over time.

The ELEQ contains 26 self-report items, rated on a 5-point Likert scale and has been developed to measure women's affective experiences of early labour. During the questionnaire's development, 3 subscales were also defined from these measures: emotional wellbeing (8 items), emotional distress (6 items) and perceptions of nursing care (8 items). There are a further 4 items within the ELEQ to be used for the total score but not within the subscales. A higher ELEQ score is representative of a more positive early labour experience so scores for the emotional distress subscale, and any other items reporting on negative experiences, were reversed, as seen and recommended in Janssen and Desmarais (2013b).

Permission to use this tool was granted by the authors (see Appendix 9), as was some minor modification to the wording of some of the questions. The word “nurse” was changed to “midwife” to better suit the UK model of maternity care. Furthermore, one of the questions specifically looked at whether the nurse spent enough time at home with the woman. Permission was granted to modify this question to be in relation to the time spent on the phone, as home visits did not form a part of this trial. Additionally, a question about the doctor’s care and team work was adapted with permission because the women eligible for inclusion were low-risk and may not have had any contact with obstetric doctors whilst in labour. Further author permission was also granted to convert the questionnaire into an online format so participants could complete this at their own convenience without the need for physical postage, thus minimising the impact on participants who were caring for newborn babies at the time of this data collection.

6.5.1.1 Hypothesis

It was hypothesised that the intervention group would report a more positive early labour experience, with a statistically significant higher mean overall ELEQ score when compared to the control group.

6.5.2 Secondary outcome measures

Since admission to hospital in early labour is associated with labour and birth with a greater risk of obstetric and medical intervention, secondary outcomes were also collected from both trial arms (birth mode, birth place, onset of labour, augmentation of labour, analgesia use in labour, neonatal resuscitation at birth, feeding method at discharge and phase of labour at admission.). The L-TEL Trial was not powered to note statistical differences with these outcomes.

To reach a consensus as to what constitutes “normal birth”, the Maternity Care Working Party (MCWP) defined it to be:

“women whose labour start spontaneously, progress spontaneously without drugs, and who give birth spontaneously” (MCWP 2007, p. 3).

This definition should exclude women who have received regional anaesthesia (i.e. epidural or spinals). The WHO adds that the mother and baby should also be well in the postpartum period (WHO 1997).

Based on the MCWP (2007) and WHO (1997) definitions of normal labour, some key variables from the collected secondary outcomes were tested in line with these definitions as presented in Table 6.

Table 6: Secondary, key variables for testing alongside a definition

Definition	Secondary outcome variable tested
“Women whose labours start spontaneously...” (MCWP 2007)	Onset of labour
“...progresses spontaneously...” (MCWP 2007)	Augmentation of labour
“and who give birth spontaneously” (MCWP 2007)	Birth mode
Exclude women who received regional anaesthesia (MCWP 2007)	Regional anaesthesia analgesia
Mother and baby should be well in the postpartum period (WHO 1997)	Neonatal resuscitation

As the L-TEL Trial was aiming to improve women’s experiences of being at home in early labour, collecting and testing about the timing of admission was deemed to be important for this field of research. For this data, active labour was defined on the hospitalised system as cervical dilation of 4 centimetres or more. This was in line with the local guideline and national guideline (NICE 2017).

6.5.3 Some qualitative context

In order to determine usability and acceptability of the intervention, as well as how women had sought their information about early labour, some questions were added to the postnatal experience questionnaire to add context and depth to the L-TEL Trial’s findings. It was proposed that this would add value to the contributions to the existing evidence base.

6.6 Trial setting and participants

The trial was undertaken at a single NHS Trust site in the south of England. The host Trust offers comprehensive maternity care and tertiary level neonatal care. Depending on risk, mothers can choose to have their babies on the labour ward, in an alongside birth centre or in a co-located birth centre. As standard, all women have the opportunity

to attend face to face, group antenatal education classes. There is a designated, telephone triage service for taking labour calls.

The generalisability between the trial population and the wider intended population must always be considered during the development of RCTs. Participants that consent to taking part in research may not accurately represent the population that would eventually use the intervention in the real world (Erves et al. 2017). This is a common limitation across clinical research. In response to this limitation, for complete transparency, this trial reported the participants' demographics for comparison.

The full eligibility criteria for participant inclusion are detailed in the integrated paper, Edwards et al. (2019). Pregnancy and the subsequent birth are commonly divided into two succinct obstetric risk categories: "low-risk" or "high-risk". As pregnancy or labour progresses, this categorisation may change as new risks emerge or decrease. Women that are assessed as low-risk are safe to receive care solely from a midwife, without input or care-planning from the medical or obstetric team. The L-TEL Trial aimed to investigate the impact of the web intervention on low-risk women, defined as per local guidelines. This is because the evidence for women remaining at home during early labour has commonly focused on those with low obstetric risk, furthermore, high-risk women are more likely to require closer monitoring and in light of this it may not be appropriate for them to remain at home in this phase. Therefore providing them with this intervention was deemed as inappropriate and potentially unsafe.

The hospital offers "needing extra support teams" (NEST) for geographically identified women who require the benefits of midwifery continuity of carer. These women are often from socially vulnerable backgrounds and receive a slightly more individualised pathway of care from a specific team of midwives. Women who receive their antenatal care from the NEST do not call the usual telephone triage service for telephone assessment; instead this is done by the midwives caring for them. Additionally, if appropriate, the midwives may visit the women during early labour in their own homes. In light of this, much of the advice and information on the web intervention was deemed as not suitable for women being cared for by NEST. For this reason, these women were not eligible for participation in the trial.

6.7 Power calculation and sample size

A power calculation was undertaken with support from a University statistician to establish a recruitment target figure suitable to measure the desired primary outcome, the total ELEQ score. In relation to women's experiences, a 10% difference is documented to be clinically meaningful for a similar scale, the Labour and Delivery Satisfaction Index (Lomas et al. 1987), for which the ELEQ was compared for construct validity (Janssen et al. 2003).

A sample size of 70 (35 in each group) was calculated to be required to detect a 10% difference in scores (111.80 vs. 101.64, as found by Janssen and Desmarais 2013a) based on a standard deviation of 12.84 (Janssen and Desmarais 2013a), a two-sided significance level of 0.05 and 90% power. To allow for 20% to not contribute to the primary analysis (Sackett et al. 2000) via attrition during follow-up, an additional 14 participants were required for recruitment.

Induction of labour (IOL) is the process of artificially starting labour before it naturally occurs. Participants who undergo an IOL will not have spent time at home in early labour so are unable to contribute to the primary analysis with an ELEQ response. At the time of undertaking the power calculation in 2016, national data estimated that approximately 27.9% of all births were induced (NHS Digital 2016) and data from the research site found 24% of women underwent an IOL. Taking consideration for the obstetrically low-risk sample group (assumed to have lower rates of IOL) a sample size of 100 participants was calculated to be required (50 in each trial arm).

This figure was deemed achievable as there was estimated to be approximately 80 eligible women per month at the research site. The recruitment period was anticipated to be 10 months.

6.8 Ethics approval

"Research ethics govern the standards of conduct for scientific researchers. It is important to adhere to ethical principles to protect the dignity, rights and welfare of research participants," (WHO, ca 2021).

Ethical considerations were made throughout the planning and implementation of this research trial. Verbal and written informed consent were sought, where participants were fully aware of the risks and benefits of taking part, this information was also provided in writing as a PIS. It was made clear on the PIS and by the researcher when taking consent that the hypothesised positive outcomes were yet to be proven. No care was removed from any participant. Women involved in the trial were encouraged to pragmatically use the intervention so to minimise any burden of being involved in the trial. Additionally, all correspondence, except the first phone call, was carried out electronically at the convenience of the participant, again to minimise the burden on the research participants.

Ethical approval was sought and granted on 15th October 2018 by the local research ethics committee and study approval by the NHS Health Research Authority (HRA) (see Appendix 10).

6.9 Amendments

During preliminary data collection, it was noted that IOL rates in participants was substantially higher than anticipated. Although rates vary across the UK, it is accepted that the number of women undergoing IOL has increased quite substantially in recent years. By 2019, at the time of data collection, 33% of all labours are reported to have been induced (NHS Digital 2020). However it is likely that, this figure has risen higher still; a report into women's experiences of maternity care found 44% of respondents to have had an IOL in 2019 - 2020 (CQC 2020).

Based on this, a substantial amendment was approved (see Appendix 11) during the trial to increase the recruitment target to 140 (70 in each trial arm) to ensure that there was enough participants to contribute to the primary analysis. A further non-substantial amendment was required to extend the trial period by 2 months in order to reach this recruitment target (see Appendix 12).

6.10 Recruitment processes

6.10.1 Identification of eligible participants

Local data predicted approximately 80 women would be eligible for participation in the LTEL Trial per month (booking obstetrically low-risk and nulliparous). Two methods of

recruitment were employed: identification of participants via their community midwives and self-identification to the researcher. A successful recruitment process, which provides strong external validity, looks to enlist a varied research sample who ideally will represent the wider population of individuals who may be impacted by any research findings (Lavrakas 2008). It was anticipated that employing two distinct methods of recruitment to the L-TEL Trial would maximise the number of women who were given the opportunity to participate; thus providing a higher probability of enlisting a wider variety of participants. Two methods of recruitment aimed to reduce any recruitment biases that may have been seen with practitioner recruitment alone. These biases may have provided individuals who were believed to have been more likely to participate, more opportunity for recruitment. To counteract this, the trial was publicised for individuals to self-identify to the researcher for participation via posters in the antenatal clinics (see Appendix 13), scanning department and on the maternity service birth centres' social media pages (Facebook). It was also acknowledged that self-identification for participation in research may present its own biases where women with a better understanding of research, or higher confidence in undertaking something new, may be more likely to self-identify. This remains a challenge across clinical research trials.

6.10.2 Community midwife training

Engaging clinical practitioners in research can be challenging when there is a need to address immediate clinical priorities in a busy NHS service; furthermore clinical practitioners often feel ambiguity about their role in research (Higgins et al. 2010). To address these challenges, an education package was developed to inform midwives of their role in identifying potential participants to the researcher (see Appendix 14) and to engage them in the aims and anticipated outcomes of the research trial. The online training package was developed by the researcher and then piloted on 5 community midwives who provided feedback about its relevance, ease of use and their subsequent understanding of the trial. All midwives fed-back positively about the online package and felt it explained the trial and their expected involvement well. In line with the midwives' feedback, the training was provided in an online format for ease of access in the community, for midwives to undertake at their own convenience, so to minimally impact on their workload. The feedback group also suggested that the 25 week antenatal appointment would be the most appropriate appointment for the identification of eligible participants to take place based on the other clinical tasks at this appointment. Based on this, it was suggested that this appointment be used but it did not stipulate that the identification could not happen at other appointments as well.

Midwives gave potential eligible participants a brief outline of the research trial; provided a PIS and with permission, submitted their contact details to the researcher.

6.10.3 Consent processes

Gupta (2013) presents consent in research to be, at its most basic level, made of three elements: adequate and comprehensive information disclosure, decision-making capacity, and voluntariness. There is a vast literature base discussing the advantages of written consent, particularly when compared to verbal consent alone (Lawton et al. 2017).

Written consent is often the ethically least complex method of taking consent. Written consent has traditionally been preferable, commonly taken on paper, alongside a signature, which provides consent traceability (General Medical Council 2010). More recently, ever-evolving and newly developing technology has superseded most of the traditional paper communication across the world; emails, e-books, SMS texts, digital messaging, social media and more broadly, the internet, has transformed the way in which acceptable communication takes place. In spite of this, digital consent in research (except in the form of surveys) has not been as widely utilised.

Ethical considerations regarding digital and online consent must be considered; it is important that the researcher can be sure that the participant providing consent has received adequate information, is voluntarily involved and has the capacity to understand their involvement. Nonetheless if the basic consent principles can be met, as described by Gupta (2013), digital and online consent could be a dynamic, cost-efficient, effective method (Brandon et al. 2016). Furthermore, completing consent at a time convenient to the participant prioritises them in the process, which should be at the forefront of good, ethical research conduct. It minimises the time, travel and organisational barriers associated with traditional, written consent taken on paper (Schenker and Meisel 2011). It was considered that online consent could be detrimental to excluding potential participants without online access. However, due to the age and demographic of the participants of this trial, it was unlikely that an online platform for consent would impact adversely. Furthermore, the intervention on trial was an online, digital tool and so individuals without online access would not have been able to participate. In line with this, access to the internet, without unacceptable cost, was specifically made an inclusion criterion for this study.

For the reasons discussed, consent for the L-TEL Trial was taken verbally and then documented online (see Appendix 15). To consent, following receipt of the PIS (see Appendix 16), the researcher made contact with potential participants to confirm eligibility and explain in further detail their proposed involvement in the trial. Participants were given the opportunity to ask questions in order to make an informed decision about providing their voluntary consent to participate. In a systematic review of how to reliably take informed consent, having a one to one conversation between researcher and potential participant was found to be the most effective method of improving the research participants' understanding of a trial (Flory and Emmanuel 2004) and so this method was employed. Following verbal consent, an online consent form was sent securely to the participant's email address. Each participant was also provided with a unique, "once-only access" username and password to complete their individual consent form; this was to ensure that the correct person completed the consent form. This identification verification process is suggested as a solution to eliminate the risk of participants taking part in the same online trial more than once (Murray et al. 2009).

A copy of this documented consent was provided to the individual for their own record, and uploaded to their hospital record. Following consent, participants were then sent an online questionnaire to collect baseline demographic information. Further information about this can be found in Section 6.11.

Participant details were recorded on EDGE (Clinical Informatics Research Unit, University of Southampton 2018) and recruitment data uploaded to the NIHR Central Portfolio Management System, an "infrastructure support for the initiation and delivery of high quality research which benefits patients and the NHS... to answer... relevant questions with scientifically sound methods" (Department of Health (DOH) 2019).

6.10.4 Successes and barriers to recruitment

The success and ease of using social media, mostly in relation to academic research output, has been documented, although its role in recruitment has been less widely discussed. Klar et al. (2020) describes social media content as being "pushed" out, where usual promotion relies on individuals "pulling" in information. The recruitment population were easily, and cost effectively reached using the maternity service's birth centre social media page (Facebook) (see Appendix 13), furthermore utilising the

maternity affiliated pages meant the poster could be virtually displayed a number of times throughout the trial period, in order to identify newly eligible women.

Of the 193 women who were identified to the researcher as eligible and were contactable, only 6 women declined to consent (3.4%) (see Figure 4 in Section 7.2). During the consent discussions with the researcher, individuals frequently reported that they were keen to participate, and pleased to be given the chance to be involved. This was because they wanted every opportunity to receive as much information about labour and birth as possible; additionally they felt involvement in the trial was “easy”. Some participants also expressed an altruistic sentiment about being involved in a trial of an intervention which could benefit other women in the future.

The main barrier to recruitment was receiving enough referrals from the midwives; in spite of the high number of eligible women that were being booked into the service, many midwives reported that they would regularly forget to speak to these women about the research trial. The term “gate keeper” is used to refer to the person or people who exist between the researcher and participant, when the researcher does not directly approach the participant for research involvement (Clark 2011). This has been documented to weaken the research process in other trials, because there is a reliance on an intermediary to undertake an important aspect of the research, such as in the identification of participants (van Teijlingen et al. 2001). This barrier to the L-TEL Trial’s recruitment was unsurprising, where clinical priorities in often busy midwifery appointments take precedence. The researcher found that speaking to individual midwives helped mitigate this barrier because it engaged practitioners to become invested in the research outcomes. Larkin (2013 p. 99) describes this process for a midwife researcher as “negotiating with gatekeepers... to gain acceptance of a new role, that of researcher”, this was certainly a relatable concept where the researcher for the L-TEL Trial had previously been a clinical midwife at the research site. For the L-TEL Trial at least, the researcher felt that these existing, professional relationships aided the mitigation of the recruitment barriers described above because the rapport documented to be important by Larkin (2013) already existed between the researcher and midwifery team. It is recognised that “exaggerated intimacy” between researcher and “gate-keeper” could place participants in a vulnerable position (Larkin 2013) but this was not the case in the L-TEL Trial, where a balanced approach was adopted. This was maintained because the midwives only identified eligible participants and did not consent them to the trial. Therefore these professional relationships had a positive impact by reminding the midwives to provide the information about the trial to potential

participants, but did not change how likely participants were to consent, which would have been unethical.

6.11 Participant demographic data

6.11.1 Baseline demographics

When conducting a RCT it is recommended that demographic and prognosis variables be described and reported for both the control and the intervention group (Roberts and Torgerson 1999). This is so the generalisability of the study's findings can be interpreted and so any significant, chance differences between the trial's groups are acknowledged and the impact on findings can be considered. For this reason, baseline characteristics are usually collected as variables that are likely to have a high impact on any trial findings. An association, or potential impact, between the baseline, demographic variables and the outcomes of interest could be detrimental to being able to contribute any impact to the studied intervention. For this reason the baseline questionnaire for this trial focused on variables that may impact on women's experiences of labour. Demographic data were collected prior to randomisation so that group allocation did not impact on women's self-reported characteristics (i.e. self-efficacy). The researcher did not see these data prior to randomisation, and the computer randomisation tool was independent to the system in which the demographic data were collected. Therefore there was no risk of selection bias during recruitment.

6.11.2 Baseline demographics: Childbirth Self-efficacy Inventory

As discussed in Chapter 4.0, the impact of self-efficacy on labour and childbirth is well documented. As the intervention had been developed to improve experiences of early labour utilising self-efficacy theory, collecting baseline data regarding this prior to randomisation was important.

The Childbirth Self-Efficacy Inventory (CBSEI) (Lowe 1993) was chosen as a tool developed to prospectively measure childbirth self-efficacy and permission was granted for its use by the author (see Appendix 17 and 18). The inventory is categorised into 4 subscales (self-efficacy expectancy for labour, outcome expectancy for labour, self-efficacy expectancy for the second stage of labour, and outcome expectancy for the second stage of labour) with 15 to 16 questions in each of these subscales. The subscales measure the behaviours that women believe may be useful to them in labour as well as their belief that they will implement these behaviours once in labour. The

subscales can be viewed individually or as a total. The questionnaire uses a 10-point Likert scale; higher scores indicate higher levels of self-efficacy. The CBSEI was validated for in English speaking countries (Lowe 1993, Drummond and Rickwood 1997, Sinclair and O'Boyle 1999), but has also been translated and validated in Spanish, Chinese Swedish, Thai and Persian with high tool reliability and validity (Cunquero et al. 2009, Ip et al. 2005, Carlsson et al. 2014, Tanglakmankhong et al. 2011, Khorsandi et al. 2008). Its high internal consistency reliability (Cronbach's $\alpha=0.86-0.96$) also contributed to why this tool was selected for use.

The Labor and Birth Self-Efficacy Questionnaire (LBSEQ) (Bocchese 1992) was also evaluated but the questionnaire had a lower reliability coefficient than the CBSEI (Lowe 1993) and further factor analysis and validation had not been conducted. Furthermore the tool had not been used or translated by any other studies and so was a less robust choice.

Additionally, the Confidence and Trust in Delivery Questionnaire (CTDQ) (Jeschke et al. 2012) was evaluated for use. Although the authors of the tool noted that the scale may be limiting due to its short length, it was found to have good internal consistency ($\alpha=0.79$). Nonetheless, the CBSEI had been more widely used, across varying language and cultures and was therefore deemed the most reliable and valid tool to assess inherent childbirth self-efficacy in the antenatal period.

6.11.3 Other baseline demographics

Alongside the baseline CBSEI data, other social demographics were collected in order to compare the intervention and control groups characteristics. This demographic data included marital status, age, ethnic origin and highest level of education achieved. Henderson and Redshaw (2017) found that there is considerable variation in women's experience of early labour by sociodemographic characteristics and in particular, women aged 20-24 years and women from ethnic minority groups reported greater worry about early labour. With the focus of the L-TEL Trial on early labour experiences it was important to report on these variables which have the potential of impacting on reported outcomes.

There is a well reported correlation between women who live in social deprivation and poorer birth outcomes (Weightman et al. 2012, Lelong et al. 2015, Draper et al. 2020). This considered, participant postcodes were translated into a measure of deprivation

for comparison between groups. The English Indices of Deprivation 2019 is a set of relative measures used to measure deprivation for specific, small areas within England. The measures are based on seven domains of deprivation and combined with varying weights to construct an overall Index of Multiple Deprivation (IMD) (Ministry of Housing, Communities & Local Government 2019). See Table 7 for further details.

The IMD (2019) also presents its data in deciles. Those areas in Decile 1 are the 10% most deprived areas nationally, and those areas in Decile 10 are the 10% least deprived areas nationally.

Table 7: The seven domains of deprivation, which combine to create the Index of Multiple Deprivation (IMD 2019) (Ministry of Housing, Communities and Local Government 2019)

Domain	Explanation	Weighting of total of Index of Multiple Deprivation (%)
Income	Deprivation relating to low income	22.5% Domain
Employment	Measures the proportion of the working age population excluded from the labour market	22.5%
Education	Measures the lack of attainment and skills	13.5%
Health	Measures the risk of premature death and the impairment of quality of life through poor physical or mental health	13.5%
Crime	Measures the risk of personal and material victimisation	9.3%
Barriers to housing and services	Measures the physical and financial accessibility of housing and local services	9.3%
Living environment	Measures the quality of both the indoor and the outdoor local environment	9.3%

6.12 Data management

Full details of data collection and management can be found in the Data Management Plan (see Appendix 19). All participants were allocated an anonymous participant

identification number so that all analyses were undertaken anonymously. All data were collected in electronic format in the first instance. This was to avoid duplication and error. All data were exported from the electronic forms into the required format for analysis. From here all data were exported to SPSS for statistical analyses.

Once in SPSS the data were coded, cleaned and checked against the original electronic questionnaires for accuracy. Frequency analysis was also run on SPSS to identify anomalies and missing entries. Approximately 15% of all data were directly cross checked against the original forms (20 out of total of 140). Starting at the second entry (LT002), every 7 entries were cross checked for accuracy (LT009, LT016 etc.). There were 2 errors found, 1 participant had provided her estimated due date rather than her date of birth in the demographic data and so this entry was removed, and 1 participant had not provided a valid postcode and so this entry was removed and this participant was included in the "Prefer not to say" category for the postcode variable. All entries in regard to the secondary outcomes were second checked by an administration assistant from the NHS research team at the host Trust. One error was identified (wrong place of birth had been listed) and so this was rectified prior to analysis. It was acknowledged that there has been a remarkably low error rate and thus there had been a notable benefit to collecting data online and in an electronic format from the outset. It removed the potential for input and human error (such as typographical errors or misplaced paper forms). It also meant participants were prompted to complete their questionnaires in full (i.e. the online forms were designed so that participants could not move on without completing each question). The forms were also developed with some questions requiring specific input format (i.e. dates) which further minimised error. If digital forms are well designed, participants can be prompted to answer only the questions relevant to them and prevent them from changing previous answers, providing more accuracy than traditional paper models of data collection (Granello and Wheaton 2004). Using filter questions, such as "Did you spend any time at home when you were in early labour?" meant that questions which required a specific response to be relevant, could be filtered out so that participants were not asked to answer irrelevant questions. In this example, any participant who answered "No" was not asked to undertake the ELEQ, which required a participant to have spent some time at home whilst in early labour.

In line with university policy and good, ethical research conduct, the anonymised data set will be uploaded to the University's electronic repository following publication of

results. All data relating to the trial was always kept password protected on a University secure lap top.

6.13 Data analyses

6.13.1 Intention to treat and other analysis

RCTs commonly rely on following participants through a journey (i.e. consent, randomisation, intervention and follow-up) and so the risk of losing participants (known as “lost to follow-up”) during this process can weaken study findings (Sanson-Fisher et al. 2007). Furthermore the validity of RCT findings can be impacted if trial groups do not adhere to the protocol (i.e. those in the control group actually receive the intervention). To minimise the impact of this participants were analysed on an ITT basis. This means that all available data was assessed based on the original, random allocation to a trial arm, regardless of noncompliance and protocol deviation (Gupta 2011). This is to maintain the prognostic balance generated from the original randomisation and to provide the best estimate of an intervention’s impact and effect (Polit and Gillespie 2010, Tripepi et al. 2020).

Whilst analysing the “Phase of labour at admission” secondary outcome on an ITT basis, it was evident that there were a large number of data entries which were missing (approximately 31% of these data in both the intervention and control group had not been collected). This was because these data had not been accurately inputted by the midwives, even though this collection should have been a routine data entry for every birth undertaken at the hospital site. Instead of a date and time of admission being collected as expected, only a date had been collected which meant establishing the phase of labour on admission was not possible. This relied on the date and time of established labour being readily available, and the date and time of admission being reliably collected so that these time points could be compared. Further considerations to this noted limitation are discussed in Chapter 8.0. The researcher knew which participants had been admitted prior to labour (those admitted for induction and those admitted for a caesarean not in labour). The availability of this outcome (prior to any labour) compared to the other variables (early labour and active labour) meant results and therefore analysis on an ITT basis was misleading and inaccurate. Based on this, analysis for this secondary outcome was undertaken including only data available (participants who were induced or admitted for a caesarean not in labour, and missing entries were excluded). In support of this decision, Gupta (2011) suggests that an accurate ITT analysis should be employed when outcome data are complete, and for

this specific outcome, this was not true. The possible biases to this data analyses are considered, particularly in relation to the impact an analysis of this type could have on the preservation of balancing confounding factors and participant demographic that the original randomisation provided (Tripepi et al. 2020). Both analyses are presented in Chapter 7.0 for transparency of findings, and then discussed further with reference to the limitations of this secondary analysis is discussed in Chapter 8.0.

6.13.2 Primary and secondary outcome analyses

The primary outcome was analysed using an independent t-test, so to compare the means of the total scores of the ELEQ between trial arms. Secondary outcomes were compared using odds ratio, to indicate the likelihood of outcomes occurring in the intervention group when compared to the control group.

Data collected from the usability and acceptability of the intervention, as well as the qualitative responses from the questions around early labour education access, were broadly thematically analysed.

Statistical support for data analyses was provided by a statistician and senior lecturer at the researcher's university (see Appendix 20).

6.14 Safety and adverse events

Safety of trial participants is the single most important aspect of conducting ethical research. During the intervention's development, it was reviewed and validated by a group of service users, senior midwives and academics to ensure that the advice being given was promoting safety (see Chapter 5.0 for details of this review process). Adverse events were monitored by the Chief Investigator and the site's midwifery research team, and a group of senior midwives at the Trust. During the trial, a woman from the control group sadly had a pre-term stillbirth. This was reviewed in context of the trial by the Chief Investigator and a group of senior midwives at the research site; it was deemed that the loss was unrelated to the involvement in the trial and so the trial continued. The participant was removed from the primary and secondary outcome analyses as it would not have been ethically appropriate to approach this individual for these data. Otherwise there were no other adverse events reported for participants during the trial.

The intervention was a low risk, educational tool which reiterated existing advice; additionally the web intervention promoted safety by instructing women when to seek support and what would be normal and abnormal during this phase. In this, the intervention posed minimal risk to research participants. This too was the opinion of the Research Ethics Committee (REC). The only identified theoretical risk was that participants in the intervention group would remain at home for too long; on assessment the likelihood of this happening was deemed to be highly unlikely and in reality this did not happen during the trial to any participant.

6.15 Conclusion

This chapter has presented a peer reviewed journal article (Edwards et al. 2019) detailing the study protocol of the L-TEL Trial. The chapter has then provided additional justification to the methodological decisions that were made during the development of this protocol. The following chapter offers the findings of the L-TEL Trial.

7.0 Findings

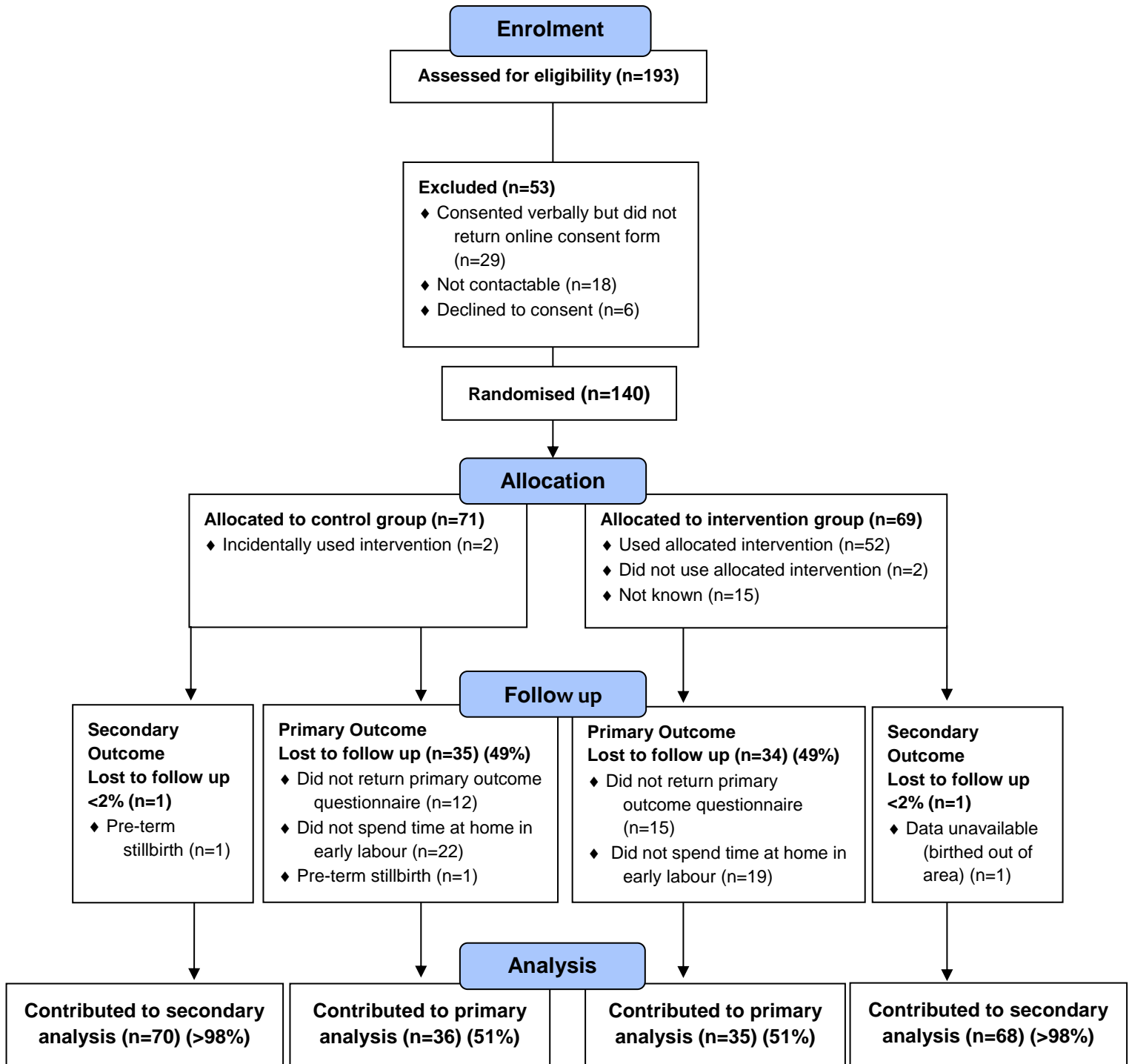
7.1 Introduction

This chapter reports the findings from the L-TEL Trial. The data are presented in narrative and visual (tabular and graphical) form. The participant recruitment and follow-up process are detailed first, followed by the trial group's demographics and CBSEI scores for comparison. The trial's primary outcome findings (ELEQ) are detailed followed by the clinical, secondary outcomes. Five key secondary outcomes are presented in more detail (onset of labour, augmentation of labour, birth mode, regional anaesthesia use, neonatal resuscitation and admission rates in active labour) as planned (see Section 6.5.2 for further details).

7.2 Participant recruitment and follow-up

In total, 193 women were identified to the researcher as eligible with an interest to participate in the L-TEL Trial. Of these, 126 had been identified by the midwives, and 67 had self-identified themselves to the researcher. All women who were contactable were confirmed to be eligible. Of these, 29 women were consented verbally on the phone but did not return their online consent forms, 18 were not contactable and 6 declined to consent. A total of 140 eligible women (75 of these had been identified by the midwife and 65 had self-identified) consented and completed the initial screening questionnaire, and were randomised to either the control group (n=71) or the intervention group (n=69). In regard to the primary outcome, data were not available for 49% of both the control and intervention group (control n=35; intervention n=34). Of these, a number of participants did not return their questionnaire for analysis (control n=12; intervention n=15), and a number of participants did not spend any time at home in early labour and so were not able to complete the required primary outcome questionnaire (ELEQ) (control n=22; intervention n=19). There was one participant in each trial group who did not contribute to the secondary analysis: one participant in the control group sadly had a pre-term stillbirth (see Section 6.13 for details) and one participant in the intervention group gave birth at a different hospital. A visual representation of this participant recruitment and follow-up and can be found in Figure 4, along with details of adherence to protocol (adapted CONSORT 2010) (Moher et al. 2001).

Figure 4: The L-TEL Trial recruitment, allocation and follow-up diagram (adapted CONSORT 2010 Flow Diagram) (Moher et al. 2001)



7.3 Participant demographics

The two trial arms' characteristics and demographics are detailed in Table 8. A visual comparison of the two trial arms' demographics suggests that for all but one variable the randomisation resulted in groups of similar demographics. There is a noted difference in the number of women who were married in the two groups; 76.1% (n=54) of participants were married in the control group compared to 58% (n=40) of participants in the intervention group. In the control group 19.7% (n=14) of participants reported to have a partner, compared to 37.7% (n=26) in the intervention group. These differences, and the potential impact on the trial's findings, will be discussed in further detail in the Chapter 8.0.

7.3.1 Participant childbirth self-efficacy measure

Alongside participant demographics, childbirth self-efficacy was measured in both the control and intervention groups using the CBSEI (Lowe 1993) to compare the labour and birth confidence between the trial groups prior to randomisation. These scores are illustrated in Table 8. The mean scores for both the outcome total score (control=15.49, intervention=15.44) and the efficacy total score are comparable between groups (control=12.01, intervention=11.94) illustrating similar reported levels of self-efficacy in both the trial arms and suggesting a successful randomisation process.

Table 8: Participant demographics and baseline CBSEI scores (Lowe 1993) by trial arm

	Control (max=71)		Intervention (max=69)	
Childbirth Self-Efficacy Inventory:				
Mean (SD) outcome total score (C=71, I=69)	15.49 (2.518)		15.44 (2.74)	
Mean (SD) efficacy total score (C=71, I=69)	12.01 (3.916)		11.94 (3.048)	
Age (C=71, I=69)				
Mean (SD) in years (C=66, I=67)	30.27 (4.108)		29.93 (4.698)	
	n	%	n	%
Prefer not to say	4	5.6	2	2.9
Provided estimated due date in error	1	1.4	0	0
Ethnicity (C=71, I=69):	n	%	n	%
White British	58	81.7	62	89.9
Other White Background	7	9.9	4	5.8
Black or Black British - African	2	2.8	0	0
Chinese	2	2.8	1	1.4
Mixed - White and Black African	1	1.4	0	0
Mixed White and Black Caribbean	1	1.4	0	0
Asian or Asian British - Indian	0	0	1	1.4
Other Mixed	0	0	1	1.4
Marital Status (C=71, I=69):	n	%	n	%
Married	54	76.1	40	58.0
Partner	14	19.7	26	37.7
Single	3	4.2	1	1.4
Civil partnership	0	0	1	1.4
Prefer not to say	0	0	1	1.4
Education (C=71, I=69):	n	%	n	%
Graduate degree	22	31.0	29	42.0
Post-graduate education	20	28.2	16	23.2
Post 16 years education	14	19.7	14	20.3
GCSE / O Level or equivalent	10	14.1	5	7.2
Foundation degree	3	4.2	1	1.4
Other	0	0	3	4.3
Prefer not to say	2	2.8	1	1.4
Index of Multiple Deprivation Decile (C=71, I=69)	n	%	n	%
1	1	1.4	2	2.9
2	7	9.9	6	8.8
3	6	8.5	8	11.8
4	12	16.9	7	10.3
5	5	7.0	7	10.3
6	9	12.7	7	10.3
7	5	7.0	7	10.3
8	8	11.3	9	13.2
9	4	5.6	6	8.8
10	11	15.5	9	13.2
Prefer not to say	3	4.2	1	1.4

7.4 Trial findings

7.4.1 Primary outcome

The next section presents the findings of the primary outcome of the L-TEL Trial: the ELEQ self-reported score, provided by individuals in both trial arms at 7-28 days following birth. A higher ELEQ score is representative of a more positive early labour experience. Scores were reversed where required to maintain this (as done by the original authors of the questionnaire) (Janssen and Desmarais 2013b). The ELEQ is made up of 26 items, split into three separate subscale scores: emotional wellbeing (8 items), emotional distress (6 items) and perceptions of midwifery care (8 items). These subscale scores can be compared independently, or added to the four other items to provide an overall total ELEQ score.

Details of the primary outcome data are visually depicted in Table 9, followed by a narrative detailing the ELEQ score as a whole, and as the three separate subscale scores.

Table 9: ELEQ total scores and subscale scores by trial arm

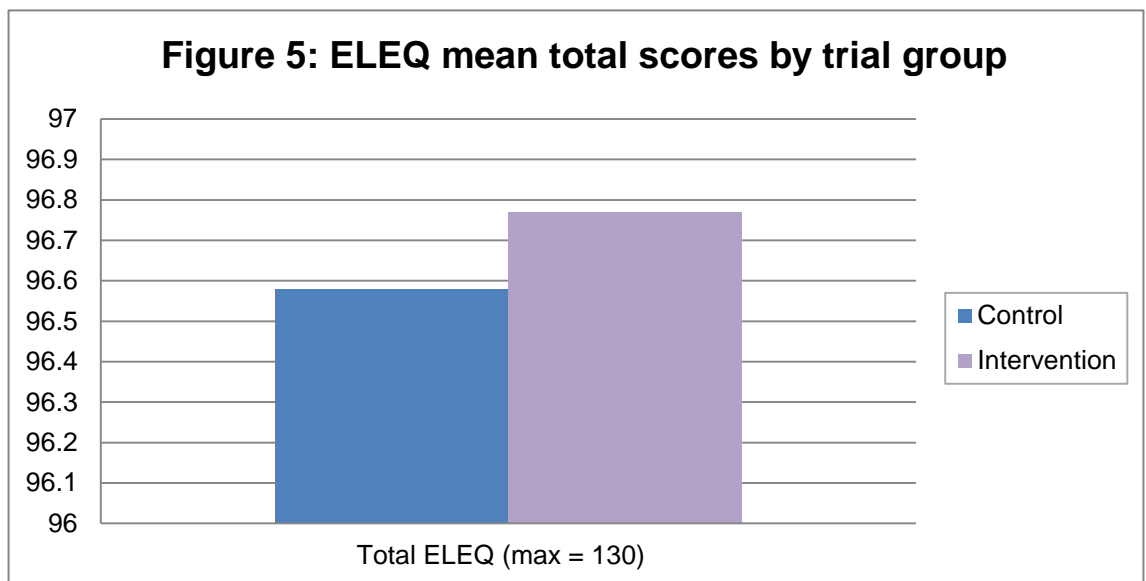
	Control (C) (n=36)		Intervention (I) (n=35)		Difference in mean score between I and C (%)
	Mean	(SD)	Mean	(SD)	
Emotional wellbeing items:					
While you were in labour at home did you feel safe?	4.67	(0.68)	4.71	(0.60)	
While you were in labour at home did you feel confident?	3.94	(0.86)	4.14	(0.94)	
While you were in labour at home did you feel happy?	3.56	(1.05)	4.03	(0.92)	
While you were in labour at home did you feel excited?	3.89	(0.95)	4.34	(0.68)	
While you were in labour at home did you feel relaxed?	3.50	(1.21)	3.63	(1.17)	
While you were in labour at home did you feel comfortable?	3.50	(1.46)	3.63	(1.17)	
While you were in labour at home did you feel in control?	3.36	(1.27)	3.71	(1.15)	
While you were in labour at home did you feel supported?	4.42	(1.03)	3.63	(0.61)	
Total: Emotional wellbeing	23.06	(4.71)	24.48	(4.25)	
Emotional distress items:					
While you were in labour at home did you feel distressed?	4.03	(1.11)	4.29	(1.15)	
While you were in labour at home did you feel insecure?	4.08	(1.11)	4.23	(1.11)	
While you were in labour at home did you feel confused?	3.94	(1.07)	4.14	(1.06)	
While you were in labour at home did you feel tense?	2.67	(1.20)	3.00	(1.33)	
While you were in labour at home did you feel in scared?	3.06	(1.40)	3.54	(1.27)	
While you were in labour at home did you feel anxious?	2.19	(1.14)	2.60	(1.40)	
Total: Emotional distress	19.97	(5.51)	21.80	(5.91)	1.83 (+9.16)

Perceptions of midwifery care items:				
When you were in labour at home, did the midwife on the phone give you the information you wanted?	4.47	(0.85)	4.20	(1.08)
When you were in labour at home, did the midwife on the phone give reassurance you when you needed it?	4.28	(0.88)	3.86	(1.62)
When you were in labour at home, did the midwife on spend enough time with you on the phone?	4.31	(1.04)	4.17	(1.12)
When you were in labour at home, did the midwife on the phone listen carefully to what you had to say?	4.58	(0.65)	4.17	(1.22)
When you were in labour at home, did the midwife on the phone treat you family and/or friends with respect?	4.50	(0.81)	4.37	(1.06)
When you were in labour at home, did the midwife on the phone respect your wishes about going to your chosen place of birth?	4.50	(0.74)	4.26	(1.15)
Did you feel that you had confidence in the midwife on the phone?	4.42	(0.84)	4.17	(1.12)
Did you feel that the midwife was at ease and calm with you?	4.72	(0.62)	4.54	(0.85)
Total: Perceptions of midwifery care	35.78	(4.85)	33.74	(7.71)
-2.04 (-5.7)				
Other items:				
Did you feel there was teamwork in the provision of your care?	4.50	(0.70)	4.09	(1.22)
Did you feel the midwife treated you in a rude way?	4.86	(0.59)	4.66	(0.77)
Would you recommend this type of early labour care and advice to a friend?	4.31	(0.95)	4.23	(1.17)
Did you feel you went to hospital at the right time?	4.11	(1.09)	3.77	(1.52)
Total score of all items	96.58	(12.57)	96.77	(16.74)
0.19 (+0.20)				

7.4.1.1 ELEQ total score

Visualisation of Q-Q plots and histograms suggested the ELEQ total item scores to be normally distributed (See Appendix 21) and that there was homogeneity of variance, as assessed by Levene's Test for Equality of Variances. Therefore an independent, 2-sided t-test was used to compare the ELEQ mean scores of the control and the intervention group.

Figure 5 illustrates the ELEQ mean total scores (three subscale scores and four separate items combined) in both the control and intervention group.

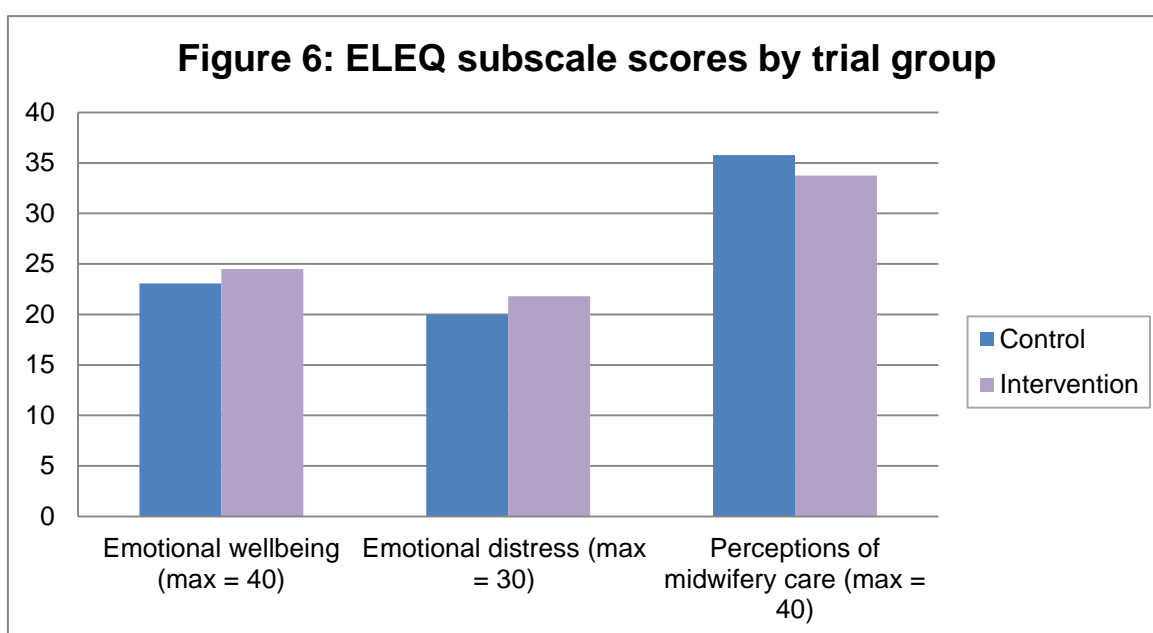


The difference in the mean ELEQ total scores was 0.19 higher in the intervention group (96.77, SD=16.74) when compared to the control group (96.58, SD=12.57) but this was not statistically significant; (SE 3.51, CI 90%, -6.04 – 5.66), $t(69) = -0.05$, $p=0.96$.

7.4.1.2 ELEQ separate subscale scores

Visualisation of Q-Q plots and histograms suggested the ELEQ emotional wellbeing subscale and emotional distress subscale scores to be normally distributed (See Appendix 21) and that there was homogeneity of variance, as assessed by Levene's Test for Equality of Variances. Normal distribution was less evident by visualising Q-Q plots and histograms from the perceptions of midwifery care subscale scores (See Appendix 21). However skewness was noted as <1 and the median scores in both groups were comparable to the means (control=38, intervention=35). Therefore an independent, 2-sided t-test was used to compare the ELEQ mean subscale scores of the control and the intervention group.

Figure 6 illustrates the three ELEQ mean subscale scores in both the control and the intervention group.



The difference in the mean ELEQ emotional wellbeing subscale scores was 1.42 higher in the intervention group (24.48, SD=4.25) when compared to the control group (23.06, SD=4.71) but this was not statistically significant; (SE 1.07, CI 90%, -3.21 – 0.35), $t(69)= 1.34$, $p=0.18$.

The difference in the mean ELEQ distress subscale scores was 1.83 higher in the intervention group (21.80, SD=5.91) when compared to the control group (19.97,

SD=5.51) but this was not statistically significant; (SE 1.06, CI 90%, -4.09 – 0.43), $t(69)= 1.35$, $p=0.18$.

The difference in the mean ELEQ perceptions of midwifery care subscale scores was 2.04 lower in the intervention group (33.74, SD=7.71) when compared to the control group (35.78, SD=4.85) but this was not statistically significant; (SE 1.52, CI 90%, -0.51 – 4.58), $t(69)= -1.34$, $p=0.19$.

7.4.1.3 Primary outcome: conclusion

The intervention group did not score statistically significantly higher in the total mean ELEQ scores, or in any of the subscale scores when compared to the control group. Based on this the hypothesis can be rejected. There were however noted differences in the subscale scores, which will be discussed in more detail in Chapter 8.0.

7.4.2 Secondary outcomes

As presented in Table 10, a number of clinical outcomes for both the control and intervention groups were collected from the hospitalised central system. This is presented alongside the hospital's data, where available, for nulliparous women from April 2019 – March 2020 as a comparator. The hospital data presents data from all nulliparous women, not exclusively low risk women, as this was the only data available to the researcher. Where annual data from the hospital was not available, the table has been shaded in grey.

Whilst there are some differences between the hospital data and the trial data, likely due to the difference in risk factors noted above, the data looks reasonably comparable suggesting that the trial succeeded in identifying a representative sample.

Table 10: Secondary outcomes by trial arm alongside local hospital data for comparison

	Control (n=71)		Intervention (n=69)		Hospital
	n	%	n	%	%
Birth mode					
Unassisted vaginal birth	33	46.5	31	44.9	45.7
Forceps	12	16.9	8	11.6	15.7
Ventouse	5	7.0	5	7.2	6.4
Caesarean section in labour	13	18.3	18	26.1	25.5
Caesarean section not in labour	7	9.9	6	8.7	6.8
Missing	1	1.4	1	1.4	
Birth place					
Labour ward	55	77.5	53	76.8	84.9
Birth centre	7	9.9	7	10.1	10.5
Co-located birth centre	7	9.9	8	11.6	4.1
Other inpatient, hospital ward	1	1.4	0	0	0.0
Missing	1	1.4	1	1.4	
Onset of labour					
Spontaneous onset	42	59.2	47	68.1	55.6
Induction of labour	22	31.0	17	24.6	33.5
No labour	6	8.5	4	5.8	10.9
Missing	1	1.4	1	1.4	
Augmentation					
No augmentation	15	21.1	27	39.1	25.6
Artificial rupture of membranes (ARM)	11	15.5	9	13.0	43.3
Oxytocin infusion only	4	5.6	5	7.2	17.8
ARM and oxytocin	8	11.3	5	7.2	13.3
Not recorded in hospital notes	31	45.1	22	31.9	
Missing	1	1.4	1	1.4	
Analgesia					
N/A (no labour)	7	9.9	6	8.7	
None	0	0	3	4.3	
Non-pharmacological analgesia only	2	2.8	2	2.8	
Inhalation analgesia only	29	40.8	33	47.8	
Regional anaesthesia (i.e. epidural)	30	42.3	23	33.3	51.7
Not recorded in hospital notes	2	2.8	1	1.4	
Missing	1	1.4	1	1.4	
Neonatal resuscitation at birth					
None	48	67.6	36	52.2	
Stimulation alone	17	23.9	21	30.4	
Stimulation and facial oxygen	2	2.8	2	2.9	
Positive pressure without drugs	1	1.4	5	7.2	
Not recorded in hospital notes	2	2.8	4	5.8	
Missing	1	1.4	1	1.4	
Feeding at discharge					
Breastfeeding	51	71.8	43	62.3	55.6
Combination feeding	9	12.7	11	15.9	19.7
Artificially feeding	7	9.9	9	13.0	24.6
Not recorded in hospital notes	3	4.2	5	7.2	
Missing	1	1.4	1	1.4	
Phase of labour at admission					
Prior to any labour	29	40.8	23	33.3	
Early labour	6	8.5	8	11.6	
Active labour	13	18.3	15	21.7	
Not recorded in hospital record	22	31.0	22	31.9	
Missing	1	1.4	1	1.4	
Apgar score (C=70, I=68)					
Median score at 1 minute	9		9		
Median score at 5minute	9		9		

As detailed in Chapter 6.0 based on the MCWP (2007) and WHO (1997) definitions of normal labour, five key secondary outcomes were tested. The timing of admission was also tested as was identified as key outcome for the focus of this research.

7.4.2.1 Onset of labour

Women in the intervention group were more likely to have a spontaneous onset of labour (68.1%) compared to the control group (59.2%) (Odds ratio (OR) 1.49, CI 90%; 0.828-2.690, $p=0.13$). This finding was not statistically significant. Both trial groups had a higher rate of spontaneous onset of labour and a lower rate of IOL when compared to the hospital's annual data. This finding was not unexpected as the hospital data included obstetrically high risk nulliparous women who would present with more clinical need for IOL.

7.4.2.2 Augmentation of labour

Women in the intervention group were more likely to progress spontaneously in labour without the need for labour augmentation (39.1%) compared to the control group (21.1%) (OR 2.17, CI 90%; 1.05-4.55, $p=0.04$). This finding was statistically significant. Furthermore, women in the intervention group were less likely to require augmentation of labour (no augmentation=39.1%) when compared to the annual data from the hospital (no augmentation=25.6%).

7.4.2.3 Birth mode

Women in the intervention group were less likely to have a spontaneous vaginal birth (44.9%) when compared to the control group (46.5%) (OR 0.94; CI 90%; 0.536-1.647, $p=0.43$). This finding was not statistically significant. Both trial arms had comparable rates of spontaneous vaginal births to the annual hospital data (45.7%).

7.4.2.4 Regional anaesthesia analgesia

Women in the intervention group were less likely to require regional anaesthesia for analgesia (33.3%) compared to the control group (42.3%) (OR 0.66, CI 90%; 0.372-1.188, $p=0.12$). This finding was not statistically significant. Both trial arms were less likely to require regional anaesthesia than the annual hospital data (51.7%).

7.4.2.5 Neonatal resuscitation

Babies born to women in the intervention group were more likely to require some level of resuscitation (40.5%) compared to the control group (28.1%) (OR 1.75, CI 90% 0.96-3.172, $p=0.06$). This finding was not statistically significant. This hospital data were not available.

7.4.2.6 Admission in active labour

7.4.2.6.1 Intention to treat analysis

Women in the intervention group were more likely to be admitted in active labour (21.7%) when compared to the control group (18.3%) (OR 1.24, CI 90% 0.618-2.494, $p=0.31$). This finding was not statistically significant. As presented and discussed in Chapter 6.0, the high rate of missing data in both trial arms was acknowledged and therefore an analysis on only those participants with this data available was undertaken for this outcome.

7.4.2.6.2 Secondary analysis for onset of labour outcome

Of the participants from each trial arm who had this data available (see Table 10) (control=19, intervention=23), those in the intervention group were less likely to be admitted in active labour (65.2%) when compared to the control group (68.4%) (OR 0.87, CI 0.292-2.562, $p=0.41$). This finding was not statistically significant. Implications in relation to this outcome are discussed in more detail in Chapter 8.0.

7.5 The intervention

Data were collected about the intervention use in both the intervention and control groups to monitor adherence to protocol. These findings are presented in Table 11. A total of 112 women (control=58; intervention=54) returned their questionnaires.

Table 11: Details of intervention use in intervention group, their birth partners, the control group and results of “Would you recommend the intervention to a friend?”

Intervention use in intervention group (n=54)	n	%
Used once	5	9.3
Used 2-3 times	34	63.0
Used 4-10 times	13	24.1
Did not use	2	3.7
Intervention use in birth partners (n=54)		
Birth partner used	16	29.6
Birth partner did not use	35	64.8
Unsure if birth partner used	3	5.6
Would you recommend the intervention to a friend? (n=54)		
Yes, would recommend	50	92.6
No, would not recommend	2	3.7
Did not use intervention to answer this question	2	3.7
Intervention use in control group (n=58)		
Did not use intervention (adhered to protocol)	56	96.6
Incidentally used intervention	2	3.4

In the intervention group 96.3% (n=52) of participants accessed the intervention and 3.7% (n=2) of participants did not. Both participants stated the reason for not accessing the intervention was because they did not remember to use it. Of those women that did access the intervention, 90.4% (n=47) accessed the intervention more than once. A total of 29.6% (n=16) of participant’s birth partners accessed the intervention, 64.8% (n=35) did not and 5.6% (n=3) of respondents were unsure if their birth partners had accessed the intervention. Of the 52 women who responded to the questionnaire, 92.6% (n=50) stated that they would recommend the intervention to a friend and 3.7% (n=2) stated they would not, 2 participants were unable to answer this question as had not accessed the intervention themselves to comment. Of the respondents in the control group, 3.4% (n=2) used the intervention in spite of not being allocated to the intervention group, 96.6% of respondents in the control group did not incidentally use the intervention.

Those in the intervention group were asked what they liked most and least about the intervention. The responses are detailed in Table 12, grouped by themes which were identified methodically by tallying key words and phrases.

Table 12: Frequency of responses in the intervention group to what was liked most and least about the web intervention

What did you like most about the web intervention?	Frequency in responses
Informative	19
User-friendly	14
The use of real women's experiences	9
Clear	7
Positive message	6
What did you like least?	
Nothing to dislike	14
Too basic	4
Clearer navigation required	3
Lack of interactivity	2
No subtitles on the videos	2
Easy to forget to use it	1

Respondents most frequently described the web intervention as “informative” and commonly cited it to be “user-friendly”. Furthermore some women reported that the use of real women’s experiences was their most favourable aspect of the web intervention. The most frequent response about what was liked least was that there was “nothing to dislike”, followed by the response that it was “too basic”.

7.6 Other sources of early labour information

As part of their postnatal questionnaire, all participants were asked about where they had sought their information about early labour. The responses were tallied for frequency and are illustrated in Table 13.

Table 13: Other sources used to access early labour information by trial arm

What sources (other than the intervention) did you use to find early labour information	Frequency in responses	
	Control	Intervention
Internet	18	16
Private antenatal classes	11	7
NHS antenatal classes	6	9
Apps on smart device	5	6
Books	5	4
Midwife	1	4
Social media	2	2
Talking to other mums	1	1
Hospital leaflets	2	0

There did not appear to be any notable differences between trial arms in the sources that were accessed for early labour information. The most commonly cited source of information was the internet (n=34), followed by antenatal classes (private=18, NHS=15). Five respondents documented their midwife as a source of early labour information during pregnancy.

7.7 Chapter conclusion

This chapter has presented the findings of the L-TEL Trial. It has presented the trial arm characteristics and demographics, the primary outcome (ELEQ) and the secondary outcomes for both trial groups. It has also presented the data collected about the intervention's use and early labour information sources that were used more generally. The following chapter will discuss these findings in the context of the wider literature and consider the L-TEL Trial's impact and relevance, alongside the trial's strengths and limitations.

8.0 Discussion

This chapter will examine the L-TEL Trial's findings and present them within the context of the wider literature. The trial's primary outcome will be discussed to establish if the hypothesis can be accepted or rejected, furthermore the secondary outcomes will also be reviewed. The methodology and trial's implementation will be explored, to identify critical strengths and weaknesses of this study and the impact these have had on the overall trial and its findings. The chapter will conclude with a discussion around the impact and implications of this research trial with regard to its contribution to knowledge in the field of early labour research and for future research opportunities.

8.1 The L-TEL Trial's position within the wider literature

The L-TEL Trial is the first study to focus on educating women about how to cope in early labour, with the primary aim of improving their experiences. It uniquely positions the woman and her experiences of this phase at the centre of the intervention; in doing this it adopts a different approach to addressing the challenges and issues that are well documented in early labour (Hemminki and Simukka 1986, Holmes et al. 2001, Bailit et al. 2005, Rahnama et al. 2006, Tilden et al. 2015, Mikolajczyk et al. 2016, Hanley et al. 2016, Beake et al. 2018, Eri et al. 2015, Miller et al. 2020). Previous research has aimed to delay admission through improved clinical service provisions such as triage, labour assessment (Janssen et al. 2003, Janssen et al. 2006, Spiby et al. 2008) and diagnosis (Cheyne et al. 2008, Bonovich 1990, Scrimshaw and Souza 1982). Instead, the L-TEL Trial was designed to address the negativities that women report with having their admission delayed, by looking to improve the experiences of early labour whilst at home. The L-TEL Trial sought to provide women with the authority to empower themselves during this phase which had been identified as a research priority in a recent study (Allen et al. 2020). Cappelletti et al. (2016 p.198) recommended that there should be "clear information and advice about early labour in order to increase women's confidence and self-efficacy, and decrease their anxiety and fear" and this is the foundation on which the L-TEL Trial was developed. Eri et al.'s (2015) metanalysis of women's experiences of this phase identified early labour to be "an unknown territory" and the L-TEL Trial has looked to focus on educating and preparing women so the reported "unknown" could be a "known", even when this was a woman's first experience of labour.

The intervention examined in the L-TEL Trial was novel. Co-created with previous service users, the intervention was shaped "by women for women" so that the

information was genuine, credible and aligned to the priorities of those receiving maternity care. Early labour research was identified by women as a key research priority nearly a decade ago (McCourt et al. 2012), and it remains highly topical since it is commonly a cause of complaint. This trial fills a gap in our current knowledge and understanding of how best to support women during this phase.

As a web-based intervention, the L-TEL Trial has been well timed, responding to the current national, maternity agenda which is looking to improve and digitalise maternity services to ensure better access for all women (NHS Long Term Plan 2019, NHS Digital ca. 2021). Furthermore, it delivers on the recommendation of a systematic review into internet usage by pregnant women (Sayakhot and Carolan-Olah 2016), providing a reliable information source online. Online sources of information have continued to grow in the last two decades. The website, www.healthtalk.org offers a wide collection of people sharing their stories about health conditions and is comparable to the intervention evaluated in the L-TEL Trial for its “peer support” concept. Ryan et al. (2017) videoed women speaking about their breast feeding experiences and these were used on the healthtalk.org platform. The Healthtalk website focuses predominantly on the concerns and problems in pregnancy such as miscarriage and fetal abnormalities. Distinctively, the L-TEL intervention focuses on a “normal”, physiological aspect of the pregnancy and childbirth journey, rather than a pathophysiology. This is the first online intervention developed specifically for improving the early labour phase and thus makes an important contribution to an area of research which is likely to dominate in the coming years.

The L-TEL intervention has contributed to meeting the recommendation put forward in Spiby et al.’s (2008) evaluation of home assessment, which called for the development and evaluation of interventions addressing women’s need for information to modify uncertainty regarding early labour and their expectations of this phase. Additionally, although developed in 2017, the intervention explored in the L-TEL Trial has aptly started to address a number of the recommendations highlighted in Beake et al.’s (2018) systematic review about providing women with realistic information about what to expect from early labour. Furthermore, Beake et al.’s (2018) review called for research into interventions to reduce women’s anxieties and it importantly indicates the need for web-based education to ensure women receive reliable information. The L-TEL Trial is in line with these recommendations. Furthermore the findings from the L-TEL Trial provide a timely response to the call for further evidence about early labour interventions in a recent Cochrane review (Kobayashi et al. 2017)

8.2 Primary outcome: ELEQ

The L-TEL Trial looked to measure the impact of the intervention on women's experiences of early labour and so the primary outcome was selected to be the ELEQ (Janssen and Desmarais 2013a), a 26 item, self-reported evaluation of early labour experiences which was undertaken online at 7-28 days postnatally. This primary outcome was chosen because it had been specifically developed and validated for evaluation of this phase, rather than as an evaluation of childbirth in its entirety. The L-TEL Trial did not demonstrate a statistically significant difference in total ELEQ scores between the control group (96.58) and intervention group (96.77). The 0.19 positive difference seen between the intervention group total score compared to the control group total score was not clinically or statistically significant. The hypothesis is therefore rejected in this case but not without the need for further exploration.

8.2.1 ELEQ: Emotional wellbeing and emotional distress subscale scores

Eri et al.'s (2015) metasynthesis of first time mother's experiences describes early labour to be an unknown territory in two ways: firstly in the personal experience of going into labour for the first time, and secondly in encountering the maternity care system. This distinction is replicated in the ELEQ and its 3 subscale scores (emotional wellbeing, emotional distress and perceptions of midwifery care). The emotional wellbeing and emotional distress scores are a measure of the personal experience of going into labour for the first time, while the perceptions of midwifery care score gauges the experiences of encountering the maternity care system.

Those in the intervention group scored higher in both the emotional wellbeing subscale (24.48) than the control group (23.06), and in the emotional distress subscale (21.80) than the control group (19.97). Although not statistically significant, the intervention group did score consistently higher than the control group in 13 out of the 14 emotional items. As the subscale scores have been independently validated (Janssen and Desmarais 2013a), it is credible to propose that those in the intervention group had a more positive emotional experience whilst at home in early labour than those in the control group.

Personal control, to help women cope in labour, was identified in Chapter 4.0 as a significant determinant of labour and childbirth satisfaction (Christiaens and Bracke 2007). Coping is defined as having the capacity to deal with something difficult successfully (Oxford English Dictionary 2010). Coping strategies during labour have

been broadly separated into two themes: thoughts and behaviours (Escott et al. 2004); it is perhaps that the L-TEL's intervention looked to address both of these themes that resulted in the small positive differences in the emotional subscale scores. Escott et al. (2004) noted that distraction, as well as positioning, were two mechanisms to strongly aid coping and both of these techniques formed a large aspect of the educational content within the intervention. Distraction not only contributes to how women can cope in labour, but also how they maintain power (Carlsson et al. 2012); power and control is known to be strongly correlated with higher satisfaction (Christiaens and Bracke 2007). Whilst it might be that the intervention did improve women's ability to cope, the extent in which formal antenatal education is transferred into practice is not reliable and should not be assumed (Spiby et al. 1999). It is perhaps that the L-TEL Trial's intervention offered the chance for women and birth partners to practice coping techniques at home, something that if lacking, causes women dissatisfaction (Spiby et al. 1999). Furthermore, the L-TEL's intervention looked to provide education which was "real", guided by women who had previously been through labour. These experiences commonly discussed the normality of pain being an aspect of childbirth that needs acceptance. Van der Gucht and Lewis (2015) suggested that future research should look at the role of antenatal education in fostering such a viewpoint in preparation for birth, to better manage expectations about the role of pain in childbirth so women can cope and have a subsequently positive birth experience. The L-TEL Trial may have gone some way to beginning to address this recommendation.

8.2.2 Perceptions of midwifery care subscale score

It is important to acknowledge that whilst making some small difference to the emotional experiences of early labour, the intervention appears to have negatively impacted on self-reported perceptions of midwifery care (the third and final subscale score). Those in the intervention group scored lower in relation to the perceptions of midwifery subscale score (33.74) when compared to the control group (35.78). The intervention group scored lower in all 8 of the individual item scores within the subscale when compared to the control group. Whilst not statistically significant, there is a need to explore this further.

Whilst the intervention group's ELEQ scores were more positive in the emotional domains, they were more negative in the perceptions of midwifery care. It is proposed that in preparing those in the intervention group for early labour (resulting in a more positive, emotional experience) their expectations for this phase were greater. This meant that although their emotional experiences of being at home were better, when

care from the health professional was sought, expectations were, at this point, met to a lesser extent than those reported by the control group. Spiby et al. (1999) found women who received antenatal education, reported a discrepancy between their antenatal expectations and the reality of the midwives' involvement in the use of coping strategies; this was speculated to be because the midwives working clinically had not been involved in the facilitation of the education. Receiving conflicting advice (or advice that does not reflect what has been received previously) is a common source of complaint within maternity, and minimising this is reflected in the national Better Births agenda (NHS England 2016). This may explain the discrepancy between the emotional subscale scores and the midwifery perception subscale scores because the midwives working clinically had not given the same information that the L-TEL Trial's intervention had provided.

An alternative theory to this discrepancy is that women commonly seek care for confirmation of normalcy (Carlsson et al. 2012) because of uncertainty in recognising when labour has started and because they require professional reassurance (Cappelletti et al. 2016). Many look for professional input on a "just in case" principle, even if they are coping well, because they lack confidence in this phase (Cheyne et al. 2007). If women in the intervention group had already prepared for what to expect, and already understood that what they were experiencing was normal, they may not have required the same care, advice and reassurance as those in the control group. Therefore, those in the intervention group may have rated their experiences of this support as less positive, because it was required to a lesser extent, or because they required different support to what was being provided. From the control group's perspective, when seeking midwifery care and on receiving reassurance, it is conceivable they reported this experience to be more positive because their desire for this advice was greater, having received less information antenatally.

This proposal is supported by previous research; Carlsson (2016) presents an important interconnection between how women view the construct of childbirth, about where they wish to be during early labour and how they experience this phase. There are women who view childbirth as a natural occurrence and in this see the home or "human nest" as the safest, most secure place during this phase (Carlsson 2016); their position in the home enables autonomy, empowerment and control. Carlsson (2016) continues to report that women who view childbirth as a natural process have commonly heard positive stories about childbirth, and refer to others who have given birth successfully; in this they inherit positivity from these stories. This is comparable to the vicarious experiences recordings that shaped the intervention of the L-TEL Trial.

Conversely, there are those women who view childbirth as a medicalised occurrence, with risk, and the need for risk elimination through intervention and for these, the hospital is considered the safest place in early labour (Carlsson 2016). These women rely on expert opinion and professional knowledge and so are likely to seek validation at the first sign of labour (Miller and Shriver 2012). In concurrence, Rämgård (2006) found that women seek the place, or thing, that represents safety and security to them during childbirth, such as contact with the midwife in early labour (Green et al. 2012).

These two groups have opposing feelings about control. There are internal and external control processes and both impact on the birth experience (Cook and Loomis 2012). Internal control refers to an individual's ability to control pain, control their emotions and control their own bodies such as with the positions they choose to adopt in labour (Hardin and Buckner 2004, Lally et al. 2014). External control refers to a women's participation in decision making (Cook and Loomis 2012). Possessing control in these domains is associated with a more positive childbirth experience (Hardin and Buckner 2004, Tinti et al. 2011, DeLuca and Lobel 2014, Jafari et al. 2017). Those women who are inclined to see childbirth as a medicalised event wish to hand over control to health professionals (Snowden et al. 2011, Carlsson et al. 2009) likely because they do not feel they possess internal control during this time. Whereas women who view childbirth as a natural process, remain in control (Carlsson 2016).

It is proposed that the intervention group were guided by the web intervention to adopt the view that childbirth is a natural event; having received stories of others successes and having had information, expectation management and time to prepare for this phase, similar to the notion proposed in Carlsson (2016). In this, they felt in control whilst in early labour and therefore did not value the care from the midwifery team as much as those women in the control group. Although not significant, in support of the proposed theory, the intervention group did score higher to the ELEQ question in relation to control (3.71) compared to the control group (3.36). On the other hand, in this proposal, the control group were more likely to view childbirth in the medicalised paradigm, and were therefore keen to hand control to the health professional because remaining at home in early labour did not provide them with a safe and secure environment. It is therefore highlighted that this is a possible explanation as to why the control group evaluated their experiences of the midwifery care higher.

The only emotional item in which the intervention group scored lower than the control group (i.e. less positively) was "...did you feel supported?" (3.63 vs. 4.42). This was

the greatest difference noted in an individual item score between trial arms. This finding could support the suggestion that the midwifery care support was meeting the needs of the women in the control group more than those in the intervention group and also leads to the notion that those in the intervention group did not require external support, because they felt more in control and empowered without it. The intervention group may have required a different type of support to what was provided to them. It should also be considered as to whether the intervention group reported to have felt less supported because the intervention negatively impacted them emotionally. However other ELEQ findings suggest that those in the intervention group were less confused, less anxious, less scared, safer, happier and more comfortable and so it is unlikely that this was the case.

A more plausible theory instead suggests that the intervention modified expectations of what support should look like in this phase, and that expectations were met to a lesser extent than those in the control group. Porter and Macintyre's (1984) seminal work would support this, where it is reported that women will evaluate existing arrangements well, until they know what else is available; this is commonly referred to as "what is, must be best" (Porter and Macintyre 1984). For those in the control group, who did not receive any alternative care or education, it is possible that they rated their care more positively because they did not know anything different. It is suggested that when women's expectation of care are low, that they will not mind what care they receive (Porter and Macintyre 1984). Conversely those in the intervention group may have had greater or different expectations of support, and therefore were more judgemental of their care experiences when they arrived.

8.2.3 An overall positive evaluation

Overall it was noted that women rated their experiences highly. This reflects the literature that suggests that satisfaction surveys (like the ELEQ), tend to have overwhelmingly positive results (van Teijlingen et al. 2003, Carr-Hill 1992) where, from a quantitative perspective at least, women report good experiences in relation to pregnancy and childbirth. In the L-TEL Trial, The ELEQ maximum total score was 130. Those in the intervention scored a mean total of 96.77 and those in the control scored a mean total of 96.58; both scores equate approximately to 74% of the maximum score. This demonstrates that overall, women in both the control and the intervention group rated their experiences of being in early labour positively. However this contradicts the body of qualitative research, where women report a largely negative experience of this phase (Allen et al. 2020, Beake et al. 2018, Eri et al. 2015).

It could be argued that women who do not have a comparator to their experiences of childbirth, may be more inclined to rate them highly, i.e. how can an individual express preference for something else if they do not know what else is, or could be, available (van Teijlingen et al. 2003). This would be true for the L-TEL Trial's study population as first time mothers. Conversely however, so too could the opposite be true, where individuals do not have a comparator and so their experiences fall short of their expectations. In support, much of the qualitative literature reports a disparity between expectations and reality, alongside a negative experience of this phase (Myhre et al. 2021, Eri et al. 2015, Nolan et al. 2011, Beebe and Humpreys 2006).

A retrospective evaluation of an experience could be tainted for the better by a positive outcome; this is referred to as recall bias (Sedgwick 2012). The ELEQ was completed following the birth, so may not be an accurate evaluation of contemporary experience as the events occurred, and instead has evaluated how the individual remembers their experience to have been. A literature review into memory of labour pain concluded that women do not always recall their labour experiences accurately and furthermore retrospectively, their memories are more likely to evoke positive feelings related to coping, self-efficacy and self-esteem (Niven and Murphy-Black 2000). Instead however, Takehara et al. (2014) found that women do accurately remember their childbirth experience for at least 5 years postpartum, and their recollection was comparable to the results of the same survey undertaken a few days following childbirth. Furthermore, the literature suggests that a negative evaluation of childbirth has the most significant impact in the long term for women (Shorey et al. 2018, Goodman et al. 2004), and so a positive evaluation of childbirth, even if overestimated, should not be of concern. A positive childbirth evaluation has been seen to contribute to self-esteem, accomplishment and good expectations for a future positive childbirth experience (Goodman et al. 2004, Slade et al. 1993). If recollections (and their subsequent positive evaluation) are to some degree an inaccurate representation of the contemporaneous lived experiences, this does not need to be of concern if the positive outcomes of these recollections prevail irrespectively.

8.2.4 ELEQ: The right tool?

With the above discussions in mind, one might ask if the ELEQ was the most suitable tool, in its entirety, to evaluate the L-TEL Trial's intervention. Although the limitations of a quantitative satisfaction score (van Teijlingen et al. 2003) have been acknowledged,

these limitations can be minimised when evaluation of satisfaction is focused on explicit areas of maternity care provision, as seen in the evaluations of specific midwifery care models in Perdok et al. (2018). As the L-TEL Trial was specifically focused on the early labour phase of the childbirth continuum, it is anticipated that those completing the ELEQ were able to recall on this specific aspect of their care more accurately than if they were required to evaluate their pregnancy, labour and childbirth experiences as a whole.

As a measure of the intended outcome, the ELEQ's two emotional subscale scores (emotional wellbeing and emotional distress) were more suited to evaluate the web intervention when compared to the ELEQ's perception of midwifery care subscale score. This is because the intervention did not specifically seek to affect how women evaluated their experiences of the physical care provided by health professionals. Conversely, the intervention was designed to improve experiences prior to seeking care from the service; this was the important distinction between this trial and the research that has preceded it. Based on this, it has been considered that the ELEQ's two emotional subscale scores could have been used to evaluate this intervention in isolation. However, this view should be adopted with caution for the following reasons.

As documented in Chapter 6.0, the ELEQ is a pre-validated tool for measuring early labour experience, and is the only tool which specifically looks at this phase. Furthermore it has been successfully translated and validated into a number of different languages (Cunquero et al. 2009, Ip et al. 2005, Carlsson et al. 2014, Tanglakmankhong et al. 2011, Khorsandi et al. 2008) and it was for these reasons that it was selected during the methodological development of this trial. The complex journey of the early labour phase will always, at some point, involve the midwife and the relationships between the woman and midwife continue to be documented as fundamental in the overall experience of early labour (Allen et al. 2020, Beake et al. 2018, Capelletti et al. 2016, Borrelli et al. 2016). Therefore to dismiss the perceptions of midwifery care subscale score of the ELEQ would not fairly represent a valid measure of a woman's complete experience of early labour. Even if the intervention can make some positive differences to women's emotional experiences, the suggestion that it could negatively impact the experiences associated with the care provided by the midwife, needs further consideration, as opposed to rejection. Instead, it should be concluded that the ELEQ remains the correct measure but recognise that the L-TEL Trial leaves a gap for further research into how maternal emotional experience can be improved, likely through enhanced self-efficacy, empowerment, autonomy, knowledge and control, without negatively impacting on the perceptions of the physical care that is

provided. This may require more investigation into how to better prepare midwives to supplement the antenatal advice and information provided in the L-TEL Trial's intervention so their support can remain of high value to women.

8.2.5 Another finding from the primary outcome

Women in the control group scored more positively to the question "Do you feel you went to hospital at the right time?" indicating more women in the control group felt their timing to hospital was right and although not statistically significant, the difference in these responses is worth consideration for further research. It is possible that in providing women with more advice about remaining at home, their expectations for when the right time to go to hospital were altered. Beake et al. (2018) suggests that providing women with more information antenatally about what to expect in early labour would better prepare them to attend hospital at the right time but the L-TEL Trial did not concur with this notion.

Conceivably, women in the intervention group had a better understanding of the negative implications of being admitted in early labour and therefore felt additional pressure to avoid this. If, on admission, participants from the intervention group were found to be in early labour, they may have had more disappointment or more understanding that this was not the "optimal" admission time and thus their scores have reflected this. Cook and Loomis (2012) found that changes to a woman's birth plan that allowed little or no control were the most disappointing. The amount of control that the woman has over changes in the birth plan (i.e. admission in early labour) will impact on how positively the birth experience is evaluated (Hauck et al. 2007).

Alternatively, those in the control group may have sought admission whilst in early labour without knowing the implications of early admission. Instead, perhaps the control group requested admission when it was personally needed, rather than at a specific, pre-determined point in their labour. If this theory were true, there may be a need to supplement the advice on the web intervention, to ensure that individuals who view the intervention but go on to require admission in early labour anyway, do not feel any sense of disappointment.

On the other hand, women in the intervention group may have reported a less positive response to this question because they remained at home, believing this was the right thing to do based on the education they had received from the intervention, when in

reality, admission was required. However this theory opposes the other ELEQ findings which found the intervention group to have a more emotionally positive experience at home. Remaining at home when admission is emotionally required has been documented in the literature to be very detrimental to experiences (Nolan and Smith 2010) and so this proposal, when viewed in conjunction with the other ELEQ findings, would appear flawed.

8.3 Secondary outcomes

Although the L-TEL Trial was not statistically powered to demonstrate significant differences in clinical outcomes, there were some findings for discussion.

8.3.1 Augmentation of Labour

Those in the intervention group were more likely to progress in labour without the need for artificial augmentation and this finding was statistically significant. Augmentation of labour is the process of artificially accelerating a labour that has spontaneously commenced by the means of rupturing the amniotic membranes or by commencing an artificial form of the hormone oxytocin. The practice of augmentation is common but the evidence around its use is deficient, although not discouraging of it either (Son 2020). Whilst artificial oxytocin can reduce the length of labour, a Cochrane review found that its use did only this, and did not reduce the number of women undergoing caesarean section (Bugg et al. 2013). In other words, reducing the length of labour may be desirable to some mothers and care providers, but it may be of no clinical benefit overall to birth outcomes and may in reality commence the cascade of intervention previously discussed in Chapter 2.0.

The hormone oxytocin, in its natural form, plays a significant part in labour progression as the responsible agent for generating uterine contractions (Uvnäs-Moberg et al. 2019). There is some correlation between positive emotion in the labouring individual and her subsequent labour progression (Leap et al. 2010b, McNelis 2013), which may go some way to explain why those in the intervention group, who reported a more positive emotional experience, required less augmentation. Rates of augmentation in the intervention group were also lower than the Trust's annual data. The Trust data however includes nulliparous women of all risk factors, where the L-TEL Trial recruited only low-risk women. Thus this finding is not unexpected because women with higher

risk factors are likely pre-disposed to require a greater level of medical and obstetric intervention.

Reducing the use of artificial oxytocin could be beneficial for a number of reasons. Firstly, women receiving artificial oxytocin require intravenous cannulation, a routine, albeit invasive, procedure with some discomfort involved and a small risk of infection (Campbell 1997). Secondly, artificial oxytocin use denies women the opportunity to birth on a midwifery led unit, where additional fetal monitoring is required due to changes in the baby's heartbeat that can be of concern (Boie et al. 2021). Women who birth at a midwifery led unit receive fewer medical interventions (National Perinatal Epidemiology Unit (NPEU) 2011). Furthermore, without the restrictions of an intravenous drip, women may be more inclined to move around and adopt more upright, mobile positions, which have been demonstrated to reduce rates of instrumental birth, reduce rates of episiotomy, shorter second stage of labour and improve maternal satisfaction (Gupta et al. 2017, Thies-Lagergren et al. 2013). The findings from the L-TEL Trial indicating lower rates of augmentation in the intervention group, for the reasons detailed, is of clinical significance. There were a large number of participants for whom these data were missing, reducing the validity of the conclusions noted and therefore a larger scale study, powered to demonstrate differences in clinical outcomes such as augmentation, is recommended.

8.3.2 Phase of labour on admission

The data collected with regard to phase of labour on admission did not demonstrate a significant difference between the intervention and control group with ITT analysis or with the secondary analysis (which was undertaken with only those participants with data available). Rationale for this secondary analysis is presented in Chapter 6.0. The limitations of the data collected are recognised and the impact of this on this finding are considered further. The limitations of the secondary analysis are also presented in this section.

As previously documented, a large proportion of participants did not have information about their phase of labour at admission documented on the hospitalised computer system. In total, 31.0% of those in the control group, and 31.9% of those in the intervention group, had this information missing. Whilst the two figures are similar, indicating a successful randomisation strategy, the high proportion of missing data limits any conclusions in relation to this outcome where it is not possible to determine if more data would have altered any differences between the trial arms.

Furthermore, as per the ITT analysis, the intervention group were more likely to be admitted in active labour (21.7%) when compared to the control group (18.3%), based on this finding it would appear the intervention group have the favourable outcome. However, due to the limitations of the data collected, the intervention group also had more recorded cases of women who had been admitted in early labour (11.6%) when compared to the control group (8.5%). This is important because it demonstrates the importance of reporting all results transparently. Viewed in isolation, the intervention group have a higher proportion of women admitted in active labour, which in the context of the labour continuum, is of clinical benefit and is considered the favourable outcome (Miller et al. 2020). However, when viewed alongside the rest of the data, in reality, the intervention group were more likely to be admitted in any kind of labour (early and active), because the control group had a higher incidence of being admitted prior to any labour. The data in regard to the participants who had been admitted prior to any labour was consistently available to collect. This was because any participants undergoing an IOL or a caesarean section prior to labour would have been admitted before any labour. Being able to establish this outcome more reliably and therefore more frequently than the other outcomes skews the findings with a bias towards “admission prior to labour”. Therefore drawing clinically meaningful conclusions from this outcome is entirely limited.

These limitations with the data collection had not been anticipated by the researcher because there is a specific space in the hospital records for this information to be documented and so it was expected that this data would have been straightforward to collect. During the data collection period it became clear that midwives were regularly documenting only the date of admission, rather than a date and a time, and thus establishing the stage of labour in which participants were admitted was not possible. For those entries with a time recorded, it was possible to collect the time of established labour and compare that against the time of admission to gauge the phase of labour on admission.

It was possible to establish reliably which participants had been admitted prior to any labour, because any participants undergoing an IOL or caesarean section not in labour would have been admitted prior to labour. However being able to establish this outcome over and above the other outcomes, skews the findings with a bias towards “admission prior to labour”. It is for this reason that the secondary analysis, on only participants with data available was undertaken. It was acknowledged that this analysis would not reliably maintain the balance that was created by the randomisation process

(Tripepi et al. 2020), however the number of participants who were eligible for this analysis were comparable between trial groups (control=19, intervention=23) and so it can be assumed that this considered impact was minimal. Another limitation for this secondary analysis is that it reduces the sample size and also the study power to provide statistically significant findings (Gupta 2011), however because this trial was not powered to show statistically significant differences in these secondary clinical outcomes, this was not deemed to be problematic in this instance.

The secondary analysis on only spontaneous labourers did not support the ITT findings demonstrating that it was the right decision to undertake this secondary analysis. The secondary analysis found that those in the intervention group were slightly less likely to be admitted in active labour (65.2%) when compared to the control group (68.4%). These findings were not statistically significant. The sample size for this secondary analysis was very limited in size and rates of active labour admission were very similar between the trial arms. Based on only this, it should be assumed that the intervention did not have any meaningful impact on the timing of admission but the generalisability of these findings and subsequent conclusion is wholly limited (McCoy 2017).

Future studies aiming to collect this outcome should consider the limitations of using hospital records to harvest data and the implications that missing inputs can have on study findings. It had been anticipated that using existing data would improve the rate of data collection, where the “gate keeper” notion within research can limit data collection for studies (Lee 2005) and whilst this may have been true for the majority of the data collected, this was not the case for this specific outcome. On reflection, it would have been valuable to audit a sample of hospital notes prior to the start of the L-TEL Trial, or better still, run a small study pilot. A pilot study is known to improve the quality and efficiency of the main study trial (van Teijlingen et al. 2001). This would have provided the researcher with the confirmation that the expected data were being collected reliably and accurately by the clinical midwives and if it was not, then would have provided the researcher with insight to put a more reliable method of data collection in place.

8.3.3 Other secondary outcomes

For the majority of clinical outcomes, there were no statistically significant differences between the intervention and the control groups. This was likely due to the small sample size, which was not powered to note differences of this nature. Furthermore, the intervention was not developed to directly impact on clinical outcomes, and instead

focused on women's experiences of being in early labour at home. It would be of benefit, to undertake future, larger research studies that can measure women's experiences and any subsequent clinical outcomes, as well as any relationship between the two.

When compared to the annual hospital data, both the intervention and control groups had more favourable outcomes (higher number of births in a midwifery led environment, higher rates of spontaneous labour, lower rates of amniotomy, lower rates of artificial oxytocin use, lower rates of regional anaesthesia). This was not unexpected where the L-TEL Trial specifically recruited low-risk women, conversely the hospital data presents women with a range of risk factors, and those women at high-risk (who would not have been eligible for this trial), would be predisposed to require a greater level of intervention. Spontaneous birth rates between both trial groups and the annual hospital data were comparable, suggesting the trial had recruited a representative sample successfully.

8.4 The intervention

The intervention in this study was co-designed for women by women, it is therefore very positive to see such a high uptake. Of the 54 women who returned their postnatal responses, over 96% indicated that they had used the online web intervention during their pregnancy. Furthermore, 87% of respondents indicated that they used the intervention more than once and almost 25% of respondents used the intervention 4-10 times. Almost 30% of respondents' birth partners also used the intervention. This suggests the intervention developed was highly acceptable to its users and also demonstrates a good level of engagement from participants with the L-TEL Trial. It is worth considering that the participants who used the intervention may have been more inclined to respond to the questionnaire and thus a bias may exist here in favour of the intervention's acceptability. In spite of this, it is undeniable that the intervention offers a flexible, web based educational tool which can be accessed at the users' convenience, at home, for as long or as little as is acceptable to that individual.

Unlike face to face education, the online format provides information without commitment, i.e. a series of educational face to face sessions offering the same advice would require a high level of commitment which might involve travelling to a new destination. In line with this, the L-TEL Trial saw a much greater compliance than other face to face educational interventions such as documented in Ip et al.'s (2009) RCT. In

Ip et al. (2009), 27% of participants did not attend all of the face to face sessions that made up the intervention. The reasons for this were detailed to be that participants were tired or sick, the weather was bad, there was no one to accompany them to sessions, they were busy at work or that work was too far from the intervention's location. Online educational tools provide immediate access to information, which is important to women (Lupton 2016, Lagan et al. 2010). The L-TEL Trial provides an intervention that removes most accessibility barriers and the high number of women accessing the intervention repeatedly corroborates this notion.

There is however an increasing amount of attention to the concept of digital exclusion, which has become more evident in the midst of the Covid-19 pandemic (Watts 2020). Any healthcare, digital intervention that may not be accessed by everyone has the risk of causing widening health disparity (Helsper 2017). Alongside the elderly population, disabled and socially deprived individuals are most at risk of digital exclusion (Gann 2019) and this should be a consideration for maternity services, particularly as digital interventions become more prevalent. Women living in deprived areas are at much higher risk of maternal and fetal morbidity and mortality (Draper et al. 2020). Whilst digital exclusion needs consideration, 99% of adults less than 44 years of age and therefore of childbearing age do access information online (ONS 2020) and so the intervention remains relevant to the population it aims to serve.

There were two respondents of the L-TEL Trial who did not use the intervention and they detailed that this was because they did not remember to. It is recognised that it may have been beneficial to provide a reminder to participants in the intervention group, so to maximise adherence to protocol. Schwebel and Larimer (2018) found that text message reminders in health care delivery increased appointment attendance and medication adherence and was helpful in promoting and shaping healthy behaviours. As a low cost, rapid form of communication (Rohman et al. 2015, Chung et al. 2015) a text reminder may have been a useful tool for improving participants' engagement with the intervention (Schwebel and Larimer 2018). As a pragmatic trial, a text reminder would have been acceptable because it is fair to assume that if adopted in a real clinical setting, reminders to use the web intervention could be provided through pregnancy via promotion on social media and during face to face midwifery appointments.

Of the respondents who used the intervention, more than 96% reported that they would recommend the intervention to a friend demonstrating that regardless of any measured

outcomes, the L-TEL Trial has offered a tool that women feel is useful enough to recommend to others. There are limitations to a single item measure, such as “Would you recommend this to a friend?” (Johanson and Doston 1994). It is recognised that questions that require only a “yes” or “no” response, may lead to a tendency for acquiescence response bias. In this, respondents may be inclined to provide the answer they believe is desired, and in being agreeable, they avoid disappointing the researcher (Knowles and Nathan 1997); in part, this may provide explanation for the very high positive response to this question.

Conversely, more contemporary research would instead indicate that pregnant women appreciate accessing information from a wide range of sources, in particular sources which can offer instant access to material (Lupton 2016), such as that offered by the intervention in the L-TEL Trial. Conceivably it is this that compelled respondents to positively indicate that they would recommend the intervention to friends, so that they too can access information, quickly, on-demand and from as many sources as possible.

When asked to describe what they liked most and least about the web intervention, alongside “informative” and “user-friendly”, many respondents commented on the use of “real women’s experiences”, which was largely the most novel aspect of this intervention (Table 13). This was not an unexpected finding, where other research has confirmed the importance of digital information for establishing connections with other mothers (Lupton 2016). Although the L-TEL Trial did not provide an intervention for making intimate relationships, it did provide information in a realistic and practical way to which pregnant mothers could relate. This intervention provides a type of digital peer support, where the mothers on the website could offer advice, in a non-professional capacity, to those with whom they have some common experience (McLeish and Redshaw 2015).

Respondents also commented on liking the “positive message” of the web intervention, an ode to the self-efficacy theory that had been the basis of its development. Furthermore, there is an increasing need to focus on providing women with a positive (albeit realistic) message about childbirth. Pregnancy, and the subsequent dominant medical model of childbirth, is commonly portrayed by the media as risky, dramatic, painful and dangerous (Luce et al. 2016, Bick 2010) which is likely to be having a negative impact on the way women feel about these life events. It is a useful finding

from the L-TEL Trial to know that the women viewing the intervention felt the informative messages were positive.

Two respondents reported that they “would have liked subtitles” on the videos, which is a point worth consideration and will be discussed in more detail in Section 8.7 of this chapter.

8.5 Safety

The intervention’s safety, and any potential risks it posed to research participants was considered at every stage of the intervention and trial’s methodological development. A theoretical risk considered was the chance of a “born before arrival” (BBA). This is the term used to describe a birth that occurs at home, or on route to a place of birth without professional attendance. Whilst a rare occurrence, it was considered that an intervention that may encourage women to remain at home confidently, may pose an increased risk of BBA. The vast majority of BBAs occur within multiparous women (McLelland et al. 2018, Thornton and Dahlen 2018) and this trial only included women who were nulliparous. Furthermore, the aim of the intervention was not to keep women at home for longer necessarily, instead it looked to keep women at home in a more positive emotional state. The advice about when to call the hospital, or the advice that was provided from the hospital about when to come to the chosen place of birth was not different for the trial group. The website actually provided a great deal of information about when to call the hospital and which number to call. Based on these considerations, the intervention did not look to pose an increased BBA risk to the trial population. None of the trial’s participants experienced a BBA.

The intervention was subject to a robust review from service users, clinicians and academics in the field prior to its trial to promote safety. Details of this can be found in Chapter 5.0. It was considered to be a low-risk, educational intervention, that was unlikely to pose any risk to participants. The success of this review process is demonstrated by the low number of adverse events that occurred during the trial period (n=1). Sadly one participant in the control group had a preterm stillbirth, which was reviewed by the Chief Investigator and a group of senior midwives at the research site and was deemed to have been unrelated to the L-TEL Trial or the intervention.

8.6 Strengths of the L-TEL Trial

The L-TEL Trial was the first trial to evaluate an educational web intervention specifically developed to improve women's experiences of early labour. Furthermore, the trial harnessed women's real experiences in a co-creation process which successfully put forward an intervention focused on what service users identified to be meaningful. Instead, previous research efforts have focused on the aspects of care that are most meaningful to service providers, leaving a dichotomy between the services that are available and the needs of those who access these services.

A RCT research design was adopted to most successfully investigate a causal link between the web intervention under investigation and women's experiences (Hariton and Locascio 2018). A pragmatic approach to the L-TEL Trial successfully investigated if the web intervention could affect women's experiences in the real world, generating new knowledge in reality, rather than a newly constructed research reality (James 2017). This has provided the L-TEL Trial with increased external validity, the measure of how applicable findings are to other contexts (Andrade 2018). This approach not only has provided insight into the intervention's impact, but also has offered an understanding of how the intervention could be adopted in wider clinical practice. For example, two participants reported that they forgot to use the web intervention and would have appreciated reminders, as documented to be valuable by Schweber and Larimer (2018). This supplementary information offers additional insight for service providers about how to improve accessibility of this intervention and for future interventions thereafter.

There was a largely positive response to the research, and this was evident in both the co-creation process of the intervention and in the recruitment for the trial itself. Within 48 hours, 116 women had responded to the invite to share their experiences of early labour for the co-creation of the web intervention, furthermore 86 of these women supplied their contact details. For these women, there was no intrinsic, direct benefit to them for their involvement and instead there appeared to be a largely extrinsic, altruistic motivation in wanting to help and support other women. This notion has been documented in Carrera et al. (2018) who found these sentiments are established in a desire for connection to common humanity, science and the community. Furthermore, specifically the "telling of birth stories" has been suggested to be an intuitive urge, to share the momentous occasion, and importantly, a method of coming to terms with their own experiences (Savage 2001, Kay et al. 2017, MacLellan 2020). In this, the L-TEL Trial's co-creation process was of great success.

The L-TEL Trial successfully recruited its target of 140 participants, demonstrating the high engagement from participants and midwifery staff involved with the recruitment process. The researcher had the opportunity to speak to potential participants during the recruitment and consent process and many women expressed that they saw their participation in the trial as “easy”, without the need to commit to any travel, face to face appointment, and many women were also pleased that all correspondence was online, which could be completed at their own convenience. Additionally, the L-TEL Trial was of low cost to run where online correspondence (including consent and collection of the primary outcome data) was free and easy to manage. In line with this, the electronic data collection (both in relation to participant demographics and in relation to the primary outcome) reduced human error, where the need for manual data input was removed. This was evident in the very low error rate that was identified during the data cleaning process.

The L-TEL Trial’s cohorts demonstrated a high adherence to protocol, only 2 participants in the control group incidentally used the intervention and only 2 participants in the intervention group did not use the intervention, strengthening the trial’s internal validity. This was a success of the L-TEL Trial where there had been consideration during methodological development as to whether a large proportion of participants in the control group would actively seek the intervention for themselves; in this password protection was considered but rejected (Edwards et al. 2019). In addition, there were a comparable number of participants from each trial that contributed to the final primary analysis.

The trial was well supported by the midwives and by the research team at the host Trust who could understand the importance of studying a midwifery-led, woman focused intervention. A midwife who identified potential participants expressed her gratitude to the researcher as she communicated that much of the research she was asked to support was entirely obstetric or medically focused and so she saw the L-TEL Trial as a refreshing addition to research in this field.

The L-TEL Trial was adopted on to the National Institute for Health Research (NIHR) Clinical Research Network (CRN) Portfolio, an “infrastructure support for the initiation and delivery of high quality research which benefits patients and the NHS... to answer... relevant questions with scientifically sound methods” (DOH 2019).

8.7 Limitations of the L-TEL Trial

In spite of sound randomisation techniques, of which neither the researcher or participant had influence, there is a difference between the control and intervention group with regard to their marital status; 76.1% of the control group were married compared to 58.0% of the intervention group. The impact on the trial in light of these differing demographics has been considered.

It is widely documented that women who are married have better pregnancy outcomes: reduced pre term birth, increased vaginal birth rates and higher breastfeeding rates (Kane 2016, Barr and Marugg 2019). There is continued debate as to whether married individuals adopt healthier behaviours as per an intrinsically different personality than their single counterparts (named marriage-selection) or whether marriage itself causes healthier behaviours (named marriage-protection) (Kane 2016).

Bird et al. (2000) found that there were other factors, often associated with lower levels of marriage union, which made a larger difference in clinical outcomes, such as smoking, strengthening the marriage-selection theory. Furthermore, many research studies fail to distinguish between married individuals and cohabiting individuals, instead grouping those cohabiting with single parents i.e. either married, or non-married. Many babies born into cohabitation relationships are born with two present parents. There has been a dramatic increase in cohabitation child-bearing in recent years, with an increase of 25.8% over the last decade (ONS 2019), thus much of the available evidence in relation to marriage is now dated and does not represent the current population (Waite 1995, Repetti et al. 2002).

In support of this, the intervention's cohort had a higher number of women who reported to have a partner (37.7%) when compared to the control's cohort (19.7%). If combined, 95.8% of women in the control group were either married or with a partner, compared to a similar figure of 95.7% of women in the intervention group who were either married or with a partner. In a recent Cochrane review, continuous support from a partner of the woman's choosing during labour has shown to be of both clinical and emotional benefit, as well as improve the birth experience (Bohren et al. 2017). Considering the L-TEL Trial focused on the emotional and experience based aspects of early labour, the difference in the cohorts of marital status is unlikely to have had an impact on trial findings where married women and women with partners are both likely to receive the emotional and continuous support documented to be important (Bohren et al. 2017).

The L-TEL Trial does however under represent women who are single (i.e. not supported by a partner), and this is certainly a limitation of this study which looks at experience at home in early labour, a concept that is likely to be impacted when support is lacking. Consequently, conclusions drawn from this trial are not generalisable to single women (i.e. unsupported by a partner) and this needs consideration for future research efforts which would be well placed to look at interventions that might support women to have positive birth experiences that are otherwise unsupported by a “traditional” birth partner or spouse.

It is also acknowledged that the L-TEL Trial’s study population under represented women from diverse ethnic groups and instead the majority of participants in both the control and the intervention group identified as “White British” or “Other White background” (control=91.6%, intervention=95.7%). Of the women who booked for maternity care in April 2020 at the Trust, 84% were of White ethnicity. This too was the case during the co-creation process, which saw a homogeneous volunteer group. The under representation of Black, Asian and Minority Ethnic groups in clinical research is not a new concept (Smart and Harrison 2017, Redwood and Gill 2013) and targeted approaches to recruitment is often required to counteract this disparity (Redwood and Gill 2013). For UK research agenda, this needs to remain a priority where women from Black, Asian and Minority Ethnic groups are at significantly increased risk during their pregnancy, birth and postnatal period (Draper et al. 2020, Knight et al. 2019). Whilst the web intervention attempted to promote diversity in the specifically developed graphics, the lack of ethnic diversity on the videos is acknowledged as a limitation. If the intervention was to be widely accessed, this would need addressing to ensure that there is better representation so that all women feel they can relate to the vicarious experiences that shaped the intervention. Furthermore, in relation to improved accessibility, two of the participants responded that the videos would be improved with subtitles. The videos on the intervention can be viewed with English subtitles, which can be generated automatically by the video platform, but this was not made clear to users on the site and therefore this feedback is justified.

It is also acknowledged that seeking the volunteers to partake in the co-creation process via a breast feeding support page was likely to have limited the demographics of those who volunteered. Higher maternal age, Black and Mixed ethnicity are associated with higher breastfeeding rates, whereas geographical deprivation is associated with lower breastfeeding rates (Oakley et al. 2014). Furthermore, breastfeeding rates have been shown to be higher amongst extraverted, emotional

stable, conscientious mothers (Brown 2014) and lower in mother experiencing anxiety (English et al. 2020). However, on speaking to the volunteers, some individuals had actually been passed the details for the co-creation opportunity by a friend, demonstrating that there was a positive, altruistic element which brought women together, where they shared the opportunity to be involved amongst one and other; this was a serendipitous finding from this co-creation process. Future research may look to seek participants for a co-creation process of this nature from a wider pool of individuals, to minimise specific characteristics associated with the recruitment methods having impact on the intervention.

Another limitation is the high number of participants who were not able to contribute to the primary analysis, mostly due to having not spent time at home in early labour, a requirement in order to complete the ELEQ. The recruitment time frame and the sample size were successfully extended to increase the chances of meeting the minimum number of participants required to demonstrate a statistical difference in the primary outcome. Although this sample size was achieved, 49% of women randomised did not contribute to the primary analysis, due to high rates of induction, planned caesarean and early admission antenatally. Although this is clearly a limitation of this trial, this finding fairly represents the situation in maternity care. It also further confirms the suitability of the pragmatic approach in which the L-TEL Trial adopted where, outside of a research context, there would be a large number of women who would use the web intervention and then go on to not use the information and advice it provides. Furthermore, the percentage of participants who contributed to the primary analysis was equivalent between the two trial arms thus not lessening the impact of the randomised trial design.

The limits of the qualitative data that were collected are also acknowledged. The qualitative questions did not harness a rich data set, which had aimed to supplement the quantitative findings. Although the responses provided good insight into the intervention's acceptability and usability, the data collection did not specifically enquire about what may have impacted on women's emotional experiences of early labour and thus there is a limitation here. In response, it may be of benefit for future research efforts to focus on both a quantitative measure of early labour experience, alongside a richer data of qualitative responses so that context and meaning can be provided to the numerical, Likert answers.

8.8 Implications for future research

8.8.1 Future research considerations

To learn from the challenges that faced the L-TEL Trial, future prospective research, recruiting women in the antenatal period, with interest in evaluating the early labour phase, will need to consider the high rates of IOL that women are now experiencing. The L-TEL Trial required a recruitment extension, both with regard to participants and timescale, and this needs future consideration. Due to these increasing rates of IOL, fewer women are likely to be categorised as “low-risk” by the time they go into labour, and so larger recruitment figures may be required to contend with this.

Additionally, the limits that were discussed with data collection, particularly in relation to the timing of admission need further consideration in future efforts, and the consideration of a pilot study, to better predict the quality of data collection would be well placed to avoid replication of the challenges the L-TEL Trial saw.

Ensuring that research populations fairly represent a wide heterogenetic group including those from Black, Asian and Mixed ethnicity backgrounds and those without support partners will help future research’s generalisability to the wider population.

The L-TEL Trial has demonstrated the success of using digital platforms to publicise research, consent participants and collect data. Online data collection and consent has not been widely explored but the L-TEL Trial has suggested that it could be an accurate means of research, with lessened commitment from participants (when compared to completing physical, postal responses), but where research output remains valuable. Furthermore, during the Covid-19 pandemic, whilst this study was in its write-up period, the need for digital resource and care provision has become increasingly vital for health literacy and accessibility (Gunasekeran et al. 2021). This digital response to Covid-19 has started to extend to the way in which research is conducted (Mitchell et al. 2020) where researchers may need to adopt online, digital recruitment and data collection methods out of necessity. This should all be considered in the methodological development of future research.

8.8.2 Research recommendations

Harnessing other women’s experiences and using these experiences to shape the intervention was novel and was evaluated positively, both by those who took part in the co-creation process and by those who used the intervention. This approach provides

service users with an altruistic motivation to share their stories in order to help others (Savage 2001, Kay et al. 2017, MacLellan 2020), and this should be merited. Future studies should adopt this co-creation approach so that women and families have a meaningful voice in directing future research, and so that interventions are focused on what women believe to be important. Future research employing co-creation processes in maternity research should aim to involve a wide, heterogeneous sample of individuals that best represents the receivers of the intervention.

The L-TEL Trial has demonstrated that an educational intervention focused on empowering women during early labour is likely to be of emotional benefit to those that use it and there may be further educational, coping strategies for use in the antenatal period that merit investigation. The L-TEL Trial has illustrated that women's emotional experiences of early labour and their experiences of encountering health professionals in this phase are two distinct concepts, which can be evaluated independently. It would be prudent for research to now focus on how the two concepts can be harmonised so that the entire labour experience continuum is positively addressed.

A large, multi-centre RCT with an increased participant size, with greater heterogeneity is recommended to investigate the novel intervention from the L-TEL Trial. This would improve the generalisability of the findings to the underrepresented demographic groups in the L-TEL Trial's study population as well as assess the acceptability of the intervention on a wider, more diverse group. A larger sample size would provide enough power to statistically evaluate clinical outcomes. It would be particularly beneficial to investigate the impact of the intervention on rates of labour augmentation, because the findings from the L-TEL Trial suggest a reduced rate of this outcome in the intervention group. Nonetheless, it is highly recommended that any future research evaluating the impact of this intervention also continues to evaluate and centralise women's experiences, so that primary focus remains with the service user, not the service provider. A larger scale trial would be well placed to better explore the qualitative experiences of research participants, to provide a deeper and richer context to any of the quantitative findings from the ELEQ. This would aid with understanding what aspects of the intervention are of most impact to women's early labour experiences and why.

9.0 Conclusion and contribution to knowledge

The web-based intervention, co-created specifically for the L-TEL Trial, did not demonstrate an objective, overall difference in women's early labour experiences based on their self-reported, total ELEQ scores. However, those in the intervention group consistently reported a better emotional experience whilst at home in early labour, with higher ELEQ scores in the emotional wellbeing and the emotional distress subscale scores. In contrast, those in the intervention group reported a less positive experience in the perceptions of midwifery care subscale score, which was evaluating their experience during early labour when accessing health professionals.

These findings have shown that women evaluate aspects of their early labour experience continuum independently, and improved experiences in one domain does not equate to overall improved experience. It has also suggested that by equipping women better to cope at home, there may be a negative impact on their experiences of the maternity services. An explanation as to the reasons for this are at present unknown and warrant further research efforts to understand.

Although the trial was not powered to demonstrate statistical differences in clinical outcomes, those in the intervention group had a lower rate of labour augmentation. To objectively prove or disprove this, a larger scale RCT, with the power to determine these differences is required.

The specifically developed web intervention captured others' experiences in a novel, co-creation process which centralised women, their experiences, their emotions and what they prioritised as a means of coping at home in early labour. Existing research to date had not done this. Those women that received the intervention positively evaluated it and this is further demonstrated in the high number of women who accessed it during their pregnancy. Web-based resources prove to be cost effective, user-friendly, accessible ways to provide women education and this intervention has successfully addressed the call for online advice that is evidenced-based, reliable and accurate.

Furthermore, the trial has moved away from the ongoing trend of evaluating service allocation and appropriation from the perspective of what is desirable to the maternity service, primarily keeping women out of hospital, often to the service users' emotional detriment. Instead this study has contributed to the early labour knowledge pool of what women find to be emotionally progressive during this phase and has looked to equip

women with the skills and coping strategies they need to remain at home readily. Distinctively, the knowledge underpinning these skills and coping strategies has come directly from other women for increased authenticity.

To conclude, the L-TEL Trial was a well-timed research study, contributing to the gaps in knowledge highlighted in several recent research papers (Spiby et al. 2008, Beak et al. 2018, Kobayashi et al. 2017, Allen et al. 2020, Cappelletti et al. 2016, Sayakhot and Carolan-Olah 2016). The L-TEL Trial adopted a robust, pragmatic, randomised approach ensuring applicability to the current NHS maternity setting whilst providing valid research findings to the field. The intervention is novel, in line with contemporary national agenda and most importantly was uniquely developed by the very people it aimed to benefit: the women. Those who have trialled it have reported an improved emotional experience whilst at home in early labour and high levels of satisfaction in its usability, as well as an eagerness to recommend its use to a friend. It has made a unique contribution to this field of early labour research and it is recommended that the intervention warrants further research, on a more heterogeneous population, with the power to measure clinical outcomes whilst preserving the primary measure of women's experiences.

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Appendices

Appendix 1: Details of databases included in Bournemouth University MySearch

Resources included in mySearch

Resource

BU Library catalogue

BURO

19th Century British Pamphlets

Academic Search Complete

Annual Reviews

Art & Architecture Complete

arXiv

Association for Computing Machinery (ACM)

BMJ Publishing

Books 24x7

British Library Document Supply centre Inside Serials & Conference Proceedings

British Library (EThOS)

Business Source Ultimate

Cambridge University Press

Center for Research Libraries

Cinahl Complete

Clinical Trials

Cochrane

Communication Abstracts

Communication Source

Complementary Index

Credo Reference

Digital Access to Scholarship at Harvard (DASH)

Directory of Open Access Journals (DOAJ)

EBSCO ebooks Academic Collection

EBSCO ebooks purchased

Education Source

Emerald

Environment Complete

ERIC

EThOS

European Union Open Data Portal

European Views of America

Government Printing Office Catalog (USA)

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Hospitality & Tourism Complete

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Ingenta

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IOP Publishing

J-Stage

Journals@Ovid

JSTOR

LEXISNexis Academic Law reviews (US Content)

Lippincott Williams & Wilkins (LWW)



LISTA


MA Healthcare

Manuscriptorium Digital Library
Medline Complete
Nature
Networked Digital Library of Theses
New Scientist
Newswires
OAPEN Library
Open SUNY Textbooks
OpenDissertations
Oxfam Policy & Practice
Oxford University Press
Project Muse
PsycArticles
PsycBooks
PsycINFO
PubMed
RCN Publishing
Regional Business News
Royal Society of Chemistry
Royal Society, The
Sage Journals
Sage Research Methods
SciELO
ScienceDirect
SciTech Connect
Scopus
Social Theory
SocINDEX with Full Text
SPORTDiscus with Full Text
SpringerLink
SSOAR - Social Science Open Access Repository
Supplemental Index
SwePub
T&F
Teacher Reference Center
Times Digital Archive
Web of Science
Westlaw UK (Journals collection only)
Wiley

Appendix 2: BU ethics approval for co-creation of web intervention

STH REP Response (Ethics ID 16682)

6  

 3 attachments (2 MB) Download all Save all to OneDrive - Bournemouth University

Dear Rebecca

Thank you for your response and revised participant documentation.

The Chair is now happy to confirm the Panel's decision to provide ethical approval for your project.

Should you need to make any modifications to your project which may affect your current ethical approval, please email researchethics@bournemouth.ac.uk. Requests and additional approval will be considered by the Panel Chair and approved by Chairs Action if appropriate. Please quote the Ethics ID related to your project.

If you have any questions, please contact me.

Kind regards
Sarah

Sarah Bell
Research Governance Adviser
Research, Knowledge Exchange Office

To keep up to date on Research Ethics @ BU – visit the [research ethics website](#)

Appendix 3: Eligibility screening questions



“What is it like to be at home in early labour?” Video recording the experiences of women to share via the web

Welcome

Hi, I'm Rebecca and I am a researcher working with Bournemouth University. We are interested in knowing more about women's experiences of being at home in early labour.

We are currently looking for women to take part in a new research study. Women who take part will have the opportunity to share their personal experiences of being at home during the beginning part of their labour. We would then like to share these experiences with mothers expecting their first baby. In doing this, we hope to improve the confidence of first time mothers.

This survey aims to find eligible women who are interested in receiving some more information about our research study.

The survey should only take 5 minutes to complete.

Any answers you choose to share are confidential.

Please click "Next" to begin.

Eligibility Questions

Have you had a baby in the last 10 years?

- Yes
- No

Eligibility Questions

When in labour, did you spend any time at home?

- Yes
- No

Thank you for answering our questions.

You may be eligible to participate in our new research study and so we would like to provide you with some more information about the study before you decide if you would like to take part.

Would you like to receive some more information about our research study?

- Yes
- No

Thank you for taking this survey.

This research is aiming to speak to women who have spent some time in labour at home within the last 10 years.

The answers you provided in the survey indicate you are not eligible to take part in this research study.

If you have any further questions about why you are not eligible, please email the researcher on rcousins@bournemouth.ac.uk.

Thank you for taking this survey.

We are interested to know why you have chosen not to receive any information about our research study. Please give us your reasons in the box below. If you would prefer not to say, please leave this box blank.

Thank you for choosing to receive some more information about taking part in our research study

So we can provide you with this information, please supply your contact details below.

Your details will be kept securely and will only be used for providing you with information about our research study. Your contact details will not be used for any other purpose and will not be passed to any other party.

Name:

Email:

Please enter a valid email address.

Contact Number:

Please enter a valid phone number.

Information about this research study will be sent to you via the email you have provided soon. Please read this information carefully. About 7 days after receiving this email we will call you on the phone number you have provided. This call will provide an opportunity for you to ask any questions before you decide if you wish to take part.

When is it most convenient for us to call you? Please select all applicable answers.

- Weekdays, morning
- Weekdays, afternoon
- Weekdays, evening
- Weekend, morning
- Weekend, afternoon
- Weekend, evening
- Other

If you selected Other, please specify:

If you do not receive any information about the study via email within 7 days of completing this survey, please contact Rebecca Cousins at rcousins@bournemouth.ac.uk or on 07724 360155.

Any questions?

Any answers you have provided during this survey will remain confidential. If you have any questions, please contact the researcher Rebecca Cousins at rcousins@bournemouth.ac.uk or on 07724 360155.

Appendix 4: Participant information sheet



Participant Information Sheet

[“What is it like to be at home in early labour?” Video recording the experiences of women to co-create a website for first time mothers](#)

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 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. Your participation is voluntary.

Who is organising/funding the research?

This research is part of a larger doctorate research (PhD) project being carried out by Rebecca Cousins, who is also a registered midwife. This research is a collaborative project between University Hospital Southampton Foundation Trust (UHSFT) and Bournemouth University (BU).

What is the purpose of the project?

“Early labour” is the beginning part of term labour. 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 confident or informed to do this and have negative experiences in this phase. This is particularly true for mothers expecting their first baby.

This research aims to collect the views, opinions and experiences of women who have already had a baby. The purpose of collecting this data will be to develop a website aiming to improve first time mothers’ experiences of early labour. The website’s content will be shaped by the responses provided and will look to offer other mother’s information about early labour, alongside the videoed early labour experiences of those who have already had a baby. We hope that participation and co-production of the website in this way will be valuable to other mothers. The website will be trialled on mothers expecting their first baby, to investigate its effect on their early labour experiences.

What would taking part involve?

If you decide to participate in this research you will be asked to take part in an individual interview, asking you to talk about your experiences of being at home in early labour. These will take place in a private area at the venue of your existing breastfeeding support group in your local area and will be conducted by the researcher. These interviews, with your permission, will have both the audio and visual recorded. These recordings will be taken by another midwife with recording experience. The interview is anticipated to take about half an hour but may be more or less depending on how much you wish to tell us. We would also like to collect some information about you (such as your age, ethnicity and the number of babies you have had). However if you would prefer not to give out this information, please let the researcher know.

What sort of questions might be asked?

The questions will ask you about your experiences of being at home in early labour. We will be interested in what coping techniques you used at home, which techniques were most useful to you and how, if at all, anyone was able to support you at home. We will ask you to talk about any strategies you used whilst in early labour. We would also like to hear about what was important to you during early labour and the things that you didn’t like or didn’t find useful. These responses will shape the content of the website.

Will I be recorded, and how will the recorded media be used?

Yes, the visual and audio of your interview will be recorded on a digital video camera. This will then be edited, together with other participants’ interviews, and published on a website about early labour. Initially the website will have a trial period and will be password protected, made

available only to a separate research group. If the trial shows the website to be useful to the research group, the website may be made publically available. You will be asked to sign a media release form.

What are the advantages and possible disadvantages or risks of taking part?

It is anticipated that the risk of taking part in this research is minimal, however labour and birth can, for some women, be an emotional and sensitive topic to discuss. The researcher will aim to conduct these interviews with sensitivity in order to minimise these risks. If there is a question(s) you would prefer not to answer, you are free to decline to answer. You will be able to suspend or stop the interview at any time, and you do not need to give a reason for doing this.

Whilst there are no immediate benefits for those people participating in this part of the project, it is anticipated that the responses will create a new website and that the recorded interviews will also go on this website. This website will then be trialled on mothers expecting their first baby. It is hoped that the website will help improve the experiences of these first time mothers.

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 do decide to take part, you will be given this information sheet to keep and asked to sign a participant agreement form and a media release form. You will be invited to a preview of the video recordings, once they have been edited. This is so you have the opportunity to see the edited recordings, so you can confirm they feel they fairly represent your experiences. Also, at this point, you will be asked to confirm that you are happy for the videos to be used on the website. If you are not, the footage you are not happy with can be removed from the edited clips. You can withdraw your consent without reason up until the point that the interview recordings are uploaded to the website (following confirmation that you are happy with the footage). After this point consent can be withdrawn on a case by case basis only and participants need to be aware that footage online is in the public domain and removing footage from the original site does not guarantee removal from the internet completely. Deciding not to take part in this research will not impact upon current or future care or studies.

How will my information be kept?

All the information that we collect about you during the course of the research will be kept in accordance with the General Data Protection Regulations (2016). All data relating to this study will be kept for 5 years on a BU password protected secure network following completion of the study. Due to the nature of the data collection and the use of visual and audio recording your identity will not be confidential but no information personal information, other than what you chose to share, will be used in this research.

Contact for further information

If you have any questions about this research, or are interested in taking part please contact:

Rebecca Cousins rcousins@bournemouth.ac.uk

Dr Sue Way SueWay@bournemouth.ac.uk

If you have any concerns about this study, please contact:

researchgovernance@bournemouth.ac.uk

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

Appendix 5: Video recording the experiences of women consent form



What is it like to be at home in early labour?" Video recording the experiences of women to share via the web

Participant Agreement Form

Rebecca Cousins (Midwife and PhD Researcher)

rcousins@bournemouth.ac.uk

07724 360155

Dr Susan Way (Academic Supervisor)

SueWay@bournemouth.ac.uk

01202 961821

**Please
Initial
Here**

I have read and understood the participant information sheet for this research project	
I confirm that I have had the opportunity to ask questions.	
I understand that my participation is voluntary.	
Before or during the interview, I am free to withdraw consent without the need to give reason.	
Should I not wish to answer any particular question(s), I am free to decline.	
I understand that the visual and audio of my interview will be recorded on a digital video camera.	
I understand that I will have 7 days following the end of my interview and recording, before the editing process, in which to withdraw consent.	
I understand that the recording of my interview will be edited together with others' interviews.	
I understand I will have the opportunity to preview the edited version of the recording prior to publication and will have a further 7 days following this preview to withdraw part or all of my consent. Following this 7 day period, withdrawal of consent will be considered on an individual basis.	
I understand that the edited recordings, once previewed, will be published on a password protected website for first time mothers to trial.	
I understand that the website may later be publically available if a positive effect on first time mothers in the trial is found.	
I agree to take part in this research.	

Name of Researcher

Date

Signature

Name of Participant

Date

Signature

Appendix 6: Media release form



“What is it like to be at home in early labour?” Video recording the experiences of women to share via the web

Media Release Form

I understand that Bournemouth University (“BU”), either itself or on its behalf, will be doing the following:

Asking me to participate in an individual interview;

Recording the interview on a digital video camera (both audio and visual)

I understand my recordings are being collected to trial on a web page and results from this trial may mean my contributions are made publically available after the trial period in the future. I grant BU and its licensees and assignees permission to use, publish, republish or otherwise transmit the contribution in any medium for all purposes throughout the world. I understand that once the 7 day period following my approval of the edited version of my recording has finished, I will have no further right to withdraw consent and my contribution. If I wish to discuss withdrawing my consent and my contribution after this time, I understand I will need to discuss this with the researcher and each case will be considered on an individual basis.

I do not object to BU:

Storing copies of the Contribution for the above purposes or to it storing my contact details on its database in case it needs to contact me; or

I will make no claim for any reason to BU in relation to the Contribution or the data contained in this release, except as permitted by law.

If you wish to discuss any of this please contact:

Rebecca Cousins 07724 360155

rcousins@bournemouth.ac.uk

Dr Susan Way - 01202 961821

SueWay@bournemouth.ac.uk

Name of Participant

Date

Signature

Name of Researcher

Date

Signature

Appendix 7: Interview schedule

“What is it like to be at home in early labour?”

Video recording the vicarious experiences – Interview schedule

- Can you tell me what your understanding is of early labour and the latent phase of labour?
- Can you talk and describe to me about what you remember about your time in early labour?
- What was the first thing you can remember doing when your labour first started?
- Before you went into labour, what did you do to prepare yourself for this phase?
- Was there anything more you wish you had done to prepare for early labour?
- Can you tell me about some of things you did that you found useful in early labour?
- How was your birth partner involved with supporting you in early labour?
- What did you do whilst you were in early labour?
- Can you think of anything you did while you were in early labour that you didn't find useful?
- What techniques did you use at home and how did these make you feel?
- If you had the chance, could you talk me through what you might do differently in early labour?
- Could you talk me through the positive things about your early labour experience?
- Could you talk me though the memorable things about your early labour experience?
- Could you talk me through the negative things about your early labour experience?
- If you could give some advice to mothers about to go into labour, what advice would you give them about being in early labour?
- Is there anything else you would like to tell me about your experience of early labour or anything else you wish to speak about?



The L-TEL Trial: The Early Labour Experience Questionnaire

Welcome

Thank you for completing this questionnaire.

The responses you choose to share will only be used in The L-TEL Trial. Your answers will remain confidential and anonymous and shared only with the researcher and the research team.

This questionnaire should take no more than 20 minutes to complete. Please make sure you click "Finish" at the end of the questionnaire to ensure your answers are submitted.

Click Next to begin.

All rights to the Early Labour Experience Questionnaire (2013) belong to Dr. Patricia Janssen and Dr. Sarah Desmarais. This questionnaire must not be copied, replicated or used without direct permission from the author(s)

Being at Home in Early Labour

Did you spend any of the time you were in labour at home?

- Yes
- No

The Early Labour Experience Questionnaire

Instructions: Please answer these questions in relation to the time you spent in early labour before you came into your chosen place of birth. Please choose the answer most appropriate for you.

i) While you were in labour at home did you feel:

	1 (Yes, definitely)	2 (Yes, somewhat)	3 (Not sure)	4 (Not very much)	5 (Not at all)
1. Safe?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Confident?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Scared?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Happy?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Excited?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Anxious?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Relaxed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Comfortable?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Tense?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Supported?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Distressed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Insecure?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. In control?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Confused?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

ii) When you were in early labour at home, did the midwife on the phone:

	definitely)	somewhat)	sure)	much)	all)
15. Give you the information you wanted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Reassure you when you needed it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Spend enough time with you (on the phone)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Listen carefully to what you had to say?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Treat your family and/or friends with respect?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Respect your wishes about going to your chosen place of birth?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Did you feel you had confidence in the midwife?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Did you feel there was teamwork in the provision of your care?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Did you feel the labour line midwife always was at ease and calm with you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Do you feel the midwife treated you in a rude way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Would you recommend this type of early labour care and advice to a friend?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Did you feel you went to your chosen place of birth at the right time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Thank you for completing the Early Labour Experience Questionnaire.

Please click Next.

Were you provided with the link to the website being trialled in The L-TEL Trial during your pregnancy?

- Yes - I WAS in the group that received the website link
- No - I WAS NOT in the group that received the website link

You indicated that you were NOT in the group that received the website link. Did you happen to view the website despite not being provided the link by the researcher?

- Yes
- No

The Website

You were randomised to the group that received the link to the website.

We would like to know if and how you used the website. We also would like some feedback from you about the website.

Did you visit the website during your pregnancy?

- Yes
- No

You indicated that you did not use the website, please could you tell us why?

If you used other sources instead to get information about early labour during your pregnancy, please list them here:

The Website

How often do you estimate that you used the website?

- Once
- 1-3 times
- 4-10 times
- More than 10 times

Did your birth partner use the website?

- Yes
- No
- Don't Know

What did you like best about the website?

What did you like least about the website?

Would you make any changes to the website?

Would you recommend the website to a friend to use?

- Yes
 No

Is there anything else you wish to tell us about your experience of the website?

Other early labour information sources...

Did you use any other sources to get information about early labour during your pregnancy?

- Yes
 No

Other early labour information sources...

Please list all the sources you used to find early labour information during your pregnancy:

Thank you

You have completed the questionnaire.

Thank you for taking part in The L-TEL Trial. Your participation has been valuable in helping us find out more about first time mother's experiences of early labour. If you have any questions about the trial please contact rcousins@bournemouth.ac.uk

If you have any unanswered questions about your birth experience, please contact Birth Afterthoughts on 023 8120 6834.

Please click "Finish"

Appendix 9: ELEQ author permissions

Rebecca Cousins
Wed 8/10/2016 14:20

To: patti.janssen@ubc.ca
Dear Professor Patricia Janssen,

I am a midwife undertaking a clinical doctorate in Midwifery at Bournemouth University, UK hoping to investigate early labour support. I am interested in your Early Labour Experience Questionnaire and although I am yet undecided as to whether I will be requesting your permission to use it in my research, I would like to know if there are any research studies that have used the ELEQ? If so would you be able to identify these for me please?

I would be in contact for specific permission if and when I decide I would like to use the questionnaire in my research.

Thank you,

Yours Sincerely
Becky Cousins
Clinical Doctorate Student and Midwife

Rebecca Cousins
Tue 11/1/2016 14:18
To: patti.janssen@ubc.ca

Dear Patti,

My PhD supervisor, Prof Vanora Hundley, recommended I email you to clarify a few things about the ELEQ.

We are hoping to conduct a small scale RCT

I hope to use your ELEQ as a method of data collection if permission granted.

I had a few things I wanted to ask you regarding the tool and my research:

1) Would it be acceptable to change the word "nurse" for "health professional" or similar, so the tool can be used to collect data about the care of non-registered health professionals, such as a doula?

2) Question 17: When you were at home in early labour, did the nurse spend enough time with you?

How was this question adapted for those in your research who did not receive a home

visit? I am hoping to use this questionnaire for all participants in my research including those who do not receive a home visit

3) Question 22: Did the nurse and doctor work as a team in providing your care? Would it be acceptable for this question to be omitted as neither arm of my trial will be receiving care from a doctor? I would love to hear your opinion on this question and how this question fitted in with your original research?

Thank you for your time and I look forward to your response.

Best wishes

Becky Cousins

(Clinical Doctorate Student and Clinical Midwife)

Janssen, Patricia <patti.janssen@ubc.ca>

Thu 11/3/2016 21:22

To:Rebecca Cousins

Hi Becky - happy for you to change the word nurse to health professional or similar. In our work - I don't think we had anyone who didn't receive a home visit. For Question 17, you could just ask if the nurse spent enough time with them on the phone. I am happy for you to omit Question 22. I have just completed an RCT of doula care for women planning a VBAC - keep me posted on the results of this study - thx, Patti

>

> Dr. Patricia Janssen

Appendix 10: Health Research Authority ethics approval

15 October 2018

Dear Miss Cousins

**HRA and Health and Care
Research Wales (HCRW)
Approval Letter**

Study title:	The Let's Talk Early Labour (L-TEL) Trial: Can an educational website affect nulliparous women's experiences of early labour - a randomised control trial
IRAS project ID:	235371
Protocol number:	N/A
REC reference:	18/SC/0396
Sponsor	Bournemouth University

I am pleased to confirm that [HRA and Health and Care Research Wales \(HCRW\) Approval](#) has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Appendix 11: Substantial amendment approval for increased sample size

24 July 2019

Dear Miss Cousins,

Study title:	The Let's Talk Early Labour (L-TEL) Trial: Can an educational website affect nulliparous women's experiences of early labour - a randomised control trial
REC reference:	18/SC/0396
Amendment number:	Substantial Amendment 1, 14/06/2019
Amendment date:	17 June 2019
IRAS project ID:	235371

The above amendment was reviewed by the Sub-Committee in correspondence.

Summary of Amendment

To increase the number of participants from 100 to 140.

Ethical opinion

The members of the Committee taking part in the review gave a **favourable ethical opinion** of the amendment on the basis described in the notice of amendment form and supporting documentation.

Appendix 12: Non-substantial amendment approval for recruitment period extension

rom; nrescommittee.southcentral-hampshirea@nhs.net <noreply@harp.org.uk>

Sent: 15 January 2020 10:17

To: Rebecca Edwards; Julie Northam; Rebecca Edwards

Subject: IRAS 235371. Amendment categorisation and implementation information

Amendment Categorisation and Implementation Information

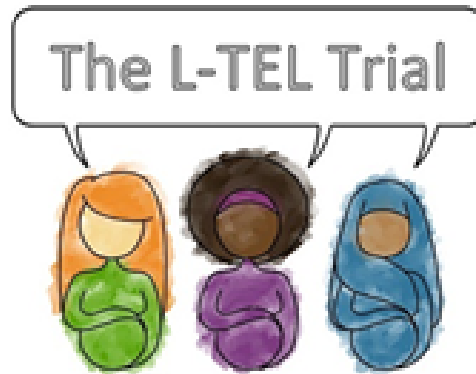
Dear Miss Cousins,

IRAS Project ID:	235371
Short Study Title:	The Let's Talk Early Labour (L-TEL) Trial
Date complete amendment submission received:	30 December 2019
Amendment No./ Sponsor Ref:	Non-SA02 - Extension
Amendment Date:	12 December 2019
Amendment Type:	Non-substantial
Outcome of HRA and HCRW Assessment	This email also constitutes HRA and HCRW Approval for the amendment, and you should not expect anything further.
For NHS/HSC R&D Office information	
Amendment Category	C

Appendix 13: The L-TEL Trial advertising poster

The L-TEL Trial(225272 (Version 2.0. 22/05/2018)

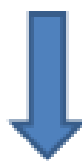

University Hospital Southampton
HMS Foundation Trust



Are you less than 30 weeks pregnant with your first baby?

Are you planning to birth on Broadlands or at The New Forest Birth Centre?

Would you like the chance to get some more advice and information about the early stages of labour?



If the answer to all of these questions is "YES" we need your help!

We are looking for women to volunteer in a research study.

We want to find out if a new website can make a difference to women's experiences of being in the beginning stages of labour.

Speak to your midwife or email rcousins@bournemouth.ac.uk for more information about The L-TEL Trial.



The L-TEL Trial: Midwives' Information

Hello Midwives!

Thank you for taking the time to complete some training about your involvement in The L-TEL Trial.

Keep a record of this training as it can be used as part of your "Continuing Professional Development" for your Revalidation!

The training should take about 5-10 minutes to complete.
Click Next to begin.

Page 2: Your Details

Please provide your details below so I can keep record of who has completed this training. These details will be kept secure and confidential.

1. Your full name:

2. Midwifery Team:

Page 3: What is the L-TEL Trial?

The L-TEL Trial is a new research trial aiming to see how an early labour website can affect first time mother's experiences of being at home in early labour.

We know low-risk women have better outcomes if they remain at home in early labour and yet many women report to feel under confident and worried to do this.

I hope the women who view the website may report to have better experiences of being at home in early labour.

Page 4: The Website

The website has been developed in line with current evidence and guidelines to provide advice, tips and encouragement as to how women and their birth partners can remain at home in early labour confidently.

Alongside this advice are videos of multiparous women talking about their own experiences of being at home in early labour. I hope this peer-support will have a positive effect on first time mothers.

There is also some safety information about when to speak to the Labour Line midwives and when to go into their place of birth, as well as information about "what is normal" and "what may not be normal" in early labour. The number for the Labour Line is on the website to ensure women are not put at risk when viewing this website.

This website is aiming to enhance the care that already exists for women and is NOT going to replace any maternity care that is already provided (i.e. antenatal education, birth chats, labour line and labour assessment will all still happen!).

Page 5: The Trial

We do not know yet if this website will have a positive impact on women.

The L-TEL trial aims to find out if the website can make a difference to women's early labour experiences.

The L-TEL trial is a **randomised** trial. This means:

- Half of the women who decide to participate will receive the link to the website (in addition to their usual midwifery care);
- The other half will NOT receive the link to the website and will also continue to receive their usual midwifery care.
- A computer will randomly choose who receives the website link and who does not.

Consented women who are allocated to the "Website Group" will receive the website link to use as they wish throughout the end of their pregnancy.

Both groups will be asked to complete an experience questionnaire postnatally and we will also look at clinical outcomes (i.e. birth mode, pain relief etc.). Comparing the results of both groups will help us understand the effect of the website.

If the website shows to have a positive impact on women it may be made publically available in our Trust in the future!

Page 6: Your involvement!

This is where I need your help!

Before I can consent women to The L-TEL Trial I need to find eligible women.

I am asking community midwives to identify women that may be interested in taking part.

Page 7: Who's eligible?

At the routine **25 week antenatal appointment (or another appropriate appointment)** I would like you to find women who are:

- Nulliparous (no previous birth >24 weeks);
- 16 years and above at the point of consent;
- Low-risk as per our Trust guidelines;
- Planning to birth at NFBC or Broadlands;
- Able to speak, read and understand English (this is for the purpose of consent and because currently we only have the website in English). Not being care for
- by a NEST (caseloading) midwifery team.

Page 8: Then what?

After finding a potential, eligible participant I would like you to:

1. Provide the woman with a Participant Information Sheet to take home and read;
2. Collect a few contact details if the woman would like to be contacted further about the trial;
3. Return their contact details to me via a simple, user friendly online form!

I am NOT asking you to consent women at this point - just identify women who are suitable, might like to take part and are happy to be contacted by me :-)

Page 9: Then what will happen to the women?

I will then be in contact with the women to check they have read the Information Sheet you supplied, answer any questions they may have and consent them to The L-TEL Trial.

Page 10: Thank you!

Now you have completed this training, you will be sent a link to the online form to collect women's contact details. Please use this link everytime you collect the contact details of a woman who may be interested in taking part.

Thank you in advance for all your support with this project - I couldn't do it without your help!

If you have any questions about anything, please don't hesitate to email me on rcousins@bournemouth.ac.uk

Thank you again!

Becky :-)



University Hospital Southampton
NHS Foundation Trust



The L-TEL Trial: Consent Form

Page 1: The L-TEL Trial

This is a consent form for The L-TEL Trial.

Please read each statement carefully. If you have any questions please email rcousins@bournemouth.ac.uk

This should take no more than about 5-10 minutes to complete.

Page 2: Your Details

Full name (please use the same name and spelling as on your maternity notes):

Date of birth: *Required*

Dates need to be in the format 'DD/MM/YYYY', for example 27/03/1980.

(dd/mm/yyyy)

Page 3: Consent

Your consent is completely voluntary and you may withdraw your consent (until the point in which your data is anonymised). Doing this will not affect any of your maternity care.

Please carefully read each of the statements below and indicate your consent to each.

I have read and understood the Participant Information Sheet for The L-TEL Trial.

I agree

I have had the opportunity to ask any questions about The L-TEL Trial.

I agree

I understand that my consent is voluntary and that I may withdraw my consent, until the point in which my data is made anonymous. Withdrawing my consent will not affect any of my future care.

I agree

I am able to access the internet without causing an inappropriate financial burden to myself

I agree

I am happy to complete the Childbirth Self-Efficacy Inventory questionnaire before I am randomised.

I agree

I understand this trial is randomised and that only **half** of the participants will receive the link to the website. I understand the other **half** will not receive the link to this website. I understand both groups will continue to receive the usual maternity care provided.

I agree

I understand a computer will randomly choose which group I am allocated.

I agree

I am happy to complete an online questionnaire about my experiences of early labour in the month after my birth.

I agree

I am happy for my maternity records and notes to be accessed by the researcher so data about my birth can be collected.

I agree

I understand that relevant sections of my medical notes and data collected during the study, may be looked at by relevant research individuals from Bournemouth University, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. This may include for the purpose of audit. I give permission for these individuals to have access to my records.

I agree

I understand my maternity records will be accessed in a safe, appropriate, confidential and responsible manner by the researcher and the research team and only data relevant to the trial will be collected.

I agree

I understand any data will be kept safely, anonymously and confidentially.

I agree

I understand that the results from this trial will be published and that my involvement in this trial will be completely anonymous in these publications.

I agree

If required, for safety reasons, I am happy for the researcher to use the contact details I provided (email address and phone number) to contact me throughout the trial.

I agree

I agree to take part in this research.

I agree



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 - rcousins@bournemouth.ac.uk

If you have any concerns about this research please contact:

Dr Susan Way - 01202 961821 or 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.



The L-TEL Trial: Childbirth Self-Efficacy Inventory

0% complete

Page 1: Childbirth Self-Efficacy Inventory

Thank you for filling out this questionnaire.

Your answers will not be used for anything other than for the purpose of The L-TEL Trial and will not be shared with anyone but the researcher and the research team.

The questionnaire should take no more than about 15 minutes. Please ensure you completely finish the questionnaire or your answers may not be submitted.

Please click Next to begin.

All rights to the Childbirth Self-Efficacy Inventory (1991) belong to Professor Nancy Lowe. Copyright © 1991 by Nancy K. Lowe. This inventory must not be copied, replicated or used without direct permission from the author.

1. First Name:

2. Surname: * Required

3. Your due date:

Dates need to be in the format 'DD/MM/YYYY', for example 27/03/1980.



(dd/mm/yyyy)

Think about how you imagine labour will be and feel when you are having contractions 5 minutes apart or less. For each of the following behaviors, indicate how helpful you feel the behavior could be in helping you cope with this part of labour by choosing a number between 1 (not at all helpful) and 10 (very helpful). * Required

Please don't select more than 1 answer(s) per row.

Please select exactly 15 answer(s).

	1 (not at all helpful)	2	3	4	5	6	7	8	9	10 (very helpful)
1. Relax my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Get ready for each contraction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Use breathing during labour contractions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Keep myself in control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Think about relaxing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Concentrate on an object in the room to distract myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Keep myself calm.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Concentrate on thinking about the baby.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. Think positively.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Not think about the pain.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Tell myself that I can do it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Think about others in my family.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Concentrate on getting through one contraction at a time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Listen to encouragement from the person helping me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Continue to think about how you imagine labour will be and feel when you are having contractions 5 minutes apart or less. For each behavior, indicate how certain you are of your ability to use the behavior to help you cope with this part of labour by circling a number between 1 (not at all sure) and 10 (completely sure)

Please don't select more than 1 answer(s) per row.

Please select exactly 15 answer(s).

	1 (not at all sure)	2	3	4	5	6	7	8	9	10 (completely sure)
16. Relax my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Get ready for each contraction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Use breathing during labour contractions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Keep myself in control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Think about relaxing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Concentrate on an object in the room to distract myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Keep myself calm.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Concentrate on thinking about the baby.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

24. Stay on top of each contraction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Think positively.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Not think about the pain.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. Tell myself that I can do it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Think about others in my family.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. Concentrate on getting through one contraction at a time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Listen to encouragement from the person helping me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Think about how you imagine labour will be and feel when you are pushing your baby out to give birth. For each of the following behaviors, indicate how helpful you feel the behavior could be in helping you cope with this part of labour by circling a number between 1 (not at all helpful) and 10 (very helpful)

Please don't select more than 1 answer(s) per row.

Please select exactly 16 answer(s).

	1 (not at all helpful)	2	3	4	5	6	7	8	9	10 (very helpful)
31. Relax my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. Get ready for each contraction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. Use breathing during labour contractions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. Keep myself in control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. Think about relaxing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. Concentrate on an object in the room to distract myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. Keep myself calm.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38. Concentrate on thinking about the baby.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

39. Stay on top of each contraction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40. Think positively.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
41. Not think about the pain.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42. Tell myself that I can do it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43. Think about others in my family.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
44. Concentrate on getting through one contraction at a time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
45. Focus on the person helping me in labour.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
46. Listen to encouragement from the person helping me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Continue to think about how you imagine labour will be and feel when you are pushing your baby out to give birth. For each behavior, indicate how certain you are of your ability to use the behavior to help you cope with this part of labour by circling a number between 1 (not at all sure) and 10 (completely sure).

Please don't select more than 1 answer(s) per row.

Please select exactly 16 answer(s).

	1 (not at all sure)	2	3	4	5	6	7	8	9	10 (completely sure)
47. Relax my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
48. Get ready for each contraction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
49. Use breathing during labour contractions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
50. Keep myself in control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
51. Think about relaxing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
52. Concentrate on an object in the room to distract myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
53. Keep myself calm.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
54. Concentrate on thinking about the baby.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

55. Stay on top of each contraction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
56. Think positively.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
57. Not think about the pain.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
58. Tell myself that I can do it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
59. Think about others in my family.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
60. Concentrate on getting through one contraction at a time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
61. Focus on the person helping me in labour.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
62. Listen to encouragement from the person helping me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This is the end of the Childbirth Self-Efficacy Inventory. Please click Next.

Page 4: The L-TEL Trial Demographics

We would also like to collect some personal details from you to allow us to see who has chosen to participate in The L-TEL Trial.

This can help us see if the results from The L-TEL Trial represent the general population. It also lets us compare the two groups in The L-TEL Trial.

Any information you choose to share will be kept strictly confidential and used anonymously.

Year of Birth (YYYY):

Home postcode:

Marital status:

- Civil Partnership
- Divorced
- Married
- Partner
- Single
- Widowed
- Prefer not to say
- Other

Ethnic origin:

- White – British
- White – Irish
- Other white background
- Black or Black British – Caribbean
- Black or Black British – African
- Other black background
- Asian or Asian British – Indian
- Asian or Asian British – Pakistani
- Asian or Asian British – Bangladeshi
- Chinese
- Other Asian background
- Mixed – white and black Caribbean
- Mixed – white and black African
- Mixed – white and Asian
- Other mixed background
- Prefer not to say
- Other

Highest level of education achieved:

- No formal education qualifications
- GCSE / O Level or equivalent
- Post 16 years education (i.e. A Level, BTEC, National Diploma or equivalent)
- Foundation degree
- Graduate degree
- Post-graduate education (Masters or PhD or equivalent)
- Other
- Prefer not to say

Appendix 18: CBSEI author's permissions

Lowe, Nancy <Nancy.Lowe@ucdenver.edu>

Fri 17/11/2017 15:06

To:

Rebecca Cousins;

You replied on 13/09/2018 11:31.

3 attachments

Dear Rebecca,

Thank you for your kind email. What an exciting project to help young women prepare for childbirth in the electronic age. I will be interested in hearing about how your research efforts unfold in this regard.

Yes, you may use the CBSEI as desired in this project. I am attaching all the relevant documents needed for your use. If you need to transfer it to an electronic format for your study, you have my permission to do so.

Best wishes with your work.

Nancy |

Lowe, Nancy <Nancy.Lowe@ucdenver.edu>

Fri 13/09/2018 11:33

To:

Rebecca Cousins;

Hi, Rebecca,

Absolutely, that makes perfect sense in the UK setting. You have my permission to change nurse to midwife.

With all best wishes,

Nancy

Nancy K. Lowe, CNM, PhD, FACNM, FAAN
Editor, *Journal of Obstetric, Gynecologic, & Neonatal Nursing (JOGNN)*
Professor
College of Nursing
University of Colorado Denver

Appendix 19: Data management plan

The Let's Talk Early Labour (L-TEL) Trial: Can an educational website affect nulliparous women's experiences of early labour - a randomised control trial

A Data Management Plan created using DMPonline

Creator: Rebecca Edwards

Affiliation: Bournemouth University

Funder: Wessex Integrated Clinical Academic Programme

Template: BU Template

ORCID iD: <https://orcid.org/0000-0002-1414-0114>

Project abstract:

Early labour is the term used to refer to the beginning part of a woman's labour. It is the period of time where there are painful contractions and the cervix makes some changes in preparation for active labour and subsequent childbirth. In UK clinical practice, cervical dilatation of 4 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 triage, assessment and labour diagnosis in an attempt to reduce early labour admission, women remain fearful and unconfident 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, web-based educational intervention on women's early labour experiences as measured by the average, total scores of a pre-validated Early Labour Experience Questionnaire (ELEQ) which has been modified with author's permission for online use. These scores will be collected at 7-28 days after birth. The trial aims to recruit one hundred low - risk, pregnant nulliparous women from a single, NHS Trust in the South of England. Participants randomised to the intervention group will receive a link to the co-created, web-based educational intervention. The intervention group will receive this link alongside all the routine maternity care. The control group will receive only the routine maternity care. Discussion: It is hypothesised that the group who receive the intervention will score higher in the ELEQ, indicating an improved early labour experience when compared to 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.

Data Collection

What types of data will you collect, create, acquire and/or record?

Control Group:

1. Initial contact details: full name, hospital number, phone number, email address.
2. Consent form: full name, date of birth
2. Demographic data: home postcode, marital status, ethnic origin, highest level of education achieved.
2. Childbirth Self-efficacy Inventory score (Lowe 1993)
3. Early Labour Experience Questionnaire (Janssen and Desmarais 2013a)
4. Qualitative responses about receiving information in early labour and adherence to study protocol
5. Coded clinical birth outcomes

Intervention Group:

Control Group:

1. Initial contact details: full name, hospital number, phone number, email address.
2. Consent form: full name, date of birth.
2. Demographic data: home postcode, marital status, ethnic origin, highest level of education achieved.
2. Childbirth Self-efficacy Inventory score (Lowe 1993)
3. Early Labour Experience Questionnaire (Janssen and Desmarais 2013a)
4. Qualitative responses about receiving information in early labour, adherence to study protocol and opinions on the intervention.
5. Coded clinical birth outcomes

What file formats will your data be collected in? Will these formats allow for data re-use, sharing and long-term access to the data?

All data will be collected initially using secure, online data collection forms which are password protected. This data will be downloaded into a Microsoft Excel format and then exported to SPSS for analysis.

If data are collected using laptops or mobile devices, explain how you will securely store and transfer the data.

All data collected, downloaded and exported will be securely held on a password protected, university laptop.

How much data do you anticipate collecting? Include an estimate of how much storage space you will require (in megabytes, gigabytes, terabytes). This estimate should also take into account storage space required for file versioning, backups, and the growth rate over time.

5 megabytes

Are there any existing data that you can re-use? If so, explain how you will obtain that data and integrate it into your research project.

The clinical outcomes will be collected from routinely collected data from the hospital system. This data will be collected by the researcher and a research administrator assistant. The clinical outcomes will be coded at source and held anonymously on an excel spreadsheet. Participants will be labeled with a unique participant identifier to further protect confidential data.

What conventions and procedures will you use to structure, name and version control your files to ensure that your data is well-organized?

A numbered, version control procedure will be used to ensure structure and organisation (i.e. Version 1.0 if amended will become Version 1.1)

Documentation & Metadata

What documentation will be needed for the data to be read and interpreted correctly in the future? This includes study-level documentation, data-level description, and any other contextual information required to make the data usable by other researchers.

Any coded data will require the original code for future analysis.

List the metadata standard and tools you will use to document and describe your data.

N/A

How will you make sure that documentation is created or captured consistently throughout your project?

In the most part, (i.e. primary outcome - Early Labour Experience Questionnaire) will be directly imported from its original source to minimise data input error. This data will then be coded by the computer to further avoid error and to promote consistency. Data will be subject to data checking processes. This includes a second checker for all secondary outcomes collected and coded manually. Furthermore, a 15% sample of all data will be cross referenced against the original sources to ensure there is consistency without error.

Ethics & Legal Compliance

Have you gotten explicit mention of consent, confidentiality, anonymisation and other ethical considerations, where appropriate?

Explicit consent has been sought via an individually password protected consent form. Data has been stored anonymously and all data has been handled in line with data protection regulation, GDPR.

How will you manage any copyright and Intellectual Property Rights (IPR)?

Bournemouth University has copyright, intellectual / property rights over the output of this research

Storage & Backup

How will your data be stored and backed up during your research project?

Data will be stored on a password protected, university laptop and backed up on a secure university system. Data will be stored for 5 years following the end of the research study.

How will you ensure that sensitive data is stored securely and only accessible to the research team during the research project?

The password protected laptop as discussed above is only accessed by the researcher.

Selection & Preservation

Where will you deposit your data?

As per University regulations, the cleaned, anonymised data will be uploaded to the University digital repository, BORDaR.

Describe how you will prepare the data for preservation and access, including any necessary procedures for data cleaning, normalisation or de-identification. Explain how you will prevent data from being lost while processing and converting files.

All data will be backed up on the university secure network prior to processing data.

How long do you need to store your data?

As per University guidelines, 5 years.

Data Sharing & Re-use

What data will you be sharing and in what form? (e.g. raw, processed, analyzed, final). Consider which data may need to be shared in order to meet institutional or funding requirements, and which data may be restricted because of confidentiality/privacy

Only final, cleaned, anonymised data will be shared if required.

How will you be sharing your data? (e.g. institutional repository, a specialized data archive, project website, informal/on-request sharing). Include a brief description of any resources needed to share your data (equipment, systems, expertise, etc.).

Institutional Repository BORDaR

Will there be any restrictions placed on your data and who may have access. If data are not openly available, describe the process for gaining access.

No restrictions.

What type of end-user license will you include with your data? Please include a copy of this license with your Data Management Plan.

N/A

Responsibilities & Resources

Who will be responsible for data management during the project? (i.e. during collection, processing, analysis, documentation)? Identify staff and organisational roles and their responsibilities for carrying out the DMP. Include time allocations and training requirements.

Rebecca Edwards (Researcher and Principle Investigator)

Agnieszka Burt (Clinical Trials Assistant of the Reproductive Health Research Team at the site of research)

What will happen when personnel changes occur or if the principal investigator leaves the institution?

The university will have access to the data regardless if the principal investigator leaves the institution.

Who will be responsible for data sharing and preservation after the project has concluded? Indicate the List the individual(s) with primary responsibility for how the data will persist over time when the original personnel have moved on.

Library staff at Bournemouth University

What resources will you require to implement your plan? Will extra people, time, hardware, storage be required? How much will this cost (estimation)?

No additional cost

Appendix 20: Letter of university statistician support

21st May 2018

Dear Rebecca

This is to confirm that I have commented and advised on your proposed statistics for the PhD research project: *The Let's Talk Early Labour (L-TEL) Trial: Can an educational website affect nulliparous women's experiences of early labour - a randomised control trial.*

Regards

Sharon

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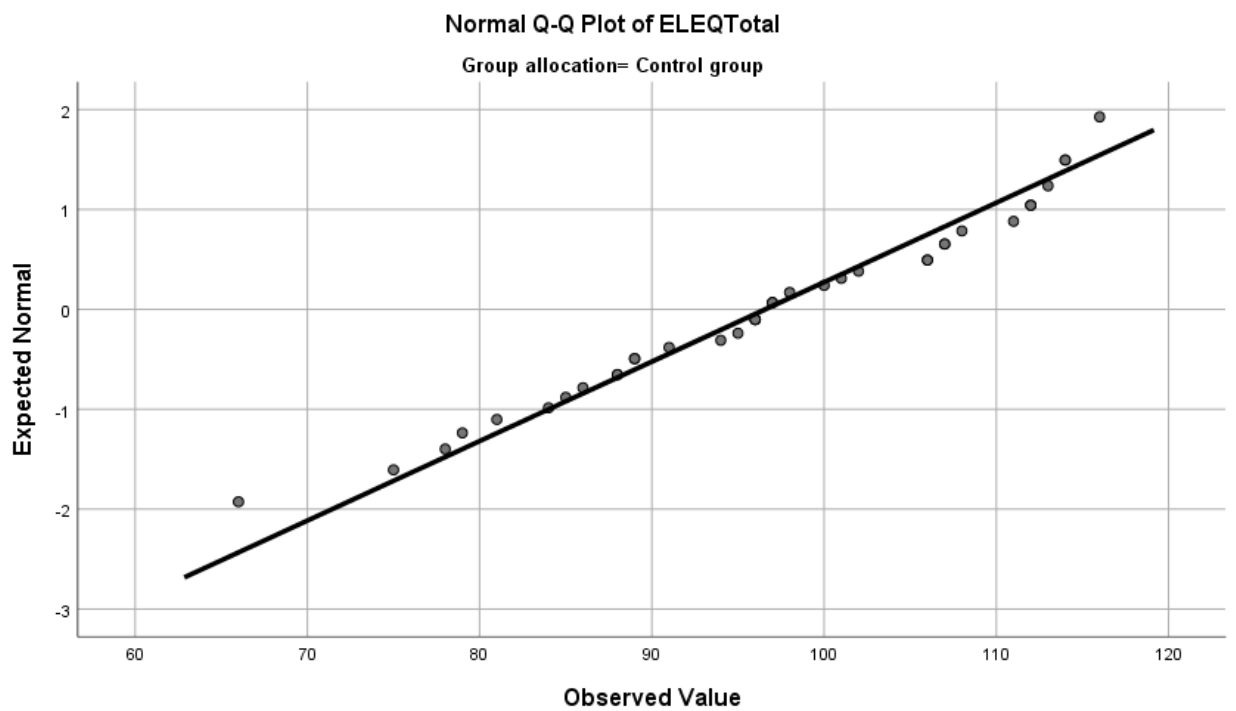
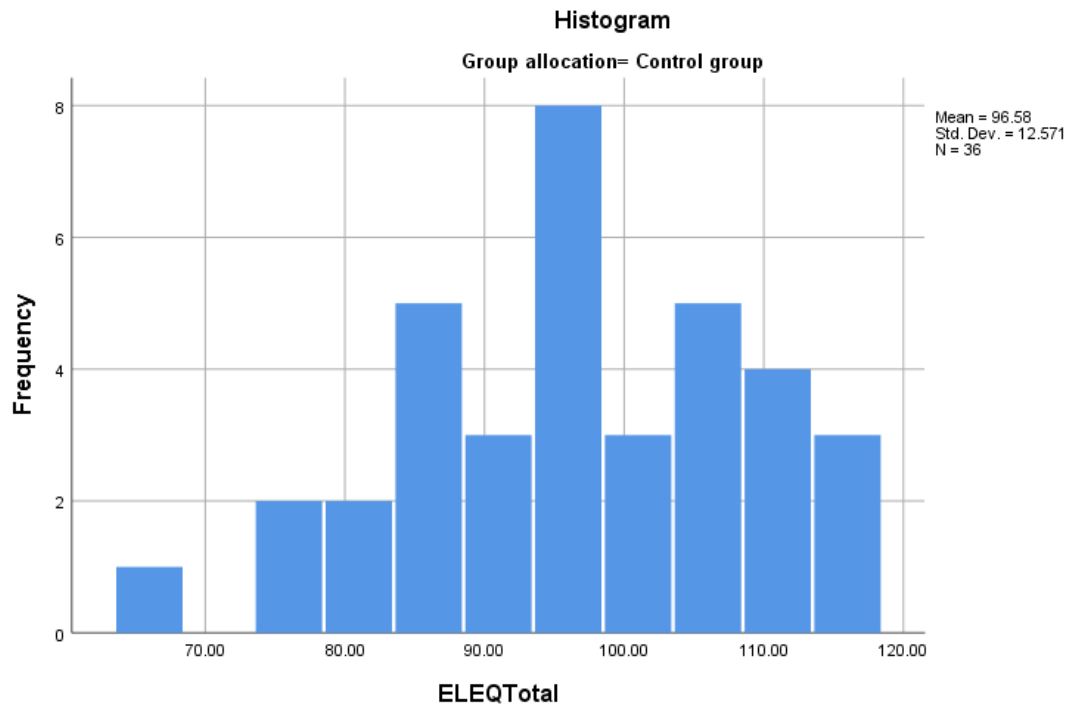
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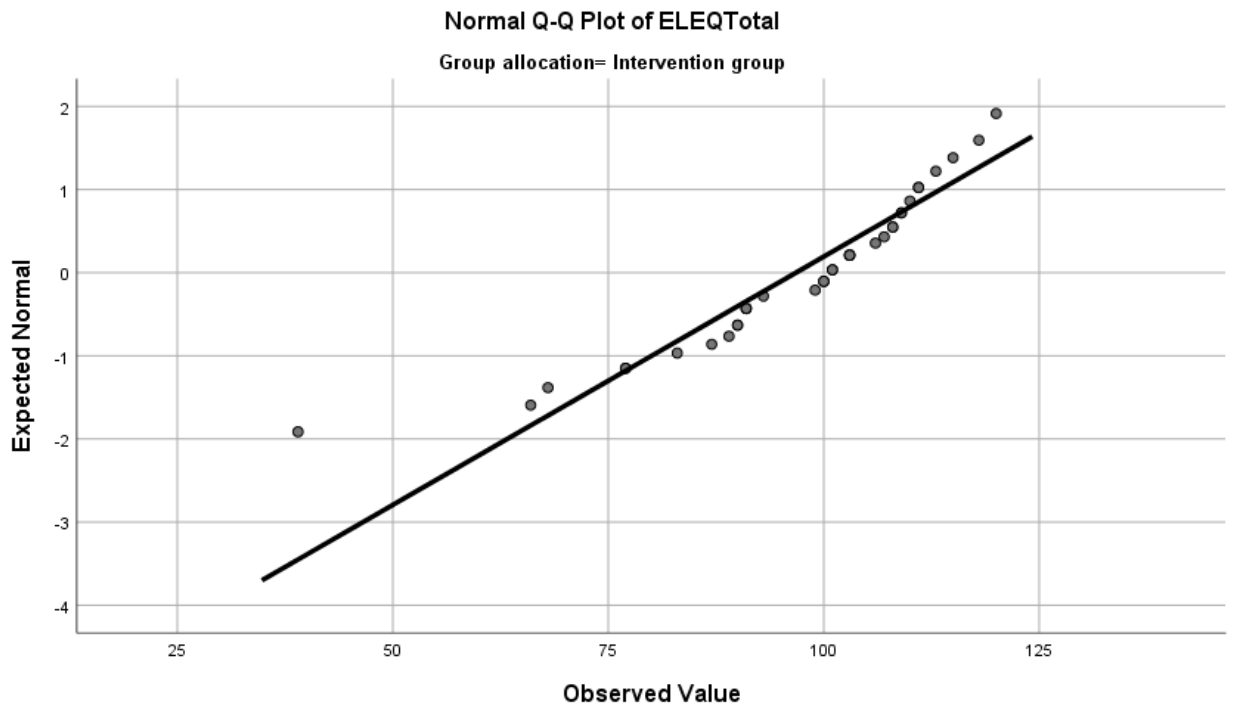
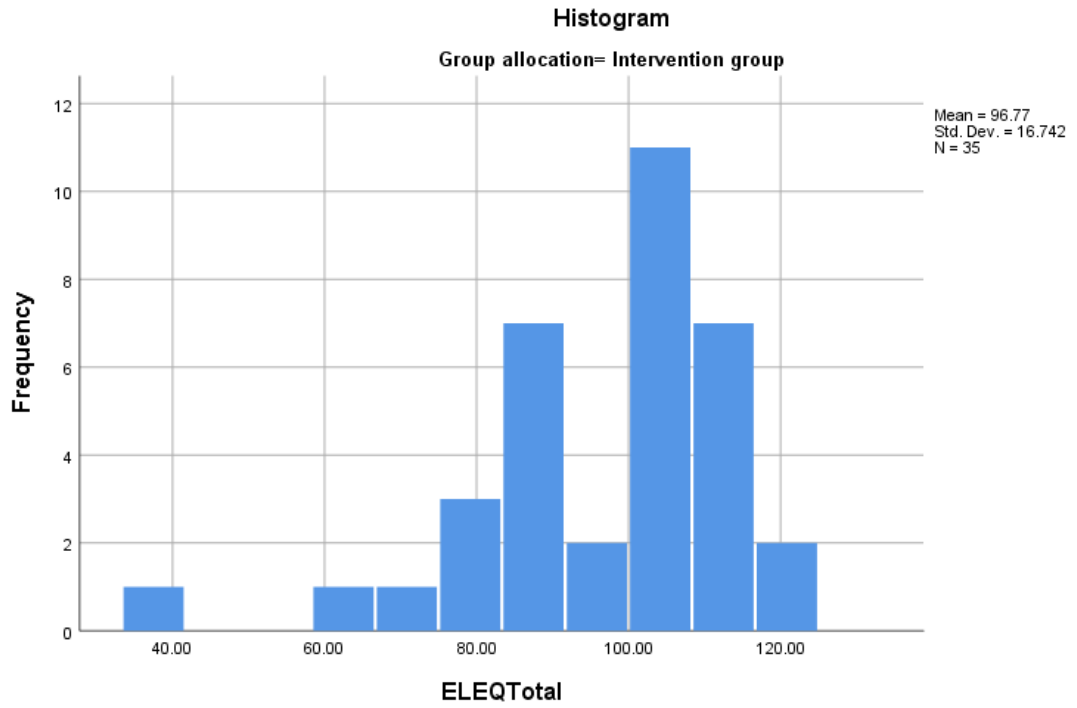
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Appendix 21: ELEQ score histograms and Q-Q plots

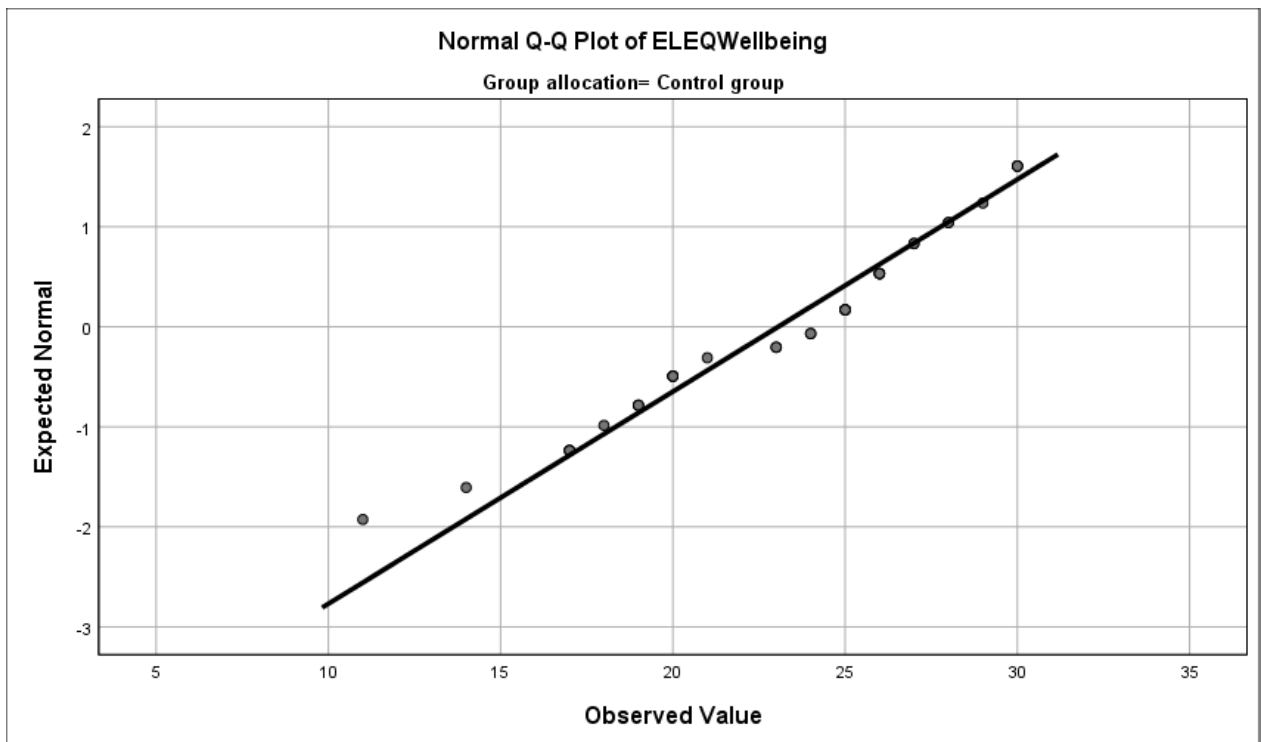
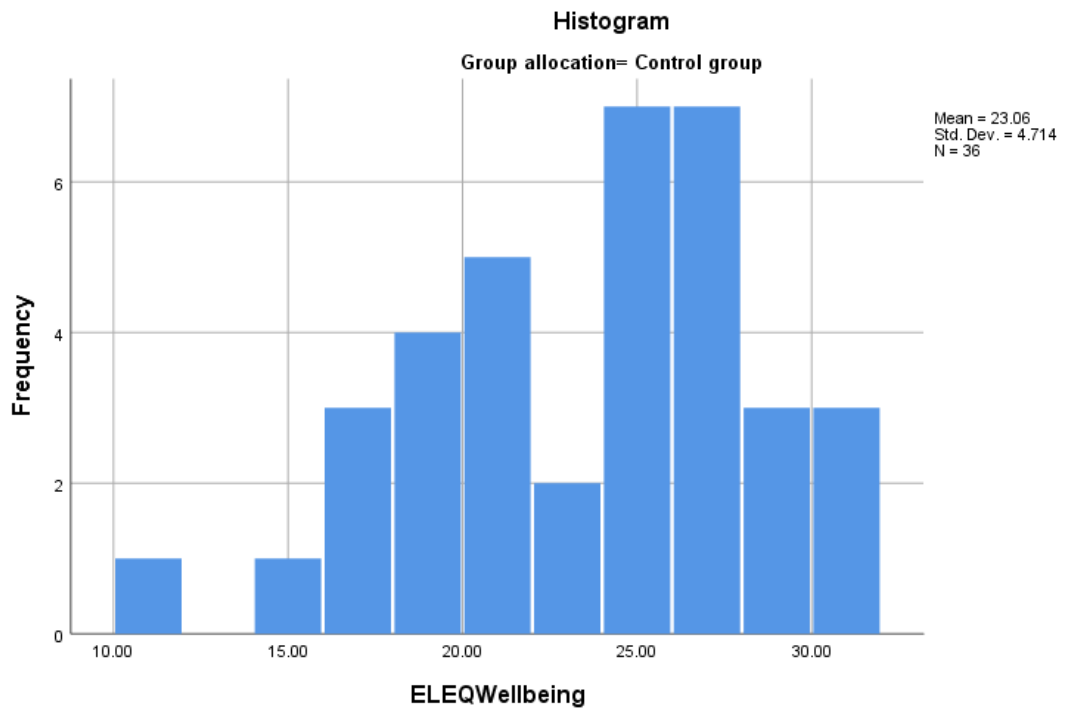
ELEQ total score control group histogram and Q-Q plot



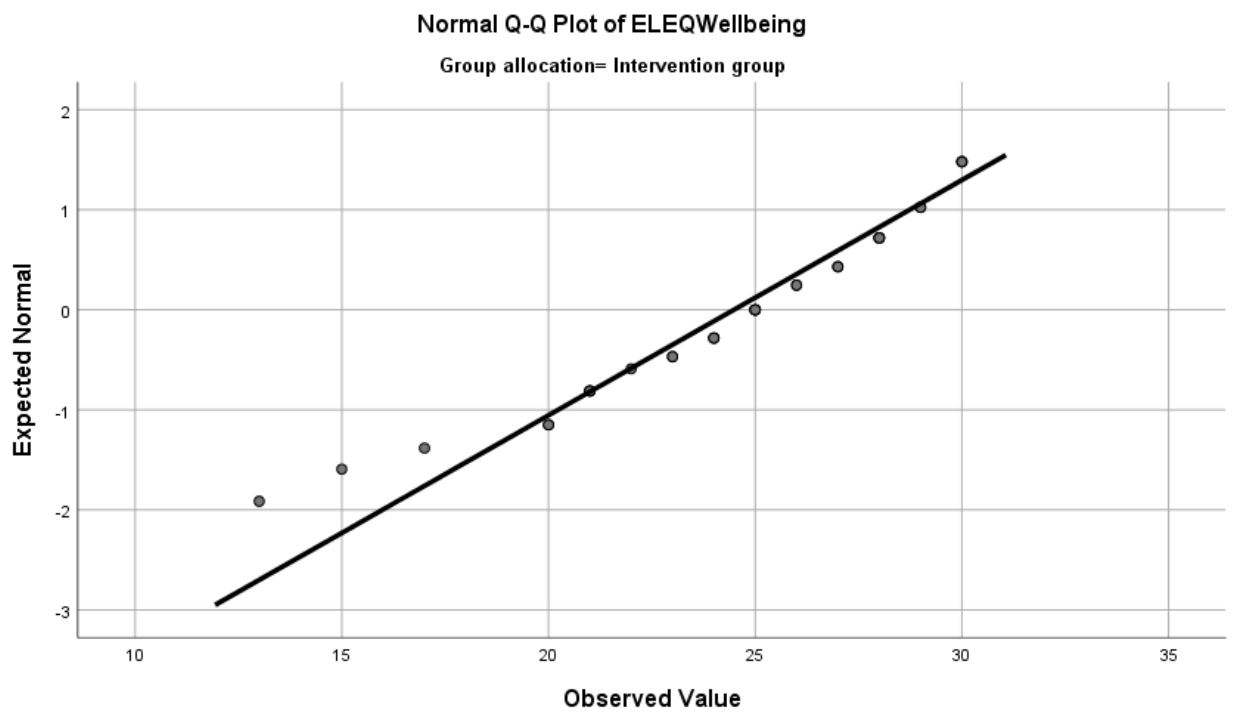
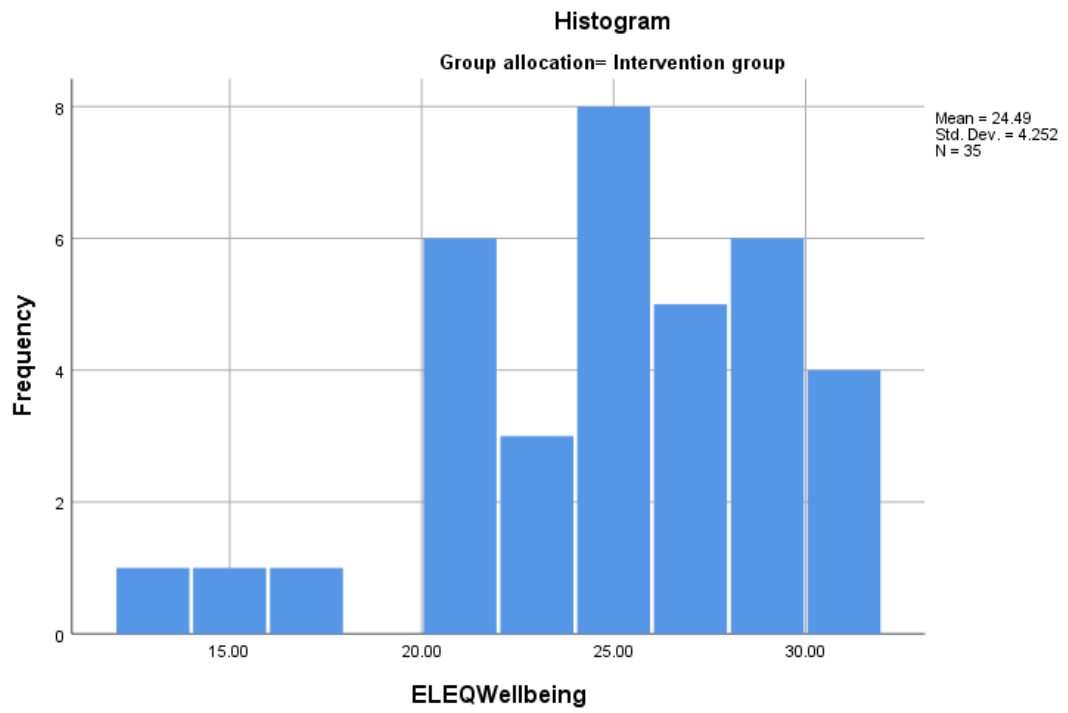
ELEQ total score intervention group histogram and Q-Q plot



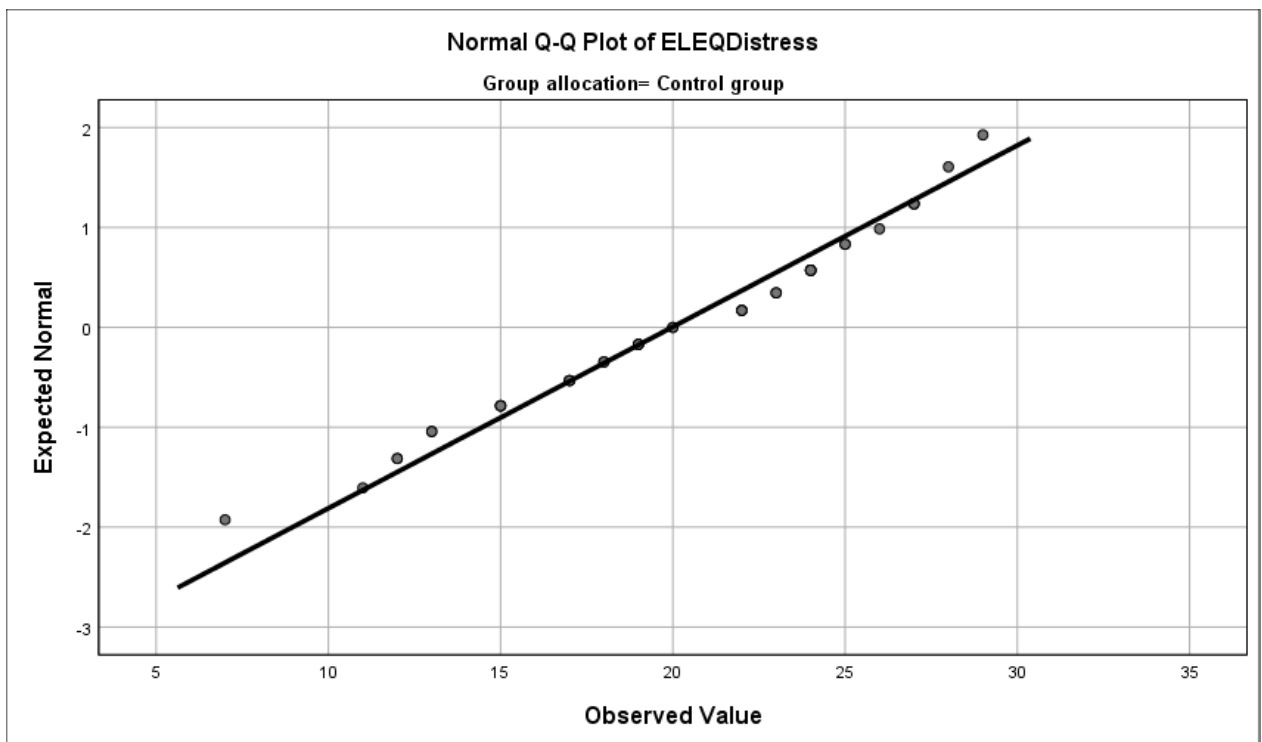
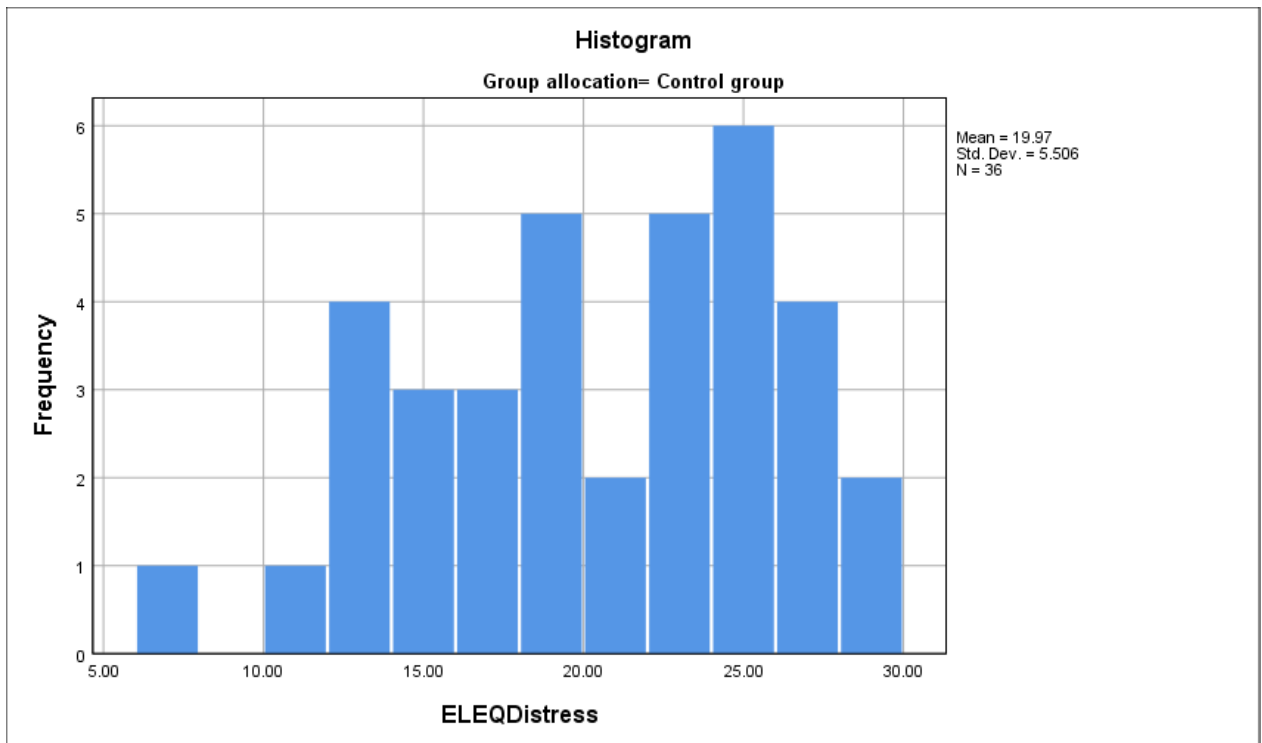
ELEQ emotional wellbeing subscale score control group histogram and Q-Q plot



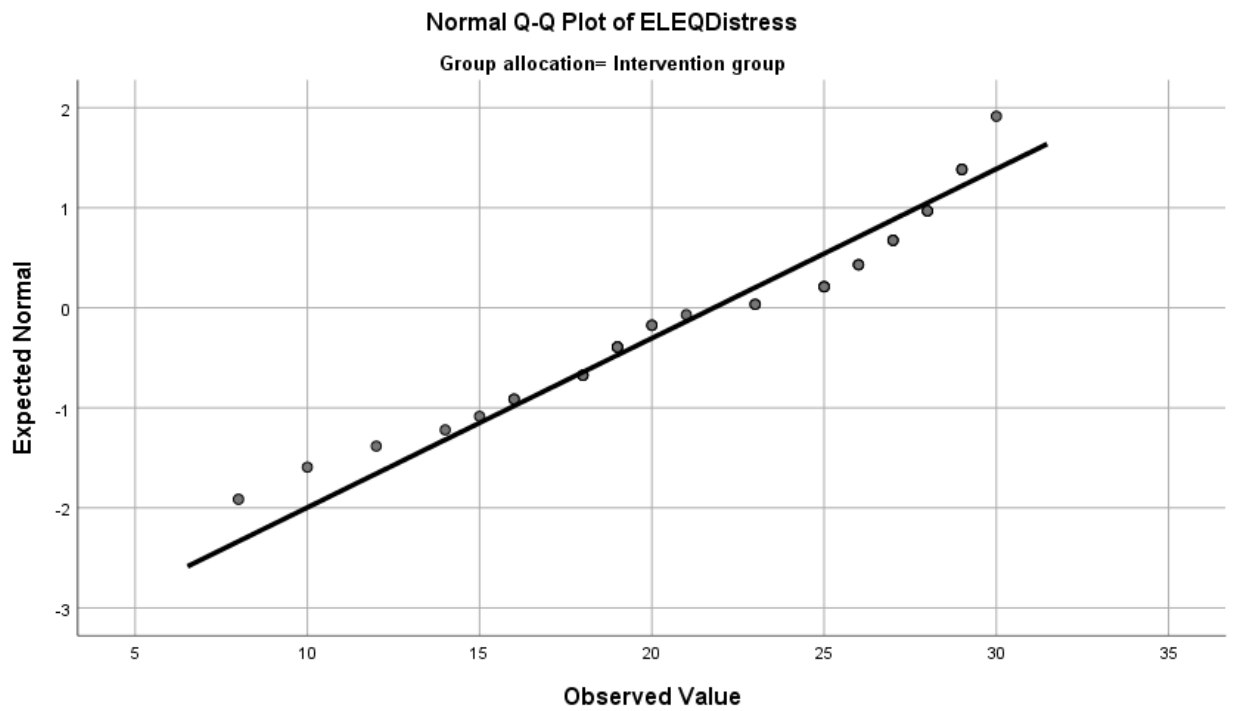
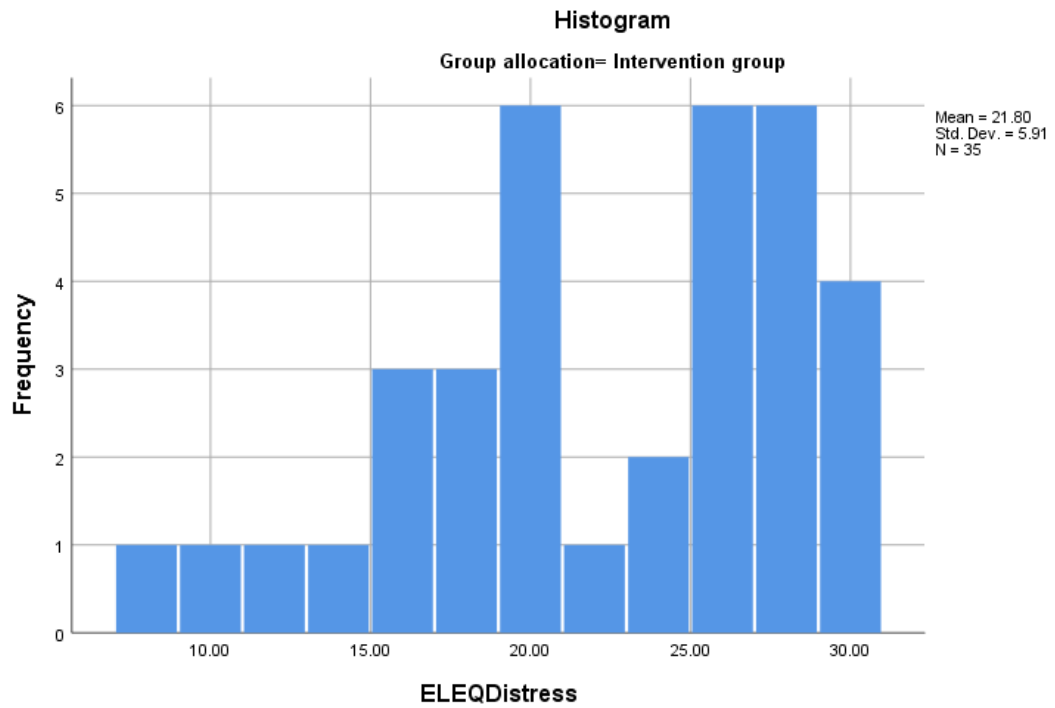
ELEQ emotional wellbeing subscale score intervention group histogram and Q-Q plot



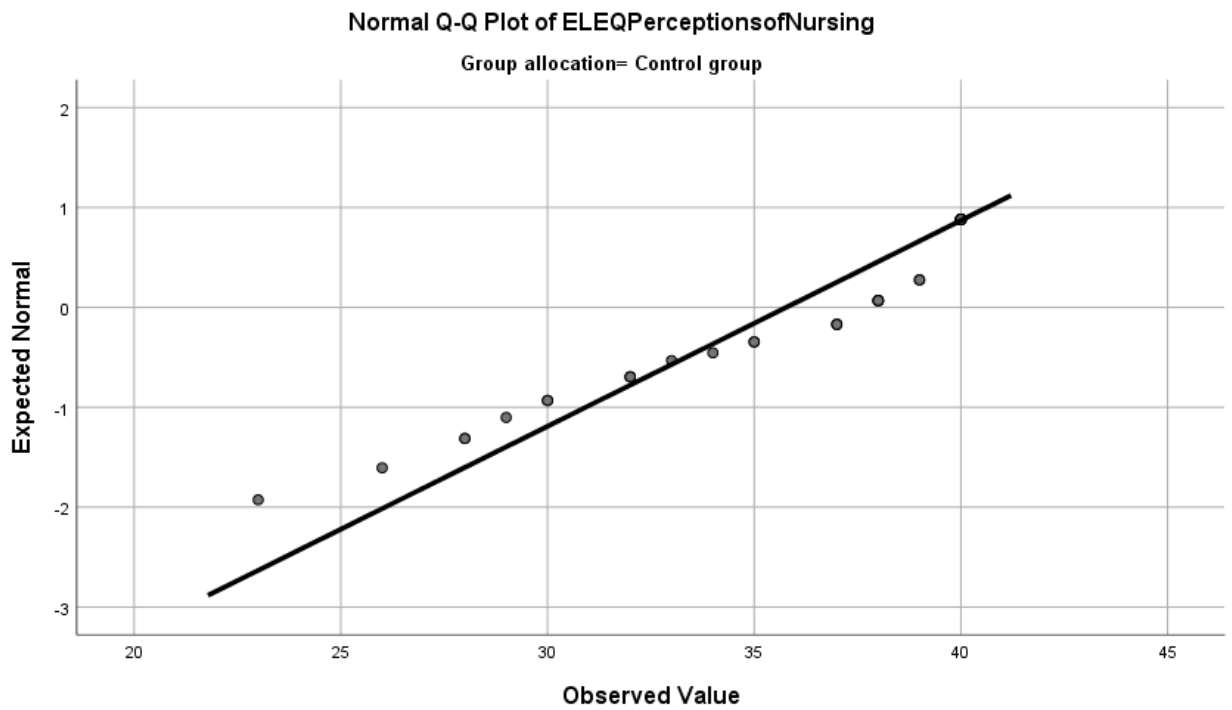
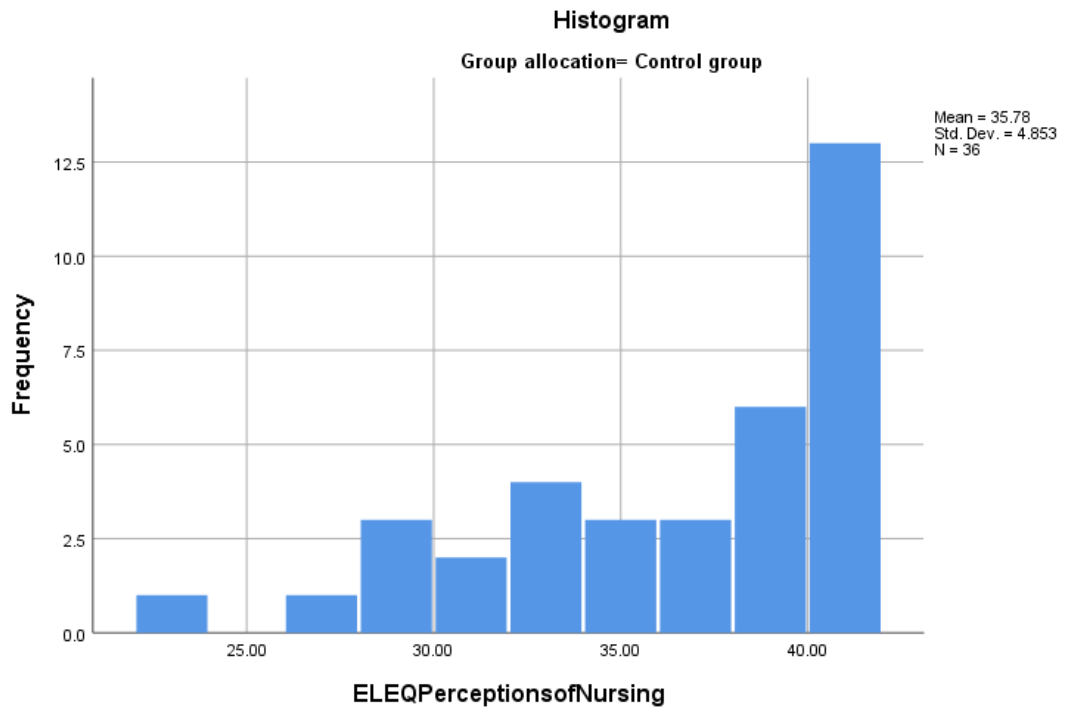
ELEQ emotional distress subscale score control group histogram and Q-Q plot



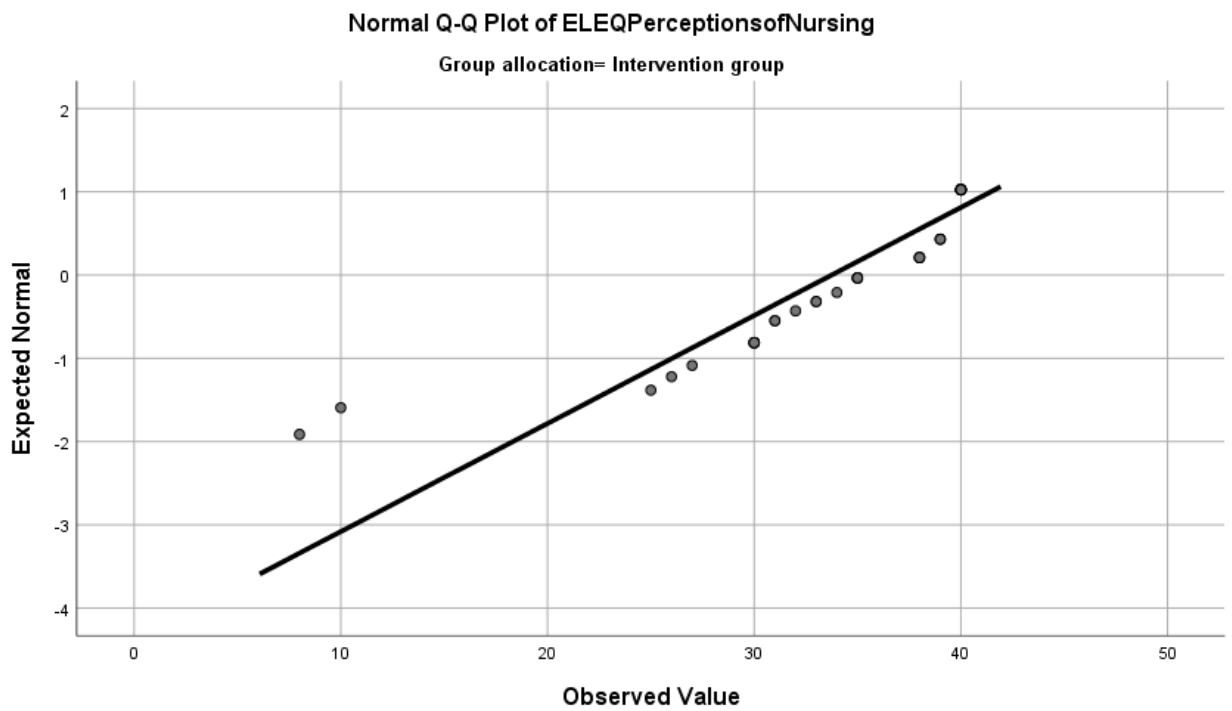
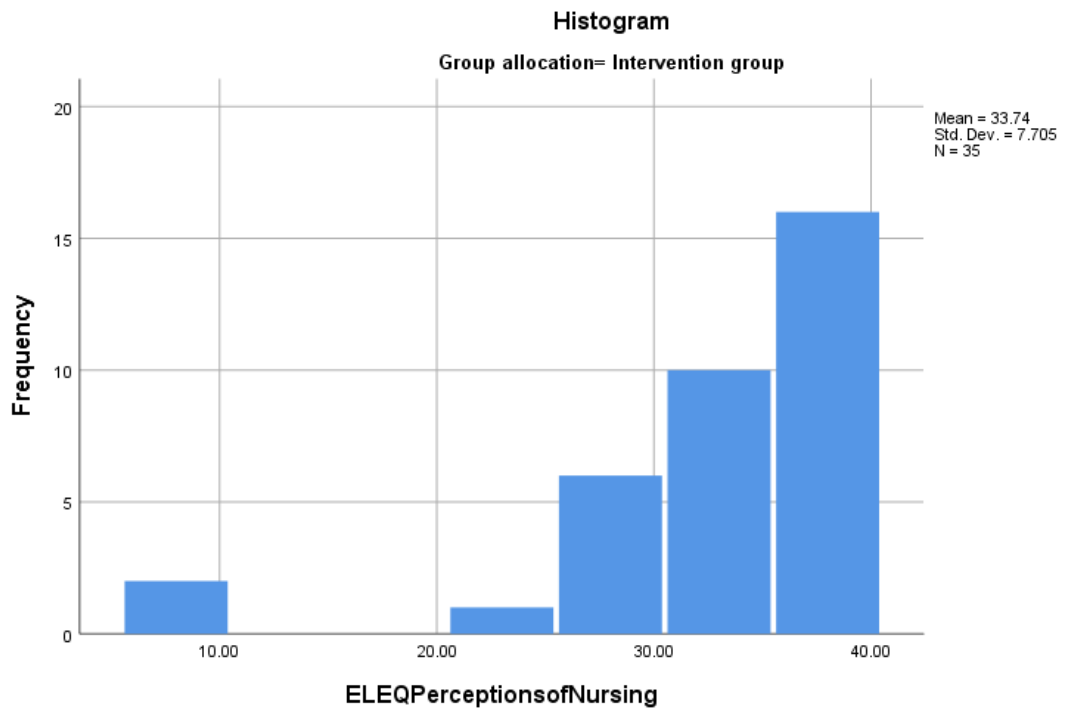
ELEQ emotional distress subscale score intervention group histogram and Q-Q plot



ELEQ perceptions of midwifery care subscale score control group histogram and Q-Q plot



ELEQ perceptions of midwifery care subscale score intervention group histogram and Q-Q plot



Abbreviations

BBA – Born before arrival

CASP – Critical Appraisal Skills Programme

CBSEI – Childbirth Self-efficacy Inventory

CI – Chief investigation

CI – Confidence interval

CMACE – Centre for Maternal and Child Enquiries

CQC – Care Quality Commission

CRN – Clinical research network

CTDQ – Confidence and Trust in Delivery Questionnaire

DOH – Department of Health

ELEQ – Early Labour Experience Questionnaire

HIC – High income country

HRA – Health Research Authority

IMD – Index of Multiple Deprivation

IOL – Induction of labour

ITT – Intention to treat

LBSEQ – Labour and Birth Self-efficacy Questionnaire

MBRRACE – Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries

MCWP – Maternity Care Working Party

MVP – Maternity Voices Partnership

NEST – Needing extra support team

NHS – National Health Service

NICE – The National Institute for Health and Care Excellence

NIHR - National Institute for Health Research

NMC – Nursing and Midwifery Council

NPEU – National Perinatal Epidemiology Unit

ONS – Office for National Statistics

OR – Odds ratio

PICO – Population, Intervention, Comparison, Outcome

PIS – Participant information sheet

PPI – Patient, public and participant involvement

PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-Analyses

RCM – Royal College of Midwives

RCT – Randomised control trial

REC – Research ethics committee

SD – Standard deviation

SE – Standard error

WHO – World Health Organization