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Let's talk early labour: The L-TEL randomised controlled trial

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ABSTRACT

Background: Women without complications have lower obstetric intervention if they remain at home in early labour but many women report dissatisfaction in doing this. Using self-efficacy theory as an underpinning framework, a web-based intervention was co-created with women who had previously used maternity services. The intervention provides early labour advice, alongside the videoed, real experiences of women.
Method: The pragmatic, randomised control trial aimed to evaluate the impact of the web-based intervention on women's self-reported experiences of early labour. Low-risk, nulliparous, pregnant women (140) were randomised. The intervention group (69) received the web-based intervention antenatally to use at their own convenience and the control group (71) received usual care. Data were collected at 7–28 days postnatally using an online version of the Early Labour Experience Questionnaire (ELEQ). The primary outcome was the ELEQ score. Secondary, clinical outcomes such as labour onset, augmentation and mode of birth were collected from the existing hospital system.
Results: There were no statistically significant differences in the ELEQ scores between trial arms. Women in the intervention group were significantly more likely to progress spontaneously in labour without the need for labour augmentation (39.1 %) compared to the control group (21.1 %) (OR 2.41, CI 95 %; 1.14–5.11).
Conclusion: Although the L-TEL Trial found no statistically significant differences in the primary outcome, the innovative intervention to support women during latent phase labour was positively received by women. Web-based resources are a cost effective, user-friendly and accessible way to provide women with education. A larger trial is needed to detect differences in clinical outcomes.

Statement of significance

Problem

Women admitted to hospital in the latent phase of labour are at risk of a cascade of unnecessary intervention.

What is known

Encouraging women to remain at home during this time using service-focused approaches has yet to demonstrate a marked difference to the timing of admission or clinical outcomes. On the contrary, women report the time they spend at home in early labour to be dissatisfying and worrying.

What this paper adds

A novel, web-based, educational resource, co-created by other service users, could improve women's experiences of the early labour phase.

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Introduction

Low-risk women, without pre-existing medical or pregnancy conditions, who are admitted to their place of birth whilst in early labour (latent phase) are at an increased risk of obstetric intervention, [1–4]. When it is required, intervention in childbirth can reduce maternal and fetal morbidity and mortality [5] but unnecessary intervention increases the risk of complication during childbirth [6]. Admission in early labour has been associated with an increased risk of caesarean section [1,7,8]. Women admitted in early labour are more likely to have oxytocin for augmentation [1,7], have epidural analgesia [1], and higher rates of labour dystocia [2].

To minimise these risks, care providers encourage women to remain at home during early labour [9,10]. However there is a plethora of research exploring the negativities that women report whilst at home in this phase [11,12]. These include the failure of health care providers to listen to women and the fact that women feel their experience is dismissed. Frequently, the expectations of this phase at home do not meet the reality of their experiences [13–15] and women find being at home without professional support and reassurance to be frightening. Furthermore identifying when to travel to the chosen place of birth can be challenging [11] and even then journeying to the birth place, receiving a labour assessment, being found to be in early labour and then sent home again is embarrassing and dissatisfying [16–18].

Considering early labour is a significant, often lengthy and painful, phase of the childbirth continuum [19] it has received notably less research attention than the active 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 and have not seen the desired improvements. 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 [20]. 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. In support, a systematic review found "a positive experience that fulfilled or exceeded… prior personal and socio-cultural beliefs and expectations" [21], [p1] was actually what mattered most to women during childbirth.

This paper reports the evaluation of a novel web intervention that was developed in line with Bandura's self-efficacy theory [22].

Methods

Aim

The aim of the randomised controlled trial was to evaluate the effectiveness of the novel, educational, web-based intervention on nulliparous women's experiences of early labour. The impact of the intervention on clinical outcomes was also assessed.

Study design

This was a pragmatic randomised controlled trial (RCT). RCTs are considered the gold standard of experimental research and the most rigorous design in determining effectiveness of a new intervention [23]. Adopting a pragmatic approach enabled the evaluation of effectiveness in a real-world setting, as opposed to measuring the efficacy of the intervention under laboratory conditions [24]. The trial was registered prospectively on the ISRCTN registry (69770712).

Intervention

The web intervention was developed in line with existing self-efficacy theory [22]. 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 [22]. High levels of self-efficacy have been demonstrated to reduce perceived levels of pain in labour [25,26], increase the time spent coping without pharmaceutical analgesia [27,28] and reduce epidural rates [29]. Importantly, self-efficacy is a key psychological factor in achieving a positive birth experience [30], particularly for first-time mothers [31]. Bandura states that it is possible to increase an individual's level of self-efficacy by influencing external sources and social factors through personal mastery, vicarious experience, verbal persuasion and emotional arousal and it was this framework that the intervention was developed using [22]. 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 1 provides definitions of these, alongside an example.

A key component of the intervention was the sharing of vicarious experience from other mothers who had been through early labour. Women who had previously used the maternity service and spent time at home in early labour were videoed speaking about their experiences and

Table 1
Modifying self-efficacy (theory from Bandura 1977).

	Definition	Use in intervention
Personal mastery	This is the notion that previous success at a specific task will improve self-efficacy regarding 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 given birth previously, have higher levels of self-efficacy when compared to nulliparous women. In the intervention nulliparous women received encouragement, support and advice from multiparous women but by definition they could not develop personal mastery until they had been through labour.
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).	Peer support groups rely on other people demonstrating success and motivating others to believe they can succeed in their journeys. The intervention employed this by using real life stories to enable nulliparous women to experience birth vicariously.
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 whilst in labour has been shown to help women cope with pain and overcome feelings of self-doubt. Guidance on positive thinking and positive words was provided in the intervention. There was also a section on the role of birth partners.
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.	The videos included discussions with women where they shared how they had coped with negative feelings and pain. Examples included breathing techniques, massage, the use of water and hynobirthing to assist with labour.

Table 2
Participant demographics and baseline CBSEI scores 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*

The Index of Multiple Deprivation Decile is used to rank geographic areas in England from the most deprived (1) to least deprived (10) and dividing them into 10 equal groups.

coping techniques during semi structured interviews. These videos were broadly edited into themes and added to an informative, educational website to be used during the antenatal period. These themes are detailed in the box below.

Subheadings identified

- 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
- 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

Table 3
ELEQ total scores and subscale scores by trial arm.

	Control (C) (n = 36)		Intervention (I) (n = 35)		Difference in mean score between I & C
	Mean	(SD)	Mean	(SD)	%
Emotional wellbeing items (range 1–5):					
While you were in labour at home					
did you feel safe?	4.67	(0.68)	4.71	(0.60)	
did you feel confident?	3.94	(0.86)	4.14	(0.94)	
did you feel happy?	3.56	(1.05)	4.03	(0.92)	
did you feel excited?	3.89	(0.95)	4.34	(0.68)	
did you feel relaxed?	3.50	(1.21)	3.63	(1.17)	
did you feel comfortable?	3.50	(1.46)	3.63	(1.17)	
did you feel in control?	3.36	(1.27)	3.71	(1.15)	
did you feel supported?	4.42	(1.03)	3.63	(0.61)	
Total: Emotional wellbeing	**23.06**	**(4.71)**	**24.48**	**(4.25)**	**1.42 (+6.16)**
Emotional distress items (range 1–5):					
While you were in labour at home					
did you feel distressed?	4.03	(1.11)	4.29	(1.15)	
did you feel insecure?	4.08	(1.11)	4.23	(1.11)	
did you feel confused?	3.94	(1.07)	4.14	(1.06)	
did you feel tense?	2.67	(1.20)	3.00	(1.33)	
did you feel in scared?	3.06	(1.40)	3.54	(1.27)	
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 (range 1–5):					
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)	
Did the midwife on the phone give reassure you when you needed it?	4.28	(0.88)	3.86	(1.62)	
Did the midwife on spend enough time with you on the phone?	4.31	(1.04)	4.17	(1.12)	
Did the midwife on the phone listen carefully to what you had to say?	4.58	(0.65)	4.17	(1.22)	
Did the midwife on the phone treat you family and/or friends with respect?	4.50	(0.81)	4.37	(1.06)	
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 (range 1–5):					
Did you feel there was teamwork in the	4.50	(0.70)	4.09	(1.22)	

(*continued on next page*)

Table 3 (*continued*)

	Control (C) (n = 36)		Intervention (I) (n = 35)		Difference in mean score between I & C
	Mean	(SD)	Mean	(SD)	%
provision of your care?					
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)**

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…

Once developed, the intervention was validated by those service users who had contributed, with an independent PPI (Patient Public Involvement) panel, and a group of clinical and academic experts in the field to ensure the information being provided was representative, evidence based and safe.

Control group

Women allocated to the control group received 'usual care'; that is, the care normally offered within the hospital. The use of 'usual care' as the comparison is appropriate in a pragmatic randomised controlled trial designed to improve current practice [32]. Pragmatic trials are designed in such a way as to change practice beyond the intervention as little as possible. Although implementation of usual care has been argued to be challenging [32], in the United Kingdom national guidance in relation to maternity care practice makes this a more viable option.

Setting and participants

The trial was undertaken at a hospital in the south of England. The hospital offers comprehensive maternity care and tertiary level neonatal care. Depending on risk, mothers can choose to birth their babies on the labour ward, in an alongside birth centre or in a co-located birth centre. As standard, at the time of the trial, all women are invited to attend face to face, group antenatal education classes. There is a designated, telephone triage service staffed by midwives for taking labour calls.

Women at low-obstetric risk were eligible to participate in the trial. High-risk women are more likely to require closer monitoring and therefore it may not be appropriate for them to remain at home in this phase. They were excluded from the study as providing them with this intervention was deemed as inappropriate and potentially unsafe. Specific eligibility criteria were:

- 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 [33]

Eligible women were identified by their community midwives and provided with a Participant Information Sheet (PIS). Posters throughout the hospital ensured that eligible participants were also be able to self-identify, via email, to the researcher. Ethical approval was sought and granted by the local research ethics committee and study approval by the NHS Health Research Authority (HRA). Recruitment ran from January 2019 to December 2019, with participant follow-up to June 2020.

Sample size calculation

A sample size of 70 (35 in each group) was calculated to be required to detect a 10 % difference in the primary outcome, the total Early Labour Experience Questionnaire (ELEQ) score [34]. The ELEQ was chosen as the principal measure of outcome rather than clinical outcomes because to show a difference in outcomes such as mode of birth would have required a much larger sample size. Moreover, the ELEQ is a prevalidated questionnaire specifically developed to measure experiences of the early phase of labour [34] and was therefore the most appropriate tool for this trial and its focus.

The sample size was calculated using the ELEQ scores reported by Janssen and Desmarais (a 10 % difference in scores 111.80 vs. 101.64) and based on a standard deviation of 12.84 [34,35], a two-sided significance level of 0.05 and 90 % power. To allow for 20 % to not contribute to the primary analysis [36] via attrition during follow-up, an additional 14 participants were required for recruitment. A further consideration was that participants who undergo induction of labour (IOL) do not spend time at home in early labour so would be unable to contribute to the primary analysis with an ELEQ response. Data from the research hospital site indicated that 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 the intervention group, 50 in the control group). The protocol was amended in June 2019 and recruitment extended to increase the sample size to 140 due to the high number of women undergoing induction of labour.

Randomisation

Participants were 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 did not let the researcher know of the details of these blocks. Given the nature of the intervention (requiring active participant engagement) it was not possible to blind participants or midwives to the allocation. Participants were notified of their allocation via email. The intervention group received a link to the web intervention and also continued to receive the standard care available. The control group did not receive the intervention link 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.

Outcome measures and data collection

Prior to participant randomisation, demographic information and scores from the existing Childbirth Self-efficacy Inventory (CBSEI) [37]

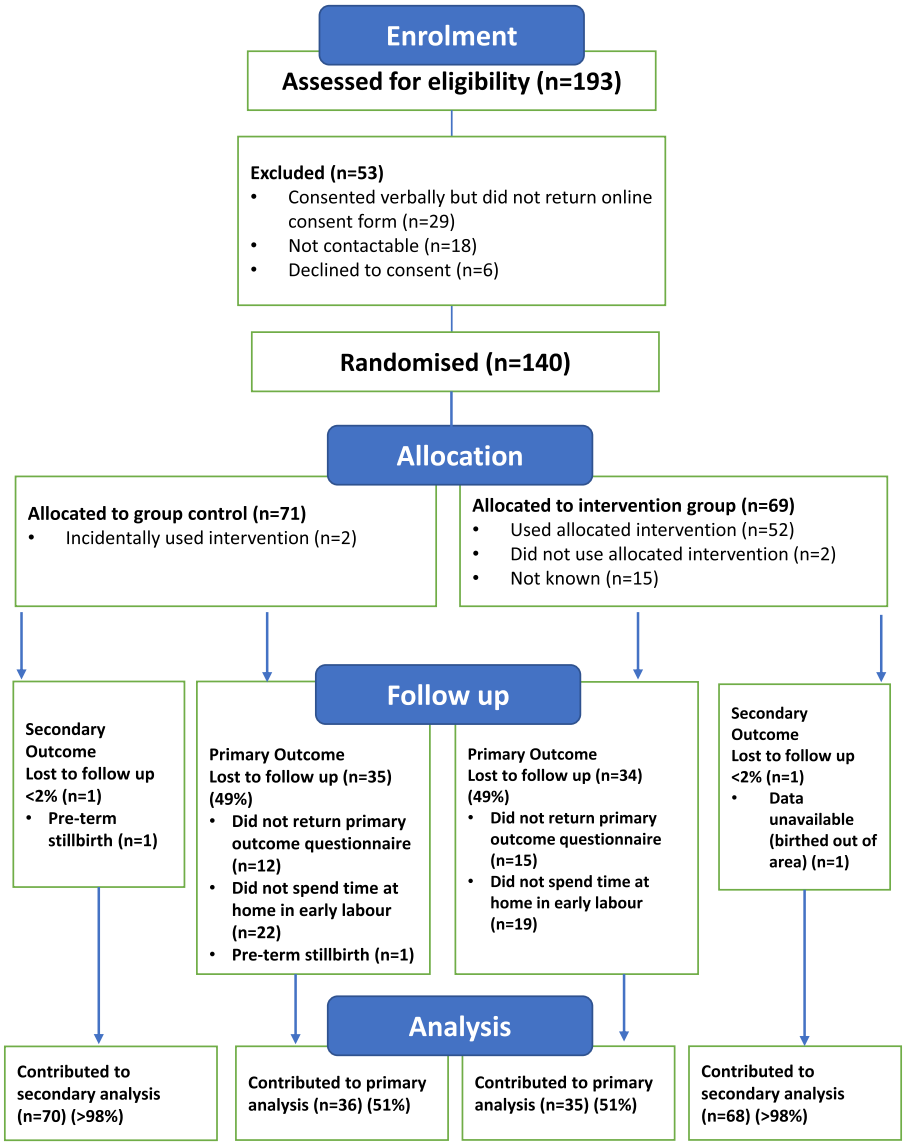

Fig. 1. Participant flow.

were collected antenatally. The CBSEI is a pre-validated, self-report instrument that measures an individual's expectancies of coping with childbirth.

The primary outcome was women's affective experience determined by the total score of the pre-existing, validated, self-report ELEQ [34]. 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. Items on the ELEQ are scored 1–5: 1 = yes definitely, 2 = yes somewhat, 3 = not sure, 4 = not very much, 5 not at all). Items reflect positive attributes such as being in control and negative attributes such as feeling distressed.

Participants received a link to a postpartum questionnaire with an online version of the ELEQ to complete. A minor modification was made to the language of the ELEQ to reflect the fact that midwives provide care in the UK not nurses. An online questionnaire was deemed by a public involvement group to be the best method for promoting follow-up and minimising the impact on mothers caring for their newborn babies. Additional questions around the intervention and other utilised sources of education were also collected. Secondary, clinical outcomes were harvested from the centralised hospital system.

Hypothesis

It was hypothesised that those who received the intervention would provide a significantly more positive overall ELEQ score when compared to the control group who did not receive the intervention.

Data analysis

Data were analysed by intention to treat (ITT) to maintain the balance and advantages generated from the original random allocation [38]. The primary outcome was analysed using an independent t-test to compare the means of the total scores of the ELEQ between trial arms. Items of the ELEQ were recoded such that a higher value represented a more positive rating. Secondary outcomes were compared using odds ratio, to indicate the likelihood of outcomes occurring in the intervention group when compared to the control group. The threshold for statistical significance was set at $p < 0.05$ indicating a 5 % risk of

concluding that a difference exists when there is no actual difference.

Results

In total, 193 women were identified as being eligible to participate in the L-TEL Trial. Of these, 126 had been identified by the midwives, and 67 had self-identified. All women who were contactable were confirmed to be eligible. Fifty-three women were excluded because they were not contactable, did not return their online consent forms, or declined to consent. A total of 140 eligible women were randomised to either the control group (n = 71) or the intervention group (n = 69) (Fig. 1).

The two trial arms' characteristics and demographics are detailed in Table 1. Randomisation appears to have resulted in groups of similar demographics with the exception of the variable marriage. Childbirth self-efficacy as measured by the CBSEI [37] illustrates similar reported levels of self-efficacy in both the trial arms prior to the intervention, suggesting a successful randomisation process.

Primary outcome

There was no statistically significant difference between ELEQ scores between the intervention and control groups. The hypothesis is therefore rejected.

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), t(69) = −0.05, p = 0.96. 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), 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), 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), t(69) = −1.34, p = 0.19.

Secondary outcomes

Table 4 presents data on clinical outcomes. More women in the intervention group had a spontaneous onset of labour (69.1 %) compared to the control group (60 %) but this was not statistically significant (OR 1.49, CI 95 %; 0.74–3.01). Although slightly more of the intervention group entered hospital in active labour (22.1 %) than the control group (18.6 %), this was not statistically significant (OR 1.24, CI 95 %; 0.54–2.85). Women in the intervention group were more likely to progress spontaneously in labour without the need for labour augmentation (39.7 %) compared to the control group (21.4 %) (OR 2.41, CI 95 %; 1.14–5.11) and this finding was statistically significant.

Similar rates of spontaneous vaginal birth were seen in both groups (OR 0.94, CI 95 %; 0.48–1.83) (Table 4). More women in the intervention group had a caesarean section in labour (26.5 %) compared to the control group (18.6 %), but the overall rate of caesarean section was similar in both groups (OR 1.36, CI 95 %; 0.66–2.80). Fewer women in the intervention group required regional anaesthesia for analgesia (OR 0.68, CI 95 %; 0.34–1.36), but this was not statistically significant. More babies in the intervention group required some form of resuscitation (47.1 %) compared to the control group (31.4 %) but this was not statistically significant (OR 0.52, CI 95 %; 0.26–1.03).

Data were collected in the postpartum questionnaire about the intervention use in both the intervention and control groups to monitor adherence to protocol (Table 5). A total of 112 women (control=58; intervention=54) returned their postnatal questionnaires.

The majority (96.3 %) of the intervention group accessed the intervention. The two respondents that did not access it said that this was because they did not remember to. Most women accessed the intervention more than once (90.4 %). Some participant's birth partners also accessed the intervention (29.6 %). The majority of the intervention group stated that they would recommend the intervention to a friend (92.6 %). Two women in the control group (3.4 %) used the intervention despite not being allocated to that group.

Table 4
Secondary Outcomes.

	Control (max n = 70)		Intervention (max n = 68)		
	n	%	n	%	X^2 p value
Phase of labour at admission					*p = 0.848*
Prior to any labour	27	*38.6*	23	*33.8*	
Early labour	6	*8.6*	8	*11.8*	
Active labour	13	*18.6*	15	*22.1*	
Not recorded in hospital record	24	*34.3*	22	*32.4*	
Birth mode					*p = 0.788*
Unassisted vaginal birth	33	*47.1*	31	*45.6*	
Forceps	12	*17.1*	8	*11.8*	
Ventouse	5	*7.1*	5	*7.4*	
Caesarean section in labour	13	*18.6*	18	*26.5*	
Caesarean section not in labour	7	*10.0*	6	*8.8*	
Birth place					*p = 0.783*
Labour ward	55	78.6	53	77.9	
Birth centre	7	10.0	7	10.3	
Co-located birth centre	7	10.0	8	11.8	
Other inpatient, hospital ward	1	1.4	0	0	
Onset of labour					*p = 0.524*
Spontaneous onset	42	*60.0*	47	*69.1*	
Induction of labour	22	*31.4*	17	*25.0*	
No labour	6	*8.6*	4	*5.9*	
Augmentation					*p = 0.226*
No augmentation	15	*21.4*	27	*39.7*	
Artificial rupture of membranes (ARM) only	11	*15.7*	9	*13.2*	
Oxytocin infusion only	4	*5.7*	5	*7.4*	
ARM and oxytocin	8	*11.4*	5	*7.4*	
Not applicable (IOL or CS)	31	*44.3*	22	*32.4*	
Unknown	1	*1.4*	0	*0*	
Analgesia					*p = 0.471*
N/A (no labour)	7	*10.0*	6	*8.8*	
None	0	*0*	3	*4.4*	
Non-pharmacological analgesia only	2	*2.9*	2	*2.9*	
Inhalation analgesia only	29	*41.4*	33	*48.5*	
Regional anaesthesia (i.e. epidural)	30	*42.9*	23	*33.8*	
Not recorded in hospital notes	2	*2.9*	1	*1.5*	
Neonatal resuscitation at birth					*p = 0.245*
None	48	*68.6*	36	*52.9*	
Stimulation alone	17	*24.3*	21	*30.9*	
Stimulation and facial oxygen	2	*2.9*	2	*2.9*	
Positive pressure without drugs	1	*1.4*	5	*7.4*	
Not recorded in hospital notes	2	*2.9*	4	*5.9*	
Feeding at discharge					*p = 0.659*
Breastfeeding	51	*72.9*	43	*63.2*	
Combination feeding	9	*12.9*	11	*16.2*	
Artificially feeding	7	*10.0*	9	*13.2*	
Not recorded in hospital notes	3	*4.3*	5	*7.4*	
Apgar score (C=70, I=68)					
Median score at 1 min	9		9		
Median score at 5 min	9		9		

Discussion

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. However, the trial found no statistically significant differences in the ELEQ primary outcome.

The novel intervention was 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

Table 5
Intervention use.

	n	%
Intervention use in the intervention group (n = 54)		
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 by birth partners of the intervention group (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 the intervention so cannot answer this question	2	*3.7*
Intervention use in the control group (n = 58)		
Did not use intervention (adhered to protocol)	56	*96.6*
Incidentally used intervention	2	*3.4*

receiving maternity care. Early labour research was identified by women as a key research priority nearly a decade ago [39], and it remains highly topical since it is commonly a cause of complaint.

Whilst there were no statistically significant differences in the ELEQ primary outcome, there were notable and consistent variations in score between the trial arms. Those in the intervention group scored more positively in both the emotional wellbeing subscale and in the emotional distress subscale than the control group. Although not statistically significant, the intervention group scored consistently higher in 13 out of the 14 emotional items. Conversely, 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 more negatively in all eight of the individual item scores within the subscale when compared to the control group.

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. In support of this theory, Spiby et al. 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 [40]. Receiving conflicting advice (or advice that does not reflect what has been received previously) is a common source of complaint within maternity [40].

An alternative theory to these noted score differences is that women commonly seek care for confirmation of normalcy [41] because of uncertainty in recognising when labour has started and because they require professional reassurance [20]. Many look for professional input on a "just in case" principle, even if they are coping well, because they lack confidence in this phase [10]. 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.

Overall it was noted that women rated their experiences highly. This reflects the literature that suggests that childbirth surveys tend to have overwhelmingly positive results [42,43] where, from a quantitative perspective at least, women report good experiences in relation to pregnancy and childbirth.

Although the L-TEL Trial was not statistically powered to demonstrate significant differences in clinical outcomes, there were some findings for discussion. There was no statistically significant difference in the phase of labour on admission between trial arms, but it should be noted that there are limitations in the data collected. 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.

It is worth noting that 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. Whilst artificial oxytocin can reduce the length of labour, a Cochrane review found that it did only this, and did not reduce the number of women undergoing caesarean section [44].

Strengths and limitations

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. There was high adherence to the protocol, only two participants in the control group incidentally used the intervention and only two participants in the intervention group did not use the intervention, strengthening the trial's internal validity. It is likely that the two control group participants received the link from a contact with intervention group, but this was not confirmed.

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. It is widely documented that women who are married have better pregnancy outcomes such as reduced preterm birth, increased vaginal birth rates and higher breastfeeding rates [45,46]. The intervention group had a higher number of women who reported to have a partner (37.7 %) compared to the control (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 birth experience [47]. 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 [47].

The L-TEL Trial does however underrepresent 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 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.

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 current 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.

A large proportion of the 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 conclusions in relation to this outcome; it is not possible to determine if more data would have altered differences between the trial arms.

Conclusion

The L-TEL Trial found no statistically significant differences in the primary outcome, the ELEQ score. However, it developed an innovative web-based intervention to support women during latent phase labour thus moving away from a model of service allocation and appropriation based on the perspective of what is desirable to the maternity service, primarily keeping women out of hospital, often to the service users' emotional detriment.

The trial contributes to early labour knowledge and developed an intervention to equip women with the skills and coping strategies they need to remain at home. Distinctively, the knowledge underpinning these skills and coping strategies came directly from other women for increased authenticity. 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 evaluated it positively 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 and accessible ways to provide women education.

The L-TEL Trial was a well-timed research study, contributing to the gaps in knowledge highlighted in several recent research papers [11,12,20,48–50]. The 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.

Ethics statement

The study was approved by the HRA and Health and Care Research Wales (HCRW) Approval – IRAS Project ID: 23571.

Author contributions

Rebecca Edwards: Conceptualization; Methodology; Data curation; Formal analysis; Project administration; Software; Writing – original draft. **Susan Way:** Funding acquisition; Conceptualization; Supervision – including methodology, data curation and analysis; Software; Writing – review & editing. **Vanora Hundley:** Funding acquisition; Conceptualization; Supervision – including methodology, data curation and analysis; Project administration; Resources; Writing – review & editing.

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