Women and Birth xxx (xxxx) xxx

Contents lists available at ScienceDirect

Women and Birth

journal homepage: www.sciencedirect.com/journal/women-and-birth

Using a birth ball to reduce pain perception in the latent phase of labour: a randomised controlled trial☆

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ARTICLE INFO

Keywords:
Birth ball
Latent labour
Labour pain
Labour onset
Childbirth

ABSTRACT

Background: Admission in the latent phase of labour is associated with higher rates of obstetric intervention. Women are frequently admitted due to pain. This study aimed to determine whether using a birth ball at home in the latent phase of labour reduces pain perception on admission.

Method: A prospective, pragmatic randomised controlled trial of 294 low risk pregnant women aged 18 and over planning a hospital birth. An animated educational video was offered at 36 weeks' gestation along with a birth ball. The primary outcome was pain on a Visual Analogue Scale on admission in labour. Participants who experienced a spontaneous labour were invited to respond to an online questionnaire 6 weeks' postpartum.

Results: There were no differences in the mean pain scores; (6.3 versus 6.5; 90%CI −0.72 to 0.37 p = 0.6) or mean cervical dilatation on admission (4.7 cm versus 5.0 cm; 95% CI −1.1 to 0.5 p = 0.58). More Intervention participants were admitted in active labour (63.6% versus 55.7%; p = 0.28) and experienced an unassisted vaginal birth (70.3% v. 65.8%; p = 0.07) with fewer intrapartum caesarean sections (7.5% v. 17.9%; p = 0.07) although the trial was not powered to detect these differences in secondary outcomes. Most participants found the birth ball helpful (89.2%) and would use it in a future labour (92.5%).

Conclusion: Using the birth ball at home in the latent phase is a safe and acceptable strategy for labouring women to manage their labour, potentially postpone admission and reduce caesarean section. Further research is warranted.

Statement of significance

Problem or issue

Hospital admission in the latent phase of labour is associated with higher rates of obstetric intervention

What is already known

Although encouraged to remain at home until active labour establishes, women cite pain and anxiety as their drivers to seeking hospital admission. They find standard professional advice generic and unhelpful.

What this paper adds

Birth balls are widely available and their use advised in labour to promote upright positioning. This paper presents the first objective evidence of using the birth ball at home in the latent phase to reduce pain perception and the impact on labour and birth outcomes.

Data Availability

The complete de-identified data set is available for research purposes on application to the corresponding author.

☆ Access to the video is available on request to the corresponding author.

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https://doi.org/10.1016/j.wombi.2023.11.008
Received 23 February 2023; Received in revised form 28 November 2023; Accepted 30 November 2023

Introduction

Most births in high-income countries occur in hospital [1]. However, admission in the latent phase of labour is associated with higher rates of obstetric intervention, including amniotomy [2], continuous electronic fetal monitoring and synthetic oxytocin augmentation [3], epidural anaesthesia and caesarean section (CS), [2–7], with the potential for increased maternal and fetal morbidity in the short and long terms [8]. Latent phase admissions to labour wards in high-income countries may be as high as 47% of all labour admissions [7]. A reduction in latent phase admissions would appear to be a key component of reducing costs to maternity care systems and a reduced burden of intervention [9].

The latent phase of labour marks the transition from pregnancy to established labour [10–13] and is considered to occur with maternal perception of the start of labour accompanied by contractions until the cervix effaces and is 3 – 6 centimetres dilated, the definition depending on the country and the locality [14–16]. Women cite pain and anxiety as their primary drivers in seeking latent phase admission [17–19] and the standard advice of 'paracetamol, a bath, mobilise and keep hydrated' is perceived as a generic, ineffective response [20,21]. A Cochrane review has concluded that to date, latent phase interventions (for assessment and support) have neither demonstrated a reduction in obstetric interventions, nor postponed hospital admission until the established phase of labour [22]. This may be because these interventions have predominantly focused on changes to service provision in high income countries rather than targeted, woman-centred interventions.

When labouring women are mobile and upright the fetal presenting part is applied to the cervix and increases oxytocin release [23]. Oxytocin and endogenous opioids modulate pain perception through an intrinsic pain modulation pathway [24,25], whilst oxytocin and prostaglandins promote uterine contractions and cervical effacement to establish labour [26]. Mobility and upright positioning are also associated with a reduced uptake of pharmacological analgesia [23]. Enhancing women's confidence and de-medicalising labour pain may also be key components since self-efficacy and confidence are associated with reduced pain perception [27], obstetric intervention and epidural use [28–30].

Vinyl physical therapy balls ('Swiss', 'Pezzi' or 'birth' balls) can be used to facilitate mobility and upright positions in early labour. Rocking, circling, making figure-of-eight movements and bouncing whilst seated on the ball alleviate pressure on the skin and promote neutral positioning of the spine and pelvis at rest [31]. Sitting on the ball may alleviate pressure on the nerve filaments over the sacroiliac area and reduce lumbar pain [32]. Using the birth ball may enhance women's self-efficacy and well-being, rather than passive compliance and there is some evidence to suggest that women who use birth balls in established labour report less pain and greater satisfaction [33,34]. Although there has been a recent review of peanut balls to decrease length of labour [35], the evidence for using birth balls in the latent phase of labour is very limited [36] and requires further examination.

Methods

The Ball Assisted Latent Labour (BALL) trial was a pragmatic single centre randomised controlled trial to evaluate the effect of using a birth ball at home in the latent phase of labour on pain perception on admission to hospital. The trial was registered with the International Standard Randomised Controlled Trials Number 10755909.

Null hypothesis

Using a birth ball at home in the latent phase of labour would not reduce pain perception on admission to hospital.

Participants

Nulliparous and parous pregnant women were eligible to participate in the study from 28 weeks' gestation if they were aged 18 and over, able to understand, read and write English and were at low risk of obstetric intervention. Participants had a singleton fetus and planned to labour and birth in hospital. Women were excluded from the trial if they were aged under 18, had a multiple pregnancy or planned to give birth either at home or with a planned CS. They were also excluded if they had a history of CS or other uterine surgery, cardiac, endocrine or obstetric complications, or used opiate analgesia or recreational drugs.

Women were identified by midwives who were working in the community. Training was provided either in the midwives' office or at the maternity ward following handovers. Women were given a Participant Information Sheet (PIS). The researcher contacted potential participants from 28 weeks' gestation onwards if their midwife had discussed the trial with them. Having ensured that the participant had read the PIS, understood the requirements of a randomised controlled trial and met the inclusion criteria, they were asked to read and sign the consent form.

The research was set in an acute NHS Trust serving a semi-rural community.

Intervention

Both Control and Intervention participants received standard antenatal care [37] and were free to access antenatal classes or resources as they wished.

Intervention arm participants were also offered the loan of an appropriately sized *Birthease* birth ball on recruitment and access to a bespoke online animated educational video entitled, '*Having A Ball in Early Labour*'. The educational video demonstrated the use of the birth ball at home in the latent phase of labour. It was developed from a Patient Public Interaction (PPI) facilitated by the local Maternity Services Liaison Committee chairperson and involved a parent and baby group (up to one year of age) at a Children's Centre. Fifteen mothers were informed of the aims of the study and shown the storyboard and the script. The script outlined why using the birth ball might be helpful. The mothers felt that the proposed script glamourised the latent phase, so it was amended to reflect the tiredness and frustration they had experienced. Their other comments about their experiences were copied verbatim with their consent, incorporated into the script and read by actors. The consensus was that the educational video format was ideal, as few mothers reported having had the time to read the maternity leaflets they had received.

Birth balls were purchased from a reputable supplier and loaned by the hospital to the women in the Intervention arm. To accommodate women of varying heights, 21×65 cm (for women <1.74 m) and 10×75 cm (for women >1.75 m) 'flat-packed' balls were obtained, each with a hand pump to inflate the ball. Cleaning before redistribution to a new participant was undertaken according to Trust local guidelines, with each ball and pump wiped and air dried before being placed in a new polythene bag. Each participant received a Safety Sheet with the birth ball. Intervention arm participants either collected their birth ball from their community midwife at their antenatal appointments or it was delivered to their home address at an agreed time. The balls were usually returned to the community midwife at a postnatal visit.

Birth balls are readily available in the United Kingdom (UK) and therefore it was possible for Control arm participants to purchase these themselves, but they were not given any advice or information about them and did not have access to the video.

Prior to accessing the video (at 36 weeks' gestation) Intervention participants completed Part 1 of the Childbirth Self-Efficacy Inventory© (CBSEI) [38] questionnaire. Three days after their first viewing, they completed another CBSEI Part 1 questionnaire.

Primary outcome

The primary outcome was pain as measured on a Visual Analogue Scale (VAS) when the participant was admitted to hospital in labour. However, 112 women did not provide a VAS score because they did not labour spontaneously at term and 33 VAS scores were missed (Fig. 1). These were equally distributed across both trial arms.

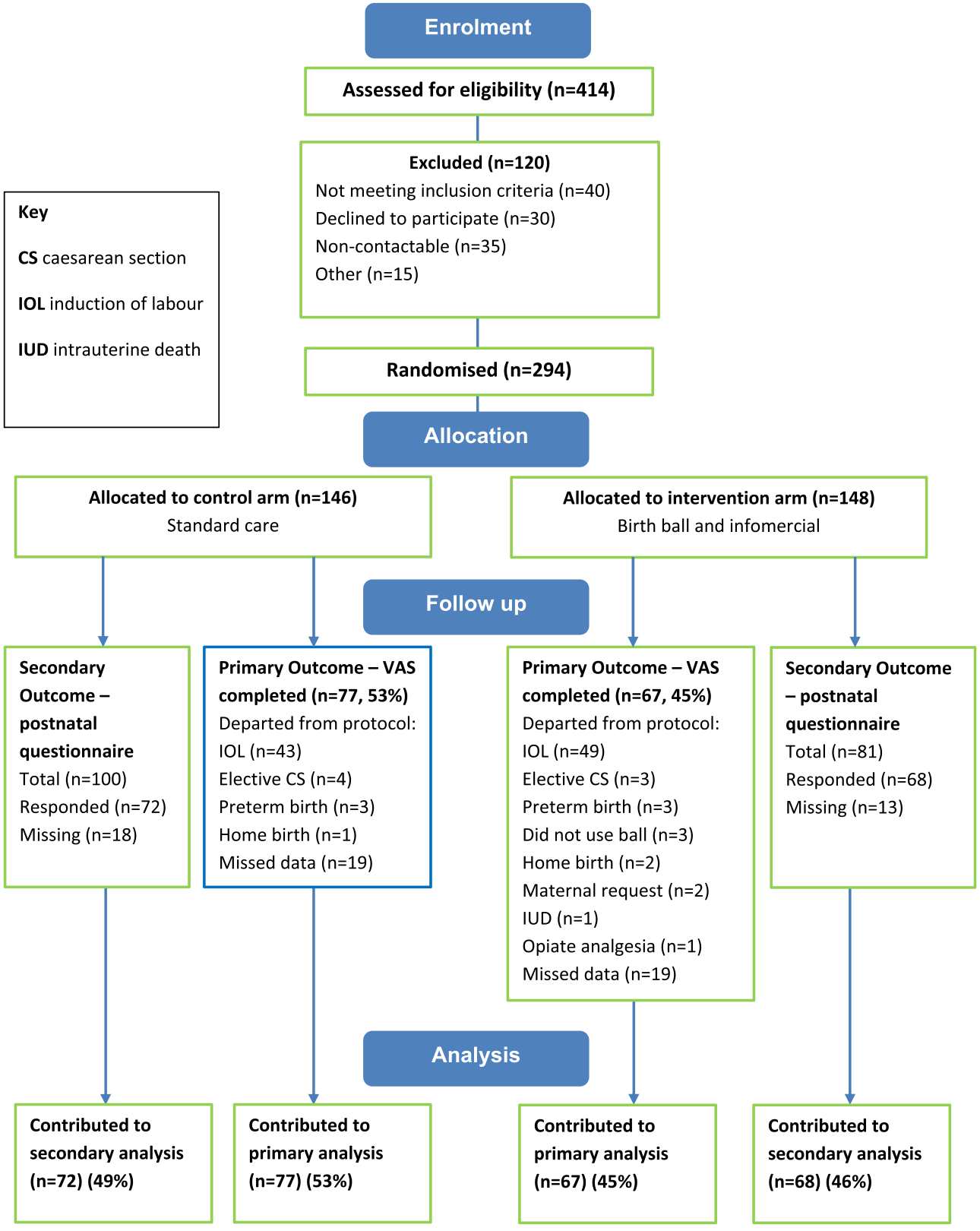

Fig. 1. Participant flow.

Secondary outcomes

- Outcome Expectancy and Self-efficacy Expectancy scores on the modified Part 1 (latent phase) CBSEI©. Outcome Expectancy represented a woman's confidence that a given strategy would prove effective, whereas Self-efficacy Expectancy represented a woman's confidence that she would be able to undertake that strategy.
- cervical dilatation on admission to maternity unit
- obstetric intrapartum interventions including continuous electronic fetal monitoring, amniotomy, intravenous synthetic oxytocin and intrapartum epidural / spinal anaesthesia
- birth mode
- ball uptake,acceptability and maternal satisfaction at 6 weeks' postpartum.

In order to determine acceptability and satisfaction of participants' early labour experience, a confidential on-line questionnaire was designed for distribution and completion at 6 weeks' postpartum. An access Uniform Resource Locator (URL) was e-mailed to all Control and Intervention arm participants who had experienced a spontaneous onset of labour (Fig. 1).

Sample size

A sample size of 276 was calculated (138 in each group) to detect a difference of one point on the VAS between the two groups (5.3 compared to 4.3) [36] based on standard deviations of 2.6 and 2.5 in each group respectively, a two-sided 5% significance level, and 90% power. To account for 20% not contributing to the main analysis [39], the sample size was set at 332 women to be recruited (166 in each trial arm).

Recruitment proceeded from 1 February 2018 – 31st October 2018; a two-month extension until 31st December 2018 was granted by the Research Ethics Committee (see below).

Randomisation

Participants were randomised using an online randomisation service [40], stratifying for nulliparity or multiparity to balance the greater obstetric intervention associated with nulliparous labours and births [41,42]. As an additional strategy against allocation bias and to balance allocation, randomisation was set to blocks of 2, 4 and 8 [43].

The nature of the intervention meant that neither the researcher, the participants nor their midwives could be blinded.

Ethical opinion and sponsorship

A favourable ethical opinion was granted by a Research Ethics Committee on 11th December 2017.

The university acted as sponsor to ensure the scientific quality of the research and that the research conduct was consistent with the Department of Health Research Governance Framework [44], superseded by that of the NHS Health Research Authority [45].

Safety and adverse outcomes

All participants were issued with verbal and written advice to contact the maternity unit directly in the event of suspected pre-term labour, vaginal bleeding, meconium stained liquor, reduced fetal movements, if feeling unwell or concerned whether antenatally or intrapartum. Intervention arm participants were issued with guidelines for safe and appropriate use of the birth balls in line with the supplier's directions, including weight limit, correct inflation and cleaning. Labour and birth outcomes were scrutinised as they became available and again formally by a Trial Management Committee meeting at the mid-point of the trial.

Statistical methods

Quantitative data were analysed on an Intention-To-Treat basis using IBM SPSS version 25.0 software. Demographic data were compared using descriptive statistics.

Only women who were admitted in spontaneous labour were included in the analysis of phase of labour on hospital admission. This was because women who had an induction of labour or who had an elective caesarean section would have entered the hospital prior to labour onset. Cervical dilatation on admission to hospital was used for this analysis, which was conducted first according to UK guidelines for the diagnosis of established labour from 4 cm cervical dilatation [15] and then according to World Health Organization (WHO) guidelines of 5 cm cervical dilatation [16].

Where women arrived in strong labour and gave birth within 1 hour of arrival without vaginal examination, they were assumed to have arrived at full dilatation.

Mean VAS scores (primary outcome) in the Intervention and Control arms were analysed using an independent t-test. The Pearson Chi-square test was used to compare latent / active labour phase admission and frequency of obstetric interventions between trial arms. Before and after results from the CSEI were compared using a paired t-test.

Participant flow

A total of 414 potential participants expressed interest in joining the trial and agreed to being contacted by the researcher (Fig. 1). Approximately a third (n = 119) were not recruited; 40 did not meet the inclusion criteria, 35 did not respond to contact, 30 declined following further information. No reason was logged for a further 14 women.

One Intervention arm participant experienced an antenatal intrauterine death and was withdrawn from the trial at that point.

Results

A total of 295 women consented to join the trial; however, one woman gave birth before randomisation and was excluded. Thus, 146 women (77 nulliparous and 69 parous) were randomly allocated to the Control arm and 148 (83 nulliparous and 65 parous) to the Intervention arm.

Baseline characteristics were similar between both trial arms (Table 1).

Table 1
Participant baseline characteristics.

n = 294	Control n = 146	Intervention n = 148
Age at giving birth	28.35	28.37
Parity n (%)		
Nulliparous	77 (52.7)	83 (56.1)
Parous	69 (47.3)	65 (43.9)
Marital status n (%)		
Single, unsupported	5 (3.4)	4 (2.7)
Single supported	18 (12.3)	19 (12.8)
Married	49 (33.6)	53 (35.8)
Living with partner	71 (48.6)	66 (44.6)
Educational achievement n (%)		
Secondary school	17 (11.6)	15 (10.1)
College	83 (56.8)	80 (54.1)
Graduate	19 (13.0)	24 (16.2)
Postgraduate	21 (14.4)	23 (15.5)
Ethnic background n (%)		
White British	141 (96.6)	136 (91.9)
White European	3 (2.1)	4 (2.7)
South East Asian	1 (0.7)	2 (1.4)
Asian	0 (0.0)	1 (0.7)
White & Black African	0 (0.0)	1 (0.7)
White & North African	0 (0.0)	2 (1.4)
Other	1 (0.7)	2 (1.4)

Adherence to the intervention was high in the Intervention arm, with 54 / 65 (83.1%) respondents reporting using the ball at home in the latent phase; in the Control arm 39 / 75 (52%) also reported using the birth ball of their own volition.

There was no difference in the mean VAS score between the trial arms; the mean VAS was 6.3 [SD 2.1] in the Control arm compared to 6.5 [SD 1.8] in the Intervention arm.

There was no difference in the mean cervical dilatation on admission to hospital in labour between the Control and Intervention arms (4.7 cm versus 5.0 cm; mean difference - 0.3, 95% CI −1.1 to 0.5). However, a higher proportion of participants in the Intervention arm were admitted to hospital in established labour (63.6% versus 55.7%) according to current national guidelines which deem 4 cm cervical dilatation to be the threshold for active labour [15]. This difference was still apparent using WHO guidelines, with the higher threshold of 5 cm cervical dilatation [16] (48.9% versus 43.2%) (Table 2).

There were no significant differences in continuous electronic fetal monitoring, amniotomy, synthetic oxytocin or prelabour / intrapartum epidural / spinal anaesthesia experienced in the trial arms (Table 3). There was a non-statistically significant difference in intrapartum CS with fewer CS in the Intervention arm compared to the Control arm (7.5% versus 17.9%; p = 0.07) More Intervention arm participants experienced induction of labour compared to the Control Arm (35.0% versus 30.4%; p = 0.36).

Intervention arm participants experienced a statistically significant increase in Outcome Expectancy and Self-efficacy Expectancy in the CBSEI© after accessing the educational video, as shown in Fig. 2.

A total of 140/181 (77%) women laboured spontaneously at term and had not withdrawn from the trial, so were eligible to complete the online questionnaire at 6 weeks' postpartum (Fig. 1). Ninety-three participants used the birth ball in the latent phase of labour. These participants reported high levels of satisfaction and acceptability with the majority of respondents stating that using the birth ball had been helpful, that they would use the ball in a future labour and / or recommend it to a friend or family member.

Discussion

The latent phase of labour is a challenge for both pregnant women and maternity care professionals, and there is a need for responsive maternity services that provide woman-centred support [46]. The BALL trial has demonstrated that using a birth ball at home in the latent phase was highly acceptable to women. It may have either encouraged them to remain at home longer or allowed their labours to establish more rapidly. There was a trend towards a lower rate of caesarean birth during labour (17.9% versus 7.5%), however this did not achieve statistical significance (p = 0.07) The study was not powered to detect differences in mode of birth as a secondary outcome, but the reduction in intrapartum CS appears positive. There is ample evidence which correlates early hospital admission in labour with an increased incidence of CS [2–7] and our findings suggest that women using the birth ball at home in the latent phase may demonstrate improved labour and birth outcomes. The potential reductions in health, service and cost burdens which may be engendered by fewer latent phase admissions alone make implementation of the birth ball cost-effective [9].

Previous studies have focussed on service changes or interventions targeted at health professionals [22]; in contrast, the intervention in this study was woman-centred and informed by PPI. Intervention arm participants reported significantly increased self-efficacy after accessing the educational video. When considered with high birth ball uptake and satisfaction, this suggests that enhanced confidence and offering a purposeful evidence-based strategy (video and birth balls) improved women's wellbeing and de-medicalised their pain experience, which in turn contributed to their decision to remain at home until their labours established. This supports our original premise that woman-centred, evidence-based strategies are more likely to improve outcomes than interventions which are merely based on service resource appropriation. Ensuring a safe and effective maternity service is essential and valuing women's voices and experiences are key components [47].

There are other confounding factors that could influence women's timing of hospital admission. These include physiology, the support of partners, geographical distance to the hospital and previous pain experiences [17,30,46]. Randomisation should have ensured that such influences were equally distributed between the two arms of the trial. Future research should explore these in more depth.

In terms of safety, the circumstances of the intrauterine death experienced by one trial participant at 38 weeks were scrutinised by local risk management and the Trial Management Committee. This Serious Untoward Incident was ascertained as coincidental to trial participation. One unplanned home birth occurred for a parous participant in the Intervention arm and she was attended by community midwives. Concerns have been raised about the potential for an increase in babies born outside hospital as a result of unit closures, however this has not been shown to lead to poorer maternal or newborn outcomes [49]. No other incidents were reported and our findings suggest that using the birth ball at home in the latent phase of labour is safe. Larger studies are needed to confirm this.

Table 2
Hospital admission outcomes.

	Control [SD]	Intervention [SD]	Mean difference	t	df	p
Mean VAS	6.3 [2.1]	6.5 [1.8]	-0.17 (90% CI −0.72 to 0.37)	-0.5	142	0.6
Mean cervical dilatation (cm)	4.7 [2.7]	5.0 [2.6]	- 0.3 (95% CI −1.1 to 0.5)	0.73	181	0.58
N = 183	N = 95 n (%)	N = 88 n (%)	Pearson Chi-square		df	p
* Latent labour admission (NICE 2017)	42 (44.2)	32 (36.4)	1.17		1	0.28
*Active labour admission (NICE 2017)	53 (55.7)	56 (63.6)				
* Latent labour admission (WHO 2018)	54 (56.8)	45 (51.1)	0.60		1	0.44
* Active labour admission (WHO 2018)	41 (43.2)	43 (48.9)				

* Data analysed only for women who laboured spontaneously, therefore not Intention-To-Treat

Strengths and limitations of this study

The BALL trial was strengthened by high engagement and support by the community and maternity staff, which resulted in a cohort that was representative of the hospital population [48]. Younger, less affluent and more vulnerable participants contributed to the trial, whereas these demographics are often under-represented in other research [49].

The high proportion of women who underwent induction of labour meant that fewer women completed the VAS (primary outcome) and this reduced the power of the study. Despite the excellent 73% data capture for participants in spontaneous labour, the BALL trial did not demonstrate a reduction in pain perception on admission to hospital. Future research into spontaneous labour onset needs to allow for wider margins for non-contributors in obstetric research cohorts with current rising labour induction rates.

The trial's pragmatic design and complex intervention both strengthen our findings about the effectiveness of using a birth ball at home in the latent phase of labour and their generalisability in 'real life'

Table 3
Secondary outcomes.

	Control n = 143 [SD] (%)	Intervention n = 138 [SD] (%)	Mean difference (95% CI)	t	df	p
Labour and birth outcomes						
Mean gestation (days) [SD]	278.2 [11.6]	280.12 [8.9]	0.58 (−1.86 to 3.02)	0.65	279	0.47
Pre-term birth (<37 +0)	7 (5.0)	3 (2.2)				
Mean birthweight (grams) [SD]	3411.57 [517.1]	3565.67 [450.0]	-10.37 (−125.68 to 104.95)	0.18	279	0.77
Mean Apgar @ 1 min	8.38 [0.1]	8.69 [0.1]	0.11 (−0.19 to 0.42)	0.72	279	0.17
Mean Apgar @ 5 mins.	8.73 [1.5]	8.98 [0.3]	0.82 (−0.18 to 0.34)	0.62	279	0.08
Birth mode				Pearson Chi-square	df	p
Unassisted vaginal births	96 (65.8)	104 (70.3)		8.57	4	0.07
Assisted births	14 (9.5)	19 (12.8)				
Pre-labour CS	4 (2.7)	3 (2.0)				
Intrapartum CS	26 (17.9)	11 (7.5)				
Vaginal breech	1 (0.7)	0 (0.0)				
Obstetric interventions						
Induction of labour	43 (30.4)	49 (35.0)		2.07	2	0.36
CEFM	95 (66.0)	88 (63.8)		0.22	1	0.64
Amniotomy	63 (44.0)	63 (45.0)		0.72	1	0.79
Synthetic oxytocin	32 (22.4)	27 (19.6)		0.34	1	0.56
Pre-labour / intrapartum epidural/spinal anaesthesia	53 (37.0)	48 (34.7)		0.16	1	0.69
Postnatal questionnaire (n = 140)						
Birth ball uptake in the latent phase	39 / 75 (52.0)	54 / 65 (83.1)				
Maternal satisfaction; found ball helpful	83 / 93 (89.2)					
Maternal acceptability; would use in a future labour	86 / 93 (92.5)					
Maternal acceptability; would recommend to a friend / family member	82 / 93 (89.1)					

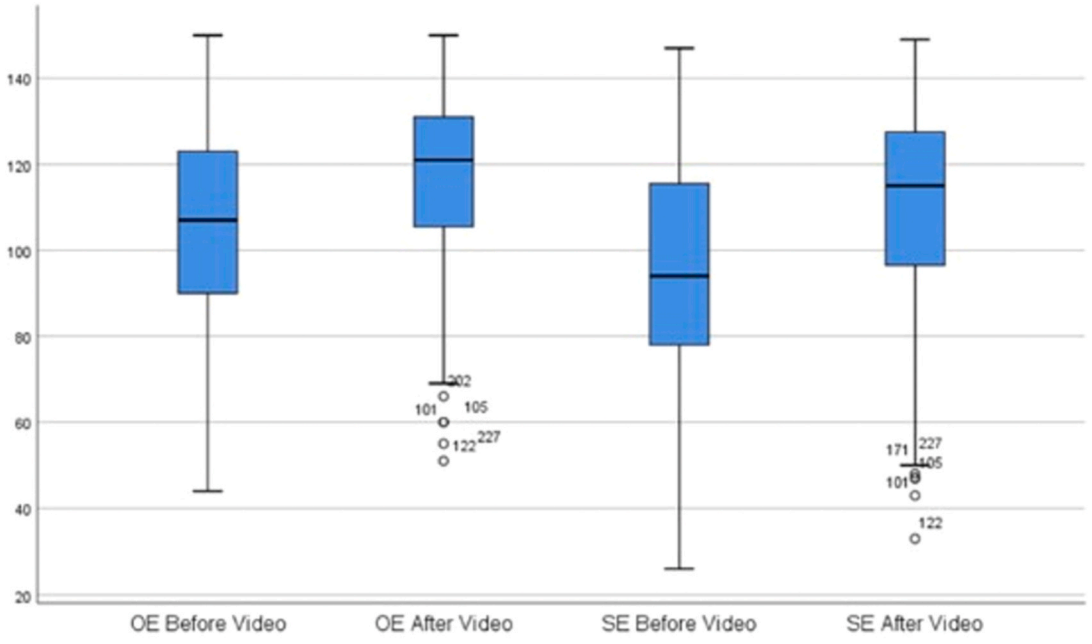

Fig. 2. Comparison of before and after values of CBSEI Outcome Expectancy (OE) and Self-efficacy and Expectancy (SE).

conditions. There was high adherence to the protocol by the Intervention arm, which has not been seen in other studies of latent phase labour [22]. Whilst there was a degree of contamination in the Control Arm with 39 / 75 (52%) questionnaire respondents reporting birth ball use at home, these participants did not have access to the educational video. The significantly enhanced self-efficacy reported by Intervention arm participants combined with the reduction in intrapartum CS may be an important factor in understanding the effectiveness of birth ball use in the latent phase of labour. They also highlight the need for women to have ready access to evidence-based strategies and information which are currently lacking [22].

Conclusions and policy implications

Overall, the BALL trial was a robust, innovative and pragmatic study. Using the birth ball at home in the latent phase is a safe, low-cost, effective and acceptable latent phase strategy for women which enhances their confidence and improves their latent phase experience. The associated reduction in latent phase admissions and intrapartum CS is promising and merits research on a bigger scale.

Ethics statement

The study was approved by HRA / NHS South Central Hampshire B Research Ethics Committee on 11th December 2017.

Funding

The BALL trial was supported through a Wessex Clinical Academic Training Programme through the NIHR. The purchase of birth balls was undertaken through an award from the Iolanthe Midwifery Trust. Sincere thanks to the families and midwives at the Isle of Wight NHS Trust.

Author contributions

VH, SW and CC conceived the study and obtained funding to support the work. DM planned the study design, designed the data collection form and analysed the data with support from VH, SW and CC. All authors interpreted the data. All authors contributed to the discussion and interpretation of the findings. All authors contributed to the planning, conduct and reporting of this research article. D.C.M. Mylod is the guarantor. All authors contributed to the writing of the paper and approved the final version. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Transparency declaration

I, Dr. Dominique Mylod, as the lead author of this work, affirms that this manuscript is an honest, accurate and transparent account of the Ball Assisted Latent Labour trial; that no important aspects of the study have been omitted and that any discrepancies from the study as originally planned have been explained.

Dissemination declaration

Findings will be made available to study participants and organisations promoting women's reproductive health and wellbeing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data Availability

The complete de-identified data set is available for research purposes on application to the corresponding author.

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